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## NOTE

# One Last Chance: *Abigail Alliance v. von Eschenbach* and the Right to Access Experimental Drugs

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## INTRODUCTION

Terminal illnesses are serious diseases that pose a significant public health burden.<sup>1</sup> The statistics for cancer and AIDS, two of the most common forms of terminal illness, are telling.<sup>2</sup> The American Cancer Society estimated that in 2007 there would be 1,444,920 new cancer cases and 559,650 cancer-related deaths.<sup>3</sup> Cancer accounts for twenty-three percent of all deaths in the United States, ranking second only to heart disease.<sup>4</sup> The Center for Disease Control estimated that 475,871 persons were living with HIV or AIDS, and 17,011 would die of AIDS in 2005.<sup>5</sup> However, hope lies in the form of experimental new drugs that may help delay the progression of terminal illnesses, or provide a cure.<sup>6</sup> Therefore, the development of and access to safe and effective new drugs is of the utmost importance to terminally ill patients as well as the public.<sup>7</sup>

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<sup>1</sup> See Ahmedin Jemal et al., *Cancer Statistics 2007*, 57 CA: CANCER J. FOR CLINICIANS 43, 43 (2007) (discussing current state of cancer epidemiology and noting cancer causes one in four deaths in United States). This Note uses cancer as a model terminal illness, as most discussion of the terminally ill refers to cancer patients and victims. See, e.g., William Breitbart et al., *Depression, Hopelessness, and Desire for Hastened Death in Terminally Ill Patients with Cancer*, 284 JAMA 2907 (2000) (using cancer patients as subjects in study of terminally ill mental health); Tracy Hampton, *Are Placebos in Advanced Cancer Trials Ethically Justified?*, 296 JAMA 265 (2006) (using cancer as representative for other terminal illnesses); Andrew Skolnick, *MediCaring Project to Demonstrate, Evaluate Innovative End-of-Life Program for Chronically Ill*, 279 JAMA 1511, 1511 (1998) (noting hospice facilities use cancer as model terminal illness). Furthermore, all the patients Abigail Alliance used as examples in its complaint suffered from various forms of cancer. See Complaint at 6-9, *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, No. 1:03CV1601, 2003 WL 23781358 (D.D.C. July 28, 2003).

<sup>2</sup> See *infra* notes 3-5 and accompanying text.

<sup>3</sup> Jemal et al., *supra* note 1, at 43, 45.

<sup>4</sup> *Id.* at 45.

<sup>5</sup> CTR. FOR DISEASE CONTROL & PREVENTION, DEP'T OF HEALTH & HUMAN SERVS., HIV/AIDS SURVEILLANCE REPORT 16-18 (2005), available at <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2005report/pdf/2005SurveillanceReport.pdf>; AVERT, United States HIV & AIDS Statistics Summary, <http://www.avert.org/statsum.htm> (last visited Apr. 11, 2008).

<sup>6</sup> For example, the new drug imatinib has shown remarkable efficacy in treating the terminal illness chronic myelogenous leukemia. See *infra* note 227 and accompanying text.

<sup>7</sup> National Cancer Institute, Clinical Trials: Questions and Answers, <http://www.cancer.gov/cancertopics/factsheet/Information/clinical-trials> (last visited Apr. 11, 2008).

The Food and Drug Administration (“FDA”) regulates the marketing of all drugs, including experimental new drugs.<sup>8</sup> The FDA requires rigorous safety and efficacy testing prior to marketing approval.<sup>9</sup> This approval process can frustrate a terminally ill patient’s urgent need to access experimental drugs when existing therapies are ineffective.<sup>10</sup> Indeed, a terminally ill patient may be dead by the time a drug obtains marketing approval.<sup>11</sup>

The Court of Appeals for the District of Columbia addressed this issue in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*.<sup>12</sup> The court held that terminally ill patients who have exhausted all approved treatment options do not have a fundamental right to access experimental drugs.<sup>13</sup> All government regulations infringing upon this right, including the FDA approval process, are subject to a rational basis analysis.<sup>14</sup> In other words, only regulations with no demonstrable rational relationship with a legitimate state interest are invalid.<sup>15</sup>

This Note argues the D.C. Circuit’s decision in *Abigail Alliance* was incorrect because it should have found a limited fundamental right. Part II summarizes the dominant Supreme Court doctrines for

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<sup>8</sup> Federal Food, Drug, and Cosmetic Act, §§ 1-902, Pub. L. No. 75-717, 52 Stat. 1040, 1040 (1938) (codified as amended in 21 U.S.C. §§ 301-399 (2000)) (giving FDA statutory authority over marketing of new drugs); see 21 U.S.C. § 355(a) (2000) (requiring manufacturers to secure FDA approval before selling new drugs in interstate commerce).

<sup>9</sup> See Kefauver-Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780, 780 (1962) (codified at 21 U.S.C. §§ 301-381 (2000)) (giving FDA statutory authority to evaluate drug efficacy in addition to safety).

<sup>10</sup> See *United States v. Rutherford*, 442 U.S. 544, 551 (1979) (finding no exception to FDA approval process for terminally ill patients); *United States v. Burzynski Cancer Research Inst.*, 819 F.2d 1301, 1313-14 (5th Cir. 1987) (finding terminally ill patients had no constitutional right to obtain specific medical treatment); *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (denying terminally ill patients right to use unapproved drug); Brief of Appellants at 2-3, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006) (No. 04-5350), 2005 WL 1826286 (arguing FDA regulation of drugs interfered with terminally ill patients’ fundamental right to access drugs). The needs of patients with nonterminal but serious conditions may also conflict with the FDA approval process. See *Gonzales v. Raich*, 545 U.S. 1, 5-8 (2005) (considering constitutionality of California statute authorizing use of marijuana for serious illnesses).

<sup>11</sup> Brief of Appellants, *supra* note 10, at 8.

<sup>12</sup> *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 696 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

<sup>13</sup> *Id.* at 711.

<sup>14</sup> *Id.* at 712.

<sup>15</sup> *Id.*

assessing fundamental rights under the Due Process Clauses of the Fifth and Fourteenth Amendments. Part II also explains the FDA approval process and discusses a past incident where the need for experimental drugs conflicted with this process. Part III discusses the facts, holding, and rationale in *Abigail Alliance*. Part IV argues the D.C. Circuit used the wrong standard to find a fundamental right to access experimental drugs. Specifically, the D.C. Circuit correctly rejected a broad fundamental right under *Washington v. Glucksberg*.<sup>16</sup> However, the court should not have stopped its analysis there. Instead, the court should have found a limited fundamental right to access experimental drugs under *Planned Parenthood of Southeastern Pennsylvania v. Casey*.<sup>17</sup> Applying this right ensures early access to promising experimental drugs while avoiding the dangers of a broad fundamental right. A broad right would harm terminally ill patients by endangering clinical research enrollment and the collection of reliable safety and effectiveness data.<sup>18</sup>

## I. BACKGROUND

A proper understanding of the interests at stake in *Abigail Alliance* lies at the intersection of science, constitutional law, and FDA statutory authority.<sup>19</sup> The FDA has statutory authority to regulate the right of individuals to access drugs.<sup>20</sup> The FDA's approval process reflects definitions of safety and efficacy accepted by the scientific community.<sup>21</sup> However, FDA restrictions on drug access are valid only if they do not infringe upon patients' fundamental rights under the Due Process Clauses.<sup>22</sup>

### A. Fundamental Rights Under the Due Process Clauses

Under the Supreme Court's substantive due process jurisprudence, the Due Process Clauses of the Fifth and Fourteenth Amendments both confer constitutional protection to certain individual rights.<sup>23</sup> Beginning

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<sup>16</sup> See 521 U.S. 702, 720 (1997); *infra* Part IV.A.

<sup>17</sup> See 505 U.S. 833, 844-45 (1992); *infra* Part IV.C.

<sup>18</sup> See *infra* Part IV.B.

<sup>19</sup> See *infra* Part II.

<sup>20</sup> See *infra* Part II.B.

<sup>21</sup> *United States v. Rutherford*, 442 U.S. 544, 555 (1979) (citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629-34 (1973)).

<sup>22</sup> See *infra* Part II.A.

<sup>23</sup> U.S. CONST. amends. V, XIV; *Troxel v. Granville*, 530 U.S. 57, 65 (2000) (recognizing that Fourteenth Amendment Due Process Clause confers protection

with *Griswold v. Connecticut*, the Supreme Court has held that the Due Process Clauses protect certain fundamental rights against government interference.<sup>24</sup> However, the Court has created several different tests for determining whether a fundamental right exists.<sup>25</sup> Most courts have followed one of two separate lines of reasoning, exemplified by *Casey* and *Glucksberg*.<sup>26</sup> In addition to these two prevalent approaches, a third approach exists under *Lawrence v. Texas*.<sup>27</sup>

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beyond procedural due process); *Washington v. Glucksberg*, 521 U.S. 702, 719 (1997) (recognizing Due Process Clauses protect liberty beyond freedom from physical restraint and fair process); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 847 (1992) (holding protection of Due Process Clauses extends to liberty interest beyond scope of Bill of Rights).

<sup>24</sup> See 381 U.S. 479, 485 (1973); see also *Glucksberg*, 521 U.S. at 720 (recognizing Due Process Clauses' protection of fundamental rights and liberty interests against government interference); *Reno v. Flores*, 507 U.S. 292, 301-02 (1993) (stating Fifth Amendment's guarantee of due process of law contains substantive component forbidding all government infringement on liberty interests). Substantive due process analysis is identical for the Fifth and Fourteenth Amendments. See *Georgia v. Randolph*, 547 U.S. 103, 144 (2006) (Scalia, J., dissenting) (considering Fifth and Fourteenth Amendment Due Process Clauses as functionally identical); *Lawrence v. Texas*, 539 U.S. 558, 578 (2003) (discussing Due Process Clauses of Fifth and Fourteenth Amendments simultaneously); *Troxel*, 530 U.S. at 65 (considering Fourteenth and Fifth Amendment Due Process Clauses as functionally equivalent); *Paul v. Davis*, 424 U.S. 693, 722 n.10 (1976) (stating Due Process Clauses of Fifth and Fourteenth Amendments both protect liberty interests).

<sup>25</sup> *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 476-77 (D.C. Cir. 2006), *rev'd*, 495 F.3d 695 (D.C. Cir. 2007) (en banc); see Brian Hawkins, Note, *The Glucksberg Renaissance: Substantive Due Process Since Lawrence v. Texas*, 105 MICH. L. REV. 409, 413 (2006) (noting lack of consistent rationale in Supreme Court jurisprudence for determining existence and scope of fundamental rights).

<sup>26</sup> See Robert C. Post, *The Supreme Court, 2002 Term, Foreword: Fashioning the Legal Constitution: Culture, Courts, and Law*, 117 HARV. L. REV. 4, 89 (2003) (comparing *Glucksberg* and *Casey* approaches); see also *Glucksberg*, 521 U.S. at 721; *Casey*, 505 U.S. at 851. Compare *Stenberg v. Carhart*, 530 U.S. 914, 921 (2000) (applying *Casey*), and *Womens' Med. Prof'l Corp. v. Baird*, 438 F.3d 595, 604-06 (6th Cir. 2006) (applying *Casey*), with *Abigail Alliance*, 445 F.3d at 476 (applying *Glucksberg*), *Hawkins v. Freeman*, 195 F.3d 732, 740 (4th Cir. 1999) (applying *Glucksberg*), and *State v. Seering*, 701 N.W.2d 655, 664 (Iowa 2005) (applying *Glucksberg*).

<sup>27</sup> 539 U.S. at 578 (invalidating statute prohibiting homosexual intercourse because statute did not further any legitimate state interest).

### 1. The *Glucksberg* Test

The *Glucksberg* test recognizes only fundamental rights that are narrow in scope and have deep roots in American history.<sup>28</sup> *Glucksberg* involved a state statute banning assisted suicide.<sup>29</sup> Three terminally ill patients, four doctors, and a nonprofit organization sued, asserting a fundamental right for a terminally ill adult to commit physician-assisted suicide.<sup>30</sup> The Supreme Court ruled that no such fundamental right existed.<sup>31</sup> In so holding, the Court established a two-prong test for identifying novel fundamental rights.<sup>32</sup>

The first prong of the *Glucksberg* test requires a careful description of the asserted fundamental right.<sup>33</sup> The plaintiffs or the court must define the fundamental right as specifically as possible.<sup>34</sup> The careful description requirement prevents the creation of overly broad fundamental rights repugnant to the doctrine of judicial self-restraint.<sup>35</sup> For example, in *Doe v. Moore*, the plaintiffs alleged infringement of rights including family association and freedom of interference from religious practices.<sup>36</sup> The Court of Appeals for the Eleventh Circuit held that the plaintiffs had defined the alleged rights too broadly to satisfy the careful description requirement.<sup>37</sup> To remedy this, the court redefined the right using facts specific to the case.<sup>38</sup>

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<sup>28</sup> *Glucksberg*, 521 U.S. at 720-21.

<sup>29</sup> *Id.* at 705-08.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 735-36.

<sup>32</sup> *Id.* at 720.

<sup>33</sup> *Id.* at 720-21 (citing *Reno v. Flores*, 507 U.S. 292, 302 (1993); *Collins v. Harker Heights*, 503 U.S. 115, 125 (1992); *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 277-78 (1990)).

<sup>34</sup> See *id.* at 722-23 (narrowing fundamental right at issue from broad rights asserted by plaintiffs to more specific right to commit suicide, including right to assisted suicide).

<sup>35</sup> See *Chavez v. Martinez*, 538 U.S. 760, 775-76 (2003) (noting vague generalities in description of right would not satisfy careful description requirement); *Reno v. Flores*, 507 U.S. 292, 302 (1993) (requiring careful description of asserted right to create new fundamental rights and further doctrine of judicial self-restraint); *Williams v. Att'y Gen. of Ala.*, 378 F.3d 1232, 1241 (11th Cir. 2004) (requiring careful description to prevent courts from extending scope of fundamental right beyond facts of case at hand).

<sup>36</sup> 410 F.3d 1337, 1343 (11th Cir. 2005).

<sup>37</sup> *Id.* at 1343-44.

<sup>38</sup> *Id.* at 1344 (redefining right as right of convicted sex offenders to refuse subsequent registration of personal information with Florida law enforcement and to prevent public posting of information); see also *Glucksberg*, 521 U.S. at 722-23 (narrowing alleged fundamental right from generalized right to control one's death to

The second prong of the *Glucksberg* test requires the asserted fundamental right to have deep roots in American history.<sup>39</sup> In addition, the right must be an essential component of liberty and justice.<sup>40</sup> In *Glucksberg*, the right to commit suicide failed the second prong because the historical record showed a deeply rooted rejection of such a right.<sup>41</sup>

If there is a fundamental right under *Glucksberg*, then the Due Process Clauses prohibit almost all governmental regulation infringing upon that right.<sup>42</sup> Only regulations narrowly tailored to serve a compelling interest are valid.<sup>43</sup> If there is no fundamental right, however, then any infringement with a rational relationship to a governmental interest is valid.<sup>44</sup> Overall, the *Glucksberg* test is a very restrictive test intended to discourage the creation of new fundamental rights.<sup>45</sup> In contrast, the *Casey* test encourages the finding of broader fundamental rights, albeit with more limited protection.<sup>46</sup>

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right to commit suicide with assistance).

<sup>39</sup> *Glucksberg*, 521 U.S. at 720-21.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* at 728 (noting history of unequivocal societal rejection of efforts to legalize assisted suicide); see also *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 269-79 (1990) (finding fundamental right to refuse lifesaving hydration and nutrition had historical support in prior case law and in common law doctrines of battery and informed consent).

<sup>42</sup> *Glucksberg*, 521 U.S. at 721 (citing *Reno v. Flores*, 507 U.S. 292, 302 (1993)).

<sup>43</sup> *Id.* This is also known as a strict scrutiny analysis. See Gerald Gunther, *The Supreme Court, 1971 Term, Foreword: In Search of Evolving Doctrine on a Changing Court: A Model for a Newer Equal Protection*, 86 HARV. L. REV. 1, 8 (1972) (describing rise of strict scrutiny standard in Warren Court). It is possible, but very difficult to have a government regulation survive a strict scrutiny analysis. *Id.*; cf. *Grutter v. Bollinger*, 539 U.S. 306, 343 (2003) (holding that state university's affirmative action admissions policy was narrowly tailored to serve compelling state interest).

<sup>44</sup> See *Glucksberg*, 521 U.S. at 728 (requiring rational relationship between suicide ban and legitimate government interests).

<sup>45</sup> See *id.* at 720-21 (emphasizing need to exercise utmost care when expanding substantive due process and considering *Glucksberg* test restrained methodology); John O. McGinnis, *Reviving Tocqueville's America: The Rehnquist Court's Jurisprudence of Social Discovery*, 90 CAL. L. REV. 485, 568-69 (2002) (arguing *Glucksberg* represented reduction in announcement of new fundamental rights); Hawkins, *supra* note 25, at 428-29 (noting only five cases out of 102 applying *Glucksberg* found fundamental rights violations).

<sup>46</sup> See *infra* Part II.A.2.

## 2. The *Casey* “Undue Burden” Test

*Casey* is the latest in a line of cases recognizing fundamental rights protecting personal dignity and autonomy.<sup>47</sup> In *Casey*, the Supreme Court evaluated five provisions of a Pennsylvania statute limiting abortion services.<sup>48</sup> The Court held that a woman has a fundamental right to obtain an abortion before viability of the fetus.<sup>49</sup> After viability, however, the state interest in protecting the life of the fetus has sufficient force to restrict a woman’s right to an abortion.<sup>50</sup> Furthermore, the Court held that the state could regulate abortion previability if the regulation did not impose an undue burden on the right to abortion.<sup>51</sup> Applying this analysis, the Court upheld four of the five provisions of the statute.<sup>52</sup>

Under *Casey*, the Due Process Clauses protect intimate choices relating to personal dignity and autonomy as fundamental rights.<sup>53</sup> However, even if a fundamental right exists, a governmental regulation is valid unless it places an undue burden on the exercise of that right.<sup>54</sup> Even statutes substantially regulating the fundamental right may be valid.<sup>55</sup>

For example, in *Casey*, the Court upheld a twenty-four hour waiting period provision because the cumulative effects, although significant, did not constitute an undue burden.<sup>56</sup> Only the spousal notification

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<sup>47</sup> Planned Parenthood of Se. Pa. v. *Casey*, 505 U.S. 833, 844 (1992). *But see* David B. Cruz, *Spinning Lawrence, or Lawrence v. Texas and the Promotion of Heterosexuality*, 11 WIDENER L. REV. 249, 253-54 (2005) (rejecting *Casey* as fundamental rights case). *See generally* *Roe v. Wade*, 410 U.S. 113 (1973) (finding fundamental right to obtain abortion within right of personal privacy); *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (finding fundamental right to procreational decisions); *Griswold v. Connecticut*, 381 U.S. 479, 483-86 (1965) (finding fundamental right to contraception existed as part of right to privacy guaranteed by Bill of Rights).

<sup>48</sup> *Casey*, 505 U.S. at 844-45.

<sup>49</sup> *Id.* at 869-70 (recognizing limited constitutional right of women to have abortion before viability).

<sup>50</sup> *Id.* at 869.

<sup>51</sup> *Id.* at 874.

<sup>52</sup> *Id.* at 879-901 (finding all provisions of statute, except spousal notification, not unduly burdensome on woman’s right to obtain abortion).

<sup>53</sup> *Id.* at 851; *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 476 (D.C. Cir. 2006), *rev’d*, 495 F.3d 695 (D.C. Cir. 2007) (en banc).

<sup>54</sup> *See Casey*, 505 U.S. at 874, 877 (recognizing invalidity of state regulations unduly burdening rights of woman seeking to terminate nonviable fetus).

<sup>55</sup> *Id.* at 877 (finding infringement requires statute to create substantial obstacle to free exercise of fundamental right).

<sup>56</sup> *Id.* at 885-87 (holding even “particularly burdensome” effect is not substantial

provision constituted an undue burden because it provided husbands with excessive power over their wives in obtaining abortions.<sup>57</sup> Similarly, in *Stenberg v. Carhart*, the Court considered a Nebraska law prohibiting partial birth abortion.<sup>58</sup> The Court held that the law placed an undue burden on a woman's right to choose because it lacked a maternal health exception.<sup>59</sup>

In summary, the *Glucksberg* and *Casey* tests provide two approaches for determining whether the Due Process Clauses protect an asserted fundamental right.<sup>60</sup> The *Glucksberg* test serves as a very conservative method for finding new fundamental rights.<sup>61</sup> However, by adopting a strict scrutiny standard, this test affords strong protection against governmental infringement of any rights established under *Glucksberg*.<sup>62</sup> In contrast, a court applying the *Casey* test is more likely to find a new fundamental right, provided it lies within the realm of personal dignity and autonomy.<sup>63</sup> However, an undue burden

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obstacle).

<sup>57</sup> *Id.* at 898.

<sup>58</sup> 530 U.S. 914, 921-22 (2000).

<sup>59</sup> *Id.* at 930; *see also* *Womens' Med. Profl Corp. v. Baird*, 438 F.3d 595, 604-06 (6th Cir. 2006) (finding application of state regulatory transfer agreement requirement to abortion clinic did not unduly burden right to abortion); *Planned Parenthood of Idaho v. Wasden*, 376 F.3d 908, 930-31 (9th Cir. 2004) (invalidating Idaho parental consent statute due to undue burden created by overly narrow medical emergency exception and lack of deadlines for judicial bypass); *Planned Parenthood of Cent. N.J. v. Farmer*, 220 F.3d 127, 141-42 (3d Cir. 2000) (invalidating New Jersey statute banning partial birth abortions because overly broad language prohibits common forms of abortion).

<sup>60</sup> *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 476-77 (D.C. Cir. 2006), *rev'd*, 495 F.3d 695 (D.C. Cir. 2007) (en banc) (comparing and contrasting *Glucksberg* and *Casey*).

<sup>61</sup> *Id.* at 476; McGinnis, *supra* note 45, at 569 (describing *Glucksberg* as creating very restrictive fundamental rights test); Paul M. Secunda, *The (Neglected) Importance of Being Lawrence: The Constitutionalization of Public Employee Rights to Decisional Non-Interference in Private Affairs*, 40 UC DAVIS L. REV. 87, 113 (2006) (describing *Glucksberg* as effort to narrow scope of substantive due process); Laurence H. Tribe, *Lawrence v. Texas: The "Fundamental Right" That Dare Not Speak Its Name*, 117 HARV. L. REV. 1893, 1918 (2004) (describing *Glucksberg* as more restrictive analysis); Hawkins, *supra* note 25, at 415 (noting *Glucksberg's* scope of new substantive due process rights applies only to judicially recognized, specific rights rather than broad constitutional principles). One commentator has noted that the fundamental right to abortion in *Roe v. Wade* would have failed the second prong of the *Glucksberg* test. McGinnis, *supra* note 45, at 569.

<sup>62</sup> *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997) (citing *Reno v. Flores*, 507 U.S. 292, 302 (1993)).

<sup>63</sup> *See* *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 833 (1992); *see also* Tribe, *supra* note 61, at 1918 (considering *Casey* "farther reaching" than *Glucksberg*).

analysis under *Casey* affords a more limited protection of any fundamental right found.<sup>64</sup> Furthermore, the *Casey* test allows for the evenhanded balancing of individual rights and government interests.<sup>65</sup>

### 3. The *Lawrence* Approach

In addition to these two tests, *Lawrence v. Texas* may offer a third approach for identifying fundamental rights.<sup>66</sup> In *Lawrence*, the Supreme Court recognized the right of individuals to engage in consensual sexual activity within the home without government interference.<sup>67</sup> The Court held that a Texas statute criminalizing homosexual sodomy infringed upon this fundamental right.<sup>68</sup> Ignoring the history and tradition requirements of *Glucksberg*, the Court focused on the laws and traditions of the past fifty years.<sup>69</sup> However, *Lawrence* did not articulate a test for identifying a fundamental right.<sup>70</sup> The opinion also did not set forth a clear standard of review.<sup>71</sup>

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Although the Supreme Court decided *Glucksberg* after *Casey*, the *Glucksberg* holding neither replaced nor overruled the *Casey* holding. *Id.* at 1918 (discussing *Casey* and *Lawrence* as two separate approaches). The *Casey* test remains a viable doctrine for substantive due process fundamental rights analysis. See *Lawrence v. Texas*, 539 U.S. 558, 573-74 (2003) (citing *Casey*, 505 U.S. at 851); Note, *Assessing the Viability of a Substantive Due Process Right to In Vitro Fertilization*, 118 HARV. L. REV. 2792, 2798-2800 (2005).

<sup>64</sup> *Casey*, 505 U.S. at 874. Scholars have argued that *Casey* embodies the idea that fundamental rights represent the allocation of decision making between individuals, private entities, and the government. Alan Brownstein, *How Rights Are Infringed: The Role of Undue Burden Analysis in Constitutional Doctrine*, 45 HASTINGS L.J. 867, 955-56 (1994) (arguing *Casey* strikes balance between upholding constitutional rights and respecting governmental interests); Daniel O. Conkle, *Three Theories of Substantive Due Process*, 85 N.C. L. REV. 63, 109 (2006); Tribe, *supra* note 61, at 1927.

<sup>65</sup> See Brownstein, *supra* note 64, at 955-56 (arguing *Casey* strikes balance between upholding constitutional rights and respecting governmental interests).

<sup>66</sup> *Lawrence*, 539 U.S. at 578. Courts and scholars disagree on whether *Lawrence* is even a substantive due process case at all. Compare *Abigail Alliance*, 445 F.3d at 477 n.8 (construing *Lawrence* as not substantive due process decision), with *Secunda*, *supra* note 61, at 116 (claiming *Lawrence* is novel type of substantive due process analysis).

<sup>67</sup> *Lawrence*, 539 U.S. at 578.

<sup>68</sup> *Id.* at 563, 577-78.

<sup>69</sup> *Id.* at 571-72.

<sup>70</sup> See *id.* at 578 (identifying statute's intrusions on personal privacy without defining difference between allowed and prohibited intrusions).

<sup>71</sup> *Id.* (invalidating statute due to lack of legitimate state interest justifying privacy intrusion). Scholars disagree on whether this constitutes strict scrutiny or rational basis review. See Cass R. Sunstein, *What Did Lawrence Hold? Of Autonomy*,

In sum, the Due Process Clauses protect certain fundamental rights from government intrusion.<sup>72</sup> At issue in *Abigail Alliance* was whether there is a fundamental right for terminally ill patients to access experimental drugs.<sup>73</sup> Notably, any such right of access would directly conflict with the FDA's regulatory control over all experimental drugs.<sup>74</sup>

### B. The FDA New Drug Approval Process

Congress gave the FDA regulatory authority over the marketing of experimental drugs.<sup>75</sup> The FDA came into existence in 1906 with the enactment of the Federal Food and Drugs Act.<sup>76</sup> In 1938, Congress enacted the Food, Drug, and Cosmetics Act ("FDCA"), mandating that manufacturers demonstrate drug safety to the FDA.<sup>77</sup> In 1962, with the passage of the Kefauver-Harris Amendments, the FDA acquired absolute authority over the efficacy of drugs.<sup>78</sup>

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*Desuetude, Sexuality, and Marriage* 15-17 (John M. Olin Law & Econ., Working Paper No. 196, 2003), available at [http://ssrn.com/abstract\\_id=450160](http://ssrn.com/abstract_id=450160) (discussing difficulty of characterizing *Lawrence* as clearly applying strict scrutiny or rational basis review). Compare *Williams v. Att'y Gen. of Ala.*, 378 F.3d 1232, 1238 (11th Cir. 2004) (interpreting *Lawrence* as applying rational basis review), and *Secunda*, *supra* note 61, at 89 (interpreting *Lawrence* as applying modified higher form of rational basis review), with *Hawkins*, *supra* note 25, at 424 (citing *Tribe*, *supra* note 61, at 1917) (finding scholarly consensus that *Lawrence* applies strict scrutiny in disguise).

<sup>72</sup> See *supra* notes 23-71 and accompanying text.

<sup>73</sup> *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, No. 03-1601, 2004 WL 3777340, at \*1 (D.D.C. Aug. 30, 2004) (mem.).

<sup>74</sup> See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 472 (D.C. Cir. 2006), *rev'd*, 495 F.3d 695 (D.C. Cir. 2007) (en banc).

<sup>75</sup> Federal Food, Drug, and Cosmetic Act §§ 1-902, Pub. L. No. 75-717, 52 Stat. 1040, 1040 (1938) (codified as amended in 21 U.S.C. §§ 301-399 (2000)) (giving FDA statutory authority over marketing of new drugs).

<sup>76</sup> Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768, 768 (repealed 1938); U.S. Food & Drug Administration, History of the FDA, <http://www.fda.gov/oc/history/historyoffda/default.htm> (last visited Apr. 11, 2008).

<sup>77</sup> U.S. Food & Drug Administration, The 1938 Food, Drug, and Cosmetic Act, <http://www.fda.gov/oc/history/historyoffda/section2.html> (last visited Apr. 11, 2008).

<sup>78</sup> Kefauver-Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780, 780 (1962) (codified at 21 U.S.C. §§ 301-381 (2000)); U.S. Food & Drug Administration, *supra* note 77; see also Michael A. Santoro, *Introduction to Part I: Profits, Patients' Rights, and Scientific Progress: The Ethics of Clinical Research Conducted in Private Enterprises*, in *ETHICS AND THE PHARMACEUTICAL INDUSTRY* 9, 13 (Michael A. Santoro & Thomas M. Gorrie eds., 2005) (noting 1960s global societal consensus requiring clinical data demonstrating safety and efficacy as prerequisite for drug marketing). Effectiveness requires a general recognition among experts that the drug actually produces the

The FDA has created a three-phase human testing scheme to determine the safety and effectiveness of new drugs.<sup>79</sup> Phase I tests drug metabolism and toxicity in twenty to eighty patients.<sup>80</sup> A secondary purpose of Phase I is to allow manufacturers to collect preliminary pharmacological data to design scientifically valid Phase II studies and, if possible, collect preliminary indicia of efficacy.<sup>81</sup> Phase II evaluates the effectiveness of the drug and its short-term side effects and risks in up to several hundred subjects in controlled clinical studies.<sup>82</sup> It is not until Phase III that large-scale human testing occurs.<sup>83</sup> Phase III involves up to several thousand human subjects in both controlled and uncontrolled trials.<sup>84</sup> Phase III studies aim to gather information for drug labeling as well as additional information on effectiveness and the risk-benefit relationship.<sup>85</sup>

Terminally ill patients often want to participate in premarket clinical trials to gain early access to new drugs that could potentially save their lives.<sup>86</sup> Due to very specific eligibility criteria, however, many terminally ill patients cannot qualify for these clinical studies.<sup>87</sup> The small sizes of Phase I and II trials also limit opportunities to

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intended results under appropriate conditions. *United States v. Rutherford*, 442 U.S. 544, 555 (1979) (citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629-34 (1973)).

<sup>79</sup> See U.S. Food and Drug Administration, *The New Drug Development Process*, <http://www.fda.gov/cder/handbook/develop.htm> (last visited Apr. 11, 2008).

<sup>80</sup> 21 C.F.R. § 312.21(a) (2006).

<sup>81</sup> *Id.* However, efficacy determinations are not a primary concern of Phase I trials. Christopher Daugherty et al., *Perceptions of Cancer Patients and Their Physicians Involved in Phase I Trials*, 13 J. CLINICAL ONCOLOGY 1062, 1063 (1995); see Sidney Taurel, *The Campaign Against Innovation*, in *ETHICS AND THE PHARMACEUTICAL INDUSTRY*, *supra* note 78, at 326, 330 (stating Phase II is start of efficacy testing in patients). Unfortunately, patients involved in Phase I trials often fail to understand that drug efficacy is not the primary purpose. Daugherty et al., *supra*, at 1066 (finding most patients' primary purpose in participating in Phase I trials was treatment).

<sup>82</sup> 21 C.F.R. § 312.21(b).

<sup>83</sup> *Id.* § 312.21(c).

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> Michael S. Simon et al., *Factors Associated with Breast Cancer Clinical Trials Participation and Enrollment at a Large Academic Medical Center*, 22 J. CLINICAL ONCOLOGY 2046, 2049 (2004).

<sup>87</sup> See *id.* at 2051-52 (listing typical reasons for clinical trial ineligibility); National Cancer Institute, *How Do I Take Part in a Clinical Trial?*, <http://www.cancer.gov/clinicaltrials/learning/how-to-take-part> (last visited Apr. 11, 2008) (citing typical clinical trial eligibility criteria such as age, gender, previous treatments, and type and stage of cancer).

participate.<sup>88</sup> Because of these difficulties in gaining early access to new drugs, terminally ill patients have challenged the existing framework of the FDA approval process.<sup>89</sup>

C. United States v. Rutherford: *No Fundamental Right to Receive Unapproved Medications*

Terminally ill patients' urgent needs have come into conflict with the FDA approval process in the past.<sup>90</sup> The FDA approval process is time-consuming and expensive for drug manufacturers.<sup>91</sup> For example, only five percent of all investigational new cancer drugs actually complete Phase III trials.<sup>92</sup> Satisfying the stringent safety and efficacy requirements of the approval process may result in patients dying before they can receive the desired treatment.<sup>93</sup> As a result, there has always been considerable demand for earlier access to potentially promising, unapproved treatments.<sup>94</sup>

The first widely publicized challenge to the FDA's prohibition of unapproved drugs came when cancer patients fought for access to laetrile.<sup>95</sup> The FDA has not approved laetrile as a drug.<sup>96</sup> However, in the 1970s, laetrile gained popularity as an allegedly effective

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<sup>88</sup> See *supra* notes 79-84 (discussing typical sizes of clinical trials at different phases).

<sup>89</sup> See *infra* Part II.C.

<sup>90</sup> See *infra* Part II.C.

<sup>91</sup> James O'Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA Approved Drugs*, 12 ANNALS HEALTH L. 295, 304 (2003) (finding average drug approval costs \$880 million and takes between seven and 10 years to get on market).

<sup>92</sup> Hampton, *supra* note 1, at 266; Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance v. von Eschenbach*, 297 JAMA 205, 206 (2007).

<sup>93</sup> Santoro, *supra* note 78, at 15.

<sup>94</sup> Letter from Ellen L. Stovall, President & CEO, Nat'l Coal. for Cancer Survivorship, and Sandra J. Horning, President, Am. Soc'y of Clinical Oncology, to FDA (Mar. 27, 2006), available at <http://www.fda.gov/ohrms/dockets/dockets/06p0135/06p-0135-cp00001-voll.pdf> (noting continuing demand for access to investigational new drugs prior to marketing approval). Today, Internet information and patient advocacy groups are the primary impetus for continued interest in early access. *Id.*

<sup>95</sup> National Cancer Institute, *Laetrile/Amygdalin (PDQ ®)*, <http://www.cancer.gov/cancertopics/pdq/cam/laetrile/HealthProfessional/page3> (last visited Apr. 11, 2008); Benjamin Wilson, *The Rise and Fall of Laetrile* (Feb. 17, 2004), <http://www.quackwatch.org/01QuackeryRelatedTopics/Cancer/laetrile.html> (last visited Apr. 11, 2008). The name "laetrile" is a commonly used acronym for the drug itself, which is a purified form of the compound amygdalin. National Cancer Institute, *supra*.

<sup>96</sup> National Cancer Institute, *supra* note 95.

anticancer treatment.<sup>97</sup> Many cancer patients eschewed standard therapies and traveled to Mexico to receive laetrile treatments.<sup>98</sup> In 1975, in *United States v. Rutherford*, terminally ill cancer patients sued to enjoin the government from prohibiting the sale of laetrile.<sup>99</sup> In ruling for the plaintiffs, the Court of Appeals for the Tenth Circuit exempted terminally ill patients from FDCA restrictions.<sup>100</sup>

The Supreme Court reversed, holding that no exception within the FDCA allows terminally ill patients to acquire unapproved drugs.<sup>101</sup> The Court noted that a heightened standard for drug effectiveness applied to terminally ill patients.<sup>102</sup> The Court warned that even safe unproven drugs with no therapeutic effect would still cause harm if they led the patient to reject proven therapies.<sup>103</sup> Finally, the Court emphasized the need to protect the terminally ill from entrepreneurs offering unproven panaceas.<sup>104</sup>

On remand, the Tenth Circuit held that patients had a fundamental right to decide whether to undergo treatment.<sup>105</sup> However, the court declined to extend its holding to the right to select a specific treatment not approved by the FDA.<sup>106</sup> Other courts have subsequently held that there is no fundamental right to access laetrile or other unapproved

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<sup>97</sup> *Id.* After *Rutherford*, researchers subsequently conducted Phase I and II studies on laetrile, and concluded that it was ineffective. See C.G. Moertel et al., *A Clinical Trial of Amygdalin (Laetrile) in the Treatment of Human Cancer*, 306 NEW ENG. J. MED. 201, 201-06 (1982) (finding laetrile was ineffective and toxic as cancer drug in Phase II study).

<sup>98</sup> Santoro, *supra* note 78, at 15; Wilson, *supra* note 95.

<sup>99</sup> *United States v. Rutherford*, 442 U.S. 544, 548 (1979).

<sup>100</sup> *Id.* at 550-51.

<sup>101</sup> *Id.* at 552.

<sup>102</sup> *Id.* at 556.

<sup>103</sup> *Id.*

<sup>104</sup> See *id.* at 558 (describing historical record of unscrupulous vendors selling unproven panaceas to exploit terminally ill patients).

<sup>105</sup> *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980) (recognizing right of patient to decide whether to undergo any kind of treatment).

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

drugs.<sup>107</sup> The D.C. Circuit adopted a similar view in its holding in *Abigail Alliance*.<sup>108</sup>

II. *ABIGAIL ALLIANCE FOR BETTER ACCESS TO DEVELOPMENTAL DRUGS V. VON ESCHENBACH*

In *Abigail Alliance*, the D.C. Circuit refused to recognize a new fundamental right under the *Glucksberg* test.<sup>109</sup> Specifically, under *Abigail Alliance*, the court held that a terminally ill patient does not have the fundamental right to access post-Phase I investigational drugs free from FDA interference.<sup>110</sup>

A. *Factual and Procedural History*

The Abigail Alliance for Better Access to Developmental Drugs (“the Alliance”) is a nonprofit organization that advocates for access to developmental drugs for the terminally ill.<sup>111</sup> In January 2003, the Alliance submitted a proposal for new regulations to the FDA.<sup>112</sup> The proposal would make post-Phase I investigational new drugs available to terminally ill patients who did not qualify for FDA clinical trials.<sup>113</sup> When the FDA rejected the proposal, the Alliance filed a Citizen Petition under 21 C.F.R. § 10.30.<sup>114</sup> The FDA did not respond within 180 days, thereby entitling the Alliance to seek judicial review.<sup>115</sup>

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<sup>107</sup> See *Mitchell v. Clayton*, 995 F.2d 772, 775 (7th Cir. 1993) (holding patients have no constitutional right to obtain specific treatment); *United States v. Burzynski Cancer Research Inst.*, 819 F.2d 1301, 1313-14 (5th Cir. 1987) (holding terminally ill patients had no constitutional right to obtain specific medical treatment); *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (holding that right of privacy and personal liberty did not encompass right to obtain laetrile free of government regulation).

<sup>108</sup> *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 711-12 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

<sup>109</sup> *Id.* at 711.

<sup>110</sup> *Id.* at 711-12.

<sup>111</sup> Complaint, *supra* note 1, at 5; Marc Kaufman, *Court Backs Experimental Drugs for Dying Patients*, WASH. POST, May 3, 2006, at A9; The Abigail Alliance Mission, <http://www.abigail-alliance.org/mission.htm> (last visited Apr. 11, 2008).

<sup>112</sup> *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 473 (D.C. Cir. 2006), *rev'd*, 495 F.3d 695 (D.C. Cir. 2007) (en banc).

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*; 21 C.F.R. § 10.30 (2006); Citizen Petition of the Abigail Alliance and Washington Legal Foundation to the Food & Drug Administration, [http://www.abigail-alliance.org/WLF\\_FDA.pdf](http://www.abigail-alliance.org/WLF_FDA.pdf) (last visited Apr. 11, 2008).

<sup>115</sup> *Abigail Alliance*, 445 F.3d at 473.

In July 2003, the Alliance sued to enjoin the FDA from barring the sale of post-Phase I drugs to terminally ill patients not in clinical trials.<sup>116</sup> The Alliance claimed that the FDA's prohibition on the sale of post-Phase I drugs violated terminally ill patients' due process right to life.<sup>117</sup> In granting the FDA's motion to dismiss, the district court held that the Alliance had failed to state a valid fundamental right to access.<sup>118</sup> The court further reasoned that the FDA's policy bore a rational relationship to the legitimate state interest of public health.<sup>119</sup>

On appeal, a three-judge panel of the D.C. Circuit overruled the district court's construction of the fundamental right issue.<sup>120</sup> The court restricted its holding to terminally ill, mentally competent adult patients for whom existing government-approved treatments were ineffective.<sup>121</sup> It held that these patients had the fundamental right to access post-Phase I investigational new drugs determined to be sufficiently safe for expanded human testing.<sup>122</sup>

The court arrived at this conclusion by applying the *Glucksberg* test to determine whether a fundamental right to access post-Phase I new drugs existed.<sup>123</sup> The court first held that the alleged fundamental right satisfied the careful description prong of the *Glucksberg* test.<sup>124</sup> Next, the court found a long-standing tradition of protecting access to potentially life-saving medication, thus satisfying the second prong of *Glucksberg*.<sup>125</sup> Finally, the court noted that the Supreme Court had

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<sup>116</sup> *Id.*; *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, 2004 WL 3777340, at \*1 (D.D.C. Aug. 30, 2004) (mem.). The lawsuit is part of the Alliance's overall goal of initiating sweeping revisions to the FDA approval process. Susan Okie, *Access Before Approval: A Right to Take Experimental Drugs?*, 355 NEW ENG. J. MED. 437, 439 (2006); *see also* ACCESS Act, S. 1956, 109th Cong. (2005) (proposing amendment of FDCA to create three-tiered approval system for new drugs).

<sup>117</sup> *Abigail Alliance*, 2004 WL 3777340, at \*1.

<sup>118</sup> *Id.* at \*11 (holding plaintiffs erroneously stated holdings of *Glucksberg*, *Cruzan*, and *Griswold* too broadly); *see also* FED. R. CIV. P. 12(b)(6).

<sup>119</sup> *Abigail Alliance*, 2004 WL 3777340, at \*12.

<sup>120</sup> *Abigail Alliance*, 445 F.3d 474-75.

<sup>121</sup> *Id.* at 486.

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

<sup>123</sup> *Id.* at 476-78. Because the court considered *Glucksberg* more restrictive, it saw no need to apply the *Casey* test. *Id.* at 477.

<sup>124</sup> *Id.* at 478 (holding Alliance's asserted right contained careful description); *see* *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997) (setting forth careful description requirement).

<sup>125</sup> *Abigail Alliance*, 445 F.3d at 480-81; *cf. Glucksberg*, 521 U.S. at 721 (setting forth requirement of deeply rooted historical recognition of right). The court based this finding on the common law doctrines of self-preservation, necessity, and liability for interfering with a rescue. *See Abigail Alliance*, 445 F.3d at 480-81; *cf. Cruzan v.*

found a right to refuse life-sustaining treatment in *Cruzan v. Director, Missouri Department of Health*.<sup>126</sup> With this in mind, the court held that the right to refuse life-sustaining treatment implied a right to access potentially life-sustaining medication.<sup>127</sup> Therefore, this latter right served as an essential component to the concept of ordered liberty required by the second prong of *Glucksberg*.<sup>128</sup>

Subsequently, in August 2007, the D.C. Circuit reversed the panel's holding in an en banc opinion.<sup>129</sup> Again applying *Glucksberg*, the en banc court held that there was no fundamental right for terminally ill patients to access post-Phase I investigational new drugs.<sup>130</sup> In so holding, the court noted that the democratic process rather than the courts should decide the broader issue of access to experimental drugs.<sup>131</sup>

### B. Rationale

Like the panel, the en banc court began its analysis by applying the *Glucksberg* test.<sup>132</sup> The court assumed without deciding that the alleged fundamental right satisfied the careful description prong of the *Glucksberg* test.<sup>133</sup> However, under the second prong of *Glucksberg*, the court held there was no history or tradition of access to experimental drugs.<sup>134</sup>

Analyzing history and tradition, the court noted the difference between the regulation of drug safety and drug efficacy.<sup>135</sup> Examining drug safety regulation, the court found a long historical tradition of state and federal government regulation of drug safety.<sup>136</sup> The court also acknowledged the possibility of a lack of drug efficacy regulation before the Kefauver-Harris Amendments.<sup>137</sup> Nevertheless, the court

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Dir., Mo. Dep't of Health, 497 U.S. 261, 269 (1990) (deriving right to refuse lifesaving hydration and nutrition from common law battery).

<sup>126</sup> *Cruzan*, 497 U.S. at 279; *Abigail Alliance*, 445 F.3d at 484.

<sup>127</sup> *Abigail Alliance*, 445 F.3d at 484-85.

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

<sup>129</sup> *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 696 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

<sup>130</sup> *Id.* at 703-11.

<sup>131</sup> *Id.* at 713.

<sup>132</sup> *Id.* at 701-02.

<sup>133</sup> *Id.* at 702.

<sup>134</sup> *Id.* at 703-11.

<sup>135</sup> *Id.* at 703.

<sup>136</sup> *Id.* at 703-06.

<sup>137</sup> *Id.* at 706.

held that a lack of government regulation alone failed to prove that the right was deeply rooted.<sup>138</sup> In addition, the court held that the common law doctrines of necessity, intentional interference with a rescue, and right to self-defense asserted by the Alliance did not apply to the asserted right.<sup>139</sup>

Thus, the D.C. Circuit concluded that no fundamental right for the terminally ill to access post-Phase I experimental drugs existed under the *Glucksberg* test.<sup>140</sup> As a result, the court applied only a rational basis review to the challenged FDA regulations.<sup>141</sup> The court found the FDA's interest in protecting patients from unsafe drugs bore a rational relationship to the challenged regulations.<sup>142</sup> Accordingly, the court affirmed the district court's grant of the FDA's motion to dismiss.<sup>143</sup>

### III. ANALYSIS

The Supreme Court should have reversed the *Abigail Alliance* decision because the holding, while mostly correct, failed to conduct a comprehensive substantive due process analysis. The D.C. Circuit's en banc opinion correctly rejected a broad fundamental right to access post-Phase I drugs under *Glucksberg*. To hold otherwise would have created a strong fundamental right that impedes the development of safe and effective drugs. However, the Supreme Court should take the analysis one step further and find that a more limited and balanced fundamental right to access experimental drugs exists under *Casey*.

#### A. *The Fundamental Right for Terminally Ill Patients to Access Post-Phase I Experimental Drugs Fails the Second Prong of the Glucksberg Test*

The D.C. Circuit correctly applied the *Glucksberg* test in finding no fundamental right for terminally ill patients to access post-Phase I investigational new drugs.<sup>144</sup> The en banc opinion chose not to determine whether this right satisfied the careful description prong of

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<sup>138</sup> *Id.* at 706-07.

<sup>139</sup> *Id.* at 707-10.

<sup>140</sup> *Id.* at 711. Finding no deeply rooted right, the court saw no need to determine whether a right to access was essential to the concept of ordered liberty. *Id.* at 711 n.19.

<sup>141</sup> *Id.* at 712.

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

<sup>143</sup> *Id.* at 714.

<sup>144</sup> See *infra* notes 146-54 and accompanying text (discussing incorrect application of *Glucksberg*).

*Glucksberg*.<sup>145</sup> However, the lower panel opinion determined this right satisfies the careful description prong because it only applies to persons in the plaintiffs' specific situation.<sup>146</sup> Nevertheless, the right fails to satisfy the deeply rooted prong and, therefore, does not qualify as a fundamental right under *Glucksberg*.<sup>147</sup>

The right to access post-Phase I drugs is not deeply rooted in history and tradition as required by *Glucksberg*.<sup>148</sup> The Abigail Alliance asserted that the common law doctrines of self-preservation, necessity, and liability for interfering with a rescue all supported the right to access.<sup>149</sup> However, these doctrines at most support a general right of access to all unapproved drugs, not specifically post-Phase I drugs.<sup>150</sup>

Post-Phase I drugs are a subset of unapproved drugs. The Supreme Court rejected the right to access unapproved drugs in *Rutherford*.<sup>151</sup>

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<sup>145</sup> See *Abigail Alliance*, 495 F.3d at 702 ("We will assume *arguendo* that the Alliance's description of its asserted right would satisfy *Glucksberg*'s 'careful description' requirement.").

<sup>146</sup> See *Doe v. Moore*, 410 F.3d 1337, 1343-44 (11th Cir. 2005) (narrowing right from generalized privacy interests to specific issue of application of Sex Offender Act to plaintiff). Compare *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006), *rev'd*, 495 F.3d 695 (D.C. Cir. 2007) (en banc) (identifying right at issue as right of terminally ill patient with no government-approved treatments to access post-Phase I experimental new drugs), with *Reno v. Flores*, 507 U.S. 292, 302 (1993) (identifying issue as right of orphaned child to be placed in custody of private custodian rather than government-operated or government-selected institution), and *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 277-78 (1990) (defining fundamental right as right of competent person to refuse lifesaving hydration and nutrition).

<sup>147</sup> See *infra* notes 148-54 and accompanying text (discussing inability of fundamental right to satisfy both prongs of *Glucksberg*).

<sup>148</sup> See *infra* notes 149-52 and accompanying text; see also *Washington v. Glucksberg*, 521 U.S. 702, 721-22 (1997).

<sup>149</sup> See *Abigail Alliance*, 495 F.3d at 703; see also *id.* at 717-19 (Rogers, J., dissenting).

<sup>150</sup> *Abigail Alliance*, 445 F.3d at 480 (discussing common law doctrines but noting that Alliance is complaining only about obstacles to post-Phase I investigational new drugs).

<sup>151</sup> See *United States v. Rutherford*, 442 U.S. 544, 558 (1979) (finding no FDCA exception for terminally ill patients to access laetrile); see also *Mitchell v. Clayton*, 995 F.2d 772, 775-76 (7th Cir. 1993) (holding patients have no constitutional right to obtain particular treatment); *United States v. Burzynski Cancer Research Inst.*, 819 F.2d 1301, 1313-14 (5th Cir. 1987) (finding terminally ill patients had no constitutional right to obtain specific medical treatment); *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (denying right to access specific medical treatment); *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980) (finding no right to take specific treatment regardless of efficacy and safety); *People v. Privitera*, 591 P.2d 919, 920 (Cal. 1979) (excluding right to medical treatment from protection of

In *Rutherford*, the Court held the legitimate state interests in public health and safety justified the FDA's ban on access to unapproved drugs.<sup>152</sup> These interests are equally compelling today; the D.C. Circuit correctly followed the *Rutherford* precedent in upholding the challenged FDA statutes.<sup>153</sup> Thus, the common law rights do not indicate a deeply rooted history of a right to access. Consequently, the right to access post-Phase I drugs fails the second prong of the *Glucksberg* test.<sup>154</sup>

Opponents may argue that restricting the scope of the right to post-Phase I drugs dispenses with the safety concerns that justified the *Rutherford* holding.<sup>155</sup> The *Rutherford* plaintiffs sought access to laetrile, a drug that had not completed Phase I trials.<sup>156</sup> Opponents may contend that *Rutherford* dealt with unapproved drugs which lack important safety data acquired in Phase I trials.<sup>157</sup> Thus, *Rutherford* does not control for post-Phase I drugs because the safety concerns that justified restricting access are absent in post-Phase I drugs.<sup>158</sup>

This argument fails, however, because characterizing Phase I as dispensing with most safety concerns is inaccurate.<sup>159</sup> Researchers agree that drug safety is an ongoing inquiry that continues throughout the FDA approval process and after approval.<sup>160</sup> Phase I trials are only the beginning of the process determining drug safety.<sup>161</sup> An important

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substantive due process); *cf. Doe*, 410 F.3d at 1344-46 (finding no right to be free from sex offender registration because prior case law did not recognize right).

<sup>152</sup> *Rutherford*, 442 U.S. at 558; *Mitchell*, 995 F.2d at 776; *Burzynski*, 819 F.2d at 1313-14; *Carnohan*, 616 F.2d at 1122; *Rutherford*, 616 F.2d at 457; *Privitera*, 591 P.2d at 920.

<sup>153</sup> See *infra* Part IV.B (discussing state interest in approval process).

<sup>154</sup> See *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (requiring fundamental rights to have deep roots in American history); *supra* notes 146-52 and accompanying text.

<sup>155</sup> See *Abigail Alliance*, 445 F.3d at 486 (considering drugs that had cleared Phase I to be sufficiently safe).

<sup>156</sup> See *id.* (distinguishing *Rutherford* because laetrile had not cleared Phase I testing); Brief of Appellants, *supra* note 10, at 40-43 (distinguishing *Rutherford* and related cases based on unapproved status of laetrile and drugs previously sought).

<sup>157</sup> *Abigail Alliance*, 445 F.3d at 486.

<sup>158</sup> *Id.*

<sup>159</sup> See *infra* notes 161-64 and accompanying text; *cf. Abigail Alliance*, 445 F.3d at 486 (defining completion of Phase I designating drugs as sufficiently safe for expanded testing with increased numbers of human subjects).

<sup>160</sup> See *infra* notes 161-64 and accompanying text.

<sup>161</sup> Donald Kennedy, *Health Roundup*, 312 Sci. 1105, 1105 (2006), available at <http://www.sciencemag.org/cgi/reprint/312/5777/1105.pdf> (stating Phase I determines only appropriate dosing ranges, not safety); Sara Gambrill, *The Right to Use Unproven*

objective of Phase II trials is to acquire further information on drug safety, and important safety findings also arise during Phase III trials.<sup>162</sup> Phase III safety findings may be particularly relevant to patients who do not qualify for Phase I or II trials, such as the plaintiffs in *Abigail Alliance*.<sup>163</sup> Even after FDA approval, serious safety issues can still arise.<sup>164</sup> Thus, given the many important safety issues that remain unresolved after Phase I, post-Phase I drugs do not differ substantially from completely unapproved drugs.<sup>165</sup> Accordingly, post-Phase I drugs have not muted the safety concerns that led the *Rutherford* Court to deny a fundamental right to access unapproved drugs.<sup>166</sup>

In summary, the D.C. Circuit correctly concluded that a specific right to access post-Phase I drugs is not deeply rooted in American history.<sup>167</sup> In its attempt to show historical evidence of access, the Abigail Alliance cited common law doctrines supporting a right explicitly rejected by the Supreme Court in *Rutherford*.<sup>168</sup> Absent any valid historical evidence, the right of terminally ill patients to access post-Phase I drugs fails the second prong of *Glucksberg*.<sup>169</sup>

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*Treatments?*, CLINICAL TRIALS TODAY, Aug. 8, 2006, available at [http://www.clinicaltrials.com/centerwatch\\_clinical\\_trial/2006/08/the\\_right\\_to\\_us\\_1.html](http://www.clinicaltrials.com/centerwatch_clinical_trial/2006/08/the_right_to_us_1.html).

<sup>162</sup> John W. Eikelboom et al., *Safety Outcomes in Meta-analyses of Phase 2 vs. Phase 3 Randomized Trials*, 285 JAMA 444, 448 (2001) (finding statistically significant difference in safety in meta-analysis comparison of Phase II and III trials for same therapy); Salim Yusuf, *Challenges in the Conduct & Interpretation of Phase II (Pilot) Randomized Trials*, 139 AM. HEART J. S136, S138 (2000) (noting key purpose of Phase II trials is to determine whether experimental treatment has acceptable level of safety).

<sup>163</sup> Eikelboom et al., *supra* note 162, at 448.

<sup>164</sup> For example, the increased risks of heart problems with Vioxx, an anti-inflammatory drug, surfaced only five years after market introduction. See Peter Jüni et al., *Risk of Cardiovascular Events and Rofecoxib: Cumulative Meta-analysis*, 364 LANCET 2021, 2025 (2004) (finding scientific evidence that Vioxx caused increased risk of myocardial infarction from 2000 onwards); Henry A. Waxman, *The Lessons of Vioxx Drug Safety and Sales*, 352 NEW ENG. J. MED. 2576, 2576 (2005) (noting Vioxx had been marketed since May 1999); News Release, Merck, Merck Announces Voluntary Worldwide Withdrawal of VIOXX (Sept. 30, 2004), available at [http://www.vioxx.com/vioxx/documents/english/vioxx\\_press\\_release.pdf](http://www.vioxx.com/vioxx/documents/english/vioxx_press_release.pdf).

<sup>165</sup> See *supra* notes 161-64 and accompanying text.

<sup>166</sup> See *United States v. Rutherford*, 442 U.S. 544, 558 (1979) (holding legitimate concerns of safety and efficacy justified denial of access to unapproved drugs); *supra* notes 161-64 and accompanying text.

<sup>167</sup> See *supra* notes 149-66 and accompanying text.

<sup>168</sup> See *supra* notes 149-53 and accompanying text.

<sup>169</sup> See *supra* notes 148-54 and accompanying text.

B. *The Right to Access Post-Phase I Experimental Drugs Under Glucksberg Would Undermine Clinical Research and Patients' Interests in Health and Safety*

The D.C. Circuit's refusal to recognize a fundamental right to access under *Glucksberg* prevented significant practical consequences for clinical research and enrollment.<sup>170</sup> The Alliance and the D.C. Circuit both agreed that FDA-approved drugs are preferred over unapproved drugs.<sup>171</sup> Aiming to minimize toxicity, Phase I trials often test doses too low to produce therapeutic responses.<sup>172</sup> Large clinical trials yield the most reliable data for safety and effectiveness.<sup>173</sup> Thus, patients have an interest in the efficiency of the FDA approval process.<sup>174</sup> Recognizing an unlimited fundamental right to access, however, would impede this process.<sup>175</sup>

Allowing terminally ill patients to access unapproved drugs would lead to decreased participation in clinical trials.<sup>176</sup> Under the existing framework, the main incentive for participating in clinical trials is obtaining access to state-of-the-art treatments.<sup>177</sup> A terminally ill

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<sup>170</sup> See *infra* notes 176-191 and accompanying text.

<sup>171</sup> Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 445 F.3d 470, 486 (D.C. Cir. 2006), *rev'd*, 495 F.3d 695, 701 (D.C. Cir. 2007) (en banc) (restricting inquiry to terminally ill patients with no approved treatment options); see also Eikelboom et al., *supra* note 162, at 448 (discussing ability of Phase III trials to identify uncommon but serious safety issues); Warren B. Sateren et al., *How Sociodemographics, Presence of Oncology Specialists, and Hospital Cancer Programs Affect Accrual to Cancer Treatment Trials*, 20 J. CLINICAL ONCOLOGY 2109, 2113 (2002) (noting large numbers of patients treated in standardized manner yielded most accurate data); Laura A. Simonoff et al., *Factors That Predict the Referral of Breast Cancer Patients onto Clinical Trials by Their Surgeons and Medical Oncologists*, 18 J. CLINICAL ONCOLOGY 1203, 1204 (2000) (finding slow completion of Phase III trials particularly detrimental because resulting lack of approved drugs increased patient demands for drugs lacking efficacy and safety data).

<sup>172</sup> Manish Agrawal & Ezekiel Emanuel, *Ethics of Phase I Oncology Studies: Reexamining the Arguments and Data*, 290 JAMA 1075, 1076 (2003); Estey E. Hoth et al., *Therapeutic Response in Phase I Trials of Antineoplastic Agents*, 70 CANCER TREATMENT REP. 1105, 1110 (1986).

<sup>173</sup> Okie, *supra* note 116, at 440; National Breast Cancer Coalition, NBCC Opposes Abigail Alliance's Petition to the FDA, [http://www.stopbreastcancer.org/index.php?option=com\\_content&task=view&id=76&Itemid=180](http://www.stopbreastcancer.org/index.php?option=com_content&task=view&id=76&Itemid=180) (last visited Feb. 18, 2008) (arguing best treatments are those supported by evidence from well-designed clinical trials).

<sup>174</sup> See *supra* notes 171-73 and accompanying text.

<sup>175</sup> See *infra* notes 176-91 and accompanying text.

<sup>176</sup> See *infra* notes 177-91 and accompanying text.

<sup>177</sup> Otis W. Brawley, Editorial, *The Study of Accrual to Clinical Trials: Can We Learn from Studying Who Enters Our Studies?*, 22 J. CLINICAL ONCOLOGY 2039, 2039 (2004)

patient's direct access to new drugs under *Abigail Alliance* would give him all the benefits of a clinical trial without the detriments.<sup>178</sup> The patient could receive the new treatment without having to worry about extra travel, testing, or getting a placebo treatment.<sup>179</sup> Clinical research enrollment would plummet as a result.<sup>180</sup> This enrollment decrease would ultimately undermine terminally ill patients' interests in having comprehensive safety and effectiveness information ascertained through clinical research.<sup>181</sup>

The use of high-dose chemotherapy with blood stem cell transplantation ("HDC-SCT") to treat breast cancer serves as one particularly costly example of early access harming research.<sup>182</sup> HDC-SCT is a very expensive treatment, costing \$60,000 to \$200,000, compared to conventional chemotherapy's cost of \$5,000 to

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(noting opportunity for receiving new therapy as reason for patient accrual to clinical trials).

<sup>178</sup> See *supra* note 177 and accompanying text (listing incentives and detriments to clinical trial participation); *infra* note 179 (same). Physicians will also find direct access to experimental therapies attractive due to the costs they incur in enrolling their patients in clinical trials. Gary I. Cohen, *Clinical Research by Community Oncologists*, 53 *CANCER J. CLINICIANS* 73, 76 tbl.2 (2003) (listing costs associated with clinical trials by community physicians); Simonoff et al., *supra* note 171, at 1204.

<sup>179</sup> Cohen, *supra* note 178, at 75 tbl.1 (listing typical patient concerns over clinical trial participation); A.J. Welton et al., *Is Recruitment More Difficult with a Placebo Arm in Randomised Controlled Trials? A Quasirandomised, Interview Based Study*, 318 *BRIT. MED. J.* 1114, 1116 (1999) (finding existence of placebo group exerted negative influence on patient decisions to participate in clinical trials); Gina Kolata, *Women Resist Trials to Test Marrow Transplants*, *N.Y. TIMES*, Feb. 15, 1995, at C8; see also Simonoff et al., *supra* note 171, at 1204 (finding slow completion of Phase III trials particularly detrimental because resulting lack of approved drugs increased patient demands for drugs lacking efficacy and safety data). "Placebo" never means "no treatment," but rather the best existing treatment or, if there is none, the best supportive and palliative care. Hampton, *supra* note 1, at 265 (recommending placebo treatment of pain and palliative care over third- and fourth-line therapies with dubious effectiveness); see, e.g., Stephen G. O'Brien et al., *Imatinib Compared with Interferon and Low-Dose Cytarabine for Newly Diagnosed Chronic-Phase Chronic Myeloid Leukemia*, 348 *NEW ENG. J. MED.* 994, 996 (2003) (using existing treatments as control for Phase III study of cancer drug imatinib).

<sup>180</sup> See *infra* notes 182-91 and accompanying text.

<sup>181</sup> See *supra* notes 172-73 (discussing importance of gathering comprehensive efficacy and safety data).

<sup>182</sup> See generally Jeffrey C. Lerner & Diane C. Robertson, *When There Are No Randomized Controlled Trials: A Case History of a Controversial Procedure for Metastatic Breast Cancer*, 14 *J.L. & POL'Y* 595 (2006) (laying out rise and fall of physician and patient interest in HCT-SCR); H. Gilbert Welch & Juliana Mogielnicki, *Presumed Benefit: Lessons from the American Experience with Marrow Transplantation for Breast Cancer*, 324 *BRIT. MED. J.* 1088 (2002) (summarizing evolution of medical knowledge and public demand for HCT-SCR therapy).

\$25,000.<sup>183</sup> Researchers published positive preliminary results in nonrandomized clinical trials for HDC-SCT in the late 1980s.<sup>184</sup>

Believing these results, patients successfully argued with the FDA for early access to HDC-SCT.<sup>185</sup> Subsequently, patients filed multiple lawsuits, many successful, requiring insurance companies to pay for their HDC-SCT.<sup>186</sup> Early access, combined with patient reluctance to receive placebos caused enrollment in randomized clinical trials to stagnate, delaying publication of valid data.<sup>187</sup>

Consequently, it was not until 1999 that researchers published the first valid randomized clinical trial results.<sup>188</sup> The data painted a sobering portrait: HDC-SCT was no more effective than standard treatments, despite the high price.<sup>189</sup> Insurance companies quickly dropped coverage for expanded access to HDC-SCT outside of clinical trials.<sup>190</sup> In sum, access to HDC-SCT outside of clinical trials impeded the acquisition of the very data showing its lack of improvement over existing therapies.<sup>191</sup>

A broad fundamental right for the terminally ill to access post-Phase I drugs creates the risk of another HDC-SCT-like tragedy repeating itself for every investigational new drug for the terminally ill.<sup>192</sup> Unrestricted early access to investigational new drugs would seriously

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<sup>183</sup> Welch & Mogielnicki, *supra* note 182, at 1088; Kolata, *supra* note 179.

<sup>184</sup> Lerner & Robertson, *supra* note 182, at 598-99; Welch & Mogielnicki, *supra* note 182, at 1088.

<sup>185</sup> Lerner & Robertson, *supra* note 182, at 599-600; Welch & Mogielnicki, *supra* note 182, at 1089.

<sup>186</sup> Lerner & Robertson, *supra* note 182, at 604-05; Welch & Mogielnicki, *supra* note 182, at 1089-90.

<sup>187</sup> Musa Mayer, *When Clinical Trials Are Compromised: A Perspective from a Patient Advocate*, 2 PLOS MED. 1060, 1061 (2005); Kolata, *supra* note 179; cf. Brian G. Feagan et al., *A Comparison of Methotrexate with Placebo for the Maintenance of Remission in Crohn's Disease*, 342 NEW ENG. J. MED. 1627, 1628 (2000) (noting similar difficulty of recruiting patients for methotrexate placebo-controlled trial due to availability of open-label methotrexate).

<sup>188</sup> Joan Stephenson, *Bone Marrow/Stem Cells: No Edge in Breast Cancer*, 281 JAMA 1576, 1576 (1999); Welch & Mogielnicki, *supra* note 182, at 1091. While researchers found positive results in a randomized clinical trial in 1995, the results were fraudulent. Lerner & Robertson, *supra* note 182, at 613-14; Welch & Mogielnicki, *supra* note 182, at 1089.

<sup>189</sup> Lerner & Robertson, *supra* note 182, at 613-14; Stephenson, *supra* note 188, at 1576; Welch & Mogielnicki, *supra* note 182, at 1089.

<sup>190</sup> Welch & Mogielnicki, *supra* note 182, at 1091; Gina Kolata & Kurt Eichenwald, *Insurer Drops a Therapy for Breast Cancer*, N.Y. TIMES, Feb. 16, 2000, at A24.

<sup>191</sup> See *supra* notes 183-90 and accompanying text (discussing HDC-SCT).

<sup>192</sup> See *supra* notes 183-90 and accompanying text (discussing HDC-SCT).

delay collection of comprehensive safety and efficacy data.<sup>193</sup> Every post-Phase I drug may look promising, but few actually acquire marketing approval.<sup>194</sup> If the terminally ill had access to post-Phase I drugs, they would have to choose from a plethora of mostly ineffective or toxic drugs.<sup>195</sup> Therefore, a broad fundamental right under *Glucksberg* would be harmful to the very population of terminally ill patients that right seeks to protect.<sup>196</sup>

In sum, the D.C. Circuit correctly applied the *Glucksberg* test to find that terminally ill patients did not have a fundamental right to access post-Phase I drugs.<sup>197</sup> In addition, the court's holding is sound from a policy perspective because it protects the crucial clinical research enrollment that a broad fundamental right would endanger.<sup>198</sup> However, though the D.C. Circuit correctly applied the *Glucksberg* test, it failed to recognize that a more limited fundamental right exists under the broader *Casey* test.<sup>199</sup>

C. *A Right to Access All Experimental Drugs Under the Casey "Undue Burden" Analysis Evenhandedly Protects Individual and Government Interests*

The D.C. Circuit did not consider, much less apply, the *Casey* test to the right to access post-Phase I drugs.<sup>200</sup> Applying *Casey* to terminally ill patients strikes a better balance between the government's interest in safety and patients' interests in personal dignity and autonomy.<sup>201</sup> Under *Casey*'s undue burden analysis, access to drugs depends on whether the FDA approval process unduly burdens a patient's access

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<sup>193</sup> See *supra* notes 183-90 and accompanying text (discussing HDC-SCT).

<sup>194</sup> Soc'y of Clinical Trials Bd. Dirs., *The Society for Clinical Trials Opposes U.S. Legislation to Permit Marketing of Unproven Medical Therapies for Seriously Ill Patients*, 3 CLINICAL TRIALS 154, 155 (2006), available at <http://ctj.sagepub.com/cgi/reprint/3/2/154.pdf> (noting only 11% of all post-Phase I cancer drugs are ultimately approved).

<sup>195</sup> *Id.*

<sup>196</sup> See *supra* notes 176-91 and accompanying text.

<sup>197</sup> See *supra* Part IV.A.

<sup>198</sup> See *supra* notes 176-91 and accompanying text.

<sup>199</sup> See *infra* Part IV.C.

<sup>200</sup> See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 701-02 (D.C. Cir. 2007) (en banc), cert. denied, 128 S. Ct. 1069 (2008) (discussing only *Glucksberg* test in summary of Due Process Clause protection).

<sup>201</sup> See *infra* Part IV.C.

to safe, effective drugs.<sup>202</sup> The limited scope of this right allows for a more balanced analysis of alleged governmental infringements than an all-or-nothing right under *Glucksberg*.<sup>203</sup> Specifically, while allowing the FDA to enforce regulations prohibiting access to unapproved drugs of unknown safety, it would guarantee the terminally ill access to unapproved drugs with promising indications of efficacy.<sup>204</sup>

Under *Casey*, individuals have a fundamental right to make intimate choices related to their personal autonomy and self-preservation.<sup>205</sup> The line of cases that led to the development of the *Casey* test recognized a range of personal decisions profoundly affecting one's life as fundamental rights.<sup>206</sup> Moreover, the Supreme Court has not foreclosed the possibility of finding new fundamental rights protecting personal autonomy.<sup>207</sup> The right to choose a treatment is essential to patients' personal autonomy because it is an integral part of being able to manage one's health.<sup>208</sup> Therefore, under *Casey*, the Court should

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<sup>202</sup> See *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 877 (1992) (stating test for determining whether undue burden exists). The right the Supreme Court should recognize under the *Casey* test should not be the right to access post-Phase I drugs, but rather the right to access all unapproved drugs generally. While this may initially appear to be dangerously broad, the limited nature of the right under *Casey* ensures that existing FDA regulations will not be swept aside. See *infra* notes 210-28 and accompanying text (discussing limited nature of rights under *Casey*).

<sup>203</sup> See *Brownstein*, *supra* note 64, at 956 (arguing undue burden standard is necessary for proper balance between protection of individual rights and proper government function); *Conkle*, *supra* note 64, at 92-99, 108-09 (noting ability of courts applying *Casey* standard to consider all interests involved, and finding *Glucksberg* too restrictive to address contemporary legal issues and interests).

<sup>204</sup> See *infra* notes 222-28 and accompanying text.

<sup>205</sup> See *Casey*, 505 U.S. at 851; *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 480-81 (D.C. Cir. 2006), *rev'd*, 495 F.3d 695, 701 (D.C. Cir. 2007) (en banc) (restricting inquiry to terminally ill patients with no approved treatment options).

<sup>206</sup> See generally *Roe v. Wade*, 410 U.S. 113 (1973) (finding fundamental right to obtain abortion within right of personal privacy); *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (finding fundamental right to procreational decisions); *Griswold v. Connecticut*, 381 U.S. 479, 483-86 (1965) (finding fundamental right to contraception existed as part of right to privacy guaranteed under Bill of Rights).

<sup>207</sup> See *Carey v. Population Serv. Int'l*, 431 U.S. 678, 684 (1977) (noting lack of outer limits to right of privacy and expressing willingness to recognize fundamental rights protecting personal decisions from governmental interference).

<sup>208</sup> *Roe*, 410 U.S. at 153 (White, J., concurring) (construing right to privacy as including freedom of individuals to care for their own health and body); Craig C. Earle et al., *Identifying Potential Indicators of the Quality of End-of-Life Cancer Care from Administrative Data*, 21 J. CLINICAL ONCOLOGY 1133, 1134 (2003) (noting terminally ill patients and family members considered access to treatment choices key element of patient choice and autonomy); cf. *Andrews v. Ballard*, 498 F. Supp. 1038, 1048 (S.D.

have recognized a fundamental right to access drugs as a logical expansion of this doctrine.<sup>209</sup>

The benefit of applying *Casey* to the issue of access is that it allows for the evenhanded balancing of individual rights and government interests.<sup>210</sup> In *Casey*, the Court noted that a woman's right to abortion conflicted with the government's interest in preserving the life of the fetus.<sup>211</sup> Similarly, in *Abigail Alliance*, the patients' right to access drugs conflicts with the government's interest in ensuring the safety and efficacy of drugs.<sup>212</sup> Applying *Casey* to *Abigail Alliance* would enable the Court to evaluate the relative strengths of these interests regarding each individual patient.<sup>213</sup>

Under such an analysis, an average, healthy adult seeking access to experimental drugs would be in a position analogous to a pregnant woman with a viable fetus.<sup>214</sup> Despite the right to privacy, the state's interest in protecting the fetus's life has sufficient force to restrict the woman's right to abortion.<sup>215</sup> Likewise, for the healthy individual, taking an unapproved drug will yield no therapeutic benefit, and does not justify the risk of harmful side effects.<sup>216</sup> Thus, the FDA's interest in safety and efficacy would be sufficiently strong to uphold most governmental regulations limiting healthy individuals' access to drugs.<sup>217</sup>

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Tex. 1980) (holding substantive due process protected right to obtain or reject medical treatment).

<sup>209</sup> *Abigail Alliance*, 445 F.3d at 480-81; cf. Earle et al., *supra* note 208, at 1134 (noting perceived importance of right to access by terminally ill patients and family members); Note, *supra* note 63, at 2793 (arguing for recognition of substantive due process right to in vitro fertilization).

<sup>210</sup> Brownstein, *supra* note 64, at 955-56; Conkle, *supra* note 64, at 109; Tribe, *supra* note 61, at 1927; see *Gonzales v. Carhart*, 127 S. Ct. 1610, 1627 (2007) (noting that balancing of interests was central to *Casey*'s holding).

<sup>211</sup> *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 869 (1992).

<sup>212</sup> See *United States v. Rutherford*, 442 U.S. 544, 555-56 (1979) (noting government interest in ensuring safety and efficacy of drugs); *supra* Part IV.B (discussing how expanded access creates disincentive for terminally ill to enroll in clinical research).

<sup>213</sup> See *Casey*, 505 U.S. at 869-70 (describing conflicting interests of women's liberty and concern for fetal life).

<sup>214</sup> See *id.* (holding fetal viability created independent existence of second life subject to state protection overriding mother's rights).

<sup>215</sup> *Id.*

<sup>216</sup> *Rutherford*, 442 U.S. at 555-56.

<sup>217</sup> See *Casey*, 505 U.S. at 869-70 (holding state interest in protecting life outweighed personal liberty interest post-viability); *Browning v. Herbert (In re Browning)*, 568 So. 2d 4, 14 (Fla. 1990) (identifying preserving life as most significant state interest); Brief of Appellants, *supra* note 10, at 17 (noting in most circumstances

Conversely, a terminally ill patient is analogous to a pregnant woman before viability.<sup>218</sup> In *Casey*, the woman's interest in privacy outweighed the state's interest in the life of the fetus.<sup>219</sup> Likewise, the patient's shortened life expectancy and diminished health would significantly diminish the government's ability to protect her from bodily harm.<sup>220</sup> As a result, the terminally ill patient's liberty interest in personal autonomy and dignity would outweigh the FDA's interest in safety and efficacy.<sup>221</sup>

Thus, under the *Casey* analysis, the FDA could not completely prohibit a terminally ill patient's access to drugs.<sup>222</sup> However, the FDA could continue to regulate access to drugs as long as it did not unduly burden the patient's exercise of that right.<sup>223</sup> For example, a prohibition on laetrile would not unduly burden a patient's right to treatment because studies revealed a lack of efficacy.<sup>224</sup> The FDA could justify its prohibition with its interest in protecting patients from toxic side effects.<sup>225</sup> In addition, the patients would not suffer any tangible loss from not being able to take an ineffective drug.<sup>226</sup> Conversely, prohibiting early access to imatinib, a drug that demonstrated exceptional efficacy during premarket approval, would

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government interest in protecting health of citizens is sufficiently compelling to override right to access).

<sup>218</sup> See *Casey*, 505 U.S. at 870 (noting woman has right to choose to terminate pregnancy before viability).

<sup>219</sup> *Id.*

<sup>220</sup> *Washington v. Glucksberg*, 521 U.S. 702, 746 (1997) (Stevens, J., concurring) (observing state interest in preserving life has less force for terminally ill patients); *In re Quinlan*, 355 A.2d 647, 664 (N.J. 1976).

<sup>221</sup> *Cf. Casey*, 505 U.S. at 870 (noting state interests only controlled post-viability).

<sup>222</sup> *Cf. id.* at 846 (recognizing right to obtain abortion pre-viability without undue governmental interference).

<sup>223</sup> See *id.* at 874. In many ways, this would be a mere extension of what the FDA already does through existing early access programs such as "Treatment IND." See 21 C.F.R. § 312.34 (2006). Treatment INDs allow use of investigational drugs for "serious or immediately life-threatening disease" in the absence of any therapeutic alternatives. *Id.*; *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 699 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

<sup>224</sup> See *supra* Part II.C.1 (noting lack of evidence of efficacy of laetrile when patients sought access). Even if laetrile had completed Phase I trials, its prohibition still would not unduly burden the terminally ill because Phase I completion does not prove efficacy. See *supra* notes 161-64 (discussing efficacy evidence yielded by research subsequent to Phase I).

<sup>225</sup> See Moertel et al., *supra* note 97, at 201-06 (discussing laetrile toxicity).

<sup>226</sup> See *United States v. Rutherford*, 442 U.S. 544, 555-56 (1979) (noting access to drugs lacking therapeutic benefit would be harmful to terminally ill patients).

probably constitute an undue burden.<sup>227</sup> Indeed, with imatinib demonstrating exceptional efficacy, barring access to imatinib as early as post-Phase I could constitute an unconstitutional undue burden.<sup>228</sup>

Opponents of the *Casey* analysis may argue the Supreme Court's holding in *Lawrence* superseded the *Casey* holding.<sup>229</sup> After all, *Lawrence* is a more recent decision relying on the same cases and concepts of personal autonomy as *Casey*.<sup>230</sup> In *Lawrence*, the court considered the laws and traditions of the past fifty years to determine what should be a fundamental right.<sup>231</sup> The traditions of the past fifty years support access controlled by government regulation, not a right of free access to drugs.<sup>232</sup> Therefore, under *Lawrence*, there would be no right to access drugs free of government regulation.<sup>233</sup>

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<sup>227</sup> Prohibiting access to imatinib would be equivalent to the ban on dilation and extraction abortion procedures that the Supreme Court invalidated in *Stenberg v. Carhart*, 530 U.S. 914, 944 (2000). Imatinib demonstrated great efficacy even in Phase I trials. See generally Brian J. Druker et al., *Efficacy and Safety of a Specific Inhibitor of the BCR-ABL Tyrosine Kinase in Chronic Myeloid Leukemia*, 344 JAMA 1031 (2001) (finding 93% positive response to imatinib in Phase I trial); Hagop Kantarjian et al., *Hematologic and Cytogenetic Responses to Imatinib Mesylate in Chronic Myelogenous Leukemia*, 346 NEW ENG. J. MED. 645 (2002) (finding 89% positive response to imatinib in Phase II trial); O'Brien et al., *supra* note 179 (establishing efficacy of imatinib in Phase III trial).

<sup>228</sup> Druker et al., *supra* note 227, at 1031 (noting exceptionally high patient response rate to imatinib in Phase I trial).

<sup>229</sup> *Lawrence v. Texas*, 539 U.S. 558, 558 (2003); see Hawkins, *supra* note 25, at 411 (identifying *Lawrence* and *Glucksberg* as dominant fundamental rights cases).

<sup>230</sup> See *Lawrence*, 539 U.S. at 565-66, 574 (citing *Griswold*, *Casey*, and other personal autonomy cases); Sunstein, *supra* note 71, at 16 (noting *Lawrence* Court's emphasis on association with *Griswold*, *Casey*, and other related fundamental rights cases).

<sup>231</sup> *Lawrence*, 539 U.S. at 571-72 (limiting historical inquiry to past 50 years); see *id.* at 572-77 (noting worldwide rejection of homosexual sodomy laws during past half century).

<sup>232</sup> See Kefauver-Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780, 780 (1962) (codified at 21 U.S.C. §§ 301-381 (2000)) (conferring authority on FDA to require evidence of drug efficacy); Santoro, *supra* note 78, at 13 (noting 1960s global societal consensus requiring clinical data demonstrating safety and efficacy as prerequisite for drug marketing); U.S. Food & Drug Administration, *supra* note 76 (discussing Kefauver-Harris Amendments). Even the FDA's early access programs for new drugs such as Treatment IND and parallel track support only a right to government regulated access. See generally 21 C.F.R. § 312.34 (2006) (describing Treatment IND program); Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People with AIDS and Other HIV-Related Disease, 57 Fed. Reg. 13,250, 13,256 (Apr. 15, 1992) (discussing final implementation of parallel track program); Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People with AIDS and HIV-Related Disease, 55 Fed. Reg. 20,856, 20856 (May 21, 1990) (proposing parallel track program for AIDS patients); Lois K. Perrin, *The Catch-22 for Persons with AIDS: To Have or Not to Have Easy Access*

However, this argument fails because courts have continued to apply *Casey's* undue burden standard even after *Lawrence*.<sup>234</sup> In addition, most courts have either refused to apply *Lawrence* or have restricted its holding to homosexual sodomy.<sup>235</sup> Finally, *Lawrence* provides little guidance to lower courts regarding the level of scrutiny to apply to a government infringement of fundamental rights.<sup>236</sup> By comparison, *Casey's* undue burden analysis provides a useful balancing test that courts have consistently utilized to uphold or invalidate statutes.<sup>237</sup> Thus, the Supreme Court should have reversed

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to *Experimental Therapies and Early Approval for New Drugs*, 69 S. CAL. L. REV. 105 (1995) (summarizing Treatment IND and parallel track programs).

<sup>233</sup> Cf. *Lawrence*, 539 U.S. at 575-77 (deriving right to homosexual sexual activity from recent decreasing criminalization and worldwide acceptance of such activity).

<sup>234</sup> See *Gonzales v. Carhart*, 127 S. Ct. 1610, 1626-27 (2007) (applying *Casey* precedent to uphold Partial Birth Abortion Ban Act of 2003); *Womens Med. Prof'l Corp. v. Baird*, 438 F.3d 595, 604-06 (6th Cir. 2006) (holding application of transfer agreement requirement for licensing of surgical facilities to abortion clinic did not constitute undue burden on right to abortion); *Planned Parenthood of Idaho v. Wasden*, 376 F.3d 908, 930 (9th Cir. 2004) (finding medical emergency exceptions of abortion statute unconstitutionally narrow); *Reprod. Health Servs. of Planned Parenthood of St. Louis Region, Inc. v. Nixon*, 185 S.W.3d 685, 691-92 (Mo. 2006) (finding 24-hour waiting period prior to obtaining abortion did not violate Fourteenth Amendment Due Process Clause).

<sup>235</sup> See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 706 n.10 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008) (refusing to use *Lawrence* analysis instead of *Glucksberg*); *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 477 n.8 (D.C. Cir. 2006), *rev'd*, 495 F.3d 695 (D.C. Cir. 2007) (en banc) (construing *Lawrence* as not substantive due process decision); *Muth v. Frank*, 412 F.3d 808, 817-18 (7th Cir. 2005) (holding *Lawrence* was not substantive due process decision); *Williams v. Att'y Gen. of Ala.*, 378 F.3d 1232, 1238-39 (11th Cir. 2004) (applying *Glucksberg* instead of *Lawrence*); *Hawkins*, *supra* note 25, at 411 (noting courts' restriction of *Lawrence* to homosexual sodomy cases and overall preference of courts to apply *Glucksberg*). Some courts follow Justice O'Connor's concurring opinion in *Lawrence*, which applied an Equal Protection Clause analysis instead of invoking the Fourteenth Amendment Due Process Clause. See *People v. Hofsheier*, 129 P.3d 29, 36 (Cal. 2006); *State v. John M.*, 894 A.2d 376, 394 (Conn. App. Ct. 2006) (citing *Lawrence* as equal protection decision); *Neifert v. Dep't of the Env't*, 910 A.2d 1100, 1112 (Md. Ct. Spec. App. 2006) (citing Justice O'Connor's concurrence in applying Equal Protection analysis); *Samuels v. N.Y. State Dep't of Health*, 811 N.Y.S.2d 136, 145 (N.Y. App. Div. 2006) (considering Justice O'Connor's concurrence as factor for restricting holding of *Lawrence*); see also *Lawrence*, 539 U.S. at 582-85 (O'Connor, J., concurring) (applying Equal Protection Clause instead of Due Process Clause).

<sup>236</sup> See *supra* note 71 (noting courts and scholars disagree on level of scrutiny *Lawrence* mandates).

<sup>237</sup> See *Stenberg v. Carhart*, 530 U.S. 914, 921-22 (2000) (invalidating partial birth abortion statute); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 874 (1992) (describing undue burden standard unambiguously); *supra* notes 56-59 and

the D.C. Circuit's holding based on *Glucksberg* and instead found a limited fundamental right to access unapproved drugs under *Casey*.<sup>238</sup>

#### CONCLUSION

The D.C. Circuit correctly rejected a strong fundamental right for terminally ill patients to access post-Phase I new drugs.<sup>239</sup> Although the needs of the terminally ill are hardly trivial, a strong fundamental right endangers clinical research necessary for safe and effective drugs.<sup>240</sup> The D.C. Circuit should have, however, analyzed the asserted right further. A better solution would have been to find a more limited fundamental right under *Casey*.<sup>241</sup> A limited right would guarantee the terminally ill a right of access, albeit only to drugs that are demonstrably effective.<sup>242</sup> Furthermore, such a right better balances the interests of both the terminally ill and the FDA. For these reasons, the Supreme Court should reverse the D.C. Circuit's decision.<sup>243</sup>

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accompanying text (discussing examples of application of undue burden test).

<sup>238</sup> See *supra* Part IV.A-C.

<sup>239</sup> *Abigail Alliance*, 495 F.3d at 711-12; see *supra* Part IV.A.

<sup>240</sup> See *supra* Part IV.B.

<sup>241</sup> See *supra* Part IV.C.

<sup>242</sup> See *supra* notes 224-27 and accompanying text.

<sup>243</sup> See *supra* Part IV.