

4-1-2017

## Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach: Access to Experimental Drugs: Is Access to Experimental Drugs a Fundamental Right When it Comes to the Treatment of the Terminally Ill?

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### Recommended Citation

Lesley, Preston W. (2017) "Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach: Access to Experimental Drugs: Is Access to Experimental Drugs a Fundamental Right When it Comes to the Treatment of the Terminally Ill?," *North Carolina Central University Science & Intellectual Property Law Review*: Vol. 10 : Iss. 1 , Article 2.  
Available at: <https://archives.law.nccu.edu/siplr/vol10/iss1/2>

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**ABIGAIL ALLIANCE FOR BETTER ACCESS TO  
DEVELOPMENTAL DRUGS V. VON ESCHENBACH: ACCESS TO  
EXPERIMENTAL DRUGS: IS ACCESS TO EXPERIMENTAL  
DRUGS A FUNDAMENTAL RIGHT WHEN IT COMES TO THE  
TREATMENT OF THE TERMINALLY ILL?**

PRESTON W. LESLEY<sup>1</sup>

**ABSTRACT**

The Due Process Clause of the Fifth Amendment to the United States Constitution provides that no person shall be deprived of life, liberty, or property, without due process of the law.<sup>2</sup> In the two hundred years since James Madison authored the Constitution, the United States Supreme Court has held that the Fifth Amendment guarantees more than just fair process, but also heightened protection against governmental interference with certain fundamental rights.<sup>3</sup> But what is a fundamental right? In the wake of landmark Supreme Court decisions, “the rights to marriage, have children, direct the education and upbringing of one’s children, marital privacy, contraception, bodily integrity, and abortion,” were all deemed fundamental rights.<sup>4</sup> But what about the fundamental right to medical treatment? Even more complex, what about the fundamental right to experimental medical treatment? The Food, Drug, and Cosmetic Act generally prohibits access to new drugs unless and until they have been approved by the Food and Drug Administration (FDA).<sup>5</sup> However, gaining FDA approval can be a long and tumultuous process. For patients with terminal illnesses, the protracted approval times can end in prolonged treatment options and even death. This article presents the conflicting issues that arise when terminally ill patients are not afforded the fundamental right to experimental medical treatment.

**PROLOGUE: THE ABIGAIL ALLIANCE**

*“This is not just about me.  
This is about so many others.”  
-Abigail Burroughs*

The Abigail Alliance was incorporated in the state of Virginia in November of 2001. However, the Alliance really started in early March of

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2. U.S. Const. amend. V.

3. *Wash. v. Glucksberg*, 521 U.S. 702, 719, 117 S. Ct. 2258, 2267 (1997).

4. *Id.* at 720, 117 S.Ct. at 2268.

5. 21 U.S.C.A. § 355(a) (2015).

2001 when Abigail, who had just turned twenty-one, had run out of conventional options in her battle against cancer, and was being treated at Johns Hopkins Hospital. Abigail's very talented oncologist urged her to try and get the EGFR<sup>6</sup> targeted drug C225 (Erbix) from small Imclone Systems or Iressa or very large Astra Zeneca. Abigail's cancer cells had a very high EGFR expression and her oncologist strongly felt these drugs had a very significant chance of saving her life.

Abigail was still strong then as we worked hard and intelligently and launched, with Abigail's involvement and help, a three-pronged approach. We lobbied the two pharmaceutical companies with much vigor including getting help from some very influential people. Then we worked hard and furiously to solicit Congressional help. With Abigail, we launched a media effort that resulted in numerous stories in the press. As tired and weak as she was, Abigail did multiple newspaper and television interviews. Through those difficult times, Abigail's devoted Mom, Kathleen Dunn, and Step Dad, Gene Krueger, did so much to care and comfort Abigail in order to help her retain as much independence as possible.

Abigail died on June 9, 2001, just a week and half after doing an extensive interview with Dale Solly of ABC WJLA TV. Abigail's words in her TV piece echoed the Abigail Alliance mission statement when she stated, "This is not just about me. I am trying to help so many others."<sup>7</sup>

-Abigail's Father, Frank Burroughs

## I. INTRODUCTION

To what extent can the terminally ill, in the United States of America, pursue experimental medical treatment? When the prognosis is poor, and there are no adequate medical alternatives, are the terminally ill afforded a fundamental right to experimental medical treatment?

In *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*,<sup>8</sup> the Supreme Court of the United States declined to hear Abigail Alliance's ("the Alliance") appeal from the United States District Court of Columbia, which left the decision that the Alliance had not provided

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6. Epidermal Growth Factor Receptor. Elevated levels of EGFR, a growth-factor-receptor tyrosine kinase, and/or its cognate ligands have been identified as a common component of multiple cancer types and appear to promote solid tumor growth. RI Nicholson et al., EGFR and cancer prognosis, *Eur J Cancer* (Sep. 2001), <https://www.ncbi.nlm.nih.gov/pubmed/11597399>.

7. Abigail Alliance, *Our Story*, The Abigail Alliance for Better Access to Developmental Drugs (2001-2009), <http://www.abigail-alliance.org/story.php> (last visited Feb 5, 2017).

8. *Abigail All. for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695 (2007).

evidence of “a right to procure and use experimental drugs that is deeply rooted in our Nation’s history” standing.<sup>9</sup> This decision need not, however, limit terminally ill patients to await the clinical testing process before gaining access to experimental drugs. The Food and Drug Administration (FDA) and Congress have created several programs designed to provide early access to promising experimental drugs when warranted.<sup>10</sup> Also, the decision left open the option for the Alliance, the FDA, and the scientific community to reach an option through the democratic process in the future.<sup>11</sup>

Medical treatment is continuously improving, and medicine has evolved exponentially since the days of treatment by bloodletting<sup>12</sup> and dressing wounds with turpentine. However, modern medicine, while effective, is not a cure-all.<sup>13</sup> The decision in *Abigail Alliance* contains an in-depth analysis of the clinical trial process that experimental medical drugs must undergo before being made available to the general public. The decision further expands upon the Court’s rationale for denying the terminally ill unfettered access to experimental drugs. Also, *Abigail Alliance* raises the issue of self-preservation, a person’s fundamental rights, and the “inevitable tension between early availability of products to patients, especially patients with refractory disease, and the need to obtain sufficient data to provide a reasonable expectation of benefit and lack of excessive harm.”<sup>14</sup>

This note will focus on the implied historical aspect, and rationale, used in the *Abigail Alliance* decision, as well as the lasting effects the decision will have on future medical advancements. This note will further provide a factual overview of the case, and summary of the government’s involvement in the regulation of medical treatment in the United States. Finally, this note buttresses the Court’s decision to preclude the terminally ill the fundamental right to experimental drugs.

## II. THE CASE

The case stems from a citizen petition the Abigail Alliance and the Washington Legal Foundation submitted to FDA in 2003, requesting the agency amend its investigational new drug application (IND) regulations to create a policy “to grant initial approval for promising drugs, biologics, and devices intended to treat life-threatening diseases with unmet needs,” and to

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9. *Id.* at 727.

10. *Id.* at 699.

11. *Id.* at 714.

12. Science Museum, Brought to Life: Exploring History of Medicine: Bloodletting, <http://www.sciencemuseum.org.uk/broughttolife/techniques/bloodletting> (last visited Feb. 10, 2017).

13. Dr. Kirkham et al., Wounds in the Middle Ages 18-20 (2014).

14. Letter from Peter J. Pitts, Associate Commissioner for External Relations, Department of Health and Human Services, to Frank Burroughs, President, Abigail Alliance for Better Access to Developmental Drugs 3 (Apr. 25, 2003).

seek “regulatory changes to permit expanded availability of developmental lifesaving drugs following phase one clinical trials and at all subsequent stages of the trial and review process.”<sup>15</sup> The Abigail Alliance began in early March of 2001, when Abigail Burroughs, who had just turned twenty-one, ran out of conventional treatment options in her battle against cancer. Abigail’s oncologist urged her family to pursue experimental treatment, which he felt would significantly improve Abigail’s chance of survival.<sup>16</sup> Abigail and her family launched an extensive effort to obtain the requested experimental drug by lobbying pharmaceutical companies, soliciting Congressional help, and rallying to media to her cause.

Unfortunately, Abigail passed before receiving experimental treatment, which may have saved her life. Nevertheless, her fight continued in the work of the Alliance. Following Abigail’s passing, the Alliance took their fight for experimental drugs to the United States Federal courts. In May, 2006, following an appeal from the United States District Court of Columbia, the United States Court of Appeals for the District of Columbia ruled in favor of the Abigail Alliance, and found that the United State Constitution protects the right of terminally ill patients to access treatments that are not approved by the Food and Drug Administration.<sup>17</sup>

On March 1, 2007, following an appeal by the FDA, the United States Court of Appeals for the District of Columbia reheard the case en banc. The question presented on appeal was whether the Constitution provides terminally ill patients access to experimental drugs that have passed limited safety trials but have not been proven safe and effective.<sup>18</sup> On August 7, 2007, the Court issued an 8-2 decision against the Abigail Alliance, reversing the previous panel decision, thereby upholding the District court’s decision that found no constitutional right to unapproved drugs by terminally ill patients.<sup>19</sup>

### III. BACKGROUND

#### 1. The Implied Rationale of the Court’s Decision: The Historical Aspect

The overriding tension within *Abigail Alliance* is the “inevitable tension between early availability of products to patients, especially patients with refractory disease, and the need to obtain sufficient data to provide a rea-

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15. Hyman, Phelps, & McNamara, D.C. Circuit Court Rules in Abigail Alliance Case; Affirms District Court Ruling That There is No Fundamental Right of Access to Experimental Drugs for the Terminally Ill, FDA Law Blog (Aug 7, 2007, 10:41 AM), [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2007/08/dc-circuit-cour.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2007/08/dc-circuit-cour.html).

16. Abigail Alliance, *supra* note 7.

17. Hyman, Phelps, & McNamara, *supra* note 15.

18. Abigail All. for Better Access to Developmental Drugs, 495 F.3d at 697.

19. *Id.*

sonable expectation of benefit and lack of excessive harm.”<sup>20</sup> But why is the United States government so concerned with the possibility of a person harming himself or herself when they are on the brink of death? The answer to this question may exist in common law, which is the precursor of the United States legal system, and the likelihood of “felo de se”, Latin for “felon of himself”, the common law legal term for suicide.<sup>21</sup>

In thirteenth century England, suicide, or “self-murder” became a crime under common law in England. However, suicide was long condemned as a mortal sin in the eyes of the Church. If a death were to be declared a suicide, the deceased would be denied a Christian burial, carried to a crossroads in the dead of night, and dumped in a pit, with a wooden stake hammered through the body pinning it in place. There would be no members of the clergy and no prayers offered. This lack of burial was morbid; however, the punishment did not end with death. The deceased’s family was stripped of their belongings and they were escheated to the Crown. As noted by historian Michael MacDonald, “the suicide of an adult male could reduce his survivors to pauperism.”<sup>22</sup>

The Court’s denial to hear the Alliance’s petition for appeal may also be akin to its decision in *Washington v. Glucksberg*.<sup>23</sup> In *Washington*, a group of doctors and terminally ill patients filed suit against the State of Washington challenging the constitutionality of a law which made it a crime to assist another in committing suicide. The district court found that terminally ill patients have a liberty interest protected by the Constitution to commit physician-assisted suicide, and the Washington law violated the Constitution. The Court of Appeals for the Ninth Circuit agreed, and affirmed the district court decision. The State of Washington appealed the decision to the United States Supreme Court, which reversed the decision of the district court and court of appeals.<sup>24</sup>

In *Washington*, the Court developed a two-part test to determine whether a liberty interest is fundamental and protected by the Due Process Clause of the Constitution.<sup>25</sup> First, the asserted right must have historically been regarded as fundamental, or as the Court reasoned, “deeply rooted in the Nation’s history and tradition.”<sup>26</sup> Second, the asserted right must be carefully

20. Letter from Peter J. Pitts, *supra* note 14.

21. Gerry Holt, When Suicide was Illegal, BBC (Aug. 3, 2011), <http://www.bbc.com/news/magazine-14374296>.

22. *Id.*

23. *Wash. v. Glucksberg*, 521 U.S. 702, 719, 117 S. Ct. 2258, 2267 (1997).

24. *Washington v. Glucksberg* – Washington Law Challenged, Law Library – American Law and Legal Information, <http://law.jrank.org/pages/24239/Washington-v-Glucksberg-Washington-Law-Challenged.html>

25. *Id.*

26. *Moore v. E. Cleveland*, 431 U.S. 494, 495, 97 S.Ct. 1932, 1934 (1977)

described and defined. The Court concluded that the asserted right to physician-assisted suicide did not meet either of those requirements. The Court reasoned that the right to assisted suicide was not deeply rooted in America's history because almost every state and most democratic nations have laws banning assisted suicide. Further, "for over 700 years, the Anglo-American common-law tradition has punished and otherwise disapproved of both suicide and assisting suicide."<sup>27</sup> A quote that harkens back to "felo de se." Chief Justice Rehnquist, who authored the majority decision, concluded with the following phrase, "Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society."<sup>28</sup>

Thus, the Court's decision in *Abigail Alliance*, along with the landmark decision in *Washington v. Glucksberg*, which denied the fundamental right to assisted-suicide, display the Court's reluctance to provide an individual with the means to commit "felo de se."<sup>29</sup> Also, both opinions reflect the Court's reluctance to make law and provide for the debate to continue in the legislature.

## 2. Government Regulation of Medical Treatment

The pillar of the Alliance's petition in *Abigail Alliance* was "preventing access to experimental drugs for terminally ill patients . . . must be subject to strict scrutiny because [it] interferes with a fundamental constitutional right."<sup>30</sup> As mentioned above, the Court described its "established method of substantive-due-process analysis" as having two primary features.<sup>31</sup> As stated in *Glucksberg*, "First, we [the Court] have regularly observed that the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed. Second, we [the Court] have required in substantive-due-process cases a careful description of the asserted fundamental liberty interest."<sup>32</sup> The Alliance argued the government's history, or lack thereof, of regulating medical treatment can be found in our Nation's history and traditions because "the government never interfered with the judgment of individual doctors about the medical effica-

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27. American Law and Legal Information, *supra* note 24.

28. *Glucksberg*, 521 U.S. at 735.

29. *Id.* at 702.

30. *Abigail All. for Better Access to Developmental Drugs*, 495 F.3d at 701

31. *Glucksberg*, 521 U.S. at 720

32. *Id.* at 720, 721.

cy of drugs until 1962.”<sup>33</sup> However, the Court in *Abigail Alliance* provided an extensive history of government regulation to counter this argument.

While the Alliance focused their argument on the medical *efficacy* (effectiveness) of particular drugs, their argument failed to realize the Nation’s regulation of the *safety* of drugs. Or as the Court stated, “the Alliance’s effort to focus on efficacy regulation ignores one simple fact: it is unlawful for the Alliance to procure experimental drugs not only because they have not been proven effective, but because they have not been proven safe.”<sup>34</sup> Thus, “in order for the Alliance to succeed on its claim of a fundamental right of access for the terminally ill to experimental drugs, the Alliance must show not only that there is a tradition of access to drugs that have not yet been proven effective, but also a tradition of access to drugs that have not yet been proven safe.”<sup>35</sup> The Court concluded that the Nation has long expressed an interest in drug regulation and provided the following history of the U.S. Government’s drug regulation.

In the early history of the United States, the Court observes not a tradition of protecting a right of access to drugs, but rather governments responding to the risks of new compounds as they become aware of and able to address those risks. Drug regulation in the United States began with the Colonies and States when the Colony of Virginia’s legislature passed an act in 1736 that addressed the dispensing of more drugs than was “necessary or useful” because that practice had become “dangerous and intolerable.”<sup>36</sup> In 1808, the territory of Louisiana passed an act requiring a diploma before permitting pharmacists to dispense drugs.<sup>37</sup> South Carolina passed a similar act in 1817, followed by Georgia in 1825, and Alabama in 1852.<sup>38</sup> In 1848, the Import Drug Act, banned “imported adulterated drugs” after a Congressional committee concluded that “this country had become the grand mart and receptacle of all the refuse [drug] merchandise . . . not only from the European warehouses, but from the whole Eastern world.”<sup>39</sup> Congress acted again when it passed the Biologics Controls Act of 1902, in response to a series of deadly reactions to a tainted diphtheria vaccine that killed children in New Jersey and Missouri.<sup>40</sup> Thus, the examples presented by the Court bolstered the argument that drug regulation is indeed rooted in America’s history and traditions.

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33. *Abigail All. for Better Access to Developmental Drugs*, 495 F.3d at 703.

34. *Id.*

35. *Id.*

36. *Id.* at 703-704.

37. *Id.* at 704.

38. *Id.*

39. *Id.*

40. *Id.* at 705.



### 3. Modern Governmental Regulation of Medical Treatment

The current regime of federal drug regulation began to take shape with the Food, Drug, and Cosmetic Act of 1938 (“FDCA”).<sup>41</sup> The FDCA requires drug manufacturers provide proof that their products are safe prior to being marketed. Additionally, the FDCA prohibits false therapeutic claims. Notably, the drug industry “strenuously objected” to the 1938 Act “ostensibly on the ground that it would deprive the American people of the right to self-medication,” an argument not unlike the Alliance’s position of today.<sup>42</sup>

Following the Court’s opinion that governmental regulation was historically rooted in our Nation’s history, the Court tackled modern governmental regulation beginning with the 1962 Amendments to the FDCA, commonly known as the Kefauver-Harris Amendments.<sup>43</sup> The Alliance contends that prior to these Amendments, which were enacted in response to birth defects in babies whose mother’s had taken Thalidomide to ease morning sickness, patients were free to make their own decisions about whether a drug may be effective.<sup>44</sup> The Kefauver-Harris Amendments set in place the extensive, and time consuming method of gaining FDA approval we know today.

As stated above, the method to obtain FDA approval can be a long and tedious process. First, an experimental drug’s sponsor, often a drug manufacturer, must submit an application for approval. The application “must contain full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.”<sup>45</sup> These reports rely largely on clinical trial with human subjects. However, before a sponsor can even begin human testing, it must submit an investigational new drug application (IND) to the FDA for approval. If the IND is approved, several phases of clinical trials can begin.<sup>46</sup> The clinical trial process averages three phases, which on average last up to seven years to complete.<sup>47</sup> Phase one consists of a small sample group to determine if the drug is safe enough for continued human testing.<sup>48</sup> Phase two studies are “well controlled” trials used to evaluate both “effectiveness” and “safety” with side effects.<sup>49</sup> Lastly, phase three is an expanded trial containing many subjects to evaluate the overall “benefit-risk” relationship.<sup>50</sup> The seven

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41. 21 U.S.C.A. § 301 (2016).

42. Abigail All. for Better Access to Developmental Drugs, 495 F.3d at 705.

43. *Id.* at 725.

44. *Id.*

45. 21 U.S.C.A. § 355 (2015).

46. *Id.*

47. Am. Compl. P15.

48. 21 C.F.R. § 312.21.

49. *Id.* § 312.21(a)(1).

50. *Id.* § 312.21(c).

years of clinical trials, the Alliance argues, is precious time a terminally ill patient could be undergoing treatment by the experimental drug.

#### IV. FROM EXPERIMENTAL TO EFFECTIVE

According to Merriam-Webster, the definition of experimental is “...done in order to see how well something works.”<sup>51</sup> The FDA defines experimental as “any use of a drug except for the use of a market drug in the course of medical practice.”<sup>52</sup> Where the above two definitions intersect is the “use” of the experimental drug in order to test its effectiveness. As previously mentioned, the FDCA generally prohibits access to new drugs unless and until they have been approved by the FDA.<sup>53</sup> However, as the Alliance alleged in *Abigail Alliance*, the experimental process is an “extremely lengthy one,” which impedes a terminally ill patient from receiving possibly life-saving medical treatment.<sup>54</sup>

Following the Courts historical approach to the Alliance’s argument that government regulation of safety and efficacy was not in existence until the 1962 Kefauver-Harris Amendments, the Court supported its decision by providing a counterarguments to the Alliance’s several common law doctrines, which argued that barring access to experimental drugs for terminally ill patients is “inconsistent with the way that our legal tradition treats persons in all other life-threatening situations.”<sup>55</sup> The Alliance argued three doctrines: 1) the doctrine of necessity; 2) the tort of intentional interference with rescue; and 3) the right to self-defense.<sup>56</sup>

##### 1. The Doctrine of Necessity

Looking first to the Alliance’s necessity argument, the Alliance invoked the common law doctrine of necessity, which “traditionally covered the situation where physical forces beyond the actor’s control rendered illegal conduct the lesser of two evils.”<sup>57</sup> However, the Alliance offers little detail about how necessity would apply to its case. Furthermore, in the 2001 case *United States v. Oakland Cannabis Buyers’ Cooperative*, the Court made it clear that Congress may eliminate a necessity defense that might otherwise be available.<sup>58</sup> Thus, in light of Congress’s limiting of experimental drugs by law, and the Supreme Court’s conclusion that the common law defense

51. Experimental, Merriam-Webster, available at <https://www.merriam-webster.com/dictionary/experimental>(last visited Feb.10 2017).

52. 21 C.F.R. § 312.3(b).

53. 21 U.S.C. § 355(a).

54. *Abigail All. for Better Access to Developmental Drugs*, 495 F.3d at 698.

55. *Id.* at 703.

56. *Id.*

57. *United States v. Oakland Cannabis Buyers’ Coop*, 532 U.S. 483, 490, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001) (quoting *United States v. Bailey*, 444 U.S. 394, 410, 100 S. Ct. 624, 62 L. Ed. 2d 575 (1980)).

58. *Id.* at 493, 121 S. Ct. at 1719.

of necessity remains controversial and cannot override a value judgment already determined by the legislature, the common law doctrine of necessity provides little support to the Alliance's proposed right.<sup>59</sup>

## 2. The Tort of Intentional Interference With Lifesaving Efforts

Additionally, the Alliance raised the tort of intentional interference with lifesaving efforts, which the Restatement of Torts defines as "intentionally preventing a third person from giving to another aid necessary to his bodily security."<sup>60</sup> But this doctrine is not analogous to the facts of this case. The Alliance seeks access to drugs that are experimental and have not been shown to be safe, let alone effective at (or "necessary" for) prolonging life. Altruistically, the Alliance concedes that taking experimental drugs can "involve enormous risks." In essence, Alliance insists on a constitutional right to assume any level of risk.<sup>61</sup> This alleged right to assume "any level of risk," especially an "enormous risk," set a substantial bar to the Alliance's argument.

## 3. The Doctrine of Self-Defense

The final, and most interesting, common law argument presented by the Alliance centered on the doctrine of self-defense. The common law doctrine of self-defense provides that "one who is not the aggressor . . . is justified in using a reasonable amount of force against his adversary when he reasonably believes (a) that he is in immediate danger of unlawful bodily harm from his adversary, and (b) that the use of such force is necessary to avoid this danger."<sup>62</sup>

The Alliance argued that the landmark abortion case of *Roe v. Wade*, which addressed a "right of personal privacy" also gave women the fundamental right to abort a fetus *at any stage of a pregnancy* if doing so is necessary to preserve the life or health of the mother.<sup>63</sup> Applying that argument here, "the Alliance argues that because its terminally ill members are in immediate danger of harm from cancer, they can use whatever medical means are necessary to defend themselves."<sup>64</sup> The Court reasoned that the Alliance's argument was not about using force to defend oneself, but about the constitutional right to "assume enormous risk."<sup>65</sup> Accordingly, "unlike the cases in which the doctrine of self-defense might be properly invoked, this case involves risk from drugs with no proven therapeutic effect, which at a minimum separates this example from the abortion "life of the mother"

59. Abigail All. for Better Access to Developmental Drugs, 495 F.3d at 708.

60. Restatement (First) of Torts § 326 (1934).

61. Abigail All. for Better Access to Developmental Drugs, 495 F.3d at 703.

62. Wayne R. Lafave, *Substantive Criminal Law* § 10.4 (2d ed. 2003).

63. *Roe v. Wade*, 410 U.S. 113, 93 S. Ct. 705 (1973).

64. Abigail All. for Better Access to Developmental Drugs, 495 F.3d at 709.

65. *Id.* at 710.

exception.<sup>66</sup> In brief, the Alliance's own acknowledgment that its right would involve "enormous risk" sets it apart from the "life of the mother" exception, which has been proven effective.

#### V. CONCLUSION

For the majority of our Nation's history the United States Court System has attempted to steer clear of decisions, which would "make law" and not "decide law." On August 7, 2007, the United States Court of Appeals for the District of Columbia continued this tradition by refusing to legislate through the Court a new fundamental right to experimental drugs.<sup>67</sup> Using the Court's rationale, this decision was made to ensure those with terminal illnesses maintain their quality of life, and not expose themselves to enhanced risk.

The efforts of the Alliance are praiseworthy; however, the burden of allowing citizens to expose themselves to detrimental harm would undoubtedly fall in the hands of the government. Accordingly, the government enacts rules and regulations to protect its citizens, not intentionally harm them. It should also be noted that the government is not the only one in opposition to the Alliance's requests. Other "members of the cancer community" have suggested that the FDA needs to maintain a strong clinical trial system as the basis of the approval of cancer drugs.<sup>68</sup> Thus, this inevitable tension rests not only in the courts, but the cancer community.

It was no mistake the Court echoed the words of Chief Justice Rehnquist at the close of its opinion, "our holding today ensures that this debate among the Alliance, the FDA, the scientific and medical communities, and the public may continue through the democratic process."<sup>69</sup> Accordingly, not all hope is lost for those who fight for access to experimental drugs when faced with certain death. Moreover, the Court has made it abundantly clear in the past and present, that this fight will take place in Congress, and not the judiciary.

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66. *Id.*

67. Abigail All. for Better Access to Developmental Drugs, 495 F.3d 695.

68. Letter from Peter J. Pitts, *supra* note 14.

69. *Wash. v. Glucksberg*, 521 U.S. 702, 735, 117 S. Ct. 2258, (1997).