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COMMENT

At the Altar of Autonomy: The Dangerous Territory of *Abigail Alliance v. von Eschenbach*¹

ANDREA BETH OTT†

[L]iberty is only implicated if others deprive me of choice, not if they simply fail to help me or fail to get out of my way.²

INTRODUCTION

Frank Burroughs watched his vibrant, teenage daughter suffer and waste away from a deadly form of head and neck cancer. Abigail was being treated at the world-

1. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

† J.D. Candidate, University at Buffalo Law School, 2010; Ph.D. Candidate, University at Buffalo Department of Philosophy, 2009. I would like to thank first and foremost the editors of the *Buffalo Law Review*, especially Amy C. Frisch, Editor-in-Chief, for her keen eye and support throughout this process. A special thank you to my Note & Comment Editor, Deanne Michelle Jeffries. I owe a great deal to Professors Sheila R. Shulman and Anthony H. Szczygiel whose courses and conversations sparked my interest in health law and to Professor Charles Patrick Ewing for his continual guidance. And finally, this Comment would not have come to fruition without the encouragement of my family and Nathan A. Heberlig.

2. CHARLES FRIED, *MODERN LIBERTY AND THE LIMITS OF GOVERNMENT* 51 (2007).

class Johns Hopkins University, but to no avail. Limited to conventional treatments and the time in which to administer them running out, Abigail desperately tried to get access to an experimental drug, Erbitux, not yet approved by the Food and Drug Administration (FDA). Abigail did not get access to Erbitux³ and passed away. Frank Burroughs listened to the stories of other families whose children and spouses suffered a fate similar to that of Abigail, along with their frustration with an often decade-long drug approval process. It was then that Frank Burroughs was inspired to form the Abigail Alliance for Better Access to Developmental Drugs (Alliance).⁴ In July 2003, this organization, along with conservative public interest group the Washington Legal Foundation, brought a suit against the FDA enjoining them from denying access to experimental drugs for the terminally ill.⁵

The administrative hurdle of drug approval, they asserted, is in violation of their substantive due process right to life as guaranteed by the Fifth Amendment of the Constitution.⁶ The district court found that the FDA's policy was rationally related to a legitimate government interest⁷ and, more significantly, the court did not find a

3. Erbitux was originally indicated for colorectal cancer and was not being tested at that time for head and neck cancer. Since Abigail's death, Erbitux has been approved for use in treatment for the type of squamous-cell carcinoma which killed Abigail. See Susan Okie, *Access before Approval—A Right to Take Experimental Drugs?*, 355 NEW ENG. J. MED. 437, 438 (2006).

4. Abigail Alliance for Better Access to Developmental Drugs, <http://abigail-alliance.org> (last visited Apr. 25, 2008). For another tragic story, see Geeta Anand, *Saying No to Penelope*, WALL ST. J., May 1, 2007, at A1.

5. Abigail Alliance for Better Access to Developmental Drugs v. McClellan, 2004 U.S. Dist. LEXIS 29594, at *5 (D.D.C. Aug. 30, 2004). The Alliance submitted a proposal to the FDA in January 2003 titled, *In Re Tier 1 Initial Approval Program*, which would make drugs available at the earliest possible stage of testing. Citizen Petition of the Abigail Alliance and the Washington Legal Foundation to the Food and Drug Administration, *In Re Tier 1 Initial Approval Program to Expedite the Availability of Lifesaving Drugs* (June 11, 2003). The access would be to drugs which have passed the Phase I safety hurdle and have generated sufficient data to move on to Phase II studies. *Id.* The failure of the FDA to respond within 180 days to the Citizen Petition entitled the Alliance to judicial review. See *McClellan*, 2004 U.S. Dist. LEXIS at *4 n.2.

6. Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 445 F.3d 470, 472 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

7. *Id.* at 475.

fundamental right and ultimately dismissed the case.⁸ Yet, in May 2006, a three-judge panel on the U.S. Court of Appeals for the D.C. Circuit found in favor of the Alliance, and remanded the case back to the district court to determine whether or not the FDA's policy was narrowly tailored to serve a compelling government interest.⁹

If a constitutional right had been found, this case would have had profound implications for science, research, and the regulation of the drug industry. However, the underlying premise of this case—namely, that terminally ill patients have an affirmative right to access early stage drugs—was misguided. The role of the FDA is to protect the nation's public health with regard to new drugs, and inherent in this idea of public health is a sacrifice of some individual liberties for the greater good.¹⁰ A fallout from availability of post-Phase I drugs would be enormous, as discussed below; this fallout would potentially affect millions of Americans to their detriment as the clinical trial system becomes compromised. More importantly, early access cannot be justified on a public health model.

The Court of Appeals for the D.C. Circuit vacated its May 2006 decision.¹¹ Granting a motion on behalf of the FDA, the court of appeals heard the case en banc on March 1, 2007, and on August 7, 2007, found in favor of the FDA,¹² resulting in a petition for certiorari to the Supreme Court of the United States.¹³ On January 14, 2008, the United States Supreme Court refused to hear the appeal; thus, the

8. *Id.* at 486. The district court did, however, find in favor of the Alliance with respect to procedural and administrative issues. *Id.* at 472.

9. *Id.* at 486. The distinction between the different Phases will be discussed *infra* Part I.A. The "compelling interest" test is a standard test for substantive due process challenges once a fundamental right has been established. If a fundamental right is not found, then the test is called the "rational basis" test—the burden is shifted to the party bringing the suit to show the government action is unconstitutional. Historically, the government has been successful in such disputes. *See, e.g.,* *Washington v. Glucksberg*, 521 U.S. 702, 727 (1997).

10. *See infra* Part III.

11. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 469 F.3d 129 (D.C. Cir. 2006).

12. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 697 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

13. *Petition for Writ of Certiorari, Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 76 U.S.L.W. 3373 (2008) (No. 07-444).

court of appeal's decision will stand.¹⁴ The Alliance has run out of legal remedies. This case clearly posed one of the most significant challenges to the FDA's regulatory authority since *United States v. Rutherford*,¹⁵ and perhaps paves the way for novel challenges to the FDA's authority in the future.

This Comment will focus primarily on the legal and philosophical arguments presented in the May 2006 decision, although some attempt will be made to sketch the continuity between such arguments and the position of the court in the FDA's August 2007 victory.

Part I of this Comment will lay out the regulatory framework through which a new drug must travel in order to be eligible for interstate commerce. Among the regulations discussed will be the proposed Access, Compassion, Care, and Ethics for Seriously Ill Patients Act (ACCESS) proposed by Senator Sam Brownback, as well as current options available to the terminally ill for access to drugs.¹⁶ The fact that there are a number of options for the terminally ill regarding access to experimental drugs may make it difficult for a court to recognize a constitutional violation on the part of the FDA. Part II will analyze the substantive due process challenge that was before the court, while Part III presents a public health perspective regarding the tension between the need to protect the public's health and the desire to protect individual liberties. Part IV examines possible implications of a hypothetical decision in the Alliance's favor. The repercussions of such a decision would be varied and complex, and areas and issues which may be touched by such repercussions run the gamut from stem cell therapy, to commodification of organs, to the

14. *Id.* at 3379. "The Chief Justice took no part in the consideration or decision of this petition." *Id.*

15. 442 U.S. 544 (1979). After many years of complying with a federal injunction to provide terminally ill cancer patients the experimental drug Laetrile, the Supreme Court unanimously lifted the injunction from the FDA holding "[t]he Federal Food, Drug, and Cosmetic Act [FDCA] makes no special provision for drugs used to treat terminally ill patients." *Id.* at 551. Many of the arguments made in the *Rutherford* case are echoed in *von Eschenbach*. It would be remiss to omit the fact that Laetrile never passed the Phase I safety hurdle. It is in that very narrow sense that the current case is distinguishable from the holding in *Rutherford*.

16. Senator Sam Brownback (R-Kan.) introduced this legislation, supported by the Alliance, which would create a three-tiered system to allow greater access to experimental drugs. ACCESS Act, S. 1956, 109th Cong. § 3 (2005).

rights of the impoverished, and the right to access medical marijuana.

I. REGULATORY BACKGROUND

A. *The Approval Process*

In 1938, Congress enacted the Food, Drug, and Cosmetic Act (FDCA) to regulate the sale of manufactured drugs.¹⁷ A new drug cannot enter interstate commerce without prior approval of the FDA.¹⁸ The FDCA requires the FDA to prevent marketing of any drug or device where potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.¹⁹ However, if a drug is intended for research purposes, Congress created an exception.²⁰ Pursuant to its authority under the FDCA, the FDA formulated rules to regulate the use of investigational drugs.²¹ In the later phases of drug testing, the FDA allows pharmaceutical companies to sell specific drugs to those individuals who happen to be in the most dire of situations through “compassionate use” programs which consist mainly of drugs in Phase III of testing—although access to drugs in Phase II is possible.²² The Phase system is at the heart of the debate and is discussed further below.

The constitutional right the Alliance sought would allow terminally ill patients to bypass the regulatory approval process established by the FDA through the powers given to it by Congress.²³ The United States’ drug approval process is one of the most strenuous and stringent in the world; the average cost of bringing a drug from

17. 21 U.S.C. §§ 301-399 (2000 & Supp. 2007).

18. *Id.* § 355(a).

19. *See id.* §§ 301-399.

20. *Id.* § 355(i).

21. 21 C.F.R. §§ 312.20-.21 (2007).

22. *See id.* § 312.7(d). However, the manufacturers cannot make a profit. They must only recover the costs of manufacturing the drug. *Id.* § 312.7(d)(3). In addition, the drug company must be willing to supply the drug and the physician must be willing to pursue an application for it. *See id.* § 312.7(d)(2). This is due to the fact that the FDA prohibits commercial sale of investigational new drugs. *Id.* § 312.7(b).

23. *See* ACCESS Act, S. 1956, 109th Cong. § 3 (2005).

preclinical tests to the pharmacy shelf is more than \$800 million and takes about twelve years.²⁴ The FDA prohibitions bar the introduction of new drugs into interstate commerce until the FDA has approved a sponsor's application.²⁵ The first step in bringing a new drug to the market is the submission of an investigational new drug application (IND).²⁶ The IND must contain all of the data from preclinical animal trials.²⁷ The preclinical phase includes testing on different nonhuman animal species in order to determine toxicity.²⁸ The questions answered at this phase are rudimentary yet crucial: Is this drug safe for testing on humans? How is this drug metabolized? Will this drug negatively impact a fetus?²⁹

The IND application is a request for permission to test the drug using human subjects. In order to survive the test for safety and, eventually, for effectiveness, a drug must survive three—and sometimes four—Phases.³⁰ Phase I typically involves the introduction of an investigational new drug into twenty to eighty subjects and is “designed to determine the metabolism and pharmacologic actions of the [new] drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.”³¹ The drugs at this stage of the process, at the end of these trials, were the drugs that the Alliance was seeking access to—drugs barely out of animal testing and, as of yet, without any evidence of efficacy. No therapeutic intent is required at this point. Phase II studies are primarily concerned with effectiveness as well as “the common short-term side effects and risks associated with the drug.”³² It is in this phase that patients with a condition

24. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 153, 166 (2003).

25. See 21 U.S.C. § 355(a).

26. See 21 C.F.R. §§ 312.20-.23.

27. See *id.* § 312.23(a)(5)(ii)-(iv).

28. See *id.* § 312.22(c).

29. See *id.* § 312.23(a)(8).

30. *Id.* § 312.21.

31. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 488 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008) (citing 21 C.F.R. § 312.21(a)(1)).

32. 21 C.F.R. § 312.21(b).

are being monitored and researched. There are usually about one hundred to two hundred subjects at this point and the lowest effective dose is given.³³ Efficacy is critical at this juncture and roughly one-third of proposed drugs drop out at the end of Phase II. Phase III studies generate “additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug.”³⁴ Thousands of subjects are enrolled during this labor-intensive Phase. It is at this stage that the gold standard of modern drug development takes place: the randomized, controlled, double-blind clinical trials.³⁵

The FDA requires certain drugs (or devices) to go through Phase IV (post-market) studies which “delineate additional information about the drug’s risks, benefits, and optimal use.”³⁶ Finally, submission of a new drug application (NDA) takes the formal step of asking the FDA to consider a drug for marketing approval.³⁷ The NDA 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.”³⁸ While it is not necessary to establish a superiority of the proposed drug in relation to already marketed drugs—as it must only perform in accord with explicit claims³⁹—less than twenty percent of proposed drugs actually survive and make it to the pharmacy shelf.⁴⁰

B. *The ACCESS Act*

The Alliance has attempted to broaden their efforts through legislative as well as judicial means. The proposed ACCESS Act by Senator Brownback is quite

33. *See id.*

34. 21 C.F.R. §312.21(c).

35. *See id.* §§ 312.21(c), 314.126.

36. *Id.* § 312.85.

37. *See id.* § 314.

38. 21 U.S.C. § 355(b)(1)(A) (2000).

39. *See id.*

40. *See, e.g.,* Joseph A. DiMasi, *Risks in New Drug Development: Approval Success Rates for Investigational Drugs*, 69 *CLINICAL PHARMACOLOGY & THERAPEUTICS* 297 (2001); Joseph A. DiMasi, *Success Rates for New Drugs Entering Clinical Testing in the United States*, 58 *CLINICAL PHARMACOLOGY & THERAPEUTICS* 1 (1995).

revolutionary.⁴¹ It seeks to amend section 506 of the FDCA in order to reduce the time a drug can be released to those in the most dire of situations.⁴² The ACCESS Act would allow a sponsor of an investigational drug to receive Tier I or Tier II approval based on the results of a Phase I clinical trial.⁴³ Sufficient evidence for this initial approval would consist of enough safety data to support conduct of a Phase II or III clinical trial, and initial evidence of effectiveness based on care histories of a small number of patients who are unable to participate in the clinical trial.⁴⁴

Furthermore, this Act would rely on “clinical evaluation, not statistical analysis.”⁴⁵ The Secretary of Health and Human Services will have no later than thirty days to either “approve the application or refer the application to the Accelerated Approval Advisory Committee.”⁴⁶ The ACCESS Act also provides for an appeals process to the Commissioner of Food and Drugs.⁴⁷

Former FDA Associate Commissioner Peter J. Pitts wrote to the Alliance with some trepidation regarding its proposed changes as they existed in its Citizens’ Petition.⁴⁸ He noted that the FDA’s accelerated programs and the Tier 1 proposal had some features in common, but what made them different was a source of great concern:

[T]he Tier 1 proposal gave “almost total weight” to early availability and too little recognition to the other considerations... In particular, making the drugs more widely available before much is known about dosage and side effects would potentially subject patients to lethal doses and serious side effects to the detriment to the patients’ remaining quality of life.⁴⁹

41. ACCESS Act, S. 1956, 109th Cong. (2005).

42. *Id.*

43. *Id.* § 3.

44. *See id.* § 3(a)-(c).

45. *Id.* § 3(b)(1)(B).

46. *Id.* § 3(b)(2)(A).

47. *Id.* § 3(b)(3).

48. *See* Brief for Appellee at 10, Abigail Alliance for Better Access to Developmental Drug v. Crawford, No. 04-5350 (D.C. Cir. 2005).

49. *Id.* at 10-11.

C. Programs Already in Place

As briefly indicated above, the FDA currently has a number of programs specifically designed to accelerate the development of new drugs for the seriously ill: Fast Track, Accelerated Approval, and Priority Review.⁵⁰ These programs have their roots in the HIV/AIDS crisis of the 1980s. Fast Track is a process to generate expedited drug development, rush the review of drugs used to treat serious diseases, and fill an unmet medical need.⁵¹ A drug that receives this designation receives a number of benefits such as frequent meetings and written correspondence with the FDA, eligibility for accelerated approval, and rolling review (i.e., a manufacturer can submit sections of a NDA as it is completed, rather than all at once).⁵² Accelerated Approval is approval of a drug based on a surrogate endpoint as opposed to waiting for year after year to determine if there has been a positive clinical outcome.⁵³

Finally, Priority Review reduces the time spent in FDA review to six months.⁵⁴ However, the length of the clinical trial period is not reduced, and the drug company must make a request for the shortened review.⁵⁵ Studies show that these FDA programs are succeeding in bringing drugs to market in a timely fashion.⁵⁶ The illnesses combated by those who benefit from expedited review include cancer,

50. U.S. Food and Drug Administration, *Fast Track, Accelerated Approval and Priority Review*, <http://www.fda.gov/oashi/fast.html> (last visited Apr. 25, 2008).

51. “[A]n unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially superior to existing therapy.” *Id.* (emphasis omitted).

52. *Id.*

53. A surrogate endpoint is a laboratory indication such as shrinkage of a tumor which “stands in” for a clinically meaningful outcome. *Id.* If it is promising enough, the FDA considers it to be a likely prediction of future results. *Id.*

54. There are two types of review: Standard Review and Priority Review. *Id.* The former is used for drugs that offer only a minor improvement of existing drugs, while Priority Review is for groundbreaking therapies that result in a significant advantage over what is currently available in the marketplace. *Id.*

55. *Id.*

56. Since 1996, sixty-eight drugs have received this quickened review from the FDA. *Id.*

Hepatitis C, and HIV/AIDS.⁵⁷

The Alliance suggested in an early appellate brief that the existing FDA policy which prohibits drug companies from recovering more than simply the cost for investigational drugs is impeding access for the terminally ill.⁵⁸ The financial disincentives for drug manufacturers is another barrier to access as “there is no compelling interest that could justify preventing those companies from earning a modest and reasonable profit. That prohibition unfairly and unduly limits terminally ill patients’ access to medications that might save their lives.”⁵⁹ Under the proposed ACCESS Act, drug sponsors would be permitted to make a profit on the sale of Initial Approval drugs.⁶⁰

II. THE DUE PROCESS CHALLENGE

Allegations of a violation of a liberty interest trigger a substantive due process analysis.⁶¹ 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 law.”⁶² Due process claims are afforded a special and often difficult analysis. The court must determine whether the asserted violation is an affront to a fundamental right which should be afforded due process protection.⁶³

Here, the Alliance was asserting that mentally competent, terminally ill patients have a constitutional right to access post-Phase I drugs once all other treatment

57. A fascinating discussion on the roots of the rise of autonomy as an ethical principle to be valued in research is found in *BELMONT REVISITED: ETHICAL PRINCIPLES FOR RESEARCH WITH HUMAN SUBJECTS* (James F. Childress, Eric M. Meslin & Harold T. Shapiro eds., 2005).

58. Brief of Appellants at 18-19, *Abigail Alliance for Better Access to Developmental Drugs v. Crawford*, No. 04-5350 (D.C. Cir. 2005).

59. *Id.* at 19.

60. ACCESS Act, S. 1956, 109th Cong. § 3 (2005). Once cost is involved, economic disparities are inevitable. *See infra* Part III.D.

61. *See, e.g., Reno v. Flores*, 507 U.S. 292 (1993).

62. U.S. CONST. amend. V.

63. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 474 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

options have been exhausted.⁶⁴ Judge Griffith, in his 2007 majority opinion, stated that the appropriate balance of access and risk could be mediated by law, however, this discussion was limited to “whether the Constitution *demand*s the balance they desire.”⁶⁵ Essentially, the Alliance was attempting to infer the existence of new constitutional rights from an analogy drawn with other fundamental rights cases that have come before the Supreme Court regarding liberty and privacy issues—specifically those pertaining to medical decisions.⁶⁶ The discussion below fleshes out the analysis performed by the court of appeals from its 2006 decision.

A. *The Analysis*

Previously, the Supreme Court held that the Due Process Clause “guarantees more than fair process,”⁶⁷ and “accords substantive protection to the rights it guarantees.”⁶⁸ Some rights are deemed fundamental and cannot be infringed upon without the burden shifting to the government to show that the infringement is narrowly tailored to serve a “compelling interest.”⁶⁹

The primary challenge faced by the *von Eschenbach* court was to determine whether a fundamental right was implicated. There are two analytical approaches that have been utilized by the Supreme Court to ascertain which rights are—and which rights are not—deemed “fundamental.”⁷⁰ Under the first approach, the Court will

64. *Id.* at 472.

65. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 710 n.17 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

66. *See, e.g.,* *Washington v. Glucksberg*, 521 U.S. 702 (1997); *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261 (1990); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Griswold v. Connecticut*, 381 U.S. 479 (1965).

67. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 475 (D.C. Cir. 2006), *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008) (quoting *Troxel v. Granville*, 530 U.S. 57, 65 (2000) (plurality opinion)).

68. *von Eschenbach*, 445 F.3d at 475 (citing *Troxel v. Granville*, 530 U.S. 57, 65 (2000) (plurality opinion)).

69. *See, e.g.,* *Reno v. Flores*, 507 U.S. 292, 302 (1993); *von Eschenbach*, 445 F.3d at 486.

70. *See* *Moore v. City of E. Cleveland*, 431 U.S. 494 (1977).

determine if a right is fundamental by assessing what “personal dignity and autonomy” demand.⁷¹ The second approach frequently employed by the Supreme Court involves an attempt to ascertain rights which are “objectively, ‘deeply rooted in this Nation’s history and tradition.’”⁷² These rights are such that they are “implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [it] were sacrificed.”⁷³ The latter analytical method has come to be known as the *Glucksberg* analysis and this is precisely the method chosen in the *von Eschenbach* case.⁷⁴ The concept and application of substantive due process in general is quite controversial and the fullest examination remains beyond the scope of this Comment.⁷⁵ Suffice it to say, judges are deeply concerned about creating “new” fundamental rights *ex nihilo*, if you will, and express the need for judicial restraint:

[W]e [the Supreme Court] ha[ve] always been reluctant to expand the concept of substantive due process because guideposts for responsible decision lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of this Court.⁷⁶

The 2006 *von Eschenbach* court effectively skirted the approach of determining what “personal dignity and autonomy”⁷⁷ demand, and focused on the more narrow

71. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992).

72. *von Eschenbach*, 445 F.3d at 476 (quoting *Moore*, 431 U.S. at 503); see also *Snyder v. Massachusetts*, 291 U.S. 97, 105 (1934).

73. *von Eschenbach*, 445 F.3d at 476-77 (quoting *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997)).

74. So named after the Supreme Court case *Washington v. Glucksberg*, 521 U.S. 702 (1997).

75. Much of the controversy in modern times surrounds the Supreme Court decision of *Lawrence v. Texas*, 539 U.S. 558 (2003), which found a fundamental right to engage in homosexual intimate relationships. See Laurence H. Tribe, *Lawrence v. Texas: The “Fundamental Right” That Dare Not Speak its Name*, 117 HARV. L. REV. 1893 (2004), for a thorough discussion of that case and the implications for the substantive due process analysis after *Lawrence*.

76. *Glucksberg*, 521 U.S. at 720 (quoting *Moore*, 431 U.S. at 502). *Glucksberg* upheld a ban on assisted suicide.

77. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992). Other fundamental rights recognized by the Supreme Court are the right to be free from intrusion in the “sacred precincts of marital bedrooms” from *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965), and the right to determine extended

Glucksberg analysis as it is now called.⁷⁸

B. *The Glucksberg Analysis*

The *Glucksberg* analysis for a fundamental right is considered to be the more restrictive of the two analyses.⁷⁹ To reiterate, this approach has two features: (1) the right must be found to be “deeply rooted in this Nation’s history and tradition”⁸⁰ and “implicit in the concept of ordered liberty,”⁸¹ and (2) a “careful description of the fundamental liberty interest” must be provided.⁸² The reasoning behind this approach is to “ensure that courts do not multiply rights without principled boundaries.”⁸³ This careful description is aiming for the most specific level of articulation of the asserted right or violation.⁸⁴ The court of appeals in the 2006 decision determined that the asserted liberty interest on behalf of the Alliance “contains the careful description we seek.”⁸⁵ Once the careful description of a liberty interest is ascertained, the question turns upon whether or not the FDA’s policies infringe on the protections guaranteed by the Due Process Clause.⁸⁶ Furthermore, if this liberty interest is deemed fundamental, which the 2006 court of appeals

family living arrangements from *Moore v. City of E. Cleveland*, 431 U.S. 494, 503-05 (1977).

78. The 2006 court averted discussion of clinics, bedrooms, and wombs by eliminating the “personal dignity and autonomy” approach. *von Eschenbach*, 445 F.3d at 476-77.

79. *Id.* at 477. A nearly identical analysis is found in the 2007 opinion. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 702 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008). For a thorough discussion of the *Glucksberg* analysis, see Brian Hawkins, Note, *The Glucksberg Renaissance: Substantive Due Process Since Lawrence v. Texas*, 105 MICH. L. REV. 409 (2006).

80. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 476 (D.C. Cir. 2006), *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008) (quoting *Moore*, 431 U.S. at 503); *see also* *Snyder v. Massachusetts*, 291 U.S. 97, 105 (1934).

81. *von Eschenbach*, 445 F.3d at 476-77 (quoting *Glucksberg*, 521 U.S. at 721).

82. *Id.* at 477.

83. *von Eschenbach*, 445 F.3d at 477 (citing *Glucksberg*, 521 U.S. at 721-23).

84. The careful description concept was first introduced in *Reno v. Flores*, 507 U.S. 292, 302 (1993).

85. *von Eschenbach*, 445 F.3d at 478.

86. *See id.*

has held that it is, the burden is placed on the FDA to demonstrate that their policy is “narrowly tailored to serve a compelling [governmental] interest.”⁸⁷ In summation, the 2006 majority found that the Alliance satisfies the narrow description requirement completely: “[t]he Alliance claims neither an unfettered right of access to all new or investigational new drugs nor a right to receive treatment from the government or at government expense.”⁸⁸

Yet, there remains a question regarding the adequacy of the first prong of the *Glucksberg* analysis. Perhaps the Alliance articulated a careful description,⁸⁹ but there has not been a successful demonstration of the fundamental right which is so “objectively, ‘deeply rooted in this Nation’s history and tradition’”⁹⁰ such “that neither liberty nor justice would exist if [it] were sacrificed.”⁹¹ The 2006 majority inferred these rights from abstract concepts of privacy, autonomy, and self-defense which is strictly prohibited by *Glucksberg*.⁹² Furthermore, no circuit court has found in favor of an affirmative access claim.⁹³ As the Tenth Circuit held in *Rutherford v. United States*, the FDA’s regulatory policies do not offend ordered liberty or

87. *Id.* at 477 (quoting *Reno*, 507 U.S. at 302).

88. *von Eschenbach*, 445 F.3d at 478.

89. Serious doubts about the careful description claim were raised in the 2007 decision: “We nonetheless have serious doubts about whether the Alliance’s *description* of its proposed constitutional right could ever pass constitutional muster. The Alliance’s claimed right depends on a regulatory determination that the drug is safe for testing, prompting an obvious question: How can a constitutional right be defined by an administrative regulation that is subject to change?” *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 703 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

90. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 476 (D.C. Cir. 2006), *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008) (quoting *Moore v. City of E. Cleveland*, 431 U.S. 494, 503 (1977)); *see also Snyder v. Massachusetts*, 291 U.S. 97, 105 (1934).

91. *von Eschenbach*, 445 F.3d at 477 (quoting *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997)).

92. As the 2006 dissent notes, “[f]undamental rights may ‘not [be] simply deduced from abstract concepts of personal autonomy.’” *von Eschenbach*, 445 F.3d at 491 (Griffith, J., dissenting) (quoting *Glucksberg*, 521 U.S. at 725).

93. *von Eschenbach*, 445 F.3d at 496 n.6 (Griffith, J., dissenting). The court cites *Mitchell v. Clayton*, 995 F.2d 772 (7th Cir. 1993), as instructive on this point.

the values of a free society.⁹⁴ Perhaps the early case of *Watson v. Maryland* best summarizes the dissent's point and serves as a transition to the discussion of the difficult task of preserving individual liberties while protecting the public's health:

It is too well settled to require discussion at this day that the police power of the States extends to the regulation of certain trades and callings, particularly those which closely concern the public health. There is perhaps no profession more properly open to such regulation than that which embraces the practitioners of medicine.⁹⁵

As predicted by many scholars, the Alliance has not proven that their claimed right is fundamental. This led to the en banc decision of the Court of Appeals for the D.C. Circuit in 2007, that "the Alliance's claim of a right of access to experimental drugs is subject only to rational basis scrutiny."⁹⁶

III. PUBLIC HEALTH VERSUS INDIVIDUAL LIBERTIES

A. *The Argument for Medical Necessity*

In support of the affirmative right to self-preservation, the 2006 majority constructed an analogy between the plight of the terminally ill and the common law principle of the necessity defense.⁹⁷ The right to self-preservation is so primal that one need only look at how this concept developed in classic tort law to recognize its weight.⁹⁸ When

94. *Rutherford v. United States* 616 F.2d 455, 457 (10th Cir. 1980).

95. *Watson v. Maryland*, 218 U.S. 173, 176 (1910) (quoted in *von Eschenbach*, 445 F.3d at 497 n.6).

96. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 712 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

97. A unique perspective on the concept of medical self-defense, and in particular an argument in support of the Alliance, can be found in Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007). See also O. Carter Snead, *Unenumerated Rights and the Limits of Analogy: A Critique of the Right to Medical Self-Defense*, 121 HARV. L. REV. F. 1 (2007) for a critique and response to Professor Volokh.

98. See generally RESTATEMENT (FIRST) OF TORTS § 197 (1934).

one is faced with impossible circumstances, the doctrine of necessity can be invoked to justify acting in a way which is not ordinarily considered appropriate or legal, a phenomenon found sprinkled throughout Anglo-American law.⁹⁹ Acting out of necessity to save oneself will often involve impinging upon the rights of others.¹⁰⁰ Impinging on the rights of others flies in the face of the traditional liberalism of a Lockean or Millian variety, although this defense has maintained its venerable reputation.¹⁰¹ However, the 2006 *von Eschenbach* majority misapplied the doctrine in this case. The standard cases of necessity focus on the sacrifice of personal property as opposed to the sacrifice of human life.¹⁰² Very few among us would argue that it is not justifiable to sacrifice property—such as boats, vehicles, etc.—when a human life is at stake. Yet, the case of *The Queen v. Dudley* is instructive on this precise point.¹⁰³ This case concerned a doomed voyage from Southampton, England. During a storm, the ship capsized and the crew was stranded at sea.¹⁰⁴ Due to starvation and unbearable thirst, they planned, plotted, and seized upon the weakest member of the crew and survived off of his flesh and blood.¹⁰⁵ The men were, to their surprise, held accountable for murder.¹⁰⁶ The defense of necessity did not justify the taking of an innocent life.¹⁰⁷ In other words, and perhaps this point is missed by those close to the case, human lives will be sacrificed with increased access to Phase I drugs (either by reduced enrollment in clinical trials or toxicity of the early stage drugs, for example).¹⁰⁸ It is perhaps more

99. A classic example is *Ploof v. Putnam*, 71 A. 188 (Vt. 1908).

100. See *The Queen v. Dudley*, (1884) 14 Q.B.D. 273, for one of the earliest decisions on the necessity defense.

101. See generally George C. Christie, *The Defense of Necessity Considered from the Legal and Moral Points of View*, 48 DUKE L.J. 975 (1999).

102. See, e.g., *Ploof*, 71 A. at 189.

103. *The Queen v. Dudley*, (1884) 14 Q.B.D. 273.

104. *Id.* at 273.

105. *Id.* at 279.

106. *Id.* at 288.

107. *Id.* at 287-88.

108. Ironically, the very spirit of human subject research is primarily utilitarian in nature which presumes a sacrifice of a few for the greater good. Yet, in this present case, the opposite holds: many will be sacrificed for the good of a few.

important to emphasize that the Alliance seeks access to drugs which are experimental and therefore have not yet been proven to be effective, much less necessary, for survival.¹⁰⁹

In the 2007 decision, Judge Griffith, this time writing for the majority, elaborated on the failed analogy of medical self-defense. What Judge Griffith found most surprising was the analogy that the Alliance attempted to forge between the Supreme Court's abortion jurisprudence and access to experimental drugs.¹¹⁰ The Alliance argued, not from a principle of privacy but, rather, that a woman's right to terminate her pregnancy at any stage is permissible if her life is in jeopardy.¹¹¹ The Alliance argued that this was not a right based on privacy, but is "grounded in traditional self-defense principles."¹¹² The analogy was that terminally ill cancer patients are in a similar situation, i.e., they are in immediate danger of succumbing to cancer and self-defense principles—like those found in the abortion cases—can justify access to "whatever medical means are necessary to defend themselves."¹¹³ However, Judge Griffith wrote that "this analogy fails because this case is not about using reasonable force to defend oneself."¹¹⁴ The Alliance was asking for a constitutional right to assume "enormous risks."¹¹⁵ This risk, at a very minimum, separates the demands of the Alliance from the "life of the mother" exception.¹¹⁶ Once again, it is worth pointing out that access to these drugs affects the clinical trial system which in turn affects thousands of individuals. A woman's decision to terminate a pregnancy is simply that—a decision between one woman and one physician.

Finally, the tort principle of liability for interference

109. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 708 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

110. *Id.* at 709.

111. *Id.*; *see also* *Roe v. Wade*, 410 U.S. 113, 152 (1973).

112. *von Eschenbach*, 495 F.3d at 709.

113. *Id.*

114. *Id.* at 710.

115. *Id.* The following point cannot be emphasized too much—these drugs are *potentially* life saving. Remember, there is no efficacy and scarce safety data when access is demanded.

116. *Id.*

with the efforts to save a life appear to have been misapplied.¹¹⁷ The scholars of the Restatements likely imagined individuals blocking rescue access at a local swimming hole rather than a sea change to a federal regulatory agency. Furthermore, the common law does not impose a duty to rescue or preserve a life, unlike the affirmative right the Alliance sought from the FDA. Indeed, this is a crucial point of difference which substantially weakens such an attempted argument by analogy. Fundamental rights cannot be inferred from common law tort principles.¹¹⁸

B. *The Argument of Lack of Regulation*

The 2006 *von Eschenbach* majority relied heavily on the argument that governmental regulation of drugs is a byproduct of modernity.¹¹⁹ Contrast this with the idea that the right to control one's own body is deeply rooted in our nation's history.¹²⁰ Prior to 1906 and the Pure Food and Drug Act,¹²¹ there were no regulations on the drug market. After 1906, misbranded and adulterated foods or drugs were prohibited from entering interstate commerce.¹²² What was not limited, however, was individual access to any and all drugs (with the exception of narcotics).¹²³ However, in 1938, Congress enacted the FDCA¹²⁴ in response to the

117. RESTATEMENT (FIRST) OF TORTS § 326 (1934).

118. It is interesting to note that the Court in *Cruzan* based a great deal of its decision on a common law concept—that forced medical treatment is a legal battery. *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 269 (1990). However, there is more consistency with the Nation's history and traditions for recognizing the right to be free from battery than the right to access drugs out of necessity. *See id.*

119. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 481 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

120. *Id.* at 480. Yet, as *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) demonstrates, that right to self-determination is not absolute. *See also infra* Part III.C.

121. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938).

122. *von Eschenbach*, 445 F.3d at 481.

123. *Id.* at 482. Narcotics were subject to the Harrison Narcotic Act of 1914, Pub. L. No. 223, 38 Stat. 785 (1914).

124. Pub. L. No. 717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. §§ 301-395).

deaths of hundreds of individuals after they ingested Elixir Sulfanilamide which at the time was sold as an antibiotic.¹²⁵ The drug approval system was quite primitive at this time, and “an NDA became automatically effective within a time frame set by the FDA unless the FDA determined that the drug was unsafe and barred its commercial distribution.”¹²⁶

Not until the Kefauver-Harris Amendments of 1962¹²⁷ did manufacturers have to provide empirical evidence of a drug’s efficacy.¹²⁸ Safety was merely sufficient.¹²⁹ After these amendments were passed, the drug industry was effectively transformed, “[t]he Amendments authorized the FDA to approve human clinical trials, regulate drug advertising, inspect drug manufacturing facilities, and promulgate good manufacturing practices... [and] required drug manufacturers to disclose to the FDA any information they received regarding the adverse consequences of approved drugs.”¹³⁰ The majority inferred a right to be *free* from regulation from the *lack* of federal regulation in this area for most of our nation’s history.¹³¹

As Judge Griffith pointed out in his dissent from the 2006 decision, “the history of the FDCA does not demonstrate a tradition protecting an individual’s right to procure and

125. *von Eschenbach*, 445 F.3d at 482.

126. *Id.* (citing James L. Zelenay, Jr., *The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?*, 60 FOOD & DRUG L.J. 261, 263-64 (2005)).

127. Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified in scattered sections of 21 U.S.C. §§ 301-81).

128. *von Eschenbach*, 445 F.3d at 482. Admittedly, efficacy has become a controversial term. See Anita Bernstein & Joseph Bernstein, *An Information Prescription for Drug Regulation*, 54 BUFF. L. REV. 569 (2006).

129. The Kefauver-Harris Amendments (or Drug Amendments) of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962), were a reaction to the Thalidomide crisis. Terrible birth defects were found in the children of mothers who ingested Thalidomide to reduce morning sickness associated with pregnancy. *von Eschenbach*, 445 F.3d at 482 (citation omitted).

130. *von Eschenbach*, 445 F.3d at 482-83 (footnote omitted).

131. In fact, the dissent from 2006 traces a long history of attempts at drug regulation and control from Colonial Virginia in the 1700s to the present. *Id.* at 494-95 (Griffith, J., dissenting). See also Abigail Alliance for Better Access to Developmental Drugs v. *von Eschenbach*, 495 F.3d 695, 706 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008), for another detailed history of drug regulation: “We end our historical analysis where the Alliance would prefer it to begin—with the 1962 Amendments to the FDCA.”

use experimental drugs; it only establishes that the federal government has not always regulated experimental drugs.¹³² The dissent also astutely observed that to follow the logic of the majority would place one in a precarious situation with regard to medical marijuana and narcotics in general:

Because Congress did not significantly regulate marijuana until relatively late in the constitutional day... there must be a tradition of protecting marijuana use. Because Congress did not regulate narcotics until 1866 when it heavily taxed opium, a drug created long before our Nation's founding... it must be that individuals have a right to acquire and use narcotics free from regulation.¹³³

Clearly, these arguments are tongue-in-cheek and were intended to express a certain truth: “[t]he fact that the Government has not always regulated a concern tells us little about whether an individual has a constitutional right to pursue that concern.”¹³⁴ The efficacy of these arguments carries over into the recent decision. Judge Griffith, this time writing for the majority in the en banc decision, stated that the Alliance cannot “override current FDA regulations simply by insisting that drugs... are safe enough for terminally ill patients.”¹³⁵

The Alliance tried to argue that the prevalence of so-called “off-label” uses of prescription drugs is an indication of inconsistent policies on behalf of the FDA.¹³⁶ However, the FDA experienced its own crisis with this policy and has taken rather strong measures to correct the situation.¹³⁷ The difference between the Tier 1 proposal and an off-label prescription is striking. The drugs that are being prescribed

132. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 486, 494 (D.C. Cir. 2006) (Griffith, J., dissenting), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

133. *Id.* at 493-94 (internal citations omitted).

134. *Id.* at 494 (citation omitted).

135. *von Eschenbach*, 495 F.3d at 705.

136. Off-label drug use is prescribing a drug for a use other than the one the FDA approved.

137. The referenced crisis is a spike in pediatric suicide rates after providers prescribed antidepressants off-label. Drug companies rarely tested their SSRIs (selective serotonin reuptake inhibitors) on the pediatric population, thus no effective dosing information was available. Providers were often left guessing at appropriate doses of these powerful drugs. What was most significant from this crisis was the advent of the so-called “black box” warning on antidepressants.

off-label have passed the requisite rigorous testing in order to come to market. There is known data about these drugs with regard to safety and effectiveness—although perhaps not for the particular condition that it is being prescribed; yet, it is not the black hole of post-Phase I either. Ironically, the right the Alliance demanded actually applies more appropriately to off-label use than to their own Tier 1 proposal. The FDA allows physicians to present information at conferences and share their ideas regarding novel uses of an already marketed drug. The physician then, in concert with his or her patient, makes an informed recommendation regarding a potential new use for a drug. This is the intimate, one-on-one medical decision that is most analogous to the rights secured in *Roe v. Wade*¹³⁸ and *Cruzan v. Director, Missouri Department of Health*¹³⁹—individual medical decisions *without* global implications should generally have constitutional protection. Conversely, individual decisions *with* global repercussions should not be afforded blanket constitutional protection.

C. *The Jacobson Precedent*

Parens patriae is the name given to the police powers, or paternal powers, of the state in order to effect public health policies and regulations.¹⁴⁰ Our Constitution and the democratic process support the government's mission to protect and preserve the public's health.¹⁴¹ *Jacobson v. Massachusetts*¹⁴² is a landmark Supreme Court case outlining the limits of individual autonomy. At the turn of the century, Massachusetts gave municipal boards of health the power to require vaccination of its inhabitants.¹⁴³ This power was for the well-being of the public in the face of a smallpox epidemic. Henning Jacobson refused the vaccine

138. 410 U.S. 113 (1973).

139. 497 U.S. 261 (1990).

140. Seatbelt and helmet laws are often grouped under this category.

141. For one of the best introductions to the fundamental principles of public health, see LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* (2000).

142. 197 U.S. 11 (1905) (focusing on a due process challenge to a mandatory smallpox vaccine).

143. GOSTIN, *supra* note 141, at 66.

and was fined five dollars.¹⁴⁴ The legal argument was that “a compulsory vaccination law is unreasonable, arbitrary and oppressive, and, therefore, hostile to the inherent right of every freeman to care for his own body and health in such way as to him seems best.”¹⁴⁵ However, the vaccination law was upheld as an appropriate exercise of the state’s police power.¹⁴⁶ As Lawrence Gostin describes, “[Jacobson’s] was a classic claim in favor of a laissez-faire society and the natural rights of persons to bodily integrity and decisional privacy.”¹⁴⁷

The Alliance was asserting a qualitatively identical right to self-determination.¹⁴⁸ However, the Supreme Court noted in its famed 1905 opinion that “the inherent right of every freeman to care for his own body and health in such way as to him seems best” is not “absolute.”¹⁴⁹ The 2006 *von Eschenbach* court heartily recognizes the limits of autonomy by citing various turn of the century cases which stand for the fundamental principle that “persons and property are subjected to all kinds of restraints and burdens”¹⁵⁰ and liberty could be sacrificed when it is essential “to secure the general comfort, health, and prosperity of the State.”¹⁵¹ Nonetheless, the 2006 decision required further inquiry as to the FDA’s countervailing interests which led to the remand.¹⁵²

144. *Id.*

145. *Jacobson*, 197 U.S. at 26.

146. *Id.* at 27-33. As Gostin notes, this case is an anomaly of sorts considering the libertarian bent of the Court during the *Lochner* era. GOSTIN, *supra* note 141, at 346 n.31.

147. GOSTIN, *supra* note 141, at 66.

148. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 475 (D.C. Cir. 2006), *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

149. *Jacobson*, 197 U.S. at 26.

150. *von Eschenbach*, 445 F.3d at 475; *see also* *R.R. Co. v. Husen*, 95 U.S. 465, 471 (1878); *Crowley v. Christensen*, 137 U.S. 86 (1890). It is not surprising that the late nineteenth century was fertile ground for such cases. Between the industrial revolution, immigration, and new epidemics, the individual frequently found his/her liberty butting up against the need of the government to protect the public’s health. *See generally* GOSTIN, *supra* note 141.

151. *Husen*, 95 U.S. at 471.

152. *von Eschenbach*, 445 F.3d at 486.

D. Liberty, Autonomy, and the Kantian Perspective

John Stuart Mill, in *On Liberty and Utilitarianism*, notes one of the essential principles that is absent from the myopic vision of the Alliance.¹⁵³ One is free to make decisions regarding his or her body until the point that it affects *others*. The Alliance fails to recognize this principle:

[T]he only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.... Over himself, over his own body and mind, the individual is sovereign.¹⁵⁴

Mill's statement succinctly describes the tension in this case specifically, and in the field of public health generally. Each individual patient has the right to make personal, intimate medical decisions which directly impact his own body.¹⁵⁵ However, the ramifications of this case will affect the health and medical outcomes of millions of Americans, not to mention the implications that follow for other medical liberties—such as the right to access marijuana for medicinal purposes.¹⁵⁶ Individual autonomy is one value among others and should perhaps not be placed at such a premium that could potentially seriously harm others.¹⁵⁷

In a sense, *von Eschenbach* was a natural outgrowth of the patients' rights movement and the gradual shift from medical paternalism to individual decision-making in that realm. However, autonomy is never absolute, as demonstrated in the *Jacobson* case, and the court should be mindful of the delicate balance between a right to self-determination on an individual basis and self-determination with population-wide repercussions.

153. JOHN STUART MILL, *ON LIBERTY AND UTILITARIANISM* (Bantam Books 1993) (1859).

154. *Id.* at 12-13.

155. Of course, this was one of the arguments made by the terminally ill individuals in *Glucksberg*. *Washington v. Glucksberg*, 521 U.S. 702, 724 (1997).

156. See *infra* Part IV.

157. ALFRED I. TAUBER, *PATIENT AUTONOMY AND THE ETHICS OF RESPONSIBILITY* 153 (2005) ("Although respecting autonomy is more important than biomedical ethics had appreciated until the last two decades [1970s and 1980s], it is not the only principle and should not be overvalued when it conflicts with other values." (citation omitted)).

The starting point of classical discussions of autonomy originates with the thought of eighteenth century Prussian philosopher Immanuel Kant. Kant often extols the virtues of the supremely autonomous individual. It is through the possession of rationality that a person manifests his or her autonomy, and it is in that capacity as an autonomous, rational individual that a person can truly act morally. The Alliance was violating the spirit, at least by implication, of Kantian ethics¹⁵⁸ which entails the famous maxim of “[s]o act as to treat humanity, whether in thine own person or in that of any other, in every case as an end withal, never as means only.”¹⁵⁹

The Alliance was not acting within this sense of rationality because it was ultimately jeopardizing the clinical trial system and, in a sense, not treating millions of Americans as ends in themselves. Kantian ethics is essentially duty-based as opposed to utilitarian. The latter recognizes mere consequences as the sole basis for action, whereas the Kantian operates from some sort of *a priori* or universal principles governing human behavior. These duties are to be universally true in every circumstance, regardless of consequences, and often mirror traditional Judeo-Christian maxims (never lie, cheat, murder, etc.). It is through respecting our duties to others that we can be considered rational beings.¹⁶⁰ The Alliance, from a Kantian perspective, could not simply act for and in its own interest at the risk of others—“as regards meritorious duties towards others: the natural end which all men have in their own happiness. Now humanity might indeed subsist, although no one should contribute anything to the happiness of others, *provided he did not intentionally withdraw anything from it...*”¹⁶¹

IV. IMPLICATIONS

This following Part unpacks the consequences that could have resulted from a decision in the Alliance's favor. Amongst topics within the backlash are the threat to the

158. See IMMANUEL KANT, *FUNDAMENTAL PRINCIPLES OF THE METAPHYSIC OF MORALS* (T.K. Abbott trans., 1988).

159. *Id.* at 58 (emphasis removed).

160. *See id.* at 59.

161. *Id.* (emphasis added).

physician-patient relationship, the continued safety and effectiveness of drugs, the protection of the vulnerable, and the possibility of unlimited suits emerging from a new fundamental right.

A. *Primum non Nocere: First Do No Harm*

One of the troubling implications which would have followed from this new constitutional right concerns a possible detrimental effect on the physician-patient relationship and the informed consent process. This relationship is already strained by the barrage of direct-to-consumer drug marketing. Physicians feel compelled to satisfy their patients and prescribe the drugs requested of them. Understandably, the situation intensifies when the patient is terminally ill. What happens to the informed consent process? In a traditional consent process, risks and benefits are discussed and options are weighed.¹⁶² However, when a drug merely passes the Phase I hurdle, which means it has been tested on twenty to eighty patients while efficacy is unknown, the consent process could be rendered inert.

The physician could be confronted with the ultimate Faustian challenge—whether or not to dispense a drug with an unknown safety profile, no published reports, and no efficacy data. A commentator observed this tension: “calling something lifesaving does not make it so” and that gone are the days when a physician can say “medicine has nothing more to offer.”¹⁶³ It appears that, implicit in the desire to enroll patients in early trials or to suggest experimental drugs, there is a basic desire for the avoidance of failure. As Matthew Miller, M.D., states, “choosing to participate [in Phase I] trials may too often represent a turning away from, rather than a reckoning with, the difficult reality that a patient has exhausted all known therapeutic options.”¹⁶⁴ This fear of brutal honesty is a further example of a weakening of the physician-patient relationship.

162. The classic tort case regarding informed consent is *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

163. Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance v. Von Eschenbach* [sic], 297 JAMA 205, 207 (2007).

164. Matthew Miller, Letter to the Editor, HASTINGS CENTER REP. Jan.-Feb. 2001, at 4, 5.

The terminally ill as a group are considered a vulnerable population which means they ought to be subject to more protections than the average medical consumer.¹⁶⁵ Opening the pharmaceutical market to Phase I drugs means charlatans will be abound to take advantage of the less restrictive laws and the most vulnerable members of our society.¹⁶⁶ This is a very real fear, as first noted by the *Rutherford Court*:

Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and "Fountain of Youth" mixtures of spices, oil, and suet.¹⁶⁷

Furthermore, are these individuals capable of consenting?¹⁶⁸ The *sine qua non* of ethical research is the doctrine of informed consent.¹⁶⁹ Informed consent protects and preserves the patient's autonomy in the following ways: protecting privacy, maintaining welfare of participants, and informing subjects of newfound risks or benefits.¹⁷⁰ However, a red flag rises when a patient is terminally ill—and possibly receiving strong pain medication for an inoperable brain tumor, or undergoing extreme emotional

165. See, for example, the discussion found in GREGORY E. PENCE, CLASSIC CASES IN MEDICAL ETHICS (5th ed. 2008). Other groups considered vulnerable are children, prisoners, minorities, and pregnant women.

166. Interestingly, there are some who believe that there is a focus on too much protection for the vulnerable—to their detriment, in fact. For a fascinating—albeit controversial—discussion on the matter, see Rosamond Rhodes, *Rethinking Research Ethics*, AM. J. BIOETHICS, Jan.-Feb. 2005, at 7.

167. *United States v. Rutherford*, 442 U.S. 544, 558 (1979).

168. Of course, the fact that one is terminally ill does not *ipso facto* imply that he or she is incompetent.

169. According to BLACK'S LAW DICTIONARY 323 (8th ed. 2004), "informed consent" is legally defined as "[a] patient's knowing choice about a medical treatment or procedure, made after a physician or other healthcare provider discloses whatever information a reasonably prudent provider in the medical community would give to a patient regarding the risks involved in the proposed treatment or procedure." For a thoughtful discussion on the nature and limits of the informed consent process, see STEPHEN WEAR, INFORMED CONSENT: PATIENT AUTONOMY AND CLINICIAN BENEFICENCE WITHIN HEALTH CARE (1998).

170. In the research context, the permission of withdrawal from a study is an additional benefit of informed consent.

and financial stress, for example. The patient's capacity¹⁷¹ for consent should then be questioned.¹⁷² Capacity includes the ability to, at a bare minimum, "understand one's diagnosis and crucial facts about one's treatment options, such as their *risks* and prognoses;... to appreciate how those facts apply to oneself;... and to reach and communicate a decision in light of that understanding, appreciation, and one's own values."¹⁷³ However, without the data on efficacy, how is consent even possible? How can a patient appropriately weigh risks and benefits when risks are unknown?

As previously discussed, the *Cruzan* decision delineated the due process "right of a competent individual to refuse medical treatment."¹⁷⁴ Yet, the Supreme Court never discussed precisely what competence means. Similarly, the Alliance never unpacked this tricky dual legal and medical concept. As the dissent in the 2006 decision pointed out, the Alliance desired to limit this new constitutional right to patients who are "mentally competent" and who have "informed access" to the experimental drugs.¹⁷⁵ Yet, "with so little data available, it is hard to understand how a patient could be truly informed about the risks—or potential benefits—associated with the drug."¹⁷⁶ Essentially, the terminally ill patients were demanding a constitutional right to make an ill-informed decision.

There is no legal precedent for that desired right. The Court in *Cruzan* rejected the right to withdrawal or refuse treatment if the individual is not competent to make the

171. Capacity is often a medical determination, whereas competence is a legal determination.

172. See, e.g., Donna L. Berry et al., *Informed Consent: Process and Ethical Issues*, 23 ONCOLOGY NURSING F. 507 (1996); Gail A. Bujorian, *Clinical Trials: Patient Issues in the Decision-Making Process*, 15 ONCOLOGY NURSING F. 779, 779-83 (1988).

173. Adrienne M. Martin, *Tales Publicly Allowed: Competence, Capacity, and Religious Belief*, HASTINGS CENTER REP., Jan.-Feb. 2007, at 33, 34 (emphasis added).

174. *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 277 (1990).

175. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 496 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008) (Griffith, J., dissenting).

176. *Id.* (quoting the FDA's response to the Alliance's Tier 1 proposal).

decision.¹⁷⁷ In fact, the *Cruzan* Court (this is a point the 2006 majority neglected to mention) allowed for state governments to require clear and convincing evidence of an individual's wishes, stating, "we conclude that a State may apply a clear and convincing evidence standard in proceedings where a guardian seeks to discontinue nutrition and hydration of a person diagnosed to be in a persistent vegetative state."¹⁷⁸ The point here is that there are limits on individual autonomy, even more so when the decisions are a matter of life and death. The *Cruzan* Court found the interests at stake to be so significant that the burden of proof must be on those who wish to discontinue treatment.¹⁷⁹ This is so, if for no other reason than because, "[a]n erroneous decision to withdraw life-sustaining treatment... is not susceptible of correction."¹⁸⁰ Furthermore, the Alliance was seeking to infer a "right" from the ability to merely "decide" whether or not to assume risks—known or unknown—from taking investigational drugs.¹⁸¹

The strain on the physician-patient relationship would be all the more exacerbated in this context. The role between research and treatment would be blurred and dangerous conflicts of interest could surface.¹⁸² The treating physician would now play the dual role of researcher and entrepreneur, while the patient would morph into a research subject and trial participant.¹⁸³ As Robert J. Wells

177. *Cruzan*, 497 U.S. at 279-80. Interestingly, the right established in *Cruzan* did not actually apply to the young woman at the heart of the controversy, Nancy Cruzan. She was in a permanent vegetative state and thus was incompetent to make the decision to have her feeding tube removed. *Id.* at 266. Furthermore, the family lacked "clear and convincing" evidence of Nancy's wishes. *Id.* at 285.

178. *Id.* at 284.

179. *Id.* at 283.

180. *Id.*

181. For a concise discussion which outlines constitutional issues involved with the end of life, see George J. Annas, *Cancer and the Constitution—Choices at Life's End*, 354 NEW ENG. J. MED. 408 (2007).

182. Human subject research is governed by the "Common Rule," 45 C.F.R. § 46 (2007). The other influential ethical codes are the aforementioned Belmont Report, The Declaration of Helsinki, and The Nuremberg Code of 1947. See also Karen Gervais, *The Ethical Foundations of the Federal Regulations Governing Human Subjects Research in the United States* (Feb. 9, 2004) (unpublished draft) (on file with Karen Gervais).

183. A thank you to Professor Sheila R. Shulman for first pointing out these issues to me. The history of human subject research is filled with egregious

of the Children's Hospital Medical Center observed, "[t]herapeutic research, of which phase I clinical trials in oncology is an example, is both therapy and research. It is impossible to separate research from clinical care..."¹⁸⁴

Academic medicine is profoundly profitable for the institutions they support and the pressure to publish is palatable. If proof of efficacy is no longer required in order to have access to a drug, medicine will be transported back to the time of the Tuskegee Syphilis Study where no "effort [was] made to establish the efficacy of old forms of treatment."¹⁸⁵

Another particularly problematic area is physician liability. Would informed consent—whatever remains of it—be enough to shield a physician from liability if the drug is ultimately ineffective, unsafe, or both?¹⁸⁶ Conversely, if a physician does not inform a patient about experimental therapies when standard therapy has failed, will he or she be liable?

Therese M. Mulvey, M.D.,¹⁸⁷ expressed deep concern over the 2006 *von Eschenbach* decision and described the

wrongs and abuses, from Nazi Germany to the Tuskegee Study. In the modern era, see, e.g., *Grimes v. Kennedy Krieger Inst. Inc.*, 782 A.2d 807 (Md. 2001). See also the infamous Jesse Gelsinger gene therapy study at the prestigious University of Pennsylvania.

184. Robert J. Wells, Letter to the Editor, *HASTINGS CENTER REP.*, Jan.-Feb. 2001, at 4, 4. It is arguable that treatment without known efficacy can even be deemed "therapeutic."

185. CARL H. COLEMAN ET AL., *THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS* 42 (2005) (quoting JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT* 2 (1981)). The Tuskegee Syphilis Study, which spanned forty years and was sponsored by the United States Public Health Service, left African Americans with untreated syphilis long after penicillin was made available to cure the disease.

186. If these treatments are unsuccessful—which would be difficult, if not impossible, to measure considering the patients are already terminal—then the research will be considered "nontherapeutic" which brings along its own set of liability issues. See, e.g., Clifton R. Gray, *The "Greater Good" . . . At What Cost?: How Nontherapeutic Scientific Studies Can Now Create Viable Negligence Claims in Maryland after Grimes v. Kennedy Krieger Institute, Inc.*, 32 U. BALT. L. REV. 1, 73-95 (2002).

187. Therese M. Mulvey, M.D., "is a community oncologist practicing in Dorchester and Quincy, Massachusetts. She is immediate past president of the Massachusetts Society of Clinical Oncologist, and also serves as Associate Editor for the Journal of Oncology Practice." Therese M. Mulvey, *Preserving Evidence-Based Oncology: We Can't Jeopardize Clinical Trials*, 2 J. ONCOLOGY PRAC. 204, 204 (2006).

events following the decision:

Word about the Abigail Alliance decision spread rapidly over the Internet,... and patients are pressing their oncologists to take advantage of this new "opportunity." It is important that oncologists be prepared to explain to their patients why such access might not be in their [best] interest, even if there are no treatment options.¹⁸⁸

Significantly, nothing in the decision required the pharmaceutical companies to provide the experimental drugs or prescribe such treatments. In a similar vein, would the pharmaceutical companies be held liable for adverse outcomes?¹⁸⁹ The proposed ACCESS Act explicitly mentions a provision for "a written waiver of the right to sue the manufacturer or sponsor of the drug, biological product, or device, or the physicians who prescribed the product or the institution where it was administered, for an adverse event caused by the product, which shall be binding in every State and Federal court."¹⁹⁰

B. *A Threat to FDA Authority*

According to the FDA's mission statement, the FDA "is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs."¹⁹¹ The country as a whole is not benefited by the FDA *qua* agency being portrayed as an evil gatekeeper determined to keep all the "magic" cures to itself. There is solid legal doctrine whereby the courts defer to agency decisions.¹⁹² Yet, if a fundamental right concerning access to these drugs is granted, the regulatory power of the FDA may very well fall prey to paralysis and eventual erosion of

188. *Id.*

189. See *Abney v. Amgen, Inc.*, 443 F.3d 540 (6th Cir. 2006).

190. ACCESS Act, S. 1956, 109th Cong. § 5(B)(ii) (2005).

191. U.S. Food and Drug Administration, *FDA's Mission Statement*, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Apr. 25, 2008).

192. The classic case on the matter is *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 866 (1984). The two part *Chevron* analysis is used to determine whether agency action is arbitrary and capricious: (1) Has Congress specifically spoken to the question at issue?; (2) If Congress has been silent on the issue, then the Court must determine whether the agency's construction of the statute in question is permissible. *Id.* at 842-43.

effective power, with no clear end to such erosion in sight. Some suggest that what is really at the heart of this conundrum is the long-standing tension involved in the question of what would constitute the best approach to the pharmaceutical industry—free market or regulation.¹⁹³ Perhaps it is an anathema to American sensibilities to obstruct the way to lifesaving treatments; yet, the Laetrile debacle, if anything, demonstrated the critical role of the FDA in protecting the public health. If the pharmaceutical industry is deregulated, who would protect patients from experimental therapies? How would the face of direct-to-consumer advertising look after deregulation?

As Lawrence O. Gostin aptly noted, “Justice Harlan, in *Jacobson*, insisted that police powers must be based on the ‘necessity of the case’ and could not be exercised in ‘an arbitrary, unreasonable manner’ or go ‘beyond what was reasonably required for the safety of the public.’”¹⁹⁴ It is fair to say that the FDA is exercising its authority in a manner consistent with the spirit of the *Jacobson* decision. Their policies are rooted firmly in established science and are indeed required for public safety. Judge Griffith echoes that sentiment in the August 2007 opinion: “The Alliance’s arguments about morality, quality of life, and acceptable levels of medical risk are certainly ones that can be aired in the democratic branches, without *injecting the courts into unknown questions of science and medicine.*”¹⁹⁵

C. Clinical Implications

On the clinical side, many cancer organizations, scientists, and physicians came out against the proposals put forth by the Alliance.¹⁹⁶ The clinical trial system was at

193. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008). Although it is an area ripe for analysis, the economic implications of the *von Eschenbach* decision (as well as implications concerning judicial activism) are beyond the scope of this Comment.

194. GOSTIN, *supra* note 141, at 68 (quoting *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1905)).

195. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 714, *cert. denied*, 76 U.S.L.W. 3373 (2008) (emphasis added).

196. The Patient Representatives to Oncologic Drugs Advisory Committee

stake; and in a country where evidence-based medicine is the gold standard, the entire process of drug development becomes threatened without these placebo trials. Why would desperately sick people want to take the chance of receiving a placebo in a Phase II study when they could receive "treatment" from Phase I?¹⁹⁷ This is what concerned Ms. Fran Visco, President of the National Breast Cancer Coalition (NBCC). She, among others, expressed extraordinary concern regarding the Alliance's Tier 1 proposals:

Public policy should discourage access to investigational drugs outside of clinical trials. Investigational treatments made outside of clinical trials have the potential to undermine the clinical trial system. There is little incentive for a patient to participate in a clinical trial if she can obtain the investigational drug outside of the trial. This makes trial accrual difficult, and may significantly undermine the ability of the investigators to determine the efficacy and safety of the intervention. That was certainly the case with bone marrow transplant for breast cancer - because it was so widely available outside of clinical trials it was extremely difficult to accrue patients to trials, and it took many years longer than it should have to learn that the high-risk and expensive procedure provides no benefit to women with breast cancer.¹⁹⁸

There is potential for public confusion regarding the issue of which drug is most safe and effective and how this drug may be best obtained. Karl Schwartz, patient consultant to the FDA and President of Patients Against Lymphoma, sounded off on the downside to a reduction in regulatory authority and standards in general: "[The Tier 1 proposal] can undermine the public confidence in marketed drugs.... For example, if three new therapies gain Tier 1 approval for a condition, which of these is best, safest, or most dangerous?"¹⁹⁹

"states that the Tier 1 program would 'likely . . . cause harm not only to patients, but also to the entire drug development program.'" Brief of Appellee, *supra* note 48, at 11 n.5.

197. Phase I trials would not have been eliminated if the Alliance had prevailed, although one might have been faced with a danger of enrollment suffering.

198. Letter from Fran Visco, President, National Breast Cancer Coalition to Mark McClellan, Commissioner, Food and Drug Administration (Sept. 9, 2003) (Docket No. 2003P-0274/CP1).

199. Letter from Karl Schwartz, Patient Consultant to the FDA to Mark McClellan, Commissioner, Food and Drug Administration (Sept. 9, 2003) (Docket No. 2003P-0274/CP1).

Furthermore, Mr. Schwartz claimed:

There will be increased risks to patients using Tier 1 approved drugs. Statistically, most drugs that complete Phase I will be judged not suitable for approval. Adding to the risks for patients would be that treating physicians, instead of trained investigators, would monitor patients receiving new and poorly-characterized drugs in local centers, perhaps without adequate resources and time.²⁰⁰

Mr. Schwartz did recognize, along with the Alliance's founder, Frank Burroughs, that although the compassionate use programs are far from ideal and in need of some kind of effective revamping, Tier I access was not itself the appropriate solution.²⁰¹

D. *A Right to Noninterference?*

The 2006 majority opinion in *von Eschenbach* did not follow its decision through to its logical conclusion, as Judge Griffith noted in his dissent.²⁰² For example, he asked, why wouldn't the majority's reasoning apply to the seriously ill?²⁰³ Those with debilitating chronic diseases are no less likely to want access as soon as possible in order to have relief. Someone with a chronic pain condition such as fibromyalgia, may be as desperate for relief as a terminally ill cancer patient.

Among those individuals seeking relief are those who desire access to medical marijuana.²⁰⁴ The *von Eschenbach* majority did not express any concern over the floodgates opening to new medical marijuana litigation.²⁰⁵ However,

200. *Id.*

201. *Id.*

202. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 486, 487 (D.C. Cir. 2006) (Griffith, J., dissenting), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

203. *Id.* at 499. Furthermore, the FDA bans importing drugs from Canada which assuredly restricts some individuals' access to drugs. Perhaps that will be the next due process challenge brought before the court.

204. *Gonzales v. Raich*, 545 U.S. 1 (2005).

205. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 478 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

Angel Raich, the woman who brought the unsuccessful Commerce Clause action against Congress' authority to regulate marijuana under the Controlled Substances Act (CSA), now brought suit against the Drug Enforcement Administration challenging the CSA as a violation of her right to medical treatment.²⁰⁶

A "negative right" is, for example, the right to pursue a course of treatment between you and your provider without interference from the government.²⁰⁷ Access to medical marijuana, abortions, and contraception all fall within the general rubric of negative rights. Simply stated, there is not a fundamental right to medical decision making as a separate category free from government interference. At the risk of a wholesale rejection of the private physician-patient relationship, the Alliance should have realized that there is applicable precedent establishing this proposition. This precedent, the 2007 court pointed out, could be found within *United States v. Oakland Cannabis Buyers' Cooperative*.²⁰⁸ That case involved an argument of medical necessity that is similar to the argumentation found in *von Eschenbach*. The patients in *Oakland* sought access to marijuana for medicinal purposes and invoked an argument based on medical necessity. The Supreme Court held that "[u]nder any conception of legal necessity, one principle is clear: The defense cannot succeed when the legislature itself has made a determination of values."²⁰⁹ Analogously, the FDA already determined that access to experimental drugs should be greatly truncated.²¹⁰ Essentially, the preservation of life, which is what the Alliance was seeking, "[c]annot justify a blanket right to obtain without any government interference every and any kind of treatment that might be available

206. A concise article on the matter is John A. Robertson, *Controversial Medical Treatment and the Right to Health Care*, HASTINGS CENTER REP., Nov.-Dec. 2006, at 15, 18; see also *Raich v. Gonzales*, 500 F.3d 850 (9th Cir. 2007). Angel Raich has not been successful in her appeal.

207. Contrast negative rights with positive rights, such as the claim that there is a universal right to healthcare.

208. 532 U.S. 483 (2001).

209. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 708 (D.C. Cir. 2007) (quoting *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 491 (2001)), cert. denied, 76 U.S.L.W. 3373 (2008).

210. *Id.*; see also 21 U.S.C. § 355(a).

and that a physician might recommend.”²¹¹

Another arena that may become ripe for judicial intervention is embryonic stem cell therapy, as scholar John Robertson observed.²¹² Controversial in and of itself, a new constitutional right to have access to life-preserving drugs could have opened the floodgate with regard to challenges to federal laws prohibiting such therapies.²¹³ Opponents of embryonic stem cell treatments might have demanded a ban against public (i.e., Medicare or Medicaid) funding for such therapy. Such is the case with abortion.²¹⁴ This, of course, will directly affect the poorest members of society, those who are unable to pay for the treatments. So, we would have a new fundamental right to access, yet a vast pool of individuals who would be too poor to pay for it. A subtle (or perhaps not so subtle) class system would then arise between those who could pay for Phase I therapies and those who could not.

This parallels a concern of the National Organization for Rare Disorders (NORD). NORD is an extremely active patient advocacy group whose efforts led to the creation of the Orphan Drug Act.²¹⁵ The recent proposals by the FDA (spurred by the *von Eschenbach* suit as well as the proposed ACCESS Act) to allow companies to charge more for the unapproved drugs could “cause a class struggle with enormous political repercussions” due to the fact that insurance companies will not pay for investigational drugs and so, only those who can pay out of pocket will actually receive access. As Therese M. Mulvey, M.D., notes, “[i]t is not difficult to imagine that payers might offer substantial resistance to covering costly cancer drugs—for either labeled or off-label uses—if they begin to be approved on the basis of no show of efficacy and little if any show of

211. *N.Y. State Ophthalmological Soc’y v. Bowen*, 854 F.2d 1379, 1390 (D.C. Cir. 1988).

212. Robertson, *supra* note 206, at 18-19. Although embryonic stem cell therapy is not currently a standard treatment for anyone, Phase I trials are predicted to begin within the next year or two. Under the *von Eschenbach* principle, there could be challenges to access these treatments. *Id.* at 18.

213. *Id.*

214. *Id.*; see also *Harris v. McRae*, 448 U.S. 297 (1980).

215. Orphan Drug Act, Pub. L. No. 94-414, § 526(a)(2), 96 Stat. 2049 (1983). The Orphan Drug Act provides incentives to pharmaceutical companies to fund research and development for drugs which affect less than 200,000 individuals. *Id.* § 1(b).

safety.”²¹⁶

Furthermore, NORD argues—contra the Alliance—that access should not be given at the end of Phase I. NORD is sensitive to the fact that companies already struggle to enroll volunteers. The ideal proposal, in fact, would be to forbid access until the end of Phase II testing, “[t]he data from Phase II trials must be compelling before access is allowed... [or] Phase II trials should be fully enrolled or completed before broader access is permitted, and only if relative safety and effectiveness is probable.”²¹⁷ Another issue that has arisen with respect to this case is that NORD believes the FDA has favored patients with cancer and HIV/AIDS, neglecting those with rare and other life-threatening diseases. NORD’s complaints point to real problems concerning access to Phase I drugs and provide possible fuel for future litigation on the part of those who are at an economic disadvantage or those who just might not have the “disease of the moment.”²¹⁸

If there had been, in fact, a decision in favor of the Alliance, then we might have occasion to discuss any relevance such a decision would have with respect to issues concerning the organ market.²¹⁹ It is common knowledge that many individuals cannot pay for organ procurement and many die each year while waiting for the necessary transplants.²²⁰ The organ donation system in our country is largely altruistic, and, thus, thousands of people are left quite helpless in the face of a necessary reliance upon the kindness of strangers.

If a fundamental right had, in fact, been established in *von Eschenbach*, a constitutional challenge could be brought against the National Organ Transplant Act of 1984 (NOTA) as an interference with a right to preserve life. Specifically, if people were permitted to sell their organs, many lives would inevitably be saved (as a transplant would presumably be quite preferable to dialysis in the case of kidney failure,

216. Mulvey, *supra* note 187, at 204.

217. Letter from Abbey S. Meyers, President of the National Organization for Rare Disorders to the Food and Drug Administration Division of Docket Management (Jan. 12, 2007) (Docket No. 2006N-0062).

218. *Id.*

219. Robertson, *supra* note 206, at 19.

220. The National Organ Transplantation Act (NOTA) makes it a federal crime to pay for organ donation. *Id.*

for example).²²¹ The government would be forced into a position of showing that the ban on selling organs is narrowly tailored to serve a compelling interest.²²² It would appear that those reasons are self-evident (e.g., averting a global organ market, prevention of the exploitation of the poor, and the commodification of persons). Yet many perceived the logic behind the FDA regulations as similarly self-evident. Now those very regulations designed to protect and preserve the public health and the public safety have been challenged as an interference with individual liberty. The negative right to healthcare could be stretched to accommodate the autonomy of a statistically small sample to the detriment of the many.

CONCLUSION

If a right to noninterference by the government was upheld in *von Eschenbach*, the courts could become overburdened with similar cases stemming from the principles, and thus precedent, established by that case. The courts, rather than the agency which was given authority by Congress to regulate the pharmaceutical industry, would become the arbiters of emerging medical technologies. With the clinical trial system weakened, millions of Americans would feel the impact of such a decline. As a society, there cannot be complete reverence to the individual right of self-determination to the detriment of an entire population—there must be a balance. The fear expressed by researchers and scientists alike regarding the potential damage to the clinical trial system is real and impending. The FDA is working with lawmakers to revise and improve its access system, and that is precisely where this debate ought to be held—the halls of Congress and not the Supreme Court. As Judge Griffith stated in the August 2007 opinion, “[o]ur 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.”²²³

221. Robertson rightly observes that the law is inconsistent with respect to the buying and selling of body parts. For instance, a woman can sell her eggs to an infertile couple, but she is barred from selling them to a researcher. Robertson, *supra* note 206, at 19.

222. An interesting discussion surrounding the consequences of an organ trade can be found in MARGARET JANE RADIN, *CONTESTED COMMODITIES* (1996).

223. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 714 (D.C. Cir. 2007), *cert. denied*, 76 U.S.L.W. 3373 (2008).

