ABIGAIL ALLIANCE IS NOT THE END: A LEGISLATIVE SOLUTION TO A HUMAN PROBLEM

by
Amy Heverly[*]

This year, the Supreme Court denied certiorari in the Abigail Alliance *case, crushing the hopes of terminally ill patients, for whom access to experimental drugs was a last hope. For others, though, there is hope for a legislative solution that would allow for access to drugs before they have finished the FDA testing process, without a Supreme Court decision declaring access a constitutional right. This Note suggests an amendment to the existing FDA regulations that would allow access to experimental drugs for patients with less than six months to live who have exhausted all FDA-approved treatment options.*

[*] J.D. Candidate 2009, Lewis & Clark Law School. I would like to thank Art LaFrance, Fidel Fajardo-Acosta, Diana Velez, and my mom, Jody Heverly. Without the support of these wonderful teachers, I would not be who I am today.

I. INTRODUCTION

Some terminally ill patients want access to drugs that have not finished the Food and Drug Administration's (FDA) testing process because they have exhausted all FDA-approved treatment options. While drug companies and the FDA are under fire for perceived under-testing on drugs like Vioxx,[1] others feel they have a constitutional right to use drugs that have not finished the entire FDA process. This Note will consider the practical and constitutional implications of this problem. It will discuss the problem from the viewpoints of the FDA, drug companies, and patients; analyze the patients' constitutional argument; and propose legislation that could satisfy all parties, potentially save lives, and promote innovation in cancer treatment.

The D.C. Circuit, in *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, most recently addressed this problem. A three-judge panel first found for Abigail Alliance (*Abigail Alliance I*), finding that terminally ill patients have a due process right to experimental and possibly life-saving drugs.[2] However, the D.C. Circuit granted re-hearing en banc and reversed (*Abigail Alliance II*), finding that there was no due process right to drugs that have not finished the FDA's testing process, and that the FDA had a rational reason for limiting access to experimental drugs.[3]

The United States Supreme Court denied certiorari of this case;[4] however, that is not the end of the story. This Note will discuss relevant Supreme Court precedent and the *Abigail Alliance* decisions, and then propose a practical solution which includes federal legislation that would modify and add to Chapter 21 of the Code of Federal Regulations. The legislation would allow for a limited group of terminally ill patients to have access to drugs after they have finished the first round of testing. It

[1] Rita Rubin, *How Did the Vioxx Debacle Happen?* USA TODAY, Oct. 12, 2004, at 01D, *available at* http://www.usatoday.com/news/health/2004-10-12-vioxx-cover_x.htm.

[2] Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006) [hereinafter *Abigail Alliance I*].

[3] Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach , 495 F.3d 695 (D.C. Cir. 2007) [hereinafter *Abigail Alliance II*].

[4] Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 128 S. Ct. 1069 (2008).

will address the issues of access, administration, monitoring, and record-keeping.[5]

Allowing access for terminally ill patients is just one part of the solution; there must also be some incentive for drug companies to participate in the program. Drug companies will be concerned about possible liability if patients have bad reactions to the experimental drugs, and will also be concerned about profit. One solution would be to force drug companies to participate, but shield them from liability. Another solution would be to allow drug companies to profit from the program.[6] The legislation proposed in this Note would allow drug companies to profit, but would not give them a complete shield from liability.

Safeguards must be added to the system because of the inherent vulnerability of the people seeking access to experimental drugs. People with terminal illnesses are likely to be willing to try almost anything if there is a possibility, however small, that it will cure their disease. This could lead to abuses of power by drug companies. Patients signing up for this program would have to be aware of the risks and give informed consent, but this does not mean that they should be subject to unreasonable risks.[7]

The legislation proposed by this Note is designed to make an exception in the existing framework of the FDA testing process to allow for greater access to experimental drugs for terminally ill patients. Some have argued that the FDA process is too paternalistic, yet ineffective, taking autonomy away from patients and giving them false confidence in new drugs.[8] This Note takes a more conservative approach in an attempt to find a solution that meets the needs of patients and drug companies, with limited effect on the FDA's current procedure.

II. THE PROBLEM AND THE PLAYERS

This Part will describe the interests of the parties involved in greater detail and review Supreme Court history that informed the substantive due process analysis of the D.C. Circuit in its *Abigail Alliance* decisions.

A. Terminally Ill Patients, Doctors, Drug Companies, and the FDA Each Have Interests to Protect

The people with the most to lose in this equation are obviously the terminally ill patients. With their lives on the line, the patients are willing

[5] *See* Appendix, *infra*.

[6] *See* Part V.C., *infra*.

[7] *See* Part V.B., *infra*, for discussion of safeguards. *See* Part II.B., *infra*, for discussion of the FDA testing phases.

[8] *FDA Criticized for Inadequate Overview of Clinical Trials*, 26 BIOTECHNOLOGY L. REP. 595 (2007); Nicole E. Lombard, Note, *Paternalism vs. Autonomy: Steps Toward Resolving the Conflict over Experimental Drug Access Between the Food and Drug Administration and the Terminally Ill*, 3 J. HEALTH & BIOMEDICAL L. 163 (2007).

to take enormous risks in trying experimental drugs, if there is a possibility that those drugs could save their lives.[9] The patients involved in the *Abigail Alliance* case have terminal illnesses, usually cancer, and have exhausted all conventional treatment options—either they were tried and ineffective, or the patient's doctor believed the patient was not strong enough to survive the conventional treatment.[10]

The Abigail Alliance for Better Access to Developmental Drugs is a non-profit organization dedicated to helping terminally ill patients, mostly with cancer, to get access to drugs that have not been approved by the FDA but may be the patient's only chance for survival.[11] They want to do this by passing legislation, like that proposed in this Note, to create a program allowing terminally ill patients to bypass the FDA testing process.[12] Abigail Alliance is named after Abigail Burroughs, a woman who died of neck cancer when she was only twenty-one years old. Abigail Burroughs tried to get access to an experimental cancer drug for months before her death. After she died, her father Frank Burroughs started Abigail Alliance to help other cancer patients in a similar situation.[13]

While Abigail Alliance focuses on cancer patients, this same problem was in the news in the 1980s and 1990s when AIDS patients wanted access to experimental treatments. In 2008, there are a variety of antiretroviral drugs available to patients diagnosed with HIV that can dramatically slow the growth of the virus.[14] AZT, the first antiretroviral drug, began clinical testing in 1986, and while it did not cure HIV or AIDS, as doctors had hoped, its ability to slow the growth of the virus was astounding.[15] People with HIV who did not qualify for the next round of clinical trials were distraught when they heard from the FDA that there was nothing they could do to get AZT but wait for official approval of the drug.[16] In response, an underground network of AIDS patients formed, and many AIDS patients tried home remedies and drugs obtained in foreign countries.[17]

There is still an issue today with foreign availability of drugs that are not yet legal in the United States.[18] This carries with it the risk that the

[9] Brief for Appellant at 9, *Abigail Alliance II*, 495 F.3d 695 (D.C. Cir. 2007) (No. 04-5350), 2005 WL 1826286.

[10] *Id.* at 16.

[11] Abigail Alliance, Abigail Alliance Mission Statement, http://www.abigail-alliance.org/mission.htm.

[12] *Id.*

[13] Abigail Alliance, Abigail Story, http://www.abigail-alliance.org/story.htm.

[14] National Institutes of Health, FDA-Approved Drugs, http://www.aidsinfo.nih.gov (follow "FDA-Approved Drugs" hyperlink).

[15] Lisa Terrizzi, *The Need for Improved Access to Experimental Drug Therapy: AIDS Activists and Their Call for A Parallel Track Policy*, 4 ADMIN. L.J. 589, 601–02 (1991).

[16] *Id.*

[17] *Id.* at 611–12.

[18] Experimental Drugs Flourish in China, ASIA TIMES, Jan. 9, 2008, *available at* http://www.atimes.com/atimes/China_Business/JA09Cb02.html.

drugs taken by these patients will be counterfeit and dangerous. It is in the government's interest to find a safer way to get experimental drugs to its terminally ill citizens, rather than have patients going to China, Mexico, or the internet to find them.

Doctors' interest is in the health of their patients and the functionality of the healthcare system. Some advocates for better access suggest that a more decentralized FDA, with more physician control of medications for terminally ill patients, would be a better system.[19] Doctors may appreciate this approach because it gives them more control over their patients' care, but, in theory, it may also expose them to greater malpractice liability. Patients or their families could then sue doctors prescribing experimental drugs with questionable efficacy if the drugs had negative effects.

Drug companies have an interest too, because they, not the FDA, develop the possibly life-saving drugs the terminally ill patients want access to. Currently, FDA regulations disallow drug companies from charging more than cost for experimental drugs.[20] Part of Abigail Alliance's argument was that if drug companies are not allowed to profit from giving access to these drugs, they will not have an incentive to allow the access or to keep developing new drugs.[21]

On the other hand, drug companies are currently under fire from consumer groups because of lack of testing of some drugs and aggressive advertising.[22] For example, the arthritis drug Vioxx was widely prescribed, but later taken off the market because it caused a heightened risk for heart attacks and strokes.[23] In November 2007, Merck, the manufacturer of Vioxx, settled a lawsuit with thousands of people who took Vioxx for $4.85 billion dollars.[24]

Giving terminally ill patients access to experimental drugs would probably not expose drug companies to lawsuits as large as the Vioxx lawsuit, because the group of people getting the drugs would be smaller. However, drug companies may still be worried about the cost of litigation and bad press if experimental drugs are ineffective or have unforeseen side effects.

---

[19] Lombard, *supra* note 8, at 186.

[20] 21 C.F.R. § 312.7(d)(3) (2007).

[21] Brief for Appellant, *supra* note 9, at 19.

[22] *See* Mark I. Schwartz, *To Ban or Not To Ban—That is the Question: The Constitutionality of a Moratorium on Consumer Drug Advertising*, 63 FOOD & DRUG L.J. 1 (2008) (discussing the First Amendment implications for banning direct-to-consumer drug advertising, and concluding it would be unconstitutional). Schwartz is Associate Chief Counsel for Biologics at the FDA.

[23] Rubin, *supra* note 1, at 01D.

[24] Carrie Johnson, *Merck Agrees to Blanket Settlement on Vioxx*, WASHINGTON POST, Nov. 10, 2007, at D01, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/11/09/AR2007110900597.html.

The FDA is also being criticized for its passivity in drug testing, resulting in unsafe drugs like Vioxx being sold in the marketplace.[25] However, the FDA performs a tough balancing act, trying to give drug companies incentives to keep producing new drugs while keeping them affordable for patients.[26] The FDA also has to deal with the directly competing values of trying to make sure drugs are safe in the long term and trying to get drugs on the market faster so that people can benefit from them.[27]

Next term, the drug company Wyeth will make a preemption argument to the Supreme Court.[28] They may argue that because the FDA regulates drug availability, drug companies should not be liable for the damages caused by unsafe drugs if the FDA said the drugs were safe. This litigation could affect terminally ill patients in a number of ways. If the drug companies win, they may be more likely to allow terminally ill patients access to experimental drugs, because they know they cannot be sued. On the other hand, if the drug companies win, they may be less likely to allow access to experimental drugs, for fear that preemption would not protect them from unapproved drug liability.

This is a life and death problem for terminally ill patients. Some commentators believe the FDA is leaning toward being even more conservative in its new drug approvals.[29] It seems so fundamental that people on the brink of death should be allowed to try whatever means necessary to save their lives, and yet that right has been repeatedly denied to terminally ill patients. Given the Supreme Court's decision not to hear the *Abigail Alliance* case, it has never been more important that the legislature act to provide a solution.

B. The FDA Has a Three-Phase Testing Process; Abigail Alliance Wants Access To Drugs After the First Phase

The first thing a drug company does when it wants to market a new drug is submit an investigational new drug (IND) application.[30] There are three types of INDs: Investigator INDs, Emergency Use INDs, and

---

[25] Rubin, *supra* note 1, at 01D.

[26] Alison R. McCabe, Note, *A Precarious Balancing Act—The Role of the FDA as Protector of Public Health and Industry Wealth*, 36 SUFFOLK U. L. REV. 787, 814 (2003).

[27] *Id.* at 789.

[28] Gardiner Harris & Alex Berenson, *Drug Companies Near Old Goal: A Legal Shield*, N.Y. TIMES, Apr. 6, 2008, at 1, *available at* http://www.nytimes.com/2008/04/06/washington/06patch.html.

[29] Matthew Perrone, *Global Market Expected to Drive Cancer Drug Growth*, FORBES, May 15, 2008, *available at* http://www.forbes.com/feeds/ap/2008/05/15/ap5011716.html.

[30] Food and Drug Administration, Drug Approval Application Process, http://www.fda.gov/cder/regulatory/applications/default.htm. For an excellent discussion of the FDA drug approval process, *see* Lois K. Perrin, Note, *The Catch-22 for Persons with AIDS: To Have or Not To Have Easy Access to Experimental Therapies and Early Approval for New Drug*s, 69 S. CAL. L. REV. 105 (1995).

Treatment INDs.[31] Treatment INDs are sometimes called compassionate use INDs, and are currently the only way for terminally ill patients who do not qualify for clinical studies to get access to experimental drugs.[32] It is a very limited exception, and does not encompass all qualified applicants.[33] The IND application must include all information about drug testing on animals or on humans, information on how the drug will be produced, and detailed information about the proposed study of the drug.[34] The company must then wait thirty days while the FDA reviews the IND application and determines if the proposed clinical test would present an unreasonable risk to participants.[35] The IND clinical trial consists of three phases.[36]

If, at any point during the testing or before the testing begins, concerns arise about the safety of the drug or the trial, the FDA can place a "clinical hold" on the investigation.[37] The drug's sponsor (usually the manufacturer) then must address whatever issue the FDA has a problem with, and the FDA will reevaluate the safety of the drug or trial.[38]

In Phase I, twenty to eighty patients try the drug, to determine its safety and early indications of effectiveness.[39] If the drug passes Phase I, it is given to more people, typically several hundred, in Phase II testing. The goal in Phase II is determining the drug's effectiveness in treating the indications described in the IND application and determine its short-term side effects.[40] The third phase is a larger clinical trial, involving several hundred to thousands of patients. This phase is necessary to gather more information about effectiveness and side effects, so that prescribing physicians can give their patients the information they need to decide whether or not to take a drug, and so that the physicians can give adequate recommendations.[41]

The legislation proposed in this Note would provide an alternate process for terminally ill patients, in effect making an exception to the rule that patients who do not qualify for Phase II studies cannot get access to investigational drugs after Phase I. While the current process is not perfect, a complete overhaul of the testing process for all patients is

[31] Food and Drug Administration, Investigational New Drug (IND) Application Process, http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm.

[32] Brief for Appellant, *supra* note 9, at 8. *See also* Perrin, *supra* note 30, at 119 (discussing compassionate use INDs).

[33] Brief for Appellant, *supra* note 9, at 8.

[34] Investigational New Drug (IND) Application Process, *supra* note 31.

[35] *Id.*

[36] Corrected En Banc Brief for Appellees at 3, *Abigail Alliance II*, 495 F.3d 695 (D.C. Cir. 2007) (No. 04-5350), 2007 WL 415084.

[37] Food and Drug Administration, Clinical Hold Decision, http://www.fda.gov/cder/handbook/clinhold.htm.

[38] *Id.*

[39] 21 C.F.R. § 312.21 (a)(1) (2007).

[40] Corrected En Banc Brief for Appellees, *supra* note 36, at 4.

[41] *Id.*

beyond the scope of this Note.[42] The proposed legislation would allow access to experimental drugs for terminally ill patients if the risks and benefits balance were in favor of access. There would be an additional physician in charge of overseeing the patient and testing process, and the drug company would have to submit the results of the terminally ill patients' use of the drug along with other testing data.[43]

III. LEGAL HISTORY

Abigail Alliance was not the first group of patients to sue the government in hopes of attaining access to experimental drugs. They were also not the first group of terminally ill patients to make substantive due process arguments. Maybe ironically, Abigail Alliance gets the most support for their right to life argument from right to die cases like *Cruzan*,[44] and abortion cases like *Roe v. Wade*[45] and *Planned Parenthood v. Casey*.[46] Their argument is also informed by medical marijuana cases. This Part includes a brief summary of these, and other important cases which influenced the Court's decision in *Abigail Alliance I* and *II*.

The goal of Abigail Alliance in bringing their lawsuit against the FDA was to gain access to drugs after Phase I testing for patients who do not qualify for Phase II trials.[47] Their argument was that terminally ill patients have a liberty interest in trying experimental new drugs when all conventional therapies have failed them, and that after Phase I testing, drugs have been proven at least minimally safe for further human testing, so the FDA has less interest in protection of the patients.[48] Rather than argue that the testing process is improper, they argue that there should be a greater exception for terminally ill patients because the effectiveness and side effects are not as important to people who are probably going to die regardless.[49]

A. Other Terminally Ill Patients Have Sued the Government and Lost

The Supreme Court had an opportunity to address this issue in *United States. v. Rutherford*, in 1979.[50] That case was brought by a group of terminally ill cancer patients who wanted access to the experimental drug

[42] *See* Harris & Berenson, *supra* note 28, at 1. ("In February, [FDA] commissioner, Andrew C. von Eschenbach, acknowledged that the agency faces a crisis and may not be 'adequate to regulate the food and drugs of the 21st century.'").

[43] *See* Appendix, *infra*.

[44] Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261 (1990).

[45] 410 U.S. 113 (1973).

[46] Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992).

[47] Brief for Appellant, *supra* note 9, at 45.

[48] *Id.* at 47.

[49] *Id.*

[50] United States v. Rutherford, 442 U.S. 544 (1979).

Laetrile before Phase I testing, so they sued the government to enjoin it from stopping a shipment of the drug.[51] Justice Marshall wrote for the unanimous court.[52] The opinion focused more on statutory construction than on substantive due process rights.[53]

According to Westlaw, *Rutherford* has been examined, discussed or cited in 269 cases in the United States. Of those, only 2, including *Abigail Alliance I*, distinguish it, and both of those cases were overruled.[54] The case law was clearly stacked against Abigail Alliance.

The year after *Rutherford*, the Ninth Circuit heard a case where an individual, Carnohan, wanted to obtain Laetrile for use as a nutritional supplement to prevent cancer.[55] The Ninth Circuit found against Carnohan on the right to privacy issue, but did not rule on his due process argument because he had not exhausted all administrative options before seeking a judicial remedy.[56] This procedural holding has been the downfall of many cases of terminally ill patients suing the government for better access to experimental drugs.[57]

The Third Circuit examined the new drug testing process in the context of new animal drugs in *United States v. Algon Chemical Inc.*[58] That case involved the labeling of new drugs sent in bulk to veterinarians.[59] The court found that the fact that the drugs were being sent to veterinarians, who knew how to handle them and were using them in their own practices, did not justify creating an exception to the FDA regulations on labeling new drugs.[60]

More recently, the District Court for the Northern District of Oklahoma relied on *Rutherford* when it denied AIDS patients access to experimental drugs because they did not fit the qualifications for the clinical trials or emergency use, and the drug did not qualify for exemption from clinical testing.[61] In that case, the patient's own doctor developed the drug and submitted the IND application, but the FDA put a clinical hold on the testing.[62] Like *Rutherford*, *Cowan* involved a drug's

---

[51] *Id.* at 548. The drug Laetrile was later found to be ineffective. *See* National Cancer Institute, Laetrile/Amygdalin, http://www.cancer.gov/cancertopics/pdq/cam/laetrile.

[52] *Rutherford*, 442 U.S. at 545.

[53] *Id.*

[54] Westlaw, Citing References for United States v. Rutherford, 442 U.S. 544 (1979).

[55] Carnohan v. United States, 616 F.2d 1120, 1121 (9th Cir. 1980).

[56] *Id.* at 1122.

[57] *See* Cowan v. United States, 5 F. Supp. 2d 1235, 1238 (N.D. Okla. 1998).

[58] United States v. Algon Chemical Inc., 879 F.2d 1154, 1155 (3d Cir. 1989).

[59] *Id.*

[60] *Id.* at 1159.

[61] *Cowan*, 5 F. Supp. 2d at 1238.

[62] *Id.* at 1239.

pre-Phase I testing, which is how the *Abigail Alliance I* court distinguished *Rutherford*.[63]

B. Other End of Life Due Process Jurisprudence Is Also Relevant

The courts rely on *Washington v. Glucksberg* for the constitutional analysis in *Abigail Alliance I* and *Abigail Alliance II*.[64] In that case, three terminally ill patients and four doctors sued the state of Washington, claiming that Washington's statute banning assisted suicide was unconstitutional.[65] The Supreme Court held that the law was constitutional, and that the patients did not have a substantive due process right to assisted suicide because that right was not deeply rooted in our nation's history.[66]

Before discussing *Glucksberg,* a discussion of *Cruzan v. Director, Missouri Department of Health* is necessary.[67] Nancy Cruzan was in a car accident in January of 1983, at the age of 25, and was deprived of oxygen for 12 to 14 minutes.[68] Afterward, Cruzan was in a persistent vegetative state for seven years and showed no indications of cognitive function. Her family wanted the hospital to remove the tubes that gave Nancy food and water, which would lead to her death, but the hospital would not do so without a court order.[69] The Court found that Nancy Cruzan had a liberty interest in refusing life-preserving treatments.[70] They found a history of this right in our nation's past, because at common law any unwanted touching was battery.[71] The Court held that if there is clear and convincing evidence that a person would want to refuse life-sustaining treatments, the hospital must take the person off those treatments.[72] Cruzan died December 26, 1990.[73]

In *Glucksberg*, the Supreme Court analyzed the constitutionality of Washington's ban on assisted suicide.[74] The court determined that the right to commit suicide was not deeply rooted in our nation's history, and that the law was rationally related to the state interest in protecting life, the vulnerable, and the medical profession.[75] The court distinguished *Glucksberg* from *Cruzan*, because the right in *Cruzan* was to refuse medical

[63] *Abigail Alliance I*, 445 F.3d 470, 486 (D.C. Cir. 2006).
[64] Washington v. Glucksberg, 521 U.S. 702 (1997).
[65] *Id.* at 707.
[66] *Id.* at 708.
[67] Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261 (1990).
[68] *Id.* at 266.
[69] *Id.* at 267–68.
[70] *Id.* at 265–69.
[71] *Id.* at 269.
[72] *Id.*
[73] University of Virginia Medical Center, The Legacy of Nancy Cruzan, http://www.healthsystem.virginia.edu/internet/him/nancycruzan.cfm.
[74] Washington v. Glucksberg, 521 U.S. 702, 707–08 (1997).
[75] *Id.* at 723–31.

treatment, which was consistent with the common law view that forced medication was battery.[76]

Oregon voters passed a ballot measure legalizing assisted suicide in certain circumstances, the Oregon Death With Dignity Act (ODWDA).[77] The ODWDA allows a doctor to prescribe a lethal amount of a painkiller to a person who is both terminally ill and competent.[78] The ODWDA was immediately challenged by those opposed to the law because they were afraid that terminally ill patients may be unfairly influenced to choose to end their lives.[79] The district court granted an injunction to analyze the law's constitutionality.[80] However, the Ninth Circuit vacated that judgment, and held that the patients and doctors bringing the suit lacked standing to challenge the law because they did not have any actual injury.[81]

The Supreme Court did not get a chance to evaluate ODWDA until 2006.[82] The case turned on issues of state versus federal law, specifically whether the Controlled Substances Act gave the Attorney General the power to revoke the registration of a physician that prescribed a lethal dose of painkillers pursuant to the ODWDA.[83] The court found in favor of Oregon, and the ODWDA is still in effect.[84]

C. Reproductive Rights and Medical Marijuana Cases Are Also Relevant

Another important area of due process jurisprudence is reproductive rights. In *Griswold v. Connecticut*, the Supreme Court held that married couples had a privacy right that entitled them to access birth control without government interference.[85] In *Eisenstadt v. Baird*, the court found it unconstitutional to allow married couples access to birth control while preventing distribution to single people.[86] These rights were based on privacy and autonomy, the same concepts argued by Abigail Alliance.[87]

In *Roe v. Wade*, the Supreme Court held that a woman had a fundamental liberty interest that protected her right to have an abortion before viability of the fetus, without the interference of the state, and

---

[76] *Id.* at 722–23.

[77] OR. REV. STAT. § 127.800 *et seq.* (2005).

[78] OR. REV. STAT. § 127.805.

[79] Lee v. Oregon, 869 F. Supp. 1491, 1493 (D. Or. 1994).

[80] *Id.*

[81] Lee v. Oregon, 107 F.3d 1382, 1387 (9th Cir. 1997).

[82] Gonzales v. Oregon, 546 U.S. 243 (2006).

[83] *Id.* at 248–49.

[84] *Id.* For more information about ODWDA and statistics, see OREGON DEPARTMENT OF HUMAN SERVICES, SUMMARY OF OREGON'S DEATH WITH DIGNITY ACT (2007), *available at* http://oregon.gov/DHS/ph/pas/docs/year10.pdf.

[85] Griswold v. Connecticut, 381 U.S. 479 (1965).

[86] Eisenstadt v. Baird, 405 U.S. 438 (1972).

[87] Brief for Appellant, *supra* note 9, at 3.

invalidated a Texas law criminalizing abortion.[88] The court found that the right to have an abortion is grounded in the right to privacy found in the 14th Amendment's due process clause.[89] However, the court found that there was a compelling state interest in protecting the life of fetuses after viability, so abortions could be criminalized after viability.[90] The court set up guidelines based on the trimester system. In the first trimester, abortion cannot be criminalized at all, because the state's interest in the life of the fetus is too small. In the second trimester, the state has a larger interest, and in the third trimester the state has an even larger interest.[91]

More recently, the Supreme Court revisited the abortion issue in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, and upheld the woman's liberty interest in procuring an abortion.[92] In *Casey*, the Court changed the trimester system set up in *Roe*, and opted instead for a system based on fetus viability outside the womb, which is around 20 weeks.[93] The Court also used the "undue burden" standard to evaluate the Pennsylvania laws requiring married women to tell their husbands before getting an abortion. The Court held that this law placed an undue burden on women, and made it less likely that battered women would get an abortion.[94]

The Court has also held that some rights, arguably based on privacy and autonomy, are not fundamental. The Supreme Court did not reach the issue of whether or not patients prescribed medical marijuana had a substantive due process right to use it in *U.S. v. Oakland Cannabis Buyers' Co-op* or *Gonzalez v. Raich*.[95] However, in both cases the Court upheld federal law making possession of marijuana illegal, regardless of a valid prescription for it under state law.[96]

This Note supports the idea of federal legislation to allow expanded access to experimental drugs for terminally ill patients. Given the case law, it is unlikely that the Supreme Court would rule in favor of terminally ill patients in another case like Abigail Alliance, so a legislative solution would be the fastest and most efficient way to get access to the

[88] Roe v. Wade, 410 U.S. 113, 117–118 (1973).

[89] *Id.* at 153.

[90] *Id.* at 164–65.

[91] *Id.*

[92] Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 846 (1992).

[93] *Id.* at 873.

[94] *Id.* at 893–895.

[95] United States v. Oakland Cannabis Buyers' Coop, 532 U.S. 483, 498–499 (2001); Gonzales v. Raich, 545 U.S. 1, 9 (2005).

[96] Justice Thomas' dissent in *Gonzales v. Oregon* takes issue with the Court holding that the Controlled Substances Act preempted state law legalizing marijuana for medical use in *Gonzales v. Raich*, but did not preempt Oregon law legalizing the prescription of a legal dose of painkillers in *Gonzales v. Oregon*, 546 U.S. 243, 299–302 (2006). The cases can be distinguished because marijuana is a schedule I controlled substance (considered the most serious), and the painkillers are schedule II.

drugs. The legislation proposed in this Note is federal, so there would not be an issue of conflict with the Controlled Substances Act as there has been with state laws like the ODWDA and medical marijuana laws.

IV. *ABIGAIL ALLIANCE V. VON ESCHENBACH*

In May 2006, the D.C. Circuit found for Abigail Alliance, holding that terminally ill patients had a substantive due process right to experimental drugs.[97] This victory was celebrated tentatively, with fears of an en banc or Supreme Court reversal.[98] Those fears came true with *Abigail Alliance II* in August 2007.[99] This Part will analyze the *Abigail Alliance* decisions and their implications for the future of terminally ill patients, and concludes that there is a legislative avenue that could result in greater access to experimental drugs for terminally ill patients.

A. There Is No Substantive Due Process Right to Use Experimental Drugs, Even to Save One's Life

A shift in attitudes about substantive due process is evident from *Abigail Alliance I*, but the holding in *Abigail Alliance II* is more consistent with the existing precedent. Abigail Alliance made four arguments for why they should be allowed access to experimental drugs. First, they argued that they had a substantive due process right, under the 14th Amendment, to save their own lives.[100] Second, they argued the common-law doctrine of necessity.[101] Third, they argued the tort of intentionally preventing a person from giving necessary aid to another.[102] Finally, they argued the common-law doctrine of self-defense.[103] In *Abigail Alliance I*, the court did not reach the second, third or fourth rationales because they found a substantive due process right. In *Abigail Alliance II*, the court addressed all four rationales and found none compelling.

The first step in analyzing the substantive due process right is to identify what that right is and give it a "careful description."[104] This is also the first area of dispute between the majority and dissent in *Abigail Alliance II*. *Glucksberg* requires a careful description of this right,[105] and the dissenters felt the majority's description was inappropriate.[106] The majority describes the right as "a constitutional right to assume . . .

---

[97] *Abigail Alliance I*, 445 F.3d 470, 486 (D.C. Cir. 2006).

[98] Lombard, *supra* note 8, at 180.

[99] *Abigail Alliance II*, 495 F.3d 695 (D.C. Cir 2007).

[100] Brief for Appellant, *supra* note 9, at 27.

[101] *Abigail Alliance II*, 495 F.3d at 708.

[102] *Id.*

[103] *Id.* at 710.

[104] Washington v. Glucksberg, 521 U.S. 702, 721 (1997).

[105] *Id.*

[106] *Abigail Alliance II*, 495 F.3d 695, 714 (D.C. Cir. 2007) (Rogers, J., dissenting).

'enormous risks' in pursuit of *potentially* life-saving drugs."[107] The dissent classifies it as the right to "attempt to preserve one's life," and says the risk factor is a separate consideration.[108]

The same judges that dissent in *Abigail Alliance II* comprised the majority in *Abigail Alliance I*, with Judge Rogers authoring both opinions and Chief Judge Ginsberg joining.[109] The right they describe in *Abigail Alliance I* is the right to "make an informed decision that may prolong life."[110] The inclusion of the "informed decision" language in their opinion in *Abigail Alliance I* implied that the judges did believe that the risk factor was important in the careful description of the right, at least initially.

The second step of the *Glucksberg* analysis is deciding whether or not the carefully described right is "objectively, deeply rooted in this Nation's history and tradition."[111] The classification of the right is so important because the second step in the analysis is based on fact, so the right description could lend itself toward specific facts which will determine which test the court uses to see if the law passes constitutional muster.

For example, in *Glucksberg*, the plaintiffs were terminally ill patients and their doctors who wanted to overturn the state of Washington's ban on assisted suicide. The right they asserted could have been described as the right to commit pre-meditated murder or the right of a mentally competent, terminally ill adult to choose to end their life, with the help of a doctor. The majority found that no matter how you describe it, the right does not exist in our Nation's history, because it is banned by most states.[112] While the Court upheld the Oregon statute allowing assisted suicide,[113] this does not mean that right is constitutionally guaranteed.[114]

The majority in *Abigail Alliance I* found the right to make an informed decision that may prolong life in our Nation's common law right over control of one's own body, privacy and autonomy, and that drug regulation is a relatively new government responsibility.[115] Furthermore, the court found that the government traditionally regulated drug manufacturers, but left the question of who should get what drugs up to doctors.[116] In support of this argument, they also

---

[107] *Id.* at 710 (citation omitted).

[108] *Id.* at 716.

[109] *Abigail Alliance I*, 445 F.3d 470, 471 (D.C. Cir. 2006). *Abigail Alliance II*, 495 F.3d at 697.

[110] *Abigail Alliance I*, 445 F.3d at 477.

[111] Washington v. Glucksberg, 521 U.S. 702, 720–721 (1997).

[112] *Id.* at 710.

[113] Gonzales v. Oregon, 546 U.S. 243, 274–275 (2006).

[114] *Glucksberg*, 521 U.S. at 710.

[115] *Abigail Alliance I*, 445 F.3d at 480–81.

[116] *Id.* at 483.

mention the practice of promoting drugs for off-label purposes.[117] The court found that the first example of the federal government's regulation of drugs for efficacy was in the Food, Drugs and Cosmetics Act of 1962.[118]

The majority in *Abigail Alliance II* saw the history very differently. While they agreed with the majority in *Abigail Alliance II* about our nation's history of not regulating drugs for efficacy, they said the government does have a history of regulating drugs for safety.[119] The court found examples of regulation of drugs far earlier than the court in *Abigail Alliance I*, including colonial legislation about the amount of drugs given.[120] It also found examples of federal legislation as far back at 1848, with the Import Drug Act.[121] According to the court, even if the FDCA is the first example of drug regulation based on efficacy, the history of drug regulation based on safety is sufficient to show that the patients' claim is not deeply rooted in our nation's history.[122]

The next step in the *Glucksberg* analysis is to determine if the right is "implicit in the concept of ordered liberty such that neither liberty nor justice would exist if [it was] sacrificed."[123] The majority in *Abigail Alliance II* did not reach this issue because they did not find necessary historical precedent to move on to the next step of the test, nor did they examine the issue *arguendo*.[124]

The dissent in *Abigail Alliance II* and the majority in *Abigail Alliance I* found a liberty interest in the patients' attempts to save their own lives through the use of experimental drugs.[125] The dissent cites an important quote from *Cruzan*, "it cannot be disputed that the Due Process Clause protects an interest in life as well as an interest in refusing life-sustaining medical treatment."[126] The dissent makes a strong argument that if people have a right to refuse life-sustaining treatment, they ought to have the right to agree to possibly life-saving, but risky, experimental drugs.[127]

---

[117] *Id. But see* Paul Elias, *Biotech's Ex-CEO Charged with Fraud*, S.F. CHRON., March 18, 2008. The promotion of off-label uses for drugs is not legal, but is commonplace. The CEO of InterMune, Inc. was charged with fraud in federal court on March 18, 2008 for promoting the use of Actimune, a drug for bone disease and immune disorders, for treating patients with idiopathic pulmonary fibrosis, a lung disease.

[118] *Abigail Alliance I*, 445 F.3d at 482.

[119] *Abigail Alliance II*, 495 F.3d 695, 703 (D.C. Cir. 2007).

[120] *Id.* at 704.

[121] *Id.*

[122] *Id.* at 706.

[123] *Id.* at 727 (Rogers, J., dissenting), *quoting* Washington v. Glucksberg, 521 U.S 702, 721 (1997).

[124] *Id.* at 703.

[125] *Id.* at 728 (Rogers, J., dissenting). *Abigail Alliance I*, 445 F.3d 470, 486 (D.C. Cir. 2006).

[126] *Abigail Alliance II*, 495 F.3d at 727–728, *quoting* Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261, 281 (1990).

[127] *Id.* at 728.

Moving on, the *Abigail Alliance II* court addressed the Abigail Alliance's common-law arguments and easily dismissed them.[128] First, they addressed the common-law doctrine of necessity. The court dismissed this argument because the drugs will not necessarily save the patients, and noted that even if they did find the argument compelling, Congress has the right to limit or eliminate the necessity defense.[129] The dissent argued that the court's logic was flawed because in a necessity situation, the actor need not know for certain that their action will be life-saving.[130] They used an example of a driver whose car is hurtling toward a cliff—they must press the brake whether they know the car will stop in time or not.[131] This analogy is flawed as well, because the driver knows that pressing the brakes, generally, are an effective way to stop a car, but the patients do not know whether the drugs are an effective or safe treatment, generally or in their specific case.

Abigail Alliance's second common-law argument was that the tort of intentional interference with lifesaving efforts applied to the government's action.[132] This is defined as "intentionally prevent[ing] a third person from giving to another aid *necessary* to his bodily security."[133] The court found that because the efficacy of these drugs has not been proven, they are not necessary for the patients, and may, in fact, hinder their bodily security.[134]

Finally, the court addressed the issue of self-defense. Abigail Alliance argued that if victims of crime are allowed to assume risks in defending their lives, victims of terminal illness should be allowed to assume risks to defend their lives against disease.[135] The Alliance analogizes their situation to that of a pregnant woman who needs an abortion to save her life. The court did not find this analogy effective because aborting the fetus in that example is known to be potentially life-saving, but the drugs in this case are not proven to be effective.[136]

The dissent argued that the court did not recognize the important rationale behind the rights to self-defense and tort of intentionally interfering with rescue. The dissenters felt that the court skipped discussion of the rights themselves, and went straight for the

---

[128] *Id.* at 707–10.

[129] *Id.* at 708, *citing* United States v. Oakland Cannabis Buyers' Coop, 532 U.S. 483, 491 (2001).

[130] *Id.* at 719 (Rogers, J., dissenting).

[131] *Id.* at 719 (Rogers, J., dissenting).

[132] *Id.* at 708.

[133] *Abigail Alliance II*, 495 F.3d at 708, *quoting* RESTATEMENT (FIRST) OF TORTS § 326 (1934).

[134] *Id.* at 709.

[135] *Id.*

[136] *Abigail Alliance II*, 495 F.3d at 709.

countervailing government interests, which should have been the next step in the *Glucksberg* analysis.[137]

B. The D.C. Circuit Disagrees About Which Test Applies—Rational Basis or Strict Scrutiny

If the carefully described right is not deeply rooted in our nation's history, and therefore not fundamental, rational basis scrutiny is appropriate.[138] Therefore, Abigail Alliance had to prove that the government's restriction on experimental drugs bore no rational relationship to a legitimate state interest to prevail.[139] The court described the government's interest as "ensuring that there is a scientifically and medically acceptable level of knowledge about the risks and benefits" of drugs before allowing them to be used by the public, in order to protect the public from potentially unsafe, ineffective or even harmful drugs.[140] The court found the FDA's testing process, and their policy of not allowing terminally ill patients to use these drugs, to be at least rationally related to that end.[141]

Given the amount of time the court spent discussing the patients' rights and the nation's history (15 pages),[142] they dealt with the rational basis test rather briskly (two pages).[143] The test does not specifically require such a careful description of the government's interest. However, it is notable that the court described the patients' interest very specifically, and the government's very broadly. Just as it is easier to find historical support for a more broad right in the first part of the *Glucksberg* test, it is easier to find rational basis for the government's action with a broader description of their interest. Given how easily the rational basis test is passed, it may be a moot point, but this author thinks that the court should have examined the government's interest as it related to those specific plaintiffs more closely.

The dissent in *Abigail Alliance II* would have remanded the case for a district judge to rule according to the strict scrutiny standard.[144] This is a significant hurdle which would make it difficult for the law to pass constitutional muster.

The majority opinion in *Abigail Alliance II* suggests that a legislative solution is possible:

> To be sure, we do not suggest that the law can never strike the balance between access to experimental drugs and risk that the

---

[137] *Id.* at 719 (Rogers, J., dissenting).
[138] *Id.* at 712, Washington v. Glucksberg, 521 U.S. 702, 722 (1997).
[139] *Abigail Alliance II*, 495 F.3d at 712.
[140] *Id.* at 713.
[141] *Id.*
[142] *Id.* at 697–711.
[143] *Id.* at 712–13.
[144] *Id.* at 728 (Rogers, J., dissenting).

> alliance suggests. We limit our analysis to whether the Constitution *demands* the balance they desire. The Alliance can, of course, advocate its position vigorously before Congress and the FDA, and convince our Nation's democratic branches that the values the Alliance favors should be protected.[145]

The Supreme Court of the United States recently denied certiorari on *Abigail Alliance*,[146] which means that if terminally ill patients want earlier access to experimental drugs, they will have to be more creative. This Note proposes legislation that could be passed by Congress and the FDA which would allow a limited set of patients to access experimental drugs.

Some commentators have suggested that the solution, at least in part, would be to decentralize the role of the FDA, and instead put more emphasis on individual patients and their doctors.[147] This approach argues that a patient's physician is in a better position to judge whether a new drug could be effective for them than the FDA.[148] The problem with this argument is that it forces doctors to prescribe treatments they probably are unfamiliar with because they are new, and to trust the manufacturers to tell them what indications the drugs are appropriate for.

The FDA is essentially the middleman between drug companies and patients; however, they also serve a regulatory function. Many commentators criticize the FDA for being overly-paternalistic in its regulation of new drugs.[149] Proponents of greater access say that adult patients can weigh the risks for themselves.[150] The position advocated in this Note may be criticized as overly-paternalistic, but it is designed with protection from abuse of a vulnerable population in mind.

V. PROPOSED LEGISLATION

In creating an expanded access program, the FDA and Congress have to think about whom it will apply to (and whom will leave out), how it will actually work, and what might happen if it goes wrong. They also will have to include some safeguards to avoid drug companies taking advantage of terminally ill people, a vulnerable group. This Part will discuss those issues and suggest a solution that is workable for all interested parties.

---

[145] *Id.* at 710 n.17.

[146] Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 128 S. Ct. 1069 (2008).

[147] Lombard, *supra* note 8, at 186.

[148] *Id.*; Michael E. Horwin, "*War on Cancer": Why Does the FDA Deny Access to Alternative Cancer Treatments?* 38 CAL. W. L. REV. 189, 213 (2001).

[149] Lombard, *supra* note 19, at 181; Won Bok Lee, Column, *Abigail Alliance v. Von Eschenbach: Constitutional Rights of Terminally Ill Patients Reconsidered*, 36 J.L. MED. & ETHICS 191, 192 (2008).

[150] Horwin, *supra* note 148, at 213. Brief for Appellant, *supra* note 9, at 31.

The legislation proposed by this Note is consistent with the Access, Compassion, Care, and Ethics for Seriously Ill Patients Act (ACCESS Act),[151] proposed by Senator Sam Brownback, and advocated for by Abigail Alliance. The ACCESS Act was read before the House and Senate in 2005 and 2006, but neither house ever voted on it and it is now considered dead.[152] The legislation proposed in this Note expands and modifies the more specific legislation proposed by Abigail Alliance in their Citizen Petition to the FDA.[153] The ACCESS Act, which would amend the U.S. Code, does not include the specific characteristics of an expanded access program;[154] the Citizen Petition, which would modify the Code of Federal Regulations (C.F.R.), does include specifics for who could be allowed to be in the program and how it would work.[155]

This Note's proposed legislation has more incentive for drug companies in it, so their lobbyists may get behind it, giving it some momentum. It also includes changing the safeguards section of the current C.F.R., to create greater protections for this population. Given the D.C. Circuit's suggestion of the legislative solution, this may be a good time for Abigail Alliance to try Congress again.[156]

A. The Exception Must Be Limited To Patients that Are Terminally Ill and Do Not Qualify for Clinical Trials

One major concern about granting more people access to experimental drugs before they are done with testing is that it will make people less likely to join the clinical trials.[157] The reasoning is that if people can get access to the drugs outside of the trials, they will know they have the real thing, but if they are in the trial they may get a placebo.[158] This is a concern for the public in general, because if drugs meant to treat serious illnesses do not go through the proper testing procedure, then anyone who gets the disease will have to go through the exception process to get the drug. The other alternative would be to have a completely different testing process for drugs that treat terminal illnesses.

---

[151] S.1956, 109th Cong. (2005), H.R. 6303, 109th Cong. (2006).

[152] Govtrack.us, H.R. 6303, http://www.govtrack.us/congress/bill.xpd?bill=h109-6303; Govtrack.us, S. 1956, http://www.govtrack.us/congress/bill.xpd?bill=s109-1956.

[153] Citizen Petition of the Abigail Alliance and the Washington Legal Foundation to the Food and Drug Administration, U.S. Dept. of Health and Human Services, *In re* Tier 1 Initial Approval Program to Expedite the Availability of Lifesaving Drugs (June 11, 2003), at 2, *available at* http://www.abigail-alliance.org [hereinafter Citizen Petition].

[154] S.1956.

[155] Citizen Petition, *supra* note 153, at 5–6.

[156] *See supra* note 145 and accompanying text.

[157] Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 NYU J. LEGIS. & PUB. POL'Y 295, 332–333 (2000).

[158] Lee, *supra* note 149, at 193; Terrizzi, *supra* note 15, at 612.

The Abigail Alliance proposal only allows patients who have applied to be in clinical tests and were denied or those from whom "the patient's physician has determined that the patient is not a reasonable candidate for a clinical trial."[159] The problem with this is that is would allow doctors to keep their patients out of the trials. This might give doctors incentive to find a way to keep their patients out. It puts them in a precarious position. In order to get access to experimental drugs, the patient should have to show that they have applied to be in a clinical trial and been denied or that they are so clearly outside the boundaries of the clinical trial that applying would be futile.

Defining "terminal illness" is another major part of the proposed legislation. The definition provided by 21 C.F.R. section 312.34 and used by Abigail Alliance in the Citizen Petition is, "an 'immediately life-threatening' disease means a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment."[160] Compare this with the ODWDA, which defines terminal disease as "an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months."[161]

The C.F.R.'s definition is broad and illusory, and the ODWDA's definition is more specific, but could be too restrictive for this purpose. The Citizen Petition does not give an explanation for why they chose not to change the wording of the definition, but one can imagine that they would want their program to reach as many people as possible.[162] On the other hand, having a hard-to-work definition could lead to confusion and more litigation down the road.

Certainly making an estimate of how long a person has to live is in inexact science, but putting some sort of time requirement in this legislation might make it easier to work. This Note proposes a nine-month limit, rather than a "matter of months."[163] It is more difficult to define parameters in the issue of early intervention in a disease likely to cause premature death. "Premature death" and "early treatment" are both terms that would need definitions. The proposed legislation in this Note takes out that portion of the definition.

---

[159] Citizen Petition, *supra* note 153, at 9.

[160] *Id.* at 4.

[161] Oregon Death with Dignity Act, OR. REV. STAT. § 178.800(12) (2005).

[162] Abigail Alliance's mission statement says that by expanding access to experimental drugs, thousands of lives could be saved per year. Abigail Alliance Mission, *supra* note 11.

[163] Citizen Petition, *supra* note153, at 4.

B. The Proposed Legislation Needs Greater Safeguards to Avoid Abuse of Power by Drug Companies

Given the vulnerability of the patients involved in an expanded access program—that is, patients with less than nine months to live—greater safeguards should be added. Currently, section 312.34(c) simply requires that the same safeguards be used in treatment INDs, as with other IND procedures.[164] Abigail Alliance's proposed legislation includes a safety mechanism in section 312.37(f).[165] This Note's proposed legislation includes the addition of safeguards in section 312.34(c). The policy reasoning is that people involved in this program are vulnerable, because in order to be in the program they must be expected to die within nine months and have exhausted all non-experimental avenues for treatment.[166] The possibility for abuse of these patients by drug companies testing new products is significant.

There is a sad history in the United States of abuse of vulnerable populations through medical experimentation.[167] While informed consent and institutional review boards are important safeguards, history tells us that they may not be sufficient.[168] The example of experimenting with radiation on poor cancer patients in Ohio in the 1960s and 1970s shows how vulnerable populations can be taken advantage of.[169]

Some commentators have suggested that giving the FDA more power, specifically the power to fine drug companies, would give the drug companies incentive to treat patients well.[170] These commentators have also noted that market forces may dictate the actions of the drug companies, and if the fines are not substantial enough, the companies may take that risk.[171] This Note will not propose that the FDA be allowed to fine drug companies, because of that concern and the concern that fines would raise a red flag for drug companies such that they would not want to participate in the program.

The ACCESS Act proposed adding an 11-member committee that would review applications for expanded access.[172] It appears that the committee's role would be to expedite the process for efficiency, not

---

[164] 21 C.F.R. § 312.34 (2007).

[165] *See* Appendix, *infra*. Citizen Petition, *supra* note 153, at 6.

[166] Appendix, *infra*.

[167] *See* Arthur Birmingham LaFrance, *Animal Experimentation: Lessons from Human Experimentation*, 14 ANIMAL L. 29, 40–41 (2007).

[168] *Id.* at 41.

[169] *See In re* Cincinnati Radiation Litigation, 874 F. Supp. 796, 800 (S.D. Ohio 1995).

[170] Lombard, *supra* note 8, at 185; Vivian I. Orlando, Note, *The FDA's Accelerated Approval Process: Does the Pharmaceutical Industry Have Adequate Incentives for Self-Regulation?,* 25 AM. J.L. & MED. 543, 564–65 (1999).

[171] Orlando, *supra* note 170, at 565.

[172] S.1956, 109th Cong. § 506(g)(3)(A) (2005).

necessarily safety and oversight.[173] This Note does not suggest another committee be added to the FDA because of a belief that more bureaucracy seldom leads to increased efficiency.

Instead, the legislation proposed by this Note includes a clause to be added to proposed section 312.37, which would require an additional physician, not affiliated with the patient beforehand and not affiliated with the drug company, be added to the patient's care team. This physician would monitor the patient during the time they use the experimental drug and notify the FDA if it appears that there are irregularities in the testing process or if the patient appears to be getting worse. At that point, FDA would review the cost-benefit analysis for that patient, and possibly take the patient off the experimental drug.[174]

C. Drug Companies Should Be Allowed Limited Profits to Encourage Participation, but They Should Not Be Completely Shielded From Liability

Section 312.7 does not allow drug companies to charge more than the cost of "manufacture, research, development, and handling of the investigational drug."[175] Abigail Alliance promotes the idea of drug companies being allowed to make a reasonable profit from giving access to patients who do not qualify for clinical trials.[176] The rationale behind this policy is that they want to foster a healthy relationship with the drug companies so that they will be able to keep innovating and coming up with new drugs—to hopefully save more lives.[177] In their brief to the D.C. Circuit, the Abigail Alliance frames the issue as one of choice for the patients.[178] If drug companies are willing to participate in greater numbers, terminally ill patients will have more choices in their treatment options and will be able to make the choice to use the experimental drug.[179]

The obvious criticism of this argument is that it is unfair for people who cannot afford whatever the drug companies are charging, and drug companies may make the price very high to take advantage of wealthy people with cancer. Furthermore, insurance companies are unlikely to fund such experimental treatments.[180]

---

[173] S. 1956 § 506(g)(1).

[174] *See* Appendix, *infra*.

[175] 21 C.F.R. § 312.7(d) (3) (2007).

[176] Citizen Petition, *supra* note 153, at 4.

[177] Abigail Alliance Mission, *supra* note 11.

[178] Brief for Appellant, *supra* note 9, at 19.

[179] *Id.*

[180] S*ee* Peter D. Jacobson, Richard A. Rettig & Wade M. Aubry, *Litigating the Science of Breast Cancer Treatment*, 32 J. HEALTH POL. POL'Y & L. 785 (2007); Eric P. Steinberg, Sean Tunis & David Shapiro, *Insurance Coverage for Experimental Technologies*, HEALTH AFFAIRS, Winter 1995, at 143, *available at* http://content.healthaffairs.org/cgi/reprint/14/4/143.pdf.

The other option to get drug companies to participate is to make such participation mandatory. The FDA could mandate that the drug companies have to give experimental drugs to any person who qualifies for the expanded access program, and force them to charge people only their overhead cost for the drugs. The problem with this plan is that drug companies' only incentive is to get the drugs past the testing point. If the cost of the expanded access program grows, it may give drug companies less incentive to keep innovating in the field of terminal illnesses.

The other issue concerning drug companies is their liability if the experimental drug harms the patient. Senate Bill 1956 includes a waiver of the right to sue the drug manufacturer or sponsor of the drug before expanded access is granted.[181] This provision, in combination with allowing drug companies to make a profit, is a recipe for drug companies to take advantage of patients. The legislation proposed by this Note includes a limit on liability for drug companies except in the case of gross negligence or malice.[182]

Increased oversight by physicians and the possibility of liability for gross negligence or malice should keep the drug companies in check. Allowing limited profits from expanded access will keep them interested in participating in the expanded access program. In a perfect world, this balance may not have to be struck, but in reality, drug companies interests play a big role in the FDA's cost-benefit analysis.[183]

If there were a problem with the expanded access program, patients probably would not be able to sue to sue the government or the FDA because of sovereign immunity. There may be a situation in which the Federal Tort Claims Act may apply, if the claim was based on the tortious act of an FDA employee.[184]

VI. CONCLUSION

The conflict between terminally ill patients wanting access to experimental drugs before they have finished FDA testing and the FDA wanting to ensure the safety and efficacy of drugs before their use by the public is seemingly impossible to overcome. However, given terminally ill patients' unique position, the cost-benefit analysis that drives FDA testing policy is not applicable to their situation. This Note proposes a program that could meet the ethical obligations of the FDA as regulator and satisfy thousands of terminally ill patients, for whom an experimental drug is their last hope for survival.

This solution should satisfy the FDA because it is narrowly focused on a specific group and includes safeguards against abuse of the patients. The expanded access program has limited application to terminally ill

[181] S. 1956, 109th Cong. § 506(b)(5)(B)(ii) (2005).

[182] Appendix, *infra*.

[183] McCabe, *supra* note 26, at 818–19.

[184] Federal Tort Claims Act, 28 U.S.C. § 1346(b), 28 U.S.C. § 2671–2680 (2000).

people, so that these drugs will not be available to the general public. The program has an added oversight feature, which will protect patients without significant additional cost to the FDA.

The solution should satisfy drug companies because it allows them to make a reasonable profit and only exposes them to liability in cases of gross negligence or malice. Participation in the expanded access program will allow them to gather more data about their products, including "off-label" uses. It could also help public opinion about drug companies, who are often seen as greedy and unethical.[185]

The solution should satisfy patients because it allows them access to experimental drugs they would not otherwise have access to, and also includes safeguards for their benefit. Patients willing to try experimental drugs are desperately looking for a cure. Their willingness to take enormous risk in the hope of finding a cure to their disease makes them vulnerable to drug companies looking to make a profit and experiment on humans. This solution adds an oversight physician to sit as a watchdog for drug company abuse and the possibility of litigation to, in theory, keep drug companies from experimenting with the lives of terminally ill patients.

The issues discussed in this Note are literally life and death. The viewpoint of the terminally ill patients is easily understandable, yet it has been 30 years since *Rutherford* and we still do not have a solution. It is time for drug companies to put pressure on the FDA to get an expanded access program going. What do they have to lose?

[185] *See* CartoonStock, Pharmaceutical Company Cartoons, http://www.cartoonstock.com/directory/P/Pharmaceutical_company.asp.

APPENDIX

Proposed Amendments to Applicable C.F.R. Sections

Changes proposed by Abigail Alliance are in **bold**.
Changes proposed by this Note are in ***bold and italics***.

21 C.F.R. § 312.7

(a) Promotion of an investigational new drug. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

(b) Commercial distribution of an investigational new drug. A sponsor or investigator shall not commercially distribute or test market an investigational new drug.

(c) Prolonging an investigation. A sponsor shall not unduly prolong an investigation after finding that the results of the investigation appear to establish sufficient data to support a marketing application.

(d) Charging for and commercialization of investigational drugs—

(1) Clinical trials under an IND. Charging for an investigational drug in a clinical trial under an IND is not permitted without the prior written approval of FDA. In requesting such approval, the sponsor shall provide a full written explanation of why charging is necessary in order for the sponsor to undertake or continue the clinical trial, e.g., why distribution of the drug to test subjects should not be considered part of the normal cost of doing business.

(2) Treatment protocol or treatment IND. A sponsor or investigator may charge for an investigational drug for a treatment use under a treatment protocol or treatment IND provided: (i) There is adequate enrollment in the ongoing clinical investigations under the authorized IND; (ii) charging does not constitute commercial marketing of a new drug for which a marketing application has not been approved; (iii) the drug is not being commercially promoted or advertised; and (iv) the sponsor of the drug is actively pursuing marketing approval with due diligence. FDA must be notified in writing in advance of commencing any such charges, in an information amendment submitted under § 312.31. Authorization for charging goes into effect automatically 30 days

after receipt by FDA of the information amendment, unless the sponsor is notified to the contrary.

(3) Noncommercialization of investigational drug. Under this section, the sponsor may not commercialize an investigational drug by charging a price larger than that necessary to recover costs of manufacture, research, development, and handling of the investigational drug. **This limitation does not apply to the use of a drug under Tier 1 Initial Approval.**

(4) Withdrawal of authorization. Authorization to charge for an investigational drug under this section may be withdrawn by FDA if the agency finds that the conditions underlying the authorization are no longer satisfied.

21 C.F.R. § 312.34

(a) General. A drug that is not approved for marketing may be under clinical investigation for a serious or immediately life-threatening disease condition in patients for whom no comparable or satisfactory alternative drug or other therapy is available. During the clinical investigation of the drug, it may be appropriate to use the drug in the treatment of patients not in the clinical trials, in accordance with a treatment protocol or treatment IND. The purpose of this section is to facilitate the availability of promising new drugs to desperately ill patients as early in the drug development process as possible, before general marketing begins, and to obtain additional data on the drug's safety and effectiveness. In the case of a serious disease, a drug ordinarily may be made available for treatment use under this section during Phase 3 investigations or after all clinical trials have been completed; however, in appropriate circumstances, a drug may be made available for treatment use during Phase 2. In the case of an immediately life-threatening disease, a drug may be made available for treatment use under this section earlier than Phase 3**~~, but ordinarily not earlier than Phase 2.~~** For purposes of this section, the "treatment use" of a drug includes the use of a drug for diagnostic purposes. If a protocol for an investigational drug meets the criteria of this section, the protocol is to be submitted as a treatment protocol under the provisions of this section.

(b) Criteria.

(1) FDA shall permit an investigational drug to be used for a treatment use under a treatment protocol or treatment IND if:

(i) The drug is intended to treat a serious or immediately life-threatening disease;

(ii) There is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease in the intended patient population;

(iii) The drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed; and

(iv) The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence.

(2) Serious disease. For a drug intended to treat a serious disease, the Commissioner may deny a request for treatment use under a treatment protocol or treatment IND if there is insufficient evidence of safety and effectiveness to support such use.

(3) Immediately life-threatening disease.

(i) For a drug intended to treat an immediately life-threatening disease, the Commissioner may deny a request for treatment use of an investigational drug under a treatment protocol or treatment IND if the available scientific evidence, taken as a whole, fails to provide a reasonable basis for concluding that the drug:

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

(B) Would not expose the patients to whom the drug is to be administered to an unreasonable and significant additional risk of illness or injury, **taking into account the risk of illness, injury, or death from the disease in the absence of the drug.**

(ii) For the purpose of this section, an "immediately life-threatening" disease means a stage of a disease which will, ***within medically reasonably judgment, produce death within nine months.*** ~~***in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment***~~.

(c) Safeguards. Treatment use of an investigational drug is conditioned on the sponsor and investigators complying with the safeguards of the IND process, including the regulations governing informed consent (21 C.F.R. Part 50) and institutional review boards (21 C.F.R. Part 56) and the applicable provisions of Part 312, including distribution of the drug through qualified experts, maintenance of adequate manufacturing facilities, and submission of IND safety reports.

(d) Clinical hold. FDA may place on clinical hold a proposed or ongoing treatment protocol or treatment IND in accordance with § 312.42.

Abigail Alliance also advocated the addition of 21 C.F.R. 312.37, specifying the procedure for Tier 1 approval.

312.37 Tier 1 Approval

(a) The Commissioner may grant Tier 1 Initial Approval to a sponsor for limited marketing based on the results of a Phase 1 trial demonstrating a safety profile sufficient to support conduct of a Phase 2 or Phase 3 clinical trial intended to further test the safety and/or efficacy of the drug and initial evidence of effectiveness based on case-history data from a small number of patients. Sufficient initial evidence of effectiveness would, for example, consist of documented improvement in a small number of patients with forms of an illness that rarely or never regress spontaneously. Statistically significant support will not be required for Initial Approval. The needed data may be generated during a Phase 1 clinical trial and/or from among the initial or later patients enrolled in a Phase 2 and/or 3 clinical trial.

(b) The Commissioner will grant or deny approval within 30 days of a request for Initial Approval, concurrent with review of a Phase 2 or 3 clinical trial protocol. Initial Approval will not be conditioned on an increase in the requirements for approval of a clinical trial protocol.

(c) A sponsor receiving Tier 1 Initial Approval must continue diligent pursuit of clinical trials and other testing required for Tier 2 Accelerated Approval and/or Tier 3 Full Approval.

(d) A sponsor receiving Tier 1 Approval must require informed consent from the patient and adverse event reporting by the prescribing physician. The sponsor shall provide all material information regarding safety and efficacy in informed consent documents and must provide prescribing physicians with any new material on a timely basis.

(e) A sponsor receiving Tier 1 Initial Approval must provide the drug only to patients who have been found ineligible for or denied participation in a clinical trial for the same drug ***or who are so clearly outside the guidelines of the proposed clinical study that application would be futile in the judgment of a reasonable physician.*** ~~***or who, in the judgment of their physician, are not reasonable candidates for a clinical trial.***~~

(f) Tier 1 Initial Approval shall be withdrawn if the drug receives Accelerated Approval or Full Approval. Initial Approval may be withdrawn if there is no entity pursuing eventual full approval for the drug. Initial approval may be withdrawn if the drug if found to be ineffective or unacceptably dangerous for the patient populations most likely to be treated, except that any patient receiving the drug under Initial approval will be allowed to continue receiving the drug subject to updated informed consent. Initial Approval may be withdrawn on the basis of ineffectiveness only if few or no patients can be expected to benefit from the drug. Initial Approval may be withdrawn on the basis of dangerousness only if the risks posed by the drug clearly outweigh the benefits.

(g) In addition to the safeguards mentioned in 21 C.F.R. 312.34(c), each patient will be assigned an overseeing physician, an independent, board certified physician to monitor that patient's care during expanded access. The oversight physician must not be affiliated with the drug's manufacturer or sponsor, or with the patient previously. The oversight physician will monitor the patient's health and the effectiveness of the drug. If at any point there are irregularities in the testing procedure, or the drug appears to be aversely affecting the patient's health, and not having any positive impact on the patient's disease. Once the Commissioner has received this notification, the FDA will review the cost-benefit analysis for that patient, and take appropriate action, as described in section (f).

(h) Every patient receiving experimental drugs through the expanded access program must sign a written waiver of the right to sue the manufacturer or sponsor of the drug, or the physician who prescribed it, for an adverse event caused by the product, which shall be binding in every State and Federal court, ***unless there is a finding of gross negligence or malice on the part of the manufacturer or sponsor of the drug, or the physician who prescribed it.***