Giving the Terminally ILL Their Due (Process): A Case for Expanded Access to Experimental Drugs through the Political Process

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Giving the Terminally Ill Their Due (Process): A Case for Expanded Access to Experimental Drugs through the Political Process

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I. INTRODUCTION

The stated purpose of the Food and Drug Administration ("FDA" or "Agency") is "to promote and protect the public health." In furtherance of this end, the FDA has created a regulatory framework to ensure that drugs marketed to the general public are both safe and effective. However, critics insist that the FDA's paternalistic drug approval process does little to achieve its goal.

At the onset of the AIDS epidemic in the 1980s, criticism of the FDA intensified, as the FDA's lengthy and expensive drug approval process hindered terminally ill AIDS patients' access to potentially lifesaving treatment. Advocates for these patients clamored for increased and expedited access to experimental drugs. In response, the FDA liberalized its experimental drug policies. This response was not enough, however, to save Abigail Burroughs. Abigail, a twenty-one year-old honors student at the University of Virginia, died in 2001 after exhausting all FDA-approved treatments for her cancer. Prior to her death, Abigail unsuccessfully attempted to gain access through clinical trials to the experimental cancer drugs Iressa and Erbitux (since approved by the FDA).

In Abigail Alliance v. Von Eschenbach, a lawsuit filed by the foundation named in Abigail's honor, a three-judge panel of the Court of Appeals for the District of Columbia Circuit ruled in May 2006 that terminally ill patients have a due process right of access to such experimental drugs. However, the D.C. Circuit reheard the case en banc and reversed the decision 8-2 in August 2007. The Supreme

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5. Siegel & Roberts, supra note 4; see also Salbu, supra note 3, at 410.
Court denied the Abigail Alliance for Better Access to Developmental Drugs's ("Abigail Alliance's" or "Alliance's") petition for a writ of certiorari in January.\(^9\) Even if the Court had taken the case, however, it likely would have followed precedent and deferred to Congress and the FDA on the question of drug regulation.\(^10\) Despite the Court's denial of Abigail Alliance's petition—and despite the likely disposition had the Court granted cert—it is time to reform the FDA framework so that it no longer impedes the access of terminally ill patients to experimental drugs.

This Note concludes that the greatest prospect for successful reform lies in the legislative process. Reform of the FDA framework through the courts or through the administrative process is likely to prove unavailing. To show why, this Note first reviews the history of FDA regulation, both generally and as applied to terminally ill patients. The Note then demonstrates that the courts cannot bring about successful reform. Proponents of greater access to experimental drugs have no statutory argument and only weak constitutional arguments. Thus, courts should exercise restraint and defer to the judgment of Congress and the FDA on the question of drug regulation—a question of science and medicine. Once the need for some government regulation of scientific and medical questions is acknowledged, Congress and executive agencies—the political branches, rather than the judicial branch—are best equipped to fine tune regulatory policy.

Because recently proposed regulatory reforms are unlikely to succeed, this Note concludes that Congress must step in. The recently proposed Access, Compassion, Care, and Ethics for Seriously Ill Patients Act ("ACCESS Act") provides a model for legislative reform of the FDA framework.\(^11\) The Note endorses the Act, along with several suggested modifications to improve the legislation and its chance of enactment. In conclusion, the Note recognizes the implications of its analysis on other questions of science and medicine—from abortion to medical marijuana to physician-assisted suicide—which are traditionally addressed by the judiciary.

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10. See, e.g., Gonzales v. Raich, 545 U.S. 1, 27-28 (2005) (deferring to Congress's prohibition of marijuana use for all purposes, including medicinal); United States v. Rutherford, 442 U.S. 544, 559 (1979) ("Whether, as a policy matter, an exemption [to the FDA drug approval process] should be created [for terminally ill patients] is a question for legislative judgment, not judicial inference.").

II. THE FDA REGULATORY SCHEME

A. The Gold Standard: A History of FDA Regulation

In 1906, President Theodore Roosevelt signed the Food and Drugs Act ("1906 Act"), delegating its implementation to the Bureau of Chemistry in the Department of Agriculture.\(^\text{12}\) This Bureau eventually became the FDA, an agency within the Department of Health and Human Services.\(^\text{13}\) Although the history of drug regulation in the United States dates back to the colonial period, when Virginia's legislature passed an act to address the dispensing of more drugs than was "necessary or useful" in 1736, no semblance of today's regulatory scheme existed prior to the 1906 Act.\(^\text{14}\)

Congress passed the 1906 Act amid public outcry over the appalling conditions of the Chicago meatpacking industry portrayed in Upton Sinclair's novel *The Jungle*.\(^\text{15}\) The 1906 Act prohibited adulterated or misbranded food or drugs from entering interstate commerce, but did nothing to prevent unsafe food or drugs from entering the market.\(^\text{16}\) With no standards in place for testing or regulatory approval of new drugs, the drug company Massengill distributed a liquid treatment for sore throats containing diethylene glycol, a deadly poison, in 1937.\(^\text{17}\) Use of this drug resulted in 107 deaths, a fine of only $26,100 for the manufacturer under the 1906 Act, and political support for more stringent federal regulation of new drugs.\(^\text{18}\)

The Massengill tragedy led to the passage of the Food Drug and Cosmetic Act of 1938 ("FDCA"),\(^\text{19}\) which required drug companies to seek FDA approval before introducing their drugs to the market.\(^\text{20}\) Although drug companies were obliged to submit a New Drug


\(^{13}\) Id.


\(^{16}\) JAMES ROBERT NIELSEN, HANDBOOK OF FEDERAL DRUG LAW 3 (1986).

\(^{17}\) Id.


\(^{19}\) *Id.*; Salbu, *supra* note 3, at 407.

\(^{20}\) Greenberg, *supra* note 4, at 302.
Application to the FDA, express regulatory approval was not required. If the FDA did not disapprove within sixty days, a New Drug Application became effective and the company was free to begin commercial development of the drug.

It took another drug-induced health crisis to create the regulatory structure that the FDA administers today. In 1962, the sleeping pill thalidomide, developed and distributed in Europe, was discovered to cause severe birth defects. Although the FDA had not approved thalidomide for use in the United States, public concern resulted in the 1962 Kefauver-Harris Amendments to the FDCA. Known as the Drug Efficacy Amendments, these provisions, still in effect, require drug companies to provide proof of both safety and effectiveness before achieving FDA approval. Moreover, the amendments require that drug companies receive approval of new drugs from the FDA and that the FDA provide guidelines to drug companies for meeting the effectiveness standard.

The Drug Efficacy Amendments established "the era of the FDA's 'gold standard' for pre-market approval of drugs." The FDA regulations implementing these amendments have changed little since 1962. The approval process begins when a company submits an Investigational New Drug ("IND") application to the FDA after initial animal testing. If approved, the company is free to begin Phase I testing of the drug on a small sample of patients or volunteers to determine the drug's safety. Phase II testing consists of randomized, double-blind clinical trials, limited to several hundred subjects, and designed to determine the drug's effectiveness in treating the target disease. Phase III testing is performed on a larger sample size of several hundred to several thousand subjects to collect more data on the drug's effectiveness and to confirm the drug's safety. Companies then submit test results to the FDA for review. Although FDA review is meant to be completed within 180 days, reports suggest that the

21. Id. at 303.
22. Id.
24. Greenberg, supra note 4, at 303.
26. Greenberg, supra note 4, at 303.
29. 21 C.F.R. § 312.21(a) (2008).
30. Id. § 312.21(b).
31. Id. § 312.21(c).
approval process often lasts for years. Only after FDA approval may drug companies begin full-scale marketing of new drugs.

The FDA's approval process for new drugs seems consistent with the FDCA's mandate to "limit interstate commerce in drugs to those that are safe and effective." Yet, as with any regulatory policy, the agency must strive to balance competing societal interests. Historically, the American public clamored for increased FDA regulation of new drugs; however, more recent criticism has focused on how the FDA's "gold standard" impedes consumer access to new, potentially lifesaving, treatments.

B. Critique of the FDA's Gold Standard

While some level of drug regulation is both necessary and desirable, debate over the appropriate level of government intervention persists. Some favor even greater regulation than the FDA currently provides—especially in light of recent publicity over the adverse side effects of FDA-approved drugs such as Vioxx and Bextra. However, criticism also centers on the adverse side effects of FDA overregulation. Specifically, critics cite the increased costs of regulation and the concomitant delay in bringing drugs to the market, as well as governmental interference with both personal autonomy and the doctor-patient relationship.

The cost of bringing a new drug to market through the FDA approval process has been estimated at between $250 and $500 million. Such exorbitant expenditures prevent small drug companies

32. McCabe, supra note 27, at 791 (noting that the review period could take up to thirty months); Perrin, supra note 15, at 113 (noting that in 1994 the average approval process lasted twenty-six months).
33. 21 U.S.C. § 355(a) (2000) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.").
34. NIELSEN, supra note 16, at 3.
35. See, e.g., Greenberg, supra note 4, at 296; Perrin, supra note 15, at 113-14.
36. Siegel & Roberts, supra note 4.
from new drug development and prevent even large multinational companies from developing potentially effective drugs that they cannot patent or that are unlikely to recoup such a large investment.\textsuperscript{40} Besides reducing innovation, extensive FDA regulation has created the "drug lag"—a delay before new drugs available in other developed nations become available in the United States.\textsuperscript{41} The delay results from the length, stringency, and cost of the FDA approval process. Moreover, the approval process may keep beneficial drugs off the market entirely; it has been argued that the FDA's current regulatory policy would have withheld approval from such drugs as penicillin and aspirin.\textsuperscript{42}

The costs of FDA regulation go beyond time and money. Consumer protection regulation may also interfere with individual autonomy. FDA policy prevents much consumer access to new drugs that have not yet completed the extensive FDA approval process.\textsuperscript{43} The limited access available is restricted to patients who manage to enroll in clinical trials.\textsuperscript{44} Thus, patients who cannot gain access to a clinical trial must wait for the approval process to run its course despite having no other treatment options.\textsuperscript{45} This regulation interferes not only with individual choice, but also with a choice that the individual made with her doctor. The FDA testing and approval process does produce valuable information that may be of great use to the general public. However, an individual patient and doctor presumably are in the best position to determine whether a particular experimental treatment is worth the risk—before the FDA approves or disapproves use of the drug for patients generally.\textsuperscript{46}

\begin{thebibliography}{9}
\bibitem{40} Horwin, \textit{supra} note 3, at 717; Dillman, \textit{supra} note 39, at 935.

\bibitem{41} Siegel & Roberts, \textit{supra} note 4; Dillman, \textit{supra} note 39, at 936. As with costs of the drug approval process, estimates of the length of the drug approval process vary greatly, as well. \textit{Compare} Salbu, \textit{supra} note 3, at 404-05 (claiming that the length of time between initial investigation and FDA approval averaged twelve years prior to reform in the 1980s), \textit{with} Lynne K. Lechter, \textit{Regulatory Overkill and the AIDS Patient}, 1 ALB. L.J. SCI. & TECH. 131, 158 (1991) (citing the average time between drug creation and FDA approval to be between seven and thirteen years).

\bibitem{42} Lechter, \textit{supra} note 41, at 159.

\bibitem{43} Perrin, \textit{supra} note 15, at 106.

\bibitem{44} \textit{Id.} Entry in clinical trials may be difficult or impossible because of the age of the patient, the patient's geographical location, or the patient's medical history. \textit{See}, e.g., Alissa Puckett, \textit{The Proper Focus for FDA Regulations: Why the Fundamental Right to Self-Preservation Should Allow Terminally Ill Patients With No Treatment Options to Attempt to Save Their Lives}, 60 SMU L. REV. 635, 643 ("Gaining access to a clinical trial is difficult. There are a limited number of spaces available for Phases II and III, and drug companies require a patient to be in a certain stage of the disease, at least eighteen years of age, and, in some cases, to not have taken certain drugs or treatments.").

\bibitem{45} \textit{See} sources cited \textit{supra} note 40.

\bibitem{46} Horwin, \textit{supra} note 3, at 708.
\end{thebibliography}
Criticism of regulatory interference with individual choice is particularly resonant in the context of terminally ill patients' access to experimental drugs. Terminally ill patients who have exhausted all available remedies face a different risk-benefit analysis than that of the general public. Experimental drugs pose little additional risk to patients facing death, whereas the slightest possibility of improvement or cure provides a great benefit. Under these circumstances, the argument in favor of liberalizing the FDA's drug approval process is surely at its strongest.

C. FDA's Response: Liberalizing the New Drug Approval Scheme

The 1980s witnessed a health crisis that increased FDA regulation could not alleviate. The AIDS epidemic highlighted the failings of the FDA's drug approval process, as the broad scope of FDA regulation prevented development of and access to new drugs for patients suffering from and dying of AIDS. AIDS activists pointed out the inadequacy of FDA policy as it related to terminally ill AIDS patients for whom approved treatments provided no relief. These patients needed either expedited approval of new drugs or access to experimental drugs before completion of the FDA's extensive approval process. Faced with political pressure from AIDS activists and enabled by the deregulatory atmosphere of the Reagan and first Bush administrations, the FDA began to liberalize its policies and promulgate regulations providing terminally ill patients, and AIDS patients in particular, earlier access to new drugs.

The FDA historically has provided a “Compassionate Use” exemption for individual patients who are ineligible for clinical trials or who have exhausted all FDA-approved treatment to access experimental drugs. On a case-by-case basis, this exemption has permitted pharmaceutical companies to provide unapproved drugs to treat severely ill patients. Traditionally, however, the FDA granted exemptions only pursuant to an application by a patient's doctor.

47. Greenberg, supra note 4, at 298.
48. Id. at 315.
49. See id. at 296 (noting that the FDA impeded “the development of, and access to, new medications”).
50. Id. at 296-97.
52. Greenberg, supra note 4, at 316.
through a process involving substantial red tape. Access depended on pharmaceutical companies supplying drugs free of charge, as the prohibition on marketing unapproved drugs remained in place.

In 1987, the FDA promulgated regulations expanding the uncodified Compassionate Use exemption. The regulations currently allow access to experimental drugs prior to completion of the FDA approval process, through a Treatment IND, if four conditions are met: (1) the drug is intended to treat a serious or life-threatening disease; (2) no satisfactory alternative exists; (3) the drug is already under investigation through FDA-controlled trials; and (4) the drug sponsor is pursuing marketing approval for the new drug actively. Furthermore, the FDA now permits drug companies to recover manufacturing, research and development, and distribution costs by charging patients for experimental drugs, thereby incentivizing companies to provide them, or at least eliminating the economic disincentive. Ordinarily, the FDA grants Treatment INDs only during Phase III trials, though under undefined "appropriate circumstances," it may grant them during Phase II. However, the Treatment IND exemption still contains an effectiveness requirement that has limited its use to drugs in the latter stages of clinical testing. Moreover, the exemption applies only to broad groups of patients needing access to a particular drug, while individual access is left to the discretion of the FDA through its informal Compassionate Use policy.

In 1988, Vice President George H.W. Bush, Chairman of the Presidential Task Force of Regulatory Relief, asked the FDA to design procedures that would expedite the marketing of new drugs intended to treat AIDS and other serious illnesses. In response, the FDA promulgated new rules, known as the Subpart E regulations, designed to encourage collaboration between drug companies and FDA officials to ensure future FDA approval. In some instances, Phase III trials

53. Id.
54. Id.
55. 21 C.F.R. § 312.34 (2008); Siegel & Roberts, supra note 4.
56. 21 C.F.R. § 312.34.
57. Greenberg, supra note 4, at 319; Shulman & Brown, supra note 51, at 505.
58. Salbu, supra note 3, at 411.
59. Greenberg, supra note 4, at 318-19; Siegel & Roberts, supra note 4.
61. Perrin, supra note 15, at 129.
62. 21 C.F.R. §§ 312.80-.88 (2008); Shulman & Brown, supra note 51, at 511; Siegel & Roberts, supra note 4; Perrin, supra note 15, at 129.
are eliminated and replaced with Phase IV post-marketing trials that shift some of the research burden until after the FDA has approved an experimental drug and the drug company has begun to recoup its investment.\textsuperscript{63} Additionally, the regulations require the FDA to consider both the severity of disease and the absence of alternative treatment in approving a drug, suggesting recognition that FDA policies should differ when applied to the terminally ill.\textsuperscript{64}

In 1992, the FDA again amended its policy through promulgation of the Accelerated Approval Regulations, which permit application of "surrogate endpoints" to measure drug efficacy.\textsuperscript{65} Although drug effectiveness ordinarily is measured by extended patient survival, the use of surrogate endpoints allows effectiveness to be measured by evidence of intermediate physiological or biochemical effects that may predict extended patient survival, but do not prove it.\textsuperscript{66} Arguably, the Accelerated Approval Regulations provide the greatest liberalization of FDA policy, as they are the only regulations that alter the traditional framework of new drug testing.\textsuperscript{67}

Congress also has made efforts to expedite FDA approval of experimental drugs through enactment of the Prescription Drug User Fee Act ("PDUFA") in 1992.\textsuperscript{68} The PDUFA permits the FDA to charge drug companies "user fees" that help to fund the FDA's approval process. The fees support a larger staff of FDA reviewers and subsidize technologies meant to accelerate approval.\textsuperscript{69} The PDUFA proved so effective in increasing FDA drug approval rates that Congress reauthorized the user fee policy in the FDA Modernization Act of 1997 and again through the Prescription Drug User Fee Amendments in 2002.\textsuperscript{70} According to a United States General Accounting Office Report to the U.S. Senate, from 1993 to 2001, the average approval time of new drug applications for standard drugs

\textsuperscript{63} Greenberg, \textit{supra} note 4, at 322-23.
\textsuperscript{64} Shulman & Brown, \textit{supra} note 51, at 512.
\textsuperscript{65} 21 C.F.R. §§ 314.500, 601.40; Greenberg, \textit{supra} note 4, at 322; Shulman & Brown, \textit{supra} note 51, at 514.
\textsuperscript{66} 21 C.F.R. § 315.500; Greenberg, \textit{supra} note 4, at 323.
\textsuperscript{67} See Shulman & Brown, \textit{supra} note 51, at 514 (arguing that, due to the flexibility of its standard, "the accelerated approval rule . . . represents the most significant departure from the traditional FDA standards for drug approval").
\textsuperscript{68} 21 U.S.C.A. §§ 379g-379h (West 2007).
\textsuperscript{69} McCabe, \textit{supra} note 27, at 792.
dropped from twenty-seven to fourteen months.\textsuperscript{71} Congress most recently reauthorized the policy in September 2007.\textsuperscript{72}

III. FURTHER CONCERNS: ARE RECENT DEVELOPMENTS ENOUGH?

In the twenty years since the FDA and Congress began responding to the AIDS epidemic, the FDA approval process has been expedited, and terminally ill patients have been granted increased access to experimental drugs.\textsuperscript{73} However, these positive results beg the question whether these new developments have done enough. The approval process remains lengthy and expensive. For patients who cannot gain access to clinical trials, the FDA's regulatory scheme prevents immediate relief.\textsuperscript{74} Although the FDA may grant a Treatment IND exemption to broad groups of patients in need, access for an individual terminally ill patient is left to the complete discretion of the FDA. Although the FDA is a consumer protection agency, perhaps its framework, guided by the FDCA, does not protect terminally ill patients adequately. Two arguments suggest the FDCA and its associated regulations should not apply to the terminally ill: a statutory interpretation argument and a constitutional argument.

A. The Statutory Interpretation Argument

In \textit{United States v. Rutherford}, plaintiffs raised a statutory argument that the FDCA should not apply to the terminally ill. Cancer patients and their spouses sought judicial review of the FDA’s determination that a substance known as Laetrile was a “new drug” under the FDCA and that, therefore, the FDA could exclude Laetrile from interstate commerce absent an approved new drug application.\textsuperscript{75} While the district court’s decision for the plaintiffs focused on the patients’ constitutional right to privacy,\textsuperscript{76} the Tenth Circuit Court of

\textsuperscript{71} Id.
\textsuperscript{73} See Shulman & Brown, supra note 51, at 505-17 (reviewing the results of the Treatment IND, parallel track, Subpart E regulations, and Accelerated Approval Regulations from their implementation through December 31, 1994).
\textsuperscript{74} See Geeta Anand, \textit{The Most Expensive Drugs—Rx for an Industry}, WALL ST. J., Dec. 28, 2005, at A1. (noting that, according to drug manufacturer Eli Lilly & Co, “[d]espite enormous advances in understanding biology, it takes roughly the same amount of time today as it did 20 years ago to bring a new drug to market . . . [and] costs about $200 million per drug”).
\textsuperscript{75} 442 U.S. 544, 548 (1979).
Appeals affirmed the district court's judgment based on its reading of the statutory language.\textsuperscript{77}

The Tenth Circuit relied on section 505 of the FDCA, which provides that the sponsor of a new drug must demonstrate "whether or not such drug is safe for use and whether such drug is effective in use" before the FDA may grant approval for introduction into interstate commerce.\textsuperscript{78} The Tenth Circuit found that this language had "no reasonable application to terminally ill cancer patients."\textsuperscript{79} In the context of terminal patients, the court concluded that there were no reasonable standards by which to measure safety and effectiveness.\textsuperscript{80} For a patient facing death, suffering an adverse effect from an "unsafe" drug constituted an inconsequential risk. For a patient who has not responded to conventional therapy, taking an "ineffective" drug is nothing new. Thus, the court found that Laetrile was as safe and effective as any approved treatment and enjoined the FDA from interfering with the plaintiffs' procurement of intravenous injections of the drug.\textsuperscript{81}

Had the Supreme Court upheld this decision, drugs taken by terminally ill patients would have been excluded from regulation under the FDCA. However, the Supreme Court reversed the Tenth Circuit, holding that the "plain and unambiguous language" of the FDCA did not provide an implicit exemption for drugs used to treat the terminally ill.\textsuperscript{82} The Court noted that "[e]xceptions to clearly delineated statutes will be implied only where essential to prevent 'absurd results' or consequences obviously at variance with the policy of the enactment as a whole."\textsuperscript{83} Looking to the legislative history of the FDCA and its consistent administration by the FDA, the Court found reasonable standards by which to measure safety and effectiveness in the context of the terminally ill.\textsuperscript{84} The Court deemed a drug safe "when the expected therapeutic gain justifies the risk entailed by its use" and a drug effective "if it fulfills, by objective indices, its sponsor's claims of prolonged life, improved physical condition, or reduced

\textsuperscript{77} Rutherford, 582 F.2d at 1236-37.
\textsuperscript{78} 21 U.S.C. § 355(b) (2000).
\textsuperscript{79} Rutherford, 582 F.2d at 1236.
\textsuperscript{80} Id. at 1237.
\textsuperscript{81} Id.
\textsuperscript{83} Id. at 552
\textsuperscript{84} Id. at 552-55.
The Court found that the application of these definitions to terminally ill patients did not produce absurd results. However, perhaps the Court meant only to discourage future litigation that would force the judiciary to administer the FDCA—a job it thought better left to Congress and the FDA. In its concluding remarks, the Court noted that, although the text of the FDCA would not allow the judiciary to exclude drugs used to treat terminally ill patients from its scope, that policy question was a matter for legislative judgment.

### B. The Constitutional Argument

Although the Tenth Circuit and the Supreme Court decided *Rutherford* on a question of statutory interpretation, the *Rutherford* plaintiffs originally challenged the FDA's policy to exclude Laetrile from interstate commerce as a violation of their constitutional rights. The district court agreed, holding that by denying terminally ill patients Laetrile "in connection with [their] own personal health-care, [the] FDA ha[d] offended the constitutional right of privacy." In addition to citing the fundamental right to privacy found by the Supreme Court in *Roe v. Wade*, the district court relied heavily on the concurring opinion of Justice Douglas in *Doe v. Bolton*, in which "the freedom to care for one's health and person" came within the purview of that right. Justice Douglas found that "the right of privacy . . . has no more conspicuous place than in the physician-patient relationship."

The Supreme Court chose to avoid the constitutional issue implicated in *Rutherford*. When faced with a similar question in 2008, the Court again side-stepped the constitutional issue by denying cert in *Abigail Alliance*. In May 2006, a three-judge panel of the Court of Appeals for the District of Columbia Circuit ruled that mentally competent, terminally ill adult patients, who have no alternative FDA-approved treatment options, have a fundamental due process right of

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85. Id. at 555.
86. Id.
90. Id. at 1301.
91. Id. at 1299 (quoting *Doe v. Bolton*, 410 U.S. 179, 213 (1973) (Douglas, J., concurring)).
92. Id.
access to potentially lifesaving post-Phase I experimental drugs.\textsuperscript{94} In November 2006, the court decided to rehear the case en banc,\textsuperscript{95} and in August 2007, the en banc court reversed the panel's decision.\textsuperscript{96} Abigail Alliance filed a petition with the Supreme Court in September 2007 requesting that the Court review and overturn the D.C. Circuit's en banc ruling. With its denial of the petition, however, the Court allowed the en banc ruling to stand.

The Abigail Alliance, the named plaintiff in \textit{Abigail Alliance v. Von Eschenbach}, is a nonprofit organization founded in 2001 by Frank Burroughs.\textsuperscript{97} The group is named for Mr. Burroughs's daughter, Abigail, an honors student at the University of Virginia. At age nineteen, doctors diagnosed Abigail with head and neck cancer. She underwent conventional chemotherapy and radiation treatments for the next eighteen months. In March 2001, Abigail ran out of FDA-approved treatment options, but her oncologist advised her that the experimental cancer drugs Iressa and Erbitux could save her life. Unfortunately, Abigail was unable to qualify for the limited clinical trials of either drug. Without access to the experimental treatments, Abigail died on June 9, 2001, at the age of twenty-one.

The Abigail Alliance filed a citizen petition with the FDA, proposing that the Agency allow earlier access to experimental drugs.\textsuperscript{98} When the FDA rejected the Alliance's proposal, the Alliance, together with the Washington Legal Foundation, filed suit against the FDA Commissioner and the Secretary of the Department of Health and Human Services.\textsuperscript{99} The plaintiffs sought to enjoin enforcement of the FDA policy barring the sale of post-Phase I experimental drugs to terminally ill patients who, like Abigail, cannot qualify for clinical trials.\textsuperscript{100} Specifically, the Alliance claimed that the FDA regulation preventing access to experimental drugs where there is insufficient evidence of effectiveness or an unreasonable risk of injury interferes with a fundamental liberty interest to access experimental drugs and

\textsuperscript{95} 469 F.3d 129 (D.C. Cir. 2006), vacating 445 F.3d 695 (D.C. Cir. 2006).
\textsuperscript{97} For relevant facts regarding the Abigail Alliance referenced in this paragraph, see \textit{Abigail Alliance} Complaint, \textit{supra} note 6, at 5.
\textsuperscript{98} Abigail Alliance, 495 F.3d at 699.
\textsuperscript{99} Id. at 700.
therefore must be subject to strict scrutiny. The district court dismissed the plaintiffs' complaint for failure to state a claim. However, applying the test for addressing substantive due process claims set forth by the Supreme Court in Washington v. Glucksberg, a divided three-judge panel of the D.C. Circuit recognized the due process right claimed by the plaintiffs and remanded the case to the district court to determine whether the FDA's policy "[was] narrowly tailored to serve a compelling [governmental] interest."

The D.C. Circuit panel relied on the Due Process Clause of the Fifth Amendment to the Constitution, which provides that "[n]o person shall be . . . deprived of life, liberty, or property, without due process of law." The clause prevents governmental interference with certain fundamental rights and liberty interests. In Washington v. Glucksberg, where it addressed whether the right to assistance in committing suicide is a fundamental right protected by the Due Process Clause, the Supreme Court enumerated three guideposts for the courts in pronouncing an unenumerated due process right. First, a court must provide a "careful description of the fundamental liberty interest." Second, a court must ask whether the right asserted is "deeply rooted in this Nation's history and tradition." Finally, a court must find the right "'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if [it] were sacrificed.'"

According to Judges Ginsburg and Rogers on the D.C. Circuit panel, Abigail Alliance fulfilled the first requirement of the Glucksberg test. The plaintiffs delineated the right to be recognized by the court in Count II of the complaint: willing and mentally competent terminally ill patients with no other treatment options have a due process right
not to be prohibited from accessing experimental drugs that have completed Phase I review.\textsuperscript{110} Alternatively stated, the FDA's policy prohibiting the sale of experimental drugs to these patients violated their due process right of access. The panel found that this description met even the narrowest interpretation of the \textit{Glucksberg} "careful description" requirement.\textsuperscript{111}

According to the panel, this right to access experimental drugs, analogous to the right of self-preservation, is "deeply rooted" in the "history and tradition" of the United States.\textsuperscript{112} The right to control one's body, including the right to self-defense and the right to self-preservation, has "deep roots in the common law." The principle of necessity permits an individual to take measures not ordinarily justified when faced with death, even if these measures interfere with the rights of others. Furthermore, common law prohibits preventing a third person from attempting to save the life of another.\textsuperscript{113} In contrast to these historic common law principles, the panel noted that drug regulation in the United States is relatively new. Not until 1906 did the FDA's precursor begin to regulate drugs with the passage of the Pure Food and Drugs Act. Not until 1962 did Congress mandate evidence of both the safety and effectiveness of new drugs. Thus, for most of the country's history, patients could obtain access to new and experimental drugs, consistent with the right of self-preservation, with little government interference.

Finally, the panel found that the Supreme Court implicitly acknowledged the right to access experimental drugs in \textit{Cruzan v. Director, Missouri Department of Health}.\textsuperscript{114} In \textit{Cruzan}, the Court assumed that an individual has a liberty interest in refusing life-sustaining medical treatment.\textsuperscript{115} The "logical corollary" to that right, according to the panel, "is that an individual must also be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life."\textsuperscript{116} Essentially, the panel argued that a liberty interest in choosing death by refusing treatment is akin to the right to choose a fighting chance at prolonged life.

\begin{itemize}
\item \textsuperscript{110} Abigail Alliance Complaint, \textit{supra} note 6, at 32.
\item \textsuperscript{111} Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470, 478 (D.C. Cir. 2006).
\item \textsuperscript{112} This paragraph cites \textit{id.} at 480-86.
\item \textsuperscript{113} \textit{Id.} (quoting \textit{RESTATEMENT (FIRST) OF TORTS} § 326 (1934)).
\item \textsuperscript{114} 497 U.S. 261 (1990).
\item \textsuperscript{115} \textit{Id.} at 279.
\item \textsuperscript{116} Abigail Alliance, 445 F.3d at 484.
\end{itemize}
Only Judge Griffith dissented. Besides taking issue with the majority's application of the *Glucksberg* test, Judge Griffith noted his concern with a number of constitutional issues that the newfound right to access experimental drugs would raise:

If a terminally ill patient has such a right, are patients with serious medical conditions entitled to the benefit of the same logic and corresponding access? If an indigent cannot afford potentially life-saving treatment, would the Constitution mandate access to such care under the right recognized by the majority? Can a patient access any drug (i.e., marijuana for medicinal purposes) if she believes, in consultation with a physician, it is potentially life-saving? Would the majority's right guarantee access to federally-funded stem cell research and treatment? Perhaps most significantly, what potential must a treatment have in order for the Constitution to mandate access?117

Arguably, the majority's opinion answers some of Judge Griffith's concerns. For example, the majority states that the right of access claimed by the Abigail Alliance "does not involve treatment by the government or a government subsidy."118 Rather, its claim was of a negative right "to be free of FDA imposition."119 However, the remainder of the en banc court of appeals agreed with Judge Griffith, reversing the panel's decision.120 Only Judges Ginsburg and Rogers, who originally had found for the plaintiffs on the panel, dissented.121

Also applying the *Glucksberg* framework, the en banc court first questioned whether the constitutional right proposed by the Alliance could satisfy the *Glucksberg* "careful description" requirement.122 The Alliance claimed that the FDA's current policy prohibiting the sale of experimental drugs violated due process rights of mentally competent terminally ill patients with no other treatment options, and that such patients had a right to access experimental drugs after they had completed the first phase of clinical testing for safety.123 Thus, the specific right proposed by the Alliance depended on a regulatory determination that a drug was safe for testing after completing Phase I trials. The en banc court claimed that it was unlikely that "a constitutional right [could] be defined by an administrative regulation that is subject to change."124 Even assuming _arguendo_ that the proposed right would satisfy the first *Glucksberg*

117. Id. at 499 (Griffith, J., dissenting) (internal citations omitted).
118. Id. at 484 (majority opinion).
119. Id.
121. Id. (Rogers, J., dissenting).
122. Id. at 702 n.6 (majority opinion).
123. Id. at 703.
124. Id. at 702 n.6.
requirement, the en banc court determined that the proposed right failed the second *Glucksberg* requirement—a right of access to experimental drugs is not "deeply rooted in our Nation's history and traditions." The court cited the origin of American drug regulation in the colonial period. In the end, the court determined that the debate among the Alliance, the FDA, the scientific and medical communities, and the public should continue through the political process.

**C. Abigail Alliance's Potential Arguments on Appeal**

If the Supreme Court had granted cert in this case, Abigail Alliance may have grounded its appeal in two arguments. An argument not addressed by either the panel or the en banc court relies on the "right to die with dignity" addressed in *Glucksberg* itself. Although the *Glucksberg* Court did not find a New York law prohibiting assisted suicide to violate a fundamental liberty interest protected by the Due Process Clause, several Justices suggested that their opinion might differ if the law at issue had prohibited "doctors from providing patients with drugs sufficient to control pain despite the risk that those drugs themselves will kill." Justice Breyer articulated the "right to die with dignity," which included the right to palliative care that may hasten death. Although the right articulated by Justice Breyer only addressed potentially lethal drugs for controlling pain, arguably this right could include the right to access potentially lifesaving experimental drugs despite the fact that they may prove lethal. Dying with dignity should allow a person to die knowing that he or she has exhausted all possible medical alternatives.

The plaintiffs' second potential argument could be styled as the right to medical self-defense. Both the D.C. Circuit panel and the en banc court addressed the issue of self-defense in response to the argument raised by the Alliance. The en banc court noted that a

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125. *Id.* at 711.
126. *Id.* at 713.
127. *Washington v. Glucksberg*, 521 U.S. 702, 791 (1997) (Breyer, J., concurring); see also *id.* at 737-38 (O'Connor, J., concurring) ("[T]here is no need to address the question whether suffering patients have a constitutionally cognizable interest in obtaining relief from the suffering that they may experience in the last days of their lives. There is no dispute that dying patients in Washington and New York can obtain palliative care, even when doing so would hasten their deaths.").
128. *Id.* at 790 (Breyer, J., concurring).
woman's right to abort a fetus at any stage of a pregnancy, if doing so is necessary to preserve her life or health, may be viewed as a traditional claim of a right to self-defense, rather than a right to privacy.\textsuperscript{130} The en banc court then deemed the Alliance's argument that the right of access to experimental drugs analogous to a right of medical self-defense—both cases involve an individual taking what otherwise may be impermissible measures in an attempt to save her life.\textsuperscript{131} However, the en banc court responded that this analogy fails "because this case is not about using reasonable force to defend oneself..."\textsuperscript{132} The en banc court's response succeeded only in restating the question.

Legal scholar Eugene Volokh argues that there is a fundamental right to self-defense, and that the right to medical self-defense is included in that right.\textsuperscript{133} The right to lethal self-defense long has been recognized by common law and by statute. In Montana v. Egelhoff, a plurality of the Supreme Court suggested that a defendant may have a fundamental right to present evidence of self-defense in a criminal case.\textsuperscript{134} In Roe v. Wade, and later in Planned Parenthood v. Casey, the Court found that a woman had a right to medical self-defense in the context of a late-term abortion necessary to preserve her life or health.\textsuperscript{135} Volokh argues: "The Supreme Court has so far recognized the medical self-defense right only in abortion cases. Yet the right can't logically be limited to situations in which the defensive procedure is abortion and rejected when a woman needs to defend herself using experimental drugs..."\textsuperscript{136}

Even if the Supreme Court were to acknowledge a fundamental right for the terminally ill to access drugs in the future—whether through a right to die with dignity or through a right to medical self-defense—the Court still could deem the FDA's policy constitutional if it found the policy narrowly tailored to serve a compelling governmental interest. Although the Supreme Court never has addressed whether the FDA's clinical trial process is narrowly tailored

\textsuperscript{130} Abigail Alliance, 495 F.3d at 709. \\
\textsuperscript{131} Id. \\
\textsuperscript{132} Id. \\
\textsuperscript{133} Volokh, supra note 129, at 1817-32. \\
\textsuperscript{134} 518 U.S. 37, 55-56 (1996). \\
\textsuperscript{135} Planned Parenthood v. Casey, 505 U.S. 833, 879 (1992); Roe v. Wade, 410 U.S. 113, 163-64 (1973). The Supreme Court did not articulate the right it identified in either case as a right to medical self-defense. Both Eugene Volokh and Abigail Alliance, however, claim that the right recognized by the Court is, essentially, just that. Although denying that the right to medical self-defense exists in the context of access to experimental drugs, the D.C. Circuit en banc did seem to accept this characterization of Roe and Casey. Abigail Alliance, 495 F.3d at 709. \\
\textsuperscript{136} Volokh, supra note 129, at 1826.
to achieve the governmental interest in approving safe and effective drugs, the Court's recent abortion decision may shed light on its likely opinion. In Gonzales v. Carhart, facing the medical community's uncertainty as to whether a particular "partial-birth" abortion procedure is ever medically necessary, the Court upheld a congressional ban on the procedure. The Court found that the ban did not place an "undue burden" on a woman's right to choose to terminate her pregnancy—even when she and her doctor concluded the procedure was medically necessary in her case. Although the "undue burden" standard is less stringent than the strict scrutiny analysis that would be applied to a fundamental right to access experimental drugs, the Alliance should be concerned that the Court upheld a policy stymieing the medical choice made by an individual in conjunction with her doctor.

D. FDA's Potential Counterargument on Appeal

Had the Supreme Court heard this case, it may have strengthened the FDA's counterargument that the Alliance's claim should be aired through the political process, rather than in court. The Alliance's position treads close to the right to access medical marijuana that the Supreme Court recently denied in Gonzales v. Raich. Furthermore, the en banc court's warning that the balance between the risks and benefits of experimental drugs is best left to the legislative and executive branches echoes the Raich's language. In Raich, the Court suggested that the litigants take their concerns to "the democratic process, in which the voices of voters allied with these respondents may one day be heard in the halls of Congress." More significantly, the en banc court and the Raich opinions are reminiscent of the Supreme Court's suggestion in Rutherford, almost three decades prior: "[w]hether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference." If Abigail Alliance v. Von Eschenbach had come before the Supreme Court, it seems likely that the Court would have continued to follow this line of reasoning, leaving the plaintiffs to take

138. Id.
139. 545 U.S. 1, 9 (2005).
140. Abigail Alliance, 495 F.3d at 713 ("Our Nation's history and traditions have consistently demonstrated that the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology . . . .").
141. 545 U.S. at 33.
their concerns to the FDA and Congress rather than to seek assistance from the Court and the Constitution.

Perhaps such a question should be addressed through the political process, rather than through the judicial system. If the FDA’s decision to interfere with a terminally ill patient’s decision made with his or her doctor raises the questions discussed above, so too does a court’s reversal of that decision. The issue involves science and medicine, which would benefit from congressional hearings or expert administrative research. The issue blurs the line between science and policy, which also suggests a need for democratic resolution.

Alternatively, Professor Jessie Hill argues that while it may be appropriate for courts to defer to legislative determinations of “social fact,” it is “another thing entirely for a legislature to decide when and whether a particular abortion procedure is medically indicated or whether cannabis has any legitimate medical use—or for that matter, to determine the value of pi.”143 For Professor Hill, “judicial deference to legislative fact-finding is particularly inappropriate with respect to medical fact.”144 Professor Hill worries that the legislature—an explicitly political branch—is not competent to make scientific or medical determinations that should be void of politics and value judgments.145 Professor Hill extends this public choice argument to determinations of administrative agencies, such as the FDA’s policy on access to experimental drugs.146

Even assuming arguendo that judicial decisions are void of the politics and value judgments that plague legislative and administrative determinations, the judiciary is still not the appropriate branch to make scientific or medical determinations. If the Supreme Court finds the right to access experimental drugs fundamental, it would constitutionalize the administrative decision that Phase I drugs are safe for human consumption. Such a decision would be reminiscent of the Court’s decision to constitutionalize the arbitrary trimester framework in Roe v. Wade,147 from which it has backed away.148

Scientific and medical knowledge and technology inevitably will change. This evolution conflicts with the Glucksberg “careful

144. Id. at 337.
145. Id. at 334-35.
146. Id. at 344-45.

description" requirement of potential due process rights. Any carefully
described right involving the current state of scientific and medical
knowledge is subject to revision. Viability now occurs before the
arbitrary third-trimester demarcation. Drugs that have completed
Phase I testing have completed only the first stage in an arbitrary
scientific experiment. There is nothing fixed, and certainly nothing
constitutional, about the timing of these scientific and medical
questions.

Instead of making wholesale medical or scientific
determinations, the judiciary is better off deferring to the political
branches on such questions. The en banc court in Abigail Alliance
claimed that

[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. Our Nation's
history and traditions have consistently demonstrated that the democratic branches are
better suited to decide the proper balance between the uncertain risks and benefits of
medical technology, and are entitled to deference in doing so.]

Neither the en banc court nor this Note suggest that Abigail
Alliance's claim to access experimental drugs is invalid, but both
suggest that such a claim may not be addressed fully through judicial
recognition of a new due process right. The right of terminally ill
patients to access experimental drugs may be beyond the judiciary's
competence, and rather than continue on its quest to constitutionalize
the issue, the Alliance should take its valid claim to the political
process.

IV. POTENTIAL MODELS OF FDA REGULATION

Even if the judiciary defers to the FDA and Congress on the
question of access to experimental drugs, the facts that a panel of the
D.C. Circuit ruled in favor of Abigail Alliance and that the Supreme
Court has intimated that drug regulation is ripe for legislative
reconsideration suggest that FDA policy may be in need of some
reform. Several models of FDA regulation have been proposed, from
completely open access to more extensive regulation than the FDA
provides. The Note will briefly discuss three potential models for FDA
regulation of experimental drugs: the Status Quo, Open Access, and
Contractarianism. An analysis of recently proposed FDA regulation on
the issue as well as the ACCESS Act—proposed legislation supported

149. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d
695, 713 (D.C. Cir. 2007) (en banc), aff'd No. 03-1601 (RMU), 2004 WL 3777340 (D.D.C. Aug. 30,
by Abigail Alliance—will follow. The Note will conclude with an endorsement of the ACCESS Act, slightly modified, as a legislative proposal that best synthesizes the beneficial aspects of the potential models and adequately addresses their alleged shortcomings.

A. Status Quo

The most obvious model of regulation is the one currently employed by the FDA, or a variation with more extensive regulation. Advocating greater regulation, some critics have taken issue with the amount of regulatory liberalization already taken by the FDA since the late 1980s, suggesting that the FDA and the public have misplaced their faith in science. These critics argue that increased access to experimental drugs has led to an inability to separate hope of recovery from the reality that most experimental drugs never will prove effective, and many may prove harmful. Citing the Nuremberg Code, they suggest that the consent of experimental subjects must be competent, voluntary, informed, and comprehending. Advocates of greater regulation claim that it is unlikely that terminally ill patients, perhaps incapacitated and certainly frightened for their lives, can provide meaningful consent when drug manufacturers market a new, untested treatment. Under these circumstances, they argue, greater access to experimental drugs is analogous to coercion.

As discussed above, greater regulation would amplify the costs and delays of the American drug approval scheme. Furthermore, the suggestion that terminally ill patients do not have the capacity to give informed consent is an example of what Steven Salbu calls "empathic failure." Empathic failure occurs when legislators and regulators are unable to understand the needs and concerns of the group they attempt to protect—in this case, terminally ill patients.

151. Id. at 774.
152. Id. at 775.
153. Id. at 777.
154. Id. (quoting F.J. Ingelfinger, Informed (But Uneducated) Consent, 287 NEW ENG. J. MED. 465, 466 (1972)).
155. See infra notes 39-46.
157. Id. at 425.
Therefore, any attempt at protection takes "an enormous leap of understanding" that is ultimately impossible.\footnote{158. Id. at 426.}

B. Open Access Model

In response to the various shortcomings of current FDA regulation, the polar opposite model, one of "open access," provides a potential solution.\footnote{159. Id. at 419.} Few advocate such a model of regulation (or lack thereof). Even Abigail Alliance, seen as an extreme promoter of terminally ill patients' rights, does not promote complete deregulation of experimental drugs.\footnote{160. Access, Compassion, Care, and Ethics for Seriously Ill Patients Act, S. 1956, 109th Cong. \S 5 (2005). This bill introduced by Senators Brownback and Inhofe in 2005 is supported by Abigail Alliance. S. 1956; see Abigail Alliance Complaint, supra note 6, at 27.} However, this model would better serve patient autonomy and self-determination.\footnote{161. Salbu, supra note 3, at 420.} Under the model, terminally ill patients would have full access to all experimental treatments, perhaps even regardless of their ability to pay.\footnote{162. Id. at 420.} Where the current regulatory scheme fails to protect the terminally ill adequately, this plan offers a new paradigm.\footnote{163. Id. at 421.}

Although individual rights advocates may favor an open access model, the model fails on several practical and philosophical levels.\footnote{164. Id. at 419.} While completely open access, in which drug manufacturers are required to provide experimental drugs to terminally ill patients regardless of their ability to pay, may promote individual autonomy, it ignores corporate autonomy.\footnote{165. Id. at 421-22.} Drug manufacturers may be unable or unwilling to provide experimental treatment outside of the clinical trial setting.\footnote{166. Id.} Furthermore, if drug manufacturers are unable to recoup the high cost of drug development through charging patients for experimental drugs, much of the incentive to develop new drugs may be lost.

From a philosophical perspective, although proponents of deregulation advocate individual choice, the value of that choice is predicated on the existence of a rational decisionmaker.\footnote{167. Greenberg, supra note 38, at 670; see also Annas, supra note 150 (noting that the decision maker must be able to give voluntary informed consent).} However, rational decisionmaking may elude patients in the absence of
information about the consequences of individual choice. The FDA regulatory scheme, mandating three phases of clinical trials as well as evidence of safety and effectiveness, provides information on which an individual can base a meaningful choice. Thus, access to experimental drugs creates a paradox: the ability to choose loses much of its value in the absence of information forced by current FDA regulatory policy.

Not only may open access undermine informed decisionmaking by terminally ill patients, but it may hinder the production of information for future decisionmaking. Critics of deregulation argue that unfettered access to experimental drugs may make it impossible to conduct scientifically valid clinical trials of new drugs. FDA regulations ordinarily require that new drugs complete three phases of clinical investigation, two of which include controlled clinical trials. Though not mandated by regulation, Phases II and III are completed by performing randomized, placebo-controlled clinical trials in which a control group of patients is randomly assigned to receive a placebo so that the effectiveness of an experimental drug may be measured against no treatment. If terminally ill patients can access experimental drugs outside of the clinical trial setting, they will have little incentive to enter these trials, lengthening the drug approval process. For those patients who do enter trials, the fear of assignment to the placebo group may provide a perverse incentive to break research protocol by taking drugs without supervision.

C. Contractarian Model

In response to criticism of both the paternalistic and open access models of regulation, Steven Salbu has proposed an alternate, contractarian model. Under this model, drug manufacturers could sell experimental drugs to any patient with a physician prescription.

168. Greenberg, supra note 38, at 672.
169. Id.
170. Id. at 673-74.
171. Annas, supra note 150, at 786; Greenberg, supra note 4, at 333.
174. Annas, supra note 150, at 786.
175. Id. at 786-87.
176. The material discussed in the remainder of this Section can be found in Salbu, supra note 3, at 422-33, 439.
Patients would sign a waiver of liability covering both physicians and manufacturers for any adverse reaction to the experimental drug. Salbu argues that this model succeeds in protecting the rights of the individual, preserving corporate autonomy, and promoting the state’s interest in public health.

Unlike the open access model, a contractarian model recognizes individual and corporate autonomy by allowing access to experimental drugs only after the voluntary agreement of both patient and drug company. Unlike the regulatory paternalism of current FDA policy, the contractarian model would treat individuals as ends rather than means by allowing terminally ill patients to contract with any willing drug provider. Under the FDA’s current policy, terminally ill patients may access experimental drugs only through clinical trials, thereby undergoing a risk to themselves for the benefit of scientific discovery. The contractarian model allows individuals’ access to experimental drugs for their own benefit, not only to further science.

In response to concerns that access to experimental drugs would endanger the clinical trial process, Salbu argues that expanded access would enhance scientific research. Although feedback from individual patients may not provide quantitative data, it may produce both research strategies and hypotheses for further study. Salbu also notes that the traditional randomized, double-blind clinical trials are not the only effective method to collect evidence on experimental drugs for statistical analysis. Furthermore, there is not a great likelihood that increased access would prevent drug manufacturers from filling clinical trials. Such concerns overlook the inability of some patients to afford experimental drugs outside the clinical trial setting and the fact that some individual patients, for altruistic or other reasons, may prefer to enter clinical trials over contracting directly with a drug company.

Salbu’s contractarian model faces much of the same criticism as open access. Lacking crucial information, individual choice may be meaningless. Advocates of the clinical trial process are unlikely to accept the arguments that clinical trials are not necessary or not endangered by increased access to experimental drugs. In addition, Salbu’s model raises two further issues addressed below: (1) the ethical and legal status of liability waivers signed by terminally ill patients; and (2) the extent to which drug manufacturers may market experimental drugs to the terminally ill.
On December 14, 2006, three weeks after the D.C. Circuit decided to rehear Abigail Alliance v. Von Eschenbach en banc, the FDA published notice of two proposed rules in the Federal Register. This development suggests that the advocacy of terminally ill patients' rights groups initiated change in the administrative process, regardless of their results in court. The proposed regulations ostensibly interpret the Food and Drug Administration Modernization Act of 1997, which amended the FDCA to include provisions for increased access to experimental drugs. Although deceptively entitled "Expanded Access to Investigational Drugs for Treatment Use," the rule essentially clarifies existing regulations and policies already in effect.

Current FDA policy allows individual access to experimental drugs on a case-by-case basis through an informal Compassionate Use exemption and allows access for broader groups of patients through the Treatment IND exemption, the requirements for which are codified in regulations. However, the FDA has faced criticism for failing to explain its procedures for granting individual patient access through either guidance documents or further regulation. Critics argue that this confusion has led to "disparate access to treatment use," as patients not treated at academic medical centers are less likely to be aware of the possibility of, or have access to, experimental drugs.
The new regulations were proposed in response to these concerns. However, the first proposed rule would do little to increase access to experimental drugs or to allow access to experimental drugs earlier in the approval process. The rule expands the existing regulation of Treatment INDs to cover access for individual patients and intermediate-size patient populations, as well as for the broader groups of patients currently covered by the Treatment IND regulation, rather than increasing or speeding access.

One notable provision does provide that, in determining whether to grant expanded access to an experimental drug, the FDA must determine "that the potential patient benefit justifies the potential risks of the treatment use and that those potential risks are not unreasonable in the context of the disease or condition to be treated." Building on the Subpart E regulations promulgated in 1988, the FDA implied that the risk-benefit analysis that it employs in approving drugs should differ for the terminally ill.

Although nominally a victory for terminally ill patients' rights advocates, the proposed rule will do little to advance their cause. The FDA states that the agency "seeks to increase awareness and knowledge of expanded access programs and the procedures for obtaining investigational drugs," rather than actually to expand or speed access. While some language in the proposal suggests that access to experimental drugs should be granted earlier for seriously and terminally ill patients, the rule still imagines broad FDA discretion. In addition, the FDA notes its concern with ensuring the integrity of the clinical trial process. As the current Treatment IND regulations grant access to drugs in the final stages of clinical testing, expanding these regulations to cover access for individual patients while maintaining the FDA's current clinical trial design likely will not ensure the terminally ill access to experimental drugs as soon as they want or need.

183. Id.
184. Id. at 75,150.
185. Id. at 75,151.
188. E.g., id. at 75,150 ("[The proposed rule] aim[s] to facilitate the availability of investigational new drugs to seriously ill patients when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition.").
189. Id.
B. ACCESS Act

A more radical proposal, backed by Abigail Alliance and introduced in the U.S. Senate in the form of the ACCESS Act in 2005, incorporates many aspects of Salbu's contractarian model within the existing regulatory framework of the FDA. The bill asserts that seriously ill patients have a “right to access” experimental drugs and that the FDA's current case-by-case Compassionate Use exemption must be extended to all seriously ill patients.

The proposed legislation envisions a three-tiered scheme to regulate new drugs. The third tier incorporates the existing approval process for experimental drugs, while the first two tiers expedite the approval process and expand access to experimental drugs during the approval process. The plan's centerpiece is the introduction of Tier 1 approval, through which a drug sponsor may submit a new drug application containing only information from completed Phase I clinical trials and any non-clinical evidence collected on the drug’s safety and effectiveness. FDA access to drugs at this stage of testing requires a seriously or terminally ill patient who has exhausted all FDA-approved treatment options; unsuccessfully sought treatment with an experimental drug (presumably through clinical trials); provided written informed consent; and provided a written waiver of the right to sue the drug manufacturer or sponsor, the prescribing physician, and the institution where the experimental drug is administered. In determining whether to approve a Tier 1 application, the FDA must compare the totality of available information to the seriousness of the condition or disease. Because Tier 1 approval allows a drug manufacturer to market drugs at a much earlier stage than do existing FDA regulations, the ACCESS Act contains a provision limiting promotional materials.

The greatest strength of the ACCESS Act would have materialized if the Supreme Court had ruled in favor of the plaintiffs in Abigail Alliance v. Von Eschenbach. If terminally ill patients had a due process right of access to experimental drugs, the bill would have provided a framework to enforce this right within the existing structure of the FDA. As a practical matter, the proposed legislation attempts to address the potential issues of manufacturer liability,
marketing of experimental drugs, and the maintenance of adequate clinical testing.

Although the ACCESS Act is a relatively recent development, criticism likely will mirror that of the open access and contractarian models. Already, the Society for Clinical Trials ("the Society") opposes the proposed legislation.193 The Society has taken issue with the "repudiation of the scientific method that is embedded in the bill."194 In particular, the Society has concerns with a provision included in the bill, unrelated to the three-tiered approval scheme, which prohibits placebo-only or no-treatment-only control groups in clinical testing.195 This provision rejects the randomized clinical trial, which is broadly accepted by the scientific community as the most reliable method to gauge the safety and effectiveness of new drugs.196 However, this criticism does not undermine the Tier 1 approval process, which would require patients to have sought treatment in clinical trials unsuccessfully before access to an experimental drug outside of the clinical setting would be granted.197

Further criticism of the ACCESS Act has focused on the precarious position in which it would place a terminally ill patient. Critics argue that requiring a patient to sign a waiver of liability in the face of a potentially lifesaving experimental treatment amounts to coercion.198 Citing evidence that only eleven percent of new drugs tested in humans ultimately achieve FDA approval, critics fear that this proposed legislation will permit drug marketing to sick and vulnerable patients.199 Not only will very few of these unapproved drugs be effective, but many also may prove substantially harmful.200 In all, the Society claims that the ACCESS Act is "not in the best interests of the patients."201 However, with modifications, the ACCESS Act could be in the best interests of all interested parties.

193. Colin B. Begg et al., Marketing Drugs Too Early in Testing, 312 SCIENCE 195 (2006);
Soc'y for Clinical Trials Bd. of Dirs., supra note 173, at 154-57.
195. Id. at 155-56.
196. Id.
198. Soc'y for Clinical Trials Bd. of Dirs., supra note 173, at 156.
199. Id. at 155.
200. Begg et al., supra note 193; Soc'y for Clinical Trials Bd. of Dirs., supra note 173, at 155.
201. Soc'y for Clinical Trials Bd. of Dirs., supra note 173, at 155.
VI. SOLUTION: BUILDING ON THE ACCESS ACT

Despite the Society's concerns, the ACCESS Act has the potential to serve the interests of terminally ill patients, as well as the FDA, the public, and the Society itself. The ACCESS Act balances the need to provide safe and effective drugs with the need to provide earlier access to those drugs for the terminally ill. Whether or not the Supreme Court determines that terminally ill patients have a due process right to access experimental drugs, Congress should pass the ACCESS Act, with a few modifications, and the FDA should implement the new regime.

Although the ACCESS Act addresses drug manufacturer liability by requiring patients to provide a written waiver of the right to sue, the issue deserves further consideration. Some critics claim that allowing terminally ill patients the option to access experimental drugs amounts to coercion. A sick, vulnerable, and possibly incapacitated patient lying in a hospital bed does not have the capacity to make a voluntary and informed decision.\(^2\) Requiring this patient to sign away the right to sue in the event of an adverse event caused by an experimental drug only compounds the ethical dilemma. Absent a statutory provision making a waiver of liability binding, under these circumstances, such waiver may be unenforceable at common law.\(^3\)

Absent a statutory provision making a waiver of liability binding, however, expanding access to experimental drugs for terminally ill patients may prove unworkable. The market for experimental drugs is unlikely to become an exceptionally profitable one for drug manufacturers, as the number of terminally ill patients in need of experimental drugs is relatively small, and the number willing and able to choose unproven and expensive new drugs is even smaller. Unable to earn substantial profits and faced with potential

\(^2\) See Annas, supra note 150, at 777 ("Incapacitated and hospitalized because of illness, frightened by strange and impersonal routines, and fearful for his health and perhaps life, [the patient] is far from exercising a free power of choice when the person to whom he anchors all his hopes asks [him to help] ... carry out some very important research ..." (quoting Ingelfinger, supra note 154, at 466)).

\(^3\) 17A Am. Jur. 2d Contracts §§ 284-85 (2004) (stating that a contractual term that relieves a party from liability may be found unenforceable if it is the product of a gross inequality in bargaining power or otherwise in violation of public policy); see also RESTATEMENT (SECOND) OF CONTRACTS § 195(3) (1981) ("A term exempting a seller of a product from his special tort liability for physical harm to a user or consumer is unenforceable on grounds of public policy unless the term is fairly bargained for and is consistent with the policy underlying that liability.").
liability from any adverse reaction, drug manufacturers will have little incentive to make experimental drugs available.

Despite critics' claims of coercion, the law often respects the autonomy of the sick and vulnerable, even those on the brink of death. The *Cruzan* opinion provides the extreme example, suggesting that an individual subsisting on life support has a constitutional right to refuse treatment.\(^{204}\) Respecting a terminally ill patient's choice to sign a contractual waiver of liability easily proceeds from respecting a terminally ill patient's decision to choose death. Evidence of the law's deference to an individual's freedom to contract, even from his or her deathbed, also may be seen in the law of wills.\(^{205}\) In light of these examples, perhaps the common law should enforce a waiver of liability signed by a terminally ill patient. Nevertheless, the ACCESS Act provision requiring a binding waiver of the right to sue conforms to the law generally. Because the provision furthers the aims of the proposed legislation by removing any disincentive to supply experimental drugs, it should be included in any legislation providing increased access to experimental drugs passed by Congress.

The ACCESS Act also briefly addresses the extent to which drug companies may market experimental drugs to the terminally ill.\(^{206}\) Under the proposed legislation, Tier 1 approval would satisfy the approval required by the FDCA before a new drug may enter interstate commerce.\(^{207}\) Ostensibly, without further restriction, Tier 1 approval alone would authorize a drug manufacturer to market its new drug like any other. However, the marketing of experimental drugs to the terminally ill requires further consideration. The Supreme Court noted in *Rutherford*:

> 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

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204. See *Cruzan v. Dir., Mo. Dept of Health*, 497 U.S. 261, 286-87 (1990) ("[W]e do not think the Due Process Clause requires the State to repose judgment on these matters with anyone but the patient herself. . . . [T]he State may choose to defer only to those wishes [of the patient], rather than confide the decision to close family members.").

205. See, e.g., *Green v. Holland*, 657 S.W.2d 572, 575 (Ark. Ct. App. 1983) ("A testatrix's old age, physical incapacity and partial eclipse of the mind will not invalidate a will if she had sufficient capacity to remember the extent and condition of the property and who her beneficiaries are. Complete sanity in a medical sense at all times is not essential to testamentary capacity provided that capacity exists at the time the will is executed, during a lucid interval."); *Bickel v. Louisville Trust Co.*, 197 S.W.2d 444, 446 (Ky. 1946) (noting that wills "are more often than otherwise executed during one's last sickness, and while he is, so to speak, on his deathbed").


207. Id.
made from glycerin and limburger cheese; mineral tablets; and 'Fountain of Youth' mixtures of spices, oil, and suet.\textsuperscript{208}

Critics' claims of coercion resonate in the context of marketing experimental drugs to the terminally ill. A terminally ill patient does not have adequate information to decide which potentially lifesaving treatment to undertake. Without limitation on drug manufacturers' ability to promote newly approved experimental drugs, patients may face a wide variety of marketed treatments among which they cannot differentiate.\textsuperscript{209}

In response to these concerns, the ACCESS Act would restrict the promotional materials authorized for Tier 1-approved drugs. The proposed legislation provides that promotional materials "may be subject to the requirements that" the drug sponsor submit copies of all promotional and advertising materials to the FDA before approval is granted and that all advertising and promotional materials must disclose the limited nature of Tier 1 approval.\textsuperscript{210} However, this conditional provision alone does not do enough to limit marketing of experimental drugs to the terminally ill.

Any promotional restrictions should be mandatory rather than left to the FDA's discretion. In particular, disclosure of the nature of Tier 1 approval is of paramount importance to potential consumers. In light of the minimal burden such disclosure would place on a drug manufacturer, there is no reason such a restriction should not be required. Moreover, the ACCESS Act should limit the parties to whom a drug manufacturer may market its product. Without advice from a physician, an individual patient is unlikely to evaluate the potential success of any drug. Although this reality may be an argument for eliminating all drug advertising, patients' general lack of information, combined with the particular vulnerability of terminally ill patients, suggests that direct marketing to the terminally ill may not only be unhelpful but also potentially harmful. Given these concerns, the marketing of Tier 1-approved experimental drugs should be limited to those who have the ability to evaluate adequately and impassively the likelihood of their success, namely physicians, hospitals, and other medical institutions.

Finally, the ACCESS Act addresses the concern that increased access to experimental drugs would endanger the clinical trial process by refusing access to experimental drugs until a patient has

\textsuperscript{208} United States v. Rutherford, 442 U.S. 554, 558 (1979).
\textsuperscript{209} Begg et al., \textit{supra} note 193.
\textsuperscript{210} S. 1956 § 506 (e) (emphasis added).
"unsuccessfully sought treatment with an experimental drug."  

Presumably, this language would require a terminally ill patient to have sought access to a particular drug through a clinical trial before access to that drug would be granted outside of the clinical setting. This ambiguity may be cured through more precise statutory language or by FDA regulations interpreting the Act, which should implement this requirement. The FDA should promulgate additional regulations prohibiting access to experimental drugs for patients currently enrolled in clinical trials to counteract patient incentive to break research protocol. These safeguards would ensure the integrity of the clinical trial process by prioritizing full participation in clinical trials and preventing sabotage to the results.

Prioritizing the existing clinical trial process raises another issue in the ACCESS Act—the provision prohibiting placebo-only or no-treatment-only control groups in clinical investigation. Supporters of this prohibition claim that the use of placebo-controlled clinical trials on terminally ill patients, in which the control group of patients receives no treatment at all, is both unethical and unnecessary. 

These supporters allege that modern scientific and statistical methods, such as the use of Bayesian statistics, would provide adequate control data without the need for an untreated control group. Evidence for this perspective is seen in the FDA’s use of such methods in testing of medical devices, in which sham surgeries are not performed to provide an untested control group. For example, the FDA uses such methods in testing medical devices—sham surgeries are not performed to provide an untreated control group in the testing of medical devices.

Then again, this provision of the ACCESS Act faces strong opposition from the scientific research establishment. The Society, in particular, argues that the most reliable method to assess the effectiveness of an experimental drug is through randomized clinical trials that include a placebo-only control group. The Society provides several accounts of drugs that appeared promising on

211. Id. § 506 (b)(5)(A).
213. Kianna’s Legacy, supra note 212.
214. Id.; see also Salbu, supra note 3, at 434-39 (discussing some data collection alternatives to randomized, double-blind, placebo-controlled experiments, including non-placebo control experiments, dose response trials, meta-analyses, and field research ).
215. Soc’y for Clinical Trials Bd. of Dir., supra note 173, at 155; see also Annas, supra note 150, at 789-91 (describing randomized clinical trials as the “gold standard” upon which experimental treatments are judged,” and asserting that there is “little dispute that the RCT is the method most likely to produce valid results”).
anecdotal evidence alone, but later proved ineffective, even in comparison to placebo treatment, after scientists performed scientifically valid, randomized, controlled clinical trials.216

Solving the debate over the necessity of placebo control groups in clinical trials of drugs for the terminally ill is beyond the scope of this Note. However, in order to succeed politically, the provision of the ACCESS Act prohibiting placebo-only or no-treatment only groups in clinical trials may need to be removed to increase the likelihood of support in Congress. Without this provision, the ACCESS Act still would provide access to experimental drugs after Phase I testing through the creation of a Tier 1 approval process, consistent with the due process right that Abigail Alliance seeks to have recognized in court. Until scholarship offers a definitive answer on the issue of placebo treatment, terminally ill patients' rights advocates calling for increased access to experimental drugs should focus their efforts on passing the Tier 1 approval process through Congress, leaving the issue of placebo treatment for another day.

Because Abigail Alliance is unlikely to find success through the judicial process, and the recently proposed FDA regulations will prove unavailing, a modified ACCESS Act is the most likely method of achieving the Alliance's goal of increased access to experimental drugs for the terminally ill. As proposed, the ACCESS Act embodies many of the strengths of Salbu's contractarian model. The modifications proposed in this Note address the model's weaknesses. On balance, the modified Act will protect both the FDA's interest in providing safe and effective drugs and the interest of the terminally ill in obtaining access to those drugs at an earlier stage of testing.

VII. CONCLUSION

Throughout the history of drug regulation in the United States, both Congress and the FDA have responded to drug-related health care crises that have called attention to shortcomings in the drug regulatory scheme. While typical government response meant increased or more stringent drug regulation, the AIDS epidemic provided an opportunity for Congress and the FDA to respond with a liberalization of the regulatory framework in an attempt to ensure AIDS patients' access to new and potentially lifesaving drugs. Although the story of Abigail Burroughs may not boast the epic proportions and political significance of the AIDS epidemic, it does

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216. Soc'y for Clinical Trials Bd. of Dirs., supra note 173, at 156.
provide the government with an opportunity to improve its experimental drug policy.

As a brief tour of Supreme Court jurisprudence suggests, the Court is unlikely to overturn the expressed opinions of Congress and the FDA, either through statutory interpretation or through recognition of a new due process right. In this act of restraint, the Court would be recognizing its limitations in the fields of science and medicine. Moreover, courts traditionally defer to Congress and agencies in light of their expertise and accountability. Although it may be intuitive to leave the science to the scientists, there is little dispute that access to drugs, experimental and otherwise, should be subject to some amount of government regulation. The question is which branch or branches of government are most competent to regulate the regulation—the judicial branch or the political branches.

In light of the dynamic nature of science and medicine, the constitutionalization of a regulatory scheme through judicial recognition of new due process rights seems unsuitable. Instead, the political branches, with their capacity for factfinding and adapting policy in the face of new and improved scientific and medical knowledge, are the appropriate branches to control the appropriate amount of regulation of the scientific and medical fields. Although determinations of the political branches necessarily will be imbued with politics and value judgments that admittedly do not belong in questions of science and medicine, there is little evidence to suggest that courts would be free of political bias on these issues. Thus, the Abigail Alliance and other terminally ill patients' rights advocates should focus their attention on the possibility of affecting change through the political rather than the judicial process.

The ACCESS Act is one potential avenue for affecting this change. With a few modifications—strengthening the provisions on experimental drug marketing and eliminating the provision prohibiting placebo-only control groups—the ACCESS Act would address the concerns of all interested parties and would become politically palliative. Regardless whether Congress enacts the ACCESS Act, in its current or suggested form, the changes to experimental drug policy it suggests deserve further examination and support. Even absent a constitutional due process right of access to experimental drugs, the values inherent in the alleged right—autonomy and self-determination—should factor heavily in any regulatory scheme in which individual lives are at stake.

This Note's conclusion—that terminally ill patients' access to experimental drugs, as a question of science and medicine, is best addressed through the political, rather than the judicial, process—has
implications beyond the experimental drug context. The same analysis could be applied to the issues of abortion, medical marijuana, and physician-assisted-suicide, among other questions of science and medicine that the judiciary confronts. Like the right to access experimental drugs, all of these issues have been the focus of due process claims in court. The values of autonomy and self-determination inhere in these cases, and the recognition of a due process right in the Constitution may seem a particularly satisfying result to some. However, this Note's analysis suggests that, as questions of science and medicine, they may be better addressed through the political process, along with Abigail Alliance's claim of increased access to experimental drugs. Relegation of these issues to the political process should not entail the disregard of values inherent in the liberty of due process rights, however. At least in the context of access to experimental drugs, the best interests of all parties are served by allowing for greater access and thus greater liberty.

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