Paternalism vs. Autonomy: Steps Toward Resolving the Conflict Over Experimental Drug Access Between the Food and Drug Administration and the Terminally Ill

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Robert Kudlack, a twenty-five-year old supervisor for the United States Department of Agriculture, was diagnosed with Ewing’s sarcoma, a rare disease causing cancerous tumors throughout his body.1 Repeated attempts to cure the disease with traditional treatments failed; Kudlack’s tumors, instead of declining in number, spread from his spine to his lungs and kidneys, reaching as far as his shoulder blades and thigh bones.2 Kudlack’s doctor believed that Yondelis, an experimental drug that attaches to a tumor and decelerates its growth, could help, and he attempted to persuade Johnson & Johnson to allow his patient to use it under a “special access program.”3 Johnson & Johnson, however, refused and the doctor could not obtain the drug because it had not yet been approved for use by the Food and Drug Administration (“FDA”).4 While the doctor points to evidence that the conditions of similar patients in prior trials were improved through use of the drug, the agency maintains that data is not available to

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2 Id. Kudlack underwent traditional treatments, including radiation, chemotherapy, and surgery.
3 Id.
4 See Kerr, supra note 1. The drug contains an artificial copy of ET743, a composite found in an ocean animal, the sea squirt. Id.
prove that the new compound is safe and effective.\(^5\)

Kudlack’s story mirrors the situation of numerous patients around the country and emphasizes the ongoing struggle between the FDA’s regulatory role in protecting the public and the terminally ill’s need for access to experimental drugs. This Note outlines the competing ends of this debate—the FDA supporters’ claim that nothing short of a comprehensive drug experimentation process can satisfy the agency’s societal role, while advocates for the terminally ill assert that open access to experimental drugs is the only way to protect their basic human rights. Part I of this Note describes the origins of the FDA’s drug regulations and the early stages of the terminally ill’s campaign for increased access. Part II discusses the FDA’s recent attempts to increase experimental drug access and the terminally ill advocates’ remaining dissatisfaction with such measures; a clash which has culminated in a controversial federal circuit decision holding that competent, terminally ill adult patients have a fundamental right to self-preservation. Part III analyzes the benefits and weaknesses for both sides and discusses future suggestions for finding a balance between the two competing interests.

I. OVERVIEW OF EARLY FDA DRUG REGULATION AND TERMINALLY ILL PATIENTS’ COMPETING LEGAL CRUSADE

A. Origins of Drug Regulation in the United States

Drug regulation was first introduced in the United States in 1906 in the form of the Pure Food and Drug Act, a Congressional response primarily compelled by public and political pressures to cure prevalent food and drug impurities.\(^6\) The act was limited in scope, focused mainly on the prevention of adulterated and mislabeled drugs.\(^7\)

\(^{5}\) See Kerr, supra note 1.


\(^{7}\) See Perrin, supra note 6, at 109 (noting statute’s requirement that drug manufacturers provide
Criticism concerning the legislation's lack of authority to adequately monitor drug safety followed, culminating in the liquid-sulfa drug disaster of 1938. This catastrophe served as the major catalyst to the creation of the federal Food, Drug and Cosmetic Act of 1938 ("FDCA"), which gave the FDA authority to examine the safety of drugs before the public could receive them. One important new provision of the FDCA was the new “accurate drug content labels” based on evaluations of product safety and quality, rendering manufacturers liable for any failures to adhere to such provisions; Relihan, supra note 6, at 234 (noting that manufacturer safety testing was not required under Pure Food and Drug Act); Batterman, supra note 6, at 196 (noting act's main function was to prevent adulterated and mislabeled drugs). The Act defined adulterated drugs as those departing from national standards or falling below marketed potency or quality, and misbranded drugs as those “sold under a false name,” “sold in the package of a different drug,” or “failing] to identify and quantify the existence or specifically enumerated addicting substances.” Batterman, supra note 6, at 196. See also Kathleen M. O'Connor, Comment, OMB Involvement in FD-A Drug Regulations: Regulating the Regulators, 38 CATH. U. L. REV. 175, 179 (1988) (noting FDA could only take action against manufacturers once nonconforming drug was made available to consumers).

See Melissa Marie Bean, Comment and Note, Fatal Flaws in the Food and Drug Administration's Drug-Approval Formula, 2003 UTAH L. REV. 881, 882-83 (2003) (noting more than 100 children were killed after consuming toxic substance diethylene glycol); Perrin, supra note 6, at 109-10 (emphasizing Pure Food and Drug Act's failure to protect public from dangerous and fruitless drugs including the fact that the sole remedy against a drug manufacturer was a $26,100 fine); Salbu, supra note 6, at 407 (indicating poisonous solvent was distributed because Pure Food and Drug Act failed to test it for safety and identifying the shortcomings of the act as a failure to forbid misleading statements on drug labels aside from ingredients, a lack of requisite drug approval by agency, and a failure to provide liability against manufacturers for injury or death caused by harmful products); Batterman, supra note 6, at 197 (noting statute prevented false advertisement but was ineffective in protecting consumer sales); Barry S. Roberts & Sara M. Biggers, Regulatory Update: The FDA Speeds Up Hope for the Desperately Ill and Dying, 27 AM. BUS. L.J. 403, 410 (1989) (indicating act's fatal flaw was its inability to regulate products before they entered commerce). See also U.S. v. Johnson, 221 U.S. 488, 498 (1911) (holding mislabeled drugs were not illegal in instances where manufacturer could show he or she was unaware of defect under Pure Food and Drug Act). But see Richard J. Nelson, Note and Comment, Regulation of Investigational New Drugs: 'Giant Step for the Sick and Dying', 77 GEO. L.J. 463, 468 (1988) (indicating while provisions were generally ineffective, there was noticeable action under act, including around 70% rejection of imported drug requests and 841 manufacturer prosecutions).

drug application ("NDA"), requiring each manufacturer to submit various materials including product contents, intended uses, safety guarantees, and production method to the Secretary of Agriculture before distributing the drug to consumers. Under the original statute, product approval was automatic if the FDA failed to reject the NDA within sixty days of the filing date. While the FDCA attempted to regulate the safety of new drugs entering commerce, it conspicuously failed to provide any consumer protection from ineffective products.

The present form of drug regulation in the United States originated as a response to the thalidomide disaster of the 1960s, yet another medical tragedy that led to national disapproval and forced the FDA to increase its centralized regulatory powers. The Kefauver-Harris Amendments to the Food, Drug and Cosmetics Act ("1962 Amendments") sought to address public concern by requiring manufacturers to provide

10 21 U.S.C. § 355(b) (1987 & Supp. 1989). Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug. Id. See Batterman, supra note 6, at 198, n. 44 (summarizing statute requirements and briefly discussing regulatory evolution).

11 See Federal Food, Drug, and Cosmetic Act, § 505(b)(1), 52 Stat. 1040, 1052 (1938) (amended by Drug Amendments of 1962, Pub. L. No. 87-781, § 104(b), 76 Stat. 780, 784 (1962) (codified at 21 U.S.C. § 355(e) (1982 & Supp. 1993); Relihan, supra note 6, at 234-35 (discussing automatic approval process). See also Nelson, supra note 8, at 198, n. 46 (identifying lack of sufficient evidence of product safety as valid reason for FDA to reject drug during 60 day period and indicating postponement of action for three times that amount of time was justifiable if determined more time was needed and manufacturer was duly notified of extension).

12 See Batterman, supra note 6, at 199 (identifying major failure of 1938 Act was lack of efficiency regulation, lending to danger of vulnerable terminally ill consumers choosing new ineffective drugs); Nelson, supra note 8, at 469 (noting FDCA did not command proof of new product's utility).

13 See Greenberg, supra note 9, at 303 (indicating while United States' refusal to approve thalidomide avoided catastrophe, public response to effects in Europe led to further reform); Nelson, supra note 8, at 469 (describing toxin's effects as including births of nearly 8,000 deformed babies to mothers who had ingested drug during pregnancy). See also Bean, supra note 8, at 883 (opining FDA researcher Dr. Francis Kelsey's refusal to distribute thalidomide amidst other countries' approval of drug helped solidify FDA's role as "model of a safe and effective regulatory agency"); Michael D. Greenberg, Information, Paternalism, and Rational Decision-Making: The Balance of FD.1 New Drug Approval, 13 ALB. L.J. SCI & TECH. 663, 665 (2003) (noting generally FDA regime was put in place to prevent further deaths from unsafe drugs).
“substantial evidence” that the new drug was both safe and effective for its intended use at its recommended dosage. Under these amendments, a manufacturer must first test the new drug at length using both laboratory and animal studies for initial safety results before filing an investigational new drug application (“INDA”). If the application is not rejected by the FDA at this stage, the product may then be used in human testing.

A key regulatory modification of the FDA’s drug approval process was the addition of three clinical experimentation phases, which must be satisfied for new products to become publicly accessible. Under Phase I, a small group of subjects are tested with the new drug for general safety precautions. Upon passing the first stage, the new drug enters Phase II, where patients affected with the illness that the product


15 21 C.F.R. § 312.23 (1995); Elizabeth Rutherford, The FDA and “Privatization”—The Drug Approval Process, 50 FOOD & DRUG L.J. 203, 212 (1995) (indicating process can take around three and a half years to complete).

16 21 C.F.R. § 312.41 (1995). See Rutherford, supra note 15, at 213, n. 85 (noting that under 21 C.F.R. § 312.23, “[f]or its INDA decisions, the FDA considers the protection of the human research subject, the adequacy of animal studies already completed, the scientific merits of the research plan, and the qualification of the investigator”).


18 21 C.F.R. § 312.21 (1988); Salbu, supra note 6, at 409 (discussing Phase I testing). See Greenberg, supra note 9, at 304 (identifying first experimental phase’s primary purpose as determining blatant harmful effects on tested subjects); Relihan, supra note 6, at 236 (noting introductory testing process involves “studies to determine the safe dosage level of the drug, tolerance to the drug, how the drug is best administered, and how the drug is eliminated from the body”); Rutherford, supra note 15, at 213 (describing first stage of testing as involving 20 to 80 subjects and lasting for around one year).
purports to counteract are tested primarily for the drug’s efficacy in addition to further safety precautions. Finally, under Phase III, more detailed safety and efficacy information is acquired through the testing of an even larger sample. Once the final phase is completed, the manufacturer may file the NDA, and the FDA will review the application and its accompanying data to affirmatively determine whether the drug should be approved. While the 1962 Amendments served as an early response to the public’s demand for safe and effective products, the modifications have also been widely criticized for their endorsement of a tedious and expensive drug approval process.

B. Beginning Stages of Terminally Ill Patients’ Legal Battle

Terminally ill patients have historically sought judicial relief in various spheres of medical regulation based primarily on their claimed right to decision-making autonomy regarding their personal health situations. One pivotal Supreme Court decision in 1979 held that the FDCA provisions under the 1962 Amendments applied to healthy and terminally ill patients alike. The court noted that while a statutory

19 21 C.F.R. § 312.21(a) (1988); Salbu, supra note 6, at 409 (detailing application of Phase II testing). See Rutherford, supra note 15, at 213 (indicating second phase involves few hundred patients who are tested with new drug for 2 years); O’Connor, supra note 8, at 183 (noting stage’s emphasis on testing drug effectiveness).

20 21 C.F.R § 312.21(b) (1988); Salbu, supra note 6, at 409 (discussing effects of Phase III testing). See Greenberg, supra note 9, at 305 (indicating following completion of third phase, new drug is determined to be “reasonably safe and effective in treating the target condition”); Rutherford, supra note 15, at 213 (indicating last testing stage involves on average 1,000 to 3,000 subjects and can last for three years). During all three testing phases, the FDA retains the authority to end experimentation upon receiving evidence the new drug is dangerous or ineffective. Reihan, supra note 6, at 237.

21 Rutherford, supra note 15, at 212-13 (noting while statute requires FDA to conclude its review within six months, agency actually averages 30 months per application). This affirmative approval process replaced the provision under the 1938 FDCA granting automatic approval to all new drugs not rejected by the FDA within 60 days. See supra note 14 and accompanying text (discussing original provision). Accounting for all of these safeguards added to the 1962 Amendments triggers a drug approval process that often lasts for six to seven years. Reihan, supra note 6, at 237.

22 See infra notes 23-29 and accompanying text (describing criticisms of FDA’s new drug regulations).

23 See infra note 26 and accompanying text (discussing most prominent legal decisions concerning terminally ill patients’ autonomy interest).

24 U.S. v. Rutherford, 442 U.S. 544, 559 (1979). The suit was brought by terminally ill cancer patients seeking access to Laetrile, a new drug that had not been found to be safe and effective under the FDCA’s drug approval process. Id. at 546. The United States Court of Appeals for the 10th Circuit had previously held that the statute’s standards had “no reasonable application to terminally ill patients.” Rutherford v. U.S., 582 F.2d 1234, 1236 (10th Cir. 1978). See also Michael
interpretation that excluded terminally ill patients was not within the judiciary’s power, such an exemption could be created by the legislation. While terminally ill patients gained legal victories in other areas of medical treatment, the courts remained steadfast through the late 1990’s in their refusal to recognize a fundamental right for terminally ill patients to receive unapproved drugs.

Amidst the terminally ill patients’ legal battle for recognized autonomy, widespread criticism of the FDA drug regulations arose, particularly following the restrictive 1962 Amendments. One such critique was the significant delay in consumer access to potentially beneficial drugs as a result of the long and tedious approval process. The so-called “drug lag,” a consequence of the statute’s strict efficacy standard, forced United States consumers to wait longer than consumers in other countries for access to new products. A second criticism of the FDA regulations


25 Rutherford, 442 U.S. at 559.

26 The victories involved terminally ill patients’ liberty rights under the 14th Amendment’s Due Process Clause to choose to consume death hastening medications and to refuse life-saving medication. See Compassion in Dying v. State of Wash., 79 F.3d 790, 793-94 (9th Cir. 1996) (holding persons have constitutional right to decide their “time and manner of death” and finding Washington statute preventing doctors from prescribing medications to accelerate death of competent, terminally ill adults unconstitutional); Cruzan v. Dir., Mo. Dep’t of Health, 497 U.S. 261, 278 (1990) (holding competent adult has constitutional right to decline medical treatment). See Cowan v. U.S., 5 F.Supp.2d 1235, 1242 (N.D.Okla. 1998) (denying terminally ill AIDS patient from receiving unapproved goat neutralizing antibody drug and holding his sickness did not confer constitutional right to receive medication not found safe and effective by FDA); Smith v. Shalala, 954 F.Supp 1, 4 (D.D.C. 1996) (holding terminally ill cancer patient had no fundamental right to receive non-approved experimental anticancer agent and emphasizing his refusal to receive approved chemotherapy).

27 See infra notes 35-42 and accompanying text (describing critiques of drug regulations).

28 See Roberts & Biggers, supra note 8, at 413 (identifying FDA’s inappropriate use of efficacy standard as major source of delay); O’Connor, supra note 7, at 185 (noting before 1962 Amendments, approval process was only two and a half years as opposed to nearly eleven years following modifications).

29 Roberts & Biggers, supra note 8, at 413.

The United States General Accounting Office (GAO) concluded that thirteen of the fourteen drugs determined to be “important” drugs by the FDA between 1975 and 1978 “became available in other industrialized nations two months to fourteen years before the United States approved them, with the average delay being four years.” Id. (quoting Barry S. Roberts & David Z. Bodenheimer, The Drug Amendments of 1962: The Anatomy of a Regulatory Failure, 1982 ARIZ. ST. L.J. 581, 587). See Perrin, supra note 6, at 115
concerned the increased costs stemming from the extensive testing requirements, resulting in reduced motivation by manufacturers to produce new drugs. It was also evidenced that despite the strict standards the regulations purported to enforce, the requisite work still failed to adequately limit ineffective drugs from entering commerce.

Criticisms surrounding the 1962 Amendments were further exacerbated by the AIDS epidemic during the 1980s. The controversy between AIDS patients and the FDA began due to a lack of approved drugs to counteract the disease, as many of those affected by the illness resorted to self-treatment in the form of untested products with unknown safety risks and effectiveness. This situation led to the formation of an influential activist coalition, whose primary goal was to improve the present government drug approval process to better suit the needs of the AIDS community. This alliance helped stimulate sufficient national outcry to force the FDA to reexamine its system in light of terminally ill patients and extreme public concern.

(indicating after costs went up amount of drugs introduced in United States dropped significantly).

30 Greenberg, supra note 9, at 298 (indicating criticism that regulations discouraged creation of new products at time of advancement and patient need); Perrin, supra note 6, at 117 (noting effects of lessened profits under regulations on new drug creation, particularly for smaller manufacturers); Roberts & Biggers, supra note 8, at 413-14 (identifying studies showing harmful effects increased costs under 1962 Amendments had on advancements in medical treatment).

31 Roberts & Biggers, supra note 8, at 414 (indicating overall efficacy of new drugs failed to improve following 1962 Amendments).

32 See infra notes 33-34 and accompanying text (describing AIDS activists' role in battle between FDA and terminally ill). See also Greenberg, supra note 9, at 308-11 (discussing evolution of AIDS epidemic generally).

33 Greenberg, supra note 9, at 310-11 (noting desperate AIDS patients attempted to create their own medications in addition to use of black market to purchase commercially unapproved drugs). AIDS sufferers also exposed themselves to additional safety risks by importing drugs from other countries and developing "guerilla clinics," centers which distribute treatment they create themselves. Batterman, supra note 6, at 207-08.

34 Greenberg, supra note 9, at 311-12 (describing formation and subsequent activities of several prominent organizations, Gay Men's Health Crisis, People With AIDS Health Group, and AIDS Coalition to Unleash Power, including their common objective of addressing dire situation of new drug regulation for AIDS patients). The AIDS activists created an even stronger political front by joining forces with pharmaceutical companies, another group frustrated with the new drug requirements, and together they pressured the FDA for regulatory change. Perrin, supra note 6, at 122.

35 See infra notes 43-63 and accompanying text (describing different exceptions and modifications the FDA added to 1962 Amendments). See also Greenberg, supra note 9, at 312 (indicating "[t]he political pressure and public awareness fostered by AIDS activists were ultimately focal to later efforts to reform the FDA drug approval process"); O'Connor, supra note 7, at 188 (noting force of AIDS epidemic in coercing FDA to revisit its experimental drug regulations).
II. CONTINUING TREND TOWARDS EXPANDING ACCESS TO NEW DRUGS FOR TERMINALLY ILL PATIENTS

A. FDA's Latest Response to Public Concern: Expanded Action Initiatives

Since its formation, the FDA has served as the United States government's major regulatory authority with the challenge of "balanc[ing] societal goals against the exercise of individual freedom" by adhering to five fundamental goals. The agency's first objective is to regulate incoming products to most effectively minimize potential public harm. Next, the FDA has the paradoxical aim of expanding individual consumer choice; the agency admits that public protection must be achieved before this goal is considered. The third goal of the FDA is to take consumer suggestions and proposals into account while modifying its regulations. The agency also strives to use reliable and coherent standards that the public can follow. Finally, the FDA aims to provide quick resolutions to all matters brought to its attention. Public concern over issues of decision-making autonomy, particularly criticism stemming from the AIDS epidemic, forced the FDA to make numerous changes to its drug regulations, while trying to retain its overall objectives; the most prominent resulting changes are discussed below.

1. Compassionate Use IND

One of the first changes the FDA implemented was the "compassionate use IND," an exemption to the general provision preventing access to unapproved drugs.

36 Perrin, supra note 6, at 113 (discussing FDA's primary objectives).
37 Perrin, supra note 6, at 114 (indicating this goal is best realized by evaluating risk levels to determine suitable standard to follow). See also supra notes 6-14 and accompanying text (indicating importance of public protection through government's immediate response to medical tragedies).
38 Perrin, supra note 6, at 114 (noting FDA's goal of "maximize[ing] individual autonomy [is] subservient to the duty to shield the consumer").
39 Perrin, supra note 6, at 114 (indicating this goal may be achieved by leaving communication outlets open to the public in order to address its response to FDA regulations).
40 Perrin, supra note 6, at 114 (noting importance of "consistent and dependable" regulations).
41 Perrin, supra note 6, at 114. While each of these goals are important, they cannot all be exercised at the same time and therefore some, such as public protection, will triumph over others. Id.
42 See infra notes 43-62 and accompanying text (describing modifications FDA made to its regulations).
43 See Perrin, supra note 6, at 119-20 (detailing specifics and forms exception takes).
Under this exception, after a terminally ill patient fails to respond to approved treatment, his or her physician files a request with the FDA, and the agency grants access to unapproved drugs on a “case-by-case basis.” While increasing the possibility of receiving drugs not yet approved under normal FDA regulations, critics note that the process inadequately serves the needs of the terminally ill due to the extensive paperwork requirements and the need for multiple party cooperation, including that of the manufacturer who must agree to provide the drug to the patient at no charge.

2. Personal Use IND

Another exception to the general FDA drug regulations is the “personal use IND,” which allows terminally ill patients to import drugs from foreign countries. The allowance is limited to small doses of particular drugs that do not pose an objectionable health risk to consumers. Again, while this exemption from the

44 Greenberg, supra note 9, at 316-17 (indicating authorization is contingent on both FDA and manufacturer cooperation); Perrin, supra note 6, at 119. The FDA typically grants those requests that indicate that ‘a manufacturer [is] willing to supply the drug, a physician [is] willing to prescribe it, a patient [is] willing to give informed consent, and [there is] some basis for believing that the treatment [is] not an outright fraud or poison.’ Perrin, supra note 6, at 119 (quoting Institute of Medicine, Conference Summary, Expanding Access to Investigational Therapies for HIV Infection and AIDS 7, 8-9 (1991)). See also Tricia Bishop, The Cost of Compassion: FDA Reconsiders Rules for Letting Patients Who Are Gravely Ill Get Unapproved Drugs, BALTIMORE SUN, Apr. 15, 2007, available at http://www.baltimoresun.com/news/health/bal-bz.compassion15apr15,1,2344620.story?ctrack=1&cset=true (providing story of terminally ill child suffering from organ failure and chronic blisters who was given access to an experimental treatment on a “compassionate use basis” and “improved 100 percent” according to his father).

45 Bishop, supra note 44 (indicating a key criticism of the compassionate use IND is the high manufacturing costs that leave little incentive for drug companies to offer treatments through the exception), Greenberg, supra note 9, at 316 (detailing exception’s shortcomings and indicating its failure to help large populations of AIDS patients); Myers, supra note 9, at 315 (noting that due to these requirements, exception is rarely used, reporting only two examples of use for AIDS medication).

46 See Greenberg, supra note 9, at 316 (providing general discussion of exemption). See also Relihan, supra note 6, at 241 (indicating exception was implemented as a result of continuing demands from AIDS activists).

47 Relihan, supra note 6, at 241 (noting program was subsequently extended beyond solely AIDS and cancer medications). While the plan originated as a temporary response, it was permanently adopted in 1989. Claire Ahern, Drug Approval in the United States and England: A Question of Medical Safety or Moral Persuasion?—The RU-486 Example, 17 SUFFOLK TRANSNAT’L L. REV. 93, 97-98 (1994). Under the present codification, the exception involves both “life-threatening or serious conditions” and “less serious medical conditions where there is no evidence that the drug involved poses any serious health risk.” Id. at 98.
guidelines increases access to experimental and unapproved drugs, critics argue that the cost of this approach offsets its beneficial potential because of the increased possibility of danger to consumers.\textsuperscript{48} Others note that the introduction of foreign drugs may interfere with clinical experimentation in the United States, and might further discourage American manufacturers from developing new products.\textsuperscript{49} AIDS activists also note that this process is available only to those who can afford the importation.\textsuperscript{50}

3. Treatment IND

One of the more widely discussed modifications to the 1962 Amendments is the Treatment IND, which grants terminally patients access to selective new treatments before the full cycle of experimental testing has been completed.\textsuperscript{51} Under this exception, available drugs are limited to those involved in a regulated clinical trial that were pre-approved by the FDA as having sufficient potential for success following the initial test results, and for which the manufacturer is diligently seeking final FDA approval once the trials are completed.\textsuperscript{52} The patients who may benefit under this exception are limited to those found to be diagnosed with a “serious or immediately life-threatening disease” for which no other approved and effective treatment is available.\textsuperscript{53} For these patients, the statute states “a drug may be made available for treatment use. .

\textsuperscript{48} Greenberg, \textit{supra} note 9, at 317 (noting terminally ill patients importing foreign products run risk of consuming unsafe and ineffective drugs due to lack of information other countries provide).

\textsuperscript{49} Greenberg, \textit{supra} note 9, at 317 (noting exception can lead to fewer willing clinical participants and identifying problem as cost-friendly foreign drugs which reduce manufacturers’ profit capacity in United States); Relihan, \textit{supra} note 6, at 242 (indicating patients with option can supplement clinical experimental dosages to prevent consuming placebo, leading to skewed data). \textit{See also} George J. Annas, \textit{The Changing Landscape of Human Experimentation Nuremberg, Helsinki, and Beyond}, 2 \textit{HEATH MATRIX} 119-20 (providing general discussion of clinical experimentation for the terminally ill).

\textsuperscript{50} Relihan, \textit{supra} note 6, at 241 (noting AIDS activists have criticized exception since its creation).

\textsuperscript{51} 21 C.F.R. \textsection 312.34 (1988).

\textsuperscript{52} 21 C.F.R. \textsection 312.34(b)(1) (1988); Margaret Salmon Rivas, \textit{The California AIDS Initiative and the Food and Drug Administration: Working at Odds with Each Other?}, 46 \textit{FOOD DRUG COSM. L.J.} 107, 118-19 (1991) (discussing statutory requirements).

\textsuperscript{53} 21 C.F.R. \textsection 312.34(b)(2)(ii) (1988).

For purposes of this section, 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. \textit{Id. See also} Relihan, \textit{supra} note 6, at 239 (noting this definition prevents some AIDS patients from qualifying). 21 C.F.R. \textsection 312.34(a) (1988) (“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”).
earlier than Phase [III], but ordinarily not earlier than Phase [II],” although in some “appropriate circumstances, a drug may be made available for treatment use during Phase [II].” While this exception changed the regulatory system the FDA proposed in 1962, critics maintain that grounds for application denial are too discretionary, the potential for dangerous and ineffective drugs is high, and the narrow criteria used does not provide terminally ill patients with sufficient access to experimental drugs.

4. Community-Based Research

Activist movement also led to the creation of community-based clinical research, allowing doctors within the community to conduct their own trials. The benefit of such an approach is that the research targets a specific population and is completed more quickly than standard clinics. Although the program was subsequently endorsed by the United States government, critics argue that colloquial physicians tend to be less qualified and therefore may provide less reliable results.

5. Fast-Track Drug Approval

The “fast-track” regulations came as a response to the FDA’s time-consuming drug approval process which delays terminally ill patients’ access to experimental

55 Rivas, supra note 52, at 120 (criticizing lack of objective standards by which FDA must determine there was “no reasonable basis” drug would be effective).
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.
56 Perrin, supra note 6, at 130 (noting program’s introduction via Community Research Initiative in 1987); Rutherford, supra note 15, at 220 (emphasizing activists role in exception’s implementation).
57 Perrin, supra note 6, at 130-31 (discussing inclusion of women and minorities in community-based research); Rutherford, supra note 15, at 220 (indicating potential for increased research pace under exception).
58 Rutherford, supra note 15, at 220 (discussing government’s use of initiative). One recorded instance in which the FDA used the community-based research exception involved the approval of aerosol pentamidine, a medication preventing pneumonia. Id. Some criticism exists concerning primary care providers’ qualifications for conducting community-based research. Id.
drugs. Under this process, certain drugs may be approved by the FDA for distribution to patients with life-threatening illnesses without the requisite Phase III clinical investigation. The FDA weighs the risks and benefits of the proposed drug to determine whether it should be approved, "taking into consideration the severity of the disease and the absence of satisfactory alternative therapy." One major criticism of this expedited approval process is that it provides only a limited solution due to the small amount of drugs it applies to and a lack of manufacturer incentives.

6. Expedited Approval and Accelerated Approval Processes

The expedited approval regulations decrease the amount of time it takes to complete clinical trials under the regulations, and thus FDA approval for new drugs can be obtained at a significantly faster rate. This process involves early and continuous collaboration between the manufacturer and the FDA where both parties plan two shortened experimentation phases in order to satisfy the agency's standards without the need for lengthy Phase III trials. The accelerated approval regulations provide "surrogate endpoints" as the basis for new drug approvals by the FDA. While this

59 Relihan, supra note 6, at 237-40 (noting that length of FDA drug regulations following 1962 Amendments led advocates to pressure government for action).
60 21 C.F.R. § 312.80 (1988) (noting FDA's recognition that "it is appropriate to exercise the broadest flexibility in applying the statutory standards, while preserving appropriate guarantees for safety and effectiveness").
62 Nelson, supra note 8, at 475 (indicating exception only affects a small number of treatments). The FDA itself notes that few drug manufacturers will likely utilize this procedure due to little profit recognition in light of the expensive sessions the drug sponsor must conduct with the FDA in Phases I and II to meet the requirements. Id.
63 21 C.F.R. § 312.80 (1999). See Greenberg, supra note 9, at 321-22 (identifying rationale behind modification as need for "flexibility" in employing FDA safety and efficacy requirements for terminally ill patients with no other available options).
64 21 C.F.R. §§ 312.82-83 (1999). See Nancy K. Plant, Adequate Well-Controlled Clinical Trials: Reopening the Black Box, 1 WIDENER L. SYMP. J. 267, 282 (1996) (indicating that following expedited process, the FDA often requires Phase IV tests after approval to provide further information of new drug's safety and effectiveness).
65 21 C.F.R. § 314.510 (1999). See Greenberg, supra note 9, at 323 (noting "[i]n contrast to earlier clinical research practice...in which positive outcome was defined in terms of extended patient survival, the accelerated approval procedure established that outcome might instead be measured by intermediate physiological or biochemical effects...); Vivian L. Orlando, The FDA's Accelerated Approval Process: Does the Pharmaceutical Industry Have Adequate Incentives for Self-Regulation?, 25 AM. J.L. & MED. 543, 547 (1999) (indicating approval may be supported on basis of preliminary safety and efficacy findings from Phase I clinical phases); Relihan, supra note 6, at 244 (quoting 57 Fed.
strategy clearly trims a few years off the overall drug regulatory scheme, critics argue that the time it takes for new products to become accessible under this scheme is still too long in light of the fragile condition of terminally ill patients.66

B. A Fundamental Right to Self-Preservation?

Despite the FDA’s recent attempts to increase access to experimental drugs for patients suffering from life-threatening illnesses, terminally ill activists remain dissatisfied with the drug approval process.67 Several commentators adopt the advocates’ position that the fundamental right to privacy includes the ability of terminally ill patients to choose medical treatments.68 Supporters further point to other court decisions in which a fundamental right to refuse life-saving treatment was found to be rational grounds for recognizing a right to choose experimental medication.69 Many terminally ill individuals hope the FDA’s attempts to increase access to experimental drugs through its regulatory modifications are indicative of a trend toward further expansion of their right to medical decision-making autonomy.70

The most recent victory for the terminally ill came in a 2006 decision by the

Reg. 13.235) (noting FDA defines surrogate marker as “a laboratory measurement or physical sign that is used in therapeutic trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions or survives and that is expected to predict the effect of therapy”).

66 See Greenberg, supra note 9, at 324 (emphasizing terminally ill patients’ desperation for new drugs).


68 Perrin, supra note 6, at 149-50.
Advocates of an expansive reading of the right to privacy claim that the right should encompass the personal therapeutic choices of the seriously or terminally ill for three reasons: (1) The freedom to care for one’s health is of a highly personal nature that should ultimately rest with the individual; (2) a regulation denying access to unapproved drugs severely interferes with the lifestyle of the terminally ill individual; and (3) only the terminally ill person is affected by the decision to choose unapproved drugs.

Id. See also Batterman, supra note 6, at 211 (opining that right to experimental treatment should be fundamental).

69 See supra note 26 and accompanying text (discussing cases in which courts have found fundamental right to life-sustaining medical treatment).

70 Batterman, supra note 6, at 220 (noting expanded action initiatives may indicate agency realization of the importance of addressing terminally ill patient’s dire situation).
United States Court of Appeals for the District of Columbia Circuit which held that competent, adult patients suffering from life-threatening disease with no other treatment options have a fundamental due process right of self-preservation.\footnote{Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, M.D., 445 F.3d 470, 486 (D.C. Cir. 2006).} This right provides access to investigational new drugs following the Phase I clinical tests for general safety precautions.\footnote{Id. at 472. The court came to its conclusion based largely on the \textit{Cruzan} court's determination that a person has a due process right to refuse life-saving medication. \textit{Id.} The decision also notes that the patients must be sufficiently informed of the drug's risks by their doctors before beginning the experimental treatment. \textit{Id.} at 484.} The constitutionality of this decision will be decided on remand, where the court must determine whether the FDA's policy is narrowly tailored to serve a compelling governmental interest.\footnote{Abigail Alliance, 445 F.3d at 486.} While terminally ill patients are hesitantly optimistic because of this recent holding, many commentators believe that the ruling will not survive Supreme Court review.\footnote{Id. at 487 (Griffith, C.J., dissenting) (arguing no fundamental right to self-preservation exists in U.S. jurisprudence); Molly McDonough, \textit{A Right to Self Preservation? Ruling on Use of Unapproved Drugs Could Have a Major Effect}, 5 NO. 19 A.B.A. J. E-REPORT 2 (2006) (indicating despite recent FDA policy changes, most critics do not expect court's holding to survive); \textit{A Court Makes Up a Right: The Founding Fathers and the FDA}, THE WASHINGTON POST, May 3, 2006, at A22 (agreeing FDA regulations must be changed, but opining solution is not within Constitution).}

\section*{III. A BALANCING ACT}

Cooperation is necessary if we are to find common ground between the FDA with its asserted role as a regulatory safeguard against potential public dangers, and the terminally ill with their unique needs in the medical community.\footnote{See infra notes 160-177 and accompanying text (discussing suggestions for future compromise between both parties).} Both sides make equally compelling claims.\footnote{See infra notes 94-177 and accompanying text (describing logical arguments supporting positions from each side).} The FDA remains concerned that increasing the access to unapproved drugs would cause more harm than good as a lack of regulation has meant in the past.\footnote{See infra notes 95-131 and accompanying text (discussing FDA's remaining concerns over further increasing access to experimental drugs). \textit{See also supra} notes 7-17 and accompanying text (describing medical tragedies prompting FDA action).} The terminally ill remain steadfast in their demands for experimental medications, emphasizing the importance of independent decision-making in such personal situations.\footnote{See infra notes 125-154 and accompanying text (describing terminally ill activists' arguments for increased access).} The District of Columbia's latest decision finding a fundamental
right to self-preservation is indicative of the growing trend in the direction toward increasing access to experimental drugs for the terminally ill.\textsuperscript{79} Still, some safeguards must accompany this expansion to prevent the FDA’s fears of a medical disaster from becoming a devastating reality.\textsuperscript{80}

A. The Value of Paternalism

The FDA has historically served an important societal function by guaranteeing the safety and efficiency of new drugs.\textsuperscript{81} The agency has taken a paternalistic approach, focusing primarily on protecting patients from exposure to dangerous or ineffective new treatments.\textsuperscript{82} Through its extended approval process, the FDA has developed an exceptional reputation, a standing the agency has sought since earlier drug-related tragedies marred its standing.\textsuperscript{83} Those who support the more restrictive role of the FDA claim that only the current strict approval process preventing the introduction of unapproved drugs can sufficiently protect consumers.\textsuperscript{84} The FDA’s arguments focus largely on popular societal values supporting their role, the historical origins of drug regulation, and concessions that the agency has already implemented to promote increased access.\textsuperscript{85}

The FDA’s present regulatory scheme reflects popular fundamental beliefs concerning treatment improvements and public protection.\textsuperscript{86} First, the FDA assists the government in its goal to provide ongoing developments in medical therapies.\textsuperscript{87}

\textsuperscript{79} See infra notes 132-143 and accompanying text (noting sway in public opinion culminating in Abigail Alliance for Better Access to Developmental Drugs decision granting fundamental interest in self-preservation). See also supra notes 76-79 and accompanying text (discussing effect of opinion). But see supra note 74 and accompanying text (indicating belief decision will not stand on remand).
\textsuperscript{80} See infra notes 173-177 and accompanying text (discussing continuing necessity of safety requirement).
\textsuperscript{81} See Relihan, supra note 6, at 232 (noting FDA’s historical role in drug regulation). See also Greenberg, supra note 13, at 665 (indicating “genuine” nature of FDA’s goals).
\textsuperscript{82} See supra notes 14-16 and accompanying text (describing current FDA process of requiring substantial evidence of safety and effectiveness of investigational drugs).
\textsuperscript{83} See Bean, supra note 8, at 883-84 (indicating this reputation stems primarily from the FDA’s treatment of thalidomide tragedy and the agency’s “cautious, lengthy, multi-stage approval process”).
\textsuperscript{84} See Relihan, supra note 6, at 233 (noting support for strict paternalistic drug regulation system).
\textsuperscript{85} See infra notes 87-112 and accompanying text (providing evidence supporting FDA’s regulatory role).
\textsuperscript{86} See Terrizzi, supra note 14, at 594-96 (discussing values upon which FDA system was created).
\textsuperscript{87} See Terrizzi, supra note 14, at 594-95 (noting agency’s role in aiding development of new and improved treatments).
Second, the agency aids the general public by protecting patients from medical harm. Increasing access to experimental drugs could disturb these protected values by creating a less efficient system for finding new treatments, and by approving dangerous drugs that may further injure the terminally ill. The FDA's safety and efficacy requirements equip this country with necessary guarantees relating to medical procedures. Providing private access to drugs would forfeit the very regulatory system that determines whether drugs are viable for the entire population.

The historical reasons for the FDA's inception are an important consideration. Prior to the current regulatory regime, patients were often injured and killed by the unsafe and untested drugs of the open marketplace. The existing system originated as the result of both public concern and demand. The pre-market approval requirements insure that new medications have undergone rigorous testing before becoming widely accessible. The regulations also protect consumers from purchasing ineffective drugs. It remains important that safety is not sacrificed for expediency, so that we can prevent future tragedies. Notably, some drugs that pass thorough the current agency's testing process later prove to be harmful, despite great efforts to test their quality. Decreasing the safety approval requirements could exacerbate this

88 See supra notes 6-14 and accompanying text (discussing FDA's immediate response to prior public concern over dangerous drugs).  
89 See Orlando, supra note 65, at 564 (noting potential detrimental consequences on safety and effectiveness of new drugs from use of "unchecked" open access market).  
90 See Orlando, supra note 65, at 564 (emphasizing importance of retaining safety requirement). See also supra notes 9-22 and accompanying text (describing evolution of present safety and efficiency requirements).  
91 See Horwin, supra note 24, at 216-17 (discussing reasons FDA provided for refusing to expand access for individual cases). The government continually stresses that the importance of protecting and providing for the general public's needs outweighs any particular individual case. Id.  
92 See Greenberg, supra note 13, at 665 (discussing historical medical tragedies that brought about FDA regulation). See also supra notes 8-16 and accompanying text (noting effects of prior catastrophes).  
93 See supra notes 8-16 and accompanying text (describing liquid-sulfa and thalidomide disasters).  
94 See supra notes 6-16 and accompanying text (noting how medical tragedies affected implementation of current regulatory regime).  
95 See supra notes 14-21 and accompanying text (describing FDA drug approval process).  
96 See supra notes 14-21 (discussing efficiency requirement).  
97 See Myers, supra note 9, at 319 (indicating majority of consumers do not want safety requirements sacrificed).  
98 See Myers, supra note 9, at 319. For example, Oraflex, a drug designed to counteract arthritis, was deemed too dangerous for the marketplace after illnesses and deaths among elderly consumers were reported following shortly after the agency's approval of the drug. Id.
problem.  

The FDA has also already made substantial concessions for the benefit of the terminally ill. The FDA’s implementation of such policies indicates the legitimate governmental interest in assisting the terminally ill while continuing to advance public health. The agency has demonstrated its willingness to make drugs for terminal illnesses accessible, particularly in situations where no alternative treatments exist. It would be politically risky for the FDA to completely remove the safety and efficacy requirements for any part of the population due to the likelihood of widespread protest coupled with the risk of a reoccurrence of earlier tragedies. Many observers expect a reversal of the recent federal circuit court holding that created a fundamental right to self-preservation. The opinion contained a sharp dissent opining that the majority had provided no evidence of a right, deeply rooted in the nation’s history, to receive and use experimental drugs. Arguably the proper route for change is through the legislature rather than the court system.

From this perspective, the positive effects of the drug approval process are readily apparent. First, the agency promotes the universal desires for better medical

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99 See Myers, supra note 9, at 319 (emphasizing necessity of safety requirement).
100 See supra notes 43-66 and accompanying text (discussing FDA’s implementation of expanded access initiatives). According to the FDA, the agency has allowed access to unapproved treatments to more than 100,000 patients with serious or life-threatening diseases. Bishop, supra note 44.
101 See supra notes 43-66 and accompanying text (indicating FDA’s promulgation of new guidelines as a result of pressures from public and political spheres).
102 See supra notes 43-66 and accompanying text (noting most exceptions are available to terminally ill patients who have no other treatment routes existing). See also Nelson, supra note 8, at 473-74 (describing FDA’s risk-benefit analysis for fast-track regulations as including consideration of other available treatment options).
103 See Rutherford, supra note 15, at 216 (discussing FDA’s justifiable reluctance in taking such extreme measures). See also Salbu, supra note 6, at 418 (noting public protection has been “driving force” behind FDA’s original model of drug regulation).
105 Abigail Alliance, 445 F.3d at 484. See supra note 74 and accompanying text (providing support for dissenting opinion).
106 See McDonough, supra note 74 (opining FDA reformation should not occur via the judiciary).
107 See supra notes 82-110 and accompanying text (describing strengths of FDA’s argument for continued regulation). See also Myers, supra note 9, at 318-19 (summarizing beneficial effects of FDA’s centralized system).
developments while protecting the general public.\textsuperscript{108} Second, the FDA prevents a reoccurrence of the medical tragedies that were originally caused, in part, by a lack of regulation.\textsuperscript{109} Finally, the agency has already increased access to experimental drugs through numerous expanded initiative programs, and there remains a lack of public support behind the idea of a constraint-free open access model.\textsuperscript{110}

**B. The Importance of Individual Autonomy**

Despite the many benefits of the FDA's current regulations, arguments supporting the terminally ill's position are similarly persuasive.\textsuperscript{111} The ability of an individual to make his or her own decisions about personal issues is a cherished and realized maxim of our society as evidenced in prior Supreme Court decisions, which grant individuals analogous rights such as the right to refuse medical treatment.\textsuperscript{112} Decisions concerning one's own death invoke this maxim and are of the utmost privacy and concern.\textsuperscript{113} Thus, the terminally ill patients' arguments center primarily on existing fundamental values, the significant consequences the current system produces, and evidence of a shift in public opinion towards increasing access for those who are terminally ill.\textsuperscript{114}

Individuals expect to be able to choose their own fate.\textsuperscript{115} This individual preference is at the crux of the terminally ill’s legal battle for access to new experimental treatment.\textsuperscript{116} The FDA’s current regulatory scheme prevents terminally ill patients from making these decisions and thus encroaches on their valued personal autonomy.\textsuperscript{117}

\textsuperscript{108} See supra notes 86-91 and accompanying text (describing FDA's role in promoting widespread values of improved treatments and public protection).

\textsuperscript{109} See supra notes 93-99 and accompanying text (explaining historical origins of agency's present role).

\textsuperscript{110} See supra notes 100-110 and accompanying text (discussing concessions FDA already made for terminally ill).

\textsuperscript{111} See infra notes 115-143 and accompanying text (discussing strengths of terminally ill patients’ argument for further adjustments to existing regulatory system).

\textsuperscript{112} See supra note 26 and accompanying text (describing legal battles terminally ill patients won in Supreme Court under 14th Amendment).

\textsuperscript{113} See supra note 26 and accompanying text (indicating decisions were based on right to accept death hastening treatments and reject life saving ones).

\textsuperscript{114} See infra notes 115-143 and accompanying text (providing evidence supporting terminally ill patients’ demands).

\textsuperscript{115} See Perrin, supra note 6, at 105 (noting significance personal autonomy carries in this society).

\textsuperscript{116} See Perrin, supra note 6, at 105 (emphasizing battle between terminally ill patients’ personal autonomy and promotion of public wellbeing).

\textsuperscript{117} See Perrin, supra note 6, at 105-06 (opining government's emphasis on “consumer protection”
Through this system, patients often miss out on promising treatments because of the requirement of proof of the new drug's effectiveness, and its corresponding delays in distribution.\textsuperscript{118}

The current regulatory regime results in significant costs for the terminally ill.\textsuperscript{119} First, the lengthy approval process causes the "drug lag," which can mean the loss of life for those waiting on potentially life-saving treatments.\textsuperscript{120} Second, this regulatory practice leads to terminally ill patients resorting to dangerous alternatives in desperation.\textsuperscript{121} For example, some individuals turn to foreign countries to receive life-prolonging medications not currently available in the United States.\textsuperscript{122} An explosion of unauthorized foreign drug importation in recent years is evidence of the measures terminally ill patients will go to obtain unavailable medications.\textsuperscript{123} Additionally, increasing amounts of terminally ill patients have begun using homemade drugs and guerilla clinics.\textsuperscript{124} Third, the current clinical experimentation procedure is ineffective for many terminally ill patients.\textsuperscript{125} Such experiments enroll only a small patient population determined by specific criteria.\textsuperscript{126} Therefore potentially beneficial treatments are offered only to a limited population—a percent of those people who need them.\textsuperscript{127} In addition, control groups within experimental samples receive a placebo in place of the new drug

\begin{footnotes}
\item[118] See Perrin, \textit{supra} note 6, at 106 (discussing how current scheme, particularly efficiency requirement, affects terminally ill patients).
\item[119] See \textit{infra} notes 123-134 and accompanying text (indicating FDA's present scheme results in "drug lag," dangerous alternative treatments, ineffective clinical experimentation, high manufacturing costs of new drugs, and a highly centralized system).
\item[120] See \textit{supra} notes 28-29 and accompanying text (discussing disapproval of "drug lag"). This reality is illustrated in Robert Kudlack's battle against Johnson & Johnson and the FDA. See Kerr, \textit{supra} note 1. \textit{See also} Relihan, \textit{supra} note 6, at 231 (criticizing "drug lag" and presenting newspaper advertisement which read "If a murderer kills you, it's homicide. If a drunk driver kills you, it's manslaughter. If the FDA kills you, it's just being cautious").
\item[121] See Relihan, \textit{supra} note 6, at 231 (emphasizing terminally ill patients' growing impatience for harsh FDA drug regulations).
\item[122] See Relihan, \textit{supra} note 6, at 231. Sources note that patients have imported drugs from various countries including Mexico, Denmark, Germany, Japan, Switzerland, and Taiwan. \textit{Id.} at 231-32.
\item[123] Relihan, \textit{supra} note 6, at 232 (indicating increased amount of "buyers clubs" has placed pressure on FDA for future action).
\item[124] Relihan, \textit{supra} note 6, at 232 (noting guerilla clinics now exist in more than forty US cities).
\item[125] See Perrin, \textit{supra} note 6, at 106 (discussing need to expand terminally ill patients' access to clinical experiments in order to receive experimental drugs being tested).
\item[126] Perrin, \textit{supra} note 6, at 106. (criticizing clinical experimentation's "inclusion and exclusion" criteria).
\item[127] Perrin, \textit{supra} note 6, at 106 (emphasizing small size of sample tested in clinical experimentation).
\end{footnotes}
so researchers can measure the results. Fourth, the FDA's process comes with a big price tag for manufacturers. These high costs discourage new medical innovations and developments. Finally, a centralized regulatory system like the FDA focuses its research capabilities on a few drugs to the exclusion of others.

Advocates also point to judicial decisions, which grant analogous rights, in order to emphasize the growing support behind their cause. The Supreme Court has expanded the zones of privacy to include personal decisions related to a variety of health issues such as the right to refuse medical treatment. For example, the Court emphasizes that every competent adult has a right to determine what will be done to his or her own body. The United States Constitution also endorses individual choice in determining one's own fate. Acknowledgment of the fundamental right of a patient to refuse necessary medical treatment supports a recognition of the fundamental right of a terminal patient without medication alternatives to elect to use an unapproved experimental drug. One decision held that the government's interest in patient's life lessens "as the degree of bodily invasion increases and the prognosis dims." The

128 Perrin, supra note 6, at 106 (indicating use of placebo further minimizes availability of new drugs to terminally ill patients).
129 See Myers, supra note 9, at 323 (noting in 1984, development of new drugs cost approximately $85 million and took 10.3 years to complete).
130 See Myers, supra note 9, at 323. Due to the current lengthy regulation process, drug manufacturers have a more difficult time making a profit, resulting in higher costs for patients and reduced incentive for manufacturers to develop future products. Id. at 323-24.
131 See Myers, supra note 9, at 324 (noting only limited numbers of drugs marketed for AIDS and cancer receive sufficient financial support for research).
132 See infra notes 136-142 and accompanying text (discussing how prior court cases provide evidence supporting terminally ill patients' demands for increased access to experimental drugs). See also supra note 26 and accompanying text (describing terminally ill patients' judicial victories in other medical areas). But see supra note 26 and accompanying text (discussing majority view that terminally ill patients do not have a fundamental right to receive experimental treatments).
133 See also Batterman, supra note 6, at 212 (detailing Court's expansion of protected decisions as including "certain activities related to marriage, procreation, contraception, family relationships, and the decision to bear children"). See also supra note 26 and accompanying text (discussing earlier opinions granting right to reject life saving medical treatment).
134 Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972) (quoting Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914)) ("The root premise is the concept, fundamental in American jurisprudence, that '[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body").
135 Batterman, supra note 6, at 216 (discussing right to privacy).
136 Batterman, supra note 6, at 217 (indicating any other resolution based on that reasoning is "logical")
137 Matter of Quinlan, 355 A.2d 647, 664 (N.J. 1976) (allowing terminally ill patient the right to reject life support). See Batterman, supra note 6, at 214 (discussing decision).
latest decision in Washington, D.C. expanded the right of the terminally ill patients' access further than any prior opinions had allowed.\footnote{138 Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, M.D., 445 F.3d 470 (D.C. Cir. 2006) (granting terminally ill patients with no medicinal alternatives fundamental right to self-preservation). See also supra notes 72-74 and accompanying text (discussing implications of Abigail Alliance decision for terminally ill patients).} Despite its criticisms, this decision may prompt the FDA to make further voluntary changes.\footnote{139 See supra note 74 and accompanying text (discussing criticisms of decision). See McDonough, supra note 74 (noting FDA commissioner’s suggestion the agency would further develop expanded access initiatives). Despite criticism of the court’s decision to grant early access to terminally ill patients following the first phase of testing, studies indicate that the chance of a fatal reaction from drugs tested after this phase is only .5 to 1 percent. Addicott, supra note 17, n. 6. On December 14, 2006, the FDA submitted a proposal to amend its current regulations. Expanded Access to Investigational Drugs for Treatment Uses, 71 Fed. Reg. 75,147 (proposed Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312). This proposed amendment states one of its purposes as an effort “to reconcile individual patients' desires to make their own decisions about their health care with society's need for drugs to be developed for marketing.” Id. at 75,150. To achieve this goal, the proposed rule primarily focuses on increasing availability to larger populations, including individual patients and intermediate-size samples. Id. at 75,147.}

From this standpoint, the negative effects of the present drug approval process cannot be ignored.\footnote{140 See supra notes 113-142 and accompanying text (describing strengths of terminally ill patients' argument for increased access). See also Myers, supra note 9, at 320 (discussing negative consequences of current FDA regulatory scheme).} First, the current system impinges on personal autonomy, a core value in this society.\footnote{141 See supra notes 117-121 and accompanying text (indicating public’s preference for freedom in personal decision making).} Second, the current system causes numerous negative consequences upon the terminally ill, such as a drug lag, dangerous alternative treatments, restrictive clinical experiments, high production costs, and a limited research focus.\footnote{142 See supra notes 122-144 and accompanying text (describing different costs of current drug regulation process).} There is substantial evidence that despite the early public outcry for strict drug regulations, attitudes supporting the terminally ill’s plight are becoming more prevalent.\footnote{143 See supra notes 135-142 and accompanying text (discussing decisions granting personal autonomy under right to privacy in various medicinal areas).}

C. Finding a Compromise

The benefits of the agency remain important and the necessary response to its imperfections is not the creation of an open access system.\footnote{144 Orlando, supra note 65, at 564 (criticizing possibility of open access method of drug} Still, the plight of the
dying patient makes the shortcomings of the current FDA regulatory system a problem that cannot be ignored. Each side’s interests must be balanced to create the most effective system for both. Some suggestions for implementing a compromise include the assistance of drug manufacturers, the decentralization of the FDA’s powers, and a decreased focus on efficacy requirements.

1. Applying Pressure on Drug Manufacturers

Not all alternatives to the current drug regulations involve a sharp decrease in the agency’s participation. Active FDA involvement can be beneficial as evidenced by the positive effects of drug regulation. Despite the increasing pressure on the FDA to improve its regulatory scheme, the agency is a neutral party charged with assessing the drug development process, and not a source of new treatments. As a result, the government has less power over what treatments are made accessible and when they are made accessible than terminally ill patients tend to believe. By increasing the agency’s power, the FDA could implement sanctions on manufacturers that fail to act in accordance with the agency’s regulations. The agency could also provide additional incentives for drug production to prevent a potential drug lag and to minimize the high distribution. See also Salbu, supra note 6, at 421-22 (indicating open access model is “fraught with both philosophical and practical difficulties” due to constraints it causes on drug manufacturers and companies).

See supra notes 122-144 and accompanying text (discussing negative effects of system on terminally ill patients). See also supra notes 27-35 and accompanying text (describing criticisms of current FDA regulatory system).

See Laetrile, supra note 24, at 268 (indicating necessity of assessing FDA’s and terminally ill patients’ interests to achieve improved system).

See infra notes 152-180 and accompanying text (discussing potential alternatives to better balance both sides’ needs).

See Orlando, supra note 65, at 564-65 (discussing potential enforcer role FDA could play in improved system that does not leave patients’ autonomy unchecked).

See Orlando, supra note 65, at 564-65 (opining expanded access initiatives have helped both the public and the drug industry). See also supra notes 6-15 and accompanying text (noting FDA’s role in alleviating medical disasters).

See Terrizzi, supra note 14, at 595 (indicating FDA’s lack of economic role in new drug development and emphasizing manufacturers’ role in conducting actual experiments to obtain approval).

See Terrizzi, supra note 14, at 595 (noting FDA does not conduct its own safety and efficiency research, but instead simply assesses data it receives from scientists as a result of their private tests).

See Orlando, supra note 66, at 564-65 (discussing potential expansion of FDA participation to improve system, including increase in agency funding to allow it to impose penalties).
costs normally associated with the approval system. This alternative would shift the pressure from the FDA to the drug manufacturers, who have more direct control in the production of new experimental therapies for the terminally ill.

2. Decentralization

The FDA's centralized regulatory system lacks a necessary focus on the individual needs of those with serious illnesses. The government's formation of the agency integrated ultimate control over the approval of the new experimental drugs. A key issue with the FDA's centralized decision making is the fact that the agency is an inadequate substitute for the physician. Terminally ill patients are not all the same, yet the system favors the opinions of the bureaucrat and the judge over that of medical doctors. It has been argued that the multi-billion dollar drug industry is the real explanation behind the FDA's decision to prevent doctors from gaining immediate access to new experimental drugs. A better alternative would be for the patient's own doctor to determine whether his or her terminally ill patient is a suitable candidate for the experimental treatment. A physician treating an individual directly is capable of a much more informed opinion than the FDA.

Under this approach, the FDA should

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153 See Orlando, supra note 66, at 565 (indicating manufacturer incentives are essential for expanded access initiatives to succeed). See Rutherford, supra note 15, at 214 (noting current disincentives present in system due to “political pressure for safe drugs, rather than fast review times; a complex regulatory framework; and a highly deferential judiciary”). See also supra notes 28-29 and accompanying text (discussing consequences of drug lag).

154 See Terrizzi, supra note 14, at 595 (indicating FDA's current lack of direct control over drug development leaves it relatively powerless to improve length of time it takes to produce new products).

155 See Horwin, supra note 24, at 213-16 (criticizing centralized decision making by bureaucrats).

156 See Rutherford, supra note 15, at 215 (noting how FDA's creation as a “powerful bureaucratic gatekeeper” created significant cost and complexity to regulatory scheme).

157 See Horwin, supra note 24, at 202 (supporting Access to Medical Treatment Act, which would allow cancer patients to work with their doctors to gain treatments).

158 See Horwin, supra note 24, at 213. Even if FDA possessed the necessary qualifications to act as physician for the complex and diverse illnesses of all terminally ill patients, it would still lack the ability to address each individual as a result of the vast numbers of cases existing today. Id. at 214.

159 See Horwin, supra note 24, at 221 (indicating costs on drug industry if FDA permits increased access to experimental drugs rather than allowing manufacturers to run tests and sell products).

160 See Horwin, supra note 24, at 213 (supporting decrease in centralized decision making by bureaucrats with increase in reliance on individual physicians).

161 See Horwin, supra note 24, at 213 (emphasizing that specifics of each individual's illness affect success of treatments). Under the FDA's proposed rule, individual patients could receive investigational drugs through a licensed physician if (i) the physician concludes that the “probable
retain the power to sanction physicians who abuse the system.\textsuperscript{162}

\textbf{3. Emphasis on Safety; De-emphasis on Efficacy}

The crux of the friction between the government and terminally ill advocates is the conflict between the lengthy process requiring safety and efficacy prerequisites for new drugs on the one hand, and the patient’s asserted right to make voluntary medical treatment decisions on the other.\textsuperscript{163} Drug regulations were put in place primarily to protect consumers from unreasonably dangerous drugs.\textsuperscript{164} The FDA’s current approval process requires substantial evidence of both the safety and efficacy of an investigational drug before it will grant its approval.\textsuperscript{165} A practical alternative would be to only require the substantial evidence requirement of the drug’s safety, which remains a valid governmental concern.\textsuperscript{166} Although a de-emphasis of the efficacy requirement could affect the development and distribution of drugs to non-terminally ill patients, adequate warnings would be supplied indicating that the effectiveness had not yet been tested.\textsuperscript{167} Clearly a terminally ill patient’s right to choose his or her own medicine is more compelling than a consumer’s right to be protected against ineffective products.\textsuperscript{168}

Additionally, the efficacy requirement is less relevant when dealing with

\textsuperscript{162} See Orlando, \textit{supra} note 65, at 565 and text accompanying note 152 (discussing increase in FDA authority to impose sanctions).

\textsuperscript{163} See \textit{supra} notes 82-88 and accompanying text (discussing need for cooperation between the two competing sides).

\textsuperscript{164} See \textit{supra} notes 6-15 and accompanying text (indicating implementation of regulations came as responses to different medical catastrophes).

\textsuperscript{165} See \textit{supra} notes 14-16 and accompanying text (defining substantial evidence requirement).

\textsuperscript{166} This process is similar to the British system, which focuses on drug safety as a primary goal but not to the exclusion of patients’ access to newer drugs. Ahern, \textit{supra} note 47, at 101. Instead, the British use a quicker system with more flexible requirements followed by a closely monitored post-marketing process. \textit{Id.} It would be practical for the United States to mirror the British system to evade the current lengthy process. \textit{Id.} The British government approves drugs on an average of two years sooner than the FDA. \textit{Id.} at 102.

\textsuperscript{167} See Ahern, \textit{supra} note 47, at 101 (applauding British system’s emphasis on post-marketing devices to regulate new drugs).

\textsuperscript{168} See Perrin, \textit{supra} note 6, at 106 (indicating “practice of consumer protection [through use of efficiency requirement] may infringe upon an individual’s autonomy in choosing medical treatment”).
terminally ill patients. The essential purpose of the requirement is to ensure that patients do not select a risky experimental drug when more traditional therapies are available. In cases involving terminally ill patients, however, the available “traditional” treatments for the particular illness are often ineffective. Such patients tend to be more concerned with potentially finding a cure than the possibility of time and money wasted on an ineffective product.

One important restraint on terminally ill patient’s access that should certainly remain in place is the safety requirement. Congress enacted the FDCA to ensure that the public would be protected against the potential dangers of unsafe products. The need to prevent the distribution of unsafe treatments is equally persuasive with regard to the terminally ill. Terminally ill patients are often in desperate situations that make them especially susceptible to exploitation. Therefore, the safety requirement must remain intact to prevent access to such dangerous products.

IV. CONCLUSION

The FDA and terminally ill patients are currently engaged in a conflict resulting in unfortunate endings for many patients. For Robert Kudlack, the terminally ill twenty-five-year-old suffering from Ewing’s sarcoma, a cure may be found if the FDA relaxed its strict adherence to an efficacy requirement. The plight of the terminally ill is yet another tragedy that has swayed society’s opinions about the state of drug regulation. While the FDA has addressed concerns by introducing expanded action initiatives,

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169 See Perrin, supra note 6, at 124 (detailing how efficiency requirement’s purpose of protecting general public is less applicable to terminally ill patients’ unique situation).
170 See Perrin, supra note 6, at 124 (representing Supreme Court’s view on reasoning behind requirement).
171 See Perrin, supra note 6, at 124 (noting many terminally ill patients are incapable of tolerating majority of conventional therapies).
172 See infra notes 174-77 and accompanying text (discussing why effectiveness requirement of new drugs need not be uniformly applied to terminally ill patients).
173 See Perrin, supra note 6, at 124 (emphasizing vulnerabilities of terminally ill).
174 See supra notes 6-15 and accompanying text (discussing FDCA’s origins as result of unsafe products causing medical disasters).
175 See Perrin, supra note 6, at 124 (opining that use of “guerilla self-help clinics, home remedies, the black market, and Compound Q” indicate necessity of safety requirements to protect terminally ill).
176 See Perrin, supra note 6, at 124 (emphasizing this scenario when terminally ill patients lack effective alternative treatments).
177 See Perrin, supra note 6, at 123-24 (providing general discussion of safety requirement’s importance).
advocates of the terminally ill maintain that not enough has been done, and it appears
the agency will have to respond yet again. This prediction is even more likely in
consideration of the recent court decision granting a fundamental right to self-
reservation. Even if the Supreme Court overturns the case, as many critics believe it
will, it seems likely that the FDA will voluntarily alter its system as it has in the past, in
order to address these substantial concerns.

The best possible result is a compromise between a tightly regulated, lengthy
drug approval process and a completely autonomous system. There are several steps the
FDA could take to appease the terminally ill and the general public while maintaining its
overall goals. Instead of solely pressuring the FDA, an agency which in practice is only
the "middle man" in this drug regulation system, demands should be made on drug
manufacturers themselves. Increasing the FDA's powers to allow sanctions against
these pharmaceutical companies would be beneficial. Also, the current system is too
centralized. More decisions concerning whether an experimental drug will be accessible
to the terminally ill should be made by actual medical professionals dealing directly with
individual patients. Finally, leniency of the efficiency requirement for new drugs for
terminally ill patients is necessary. While the safety of the drugs must not be
compromised, terminally ill patients should be able to risk taking an ineffective drug if it
could potentially save their lives.