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Alicia Seibel

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**THE LIMITS TO LIFE: WHAT THE D.C. CIRCUIT'S DECISION IN
ABIGAIL ALLIANCE v. VON ESCHENBACH MEANS FOR MEDICAL
FUTILITY STATUTES**

INTRODUCTION

The specter of death is rarely met with open arms. The sick are told by their friends and loved ones to fight their illnesses. Even after an ill individual has become incapacitated and can no longer consent to the fight, the individual's family often insists on continuing medical treatment. Can a health care provider determine that medical resources should not be used to assist that fight if the provider decides that the fight is futile? May a state legislature authorize providers to make that determination and act on it? If a provider has made and implemented the decision to unilaterally terminate care pursuant to state legislative authorization, how should a court evaluate that decision if it is challenged?

The decision to withdraw medical treatment with the understanding that death will shortly follow has received much recent attention,¹ but the converse of the "right to die"² exists in the denial of treatment sought to prolong life when a physician determines the treatment is simply prolonging a "biological organism and not . . . a 'life.'"³ Such treatment falls under the category of medical futility.⁴ The majority of state legislatures have crafted statutes permitting health care providers to deny treatment to patients if the provider determines the treatment is medically inappropriate.⁵ While health care providers are largely unwilling to employ such statutes to unilaterally abandon or terminate treatment,⁶ the existence of such statutes indicates that state

1. See *Schiavo ex rel. Schindler v. Schiavo*, 403 F.3d 1289, 1295 (11th Cir. 2005) ("Not only has Mrs. Schiavo's case been given due process, but few, if any, similar cases have ever been afforded this heightened level of process." (quoting *In re Guardianship of Schiavo*, 916 So.2d 814, 817 (Fla. Dist. Ct. App. 2005))).

2. See, e.g., *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 277 (1990) ("This is the first case in which we have been squarely presented with the issue whether the United States Constitution grants what is in common parlance referred to as a 'right to die.'").

3. Daniel Robert Mordarski, Comment, *Medical Futility: Has Ending Life Support Become the Next "Pro-Choice/Right to Life" Debate?*, 41 CLEV. ST. L. REV. 751, 752 (1993).

4. *Id.*

5. Thaddeus Mason Pope, *Medical Futility Statutes: No Safe Harbor to Unilaterally Refuse Life-Sustaining Treatment*, 75 TENN. L. REV. 1, 1 (2007).

6. *Id.* at 4.

legislatures have recognized public policies supporting the denial of life-sustaining treatment in some circumstances.

In *Abigail Alliance v. Eschenbach*, an en banc D.C. Circuit Court of Appeals reversed a previous decision by a panel of the court to hold that terminally ill individuals do not have a fundamental constitutional right to access experimental drugs not yet approved for widespread use by the Food and Drug Administration (FDA).⁷ By upholding the limitations placed on public access to medicines as laid out in the Food, Drug and Cosmetic Act (FDCA) and FDA regulations enforcing those limitations, the court reaffirmed that “the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology.”⁸ The court concluded that a patient at the end of his or her life cannot claim a constitutional right to the treatment of his or her choosing if the federal legislature has restricted access to that treatment.⁹

This Comment will discuss the role of courts in evaluating the availability of desired medical treatment for the terminally ill in the context of state medical futility statutes. This Comment will argue that under the current models of state medical futility statutes, courts should not follow the D.C. Circuit’s deferential lead. Part I examines the origins of medical futility disputes and courts’ involvement in such disputes. Part II examines the genesis of state futility dispute statutes and the currently advocated process-based model. Part III focuses on the FDCA, the regulations promulgated by FDA under the FDCA, and the deference that courts have shown to FDA’s judgment in response to challenges to FDA regulations. Part IV looks at the reasoning of the court in *Abigail Alliance*. Finally, Part V provides a critical analysis of the D.C. Circuit’s decision and argues that the court’s deference to agency-placed limits on access to medical treatment in that case should not be followed by courts when evaluating current state medical futility statutes, as the current statutes entrust legislative interpretation to a small number of private individuals and do not allow for judicial oversight of that interpretation.

I. THE ORIGINS OF MEDICAL FUTILITY DISPUTES

A. *Medical Futility Generally*

A medical futility dispute emerges when a physician believes further treatment is no longer appropriate but the patient’s family or surrogate wants treatment continued.¹⁰ The family or surrogate might want treatment to be

7. 495 F.3d 695, 711 (D.C. Cir. 2007).

8. *Id.* at 713.

9. *Id.*

10. Mordarski, *supra* note 3, at 752.

continued because they believe the physician's prognosis is wrong, they are in denial about the patient's realistic chances of recovery, or they believe a miracle will occur.¹¹ Alternately, the physician might want treatment discontinued for reasons of professional integrity, due to concern for the patient's well-being, so as to prevent the patient's family from experiencing false hope, and to maximize limited health resources.¹²

The concept of medical futility began with physician- or provider-advocated withholding or withdrawal of life support systems or the removal of food and hydration from a patient in a prolonged vegetative state.¹³ Under such circumstances, the physician or provider found the prolonging of the patient's life to be "legally, ethically and medically inappropriate."¹⁴ In the 1990s, professional medical associations, institutions, and providers began enacting policies and guidelines to allow providers to unilaterally discontinue "medically inappropriate" care even when the patient's family or surrogate wants the treatment continued.¹⁵

While the notion of treatment that constitutes "medical inappropriateness" in medical futility disputes was initially limited to providing life support or food and hydration to a patient in a persistent vegetative state, that definition has expanded.¹⁶ Now there is no consensus in the medical community, the bioethical community, or among the public as to what constitutes medical inappropriateness.¹⁷ Definitions of medical inappropriate care vary, often depending on the circumstances,¹⁸ and no definition of medical futility has been universally accepted.¹⁹

The attempt to define medical futility in terms of clinical criteria has been considered the "first generation" of the medical futility debate.²⁰ The narrowest definition of medical futility uses brain death as a standard for

11. Pope, *supra* note 5, at 10–11.

12. *Id.* at 15–18.

13. *See* Mordarski, *supra* note 3, at 752.

14. *Cf. id.* (noting that in early "right to die" cases physicians typically asserted that withholding or withdrawing life sustaining treatment was "legally, ethically and medically inappropriate")

15. Pope, *supra* note 5, at 3–4.

16. *See id.* at 26.

17. *Id.*

18. *Id.*

19. Bryan Rowland, Comment, *Communicating Past the Conflict: Solving the Medical Futility Controversy with Process-Based Approaches*, 14 U. MIAMI INT'L & COMP. L. REV. 271, 277 (2006) (quoting AscensionHealth.org, Health Care Ethics: Futility, <http://www.ascensionhealth.org/ethics/public/issues/futility.asp> (last visited July 22, 2009)).

20. Jeffrey P. Burns & Robert D. Truog, *Futility: A Concept in Evolution*, 132 CHEST 1987, 1988 (2007).

medical inappropriateness.²¹ Brain death is considered the only situation where medical intervention of any sort is considered futile,²² and “[t]here is a consensus that it is ethically, legally, and medically appropriate to stop [treatment] for a brain-dead patient.”²³

The next most restrictive definition of medical inappropriateness is physiological futility.²⁴ Physiological futility refers to treatment that will produce no measurable effect on the patient, and such an evaluation is objective.²⁵ Providers are able to determine physiological futility based on clinical knowledge, and “[e]ven the biggest opponents of unilateral decision making” would agree medical treatment with no physiological effect could be properly refused by a provider.²⁶

The last two definitions of futile care are more expansive. Both definitions are subjective. The first definition is a quantitative standard of futility, which depends upon a consensus of whether the treatment sought can achieve the patient’s goals for recovery.²⁷ The second definition is a qualitative standard of futility, which depends upon the physician’s evaluation of whether the patient’s goals for recovery are worth pursuing.²⁸ Qualitative futility is found in three forms: where the potential burdens to the patient outweigh the benefits to the patient, where the potential benefits to the patient are not worth the health care resources to be consumed, and where the treatment sought will not “provide the patient a quality of life worth living.”²⁹

The various definitions of medical futility have been debated for years, with only brain death and physiological futility supported by a consensus in the medical, legal, and bioethical communities.³⁰ However, those communities

21. Robert D. Truog, *Brain Death—Too Flawed to Endure, Too Ingrained to Abandon*, 35 J.L. MED. & ETHICS 273, 276–77 (2007).

22. *Id.* at 277.

23. Pope, *supra* note 5, at 27.

24. *Id.* at 28.

25. *Id.* at 28–29.

26. *Id.* at 29–30.

27. Pope, *supra* note 5, at 32.

28. *Id.* at 34.

29. *Id.* at 35. While the debate about medically inappropriate care did at one point contemplate a cost-benefits analysis of the treatment sought as a method for drawing the line at where treatment became futile, current evaluations of futility standards have been careful to differentiate between futility and rationing. See Burns & Truog, *supra* note 20, at 1989–90 (“[R]ationing arguments must always balance the benefits of a diagnostic or therapeutic intervention against its costs Futility arguments are fundamentally different, in that they claim that the intervention in question is devoid of benefit In light of this distinction, it should be clear that futility policies should never be invoked as a method of cost control.”); see also Rowland, *supra* note 19, at 279 (“Futility is not rationing health care.”). This Comment will not discuss rationing as a form of evaluating medical futility.

30. Pope, *supra* note 5, at 41.

failed to arrive at a consensus on the definition of medical futility under other circumstances that more commonly give rise to medical futility disputes.³¹ The lack of a universal definition of medical futility resulted in one hospital's reluctance to terminate care even when such care met the hospital's own definition of futility.³² Despite the presence of a futility policy, health care providers did not halt futile treatment.³³ The ineffectiveness of this first generation of futility definitions led to another model for approaching the definition of futility.

Identifying medical futility disputes through a defined set of procedural steps has been considered the "second generation" of the medical futility debate.³⁴ Under this approach, hospitals use an internal ethics committees to determine if the treatment sought by a patient's surrogate is futile and then follow a defined set of steps that can lead to unilateral termination of care if no agreement with the family can be reached or alternate arrangements can be made.³⁵ If the ethics committee supports the physicians' view that treatment is futile, the hospital negotiates with the patient's family to attempt to arrive at a consensus for continued care.³⁶ If such a consensus cannot be reached, the hospital will try to transfer the patient to a facility that will provide the care sought.³⁷ If such a provider cannot be found, the hospital could try to have an alternate surrogate appointed by a court, with the assumption that the alternate surrogate will be more amenable to negotiation.³⁸ If the attempt to appoint an alternate surrogate is unsuccessful, the hospital could unilaterally withdraw care.³⁹ Many hospitals nationwide have adopted the procedural approach as hospital policy.⁴⁰ As part of hospital policy, the decision to unilaterally terminate care is open to challenge through the legal system.⁴¹

31. *Id.* at 41–42.

32. *See* Burns & Truog, *supra* note 20, at 1989–88.

33. *Id.*

34. *Id.* at 1989.

35. Pope, *supra* note 5, at 23. While there are no set requirements for the membership of a hospital ethics committee, membership of such committees typically consists of doctors, nurses, and other hospital employees. Burns & Truog, *supra* note 20, at 1990–91. Most committees also have non-medical personnel members from the local community, but "these are often grateful former patients of the hospital." *Id.*

36. Burns & Truog, *supra* note 20, at 1989.

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. Burns & Truog, *supra* note 20, at 1989. These challenges could arise in the form of civil, criminal, and disciplinary sanctions. Pope, *supra* note 5, at 43. Common civil claims filed against providers after the unilateral termination of treatment include actions for informed consent, medical malpractice, and wrongful death. *Id.* Common criminal charges filed against providers include patient neglect and murder. *Id.* at 47. Disciplinary sanctions against a provider

The American Medical Association (AMA) endorsed a process-based approach in 1999, noting that “definitions of futile care are value laden” and that “universal consensus on futility care is unlikely to be achieved.”⁴² The process recommended by the AMA involved seven steps in total, “aimed at deliberation and resolution including all involved parties, . . . securing alternatives in the case of irreconcilable differences, and . . . closure when all alternatives have been exhausted.”⁴³

Prior to the enactment of state medical futility statutes, many professional medical associations, health care providers, and institutions decided that it would be appropriate for providers to withhold or withdraw treatment unilaterally in cases of medical disputes and enacted policies reflecting this determination.⁴⁴ These policies took the form of both clinical definitions of futile care and process-based approaches to resolving medical futility disputes. As hospital policies, any decision arrived at by the treating physician or the hospital ethics committee was open to judicial challenge by the patient’s family or surrogate.⁴⁵ As such, despite the presence of these policies, providers were still reluctant to act for fear of the legal repercussions.⁴⁶ In response, state legislatures began passing medical futility statutes to offer providers that protection.⁴⁷

B. *Medical Futility Cases Prior to State Statutes: Hospital Ethics Committees*

There are limited court judgments evaluating health care providers’ decisions to unilaterally withhold or terminate treatment prior to the enactment of state medical futility statutes.⁴⁸ Under such circumstances, the providers were relying upon their own policies authorizing the unilateral removal or cessation of treatment.⁴⁹ In the absence of state statutes protecting unilateral treatment decisions, providers often depended on the evaluation of a hospital’s ethics committee to buttress the treating physician’s determination that the care

typically include damages under state health care decision statutes for failing to comply with patient and surrogate decisions when “intentional statutory violations occur.” *Id.* at 49.

42. Council on Ethical & Judicial Affairs, Am. Med. Ass’n, *Medical Futility in End-of-Life Care: Report of the Council on Ethical and Judicial Affairs*, 281 JAMA 937, 937 (1999).

43. *Id.*

44. Pope, *supra* note 5, at 3–4.

45. Burns & Truog, *supra* note 20, at 1989.

46. Pope, *supra* note 5, at 4.

47. *See Id.* at 53; *see also* Rowland, *supra* note 19, at 308 (discussing the Texas Advanced Directive Act of 1999).

48. *See* Mordarski, *supra* note 3, at 762.

49. Pope, *supra* note 5, at 3–4.

sought by the patient's surrogate was medically inappropriate.⁵⁰ The support for the doctor's determination would be used to attempt to sway the patient's surrogate to accede to the withdrawal or termination of treatment.⁵¹ While process-based hospital policies required the use of an ethics committee to arrive at the determination that treatment sought was futile, hospitals employing policies involving a clinical definition of futility also often used ethics committees.

If an ethics committee was involved in the decision to unilaterally halt treatment, the decision was used by hospitals as evidence in lawsuits brought by surrogates objecting to that decision. The decision of the ethics committee was often convincing to a judge or jury. In *Gilgunn v. Massachusetts General Hospital*, the daughter of a deceased elderly patient sued Massachusetts General Hospital after the hospital disconnected her comatose father's life support in violation of her instructions.⁵² After the hospital presented evidence that the treating physician had obtained an ethics consultation and the subsequent approval of the head of the ethics committee to remove life support, a jury refused to award damages against the hospital.⁵³

The evaluation of an ethics committee is not always persuasive. In *Rideout v. Hershey Medical Center*, the court imposed liability on a hospital for ending life support for an incompetent patient in violation of the surrogate's wishes.⁵⁴ In *Rideout*, the parents of a two-year-old girl who had a malignant tumor in her brain brought a wrongful death action after the treating physician determined her condition was incurable and deteriorating, and therefore, unilaterally removed her ventilator.⁵⁵ The physician had the approval of the hospital's ethics committee,⁵⁶ but the court nonetheless found the hospital liable for the patient's death.⁵⁷

Similarly, the evaluation of an ethics committee is not always considered useful for evaluating the issue before the court in a dispute relating to medical futility. The court in *In re Howe* found the ethics committee's evaluation of futility irrelevant to its decision of whether to remove the patient's surrogate from her role.⁵⁸ In *Howe*, the court ordered the surrogate of a patient suffering

50. Norman L. Cantor, *Twenty-Five Years After Quinlan: A Review of the Jurisprudence of Death and Dying*, 29 J.L. MED. & ETHICS 182, 185 (2001).

51. *Id.*

52. *See id.*

53. *See id.*

54. *Rideout v. Hershey Med. Ctr.*, 30 Pa. D. & C. 4th 57, 83–84 (Pa. Com. Pl. 1995); *see also* Cantor, *supra* note 50, at 186 (discussing the *Rideout* case).

55. *Rideout*, 30 Pa. D & C 4th at 59–62.

56. *Id.* at 62.

57. *Id.* at 70; *see also* Cantor, *supra* note 50, at 186.

58. *In re Howe*, No. 03-P-1255, 2004 WL 1446057, at *20–21 (Mass. Prob. & Fam. Ct. Dept. Mar. 22, 2004).

from amyotrophic lateral sclerosis to make her decisions based on an assessment of the patient's best interests.⁵⁹ The court felt that there was insufficient evidence to find that the surrogate, who was the patient's sister, should be removed for insisting on life-sustaining treatment even after the hospital determined that the treatment demanded was inappropriate.⁶⁰ While the court did not determine whether the treatment demanded by the surrogate was inappropriate or that the hospital must conform to the surrogate's wishes, it did not defer to the ethics committee's evaluation. The patient's surrogate and the hospital eventually arrived at an agreement to extend aggressive life-sustaining care, and the patient died less than a month before treatment was scheduled to be terminated.⁶¹

The court in *Causey v. St. Francis Medical Center*⁶² also found the hospital ethics committee's futility determination irrelevant to the issue before it. In *Causey*, the court held that a physician's liability for unilaterally removing life support from a comatose patient depended on whether the physician deviated from the standard of care.⁶³ While the hospital's Morals and Ethics Board agreed with the physician's decision to discontinue life-support treatment, the court found that the complaint raised by the patient's surrogate must first be submitted to a medical review panel for a determination of whether the physician and the Board departed from the prevailing standard of care.⁶⁴ The court found such determination required under the Louisiana Medical Malpractice Act, rendering the surrogate's claim premature without it.⁶⁵

In some situations the ethics committee will not go along with the treating physician's determination that medical care is inappropriate.⁶⁶ In *In re Helga Wanglie*, a hospital sought a judicial determination that it could change the guardian for a permanently comatose patient after the guardian, the patient's husband, insisted on the continuation of life support.⁶⁷ Prior to seeking judicial assistance, the hospital's ethics committee evaluated the situation and concluded that the hospital staff should continue treatment.⁶⁸ The judge

59. *Id.* at *21.

60. *Id.* at *20–21.

61. Richard Moore, *An End-of-Life Quandary in Need of a Statutory Response: When Patients Demand Life-Sustaining Treatment that Physicians Are Unwilling to Provide*, 48 B.C. L. REV. 433, 467 (2007).

62. *Causey v. St. Francis Med. Ctr.*, 719 So. 2d 1072 (La. Ct. App. 1998).

63. *Id.* at 1076.

64. *Id.*

65. *Id.*

66. Mordarski, *supra* note 3, at 763–64.

67. *See id.* at 764–65 (discussing *In re Helga Wanglie*, No. PX-91-283 (Hennepin County, Minn., 4th Dist. Ct., P. Ct. Div. July 1, 1991) (unreported opinion)); *see also* Cantor, *supra* note 50, at 185.

68. Mordarski, *supra* note 3, at 763–64.

determined that the husband would remain as guardian and life support was continued.⁶⁹

Finally, prior to the enactment of medical futility statutes, not all cases relating to the cessation of treatment involved a hospital ethics committee's determination. In *Velez v. Bethune*, the court held that a physician had no right to independently decide to discontinue the medical treatment of an infant even if the child was terminally ill and about to die.⁷⁰ The child was born on the side of a highway after a twenty-four week gestation period and died nine days later, after the treating physician ordered the discontinuation of resuscitation.⁷¹ The mother of the child alleged in her complaint that the treating physician discontinued medical care without discussing the decision with her or the child's father.⁷² The court made no mention of the involvement of an ethics committee in the physician's decision to halt treatment, and the court found that the treating physician could not decide on his own to terminate medical treatment of the child.⁷³

Medical futility disputes arise when a health care provider determines that treatment desired by a patient or the patient's surrogate is not medically appropriate. Before the enactment of state statutes authorizing providers to unilaterally deny or terminate medically inappropriate treatment, providers did decide to restrict such treatment. These decisions were made pursuant to hospital policies that often included consultations with a hospital ethics committee in an attempt to persuade the patient or surrogate to agree to the cessation of treatment. In the few situations where a physician halted life support and the patient's surrogate took the issue to court, the decisions of hospital ethics committees were given varying weight in the courts' final decision and were not always dispositive. Thus, a hospital seeking to discontinue medically inappropriate care could not depend on the treating physician's evaluation, the ethic committee's determination, or the authority of its own policies to withstand judicial scrutiny.

II. THE ENACTMENT OF STATE FUTILITY STATUTES

A. *The Different Types of State Futility Statutes*

In the early 1990s, many states enacted legislation allowing health care providers to unilaterally refuse to provide treatment that they consider medically inappropriate.⁷⁴ Prior to the enactment of medical futility statutes,

69. *Id.* at 764.

70. *Velez v. Bethune*, 466 S.E.2d 627, 629 (Ga. Ct. App. 1995).

71. *Id.* at 628.

72. *Id.*

73. *Id.* at 629.

74. Pope, *supra* note 5, at 50.

commentators had argued for their establishment.⁷⁵ These statutes have taken several different forms.

1. The Uniform Health Care Decisions Act

The Uniform Health Care Decisions Act (UHCDA) was drafted in 1993 to allow an individual to preemptively create a plan to specify what health care he or she would desire in all situations and to resolve state conflicts in advance health-care directives.⁷⁶ In addition to permitting the individual to decline treatment or request that treatment be discontinued, the UHCDA authorized a health care provider to decline to honor a request for treatment “for reasons of conscience or if the instruction or decision requires the provision of medically ineffective care or care contrary to applicable health-care standards.”⁷⁷ No other definition of “medically ineffective care or care contrary to applicable health-care standards” is given by the UHCDA. The UHCDA has been adopted by more states than any other model of state futility statute.⁷⁸ After it was completed, the UHCDA was codified by ten states over the course of the next twelve years.⁷⁹

The UHCDA outlines a process that a health care provider must follow if it wishes to unilaterally terminate a patient’s treatment.⁸⁰ First, the provider informs the patient or surrogate that it wishes to terminate the treatment.⁸¹ Second, the provider must “immediately make all reasonable efforts” to transfer the patient to another provider willing to continue the treatment requested, while the current provider still continues supplying the treatment.⁸²

75. See, e.g., Mordarski, *supra* note 3, at 783 (“Although the issue of communication and medical futility is best resolved within the medical community itself, if the medical community does not accept this responsibility, then each state legislature should become involved.”).

76. UNIF. HEALTH-CARE DECISIONS ACT §§ 1–19, 9 U.L.A. 83–129 (2005 & Supp. 2008), *reprinted in* 22 ISSUES L. & MED. 83, 83 (2006). The Act was recommended for enactment in all states at the annual meeting of the National Conference of Commissioners on Uniform State Laws, held from July 30 to August 6, 1993, and was approved by the American Bar Association on February 7, 1994.

77. *Id.* at 83–84.

78. Pope, *supra* note 5, at 53.

79. *Id.* at 53; see also ALA. CODE §§ 22-8A-1 to -13 (LexisNexis 2006); ALASKA STAT. §§ 13.52.010 to .395 (2006); CAL. PROB. CODE §§ 4600–4806 (West Supp. 2008); DEL. CODE ANN. tit. 16 §§ 2501–2518 (2003); HAW. REV. STAT. ANN. §§ 327E-1 to -16 (2008); ME. REV. STAT. ANN. tit. 18 §§ 5-801 to -817 (Supp. 2007); MISS. CODE ANN. §§ 41-41-201 to -229 (2005); N.M. STAT. ANN. §§ 24-7A-1 to -18 (Supp. 2006); TENN. CODE ANN. §§ 68-11-1801 to -1815 (2006); WYO. STAT. ANN. §§ 35-22-401 to -416 (2007).

80. Pope, *supra* note 5, at 54.

81. UNIF. HEALTH-CARE DECISIONS ACT § 7(g), 9 U.L.A. 118–19.

82. *Id.* The provider’s inability to find another provider willing to continue treatment “serves as a check on the system to be sure that the hospital’s position is not out of line with medical standards within the community at large.” Burns & Truog, *supra* note 20, at 1989. This then serves to establish the standard of care for the patient. The plaintiff in a medical malpractice

If the provider is unable to find another provider to take the patient, however, then the provider may refuse the treatment request.⁸³ The patient or surrogate may petition the courts for judicial relief to “enjoin or direct a health-care decision or order other equitable relief” if the patient or surrogate disagrees with the decision made.⁸⁴

2. Other State Futility Statutes

The UHCDA is not the only form of state futility statute. Other states have adopted statutes authorizing the unilateral withholding or withdrawal of medically inappropriate treatment by a health care provider. Other state futility statutes can be distinguished by their various definitions of what constitutes medically inappropriate treatment.⁸⁵ Some statutes provide no definition of medical inappropriateness.⁸⁶ Most statutes offer some definition of medical inappropriateness, including definitions based on “usual and customary standards of medical practice,”⁸⁷ “reasonable medical standards,”⁸⁸ “responsible medical practice,”⁸⁹ and “accepted medical standards.”⁹⁰

Still other states have medical futility statutes in place that are considered “narrow” statutes.⁹¹ These statutes permit unilateral decisions in carefully defined circumstances.⁹² These statutes offer tighter restrictions on the type of treatment that can be discontinued, what the expected effect of the treatment must be before it can be discontinued, and the extent to which a provider may take action where a surrogate has requested treatment.⁹³

case must prove the standard of medical care and show that the defendant-physician departed from that standard of care in treating the plaintiff. Jay M. Zitter, Annotation, *Standard of Care Owed to Patient by Medical Specialist As Determined by Local, “Like Community,” State, National, or Other Standards*, 18 A.L.R. 4th 603, 606–07 (1982). If the hospital can show that other area hospitals refused to treat the patient in the manner requested, the hospital can establish that it did not deviate from the relevant standard of care by refusing to treat the patient in the manner requested and can therefore rebut a charge of medical malpractice. *Id.*

83. See Pope, *supra* note 5, at 60–61; see UNIF. HEALTH-CARE DECISIONS ACT § 7(e)–(g) at 118–19 (noting that a provider who refuses to continue medically ineffective care “shall . . . provide continuing care to the patient until a transfer can be effected”).

84. UNIF. HEALTH-CARE DECISIONS ACT § 14, 9 U.L.A. 125, 129.

85. Pope, *supra* note 5, at 57.

86. See, e.g., LA. REV. STAT. ANN. § 40:1299.58.1(A)(4) (2008); VA. CODE ANN. § 54.1-2990(A) (2005).

87. See, e.g., CONN. GEN. STAT. ANN. § 19a-571(a)(1) (West 2003 & Supp. 2009).

88. See, e.g., GA. CODE ANN. § 31-32-10(3) (2006 & Supp. 2008); 755 ILL. COMP. STAT. 45/4-8(c) (2008).

89. See, e.g., N.H. REV. STAT. ANN. § 137-J:7(I) (LexisNexis 2006).

90. See, e.g., ALA. CODE § 22-31-2 (LexisNexis 2006).

91. Pope, *supra* note 5, at 64.

92. *Id.*

93. *Id.*

First, with regards to the type of treatment that can be discontinued, some “narrow” statutes authorize providers to unilaterally withhold only CPR.⁹⁴ Other statutes authorize providers to unilaterally withhold only “artificially administered nutrition and hydration.”⁹⁵

Second, with regards to the expected effect of the treatment sought to be discontinued, some statutes authorize providers to make unilateral decisions only under certain definitions of medical inappropriateness.⁹⁶ These definitions include situations involving brain death, physiological futility, or permanent unconsciousness.⁹⁷

Finally, with regards to the extent to which a provider may take action where a surrogate has requested treatment, some statutes authorize providers to unilaterally withhold or withdraw treatment only when neither the patient nor the patient’s surrogate has provided opposing directions.⁹⁸

B. Court Challenges to State Futility Statutes

Since state medical futility statutes are a recent phenomenon, and given that health care providers are still reluctant to take unilateral action despite the presence of such statutes, few cases deal with challenges to state medical futility statutes after a provider has terminated treatment in opposition to a surrogate’s wishes.

1. Direct Challenges to State Medical Futility Statutes

*Hudson v. Texas Children’s Hospital*⁹⁹ was the first case in which a court upheld a provider’s decision to withdraw life-sustaining care while the patient was still alive on the basis of a state medical futility statute.¹⁰⁰ In *Hudson*, the mother of an infant born with thanatophoric dysplasia sought an injunction to require the hospital to continue providing life-sustaining care to her child.¹⁰¹ Thanatophoric dysplasia, a rare and fatal type of dwarfism,¹⁰² required the child to be placed on a ventilator.¹⁰³ The child’s treating physicians determined that continuing treatment was inappropriate.¹⁰⁴ The hospital’s

94. See, e.g., VT. STAT. ANN. tit. 18, § 9708 (2007).

95. See, e.g., OR. REV. STAT. § 127.580 (2007).

96. Pope, *supra* note 5, at 65.

97. *Id.*

98. See, e.g., OR. REV. STAT. § 127.580.

99. 177 S.W.3d 232, 238 (Tex. Ct. App. 2005) (remanding the case following the trial judge’s refusal to recuse himself). On remand, the trial judge refused to issue an injunction to force the hospital to continue medical care. Moore, *supra* note 61, at 461.

100. Moore, *supra* note 61, at 466.

101. *Hudson*, 177 S.W.3d at 233.

102. Moore, *supra* note 61, at 461.

103. *Hudson*, 177 S.W.3d at 233.

104. *Id.*

bioethics committee agreed with the decision and informed the mother that the hospital would discontinue treatment within ten days unless she found another hospital willing to provide care.¹⁰⁵

The process followed by the hospital was done in accordance with the Texas Advance Directives Act¹⁰⁶ (Texas Act), which sets out a process-based approach for medical futility decisions.¹⁰⁷ Under that approach, the hospital informs the patient's surrogate of the physicians' adverse decision; reviews the decision using the hospital's ethics committee; if the committee supports the adverse decision, the hospital assists the surrogate in finding a facility willing to provide treatment; and ultimately, if such a facility cannot be found, the physician terminates treatment.¹⁰⁸

While the mother in *Hudson* brought claims under several federal and state statutes, the only claim that survived the hospital's motion for summary judgment was her claim for injunctive relief under the Texas Act.¹⁰⁹ If granted, the injunction sought in *Hudson* would have forced the hospital to continue providing life-sustaining care for a period longer than the statutory period required while the hospital searched for another willing provider.¹¹⁰ This is the only remedy available under the Texas Act.¹¹¹ The trial judge entered a temporary restraining order preventing the hospital from halting treatment during the ensuing litigation, but ultimately denied her injunction.¹¹² Although a procedural error by the judge led to an appeal and reversal of his denial, on remand the trial judge affirmed the denial.¹¹³ The hospital withdrew the life-sustaining treatment, and the child died moments afterwards.¹¹⁴

2. Federal Preemption Under EMTALA

Other judicial evaluations of state futility statutes have found such statutes preempted by federal law. For example, *In re Baby K* the court found that the treatment requirements of the Emergency Medical Treatment and Active Labor Act (EMTALA) superseded a state futility statute.¹¹⁵ In *Baby K*, the court held

105. *Id.*

106. TEX. HEALTH & SAFETY CODE ANN. § 166.001 to .166 (Vernon 2001 & Supp. 2008).

107. Moore, *supra* note 61, at 462.

108. *Id.* at 459–60.

109. *Hudson*, 177 S.W.3d at 234.

110. *Id.*

111. *See* § 166.046(g).

112. *Hudson*, 177 S.W.3d at 235.

113. Moore, *supra* note 61, at 461.

114. *Id.*

115. *In re Baby K*, 16 F.3d 590, 597 (4th Cir. 1994); *see also* Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (2006) [hereinafter EMTALA]. The EMTALA statute states:

that a hospital was required to provide stabilizing treatment to an infant even though the hospital considered the treatment medically inappropriate.¹¹⁶ In its argument for discontinuing care, the hospital relied on the Health Care Decisions Act of Virginia, which provided that “[n]othing in this article shall be construed to require a physician to prescribe or render medical treatment to a patient that the physician determines to be medically or ethically inappropriate.”¹¹⁷ The hospital in *Baby K* also attacked its obligations under EMTALA, arguing its duties to provide adequate screening and stabilization of emergency care patients under that Act did not include the care sought by Baby K’s mother.¹¹⁸

In *Baby K*, the hospital sought a declaratory judgment that it was not required to provide treatment other than nutrition, hydration, and warmth to an anencephalic infant.¹¹⁹ Anencephaly is a condition in which a child is born without major portions of the brain, skull, and scalp.¹²⁰ Baby K did have a brain stem, enabling her to perform basic physiological functions, but she lacked a cerebrum and was therefore permanently unconscious.¹²¹ Baby K’s treating physician explained to her mother that life support services were inappropriate, but her mother insisted that the doctors continue providing Baby K with mechanical breathing assistance when she had trouble breathing on her own.¹²² Baby K was discharged to a nursing home, but she was readmitted three times to the emergency room after she had trouble breathing.¹²³ The hospital sought the declaratory judgment after Baby K’s second admission.¹²⁴

The court in *Baby K* upheld the duties required by EMTALA over the hospital’s right to terminate care it found medically inappropriate.¹²⁵ The court in *Baby K* found that the hospital’s desire to withhold care conflicted with the

In the case of a hospital that has a hospital emergency department, if any individual . . . comes to the emergency department and a request is made on the individual’s behalf for examination or treatment . . . , the hospital must provide for an appropriate medical screening examination

. . . [A]nd [if] the hospital determines that the individual has an emergency medical condition, the hospital must provide either . . . for such further medical examination and such treatment as may be required to stabilize the medical condition, or for transfer of the individual to another medical facility

42 U.S.C. § 1395dd(a)–(b)(1).

116. *Baby K*, 16 F.3d at 597–98.

117. *Id.* at 597 (quoting VA. CODE ANN. § 54.1-2990 (2005)).

118. *Id.* at 595.

119. *Id.* at 592.

120. *Id.*

121. *Baby K*, 16 F.3d at 592.

122. *Id.* at 592–93.

123. *Id.*

124. *Id.*

125. *Id.* at 598.

hospital's duty to provide stabilizing treatment for Baby K under EMTALA.¹²⁶ The court determined that Virginia's state medical futility statute was preempted in this situation by EMTALA.¹²⁷

Other judicial decisions have subsequently clarified the decision of the court in *Baby K* and noted that EMTALA was not intended to govern medical care beyond that which was required to immediately stabilize a patient seeking emergency care. In *Bryan v. Rectors & Visitors of University of Virginia*, the same court that decided *Baby K* again addressed the issue of whether a hospital's unilateral decision to terminate a patient's care violated EMTALA.¹²⁸ In *Bryan*, the court held that a hospital's decision to enter an anti-resuscitation order for an elderly patient and then not resuscitate the patient after her heart attack eight days later did not violate EMTALA.¹²⁹ The patient had been admitted to the hospital emergency room with respiratory distress, and twelve days after her admittance the hospital staff entered a "do not resuscitate" order for her against her family's wishes.¹³⁰ The court in *Bryan* found that Congress intended EMTALA "to regulate the hospital's care of the patient only in the immediate aftermath of the act of admitting her for emergency treatment" and could not "plausibly be interpreted to regulate medical and ethical decisions outside that narrow context."¹³¹

In re AMB, the Michigan Court of Appeals similarly strictly construed the emergency care requirements of EMTALA.¹³² The court in *AMB* held that a family court improperly entered an order withdrawing life support from a premature infant, Baby Allison, because the court failed to properly notify Baby Allison's parents.¹³³ After life support had been withdrawn and the child had died, attorneys representing the Family Independence Agency of the family court and Baby Allison agreed to present arguments to the court to "clarify the record and examine the issues."¹³⁴ When evaluating the claim that the family court's order to withdraw life support from Baby Allison violated the hospital's duty to provide stabilization under EMTALA, the court distinguished the situation in *Baby K* from Baby Allison's circumstances.¹³⁵ The court noted that Baby Allison was never admitted for emergency care and that the hospital did not try to treat Baby Allison any differently than other

126. *Baby K*, 16 F.3d at 597.

127. *Id.*

128. *Bryan v. Rectors & Visitors of Univ. of Va.*, 95 F.3d 349, 349–50 (4th Cir. 1996).

129. *Id.* at 350–51.

130. *Id.* at 350.

131. *Id.* at 352.

132. *In re AMB*, 640 N.W.2d 262, 286 (Mich. Ct. App. 2001).

133. *Id.* at 311.

134. *Id.* at 275.

135. *Id.* at 289.

patients requiring her treatment.¹³⁶ The court found EMTALA inapplicable for other reasons, noting that “[t]he standards EMTALA puts in place affecting treatment specifically control hospital conduct, not patient autonomy or decisions by appropriate surrogates.”¹³⁷ Despite the ruling of the court in *Baby K*, that EMTALA preempted a state medical statute, the subsequent decisions of *Bryan* and *AMB* indicate a judicial unwillingness to extend EMTALA beyond Congress’ stated purpose of prohibiting patient-dumping.

3. Other Federal Preemption Challenges to Medical Futility Statutes

Despite the lack of litigation contesting state medical futility statutes, commentators have recognized other potential federal preemption issues with regards to state medical futility statutes apart from EMTALA. Among these challenges is unconstitutionality.¹³⁸ The unilateral termination of treatment may violate a patient’s First Amendment rights if the patient or surrogate demands treatment based on religious convictions.¹³⁹ A patient’s Eighth Amendment rights may be violated if the patient is a prisoner and thus such termination may be considered cruel and unusual punishment.¹⁴⁰ It has been argued that “unilateral termination is inconsistent with equal protection, the right to life, and the freedom of expression.”¹⁴¹ It has also been held that the Due Process Clause of the Fourteenth Amendment prohibits the unilateral discontinuation of medical treatment.¹⁴²

C. Current State Futility Statutes

Despite the risk of federal preemption under EMTALA or the risk of unconstitutionality, state medical futility statutes are still being employed. The state that has had the most success with its futility statute is Texas; assuming that success is measured as the ability of a provider to lean on the state’s medical futility statute as a means of unilaterally terminating treatment.¹⁴³ Texas employs a process-based futility statute.¹⁴⁴

At the first stage, an ethics committee reviews the treating physician’s decision that continuing treatment would be inappropriate.¹⁴⁵ The patient’s surrogate must be notified forty-eight hours before the review and is entitled to

136. *Id.*

137. *AMB*, 640 N.W.2d at 289.

138. Pope, *supra* note 5, at 77.

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.*

143. Pope, *supra* note 5, at 1.

144. *Id.* at 79; *see also supra* text accompanying notes 107–108.

145. TEX. HEALTH & SAFETY CODE ANN. § 166.046(a) (Vernon 2001 & Supp. 2008).

attend the meeting and receive a written explanation of the committee's decision.¹⁴⁶

The second stage begins after the ethics committee decides to terminate treatment. At this stage, the provider must try to transfer the patient to a provider that is willing to continue treatment.¹⁴⁷ The provider must continue to provide the treatment sought throughout the first and second stages and for ten days after the ethics committee hands down its decision to the patient's surrogate.¹⁴⁸ If the provider cannot find a provider willing to continue the treatment, the provider may unilaterally stop treatment on the eleventh day.¹⁴⁹

Under the Texas statute, a patient's surrogate cannot challenge the decision of the hospital ethics committee in court.¹⁵⁰ The only judicial recourse available for a surrogate is an injunction to extend the ten-day period after the provider determines that it will end treatment.¹⁵¹ The court is permitted to extend the time period "only if the court finds, by a preponderance of the evidence, that there is a reasonable expectation that a physician or health care facility that will honor the patient's directive will be found if the time extension is granted."¹⁵² Under Texas law, then, a hospital ethics committee's evaluation that a treatment sought is futile is a final decision on the merits.

Commentators have suggested that the reason Texas's state medical futility statute has been so effective is because it is focused on a definite process.¹⁵³ While other state statutes rely on imprecise standards to identify "medically inappropriate" medicine, Texas's statute defines a provider's duty solely in terms of process and is the only state statute to do so.¹⁵⁴ Accordingly, Texas's statute is considered the only effective state medical futility statute,¹⁵⁵ and its process-based approach is considered the best method for resolving medical futility disputes.¹⁵⁶ Several commentators have argued that other states should model their medical futility statutes on Texas's.¹⁵⁷

146. *Id.* § 166.046(b).

147. *Id.* § 166.046(d).

148. *Id.* § 166.046(e).

149. *Id.*

150. Burns & Truog, *supra* note 20, at 1991.

151. *See id.*; *see also* § 166.046(g).

152. § 166.046(g).

153. Pope, *supra* note 5, at 80.

154. *Id.* at 1, 80.

155. *Id.* at 1.

156. Moore, *supra* note 61, at 468; *see also* Rowland, *supra* note 19, at 274.

157. Rowland, *supra* note 19, at 309; *see also* Pope, *supra* note 5, at 1.

III. THE FOOD, DRUG AND COSMETIC ACT: THE ENACTMENT OF THE FDCA, FDA REGULATIONS, AND CHALLENGES TO BOTH

A. *The Legislative History of the FDCA*

The Food, Drug and Cosmetic Act (FDCA) was passed by Congress in 1938 “[t]o prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.”¹⁵⁸ In 1962, the FDCA was amended to add specific requirements that must be met before the drugs receive approval by FDA.¹⁵⁹ The amendments were enacted “[t]o protect the public health by amending the [FDCA] to assure the safety, effectiveness, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority; and for other purposes.”¹⁶⁰ These 1962 amendments to the FDCA were at issue in *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*.¹⁶¹

Under the FDCA, “[n]o person shall introduce . . . into interstate commerce any new drug, unless an approval of an application [is] filed . . . with respect to such a drug.”¹⁶² Such an application will not be approved by the Secretary of Health, Education, and Welfare in the absence of “adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested,” if “the results of such tests . . . do not show that such drug is safe for use under such conditions,” if there is “insufficient information to determine whether such drug is safe for use under such conditions,” or if “the information submitted . . . as part of the application . . . [shows] a lack of substantial evidence that the drug will have the effect it purports.”¹⁶³

To meet the requirements of the FDCA, FDA promulgated detailed regulations that must be followed by the proponent of a new drug. The current FDA approval process that a new drug must undergo before it can be marketed to the general public has three basic phases.¹⁶⁴ A fourth post-marketing investigational phase may be conducted to ascertain additional information about the “drug’s risks, benefits, and optimal use.”¹⁶⁵ An investigational new

158. Food, Drug and Cosmetic Act, Pub. L. No. 717, 52 Stat. 1040, 1040 (1938) (codified as amended at scattered sections of 21 U.S.C. (2006)).

159. See 21 U.S.C. § 355 (2006).

160. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, 780 (codified as amended at scattered sections of 21 U.S.C. (2006)).

161. 495 F.3d 695, 705. (D.C. Cir. 2007).

162. 21 U.S.C. §355(a).

163. *Id.* § 355(d).

164. 21 C.F.R. § 312.21 (2008).

165. *Id.* § 312.85.

drug application (IND) may be submitted for clinical investigation in one or more phases.¹⁶⁶

The approval process begins when a drug sponsor submits an IND to FDA, indicating that the sponsor intends to conduct clinical studies on an investigational drug.¹⁶⁷ A sponsor “may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization.”¹⁶⁸ The IND must include the sponsor’s general plan for investigation and the protocols intended to be followed for human testing.¹⁶⁹ FDA has set out a specific and detailed format that an IND must take,¹⁷⁰ and a sponsor must annually report on an IND to describe the status of current studies and update the plan for the upcoming year.¹⁷¹ An IND goes into effect and authorizes a sponsor to begin its investigation thirty days after FDA receives the IND, unless FDA notifies the sponsor that a clinical hold has been placed on the IND, or on earlier notification to the sponsor that the investigation can begin.¹⁷²

In the first phase, the investigational new drug is introduced to human subjects in studies on patients or volunteer subjects.¹⁷³ The total number of subjects in a Phase 1 study is typically between twenty and eighty.¹⁷⁴ Phase 1 studies are designed to evaluate how the drug affects humans, “the side effects associated with increasing doses,” and “gain early evidence on [the drug’s] effectiveness.”¹⁷⁵ To pass on to Phase 2, Phase 1 studies must gather an adequate amount of “information about the drug’s pharmacokinetics and pharmacological effects.”¹⁷⁶ In addition to studies evaluating the drug’s side effects, Phase 1 also includes separate studies that evaluate “drug metabolism, structure-activity relationships, and mechanism of action in humans” and “explore biological phenomena or disease processes” through use of the investigational new drug as a research tool.¹⁷⁷

In the second phase, the investigational new drug is subject to more “well-controlled, scientifically valid . . . studies.”¹⁷⁸ The total number of subjects in

166. *Id.* § 312.21.

167. *Id.* § 312.20(a).

168. *Id.* § 312.3(b).

169. 21 C.F.R. § 312.22(c).

170. *Id.* § 312.23.

171. *Id.* § 312.22(c).

172. *Id.* § 312.40(b)(1)–(2).

173. *Id.* § 312.21(a)(1).

174. 21 C.F.R. § 312.21(a)(1).

175. *Id.*

176. *Id.*

177. *Id.* § 312.21(a)(2).

178. *Id.* § 312.21(a)(1).

a Phase 2 study is typically no more than several hundred.¹⁷⁹ Phase 2 studies are used “to evaluate the effectiveness of the drug for a particular indication” in patients afflicted “with the disease or condition under study.”¹⁸⁰

To reach the third and usually final phase, there must be “preliminary evidence suggesting effectiveness of the drug.”¹⁸¹ Once such evidence has been obtained, Phase 3 studies expand the previous studies into controlled and uncontrolled studies.¹⁸² The total number of subjects in Phase 3 studies is typically between several hundred and several thousand.¹⁸³ The purpose of Phase 3 studies is to collect the information required “to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.”¹⁸⁴

Throughout the three basic phases of the FDA approval process, FDA reviews the IND.¹⁸⁵ FDA’s purpose is to monitor “the safety and rights of [the human] subjects” in Phase I and “help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug’s effectiveness and safety” in Phases 2 and 3.¹⁸⁶ If at any point FDA feels that a deficiency exists in a clinical investigation, FDA will try to resolve the matter with the sponsor or place a clinical hold on the IND.¹⁸⁷ Once a drug receives FDA approval by passing through all phases of FDA’s specified process, the drug’s sponsor may begin to market it to the general public.¹⁸⁸

B. *Judicial Challenges to the FDCA*

The FDCA has previously been challenged by groups desiring earlier access to investigational drugs making their way through the FDA approval process. These challenges have helped shape an understanding of the regulatory approval process outlined by FDA to put the text of the FDCA into action and to what extent a drug sponsor or drug consumer may oppose the process.

The Supreme Court’s decision in *United States v. Rutherford* examined the application of the FDA approval process to drugs for the terminally ill.¹⁸⁹ In *Rutherford*, the Supreme Court held that there is no express or implicit exemption from the approval process in the FDCA for drugs going to

179. 21 C.F.R. § 312.21(b).

180. *Id.* § 312.21(b).

181. *Id.* § 312.21(c).

182. *Id.*

183. *Id.*

184. 21 C.F.R. § 312.22(a).

185. *Id.*

186. *Id.*

187. *Id.* § 312.42(c)–(d).

188. *See* 21 U.S.C. § 355(a) (2006).

189. *United States v. Rutherford*, 442 U.S. 544, 546 (1979).

terminally ill patients.¹⁹⁰ The plaintiffs in *Rutherford*, a group of terminally ill individuals and their spouses filed suit to enjoin FDA from interfering with the shipment and sale of laetrile, a drug that had not yet undergone the full FDA approval process.¹⁹¹ The issue directly before the Court in *Rutherford* was whether the safety and efficacy standards of the FDCA were relevant to the terminally ill and if there was therefore an implied exemption to the statute for the terminally ill.¹⁹² The Court found that the objectives of the approval process as noted in the FDCA—namely, assurances that a drug is safe and effective—were still applicable to those drugs sought by patients who are terminally ill.¹⁹³ The Court noted that “federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy.”¹⁹⁴ The Court further stated that “[w]hether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference.”¹⁹⁵

The Court’s decision in *Rutherford* was also affected by the “substantial deference” given “the construction of a statute by those charged with its administration”—in this case, FDA.¹⁹⁶ The Court found “[s]uch deference is particularly appropriate where, as here, an agency’s interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives.”¹⁹⁷ Since FDA had not previously made exceptions from its approval process for drugs used by the terminally ill, the Court noted its reluctance “to disturb a longstanding

190. *Id.* at 552.

191. *Id.* at 548.

192. *Id.* at 554–55. The district court had determined that the record supported the decision of the Commissioner of the Food and Drug Administration that laetrile was a new drug under § 201(p)(1) of the FDCA and that laetrile was not exempted from the requirements of the FDCA under a 1938 grandfather clause. *Id.* at 550. The district court then determined that the record did not support the Commissioner’s determination that laetrile was not exempted from the requirements of the FDCA under a 1962 grandfather clause and found that laetrile was exempt under that clause. *Id.* The district court alternately held that “denying cancer patients the right to use a nontoxic substance in connection with their personal health” violated the patients’ constitutional privacy rights. *Id.* However, the court of appeals did not address the statutory or constitutional determinations and instead held that “the ‘safety’ and ‘effectiveness’ terms used in the statute have no reasonable application to terminally ill cancer patients.” *Id.* at 550–51. Therefore, the court only addressed the question of whether the safety and effectiveness terms of the FDCA applied to terminally ill patients.

193. *Id.* at 552.

194. *Rutherford*, 442 U.S. at 555.

195. *Id.* at 559.

196. *Id.* at 553.

197. *Id.* at 554.

administrative policy that comports with the plain language, history, and prophylactic purpose of the Act.¹⁹⁸

Access to potentially life-saving drugs was also the issue in *Abigail Alliance*. In *Abigail Alliance*, the D.C. Circuit Court of Appeals' decision was an en banc reversal of their previous panel decision.¹⁹⁹ In the panel decision, the court held that there was a constitutional right of access to experimental drugs for terminally ill patients.²⁰⁰ The court found that where terminally ill adults had no other government-approved treatment options, those patients' rights to obtain investigational drugs that had passed Phase 1 of the FDA approval process were protected by the Due Process Clause.²⁰¹ The court distinguished the case from *Rutherford*, noting that laetrile, the drug at issue in *Rutherford*, had not yet cleared Phase 1.²⁰² Therefore, in *Rutherford* the government presented a more compelling interest in denying the public access to the drug, as it had not yet been determined if laetrile was poisonous and FDA had not yet approved the drug for basic human testing.²⁰³ The court in the *Abigail Alliance* panel decision, however, determined that the government's interest in denying public access to investigational drugs was weaker because these drugs had passed Phase 1 studies and were deemed safe for expanded human testing.²⁰⁴ Thus, in its panel decision, the *Abigail Alliance* court found that the government's interest in protecting the public infringed upon an individual's liberty to receive investigational drugs.²⁰⁵

IV. REASONING OF THE COURT IN THE EN BANC ABIGAIL ALLIANCE DECISION

The dispute in the panel and en banc *Abigail Alliance* decisions was the same: the right of access to investigational drugs for terminally ill patients.²⁰⁶ These patients and their spouses demanded access to drugs that had passed Phase 1 of the FDA approval process.²⁰⁷ A drug that FDA permits to pass Phase 1 is considered safe and promising enough for expanded human testing.²⁰⁸ The Alliance asserted that the right of the terminally ill to have

198. *Id.*

199. *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 495 F.3d 695, 697 (D.C. Cir. 2007).

200. *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007).

201. *Id.*

202. *Id.*

203. *Id.*

204. *Id.*

205. *Abigail Alliance*, 445 F.3d at 486.

206. *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 495 F.3d 695, 697 (D.C. Cir. 2007).

207. *Id.* at 699.

208. *Id.* at 701.

access to drugs that have passed Phase 1 was protected by the Due Process Clause.²⁰⁹ As such, the Alliance argued that the FDA regulations “preventing access to experimental drugs for terminally ill patients where there is insufficient evidence of effectiveness or where there is an unreasonable risk of injury” and “prohibiting drug manufacturers from profiting on the sale of experimental drugs” should be subjected to strict scrutiny for interfering with a fundamental constitutional right.²¹⁰

The Alliance argued that the regulations violated the Constitution by interfering with the rights guaranteed by the Due Process Clause.²¹¹ Under the Fifth Amendment’s Due Process Clause, “[n]o person shall . . . be deprived of life, liberty, or property, without due process of law.”²¹² As noted by the court, the Supreme Court has interpreted the rights protected under the Due Process Clause to be subject to strict scrutiny.²¹³ Additionally, as the rights protected by the Due Process Clause are not delineated in the Constitution, the court said that it was cautioned by the Supreme Court to limit expanding those rights.²¹⁴

According to the court in *Abigail Alliance*, the Supreme Court’s “established method of substantive-due-process analysis” has two requirements that must be met for a right to be recognized as protected under the Due Process Clause.²¹⁵ These two requirements emerged from the Court’s decision in *Washington v. Glucksberg*.²¹⁶ The court in *Abigail Alliance* noted that the first requirement is that a right is “deeply rooted in this Nation’s history and tradition and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed.”²¹⁷ The second requirement is that a request for judicial recognition of a due process right provides “a careful description of the asserted fundamental liberty interest.”²¹⁸

The court assumed *arguendo* that the Alliance met the careful description requirement and focused on whether the Alliance was able to prove that the Alliance’s asserted right to drugs for terminally ill patients was sufficiently supported by “our Nation’s history, legal traditions, and practices.”²¹⁹ The court noted that the Alliance’s claim for constitutional protection rested on two arguments: first, that “common law and historical American practices have traditionally trusted individual doctors and their patients with almost complete

209. *Id.*

210. *Id.*; see also 21 C.F.R. §§ 312.34(b)(3), 312.7 (2008).

211. *Abigail Alliance*, 495 F.3d at 701.

212. U.S. CONST. amend. V.

213. *Abigail Alliance*, 495 F.3d at 702.

214. *Id.*

215. *Id.* (construing *Washington v. Glucksberg*, 521 U.S. 702 (1997)).

216. *Id.* (citing *Glucksberg*, 521 U.S. at 720–21).

217. *Id.* (quoting *Glucksberg*, 521 U.S. at 720–21).

218. *Abigail Alliance*, 495 F.3d at 702 (quoting *Glucksberg*, 521 U.S. at 720–21).

219. *Id.* at 702–03 (quoting *Glucksberg*, 521 U.S. at 710).

autonomy to evaluate the efficacy of medical treatments” and second, that the current FDA regulations are “inconsistent with the way that our legal tradition treats persons in all other life-threatening situations.”²²⁰

To support its first argument, the Alliance noted that the government did not interfere with doctors’ judgments about the efficacy of drugs until the FDCA was amended in 1962 to include the current FDA approval process.²²¹ The court dismissed this analysis, noting that the Alliance ignored the “Nation’s history of regulating the safety of drugs.”²²² The court examined the Nation’s early state regulation of drugs, finding that Virginia had regulated drugs due to safety concerns as early as 1736 and at least twenty-five states or territories had regulated impure drugs by 1870.²²³ The court also noted several examples of federal government intervention in the drug market, beginning with the Import Drug Act of 1848 that banned “imported adulterated drugs.”²²⁴ The court found that the Nation’s history did include regulation of drugs for safety, and the court noted that some of that regulation did involve regulation of drug efficacy.²²⁵

Even allowing that perhaps the Nation’s history did not show a tradition of regulating drug efficacy, the court still found the Alliance’s argument unpersuasive.²²⁶ As the court noted, “an arguably limited history of efficacy regulation . . . does not establish a fundamental right of access to unproven drugs.”²²⁷ Such a limited history of governmental regulation, if alone used to establish a lack of a traditional governmental interference, could support “sweeping claims of fundamental rights.”²²⁸ Limited history of regulation is evidence that a right may be “deeply rooted” under the *Glucksberg* analysis, but such history does not automatically point to constitutional protection.²²⁹

The Alliance also argued that several common law doctrines supported its argument that restricting access to investigational drugs for the terminally ill violated the rights of the terminally ill.²³⁰ The Alliance argued that the doctrine of necessity, the tort of intentional interference with rescue, and the

220. *Id.* at 703 (quoting Brief of Appellant at 31, *Abigail Alliance v. Eschenbach*, No. 04-5350 (D.C. Cir. Sept. 21, 2006)) (internal quotation marks omitted).

221. *Id.*

222. *Id.*

223. *Abigail Alliance*, 495 F.3d at 703–04.

224. *Id.* at 704 (quoting Import Drug Act, Ch. 70, 9 Stat. 237 (1848)) (internal quotation marks omitted).

225. *Id.* at 706.

226. *Id.*

227. *Abigail Alliance*, 495 F.3d at 706.

228. *Id.* at 706–07.

229. *Id.* at 707.

230. *Id.*

right to self-defense all lent support to its position.²³¹ The Alliance asserted that the right of self-preservation present in each common law doctrine would give the terminally ill the right to use drugs that had been preliminarily judged safe enough for expanded human testing and promising enough to potentially save the patients' lives.²³² The court found that each common law doctrine failed as an analogy to the situation in *Abigail Alliance*, and the court felt that none of the doctrines aided the Alliance's position.²³³

The court ultimately found the Alliance's argument for access to experimental drugs for the terminally ill unsupported.²³⁴ The court noted that the Alliance had not shown that the right to use experimental drugs was deeply rooted in the Nation's history.²³⁵ The court felt that the Alliance had not shown that the Nation's legal traditions, as evidenced by several common law doctrines, justified allowing citizens a constitutional right to drugs that had not yet been deemed acceptable for public use.²³⁶ The court held that the Alliance failed to meet the requirements for a fundamental constitutional right under the Supreme Court's *Glucksberg* analysis.²³⁷

Since the right sought by the Alliance was not fundamental, the court found that it was only required to subject the right sought to rational basis scrutiny.²³⁸ Under the rational basis test, the Alliance was required to prove that the government's restriction on the right asserted had no rational relationship to a legitimate state interest.²³⁹ The court found the Alliance could not show the regulations challenged had no rational relationship to a legitimate state interest, as the government does have a valid interest in having a minimum amount of knowledge about the benefits and risks of a drug and in preventing citizens from receiving drugs for which the government does not yet have such minimum knowledge.²⁴⁰ Although the Alliance suggested that the government's safety concerns do not apply to terminally ill patients willing to accept the risks associated with investigational drugs, the court found that argument unpersuasive.²⁴¹ The court in *Abigail Alliance* held that "FDA's policy of limiting access to investigational drugs is rationally related to the

231. *Id.*

232. *Abigail Alliance*, 495 F.3d at 707.

233. *Id.* at 708–10.

234. *Id.* at 711.

235. *Id.*

236. *Id.*

237. *See Abigail Alliance*, 495 F.3d at 712.

238. *Id.*

239. *Id.*

240. *Id.* at 713.

241. *Id.*

legitimate state interest of protecting patients, including the terminally ill, from potentially unsafe drugs with unknown therapeutic effects.”²⁴²

The dissent in *Abigail Alliance* was authored by Judge Judith Rogers, the author of the majority opinion in the previous panel decision.²⁴³ The dissent was joined by Chief Judge Douglas Ginsberg, the other member of the majority in the panel decision.²⁴⁴ According to the dissenters, “the court fundamentally misunderstands the right claimed by the Alliance and trivially casts it as a function of the regulatory scheme.”²⁴⁵

Judge Rogers and Chief Judge Ginsberg found fault with the majority’s application of the *Glucksberg* analysis and found the majority opinion to contain a “stunning misunderstanding of the stakes.”²⁴⁶ The dissent recast the *Glucksberg* historical inquiry into the Nation’s traditions as an investigation not of governmental regulation of safety but of the right of self-preservation.²⁴⁷ The dissent found that the Alliance had shown a deeply rooted right under *Glucksberg*.²⁴⁸ Based on the common law doctrines of self-defense, necessity, and intentional interference with rescue and congressional deference to those doctrines, the dissent found that there was a deeply rooted tradition in the Nation’s history of protecting life by authorizing attempts to save it.²⁴⁹

The dissent also criticized the majority’s reasoning in determining that a historical absence of governmental regulation does not alone demonstrate that a right is not fundamental.²⁵⁰ The court found that conclusion unsupported by the Supreme Court, which has concluded that a right does not have to be explicitly acknowledged by legislation to be considered “deeply rooted,” and unheeding of the second prong of the *Glucksberg* analysis, which requires specificity in claiming a fundamental right.²⁵¹ The dissent found that shifting the inquiry to governmental safety regulation as opposed to governmental efficacy regulation avoided the sparse history of efficacy regulation.²⁵² The dissent felt the Alliance presented adequate evidence of the common law doctrines promoting preservation of life and a national history of access to

242. *Abigail Alliance*, 495 F.3d at 713.

243. *Id.* at 714 (Rogers, J., dissenting); see *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 445 F.3d 470, 471 (D.C. Cir. 2006), *rev’d en banc*, 495 F.3d 695. See generally Roger Pilon, Op-Ed., *The New Right to Life*, WALL ST. J., Aug. 10, 2007, at A11 (stating that Judge Rogers was the author of the panel’s majority opinion).

244. See sources cited *supra* note 243.

245. *Abigail Alliance*, 495 F.3d at 716 (Rogers, J., dissenting).

246. *Id.* at 714.

247. *Id.* at 716.

248. *Id.* at 717.

249. *Id.*

250. *Abigail Alliance*, 495 F.3d at 717 (Rogers, J., dissenting).

251. *Id.* at 718.

252. *Id.* at 724.

experimental drugs to meet the first requirement for a fundamental right under *Glucksberg*.²⁵³

The dissent continued to apply the *Glucksberg* analysis to the fundamental right claimed by the Alliance.²⁵⁴ The court moved on through the first prong of *Glucksberg*, evaluating whether the right to investigational drugs for the terminally ill was “implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed.”²⁵⁵ In doing so, the dissent found that the right sought by the Alliance was bound up with the notion of liberty.²⁵⁶ The dissent noted that the “[t]he core of liberty is autonomy,” and that current FDA policy violated the self-determination of terminally ill individuals.²⁵⁷ The dissent also found that the second prong of the *Glucksberg* analysis, the “careful description of the asserted fundamental liberty interest,” was satisfied by the Alliance: “the Alliance’s liberty claims are not grounded in the abstract notion of personal autonomy but rather in the specific right to act to save one’s own life.”²⁵⁸

The dissent believed that the Alliance’s claimed fundamental right of access to investigational drugs for the terminally ill passed the *Glucksberg* test.²⁵⁹ The dissent felt the case should be remanded for a determination of whether the government can present a compelling enough reason to satisfy the strict scrutiny test, thereby justifying the fact that the current FDA approval process infringes on the fundamental constitutional rights of the terminally ill.²⁶⁰

V. A CRITICAL ANALYSIS OF THE COURT’S DECISION IN *ABIGAIL ALLIANCE* AND ITS APPLICATION TO STATE MEDICAL FUTILITY STATUTES

In *Abigail Alliance*, the D.C. Circuit Court of Appeals refused to recognize a constitutional right for the terminally ill to obtain a promising drug not yet available to the general public.²⁶¹ The court upheld FDA’s right to adhere to the current approval process regulations, passed by the agency under the FDCA.²⁶² Under these regulations, a drug cannot be offered to the general public until extensive studies have established its safety and efficacy.²⁶³ In

253. *Id.* at 726–27.

254. *Id.* at 727.

255. *Abigail Alliance*, 495 F.3d at 727 (Rogers, J., dissenting) (quoting *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997)).

256. *Id.*

257. *Id.* at 727–28.

258. *Id.* at 716.

259. *Id.* at 728.

260. *See Abigail Alliance*, 495 F.3d at 728 (Rogers, J., dissenting).

261. *Id.* at 697 (majority opinion).

262. *Id.* at 713.

263. *See* 21 U.S.C. § 355(a)–(b) (2006).

Abigail Alliance, the court affirmed that the government can restrict the public's access to drug treatments through agency-created regulation enacted under limiting legislation.²⁶⁴

Medical futility statutes seem to operate in a similar fashion, and should therefore seem to be subject to similar deference by the courts. Under current state futility statutes, a health care provider can restrict a patient's access to medical treatment if the provider feels the treatment sought falls into some category of medical inappropriateness. The state legislature sets the limits for access to treatment by passing medical futility statutes, which hospitals then enforce through their own regulations delineating what constitutes medical inappropriateness. It would seem that the hospital regulatory decisions should be subjective to the same judicial deference as FDA's regulatory decisions.

Determinations of futility under current medical futility statutes are undeserving of the level of judicial respect that the court showed the FDA regulations in *Abigail Alliance* and that courts have generally shown FDA regulations when those regulations have been questioned. FDA is the intermediary enforcing the FDCA. An individual hospital is the intermediary enforcing a state medical futility statute. The court in *Abigail Alliance* affirmed the regulations passed by FDA—an administrative agency—to enforce the FDCA; a court affirming a medical futility decision would be deferring to the unique determinations of a single hospital under a state medical futility statute.

While the promulgation of FDA regulations requires the input of a wide range of parties with varying areas of expertise on a national scale, a medical futility determination involves the value judgments of a handful of individuals with the same medical background from the same locality. Since there is no consensus on what constitutes medical futility, hospital determinations of futility can vary widely. A state employing a futility statute that uses a clinical definition of futility entrusts interpretation of the controversial term "medical inappropriateness" to a single doctor or hospital. A state employing a process-based futility statute depends on a single hospital's ethics committee to determine what constitutes medical inappropriateness. In either situation, a determination of futility is made largely, if not completely, by medical personnel with no input from the non-medical community. In a medical futility dispute, which pits the wishes of a patient's family to prolong life against the evaluation of the patient's doctor that the life is not worth prolonging, consideration of the non-medical values that a family may attach to a life should not be ignored.

Medical futility decisions do not have procedural safeguards built in that are equivalent to the administrative regulation approval process. FDA

264. *Abigail Alliance*, 495 F.3d at 713.

regulations undergo an extensive evaluation process.²⁶⁵ This process also helps to ensure that the regulations achieve the objectives of the statute authorizing them and that the regulations are worthy of substantial judicial deference.²⁶⁶ A hospital's futility determination, if made under a state futility statute, is not subject to any oversight. While a clinical definition statute may encourage a hospital to seek a provider willing to continue treatment considered inappropriate, and while a process-based statute requires such an inquiry, that investigation is limited to area hospitals to which transfer is possible. A decision that treatment is futile is, at most, a local consensus among area hospitals that will not be further evaluated.

Under either current conception of medical futility statute, the role of the courts has been steered away from the actual issue of futility. Hospitals are reluctant to rely on medical futility statutes to unilaterally terminate care. As a result, there are virtually no direct challenges to a decision to terminate treatment. When medical futility disputes do involve the courts, courts are asked to look at such questions as the fitness of the surrogate or the possibility that medical decisions are preempted by federal regulation instead of directly

265. For example, when the FDA revised the regulations governing the new drug approval process in 1987, part of the revision process involved creating new procedures for reviewing new drug applications and monitoring the progress of investigational drug use. New Drug, Antibiotic, and Biologic Drug Products Regulations, 52 Fed. Reg. 8798 (Mar. 19, 1987) (to be codified at 21 C.F.R. pts. 312, 314, 511, and 514). In the supplemental information released with the text of the new rule, the FDA noted the thorough research involved in promulgating these regulations:

In preparing the final rule, FDA carefully reviewed more than 50 comments received from pharmaceutical manufacturers, trade associations, health professionals, professional societies, and consumer organizations. In addition, FDA managers met with agency employees in order to gain their views as part of the internal decisionmaking process. The agency also considered the recommendations of the Congressionally sponsored Commission on the Federal Drug Approval Process. In preparing the final rule, therefore, the agency has considered views of persons representing virtually all groups having an interest in the investigational drug process.

Id.

266. Judicial deference for statutorily authorized agency regulation, even in the absence of unambiguous congressional delegation, is well-established. In *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984), the Supreme Court held that when a legislative delegation to an agency on a particular question is implicit rather than explicit, a court may not substitute its own construction of the statutory provision for a reasonable interpretation made by the administrator of the agency. "[I]n *Chevron* the Court expressly formulated the principle of deference to an administrative interpretation when the statute is silent or ambiguous with respect to the specific issue." Kristine Cordier Karnezis, Annotation, *Construction and Application of 'Chevron Deference' to Administrative Action by United States Supreme Court*, 3 A.L.R. FED. 2d 25 (2005). The court in *Abigail Alliance* does not reference *Chevron* in arguing for judicial deference to FDA regulations, but *Chevron* recognized that "[w]hen a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail." *Chevron*, 467 U.S. at 866.

addressing the provider's decision. Cases that emerge from clinical definitions of futility, then, focus on issues other than the evaluation of futility under that definition. Process-based futility statutes have extra protection to ensure that physicians' decisions are consistent with current medical practice, but such statutes still vest substantive decisions in the hands of a few physicians and fail to offer adequate judicial recourse to those affected by the decisions. As exhibited by Texas's futility statute, the decision of the ethics committee can only be postponed to allow the patient's surrogate to find another provider willing to offer care. Under process-based futility statutes, a determination that treatment is futile cannot be attacked through the judicial process. Medical futility statutes based on clinical definitions of futility offer no means of checking the discretion of a single doctor or hospital, and process-based futility statutes likewise do not permit the decisions of the ethics committee to be challenged on the merits. Current state medical futility statutes remove courts entirely from the question of medical futility, and given that such decisions are made by only a handful of individuals, those adversely affected by the decisions should be permitted meaningful judicial recourse.

If current state futility statutes offer inadequate judicial oversight of decisions that require overseeing, what possible alternatives exist? If a medical futility determination is made pursuant to a hospital policy, the patient's family may turn to the courts for relief based on the merits of their claim. The history of medical futility has shown that hospitals are reluctant to make futility determinations based only on hospital policy, however, and the elimination of state legislation authorizing futility determinations would likely eliminate all unilateral decisionmaking by providers. To preserve the ability of providers to terminate medically inappropriate care, the history of futility disputes has shown that medical futility statutes are required. A new conception of a state futility statute is needed—one that takes into account a broader range of values than those of the doctors at a given hospital and one that gives courts a more meaningful role. This Comment does not provide a ready solution and only argues that the current statutes are inadequate.

Medical futility statutes and the FDA approval process are not permanently fixed, and both can be changed through the legislative process to take all relevant factors into account. The court in *Abigail Alliance* leaves open the possibility that the current FDA screening process can be changed, if such changes are deemed appropriate.²⁶⁷ In fact, in response to *Abigail Alliance*, FDA has proposed new guidelines to allow terminally ill patients earlier access

267. *Abigail Alliance*, 495 F.3d at 713 (“Although in the Alliance’s view the FDA has unjustly erred on the side of safety in balancing the risks and benefits of experimental drugs, this is not to say that the FDA’s balance can never be changed.”).

to promising treatments.²⁶⁸ The medical futility debate likewise continues, as states have continued to revise their futility definitions.²⁶⁹ Given the interests at stake, the continuance of such debate about the value of life should always be encouraged and broadened to include as many viewpoints as possible.

CONCLUSION

The court in *Abigail Alliance* found that the Alliance had not proved that a right to use experimental drugs is guaranteed by the Constitution, and concluded that it should not “inject[] the courts into unknown questions of science and medicine.”²⁷⁰ Limitations on access to medical treatment exist at the state level as well, as states have recently enacted laws intended to allow health care providers to unilaterally terminate inappropriate medical treatment. The current system of state statutes is flawed, however, as individual hospitals are entrusted to make substantive decisions about the appropriateness of care for their patients. The state statute model that commentators have begun to advocate then offers no opportunity to challenge a decision of medical futility on its merits. Under current state statutes, the definition of “medically inappropriate” depends largely on what one group of local doctors believes it should mean. These decisions should not be subject to the same deference as the court in *Abigail Alliance* gave the decisions of the FDA. In *Abigail Alliance*, the court expressed a desire that “this debate among the Alliance, the FDA, the scientific and medical communities, and the public may continue through the democratic process.”²⁷¹ As long as there is still the need for such debate about medical treatment, the courts should not blindly acquiesce to the judgment of a handful of clinicians whose opinions on morality, quality of life, and medical risk may not be representative of the communities in which they live.

ALICIA SEIBEL*

268. Ronald L. Trowbridge & Steven Walker, Op-Ed., *The FDA's Deadly Track Record*, WALL ST. J., Aug. 14, 2007, at A17.

269. Compare, e.g., GA. CODE ANN. § 31-32-10 (Supp. 2008) (describing “liability of health care provider[s] or facilit[ies]”: under the Georgia Advance Directive for Health Care Act), with § 31-36-8 (2006) (repealed 2007) (describing the “immunity from liability of disciplinary actions” of anyone who acted in good faith reliance on the directions of a health care agent under Georgia law pertaining to durable powers of attorney for health care).

270. *Abigail Alliance*, 495 F.3d at 713.

271. *Id.* at 714.

* J.D. Candidate, Saint Louis University School of Law, 2009; B.A., Rice University. I would like to thank Professor John Griesbach for his invaluable input on this Comment.

