
Futile Care, Experimental Treatments, and the Right to Try Movement: Could the Charlie Gard Case Happen in America?

“To postpone the withdrawal of treatment, which is otherwise accepted to be the better course for this young child, to go to America to receive treatment which has ‘zero’ prospect of improving his condition, would only prolong his existence in a manner which all, most sadly, agree can no longer be justified as being in his best interests.”¹

I. INTRODUCTION

Medical ethics scholars and legal commentators were looking to England this summer, awaiting a final ruling on the Charlie Gard case.² On July 27, 2017, the European Court of Human Rights (ECtHR) announced it would not interfere with the United Kingdom Supreme Court’s ruling denying parents of a terminally ill infant the right to travel to America for an experimental treatment.³ In early spring, the Family Division of the High Court in London began analyzing the case, and announced on April 11, 2017, that doctors could stop providing the life-supporting treatments they had been administering to Charlie Gard—then eight months old and afflicted with terminal mitochondrial DNA

1. In the Matter of Charles Gard [2017] EWCA (Civ) 410 [49], [2018] 4 WLR 5 (Eng.) (discussing why court determined ending treatment proper in Charlie Gard case).

2. See Matt Pickles, *The Ethical Legacy of the Charlie Gard Case*, U. OXFORD: ARTS BLOG (July 24, 2017), <http://www.ox.ac.uk/news/arts-blog/ethical-legacy-charlie-gard-case> [<https://perma.cc/K5C7-XPGE>] (discussing ethical implications of Charlie Gard case). Oxford University Professor Julian Savulescu discussed the ethical issues in using experimental procedures for medical innovation while still ensuring the process values human life. See *id.*

3. See In the Matter of Charles Gard, EWCA (Civ) 410 [117]-[119] (announcing decision to deny further treatment in America); Gard v. United Kingdom, Eur. Ct. H.R. ¶ 124 (2017), <https://hudoc.echr.coe.int/eng/?i=001-175359> [<https://perma.cc/9JF7-76PB>] (outlining final decision of appeal to ECtHR); Ariel L. Bendor & Zeev Segal, *Constitutionalism and Trust in Britain: An Ancient Constitutional Culture, A New Judicial Review Model*, 17 AM. U. INT’L L. REV. 683, 714-15 (2002) (discussing judicial review process of ECtHR and interaction with lower national courts); *Charlie Gard Parents Lose European Court Appeal*, BBC (June 27, 2017), <http://www.bbc.com/news/uk-england-40423371> [<https://perma.cc/V6S7-J8K9>] (outlining timeline of Charlie Gard court case and subsequent appeals). The ECtHR’s review power is considered “non-pure,” and is not binding on British Parliament, but its decisions are very influential. See Bendor & Segal, *supra*, at 719; see also *Alfie Evans: Sick Toddler’s Life Support ‘Can End’*, BBC (Feb. 20, 2018), <http://www.bbc.com/news/uk-england-merseyside-43133434> [<https://perma.cc/U2ZW-7GJ6>] (explaining court decision to discontinue life support for another terminally ill British infant). On February 23, 2018, the decision was made to withdraw ventilation for a twenty-one-month-old afflicted with a mysterious degenerative neurological illness that left him in a semi-vegetative state. See *Alfie Evans: Sick Toddler’s Life Support ‘Can End’*, *supra*. The High Court in London held that medical evidence established further treatment would be futile, and active treatment would not be in the infant’s best interests. See *id.*

depletion syndrome (MDDS).⁴ Three court of appeals judges then heard and dismissed the case on May 25, 2017, discussing the irreversible brain damage already sustained by the patient, as well as his inability to breathe on his own.⁵ The Gards' appeal, which was later denied by the ECtHR, sought a declaration that it was both lawful and in the best interest of their child to transport him to the United States for nucleoside therapy, an experimental treatment not likely to improve his condition.⁶ The parents' efforts at the United Kingdom Supreme Court and ECtHR were ultimately unsuccessful, with judges at both levels agreeing with the lower court of appeals' decision.⁷

Nearly four years earlier, on December 9, 2013, an American teenager, Jahi McMath, entered the Children's Hospital in Oakland, California, for a routine

4. See *In the Matter of Charles Gard* [2017] EWHC (Fam) 972 [4], [52] [128]-[129], [2018] 1 All ER 569 (Eng.) (noting Gard's age and condition, and announcing court decision to deny further futile treatment). The news provided detailed timelines of each important date of this battle. See *Charlie Gard Parents Lose European Court Appeal*, *supra* note 3 (offering overview of Charlie Gard's condition). The extremely rare condition, thought to affect Charlie Gard and only fifteen other children worldwide, causes progressive muscle weakness and brain damage. See *id.*; see also Rachel Rettner, *Charlie Gard Controversy: What Causes Infant's Rare Condition?*, LIVE SCI. (July 5, 2017), <https://www.livescience.com/59701-charlie-gard-rare-condition.html> [https://perma.cc/NPS3-GGEM] (explaining science of disease and lifespans of other afflicted children). Babies with the same gene mutation do not typically live past infancy. See Rettner, *supra*. A 2008 study of seven infants with MDDS found that all infants died before they were four months old. See *id.*

5. See *In the Matter of Charles Gard*, EWCA (Civ) 410 [117]-[119] (holding hospital did not need to provide life-sustaining treatment because further treatment not medically appropriate). The court's judgment discussed the baby's life: he was not responding to any stimulus, his brain function had been declining, he had additional afflictions of congenital deafness and severe epilepsy, and his life expectancy was likely only months. See *id.* [11].

6. See *In the Matter of Charles Gard* [2017] EWCA (Civ) 410 [13], [2018] 4 WLR 5 (Eng.). The opinion explained the treatment:

The alternative treatment for which the parents earnestly argue is called "nucleoside therapy". In very simple terms, nucleoside therapy involves introducing an alternative source of energy that can be used by the cells in a patient's body to replace the lack of energy resulting from MDDS. The energy is provided within a chemical compound which is simply added to the patient's food. MDDS, which can affect all human cells, has a particular impact both upon the muscles and upon the brain. There is some limited evidence of nucleoside therapy achieving a positive outcome for patients with a different genetic mutation, known as TK2, where the MDDS primarily affects the muscles, rather than the brain As there has been no experimentation even on animals with RRM2B, it is simply not known whether the nucleoside therapy would or would not penetrate and be effective within the brain.

Id.

7. See *Charlie Gard Parents Lose European Court Appeal*, *supra* note 3 (outlining timeline of appeal); see also *Frequently Asked Questions About the Charlie Gard Court Case*, GREAT ORMOND STREET HOSP. FOR CHILD., NHS FOUND. TR. (June 2, 2017), <http://www.gosh.nhs.uk/frequently-asked-questions-about-charlie-gard-court-case> [https://perma.cc/UEN4-WJJW] (offering hospital's press release summary of legal proceedings). As Great Ormond Street Hospital explained, if parents disagree with doctors about a child's future treatment, it is within the normal legal process to ask the courts to rule and make a final determination. See *Frequently Asked Questions About the Charlie Gard Court Case*, *supra*. The hospital stated it had "applied to the High Court for judges to decide whether withdrawal of ventilation and providing palliative care instead of experimental treatment was in Charlie's best interests." *Id.* On June 8, 2017, the United Kingdom Supreme Court ruled that the lower court decisions were correct and it was in Charlie's best interests to be assisted with dying with dignity. See *id.*

removal of her tonsils and adenoids.⁸ The surgery was unsuccessful and resulted in excessive bleeding that led to cardiac arrest; three days later, the patient was pronounced brain dead.⁹ Although the diagnosis of brain death was official, Jahi's mother claimed her daughter was still alive, and wanted to transport her to a New Jersey facility that provided a religious exemption for brain death.¹⁰ The doctors overseeing Jahi argued that they had no duty to continue providing medical support after brain death, but were subsequently court ordered to continue providing treatment to Jahi until December 30, 2013.¹¹ Jahi's mother was ultimately allowed to move her daughter to the New Jersey hospital, and recent reports state that she is responding to commands to move her fingers.¹²

In both the British and American cases discussed, the same issues emerge as to when parents' medical decisions for their children should be honored over the opinions of medical professionals or court orders.¹³ The Charlie Gard case was complicated by the fact that the proposed experimental treatment was not supported by strong evidence of its potential success.¹⁴ In fact, the doctor

8. See *McMath v. California*, No. 15-cv-06042-HSG, 2016 WL 7188019, at *1 (N.D. Cal. Dec. 12, 2016) (offering case's factual history).

9. See *id.* at *2 (discussing medical events at hospital between routine procedure and brain death). The judge heard testimony from several physicians, including a court-appointed independent physician, before declaring Jahi *McMath* brain dead and deceased under California law. See *id.*

10. See *id.* at *1 (explaining mother's belief of Jahi's health status and subsequent move to New Jersey medical facility). Jahi's mother claimed that Jahi was not brain dead, and that she had a right to receive healthcare. See *id.*

11. See *id.* at *2 (outlining legal proceedings after declaration of brain death). On January 17, 2014, the court denied a renewed motion to insert feeding and tracheal tubes. See *id.* The judge held that feeding and tracheal tubes "would arguably be medically ineffective or contrary to generally accepted health care standards, or could violate medical or ethical norms." *Id.*

12. See Craig Turpin, *Girl Thought to be Brain Dead May Still be Alive, Judge Says*, NJ.COM (Sept. 7, 2017), https://www.nj.com/somerset/index.ssf/2017/09/girl_thought_to_be_brain_dead_may_still_be_alive.jhtml [<https://perma.cc/7EWA-ZRRW>] (reporting 2017 updates of *McMath* case). In reporting on the *McMath* case, Craig Turpin also discussed New Jersey's religious exemption law for families objecting to ending life support. See *id.*; see also N.J. STAT. ANN. § 26:6A-5 (West 1991) (outlining declaration of death exemption to accommodate personal religious beliefs). The statute states that a physician shall not declare a patient brain dead based on neurological criteria if the patient's family or other people knowledgeable about the patient's personal religious beliefs state the declaration would violate the personal religious beliefs of the individual. See § 26:6A-5 (West). If this exemption is utilized, the time of death can only be declared based on cardio-respiratory criteria, as opposed to the moment of brain death. See *id.*

13. See Paymon Mohtashami Bidari, Note, *An Incompetent Child's Right to Have Medical Treatment Terminated When There Is Uncontroverted Evidence That Medical Assistance Is Futile*, 17 J. JUV. L. 1, 1-2 (1996), https://www.nj.com/somerset/index.ssf/2017/09/girl_thought_to_be_brain_dead_may_still_be_alive.jhtml [https://perma.cc/7EWA-ZRRW] (reporting 2017 updates of *McMath* case). In reporting on the *McMath* case, Craig Turpin also discussed New Jersey's religious exemption law for families objecting to ending life support. See *id.*; see also N.J. STAT. ANN. § 26:6A-5 (West 1991) (outlining declaration of death exemption to accommodate personal religious beliefs). The statute states that a physician shall not declare a patient brain dead based on neurological criteria if the patient's family or other people knowledgeable about the patient's personal religious beliefs state the declaration would violate the personal religious beliefs of the individual. See § 26:6A-5 (West). If this exemption is utilized, the time of death can only be declared based on cardio-respiratory criteria, as opposed to the moment of brain death. See *id.*

14. See *In the Matter of Charles Gard* [2017] EWCA (Civ) 410 [16]-[17], [2018] 4 WLR 5 (Eng.) (discussing expert testimony presented to court regarding nucleoside treatment). The court highlighted that "Dr. I," the American doctor purporting to know a treatment that may have aided Charlie Gard, was the only expert suggesting any potential benefit of the treatment. See *id.* [23]. The hearing judge considered testimony from two

testifying in support of the procedure admitted there was no clear evidence the treatment had even been administered to an animal or patient with the same deficiency as Charlie Gard.¹⁵ While some American states, like Texas, allow hospitals to overrule requests for what they see as “futile care,” federal law diverges from this approach.¹⁶ For patients arguing to try a treatment with low possibilities of a favorable outcome, the long-debated Right to Try Act recently became law.¹⁷ The Act allows American citizens access to the same type of experimental drugs the British courts had decided against—not yet federally approved treatments, available to terminal patients, with minimal testing proving their efficacy.¹⁸

This Note examines the limits of experimental medicine and treatment, particularly when minors are involved and doctors or the court system disagree with a parent’s medical decision for his or her child.¹⁹ Through the lens of the recent Charlie Gard case, the Jahi McMath matter, as well as other prominent

experts who stated the treatment would not have resulted in any potential benefit for Charlie Gard, and five more medical professionals considered leading authorities in their field offered opinions to the judge as well. *See id.* [20]-[23]. Upon hearing the testimony, the judge remarked: “The entire highly experienced UK team, all those who provided second opinions and the consultant . . . share a common view that further treatment would be futile. For the avoidance of any doubt, the word ‘futile’ in this context means pointless or of no effective benefit.” *Id.* [22].

15. *See id.* [24] (discussing expert testimony from Dr. I after seeing more recent brain scans of Charlie Gard). Dr. I admitted the probability of any benefit was “low, but not zero” and admitted there would be “no reversal of the structure of Charlie’s brain.” *Id.*

16. *E.g.*, KY. REV. STAT. ANN. § 311.631 (West 2004) (presenting Kentucky Living Will Directive Act); TEX. HEALTH & SAFETY CODE ANN. § 166.046 (West 2017) (discussing procedure if physician feels directive or treatment futile); *see* 21 U.S.C. § 360bbb-0a (2018) (expanding terminally ill patient’s ability to contravene physician’s determination to not treat). The Texas statute allows for an attending physician to refuse to honor a patient’s advanced directive or healthcare or treatment decision if the doctor’s medical opinion is that the treatment is medically inappropriate or futile. *See* HEALTH & SAFETY § 166.046. A mandatory committee review process then follows the doctor’s refusal, at which point the committee determines whether the requested treatment is indeed medically unnecessary. *See id.*

17. *See* S. 204, 115th Cong. § 2 (2018) (enacted) (outlining Right to Try Bill passed by Senate, signed into law by President Trump); *see also* Robert Pear & Sheila Kaplan, *Senate Passes F.D.A. Funding and ‘Right to Try’ Drug Bills*, N.Y. TIMES (Aug. 3, 2017), <https://www.nytimes.com/2017/08/03/us/politics/fda-senate-experimental-drugs-terminally-ill-patients.html?mcubz=3> [<https://perma.cc/66UY-PAZM>] (arguing Bill increases access to experimental drugs for terminally ill patients). The Bill passed the Senate and was signed into law on May 30, 2018. *See* Michael Nedelman & Jacqueline Howard, *‘Right-to-try’ Bill Passes Congress*, CNN (May 29, 2018), <https://www.cnn.com/2018/05/22/health/right-to-try-legislation-congress/index.html> [<https://perma.cc/8R2G-FWLP>]. The Bill also included support for more cancer treatment drug access for children. *See* Pear & Kaplan, *supra*.

18. *See* 21 U.S.C. § 360bbb-0a (detailing expanded access to experimental drugs to patients who exhausted all other options); In the Matter of Charles Gard [2017] EWCA (Civ) 410 [117]-[119] (detailing rationale behind affirming lower court’s decision experimental treatment not in Charlie Gard’s best interest). Supporters argue that citizens who are dying should have access to try any drugs manufactured that may help their conditions, while critics are wary pharmaceutical companies will be able to take advantage of ill patients willing to pay exorbitant prices for drugs. *See* Ellen A. Black, *State “Right to Try” Acts: A Good Start, but a Federal Act is Necessary*, 45 SW. L. REV. 719, 733, 743-46 (2016) (providing context for support and criticism of Act). Professor Ellen A. Black discusses the preemption issues that will emerge, explaining the critics’ argument that if any state acts on the issue it will be preempted from doing so by federal law. *See id.* at 740, 742-43.

19. *See infra* Part II.

American cases, this Note discusses parental rights and suggested limits for those rights.²⁰ This Note compares and contrasts the older ideas immortalized in the Texas Advanced Directive Act, and evaluates the danger of new American Right to Try legislation.²¹ Using the Charlie Gard case as a model, and applying the proposed U.S. Bills and subsequently enacted Act, this Note analyzes the future of experimental treatment for terminally ill children.²² Although the Right to Try legislation seems to drastically expand patient rights, this Note examines how healthcare decisions in line with the Texas Advance Directives Act, or with the existing process for requesting early access to experimental drugs through the Food and Drug Administration (FDA), will ensure incapacitated minor patients are not forced to undergo futile interventions.²³

II. HISTORY

A. *The Charlie Gard Legal Battle*

Charlie Gard's parents sought an order to release their baby to them so he could be transported to the United States for experimental treatment, but were unsuccessful with their domestic and ECtHR appeals.²⁴ The ECtHR ultimately considered two decisions from the case's earlier proceedings—a review of the treating hospital's successful application for a declaration allowing the lawful withdrawal of artificial ventilation for the infant, and an opinion on whether it was in the infant's best interest to undergo experimental treatment in the United States.²⁵ The parents argued that the lower court decisions in favor of the hospital

20. See *infra* Sections II.C-E; see also *In re Baby "K"*, 16 F.3d 590, 592 (4th Cir. 1994) (holding hospital not authorized to decline to provide stabilizing treatment it considered inappropriate). *In re Baby "K"* considered whether a hospital was obligated to provide more than treatment for warmth, nutrition, and hydration to an anencephalic infant. *In re Baby "K"*, 16 F.3d at 592. Babies afflicted with this congenital malformation are born without major portions of their brain, skull, and scalp. See *id.* The court held that the hospital was required to provide respiratory support if the baby presented at the hospital was in distress and treatment was requested. See *id.* at 598.

21. See *infra* Sections II.C-E.

22. See *infra* Part III.

23. See *infra* Section II.D, Part III; see also 21 U.S.C. § 360bbb-0a (outlining Right to Try Act's expanded access to experimental drugs for terminally ill patients); TEX. HEALTH & SAFETY CODE ANN. § 166.046(a) (West 2017) (discussing procedure if physician believes following advanced directive not beneficial to patient); Shannon Firth, *Will 'Right to Try' Bill Actually Help Anyone?*, MEDPAGE TODAY (Aug. 11, 2017), <https://www.medpagetoday.com/publichealthpolicy/fdageneral/67222> [<https://perma.cc/KX6U-GGQ2>] (discussing concerns regarding Right to Try movement).

24. See *In the Matter of Charles Gard* [2017] EWCA (Civ) 410 [7], [118], [2018] 4 WLR 5 (Eng.) (holding hospital not required to provide life-sustaining treatment because further treatment not appropriate); *Gard v. United Kingdom*, Eur. Ct. H.R. ¶¶ 124-25 (2017), <https://hudoc.echr.coe.int/eng?i=001-175359> [<https://perma.cc/9JF7-76PB>] (declaring complaint "manifestly ill-founded"); Bendor & Segal, *supra* note 3, at 714-15 (explaining ECtHR authority to review to ensure protection of human rights).

25. See *Gard*, Eur. Ct. H.R. ¶¶ 55-56 (discussing issues for consideration in ECtHR review). The domestic court decisions on the two issues had concluded the hospital could lawfully withdraw life sustaining treatment and begin giving the infant palliative care because Charlie Gard would likely be harmed if his present suffering

violated their child's right to life, liberty, a secure and fair trial, and privacy, in addition to interfering with their parental rights.²⁶

As the ECtHR analyzed the parents' claims, it considered domestic and international legal principles.²⁷ The Children Act 1989 provides that "the child's welfare shall be the court's paramount consideration," and the court has the power to make orders regarding children in specific circumstances.²⁸ The role of the courts in settling disputes has been announced in prior decisions:

As a dispute has arisen between the treating doctors and the parents, and one, and now both, parties have asked the court to make a decision, it is the role and duty of the court to do so and to exercise its own independent and objective judgment. . . . The right and power of the court to do so only arises because the patient, in this case because he is a child, lacks the capacity to make a decision for himself.²⁹

The ECtHR reviewed how the domestic court applied this objective standard when reviewing the Charlie Gard case, considering whether palliative care or experimental treatments were in the minor's best interests.³⁰ The court held that the decisions in the lower courts were based on "extensive and high-quality expert evidence," and found that the courts did not disproportionately interfere with parental rights about medical treatment choices.³¹ The ECtHR also

was prolonged with no chance of improvement. *See id.* ¶¶ 19-23, 28-31. The court further held the experimental treatment would not benefit the infant. *See id.* ¶¶ 22, 28.

26. *See id.* ¶¶ 55-56 (summarizing basis of allegations in parents' suit).

27. *See id.* ¶¶ 40-54 (outlining relevant domestic law and cases relied upon to make decision).

28. *See id.* ¶¶ 40-42 (highlighting section of statute granting courts power to overrule parental decisions). The courts' ability to make certain decisions about child welfare can be exercised through a "specific issue" order. *See id.* Case law interpreting this power has held that "overriding control is vested in the court exercising its independent and objective judgment in the child's best interests." *Id.* ¶ 43.

29. *See NHS Trust v. MB* [2006] EWHC (Fam) 507 [16(i)]-[16(iii)], [2006] 2 FLR 319 (Eng.) (discussing role of courts in resolving treatment disputes about children). The opinion clarified the nature of the objective approach to be used by the courts, emphasizing three considerations to make when determining best interest standards decisions:

The matter must be decided by the application of an objective approach or test. . . . The test [must be in] the best interests of the patient. Best interests are used in the widest sense and include every kind of consideration capable of impacting on the decision. These include, non-exhaustively, medical, emotional, sensory (pleasure, pain and suffering) and instinctive (the human instinct to survive) considerations. . . . It is impossible to weigh such considerations mathematically, but the court must do the best it can to balance all the conflicting considerations in a particular case and see where the final balance of the best interests lies.

Id. [16(iv)]-[16(vi)].

30. *See Gard v. United Kingdom*, Eur. Ct. H.R. ¶¶ 105-08 (2017), <https://hudoc.echr.coe.int/eng?i=001-175359> [<https://perma.cc/9JF7-76PB>] (explaining denial of experimental treatment appropriate objective decision).

31. *See id.* ¶¶ 124-25 (justifying choice to uphold lower court decisions).

supported the lower court's holding that the parents' desire for experimental treatment would be futile, and was not a viable option.³²

B. Futile Treatment Determinations and Ethical Concerns

The ECtHR's ruling affirmed the decision that the parents' requested experimental treatment would be futile for the infant.³³ The ECtHR based its decision partly on medical testimony stating the treatment would not improve the minor's condition and could possibly cause pain or suffering.³⁴ The domestic appellate court who first reviewed this decision noted that examining the merits of an experimental treatment was a proper "child focused, court-led evaluation" of the baby's best interests.³⁵ The cultural difference in medicine can be summarized with one of the appellate court judge's commentary on testimony by an American expert, Dr. I: "Dr[.] I[,] who has not had the opportunity of examining Charlie, and who operates in what has been referred to as a slightly different culture in the United States where anything would be tried, offers the tiniest chance of some remotely possible improvement."³⁶ The court's decision illustrates that governments and courts must fulfill a regulatory duty to protect patients from harm caused by treatments that do not have proof of efficacy or scientific validity.³⁷

The courts weighed the miniscule chance of success against the possible suffering the treatment would cause the infant, and ultimately settled the conflict between the hospital and the parents.³⁸ The difficulty this case presented for many was that the court made a decision regarding the limit of the current state

32. See *id.* ¶ 28 (claiming experimental treatment futile option).

33. See *Gard*, Eur. Ct. H.R. ¶¶ 124-25 (affirming lower court opinion finding experimental treatment futile).

34. See *id.* ¶¶ 30-31 (defending view treatment not appropriate for Charlie Gard). Although media coverage portrayed the experimental treatment as groundbreaking, the court noted it had not even been tested on mice. See *id.*

35. See *In the Matter of Charles Gard* [2017] EWCA (Civ) 410 [118], [2018] 4 WLR 5 (Eng.) (concluding review of treatment request properly handled). The discussion of the efficacy of the treatment itself showed the parents' wishes were being considered and objectively judged. See *id.*

36. See *id.* [127] (illustrating disapproval of American approach of trying any treatment). But see Nick Triggle, *Charlie Gard: A Case that Changed Everything?*, BBC (July 29, 2017), <http://www.bbc.com/news/health-40644896> [<https://perma.cc/Q58R-WNH3>] (describing backlash against hospital during case). Although the court may have criticized the American propensity for over-treatment, the hospital—one of the world's most respected children's hospitals—received abuse and threats throughout the development of the case. See *id.*

37. See *In the Matter of Charles Gard*, EWCA (Civ) 410 [119] (identifying court's necessary intervention); Robert D. Truog, *The United Kingdom Sets Limits on Experimental Treatments: The Case of Charlie Gard*, 318 [J]AMA 1001, 1001-02 (2017) (describing conflicting views regarding access to experimental treatments).

38. See Pickles, *supra* note 2 (discussing ethical implications of Charlie Gard case); see also Jane Dreaper, *Stopping Conflict 'Boiling over' at Children's Hospitals*, BBC (Aug. 25, 2017), <http://www.bbc.com/news/health-41037181> [<https://perma.cc/P2EL-3V37>] (examining factors leading to escalation of tensions between families and hospital staff). Recent research has suggested that much of the conflict at hospitals can be avoided with simple steps such as asking parents what they think at meetings; this research is becoming more widely known due to the Charlie Gard case. See Dreaper, *supra*.

of medicine when the parents were not yet ready to accept that decision.³⁹ In both the United Kingdom and the United States, patients cannot demand nonbeneficial treatments simply because they have the money to pay.⁴⁰ Although Charlie Gard's parents raised over \$1.6 million to fund the treatment, experts did not believe the treatment would benefit the infant, and courts confirmed the treatment was not a right simply because it could be funded.⁴¹

C. Treatment of Minors in the United States

Without a human rights court like the ECtHR in the United States to provide uniform guidance on the right to treatment and best interest conflicts regarding minors and their parents, the amount of deference that should be given to parental choices is frequently litigated in American courts.⁴² Most similar in approach to the logic explained by the ECtHR, the pure objective test provides that treatment should be ended if the burdens of living outweigh the benefits, with no consideration given to the patient's wishes.⁴³

Complicating any decision regarding a patient's wishes is the fact that minors are generally unable to give legal consent for their own treatment and diagnosis.⁴⁴ Because of this, minors are often completely reliant on their parents to make treatment decisions on their behalf, with little ability to interfere even if the minor patient is at an age and mental state to understand his or her condition and

39. See Pickles, *supra* note 2 (outlining ethical questions brought to forefront of news media during case).

40. See Truog, *supra* note 37, at 1001-02 (stating limits of requesting treatments in hospitals); Dan Bilefsky, *Charlie Gard Dies, Leaving a Legacy of Thorny Ethics Questions*, N.Y. TIMES (July 28, 2017), <https://www.nytimes.com/2017/07/28/world/europe/charlie-gard-dead.html> [http://perma.cc/2PEZ-SQ32] (discussing dangers of unlimited access to experimental treatments).

41. See Truog, *supra* note 37, at 1001-02 (discussing frustration of patients wanting unproven experimental treatments). Critics of the court's view feel that any treatment patients want and can afford should be accessible. *See id.*; see also John D. Lantos, *The Tragic Case of Charlie Gard*, 171 [J]AMA PEDIATRICS 935, 935 (2017) (emphasizing court claimed decision not about cost of treatment or ability to pay). The issues in the case were whether the infant was in pain and the therapy could benefit him, not the treatment's cost or the patient's ability to pay. *See Lantos, supra*, at 935.

42. See Seema K. Shah et al., *Charlie Gard and the Limits of Best Interests*, 171 [J]AMA PEDIATRICS 937, 937 (2017) (outlining general standards for state intervention); Bidari, *supra* note 13, at 1-2 (introducing different standards used by courts to determine if futile treatment inappropriate). For over 200 years, the best interest standard has been the legal and ethical standard regarding medical decisions made on behalf of minors. *See Shah et al., supra*, at 937. Some courts have utilized a limited objective test, ending treatment if there is reliable evidence the patient would not want the treatment, as well as proof that the burden of extending the patient's life outweighs any potential benefits. *See Bidari, supra* note 13, at 2 (articulating limited objective test approach to making court decisions). This approach is criticized because the minor patient must have shown or implied a desire to stop the treatment, an action that is often unrealistic for small children or unconscious patients. *See id.*

43. *See Bidari, supra* note 13, at 2 (detailing pure objective test approach to making court decisions). For this approach, the patient's pain must be so unavoidable and severe that giving the patient further "life-sustaining treatment would be inhumane." *See id.*

44. *See* Swapna Patel, Comment, *Do I Have a Voice? Juvenile Medical Consent*, 26 J. JUV. L. 111, 111 (2006) (analyzing difficulties of obtaining consent from minors for treatment). This general rule is based on the idea that minors do not yet possess the ability to make educated medical decisions. *See id.*

possible treatment options.⁴⁵ The state typically only interferes in parental decisions about routine medical choices if the decision could be considered child abuse or neglect.⁴⁶ These debates generally would not arise when considering a situation like the Charlie Gard case because an infant, much like an unconscious patient, would never be considered able to make his or her own choices regarding medical treatment.⁴⁷

1. American Tendency to Resolve Disputes in Favor of Parental Discretion

Litigation regarding medical decisions on behalf of minors generally concerns conflicts between parents and treating physicians, with one party wishing to end life-sustaining treatment and the other advocating to continue providing the support.⁴⁸ Medical professionals often argue that ending life support conflicts with their obligation to care for the health and safety of their patients, even if family members are requesting otherwise.⁴⁹ The standard for making decisions for incapacitated adults has been long settled; it requires “clear and convincing evidence” that a patient would desire withdrawal of life-sustaining treatment, and that ending treatment would be constitutionally permissible.⁵⁰ A crucial difference is that adults are more likely to have the foresight to preserve their rights in a living will, and have more agency to make their own decisions prior

45. See Jennifer L. Rosato, *The Ultimate Test of Autonomy: Should Minors Have a Right to Make Decisions Regarding Life-Sustaining Treatment?*, 49 RUTGERS L. REV. 1, 4-5 (1996) (discussing general process of obtaining medical consent for minors through parents).

46. See *id.* at 5 (contrasting rights of minors and adults when making treatment choices); Shah et al., *supra* note 42, at 937 (introducing concept of “harm principle”). The harm principle refers to the idea that clinicians should only attempt to go against a parent’s wishes if there is a serious risk of harm to the child and if intervening would likely prevent the harm. See Shah et al., *supra* note 42, at 937.

47. See Rosato, *supra* note 45, at 8 (positing only competent minors able to exercise autonomy); see also Jalayne Arias, *A Child’s Voice in Pediatric Cancer Treatment: A Minor’s Role in the Informed Consent Process*, HEALTH L., June 2011, at 39, 39 (examining informed consent laws regarding minors). Informed consent laws that allow minors to consent in narrow circumstances do not articulate a clear standard to determine when a minor is capable of making critical medical decisions. See Arias, *supra*, at 39.

48. See generally *McMath v. California*, No. 15-cv-06042-HSG, 2016 WL 7188019 (N.D. Cal. Dec. 12, 2016) (analyzing conflict between hospital and parents regarding treatment of minor); *Fonseca v. Kaiser Permanente Med. Ctr. Roseville*, 222 F. Supp. 3d 850 (E.D. Cal. 2016) (considering conflict between parents and hospital about ending treatment).

49. See John D. Hodson, Annotation, *Judicial Power to Order Discontinuance of Life-Sustaining Treatment*, 48 A.L.R. 4th 67, § 2(a) (1986) (providing judicial and legislative background on discontinuing life support). Fear of breaching their duty of care and of prosecution may also lead doctors to resist ending life-sustaining treatment. See *id.*

50. See *Cruzan ex rel. Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 284 (1990) (holding Missouri statute requiring patient intent before ending life support constitutional). *Cruzan ex rel. Cruzan* involved an adult patient who was incompetent and in a persistent vegetative state due to severe injuries resulting from an accident. See *id.* at 265. Her parents wanted to end life-sustaining treatment, but the hospital refused to do so. See *id.* at 267-68. When summarizing the state supreme court’s decision, the Supreme Court noted that the state court “rejected the argument that [her] parents were entitled to order the termination of her medical treatment, concluding that ‘no person can assume that choice for an incompetent in the absence of . . . clear and convincing . . . evidence’” of the patient’s wishes. *Id.* at 268-69

to becoming incompetent.⁵¹ Cases concerning minors without a will are more likely to be argued through the vein of defending a family's right to privacy or religious freedom.⁵²

The "clear and convincing" evidence standard is rarely applied in cases concerning minors, although a modified use is typical under these circumstances.⁵³ In *In re Christopher I.*,⁵⁴ the appellate court affirmed an order from the Orange County Juvenile Court, holding that the termination of life-sustaining medical treatment for a child in a persistent vegetative condition with no cognitive function was proper because there was clear and convincing evidence the medical decision was in the child's best interest.⁵⁵ Although the court ultimately deferred to the mother's wishes and agreed that terminating support was proper, the father of the child argued against this decision.⁵⁶ The father's abuse caused the child's vegetative state, leading the court to consider the mother's wishes and other objective evidence rather than the father's opinion.⁵⁷

2. *Baby "K" and the Emergency Medical Treatment and Active Labor Act*

Courts must consider a statutory hurdle when analyzing whether discontinuing life support is appropriate—a federal statute, the Emergency Medical Treatment and Active Labor Act (EMTALA).⁵⁸ The statute outlines

51. *See id.* at 338-39 (Stevens, J., dissenting) (articulating clear and convincing evidence standard's disparate treatment of minors); *see also* MO. REV. STAT. § 459.010-.055 (2018) (presenting Missouri Living Will Statute interpreted in *Cruzan ex rel. Cruzan*). The statute, which presented the framework for creating a living will, was interpreted to show a state policy favoring the preservation of life. *See Cruzan ex rel. Cruzan*, 497 U.S. at 268; *id.* at 338-39 (Stevens, J., dissenting) (stating Court's decision neglects child inability to make living will). *But see In re Quinlan*, 355 A.2d 647, 671-72 (N.J. 1976) (debating termination of life support for comatose adult patient). In contrast, the *In re Quinlan* court affirmed that an adult patient's guardian may opt to terminate the patient's non-cognitive vegetative existence by natural forces if doctors concur there is no hope for recovery, even if there is no proof the patient would have chosen the same outcome. *See id.* The decision to terminate treatment was deemed an extension of the patient's own right to privacy, asserted on her behalf by her guardian. *See id.*

52. *See McMath*, 2016 WL 7188019, at *1 (discussing parental arguments for religious freedom and right to privacy). In *McMath*, the court ultimately deferred to the parents, allowing them to move their daughter to a state where she would be kept alive under a hospital's religious exemption. *See id.*

53. *See Orange Cty. Soc. Servs Agency v. Moises I. & Tamara S. (In re Christopher I.)*, 131 Cal. Rptr. 2d 122, 125-26 (Cal. Ct. App. 2003) (explaining juvenile court's decision to terminate life support). The court noted that the decision regarding withdrawing life-support from a dependent child requires consideration of several factors, including: the child's then-current state of functioning, prognosis for recovery, and life expectancy; the amount of pain caused by the condition and various other medical conclusions on potential treatments; and the presentation of the evidence before the court. *See id.* at 135.

54. 131 Cal. Rptr. 2d 122 (Cal Ct. App. 2003).

55. *See id.* at 125 (affirming clear and convincing evidence standard when determining child's best interest).

56. *See id.* at 141 (discussing father's opposition to ending life support).

57. *See id.* at 125 (outlining earlier court decision examining abuse of child patient).

58. *See* Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (2018). EMTALA outlines that if any person arrives at an emergency room in a hospital that accepts federal funds with an emergency medical condition, the hospital must utilize their staff and resources to stabilize the person, and can only transfer the person if there is consent or stabilization to the point where the transfer is safe. *See id.* § 1395dd(b)-(c).

hospitals' obligations to provide stabilizing treatment to patients presenting in an emergency room with an emergency medical condition, or to transfer the patients to more equipped hospitals if appropriate.⁵⁹ Although seemingly tangential to the Charlie Gard case, this statute is frequently implicated in lawsuits filed by American families seeking mandated life-sustaining treatment for their children.⁶⁰

A noteworthy case examining this point involved Baby "K," an infant with anencephaly; a congenital defect that had no known cure or treatment at the time of the baby's birth and results in very diminished brain functions.⁶¹ The hospital personnel, as well as an ethics committee, consulted about the matter and agreed ventilator care for the infant was futile and inappropriate, but the parents still declined to sign a Do Not Resuscitate order.⁶² The infant was transferred to a nursing home, under the condition that the baby could be taken back to the hospital if under respiratory distress.⁶³ The essence of the hospital's EMTALA argument was that it did not violate the Act by not providing ventilator support because the stabilizing treatment required by the statute should not include this type of support.⁶⁴ Even though the hospital opposed providing treatment it deemed futile, the court held that medical staff was obligated to provide the required ventilator treatment if the baby presented in respiratory distress.⁶⁵

D. Access to Experimental Treatments and the Right to Try Movement

Just as conflicts may arise between hospital personnel and guardians regarding continuing futile (but generally medically accepted) treatments, the Charlie Gard case touches on an equally important point of contention in these cases—how much power the government should have in blocking terminal patients' access to largely untested experimental.⁶⁶ Following the leads of states

59. See *id.* (outlining hospitals' obligations to provide medical treatment to people with emergency medical conditions).

60. See, e.g., *In re Baby "K"*, 832 F. Supp. 1022, 1027 (E.D. Va. 1993) (finding hospital required to provide respiratory support to anencephalic infant under EMTALA), *aff'd*, 16 F.3d 590 (4th Cir. 1994).

61. See *id.* at 1024-25 (outlining facts of case and prognosis for infant). The baby had limited brain stem reflexive responses, was permanently unconscious, and had no ability to hear or see, but had gained weight since birth, had a normal heart rate, blood pressure, and some other bodily functions. See *id.* at 1025.

62. See *id.* (detailing hospital's argument to discontinue ventilator).

63. See *id.* (explaining conditions of infant's transfer to nursing home).

64. See *In re Baby "K"*, 832 F. Supp. at 1026-27 (explaining rationale for hospital's opposition).

65. See *id.* at 1027 (outlining court's response to hospital's claim EMTALA not applicable). The court noted that failure to stabilize the infant's condition if the baby presented in respiratory distress would cause bodily harm and violate EMTALA. See *id.* at 1026-27. Importantly, the obligations under EMTALA end after the immediate acute medical emergency is stabilized. See *Bryan v. Rectors & Visitors of Univ. of Va.*, 95 F.3d 349, 352 (4th Cir. 1996) (limiting scope of obligations under EMTALA). The *Bryan* court held that the hospital's failure to continue providing stabilizing treatment after already providing it for twelve days following the patient's admission did not violate EMTALA. See *id.* at 353.

66. See Michael Rosenblatt & Bruce Kuhlik, *Principles and Challenges in Access to Experimental Medicines*, 313 [J]AMA 2023, 2023-24 (2015) (highlighting safety concerns when granting "compassionate use" of experimental drugs). Early access programs that grant terminally ill patients permission to use drugs not yet

such as California, federal legislation was passed that allows terminally ill people the right to try, and grants terminally ill patients greater access to experimental or not yet fully approved treatments and medications.⁶⁷ Proponents claim that terminally ill patients, with their doctors' guidance, should have the choice to use an unapproved drug rather than rely on the FDA to determine their fate.⁶⁸ Placating many opponents of the state legislative efforts, as well as those who claim state laws on the issues are federally preempted, federal legislation seems more likely to set unified safety standards for allowing early access to such forms of treatment.⁶⁹ Even though the Right to Try Act addresses safety concerns, fears remain that the guiding principle of decision making may be lost with a broad-sweeping rule on complex ethical and medical decisions; doctors cannot be sure they are maximizing the potential benefit for their patients and minimizing potential harm if they are applying a broad decision to all terminal patients seeking to use any unapproved drug.⁷⁰

1. *Expanded Access to Drugs and Emerging Ethical and Safety Concerns*

A main critique raised by physicians and others in the medical community is that the drugs that would become more widely available to terminally ill patients have no proven effectiveness.⁷¹ Manufacturers have equally valid reasons to be

approved for mainstream prescription use are hailed as compassionate solutions to save lives, but many scientists voice concerns that the drugs are not approved because they may be harmful. *See id.* The public is often extremely supportive of these early access efforts simply because the media focuses on individual stories rather than the logistical details of the requests, such as fairness, ethical issues, drug supply levels, and financing. *See id.*

67. *See* S. 204, 115th Cong. § 2 (2017) (enacted) (detailing Senate bill on early access programs); *see also* CAL. HEALTH & SAFETY CODE § 111548.2 (West 2017) (outlining California statute authorizing availability of investigational drugs to eligible patients); Pear & Kaplan, *supra* note 17 (providing overview of voting phases for Senate Bill).

68. *See* Black, *supra* note 18, at 721 (explaining reasoning behind state Right to Try acts); *see also* *Expanded Access*, FDA (Nov. 8, 2018), <https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm> [<https://perma.cc/NNB2-GE63>] (explaining process to use experimental drug outside of clinical trial). Generally, expanded access—otherwise known as compassionate use—involves using an experimental medical device or treatment; in other words, a device or treatment the FDA has not yet approved. *See Expanded Access, supra.* The FDA expanded access policy stresses that it is preferred for patients to use investigational medical products during clinical trials whenever possible, because these trials will produce data that may aide the product's approval and, thus, wider availability. *Id.* If the patient is not eligible for inclusion in a clinical trial, patients may be eligible to receive the drug through the FDA process. *See id.*

69. *See* Black, *supra* note 18, at 740-41 (explaining arguments made by opponents of Right to Try legislation). The state legislation on this issue may be preempted because the FDA already has existing protocols for when compassionate use of experimental drugs is permissible. *See id.*

70. *See* Rosenblatt & Kuhlik, *supra* note 66, at 2023 (predicting issues for doctors and patients created by expanded access programs).

71. *See* Julie A. Jacob, *Questions of Safety and Fairness Raised as Right-to-Try Movement Gains Steam*, 314 [J]AMA 758, 760 (2015) (discussing safety concerns of allowing drug consumption before testing completed); *see also* Carlos Ballesteros, *Critics Warn Trump's Koch-Backed 'Right to Try' Bill is Dangerous for Patients*, NEWSWEEK (Jan. 31, 2018), <http://www.newsweek.com/koch-brothers-conservative-groups-behind-trumps-right-try-bill-796185> [<https://perma.cc/GQ9J-TZZP>] (arguing patient safety threatened by Right to Try Bill). According to Dr. David Gorski, a surgical oncologist and a professor of surgery and oncology, “[i]t can’t

wary of allowing their drugs to be consumed too early in the testing process; a severe—or widely publicized—reaction could seriously damage their chances of successfully getting FDA approval or effectively marketing the drug after it is completely developed.⁷² Bioethicists oppose the movement as well, arguing terminally ill patients will be coerced into trying medications they would not have otherwise tried, and that the laws may simply foster false hope.⁷³ Still, others argue against Right to Try legislation from a more pragmatic position—since the 1980s, the FDA has already had its own program where terminally ill patients can request expanded, early access to drugs undergoing the testing process.⁷⁴ The current process reportedly is not overly burdensome or restrictive, with physicians reporting the paperwork takes approximately two hours to complete, and with ninety-nine percent of approximately 1,000 requests per year already granted.⁷⁵

Proponents of the movement focus on advancing their argument that the Right to Try Act would allow terminally ill patients access to drugs that could potentially save their lives, but are not yet available through traditional prescriptions and pharmacy pick up.⁷⁶ In some instances, the patients may be able to access the medications years before they would otherwise be available.⁷⁷ Additionally, proponents emphasize that the Act does not compete with the FDA approval process, but rather with the three percent of the population that could access the medications through clinical trials.⁷⁸

be stated too often: The goal of right-to-try is not to help terminally ill patients. It's to diminish and weaken the FDA. That's why this latest push to pass federal right-to-try legislation needs to be stopped." Ballesteros, *supra*.

72. See Jacob, *supra* note 71, at 759 (highlighting manufacturers' concerns about expanding access). Manufacturers may also be concerned that if there is a way to access the drug other than through the trials, then patients may no longer participate in randomized clinical trials where they have a chance of receiving the placebo rather than the medication, which is crucial for the FDA approval process. See *id.*

73. See *id.* at 758 (criticizing proposed legislation on ethical grounds); see also Rick Morgan, *Trump Pushing Ahead on Koch-Backed Experimental Drugs 'Right to Try' Agenda*, CNBC (Feb. 21, 2018), <https://www.cnbc.com/2018/02/21/president-trumps-support-for-risky-experimental-drugs-sidesteps-fda.html> [<https://perma.cc/C4RX-7D5P>] (presenting potential Right to Try Bill safety issues); Jill Sheridan, *National Right to Try Law Passes, Bears Name of Hoosier Boy*, WFYI INDIANAPOLIS (May 23, 2018), <https://www.wfyi.org/news/articles/national-right-to-try-law-passes-bears-name-of-hoosier-boy> [<https://perma.cc/PNH2-7M8U>] (illustrating how few success stories used to bolster Right to Try movement).

74. See Jacob, *supra* note 71, at 758 (discussing current process of requesting early access through FDA). Some patients and doctors did raise concerns that after the application is submitted, approval can take two to four months. See *id.* Additionally, critics point out that the FDA does not publicize specific drugs approved for early access programs. See *id.*

75. See *id.* at 758-59 (outlining success of requests through traditional process); see also Goldwater Inst., *Federal Right to Try: Questions and Answers*, RIGHT TO TRY (2017), <http://righttotry.org/rtt-faq/> [<https://perma.cc/X4JE-8969>] (explaining new process for expanded access). Critics of the FDA's data highlight that some patients requesting treatment may not receive it until after they have passed or are too ill to begin a new treatment course. See Jacob, *supra* note 71, at 758.

76. See Goldwater Inst., *supra* note 75 (explaining basics of Right to Try Act and advocating for movement).

77. See *id.*

78. See *id.* (highlighting Right to Try Act targets gap in patient access). About one million Americans die of terminal illnesses every year, and the Act seeks to offer cures to those unable to gain access to a clinical trial. See *id.*; see also Goldwater Inst., *Right to Try Fact vs. Fiction*, RIGHT TO TRY (Sept. 28, 2017), <http://righttotry.org>

In combination with the FDA's existing process to request early access, the 21st Century Cures Act requires drug companies to be more transparent about who gets access to medications being tested and how long the process is expected to take, allowing patients and providers to make more informed decisions about requesting drugs.⁷⁹ If drug development were to become more patient-centric, the need for specific legislation may be diminished.⁸⁰

2. *The Right to Try Act and Financial Concerns*

Regardless of which path patients utilize to access experimental or early access drugs, issues regarding equal access are unavoidable.⁸¹ Because of the extremely high prices of many of these drugs and the lack of set insurance prescription rates, companies are essentially free to charge vulnerable, desperate patients any price they decide.⁸² Without the insurance coverage, doctors are

[g/right-to-try-fact-vs-fiction/ \[https://perma.cc/E89X-KDNF\]](https://perma.cc/E89X-KDNF) (debunking common myths about Act).

While the FDA does approve almost all of the compassionate use applications it receives, it is beyond comprehension that fewer than one out of every one-thousand terminal patients would wish to do so. Something is clearly amiss in a system that is so bureaucratic and time-consuming that fewer than one-tenth of one percent of terminal patients can take advantage of the FDA's compassionate use exception. The FDA granted fewer than 1,300 compassionate use requests in 2015. That same year, more than 1.3 million died from the three leading disease killers of heart disease, cancer, and chronic obstructive pulmonary disease (COPD), alone. . . . Federal Right to Try legislation would make compassionate use the rule, not the exception.

Goldwater Inst., *supra*. Additionally, the legislation works in tandem with the FDA safety requirements, rather than as a way to thwart regulations. *See id.*

79. *See* 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016) (outlining responsibilities of federal agencies under legislation); Joshua M. Sharfstein & Michael Stebbins, *Enhancing Transparency at the US Food and Drug Administration*, 317 [J]AMA, 1621, 1621 (2017) (emphasizing importance of transparency for biomedical community). Because the FDA does not disclose when drugs are tested through clinical trials, patients and physicians are not able to make the most informed decisions on potential treatment possibilities if trials are halted because of safety issues, new applications are filed, or drugs or devices qualify for expedited reviews. *See* Sharfstein & Stebbins, *supra*, at 1621 (discussing FDA's obligation to ensure medical advances safe and effective).

80. *See* PRACTICAL LAW LIFE SCIS., 21ST CENTURY CURES ACT: KEY FDA PROVISIONS ON DEVELOPING PHARMACEUTICALS § 3002 (2017), Westlaw W-007-6226 (outlining main provisions of 21st Century Cures Act).

81. *See* Jacob, *supra* note 71, at 760 (discussing distributive justice problems associated with inability to finance treatments). As traditional insurance does not often cover experimental or unapproved treatments, there is a concern that those with the most "likable" stories are more likely to be funded, or that only those with extensive resources or strong networking and financial connections will receive the treatment. *See id.* Ethicists also stress that the patients who ultimately receive the experimental treatments (outside of traditional clinical trial settings) will not necessarily seem fair to the public, or those applying. *See id.* Dave Wendler, Ph.D., head of the section on research ethics in the department of bioethics at the National Institutes of Health Clinical Center, states that "[t]here is a natural tendency to regard the needs and concerns of identifiable people more than the people you don't see pictures of," stressing the danger of the Right to Try Act being used for only those with the most publicized, funded campaigns. *See id.*

82. *See* Jennifer Rudenick Ecklund & Andrew Cookingham, *Strategies for Responding Effectively to a Denial of Treatment as Experimental or Investigational*, AM. HEALTH LAW. ASS'N J. HEALTH & LIFE SCI. L., June 2015, at 8, 22-23 (explaining procedure for determining whether treatment experimental and not covered

forced to balance their desire to provide any hope of treatment to their terminal patients with the risk of unknown side effects and outcomes.⁸³

As with all financial concerns, fears that the impoverished will be disproportionately affected are frequently voiced, which is already a common problem impeding access to healthcare for many.⁸⁴ Advocates of the movement, however, state that access and financial concerns will be addressed properly because the existing FDA payment rules will apply, regulating early access prices.⁸⁵ Additionally, the law's proponents stress that those seeking the drugs are now being forced to pay whatever price foreign manufacturers demand, and the proposed process would reduce obstacles for Americans placed in this position.⁸⁶

E. Alternative Approaches to Futile Care Requests

Circumventing the issue of parental decisions and conflict over access to experimental drugs, some state legislation—most notably that of Texas—allows healthcare providers to have more definitive power over treatment choices.⁸⁷ The Texas Advance Directives Act provides freedom from liability for withholding life-sustaining treatment if physicians or healthcare providers exercise reasonable care while doing so.⁸⁸ If a treating physician refuses to

because outside scope of plan); Natalie L. Regoli, *Insurance Roulette: The Experimental Exclusion & Desperate Patients*, 22 QUINNIAC L. REV. 697, 701-04 (2004) (describing experimental treatment exclusion).

83. See Regoli, *supra* note 82, at 708-09 (discussing insurance procedures to deny coverage); see also Jennifer Belk, Comment, *Undefined Experimental Treatment Exclusions in Health Insurance Contracts: A Proposal for Judicial Response*, 66 WASH. L. REV. 809, 809-10 (1991) (highlighting general insurance policy exclusion of experimental treatments).

84. See *Miller ex rel. Miller v. Whitburn*, 10 F.3d 1315, 1320 (7th Cir. 1993) (analyzing denial of experimental treatment to child recipient of Medicaid). As delineated in *Miller ex rel. Miller*, federal assistance programs typically do not cover experimental treatments. See *id.* at 1319-20. The court noted that the definition of “experimental” it offered barely differed, if at all, from the criteria the Department of Health and Human Services developed in determining whether a specific procedure could be categorized as experimental. See *id.* at 1320. People relying on federal funding have access that is even more impeded than other American citizens, with determinations of coverage made based on: the medical community’s prior and contemporary judgment “as evidenced by medical research, studies, journals[,] or treatises”; the extent that the service is recognized and covered by private health insurers and Medicare; and the opinions of “experts and specialists in the medical specialty area in which the service is applicable or used.” *Id.*

85. See *Goldwater Inst.*, *supra* note 78 (arguing manufacturers cannot abuse patients’ financial means).

86. See *id.* (stating Bill better for patient treatment, length of life, and quality of life).

87. See TEX. HEALTH & SAFETY CODE § 166.044 (West 2017) (outlining limitation of liability for withholding or withdrawing life-sustaining procedures); *id.* § 166.046(a) (explaining procedure for refusing to honor directive or treatment decision). Both sections of the statute helped to clarify how doctors were to proceed if they felt requested treatment was futile, as well as assured their adherence to the American Medical Association (AMA) guidelines would not necessarily expose them to liability. See HEALTH & SAFETY §§ 166.044, 166.046(a).

88. See *id.* § 166.044 (outlining limitation of civil liability for physicians who withhold life-sustaining treatment); *id.* § 166.046(a)-(b)(1) (delineating procedure for review of physician refusal to honor advance directive or treatment decision). In limiting liability, the statute dictates: “A physician or health care facility that causes life-sustaining treatment to be withheld or withdrawn from a qualified patient in accordance with this subchapter is not civilly liable for that action unless the physician or health care facility fails to exercise

provide life-sustaining treatment because he or she feels it is medically inappropriate or futile, an ethics committee then reviews the decision to see if it is indeed medically inappropriate.⁸⁹ While the committee meets, the treating physician must continue to provide the patient with life-sustaining treatment.⁹⁰ The ethics committee process has been upheld by judicial review in states such as Kentucky, and is a potential way to resolve certain treatment disputes internally.⁹¹

Many medical and ethical experts agree that providing futile care where life may be extended by years with no improvement in quality strains the healthcare system without achieving the medical community's objective of improving patient outcomes.⁹² Generally, medical decisions are made by considering four bioethical principles—respect for autonomy, beneficence, non-maleficence, and justice—and the argument can be made that continuing futile care violates all four principles.⁹³ With Americans placing increasing importance on autonomy,

reasonable care when applying the patient's advance directive." See HEALTH & SAFETY § 166.044(a); see also Robert Pear, *House Rejects Bill to Give Patients a 'Right to Try' Experimental Drugs*, N.Y. TIMES (Mar. 13, 2018), <https://www.nytimes.com/2018/03/13/us/politics/house-rejects-right-to-try-bill.html> [https://perma.cc/9Z2E-PNBZ] (discussing protection from liability included in Bill).

89. See HEALTH & SAFETY § 166.046(a), (b)(1), (b)(4)(B) (listing procedure for ethics committee review of physician refusal to follow advance directive). If the attending physician, patient, or individual making healthcare decisions for the patient disagrees with the committee's decision, "the physician shall make a reasonable effort to transfer the patient to a physician who is willing to comply with the directive." *Id.* § 166.046(d).

90. See *id.* § 166.046(a) (explaining statutory obligation to continue providing care to patient during review process). Outlining the exact requirements for the review process, the statute states that "if an attending physician refuses to honor a patient's advance directive . . . the physician's refusal shall be reviewed by an ethics or medical committee. The attending physician may not be a member of that committee. The patient shall be given life-sustaining treatment during the review." *Id.*

91. See *Woods v. Commonwealth*, 142 S.W.3d 24, 30-31 (Ky. 2004) (upholding constitutionality of guardian *ad litem* decision to withdraw ventilator). The *Woods* court recognized a guardian *ad litem*'s acceptance of an ethics committee decision to end futile treatment as constitutional. See *id.*; see also KY. REV. STAT. ANN. § 311.631 (West 2004) (delineating Kentucky Living Will Directive Act referenced in *Woods*). The court stated:

We find no constitutional infirmity *per se* in the Kentucky Living Will Directive Act. It specifically avoids violating the inalienable right to life because it does not "condone, authorize, or approve mercy killing or euthanasia," or "permit any affirmative or deliberate act to end life other than to permit the natural process of dying."

See *Woods*, 142 S.W.3d at 42. Additionally, the court stated that "the patient's liberty interest to be free of treatment outweighs any interest the patient may have in maintaining a biological existence." See *id.*; see also Robert L. Fine, *Medical Futility and the Texas Advance Directives Act of 1999*, 13 BAYLOR MED. CTR. PROC. 144, 145 (2000) (suggesting Massachusetts judicial support regarding doctor's determination of medical futility).

92. See Mary Johnston, Article, *Futile Care: Why Illinois Law Should Mirror the Texas Advanced Directives Act*, ANNALS HEALTH L. ADVANCE DIRECTIVE, Spring 2014, at 27, 27 (arguing against unnecessary medical procedures because harmful to healthcare system and patients).

93. See *id.* at 30-33 (explaining futile care violates basic medical ethics principles). Importantly, futile care is not equivalent to all end-of-life care, as palliative care has the goal of relieving pain and suffering, while futile care does not relieve pain and suffering or improve the patient's underlying medical conditions. See *id.* at 29-30. Regarding the medical ethics principles, respect for autonomy refers to both the patient's and doctor's rights to make their own decisions, beneficence requires doctors to promote the well-being of their patients, non-

even in the face of definitive medical advice, patients and family members may continue to request futile treatments, which could potentially place a great strain on the patient's dignity and bodily integrity.⁹⁴

III. ANALYSIS

Widespread international media coverage of dramatic cases like the recent Charlie Gard case, and past American controversies over Baby "K" and Christopher I., often inspire blind advocacy for strong laws championing parental rights to request experimental treatment for their children.⁹⁵ While this sounds like an easy point a politician could advance to gain support, constituents must first take a deeper look at the potential consequences of this movement and see how drastically and negatively this movement could affect the path of any case similar to the Charlie Gard case that occurred in England.⁹⁶ Politicians often fear that by opposing any sort of Right to Try legislation, they will seem callous and cold; while the reality is that the current FDA drug testing phases are in place to protect the public from side effects of drugs not yet proven safe or effective for public use.⁹⁷ Although some may argue it is overly burdensome and bureaucratic, the medical community widely sees Right to Try legislation as

maleficence imposes a duty on physicians not to cause unnecessary harm, and justice refers to achieving the correct distribution of scarce medical resources. *See id.* at 30-32; *see also* Fine, *supra* note 91, at 145 (discussing AMA approach to medical futility issues). The AMA Council on Ethical and Judicial Affairs recommended guidelines on medical futility that involved a process-based approach, with counseling and deliberation, and an eventual transfer of the patient to an alternative provider if the disagreement could not be resolved. *See* Fine, *supra* note 91, at 145. If no resolution could be achieved and no transfer to a willing provider could be arranged, according to ethical standards, stopping treatment was acceptable. *See id.* The guidelines did note that the legal ramifications for stopping treatment were uncertain, an important point clarified by the Texas Advance Directives Act. *See id.* Before this uncertainty was remedied, however, the AMA guidelines could not be effectively followed by doctors without fear of liability. *See id.* The Texas Advance Directives Act is viewed as in sync with the AMA guidelines. *See id.*

94. *See* Arthur L. Caplan, *Little Hope for Medical Futility*, 87 MAYO CLINIC PROC. 1040, 1040 (2012) (emphasizing danger of society's fixation on autonomy over bodily dignity). Because of the fixation on autonomy, focus on more effective end-of-care procedures may be more frequently needed than end-of-life decision-making committees. *See id.*

95. *See generally In re Baby "K"*, 832 F. Supp. 1022 (E.D. Va. 1993) (finding hospital obligated to provide respiratory support to anencephalic infant under EMTALA), *aff'd*, 16 F.3d 590 (4th Cir. 1994); *In re Christopher I.*, 131 Cal. Rptr. 2d 122 (Cal. Ct. App. 2003) (explaining juvenile court decision to terminate life support). *In re Christopher I* examined a situation where the court held there was clear and convincing evidence that ending life-sustaining treatment was in the best interests of a terminally ill child, reaching a decision where the public could easily perceive the judicial interference was inappropriate. *See* 131 Cal. Rptr. 2d at 125.

96. *See* Jacob, *supra* note 71, at 759 (highlighting issues of safety and fairness resulting from proposed legislation). In her article, Jacob present arguments that the expanded access to drugs would not be as beneficial as widely believed. *See id.* While many argue these laws represent capitalism's market freedom, "[r]ight-to-try laws are 'symbolic of the desire for hope, that newer is always better,' said Nancy Berlinger, PhD, a research scholar with the Hastings Center, a bioethics institute." *See id.* Reflecting on general trends, Jacob also discusses that throughout the years, various drugs have been promoted as promising treatment options, and only much later proven ineffective or unsafe. *See id.*

97. *See supra* notes 71-73 and accompanying text (discussing safety concerns regarding legislation).

unnecessary, with routes to petition for early use of not yet FDA passed drugs already commonly, and successfully, used when patients request to do so.⁹⁸

A main concern for opponents of the Right to Try legislative movement is that parents will subject children to futile treatment simply because it will be accessible, not because it will improve the child's prognosis or quality of life.⁹⁹ Citizens may strongly feel this private family domain should not be subjected to judicial interference, but there are strong arguments that emotional guardians may not make the most selfless choices for their sick children.¹⁰⁰ If there is no proof a treatment will help a child, and potential side effects are not known, it does not seem beneficial to allow parents to continue electing futile treatment simply because there are laws that say they may do so.¹⁰¹ Issues also arise when the medical community claims further treatment may cause additional pain without benefit—arguing that the family should still have a relatively unrestrained right to try experimental drugs will undoubtedly lead to enormous amounts of litigation.¹⁰² The FDA and pharmaceutical companies will likely find ways to avoid liability if families later claim a patient was negatively impacted, but allowing a medical system to run unchecked by judicial remedies likely will not lead to just administration of the drugs.¹⁰³

Financial status will likely be more important in determining patient outcomes than ever before.¹⁰⁴ Consequently, lower income families or families unable to

98. See Jacob, *supra* note 71, at 759 (highlighting efficacy of current FDA early access process); see also *Expanded Access*, *supra* note 68 (discussing procedure to request use of experimental drug outside of clinical trial). On its website, the FDA states that it approves ninety-nine percent of the requests it receives, and treatment can begin thirty days after the FDA receives the request, or earlier if the FDA contacts the physician who filed the application. See *Expanded Access*, *supra* note 68.

99. See Johnston, *supra* note 92, at 34 (arguing futile treatment harmful to healthcare system and patients). A central argument against futile care is that technological advances extend patients' lives, but their underlying conditions are not treated or improved. See *id.*

100. See Pickles, *supra* note 2 (outlining ethical dilemmas raised by cases like Charlie Gard's). Although Matt Pickels, an ethicist, opposed the ultimate court decision, he discussed the need for legal protections when parents request unnecessary medical procedures. See *id.* However, he argues that these legal protections should not come into play unless there is disagreement between parents, a need to immediately prevent travel for medical care, a decision that would jeopardize the child's safety, or a clear medical opinion that the parents' choice is unreasonable. See *id.*

101. See Firth, *supra* note 23 (discussing concerns regarding Right to Try movement). The medical community raised concern with the Bills; on the issue of Right to Try legislation, the American Society of Clinical Oncology stated: "We don't support right-to-try legislation, however, because these laws ignore key patient protections without actually improving patient access to investigational drugs outside of clinical trials." *Id.*

102. See *supra* notes 71-73 and accompanying text (discussing concerns raised by medical community regarding legislation and potential effects on patients).

103. See Rosenblatt & Kuhlik, *supra* note 66, at 2024 (discussing problems arising from public perception of early access programs). The public and the media are often more persuaded by individual stories than scientific studies, without truly considering efficacy or outcomes of controlled studies. See *id.* Without interference and education from authorities, unsafe or untested drugs may be more frequently requested and consumed. See *id.*

104. See Firth, *supra* note 23 (highlighting concerns regarding access to consumers under Right to Try Bill). The Bill has been criticized as potentially costly to consumers: "The [B]ill does limit what patients can be charged for investigational drugs to companies' actual direct costs of providing them. (But enforcement could be difficult: [C]ompanies are not required to inform regulators of what they provide to individual patients, nor

mount largescale fundraising campaigns will be left without the same access to drugs as wealthier patients, which is an outcome that seems to directly conflict with the stated intent of the movement.¹⁰⁵ If judges and hospital ethics committees are unable to act as moderators to override emotion-driven, but likely harmful, last ditch efforts by families, then financial considerations will become the final hurdle to determine which patients can access experimental, but likely futile, treatments.¹⁰⁶

Pharmaceutical companies will likely oppose the movement because of the potential for negative publicity; if they are forced to allow access to drugs they have no solid evidence will be effective, there will be nothing stopping families that suffer negative outcomes from going to the press to share horrible anecdotes regarding drugs that the company knew were not yet ready for public consumption.¹⁰⁷ While this may very well affect the public's opinion of the pharmaceutical company in question, it may also ultimately save them money—evidence a drug will not work may result in a canceled trial, saving companies the cost of large clinical trials, and they will likely be shielded from liability for any negative effects.¹⁰⁸ Conversely, there is the slight possibility the companies

the costs to patients.)” *Id.*; see *supra* note 82 and accompanying text (explaining insurance industry’s general refusal to cover experimental treatments). Much like the court systems, the insurance industry also largely refuses to be involved with coverage for experimental procedures. See *supra* note 82 and accompanying text.

105. See Rosenblatt & Kuhlik, *supra* note 66, at 2023 (examining issues of fairness relating to early access programs). Fairness should require prioritization of patient safety, but financial considerations could impede this process. See *id.*

106. See Belk, *supra* note 83, at 809 (explaining health insurance typically denies experimental treatments). As well as potentially allowing companies to directly charge consumers under the Right to Try Act, patients may also lose another judicial remedy—the right to petition for insurance coverage of experimental procedures denied as unproven. See *id.*

107. See Rosenblatt & Kuhlik, *supra* note 66, at 2024 (listing unresolved issues stemming from early access programs). On the issue of publicity, the media could end up detrimentally affecting trials:

Although the media’s “story line” regarding EAPs [expanded access programs] often pits patients against industry, it rarely presents the individual’s interest vs that of the larger group with the same disease. If early access slows or compromises clinical trials, then many patients will be deprived. Because many patients requesting early access are extremely ill and are outside the profile of patients eligible to participate in clinical trials, serious adverse events, including death, occur. If such an event occurs in an EAP, it might not be possible to determine if it is drug-related. As a result, a promising therapy might be delayed, or even abandoned before sufficient clinical trial data can be generated.

Id.

108. See Firth, *supra* note 23 (discussing need for pharmaceutical industry involvement in Right to Try movement). Although it is unclear if the industry as a whole will embrace the legislation, there was no widespread support for the Act, and some companies, like Merck, have opposed it as well intentioned but unlikely to lead to production of innovative, safe new drugs. See *id.* Additionally, the Act’s text does not force companies to provide requested early access to their medications. See *id.*; see also Ballesteros, *supra* note 71 (discussing limitations of safety monitoring under Right to Try Bill). If a patient uses an experimental drug under this Act and suffers an adverse reaction or even dies in a way that is clearly linked to the drug, other people may not be warned because the FDA cannot consider that data when later deciding if they should approve the drug. See Ballesteros, *supra* note 71; see also Pear, *supra* note 88 (discussing protection from liability included in Act). The Act protects pharmaceutical companies from the legal hazards of providing unapproved drugs, and hospitals

will feel the effects of positive stories emerging from perceived miracle cures, essentially leading to free press, and a “cured child” to bolster public opinion regarding the drug while further testing occurs.¹⁰⁹ If a company thinks a drug may be effective, there is the potential that pharmaceutical companies could “poach” highly public, wealthy families in desperate situations hoping the drug will work; a future where pharmaceutical representatives can influence desperate medical choices and undermine the FDA process is likely if people have free access to any treatment they can afford.¹¹⁰ Through the Right to Try legislation, drug companies will essentially have a liability-free method of testing drugs without any indication of their efficacy, a point raised by medical groups publicly opposing the movement.¹¹¹ The FDA’s power and function as a gatekeeper for the American public’s safety will be irreversibly damaged, and pharmaceutical companies will now have a method to provide immediate access to any drugs they choose.¹¹²

The legislation also duplicates options already available to families seeking early access to medications.¹¹³ The medical community widely states that the data does not support the claim that the FDA system is ineffective or slow in approving requests for early access, and still argues that many of these requests only foster false hope for families already suffering with the reality of a terminally ill family member.¹¹⁴ From a safety perspective, the FDA program has the added protection of a treating physician vouching that the early expanded access to the drug will not subject the patient to more risk than condition they are already afflicted with—an option not available under the new legislation.¹¹⁵

Considering the Charlie Gard case and the hypothetical outcome if it were to occur in America, it would likely be difficult for the family to attain the requisite support from a treating physician, a determination from the FDA that the drug had sufficient evidence and support of efficacy for his condition, and a

and doctors cannot be found liable either unless they engaged in gross negligence or willful, reckless, or criminal misconduct. *See* Pear, *supra* note 88.

109. *See* Sheridan, *supra* note 73 (highlighting successful patients behind naming of new law).

110. *See* Ballesteros, *supra* note 71 (highlighting safety concerns with Bill).

111. *See id.* (discussing limited liability for companies and doctors under Bill). The Right to Try Act limits patients’ legal recourse in the event of malpractice or negligence; under the current FDA regulations, patients retain their right to sue and cases are monitored by an institutional review board. *See id.* The Right to Try Act, however, shields physicians administering medications and states they generally cannot be held liable. *See id.*

112. *See* Morgan, *supra* note 73 (detailing medical opposition to Bill). As of February 6, 2018, thirty-eight patient advocate groups had written to Congress to argue the Bill would harm terminally ill patients. *See id.* The groups included organizations like the American Lung Association and the American Cancer Society Cancer Action Network. *See id.* These groups expressed concerns that the Bill would potentially exploit vulnerable patients and provide any unethical pharmaceutical company ways to sell possibly unsafe medicine directly to consumers without FDA oversight. *See id.*

113. *See id.* (outlining success of current FDA request process). The letter to Congress from patient advocacy groups highlighted the success of the current FDA expanded access program, stating the approval rate reported by the FDA was 99.7% and discussing FDA efforts to even further streamline the process. *See id.*

114. *See* Jacob, *supra* note 71, at 758-59 (discussing physician opposition to bills).

115. *See Expanded Access*, *supra* note 68 (outlining requirements for expanded access requests).

declaration that the treatment would cause less potential harm than the condition itself.¹¹⁶ A situation like that is precisely where the Right to Try Act comes into play, essentially allowing parents to become doctors, disregarding all medical advice and possibly subjecting a terminally ill child to anything they can afford.¹¹⁷ Although Americans typically do not feel the government makes decisions in the best interest of all individuals, this may be a situation where objective policy and judicial review is necessary to protect patient safety and override emotional, hasty treatment decisions unlikely to benefit patients.¹¹⁸

IV. CONCLUSION

The Charlie Gard case and its controversy are strong indicators of current public sentiment regarding the right to treatment. The resulting international debate coincided with a renewed American opinion of a citizen's right to try drugs that the FDA has not approved. The Charlie Gard issue highlighted the legal concerns that arise when parents consider subjecting a child without the capacity to consent to treatment that the medical community considered futile. Situations like this will only become more commonplace in America with the Right to Try Act enacted, and hospitals and doctors will be administering drugs and treatments for which they cannot guarantee regulation or safety.

Any bill aiming to expand access by terminally ill patients seems likely to gain widespread support from both citizens and politicians. Looking back at past American medical ethics dilemmas, the Charlie Gard case, and the European resolution, it becomes clear that expanded access will not be the immediate panacea many imagine. Going forward, the Act's implications on patient safety and drug regulation must be considered by politicians, patients, doctors, and citizens, and should be carefully balanced with the general desire to have the freedom to make medical decisions for ourselves and our children.

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116. *See id.* (explaining FDA application process to use experimental drug outside of clinical trial).

117. *See* Bidari, *supra* note 13, at 2-3 (analyzing when court denial of parental requests for juvenile futile treatment appropriate). Bidari discusses cases where emotional, parental requests to continue futile treatment were overruled by court decisions, a process that the legislation could drastically interfere with. *See id.*

118. *See* Rosenblatt & Kuhlik, *supra* note 66, at 2024 (stressing unresolved problems with administration of early access programs). Regarding the necessity of objective decision makers, Rosenblatt and Kuhlik point out:

Decision making around patient eligibility for an EAP is often complex and emotionally charged. Regulatory authorities should retain their independent role in overseeing these programs. In addition, consideration should be given to establishing "appeals boards" that include members external to the biopharmaceutical company. The model for determining access for organ transplantation has elements that may guide EAPs, although substantial differences exist that weigh oppositely.