

# THE FUTILITY OF FUTILITY: AN ANALYSIS OF THE CHARLIE GARD CASE WITHIN THE FRAMEWORK OF U.S. LAW

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## TABLE OF CONTENTS

INTRODUCTION .....	464
I. BACKGROUND.....	467
A. <i>Child, Family, and State</i> .....	467
B. <i>Research Laws and the Right to Experimental Treatment</i> .....	470
1. Research Laws .....	470
2. The Right to Experimental Treatment .....	473
C. <i>Withdrawal of Life-Sustaining Treatment in the Face of Futility</i> .....	478
II. ANALYSIS: WHO SPEAKS FOR THE CHILD? .....	481
A. <i>What Would Have Happened to Charlie Gard in the United States</i> .....	481
B. <i>Futility Statutes</i> .....	488
1. Red Light.....	488
2. Yellow Light.....	490
3. Green Light.....	491
III. PROPOSAL.....	494
A. <i>Counterarguments</i> .....	498
CONCLUSION.....	500

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## INTRODUCTION

It is extraordinarily difficult to determine the appropriate course of treatment for a child with a terminal illness. One possible approach is to assess the futility of all possible treatments. But what constitutes futility? The medical community seems comfortable with saying that treatment can be medically futile in a specific context, but formulating an objective and precise definition of this concept is the topic of ongoing debate.<sup>1</sup> This Note uses the case of Charlie Gard (Charlie) to illustrate the complexities of defining a condition or treatment as medically futile and to show that such an endeavor is itself futile.

Charlie was born on August 4, 2016 with a rare and fatal mitochondrial DNA depletion syndrome.<sup>2</sup> Within his first few weeks of life, his parents noticed that he was unable to support his head in the same way babies of a similar age could.<sup>3</sup> By October 2, 2016, his parents noticed that he was not gaining weight despite being fed every two to three hours.<sup>4</sup> By October 11, 2016, Charlie was lethargic and his breathing was shallow.<sup>5</sup> He was then admitted to Great Ormond Street Hospital for Children, where he would remain until his death.<sup>6</sup>

Eager to find a treatment for their son, Charlie's parents wanted to transfer him to Columbia University Medical Center to be treated with an experimental nucleoside therapy designed by Dr. Hirano.<sup>7</sup> On the other hand, Charlie's doctors at Great Ormond Street Hospital in the

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<sup>1</sup> See Nancy S. Jecker, *Medical Futility*, U. WASH. SCH. OF MED., <https://depts.washington.edu/bioethx/topics/futil.html> [<http://perma.cc/V45Y-UD8Y>] (last modified Mar. 14, 2014) (explaining that lack of clarity regarding the definition of medical futility stems from the fact that the term invites subjective values to define it: “[M]edical futility can create the false impression that medical decisions are value-neutral and based solely on the physician’s scientific expertise. Yet clearly this is not the case. The physician’s goal of helping the sick is itself a value stance, and all medical decision making incorporates values.”); see also *infra* Section I.C (explaining how the word “futile” is ambiguous, and thus subject to multiple interpretations that would affect the determination of whether a certain course of treatment is in fact futile). See generally Peter A. Clark, *Medical Futility in Pediatrics: Is it Time for a Public Policy?*, 23 J. PUB. HEALTH POL’Y 66, 69 (2002).

<sup>2</sup> *Great Ormond Street Hospital v. Yates* [2017] EWHC (Fam) 972 (Eng.), <http://www.bailii.org/ew/cases/EWHC/Fam/2017/972.html> [<http://perma.cc/ZEN7-B3N5>].

<sup>3</sup> *Id.* at [44].

<sup>4</sup> *Id.* at [65].

<sup>5</sup> *Id.* at [45].

<sup>6</sup> *Id.*

<sup>7</sup> See Paul Harper, *Who is Michio Hirano? Charlie Gard Doctor from the US Who Believed Nucleoside Bypass Therapy Could Help Tot*, THE SUN (July 28, 2017, 7:19 PM), <https://www.thesun.co.uk/news/4019994/michio-hirano-charlie-gard-doctor-nucleoside-bypass-therapy> [<http://perma.cc/QQ2R-ZT7R>]. Dr. Hirano is a neurologist and Medical Director of the Laboratory of Molecular Genetics/Laboratory of Metabolic and Mitochondrial Disease at Columbia University. *Michio Hirano, MD*, COLUM. U. DEP’T OF NEUROLOGY, <http://columbianeurology.org/profile/mhirano> [<http://perma.cc/R5X-58P7>] (last visited Aug. 27, 2018).

United Kingdom felt that, medically, it was in Charlie's best interest<sup>8</sup> to be removed from life support and to die with dignity.<sup>9</sup> Because the hospital disagreed with Charlie's parents regarding the best course of treatment, on March 3, 2017, judicial intervention was sought in order to override their parental responsibility.<sup>10</sup> On July 24, 2017, Charlie's parents ended the legal battle over their son's right to experimental and life-sustaining treatments,<sup>11</sup> as any treatment would have been futile in improving or prolonging his quality of life.<sup>12</sup> Charlie died shortly thereafter.<sup>13</sup>

The legal issues presented in Charlie's case raise significant questions about a U.S. state's role in medical decisions, family members' interests, and the ethics of using experimental treatment.<sup>14</sup> Specifically, this case raises two questions: (1) who is the best authority to determine, in the face of futility, whether prolonging or withdrawing life-sustaining treatment is in the best interest of a minor; and (2) whether state or physician-made decisions regarding end-of-life care and experimental treatment, which are based predominantly on medical speculation, can be enforced against a parent's wishes.<sup>15</sup> These questions, and Charlie's case in general, exemplify the pitfalls and inconsistencies of defining futility broadly.

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<sup>8</sup> For the purposes of this Note, any mention of the best interest standard is referring to the medical, and not legal, standard. The best interest standard is "the most widely embraced guidepost for surrogate decisions . . . [and] serves primarily to protect and promote the well-being of vulnerable patients," such as infants or those who are unable to make their own decisions and for whom there is no indication of their prior wishes. *WHEN OTHERS MUST CHOOSE: DECIDING FOR PATIENTS WITHOUT CAPACITY*, N.Y. ST. TASK FORCE ON LIFE & L. 55 (1992), [https://www.health.ny.gov/regulations/task\\_force/reports/publications/docs/when\\_others\\_must\\_choose.pdf](https://www.health.ny.gov/regulations/task_force/reports/publications/docs/when_others_must_choose.pdf) [<http://perma.cc/Q84K-P8K2>].

<sup>9</sup> 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/SY4A-B8A4>].

<sup>10</sup> *Reality Check: Why Don't Charlie Gard's Parents Have the Final Say?*, BBC NEWS (July 14, 2017), <http://www.bbc.com/news/uk-40600932> [<http://perma.cc/67R4-3XXP>]; *Charlie Gard: The Story of His Parents' Legal Fight*, BBC NEWS (July 27, 2017), <http://www.bbc.com/news/health-40554462> [<https://perma.cc/WS5S-RWXH>].

<sup>11</sup> See *Charlie Gard: The Story of His Parents' Legal Fight*, *supra* note 10.

<sup>12</sup> Susan Scutti, *Could Charlie Gard's Case Happen in the United States?*, CNN HEALTH (July 6, 2017, 2:17 PM), <http://www.cnn.com/2017/07/06/health/charlie-gard-us-laws/index.html> [<https://perma.cc/7E84-Q4Y7>].

<sup>13</sup> Charlie died on July 28, 2017 after his life support was withdrawn. Gregg Heffer, *Timeline: Parents' Battle to Save Charlie Gard*, SKY NEWS, <http://news.sky.com/story/timeline-parents-battle-to-save-charlie-gard-10914755> [<http://perma.cc/HJY5-5NRH>] (last visited Aug. 27, 2018).

<sup>14</sup> Michael S. Dauber, *Charlie Gard, Compassionate Use, and Single-Payer Health Care*, HASTINGS CTR. (July 26, 2017), <http://www.thehastingscenter.org/charlie-gard-compassionate-use-single-payer-health-care> [<http://perma.cc/9VDT-YH69>].

<sup>15</sup> Michael S. Dauber, *Why Charlie Gard's Case is So Disturbing to Americans*, STAT NEWS (July 13, 2017), <https://www.statnews.com/2017/07/13/charlie-gard-life-support-ethics> [<http://perma.cc/FM9P-TULM>].

In mediating medical futility disputes,<sup>16</sup> parents' interests in making their children's medical decisions must be balanced against the states' interests in protecting minors from unnecessary or prolonged harm, as well as maintaining the integrity of the medical profession.<sup>17</sup> Current U.S. futility statutes do not properly balance these countervailing interests because they give no guidance as to what can, or should be, characterized as medically futile.<sup>18</sup> The guidelines set forth by the American Thoracic Society (the ATS) remedy this problem,<sup>19</sup> and states should amend their futility statutes to reflect its recommendations.

Part I of this Note examines the disparate legal frameworks of the United States and the United Kingdom with respect to parental rights. Next, this Part analyzes an infant's right to have access to experimental treatment for life-prolonging or life-sustaining purposes in the United States.<sup>20</sup> Finally, this Part examines the right to withdraw life-sustaining treatment, exploring the countervailing interests of parents and states. Due to the states' police powers under the Tenth Amendment<sup>21</sup> to regulate the health, safety, and welfare of its inhabitants, futility statutes vary across states. Part II analyzes three distinct approaches: in "red light" states, providers cannot withdraw life-sustaining treatment without parental or surrogate consent; in "yellow light" states, providers must abide by judicial standards when withdrawing life-sustaining treatment; and in "green light" states, providers can withdraw treatment without parental or surrogate consent.<sup>22</sup>

Lastly, Part III of this Note proposes that the ATS's procedural guidelines for assessing medical decisions in the face of futility should be adopted by all states. The lack of a uniform definition of medical futility results in subjective, value-laden interpretations and vague state policies.<sup>23</sup> This contributes to the inherent flaws apparent in each of the three types of futility statutes in the United States. Although the states are laboratories of experimentation, the Constitution creates a floor for

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<sup>16</sup> See *infra* sources cited note 169 and accompanying text.

<sup>17</sup> See generally *infra* Section I.A.

<sup>18</sup> See discussion *infra* Section II.B.

<sup>19</sup> See discussion *infra* Part III.

<sup>20</sup> "Life-prolonging medical treatment, as distinguished from life-saving treatment, means intrusive medical treatment where there is no prospect of recovery. Recovery does not mean the ability to remain alive but rather life without intolerable suffering." 109 MASS. CODE REGS. 11.13(1) (2018).

<sup>21</sup> "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. CONST. amend. X.

<sup>22</sup> Thaddeus M. Pope, *Dispute Resolution Mechanisms for Intractable Medical Futility Disputes*, 58 N.Y.L. SCH. L. REV. 347, 350 (2014).

<sup>23</sup> Judith F. Daar, *Medical Futility and Implications for Physician Autonomy*, 21 AM. J.L. & MED. 221, 223 (1995) ("A review of existing case and statutory law in the area of medical futility shows that courts and lawmakers have promulgated vague and ill-defined policies . . .").

the fundamental right<sup>24</sup> of child-rearing,<sup>25</sup> and current state statutes do not meet this constitutional standard. The red and yellow light futility statutes do not afford proper balance between the interests of the state and parents, and the green light futility statutes are overly paternalistic.<sup>26</sup> Accordingly, the guidelines dictate that the word “futile” should only be used in “rare situations in which surrogates request interventions that simply cannot accomplish their intended physiologic goal” and should otherwise be replaced with “potentially inappropriate.”<sup>27</sup> This characterization would help remove subjective, valued judgments from the determination of futility and would allow for an effective process-based dispute resolution.<sup>28</sup> Adopting these guidelines would thus help clarify and unify the medical goals at issue so as to best balance the interests of the parent, child, and state.

## I. BACKGROUND

In order to analyze what would have happened to Charlie if he had been treated in the United States, this Part explores the scope of parental and state rights with respect to medical decision-making on behalf of infant minors against the backdrop of research laws, access to experimental drugs, and withdrawal of life-sustaining treatment in the face of futility.

### A. *Child, Family, and State*<sup>29</sup>

Parents’ liberty interests over the care of their children is one of the oldest fundamental rights recognized by the Supreme Court.<sup>30</sup> The

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<sup>24</sup> “Fundamental rights are those rights that are ‘objectively rooted in the nation’s history, and so implicit in the concept of ordered liberty, such that neither liberty nor justice could exist if [these fundamental liberty interests] were sacrificed.’” Martin A. Schwartz, *Due Process and Fundamental Rights*, 17 *TOURO L. REV.* 237, 244 n.32 (2016) (citing *Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997)).

<sup>25</sup> This is rooted in the liberty of the (substantive) due process clause. See U.S. CONST. amend. XIV. See generally Section I.A.

<sup>26</sup> See discussion *infra* Section II.B.

<sup>27</sup> Gabriel T. Bosslet et al., *An Official ATS/AACN/ACCP/ESICM/SCCM Policy Statement: Responding to Requests for Potentially Inappropriate Treatments in Intensive Care Units*, 191 *AM. J. OF RESPIRATORY AND CRITICAL CARE MED.* 1318 (2015), <https://www.thoracic.org/statements/resources/cc/inappr-ther-st.pdf> [<http://perma.cc/4BY3-WDJT>].

<sup>28</sup> See discussion *infra* Part III.

<sup>29</sup> A comprehensive discussion of parental substantive due process rights is outside the scope of this Note. Instead, the discussion will focus on parental rights in the context of medical decision-making.

<sup>30</sup> *Troxel v. Granville*, 530 U.S. 57, 68 (2000) (holding that “so long as a parent adequately cares for his or her children (*i.e.*, is fit), there will normally be no reason for the State to inject itself into the private realm of the family” to contradict a parent’s decision concerning

ability of parents to speak on behalf of their minor children is a right that is deeply rooted in U.S. tradition and common law. It has been suggested that not only is there a presumption that parents have their children's best interests in mind when making medical decisions,<sup>31</sup> but also that the Constitution requires states to respect those decisions.<sup>32</sup> Balanced against that liberty interest are the states' police powers as *parens patriae*<sup>33</sup> to protect minors from harm and to ensure that health care and treatment decisions are made in the best interest of the child.<sup>34</sup> States also have a compelling interest in protecting the integrity of the medical profession.<sup>35</sup> States can therefore set statutory guidelines to prevent and mitigate these harms.<sup>36</sup>

In the United States, if parents have been properly informed of their child's medical condition, treatment options, and prognosis, courts will generally defer to parental discretion in determining what is in the best interest of their child, even if it is not exactly in accord with current medical standards.<sup>37</sup> This determination of the child's best interest is

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childrearing). "The liberty interest . . . of parents in the care, custody, and control of their children—is perhaps the oldest of the fundamental liberty interests recognized by [the] Court." *Id.* at 65.

<sup>31</sup> See *In re L.H.R.*, 321 S.E.2d 716, 722 (Ga. 1984) (noting that "[t]he law's concept of the family rests on a presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions. More importantly, historically it has recognized that natural bonds of affection lead parents to act in the best interests of their children.") (quoting *Parham v. J.R.*, 442 U.S. 584, 602 (1979)); see, e.g., *In re Guardianship of Barry*, 445 So. 2d 365, 371 (Fla. Dist. Ct. App. 1984) (holding that "in the case of a child who has not reached maturity, it is the parents and their medical advisors who generally must make these [best interest] decisions. And, where judicial intervention becomes necessary or desirable, the court must be guided primarily by the judgment of the parents who are responsible for their child's well-being, provided, of course, that their judgment is supported by competent medical evidence.").

<sup>32</sup> *In re L.H.R.*, 321 S.E.2d at 722 ("The right of the parent to speak for the minor child is so imbedded in our tradition and common law that it has been suggested that the constitution requires that the state respect the parent's decision.").

<sup>33</sup> "[T]he state in its capacity as provider of protection to those unable to care for themselves." *Parens patriae*, BLACK'S LAW DICTIONARY (10th ed. 2014).

<sup>34</sup> See *Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944) (holding that parental authority is not absolute and can be curtailed in order to promote the child's best interest).

<sup>35</sup> *Washington v. Glucksberg*, 521 U.S. 702, 703–04 (1997) (explaining that "legitimate government interests" include "protecting the medical profession's integrity and ethics and maintaining physicians' role as their patients' healers . . .").

<sup>36</sup> See *infra* Section II.B (discussing the futility statutes).

<sup>37</sup> See *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 627 (1986) (noting that with respect to medical care of handicapped infants, "state law vests decisional responsibility in the parents, in the first instance, subject to review in exceptional cases by the State acting as *parens patriae*"); see also *id.* at 627 n.13 ("Traditional law concerning the family, buttressed by the emerging constitutional right of privacy, protects a substantial range of discretion for parents. Second, as persons unable to protect themselves, infants fall under the *parens patriae* power of the state. . . . [A]s long as parents choose from professionally accepted treatment options the choice is rarely reviewed in court and even less frequently supervised.") (internal quotation marks omitted); Child Abuse and Neglect Prevention and Treatment Program, 50 Fed. Reg. 14878–01, 14880 (Apr. 15, 1985) (to be codified at 45 C.F.R. pt. 1340) ("The decision to provide or

quite ambiguous within the context of experimental treatment, as the cost-benefit analysis<sup>38</sup> can be unknown due to inadequate testing. It has been argued that when the potential benefits of the treatment are unclear, or are outweighed by substantial possibility of harm, parents should have the right to determine which course of treatment is in the infant's best interest.<sup>39</sup>

In comparison, in the United Kingdom, parents do not have constitutionally protected parental rights.<sup>40</sup> Pursuant to the Children Act of 1989, parents are bestowed with parental responsibilities.<sup>41</sup> When there is a disagreement over deciding which course of treatment is in the best interest of the child, the courts in the United Kingdom presume that the judge<sup>42</sup> is in the best position to make that determination.<sup>43</sup> Given that Charlie's condition had deteriorated to the point at which his life could not have been improved by the experimental nucleoside therapy,<sup>44</sup> the court determined that it was not in his best interest to

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withhold medically indicated treatment is, except in highly unusual circumstances, made by the parents or legal guardian.”).

<sup>38</sup> In which the inquiry will focus on whether the treatment will effectuate a clear medial benefit. See Seema Shah, *Does Research with Children Violate the Best Interests Standard? An Empirical and Conceptual Analysis*, 8 NW. J.L. & SOC. POL'Y 121, 127 (2013). See generally *The Ethics of Clinical Research*, STAN. ENCYCLOPEDIA PHIL., <https://plato.stanford.edu/entries/clinical-research> [<http://perma.cc/HS3G-TRGY>] (last updated Feb. 27, 2017).

<sup>39</sup> See *Developments in the Law—Medical Technology and the Law*, 103 HARV. L. REV. 1519 (1990); LAINIE FRIEDMAN ROSS, CHILDREN, FAMILIES, AND HEALTH CARE DECISION MAKING, 142 (1998) (“[W]hen the [experimental] treatment has a low probability of success, is likely to result in a poor quality of life, or is experimental, the parents are free to decide whether the benefits outweigh the risks and costs. It is a value-laden, quality-of-life decision that should be theirs to make.”).

<sup>40</sup> In fact, the United Kingdom does not have a written, codified constitution. Robert Blackburn, *Britain's Unwritten Constitution*, BRITISH LIBR. (Mar. 13, 2015), <https://www.bl.uk/magna-carta/articles/britains-unwritten-constitution> [<http://perma.cc/4VMB-RYJB>].

<sup>41</sup> *Reality Check: Why Don't Charlie Gard's Parents Have the Final Say?*, *supra* note 10 (explaining that these parental responsibilities encompass “all the rights, duties, powers, responsibilities and authority which, by law, a parent of a child has in relation to the child and his property.”).

<sup>42</sup> This is “because of the country's single-payer national health system. It's more routine for the . . . courts, to make decisions about what's acceptable care, what's excessive care and even, as in Charlie's case, when care should stop.” Alice Park, *When Parents and Doctors Disagree on What Futile Means*, TIME (July 13, 2017), <http://time.com/4856228/charlie-gard-parents-doctors-trump-pope> [<http://perma.cc/4MZY-8P2T>].

<sup>43</sup> *Wyatt v. Portsmouth NHS Trust* [2005] EWHC (Ch) 117 (Eng.) (noting that a judge does this by looking at the situation from the assumed perspective of the child, while considering the surrounding medical, emotional, and other welfare issues. Welfare issues include the ability for intellectual milestones and assessment of overall quality of life); Justice Nicholas Francis, *Decision and Short Reasons to be Released to the Media in the Case of Charlie Gard*, JUDICIARY OF ENG. & WALES 3 (Apr. 11, 2017), <https://www.judiciary.gov.uk/wp-content/uploads/2017/04/gard-press-summary-20170411.pdf> [<https://perma.cc/223G-K53J>] (“[O]verriding control is vested in the court exercising its independent and objective judgment . . .”).

<sup>44</sup> “Charlie [was] unable to move his legs and arms, breathe unaided or hold his eyelids open. He [was] also deaf, ha[d] severe epilepsy and his heart, liver and kidneys [were] affected.” *Reality Check: Why Don't Charlie Gard's Parents Have the Final Say?*, *supra* note 10; see also

prolong his inevitably transient life.<sup>45</sup>

## B. *Research Laws and the Right to Experimental Treatment*

### 1. Research Laws

Research laws regulate the protection of human subjects in medical research.<sup>46</sup> Internationally, these laws and regulations significantly evolved subsequent to World War II.<sup>47</sup> In response to the Nuremberg Trials,<sup>48</sup> the Nuremberg Code (the Code) was introduced in August of 1947.<sup>49</sup> The Code set forth rules embodying the legal and ethical principles that must be addressed when conducting clinical research experiments on humans.<sup>50</sup> Prior to its adoption, there were no national or international laws differentiating legal and illegal practices.<sup>51</sup> The Code's central principle is the concept of informed and voluntary consent.<sup>52</sup>

Thereafter, the Declaration of Helsinki (the Declaration)<sup>53</sup> was promulgated by the World Medical Association in 1964 to address the

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*infra* sources cited note 143; *infra* sources cited note 168.

<sup>45</sup> Great Ormond Street Hospital v. Yates, [2017] EWHC (Fam) 1909 [3] (Eng.).

<sup>46</sup> *Information on Protection of Human Subjects in Research Funded or Regulated by U.S. Government*, U.S. DEP'T HEALTH & HUMAN SERVS., <https://www.hhs.gov/1946inoculationstudy/protection.html> [<https://perma.cc/DXW3-ZBX6>] (last visited Sept. 11, 2018).

<sup>47</sup> ROBERT H. MNOOKIN & D. KELLY WEISBERG, *CHILD, FAMILY, AND STATE: PROBLEMS AND MATERIALS ON CHILDREN AND THE LAW* 439 (6th ed. 2009).

<sup>48</sup> The Nuremberg Trials were a series of thirteen trials between 1945 and 1949 in which Nazi Party officials, high ranking military officers, German industrialists, lawyers, and doctors were indicted for committing crimes against peace and humanity. Specifically, these crimes against humanity included medical experiments on prisoners of war. History.com Staff, *Nuremberg Trials*, A&E NETWORKS (2010), <http://www.history.com/topics/world-war-ii/nuremberg-trials> [<http://perma.cc/R2VF-TUAQ>].

<sup>49</sup> MNOOKIN & WEISBERG, *supra* note 47, at 439. Evelyne Shuster, *Fifty Years Later: The Significance of the Nuremberg Code*, 337 NEW ENG. J. MED. 1436 (1997), <https://www.nejm.org/doi/full/10.1056/NEJM199711133372006> [<https://perma.cc/8RNN-26QC>].

<sup>50</sup> MNOOKIN, *supra* note 47, at 439.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*; see, e.g., Candace Cummins Gauthier, *Philosophical Foundations of Respect for Autonomy*, 3 KENNEDY INST. ETHICS J. 21, 22 (1993) (discussing the importance of informed consent as the ethical convictions surrounding respect for personhood. Gauthier notes that respect for patient autonomy "requires health care providers to allow and encourage fully competent patients to make decisions about their own lives and medical treatment without attempting to control those decisions.").

<sup>53</sup> The Declaration of Helsinki is an international guide designed to protect human subjects in research trials. It is recognized in the United States, and has been cited by many U.S. courts. Vera Sharav, *Does the FDA Have the Authority to Trump the Declaration of Helsinki?*, ALL. FOR HUMAN RESEARCH PROTECTIONS, <http://ahrp.org/does-the-fda-have-the-authority-to-trump-the-declaration-of-helsinki> [<http://perma.cc/D7S9-Z8JV>] (last visited Sept. 1, 2018).

shortcomings of the Code.<sup>54</sup> The Declaration articulated that those unable to consent, such as children, require proxy consent in order to participate in research trials.<sup>55</sup> Additionally, it introduced the concept of therapeutic research in comparison to nontherapeutic research.<sup>56</sup> Of particular importance to this Note, paragraph 32 of the Declaration articulates that physicians can sometimes treat patients with experimental treatments not yet approved or licensed due to incomplete clinical research trials.<sup>57</sup>

In 2002, the Council for International Organizations of Medical Sciences (CIOMS) set forth the “International Ethical Guidelines for the Biomedical Research Involving Human Subjects.”<sup>58</sup> CIOMS specifically promulgated these guidelines for the ethical review of emergency compassionate use of an investigational therapy.<sup>59</sup> It notes that in some countries, physicians may undertake compassionate use of an experimental treatment<sup>60</sup> before obtaining the approval of an ethics committee, provided that the patient requires emergency treatment and the only available treatment option is one that is still undergoing research.<sup>61</sup>

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<sup>54</sup> MNOOKIN & WEISBERG, *supra* note 47, at 439.

<sup>55</sup> *Id.* Legal representatives, including parents or guardians, can provide proxy consent for minor children. D. M. Foreman, *The Family Rule: A Framework for Obtaining Ethical Consent for Medical Interventions from Children*, 25 J. MED. ETHICS 491, 494 (1999), <http://jme.bmj.com/content/medethics/25/6/491.full.pdf> [<http://perma.cc/6MXL-BWLM>] (“[T]he ethics of acceptance of ‘proxy consent’ in research is determined by the family rule.”).

<sup>56</sup> John R. Williams, *The Declaration of Helsinki and Public Health*, 86 BULL. WORLD HEALTH ORG. 650 (2008), <http://www.who.int/bulletin/volumes/86/8/08-050955.pdf?ua=1> [<https://perma.cc/DS2M-HSVD>]. Nontherapeutic research is research that “may add to scientific knowledge and/or benefit others, but any benefit to the child research participant is but a coincidental theoretical possibility and not a primary objective.” Sonja Grover, *On the Limits of Parental Proxy Consent: Children’s Right to Non-Participation in Non-Therapeutic Research*, 1 J. ACAD. ETHICS 349 (2003), <https://link.springer.com/article/10.1023/B:JAET.0000025606.40005.bc> [<http://perma.cc/CDA9-6NRC>]. In contrast, therapeutic research “is intended to provide actual or potential personal benefit to each participant though this is of course not guaranteed.” *Id.* at 350.

<sup>57</sup> World Med. Ass’n, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 79 BULL. WORLD HEALTH ORG. 373, 374 (2001) (“In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician’s judgment it offers hope of saving life, re-establishing health or alleviating suffering.”).

<sup>58</sup> COUNCIL FOR INT’L ORGS. OF MED. SCIS. & WORLD HEALTH ORG., INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2002), [https://cioms.ch/wp-content/uploads/2016/08/International\\_Ethical\\_Guidelines\\_for\\_Biomedical\\_Research\\_Involving\\_Human\\_Subjects.pdf](https://cioms.ch/wp-content/uploads/2016/08/International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf) [<http://perma.cc/S25L-74X6>].

<sup>59</sup> *Id.*

<sup>60</sup> While this “compassionate use treatment” is not necessarily regarded as research, it undoubtedly contributes to the ongoing research regarding the safety and efficacy of the therapy administered. *Id.*

<sup>61</sup> *Id.* (“Exceptionally, a physician may undertake the compassionate use of an investigational therapy before obtaining the approval or clearance of an ethical review

The United States has created its own research laws and regulations.<sup>62</sup> The Belmont Report (the Report) was published in 1979, followed by the codification of Titles 21 and 45 of the Code of Federal Regulations in 1996.<sup>63</sup> The Report summarizes ethical principles and guidelines for human research subjects.<sup>64</sup> It found that the principle of beneficence<sup>65</sup> supports involving children in clinical research trials, even if they are not the direct beneficiaries of the treatment.<sup>66</sup> Additionally,

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committee, provided three criteria are met: a patient needs emergency treatment, there is some evidence of possible effectiveness of the investigational treatment, and there is no other treatment available that is known to be equally effective or superior.”).

<sup>62</sup> The Tuskegee Studies greatly influenced the government’s own research practices. *How Tuskegee Changed Research Practices*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/tuskegee/after.htm> [<http://perma.cc/W9N9-57BH>] (last updated Feb. 22, 2017) (“The rules and policies for human subjects research have been reviewed and revised many times since they were first approved. From 1980–1983, the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research looked at federal rules for doing research on human subjects to see how well those rules were being followed. An Ethics Advisory Board was formed in the late 1970s to review ethical issues of biomedical research. In 1991, federal departments and agencies (16 total) adopted the Federal Policy for the Protection of Human Subjects.”). The Tuskegee studies were a government research trial, spanning forty years, in which hundreds of African-American men with syphilis were left untreated, when there was a proven effective treatment, so that scientists could study the disease’s effects. Olivia B. Waxman, *How the Public Learned About the Infamous Tuskegee Syphilis Study*, TIME (July 25, 2017), <http://time.com/4867267/tuskegee-syphilis-study> [<http://perma.cc/A54E-W6AG>].

<sup>63</sup> See MNOOKIN & WEISBERG, *supra* note 47, at 440; 21 C.F.R. pt. 50; 45 C.F.R. pt. 46; U.S. DEP’T OF HEALTH & HUMAN SERVS., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), [https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c\\_FINAL.pdf](https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf) [<http://perma.cc/EV2L-8UHV>] [hereinafter THE BELMONT REPORT].

<sup>64</sup> Including concepts of respect for personhood, beneficence, justice, informed consent, and assessment of risks and benefits. THE BELMONT REPORT.

<sup>65</sup> Beneficence is a fundamental ethical principal of healthcare and bioethics. Frank Stuart Kinsinger, *Beneficence and the Professional’s Moral Imperative*, 16 J. CHIROPRACTIC HUMAN. 44, 44–46 (2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3342811/pdf/main.pdf> [<https://perma.cc/2PJP-NY7B>] (“In the health care milieu, modern thought on beneficence embraces humanism. All persons have immutable rights to life and liberty, and these rights are to be respected, nurtured, and facilitated. Reverence toward the patient and his or her suffering experience shows respect for the individual and for life itself. Practitioners are to act in a way that contributes to the patient’s health and well-being and to take care to refrain from doing anything that would cause harm.”); *see also* Clark, *supra* note 1, at 74 (“Beneficence involves the obligation to prevent and remove harms and to promote the good of the person by minimizing the burdens incurred and maximizing the benefits to the patient and others. Beneficence includes nonmaleficence, which prohibits the infliction of harm, injury, or death upon others.”).

<sup>66</sup> THE BELMONT REPORT, *supra* note 64 (noting that there remains an ethical dilemma when research “presents more than minimal risk without immediate prospect of direct benefit to the children involved,” and that some argue that such research is inadmissible, while others believe that this would greatly benefit children in the future and therefore should be admissible); *see also* Paul Litton, *Non-Beneficial Pediatric Research and the Best Interests Standard: A Legal and Ethical Reconciliation*, 8 YALE J. HEALTH POL’Y, L. & ETHICS 359, 420 (2008).

within Title 21, 21 C.F.R § 50.52<sup>67</sup> is most relevant to Charlie's case, as the treatment proposed by Dr. Hirano had not been tested on subjects containing the mutation that Charlie inherited, but had been proven effective for those suffering from a different mutation.<sup>68</sup> This Section sets forth guidelines for performing such research on children, elucidating that the anticipated benefits must justify the risks, and that there must be proper informed consent.<sup>69</sup> The same guidelines are set forth by 45 C.F.R § 46.405 with respect to whether the U.S. Department of Health and Human Services can conduct or fund research that involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects.<sup>70</sup>

## 2. The Right to Experimental Treatment

The ability to have access to experimental treatment is not a fundamental right protected by the Constitution.<sup>71</sup> In *United States v. Rutherford*, the Supreme Court held that Congress can authorize the Food and Drug Administration (FDA) to create a rule that denies terminally ill patients access to drugs that are safe but whose efficacies are unproven.<sup>72</sup> In fact, the federal district court that first heard the

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<sup>67</sup> Entitled "Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects." 21 C.F.R § 50.52 (2018).

<sup>68</sup> Michael Edison Hayden & Devika Umashanker, *Inside the Experimental Treatment Considered for Baby Charlie Gard*, ABC NEWS (July 19, 2017, 7:20 PM), <http://abcnews.go.com/Health/inside-experimental-treatment-doctors-charlie-gard/story?id=48723678> [http://perma.cc/W9LL-HQDU] ("The medication has been tested on mice and a small number of people with a different mitochondrial condition, some of whom have shown measurable improvement. But the drug has never been tested on people with Charlie's specific condition."). It is also important to note that the article relates the story of Art and Olga Estopinan's six-year-old son, Art Jr., who, like Charlie, was diagnosed with a mitochondrial depletion syndrome during infancy. *Id.* While his doctors had told his parents that there was little to no chance of survival, Art Jr. was the first child to receive the experimental nucleoside treatment administered by Dr. Hirano. *Id.* The treatment proved successful, as Art Jr. had regained basic motor skills, and although he requires continuous care, eats through a feeding tube, and is in a wheelchair, he can speak and entertain himself with an iPad. *Id.* This supports the argument that it is the parents, and not the doctors, who are best suited to determine what is in the best interest of the child, and that a limited quality of life is still acceptable and meaningful. *Id.*

<sup>69</sup> 21 C.F.R. § 50.52 (2018) ("(a) The risk [must be] justified by the anticipated benefit to the subjects; (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians as set forth in § 50.55."); 21 C.F.R. § 50.55(e)(1) (2018).

<sup>70</sup> 45 C.F.R. § 46.405 (2018).

<sup>71</sup> See *Montana Cannabis Indus. Ass'n v. State*, 286 P.3d 1161, 1166 (Mont. 2012) ("In pursuing one's own health, an individual has a fundamental right to obtain and reject medical treatment. But, this right does not extend to give a patient a fundamental right to use any drug, regardless of its legality. No court has acceded to this type of affirmative access claim . . .") (internal citations omitted).

<sup>72</sup> *United States v. Rutherford*, 442 U.S. 544, 551 (1979). *But see* JERRY MENIKOFF, LAW AND

*Rutherford* case asserted that the constitutionally protected right of privacy prevented the government from denying access to an experimental drug.<sup>73</sup> However, this constitutional argument was not addressed by the Supreme Court's opinion on certiorari.<sup>74</sup>

Moreover, in the seminal case *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*,<sup>75</sup> plaintiffs brought suit advocating for access to Phase 1<sup>76</sup> experimental treatment for patients who had no other medical options for life-sustaining or life-prolonging care.<sup>77</sup> Plaintiffs argued that denial of such treatment violated the Due Process Clause under the Fifth Amendment.<sup>78</sup> A three-judge panel of the D.C. Circuit ruled that terminally ill patients whose only treatment options were not government-approved had a constitutionally protected right to obtain access to such treatment free from government intervention.<sup>79</sup> However, this holding was later reversed en banc.<sup>80</sup> The en banc panel asserted there is no constitutionally protected right for terminally ill patients to be treated with drugs not yet approved by the FDA, even if there is a high probability that the patients would die before the drug is approved.<sup>81</sup>

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BIOETHICS: AN INTRODUCTION 214 (2001) (“[E]ven if Congress did grant that power to the FDA, is that unconstitutional? We know that the right of privacy created by the Fourteenth Amendment prevents the government from inappropriately interfering in various aspects of a person’s life (such as a woman’s attempt to get an abortion). Isn’t it possible that the right of privacy would protect a terminally ill person’s right to take a safe, though unproven, drug?”). See generally *Roe v. Wade* 410 U.S. 113 (1973) (setting forth the proposition that within the right to privacy includes the right to bodily integrity, and the right to have decisional autonomy, that is the ability to make certain important intimate decisions about the body and medical care).

<sup>73</sup> *Rutherford v. United States*, 438 F. Supp. 1287, 1301 (W.D. Okla. 1977) (“By denying the right to use a nontoxic substance in connection with one’s own personal health-care, FDA has offended the constitutional right of privacy.”); MENIKOFF, *supra* note 72, at 214 (“[T]he right of privacy did prevent the government from denying a patient access to Laetrile.”).

<sup>74</sup> MENIKOFF, *supra* note 72, at 214.

<sup>75</sup> 495 F.3d 695 (D.C. Cir. 2007) (en banc), *cert denied*, 552 U.S. 1159 (2008).

<sup>76</sup> See Susan Okie, *Access Before Approval—A Right to Take Experimental Drugs?*, 355 N. ENG. J. MED. 437, 438–40 (2006), <http://www.nejm.org/doi/full/10.1056/NEJMp068132#t=article> [<http://perma.cc/9ARG-GEV5>] (explaining that a drug undergoes three phases of clinical trials before FDA approval: phase 1 is designed to study the toxicity of the drug and its potential effects at different dosages; phase 2 studies efficacy, risks, and side effects; and phase 3 provides more conclusive data regarding efficacy and safety, allowing for a cost-benefit analysis of using the drug to treat the specific condition).

<sup>77</sup> *Abigail All.*, 495 F.3d at 699.

<sup>78</sup> *Id.* at 700–01; Shira Bender et al., *Access for the Terminally Ill to Experimental Medical Innovations: A Three-Pronged Threat*, 7 AM. J. BIOETHICS 3 (2007); see U.S. CONST. amend. V.

<sup>79</sup> *Abigail All. v. von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006) (holding that “where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient’s informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials warrants protection under the Due Process Clause.”).

<sup>80</sup> *Abigail All.*, 495 F.3d at 701.

<sup>81</sup> *Id.* at 712–13. (holding that the government has the right to decide, on state interest

Although access to experimental treatment is not constitutionally protected as a fundamental right, in some instances it can be protected by statute. For example, *In re Baby K*,<sup>82</sup> the court held that the plain language of the Emergency Medical Treatment and Active Labor Act<sup>83</sup> could not be ignored.<sup>84</sup> Since there was no explicit statutory language or legislative history alluding to congressional intent to suggest otherwise, the court reasoned that physicians must provide the requested stabilizing treatment even when it exceeds the prevalent standard of medical care.<sup>85</sup> In this case, the physicians treating the infant—who was born with a congenital condition for which there was no treatment and from which infants die shortly after birth—claimed that aggressive, life-sustaining treatment would not serve an effective therapeutic or palliative purpose.<sup>86</sup> In their professional opinions, treating the condition would be futile.<sup>87</sup> They thus believed there was no requirement to provide stabilizing treatment.<sup>88</sup> However, as the statute dictates, even when a physician receives a request for treatment they believe is inappropriate<sup>89</sup> due to their assessment of the patient's condition as medically futile, they are required to provide such treatment even if it might exceed the general standard of care.<sup>90</sup>

The right to access experimental treatment can also be protected by federal regulations. In the United States, patients who are out of treatment options can apply to specific drug companies and the FDA to use experimental drugs outside of a clinical research setting.<sup>91</sup> Under the

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grounds, to protect its citizens from the unknown, and potentially dire, effects of experimental drugs).

<sup>82</sup> 16 F.3d 590 (4th Cir. 1994).

<sup>83</sup> 42 U.S.C. § 1395dd (2012).

<sup>84</sup> *In re Baby K*, 16 F.3d at 596.

<sup>85</sup> *Id.* at 594 (The statute provided that “once an individual has been diagnosed as presenting an emergency medical condition, the hospital must provide that treatment necessary to prevent the material deterioration of the individual’s condition or provide for an appropriate transfer to another facility.”).

<sup>86</sup> *Id.* at 592–93.

<sup>87</sup> *Id.* at 596.

<sup>88</sup> *Id.*

<sup>89</sup> And therefore, the treating physicians may be faced with a moral or ethical dilemma in responding to those requests. *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> See U.S. FOOD & DRUG ADMIN., EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE—QUESTIONS AND ANSWERS 2 (2016), <https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf> [<http://perma.cc/U53Z-SDAU>]; see also Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL’Y 295 (2000) (explaining that the AIDS epidemic in the 1980s gave rise to this compassionate use exception. During those years, the disease was considered lethal as there was no effective treatment that was available commercially and the government did not allow use of experimental drugs. Although the FDA had an interest in ensuring the efficacy and safety of drugs, these terminally ill patients with no other medical options were willing to take a risk because of the possibility of limited improvement. As such, this exception allows for those with desperately ill diseases to be given limited access to experimental treatments with initially

FDA's compassionate use<sup>92</sup> exception of the Expanded Access Program,<sup>93</sup> a patient may obtain access to pre-approved treatment if the FDA determines (1) that patient has a serious or life-threatening disease and there is no established treatment alternative; (2) the benefits justify the risks of treatment; and (3) the administration of the drug will not interfere with the completion of its clinical research trials.<sup>94</sup> However, it appears that it is rather difficult to obtain treatment under the compassionate use exception.<sup>95</sup> While the FDA approves about ninety-nine percent of compassionate use requests,<sup>96</sup> drug manufacturers will often refuse to distribute the experimental medication, fearing that either the FDA could use the results of its consumption against them, or that patients who might be injured from using these unapproved drugs will sue.<sup>97</sup>

In response to the shortcomings of the FDA's Expanded Access Program, the Goldwater Institute has encouraged the adoption of Right to Try laws among states.<sup>98</sup> Right to Try laws allow physicians and drug companies to treat those suffering from life-threatening conditions that have no known effective treatments with non-FDA approved medications.<sup>99</sup> The thirty-eight states that have adopted such laws have

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promising results, while simultaneously using those who ingest the drugs for research data required by the FDA).

<sup>92</sup> Compassionate use refers to the use outside of a clinical trial of an investigational medical product (i.e., one that has not been approved by the FDA). *Expanded Access (Sometimes Called "Compassionate Use")*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm> [http://perma.cc/NBM6-TSXD] (last updated June 19, 2018).

<sup>93</sup> EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE— QUESTIONS AND ANSWERS, *supra* note 91, at 2 ("Expanded access refers to the use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than to obtain the kind of information about the drug that is generally derived from clinical trials. FDA has a long history of facilitating expanded access to investigational drugs for treatment use for patients with serious or immediately life-threatening diseases or conditions who lack therapeutic alternatives.")

<sup>94</sup> 21 C.F.R. § 312.305(a)(1-3) (2017).

<sup>95</sup> 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> [http://perma.cc/S4TM-ALTX]; see also MARK FLATTEN, DEAD ON ARRIVAL: FEDERAL "COMPASSIONATE USE" LEAVES LITTLE HOPE FOR DYING PATIENTS 2 (2016), [https://www.heartland.org/\\_template-assets/documents/publications/dead\\_on\\_arrival\\_downloadable\\_pdf.pdf](https://www.heartland.org/_template-assets/documents/publications/dead_on_arrival_downloadable_pdf.pdf) [http://perma.cc/FTB8-L25M] ("[A]n investigation by the Goldwater Institute shows that the entire system for gaining access to an unapproved medication is so rigged with bureaucracy and disincentives that it is bound to fail in most cases. . . . [It] ensur[es] that only a tiny number of patients are able to navigate the complex, costly, and time-consuming maze that must be cleared just to file a compassionate use application for the FDA to consider.")

<sup>96</sup> Pear & Kaplan, *supra* note 95.

<sup>97</sup> *Id.*

<sup>98</sup> See FLATTEN, *supra* note 95, at 4.

<sup>99</sup> *Id.*; see FAQ, RIGHT TO TRY, <http://righttotry.org/faq> [https://perma.cc/KKT2-TQYD] (last visited Sept. 2, 2018) ("Right To Try allows terminally ill Americans to try medicines that

done so with “overwhelming bipartisan support and almost no opposition.”<sup>100</sup> Recently, on May 30, 2018, the Right to Try Act became law, expanding the access to experimental drugs for those who suffer from terminal illnesses.<sup>101</sup> Specifically, the bill promulgates uniform, national rules for distributing experimental drugs to terminally ill patients that shield pharmaceutical companies and doctors from legal liability.<sup>102</sup> It is important to note that the bill recognizes that access to experimental drugs is within the scope of individual liberty, which is a fundamental right protected by the Constitution.<sup>103</sup>

Alternatively, under the principle of altruism, parents are justified in enrolling their children in clinical research trials even if there is a low probability that it could therapeutically benefit their children: it contributes to research that will ultimately benefit other children with similar conditions in the future.<sup>104</sup> This participation can still be

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have passed Phase 1 of the FDA approval process and remain in clinical trials but are not yet on pharmacy shelves. Right To Try expands access to potentially life-saving treatments years before patients would normally be able to access them.”); see also Alison Bateman-House et al., *Right-to-Try Laws: Hope, Hype, and Unintended Consequences*, 163 ANNALS INTERNAL MED. 796 (2015) (“Right-to-try laws are based on model legislation promulgated by a libertarian think tank, the Goldwater Institute, and are promoted as helping terminally ill patients access investigational medical products . . . . The right-to-try approach seeks to nullify the FDA’s power to approve or reject such agreements, a change that advocates claim will increase the number of patients accessing investigational products.”).

<sup>100</sup> FLATTEN, *supra* note 95, at 4; see Rachel Alexander, *Parental Rights in the U.S.—Could the Charlie Gard Case Happen Here?*, THE STREAM (July 27, 2017), <https://stream.org/parental-rights-in-the-u-s-could-the-charlie-gard-case-happen-here> [http://perma.cc/6CVB-GQF5]; see also The Associated Press, *Pennsylvania Enacts ‘Right to Try’ Law for Terminally Ill*, PENNLIVE, [http://www.pennlive.com/news/2017/10/pennsylvania\\_enacts\\_right\\_to\\_t.html](http://www.pennlive.com/news/2017/10/pennsylvania_enacts_right_to_t.html) [http://perma.cc/TYC8-6KJS] (last updated Oct. 11, 2017) (noting that Pennsylvania is the thirty-eighth state to enact a Right to Try law).

<sup>101</sup> Pub. L. 115-176, 132 Stat. 1372 (2018), <https://www.congress.gov/bill/115th-congress/senate-bill/204/text?q=%7B%22search%22%3A%5B%22right+to+try%22%5D%7D&r=1> [http://perma.cc/XQ2L-KL82]; Pear & Kaplan, *supra* note 95 (“The ‘right to try’ bill, introduced by Senator Ron Johnson, Republican of Wisconsin, aims to establish a new pathway for terminally ill patients to gain access to experimental drugs that have not been approved by the F.D.A. These patients are often extremely ill and unable to participate in clinical trials, or have no other treatment options.”).

<sup>102</sup> Pear & Kaplan, *supra* note 95 (“The [proposed] bill would establish national standards and rules to help channel drugs still under development to terminally ill patients. . . . It would also shield pharmaceutical companies and doctors from some of the legal risks of providing [unapproved] drugs . . .”).

<sup>103</sup> S. 204, 115th Cong. § 3(3) (“It is the sense of the Senate that section 561B of the Federal Food, Drug, and Cosmetic Act, as added by section 2 . . . only expands the scope of individual liberty and agency among patients, in limited circumstances . . . .”); see U.S. CONST. amend. XIV (“. . . nor shall any State deprive any person of life, liberty, or property, without due process of law . . .”).

<sup>104</sup> Litton, *supra* note 66, at 390–91. This might raise an issue of informed consent, as the “voluntary” consent to enroll an ill child in an experimental clinical research trial that might do more harm than good, is compelled by the parent’s desperation to exhaust every possible option after conventional therapies have failed. Rhonda Gay Hartman, *Noblesse Oblige: States’ Obligations to Minors Living with Life-Limiting Conditions*, 50 DUQ. L. REV. 333, 366–67 (2012). *But see* MHAIRI COWDEN, CHILDREN’S RIGHTS: FROM PHILOSOPHY TO PUBLIC POLICY 111–12

considered in the best interest of the child because, from a policy perspective, participation in non-beneficial pediatric research endorses that research study.<sup>105</sup> Moreover, due to the unknown nature of experimental treatment, it could ultimately prove beneficial to the child.<sup>106</sup>

### C. *Withdrawal of Life-Sustaining Treatment in the Face of Futility*

While the term futility has been defined outside the medical context,<sup>107</sup> according to the American Medical Association (the AMA), medical futility cannot be meaningfully defined<sup>108</sup> as its interpretation is inherently subjective.<sup>109</sup> Because futility is framed as an inquiry of potential benefits, determining whether treatment is medically futile is contingent upon determining what is in the best interest of the patient.<sup>110</sup>

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(2016). The United Kingdom does not accept an altruistic reason as valid for allowing the use of experimental treatment. Justice Nicholas Francis, *supra* note 43, at 5 (stating that “medical science may benefit, objectively, from the experiment, but experimentation cannot be in Charlie’s best interests unless there is a prospect of benefit for him.”).

<sup>105</sup> Litton, *supra* note 66, at 420 (“Each child has reason to endorse both a policy permitting non-beneficial pediatric research and to participate in a practice from which she benefits.”). The justification in a child’s involvement with pediatric research that might be therapeutic, but ultimately not beneficial, “offers a plausible amendment to informed consent practices and helps explain shared institutions regarding the conditions under which it is appropriate to conduct pediatric research.” *Id.* These trials would have to comply with the guidelines set forth by the Council for International Organization of Medical Sciences. MNOOKIN & WEISBERG, *supra* note 47, at 439.

<sup>106</sup> Litton, *supra* note 66, at 420.

<sup>107</sup> “The inadequacy to produce a result or bring about a required end; ineffectiveness.” *Futility*, OXFORD ENG. DICTIONARY (4th ed. 1989).

<sup>108</sup> Peter A. Clark, *Medical Futility: Legal and Ethical Analysis*, 9 AM. MED. ASS’N J. ETHICS 375, 378 (2007) (citing AM. MED. ASS’N, CODE OF MEDICAL ETHICS 2.035 (2006)).

<sup>109</sup> As a result, “futility has been confused with interventions that are harmful, impossible, and ineffective.” Clark, *supra* note 1, at 69. Nevertheless, medical futility has come to be defined as:

[A]n action, intervention, or procedure that might be physiologically effective in a given case, but cannot benefit the patient, no matter how often it is repeated. A futile treatment is not necessarily ineffective, but it is worthless, either because the medical action itself is futile (no matter what the patient’s condition) or the condition of the patient makes it futile.

*Id.* (citing LAWRENCE J. SCHNEIDERMAN & NANCY S. JECKER, *WRONG MEDICINE: DOCTORS, PATIENTS, AND FUTILE TREATMENT* 11 (1995) (defining medical futility as “any effort to provide benefit to a patient that is highly likely to fail and whose rare exceptions cannot be systematically produced.”)).

<sup>110</sup> Clark, *supra* note 1, at 70; *see also* ROSS, *supra* note 39, at 40 (“[The best interest standard] is valid even if the patient has never been competent . . .”). *But see* Alex Fleming, *Medical Futility & Parental “Rights”: A Glimpse into the Charlie Gard Case*, VOICES IN BIOETHICS (Sept. 14, 2017), <http://www.voicesinbioethics.net/newswire/2017/9/14/medical->

In the United States, parents have the authority to make decisions regarding the withdrawal of life-sustaining medical treatment on behalf of their minor children<sup>111</sup> since they speak for them with respect to medical treatment decisions.<sup>112</sup> In making such a decision, parents must use the best interest standard.<sup>113</sup> The best interest standard encompasses a good faith determination<sup>114</sup> and includes the following: (1) the consideration of holistic evidence assessing the patient's physical, sensory, emotional, and cognitive functioning; (2) the amount of physical pain that can result from the condition itself, the treatment, and termination of treatment; (3) the projected life expectancy and possibility of recovery with and without the treatment; and (4) the risks, side effects, and benefits of all viable treatment options.<sup>115</sup> If there is a

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futility-parental-rights-a-glimpse-into-the-charlie-gard-case [http://perma.cc/YN9G-QCCR] (“In cases involving patients whose care is deemed futile or useless, health care providers and policy-makers, while seeking to do what is in the ‘best interests’ of the patient, can easily become prey to the temptation of substituting their own personal opinions for how they themselves would wish to be treated if placed in the patient’s shoes. Tom Beauchamp and James Childress state: ‘The most appropriate standard in cases of . . . seriously ill newborns, is that of best interests, as judged by the best estimate of what reasonable persons would consider the highest net benefit among the available options.’ These sorts of judgements are all but natural; however, can be misplaced if one is attempting to define the quality of another person’s life, even if that person is an infant and has a minimal grasp of the world around him.”).

<sup>111</sup> *In re Rosebush*, 491 N.W.2d 633, 637 (Mich. Ct. App. 1992) (holding that “parents are empowered to make decisions regarding withdrawal or withholding lifesaving or life-prolonging measures on behalf of their children.”); *see e.g.*, *Lucas v. Awaad*, 830 N.W.2d 141, 150–51 (Mich. Ct. App. 2013) (holding that “[t]he doctrine of informed consent requires a physician to warn a patient of the risks and consequences of a medical procedure. As a result, a doctor must engage in a substantive discussion with the parent of a minor patient in order to share these risks and consequences and to obtain the parent’s consent for the proposed medical procedure.”) (internal quotations omitted).

<sup>112</sup> *See Parham v. J.R.*, 442 U.S. 584, 621 (1979) (Stewart, J., concurring); *see also In re L.H.R.*, 321 S.E.2d 716, 722 (Ga. 1984).

<sup>113</sup> *See Rosebush*, 491 N.W.2d at 637; *see also* WHEN OTHERS MUST CHOOSE: DECIDING FOR PATIENTS WITHOUT CAPACITY, *supra* note 8.

<sup>114</sup> It is important to note that in the context of weighing the benefits and burdens for an infant whose condition has been deemed futile, such examination should be made holistically and in conjunction with his position as part of the family unit. Fleming, *supra* note 110 (arguing that the examination should be “concerned with the infant in his or her physical, familial, and spiritual totality, with a focus on the family unit . . .”); *see also* June Carbone, *Legal Applications of the “Best Interest of the Child” Standard: Judicial Rationalization or a Measure of Institutional Competence?*, 134 J. AM. ACAD. PEDIATRICS S111, S119 (2014), [http://pediatrics.aappublications.org/content/pediatrics/134/Supplement\\_2/S111.full.pdf](http://pediatrics.aappublications.org/content/pediatrics/134/Supplement_2/S111.full.pdf) [http://perma.cc/LLT3-A687] (“The best interest of the child standard can only advance children’s interests when it is sensitive to the importance of the family in creating the context in which children experience the world.”).

<sup>115</sup> *In re Conroy*, 486 A.2d 1209, 1249 (N.J. 1985) (Handler, J. concurring in part and dissenting in part); *see also* Clark, *supra* note 1, at 68 (“[The] well-established ‘best interest’ standard assumes both a connectedness of the patient to family and physician and a communication process that allows surrogates to decide based on objective, community-based best interest standards.”). *But see* Fleming, *supra* note 110 (The assessment of best interest is “commonly applied to cases where there appears to be little hope of benefit for the patient, [and] ‘asks the decision-makers to weigh the “net benefit” for each possible option and subtract

fundamental difference in opinion<sup>116</sup> between the parents, who have assessed what is in the best interest of their child, and the treating physicians, who have a duty to do no harm,<sup>117</sup> a consultation with an ethics committee could best balance the countervailing perspectives.<sup>118</sup>

Surrogate decision-making, such as that of parents for their child, or a court for a minor, cannot be based on the subjective assessment of

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the “net burdens” of those options.’ This utilitarian way of thinking seeks to maximize what is ‘good’ and minimize pain and suffering. This method, if seeking only to eliminate one’s suffering, can prove disastrous for patients and infants alike, for ‘the ability to feel pleasure and avoid pain . . . [is] a difficult condition to assess in the neonate.’”)

<sup>116</sup> See Clark, *supra* note 1, at 68 (while parents might want to exhaust every option even in the face of futility, “[p]hysicians argue that many of these interventions are burdensome for the child and medically inappropriate because they fail to achieve the proper physiological effect and result in a misallocation of medical resources.”).

<sup>117</sup> Non-maleficence, or “to do no harm,” is one of the four principles of bioethics that ensures patient safety and care. See *How the Four Principles of Health Care Ethics Improve Patient Care*, ST. JOSEPH’S U., <https://online.sju.edu/graduate/masters-health-administration/resources/articles/four-principles-of-health-care-ethics-improve-patient-care> [http://perma.cc/D84E-72CJ] (last visited Sept. 3, 2018); Thomas R. McCormick, *Principles of Bioethics*, U. WASH. SCH. MED., <https://depts.washington.edu/bioethx/tools/princpl.html> [http://perma.cc/YU2K-MTSQ] (last modified Oct. 1, 2013). It originated from Hippocratic literature, which “directed physicians ‘to help and do no harm.’” *Id.*; see *Greek Medicine*, NAT’L LIBR. MED., [https://www.nlm.nih.gov/hmd/greek/greek\\_oath.html](https://www.nlm.nih.gov/hmd/greek/greek_oath.html) [http://perma.cc/6JQ4-7DNV] (last updated Feb. 7, 2012); see also Howard Markel, “I Swear by Apollo” – On Taking the Hippocratic Oath, 350 NEW ENG. J. MED. 2026 (2004).

<sup>118</sup> PRESIDENT’S COMM’N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMEDICAL BEHAVIORAL RESEARCH, DECIDING TO FOREGO LIFE-SUSTAINING TREATMENT: A REPORT ON THE ETHICAL, MEDICAL, AND LEGAL ISSUES IN TREATMENT DECISIONS (1983) (rejecting seeking judicial intervention in evaluating whether to withhold or withdraw life-sustaining treatment in children and incompetent adults, and arguing that hospitals must establish institutional procedures, such as an ethics committee, to foster effective decision making for these individuals); see Elizabeth Heitman, *Institutional Ethics Committees: Local Perspectives on Ethical Issues in Medicine*, in SOCIETY’S CHOICES: SOCIAL AND ETHICAL DECISION MAKING IN BIOMEDICINE 409, 410–12 (1995) (explaining that the American Academy of Pediatrics “issued guidelines for the establishment of multidisciplinary ‘infant bioethics committees’ to review the proposed nontreatment of severely impaired infants using a best-interests standard that recognized the limits of technological intervention” and noting that “in 1984, the [AMA and American Hospital Association] each called for the formation of voluntary ethics committees in hospitals and other inpatient institutions to ‘consider and assist in resolving usual, complicated ethical problems’ in such areas as quality of life, terminal illness, and the use of limited resources.”). Compare *In re Quinlan*, 355 A.2d 647, 688–669 (N.J. 1976), *cert denied*, 429 U.S. 922 (1976) (asserting that the court was not the proper forum for determining whether life-sustaining treatment should be withdrawn or withheld, and that those decisions should be made by consulting an ethics committee) (citing Dr. Karen Teel, *The Physician’s Dilemma: A Doctor’s View: What the Law Should Be*, 27 BAYLOR L. REV. 6 (1975) (“[I]t would be more appropriate to provide a regular forum for more input and dialogue in individual situations and to allow the responsibility of these judgments to be shared. Many hospitals have established an Ethics Committee composed of physicians, social workers, attorneys, and theologians, which serves to review the individual circumstances of ethical dilemma and which has provided much in the way of assistance and safeguards for patients and their medical caretakers.”)), with *Re R (A Minor) (Wardship: Consent to Treatment)* [1992] EWHC (Fam) 11 (“No doctor can be required to treat a child, whether by the court in the exercise of its wardship jurisdiction, by the parents, by the child or anyone else.” Outlining the policy in the United Kingdom, in which doctors do not have to preserve or prolong the lives of ill children).

quality or value of life.<sup>119</sup> Just because the minor's prognosis is unclear or limited does not mean that treatment should automatically be withdrawn, that it is in his best interest to die, or that he cannot enjoy the rest of his life.<sup>120</sup> Therefore, instead of characterizing a condition as futile, and having that classification influence whether life-sustaining treatment should be withdrawn, it should be assessed whether the treatment, or lack thereof, satisfies the intended medical goal.<sup>121</sup>

## II. ANALYSIS: WHO SPEAKS FOR THE CHILD?

### A. *What Would Have Happened to Charlie Gard in the United States*

In order to determine what would have happened to Charlie in the United States, we must assess the constitutional rights at issue. In analyzing whether a right is fundamental, the judicial body is constrained by “the teachings of history, [and the] solid recognition of the basic values that underlie our society.”<sup>122</sup> American law has historically reflected the view consistent with Western civilization that the family is a unit, with parents having broad authority over their minor children.<sup>123</sup> The U.S. constitutional system has rejected that a child is “the mere creature of the State,” and has instead proclaimed that parents generally have the right to guide their children.<sup>124</sup> It can be

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<sup>119</sup> *In re Conroy*, 486 A.2d at 1232–33 (surrogate decision-making cannot be based on a subjective determination of the “personal worth or social utility of another’s life, or the value of that life to others.”). It would neither be appropriate for a court nor for a surrogate to decide that a minor’s life is “not worth living simply because, to that person, the patient’s ‘quality of life’ or value to society seems negligible,” and thus withhold life-sustaining experimental treatment. *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> See MENIKOFF, *supra* note 72, at 365; see also *Causey v. St. Francis Med. Ctr.*, 719 So. 2d 1072, 1075 (La. Ct. App. 1998) (“To focus on a definition of ‘futility’ is confusing and generates polemical discussions.”).

<sup>122</sup> *Griswold v. Connecticut*, 381 U.S. 479, 501 (1965) (Harlan, J., concurring).

<sup>123</sup> *Parham v. J.R.*, 442 U.S. 584, 604 (1979) (holding that “our precedents permit the parents to retain a substantial, if not the dominant, role in the decision, absent a finding of neglect or abuse, and that the traditional presumption that the parents act in the best interests of their child should apply.”).

<sup>124</sup> *Id.* at 602 (parents generally “have the right, coupled with the high duty, to recognize and prepare [their children] for additional obligations”) (citing *Pierce v. Society of Sisters*, 286 U.S. 510, 535 (1925)) (alteration in original); see also *Wisconsin v. Yoder*, 406 U.S. 205, 213–14 (1972) (“[T]he values of parental direction of . . . upbringing . . . of their children in their early and formative years have a high place in our society.”); *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944) (“It is cardinal with us that the custody, care and nurture of the child reside first in the parents, whose primary function and freedom include preparation for obligations the state can neither supply nor hinder. And it is in recognition of this that these decisions have respected the private realm of family life which the state cannot enter.”) (internal citations

inferred that this includes a parental duty to make medical decisions that are in the best interests of their children.<sup>125</sup> Therefore, it can be argued that there is a fundamental right for parents to decide what is in their child's best interest when faced with difficult medical decisions related to treatment uncertainty or futility, and in these cases, decision-making should be deferred to the parents.<sup>126</sup> It is only when parents' refusal of treatment involves a risk of harm to the child<sup>127</sup> that it is considered not in the child's best interest and could constitute child abuse.<sup>128</sup> In those situations, and those in which parents' decisions impede the physician from fulfilling his ethical duty of not causing harm,<sup>129</sup> the state can interfere, asserting its status as *parens patriae* to prevent the child from being harmed and protect the integrity of the medical profession.<sup>130</sup>

Five months after Charlie's birth, and four months after he was diagnosed with a rare mitochondrial DNA depletion syndrome, his mother found an American doctor who was willing to offer Charlie an experimental nucleoside treatment that was successful in treating children who had a similar condition but had never been used on someone who had his exact mutation.<sup>131</sup> Pursuant to paragraph 32 of the Declaration, a physician can, with the informed consent of the patient—or in this case, the patient's parents as proxy—use unapproved experimental treatment when there are no other proven alternatives for treatment, and where, in the physician's judgment, the experimental treatment has the ability to either alleviate suffering or prolong life.<sup>132</sup> This proposition is further supported by the Belmont Report, and Titles 21 and 45 of the Code of Federal Regulations.<sup>133</sup> Although the treatment might not be the prevailing standard of care<sup>134</sup> and could involve a

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omitted); *Meyer v. Nebraska*, 262 U.S. 390, 400 (1923) (“[I]t is the natural duty of the parent to give his children education suitable to their station in life.”).

<sup>125</sup> See, e.g., *Parham*, 442 U.S. at 602 (“The law’s concept of the family rests on a presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life’s difficult decisions. More important, historically it has recognized that natural bonds of affection lead parents to act in the best interests of their children.”).

<sup>126</sup> See *supra* sources cited note 37.

<sup>127</sup> These situations arise when, for example, “parents indicate that they are willing to sacrifice the child’s interests to vindicate the parents’ beliefs or commitments.” See generally *Carbone*, *supra* note 114, at S115.

<sup>128</sup> See *id.*

<sup>129</sup> See *Greek Medicine*, *supra* note 117.

<sup>130</sup> See *supra* sources cited note 37.

<sup>131</sup> *Hayden & Umashanker*, *supra* note 68; see *Heffer*, *supra* note 13.

<sup>132</sup> *World Med. Ass’n*, *supra* note 57, at 374.

<sup>133</sup> See *supra* Section I.B.1.

<sup>134</sup> But, this is a subjective standard. *Developments in the Law—Medical Technology and the Law*, *supra* note 39, at 1592 (“Neonatologists, recognizing that neonatal intensive care decisionmaking [sic] is a complex process and that treatment decisions often have unpredictable outcomes, believe that statues phrased in terms of ‘reasonableness’ and ‘futility’

greater than minimal risk—as it has never been tested on those who presented the same mutation as Charlie had—because this could be the only way to stabilize him, and because there was a possibility for direct therapeutic benefit in his best interest, albeit slim, statutory law would protect the right to obtain such treatment.<sup>135</sup>

Accordingly, Charlie could have received access to the experimental nucleoside treatment in the United States if (1) in Dr. Hirano’s medical judgment it offered hope of saving his life or alleviating his suffering, and there was no other proven therapeutic treatment;<sup>136</sup> (2) there was proper informed consent;<sup>137</sup> (3) subjecting Charlie to this treatment was truly in his best interest; and (4) if either the FDA, under its Expanded Access Program, or the state, under its Right to Try Law, approved of such a request. Here, there was no alternative treatment option except withdrawal of palliative care.<sup>138</sup> Dr. Hirano had reason to believe that the experimental nucleoside treatment could benefit Charlie, as he had prior success with treating another infant who was born with a different form of the mitochondrial depletion syndrome.<sup>139</sup> Additionally, full informed consent is characterized by the disclosure of risks, benefits, and alternatives of a treatment, as well as the identification of experimental procedures and unknown risks.<sup>140</sup> Therefore, when there are no other treatment options,

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cannot provide sufficient guidance.”).

<sup>135</sup> 45 C.F.R. § 46.405 (2018); *see supra* sources cited note 69; *see also In re Baby K*, 16 F.3d 590, 596 (4th Cir. 1994) (inferring that doctors are required to provide medical care even if it is considered “outside the prevailing standard of medical care.”).

<sup>136</sup> World Med. Ass’n, *supra* note 57, at 374.

<sup>137</sup> Kristina M. Cordasco, *Obtaining Informed Consent from Patients: Brief Update Review*, in MAKING HEALTH CARE SAFER II: AN UPDATED CRITICAL ANALYSIS OF THE EVIDENCE FOR PATIENT SAFETY PRACTICES 461, 462 (Agency for Health Care Research & Quality, 2013), [https://www.ncbi.nlm.nih.gov/books/NBK133363/pdf/Bookshelf\\_NBK133363.pdf](https://www.ncbi.nlm.nih.gov/books/NBK133363/pdf/Bookshelf_NBK133363.pdf) [https://perma.cc/DZ9R-AN7C] (noting that proper informed consent contains seven elements: “(1) Discussing the patient’s role in the decision-making process; (2) Describing the clinic issue and suggested treatment; (3) Discussing alternatives to the suggested treatment (including the option of no treatment); (4) Discussing risks and benefits of the suggested treatment (and comparing them to the risks and benefits of alternatives); (5) Discussing related uncertainties; (6) Assessing the patient’s understanding of the information provided; and (7) Eliciting the patient’s preference (and thereby consent). Not every detail needs to be discussed, but all details needed for a ‘reasonable person’ to make a decision must be provided.”).

<sup>138</sup> *See generally Charlie Gard: The Story of His Parents’ Legal Fight*, *supra* note 11.

<sup>139</sup> *See Hayden & Umashanker*, *supra* note 68.

<sup>140</sup> 21 C.F.R. § 50.25(a)(1) (2018). There is an argument that one cannot consent to something unknown. Therefore, in the context of experimental treatment, informed consent is a fallacy, as there could be potentially harmful side effects that, by virtue of the infancy of its testing, are unknown to the physician and parents. *See COWDEN*, *supra* note 104. However, this cannot be so because “[i]f one cannot consent to unknown risks, this would mean that no one could consent to research or potentially experimental treatment. What is needed for informed consent is for the decision maker to understand the known risks and that unknown risks potentially exist.” *Id.*

and experimental treatment remains the only hope, parents such as Charlie's might well have accepted and consented to the unknown risks.

Thereafter, it must be determined whether subjecting Charlie to experimental treatment would have been in his best interest or medically futile. When the only treatment option available is experimental, parents are tasked with the responsibility of weighing the unknown risks and burdens with the benefits of such a treatment.<sup>141</sup> Using the best interest standard, Charlie's parents would have made a good faith determination in their assessment of (1) their son's physical, sensory, emotional, and cognitive functioning; (2) his level of pain; (3) his life expectancy with and without the treatment; and (4) the potential risks and benefits of undergoing experimental treatment as opposed to withdrawing life-sustaining measures.<sup>142</sup>

Charlie's condition caused him progressive muscle, organ, and brain deterioration, compromising his ability to react physically, cognitively, and emotionally to external stimuli.<sup>143</sup> Dr. Hirano's experimental nucleoside treatment had already proved successful in treating an infant with a different form of a mitochondrial depletion syndrome, in that it prevented further deterioration and restored the ability to perform basic motor skills.<sup>144</sup> From his parent's perspective, there was a real possibility that Charlie could survive,<sup>145</sup> and even

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<sup>141</sup> See ROSS, *supra* note 110, at 142 (it is ultimately a "value-laden, quality-of-life decision that should be theirs to make."); *Developments in the Law—Medical Technology and the Law*, *supra* note 39, at 1597; see also Lainie Friedman Ross, *Against the Tide: Arguments Against Respecting a Minor's Refusal of Efficacious Life-Saving Treatment*, 18 CAMBRIDGE Q. HEALTHCARE ETHICS 302 (2009) (asserting that in the United States, when the only course of treatment is experimental, parental discretion has a more influential role).

<sup>142</sup> *In re Conroy*, 486 A.2d 1209, 1230–31 (N.J. 1985).

<sup>143</sup> Telegraph Reporters, *Who is Charlie Gard, What is the Disease He Suffered from and What Happened in the Court Case?*, THE TELEGRAPH (July 31, 2017), <http://www.telegraph.co.uk/news/0/charlie-gard-mitochondrial-disease-suffers-legal-battle> [<http://perma.cc/AS9Z-LARD>]; see also Natasha Hammond-Browning, *When Doctors and Parents Don't Agree: The Story of Charlie Gard*, 14 J. BIOETHICAL INQUIRY 461, 463 (2017) ("Charlie had severe progressive muscle weakness and could not move his arms or legs or breathe unaided. He was persistently encephalopathic so, whilst not brain dead, there was no usual signs of normal brain activities such as responsiveness . . . or interaction . . .").

<sup>144</sup> Hayden & Umashanker, *supra* note 68.

<sup>145</sup> *But see* Bender, *supra* note 78, at 4 (arguing that allowing patients access to Phase I drugs would likely (i) give rise to therapeutic misconception, where research subjects can falsely believe they are receiving therapeutic benefit from their participation in the study, even if they are told that they are only receiving a placebo, which could affect the scientific process and lead to ineffective treatment to becoming the standard of care; (ii) slow enrollment in clinical trials, which can delay the results of efficacy of the treatment; and (iii) allow drug companies to profit before completing clinical trials, which would lead them to prematurely cease the trials as it would be considered an unnecessary expense); Gail E. Henderson et al., *Clinical Trials and Medical Care: Defining the Therapeutic Misconception*, 4 PLOS MED. 1735, 1735–38 (Nov. 2007) ("[Therapeutic misconception] occurs when a research subject fails to appreciate the distinction between the imperatives of clinical research and of ordinary treatment, and therefore inaccurately attributes therapeutic intent to research purposes.") (internal quotation

though he might live a life with disabilities, it could still be a meaningful life for him. When assessing what is in best interest of a child, subjective opinions and biases regarding the “value-laden” characterization of quality of life cannot dictate the decisional outcome; a limited quality of life can nonetheless be meaningful.<sup>146</sup> Therefore, from his parents’ perspective, it would have been in Charlie’s best interest to pursue a treatment that had shown promising effects, instead of continuing to let his brain and muscles deteriorate, which could have possibly caused him more prolonged harm and suffering.<sup>147</sup>

Thereafter, using the best interest standard, Charlie’s parents would have had to assess whether the treatment would have caused Charlie such pain that administering it and other life-sustaining measures would have been inhumane.<sup>148</sup> Analyzing this prong in conjunction with the Child Abuse Amendments of 1984,<sup>149</sup> when his parents initially requested experimental treatment, Charlie was not chronically and irreversibly comatose, the administration of the treatment would neither prolong dying nor be ineffective as there was evidence of its efficacy, and thus it would not have been “virtually futile” or inhumane.<sup>150</sup> Moreover, even though the potential benefits and risks were not fully known with absolute certainty,<sup>151</sup> the principle of altruism can justify such a treatment.<sup>152</sup> Administering the experimental nucleoside treatment would have advanced research to help children in the future who are suffering from Charlie’s condition, and would have

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marks omitted).

<sup>146</sup> See ROSS, *supra* note 110, at 142.

<sup>147</sup> Heffer, *supra* note 13 (quoting Mr. Gard as saying: “This is about a sweet, gorgeous, innocent little boy who was born with a rare disease who had a real, genuine chance at life and a family who loved him so very dearly—and that’s why we fought so hard for him.”); see Hayden & Umashanker, *supra* note 68; see also James Rachels, *Active and Passive Euthanasia*, 292 NEW ENG. J. MED. 78 (1975), <http://rintintin.colorado.edu/~vancecd/phil1100/Rachels.pdf> [<http://perma.cc/2XYN-PLMA>].

<sup>148</sup> See generally *In re Conroy*, 486 A.2d 1209 (N.J. 1985).

<sup>149</sup> The Child Abuse Prevention and Treatment Act was enacted in 1974 to mandate the reporting of suspected child abuse. Daniel J. Mumaw, *The Child Abuse Amendments of 1984: The Infant Doe Amendment*, 18 AKRON L. REV. 515 (1985). The Act was amended several times, with the most recent amendment in 1984. *Id.* The Child Abuse Amendments of 1984 dictate that treatment may be withheld if, in the treating physician’s reasonable medical judgment, continuation of such treatment provides no medical benefit, or does more harm than good. 42 U.S.C. § 5106g(5) (2012) (“[Treatment may be withheld] when, in the treating physician’s or physicians’ reasonable medical judgment—(A) the infant is chronically and irreversibly comatose; (B) the provision of such treatment would—(i) merely prolong dying; (ii) not be effective in ameliorating or correcting all of the infant’s life-threatening conditions; or (iii) otherwise be futile in terms of the survival of the infant; or (C) the provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.”).

<sup>150</sup> 42 U.S.C. § 5106g(5).

<sup>151</sup> Which could fuel the argument that such treatment would in fact be futile and inhumane.

<sup>152</sup> Litton, *supra* note 104, at 390–91.

therefore comported with the best interest standard.<sup>153</sup> Since it is the parents' constitutional right<sup>154</sup> to assess these determinations, absent unequivocal evidence this would have undoubtedly harmed Charlie such that the state could have intervened,<sup>155</sup> Charlie's parents would have received extreme deference, especially because the decision was regarding access to experimental treatment.<sup>156</sup>

Consequently, if both the doctor and parents approved the use of experimental treatment, it must next be analyzed whether Charlie could have obtained access to it either under the FDA's Expanded Access Program, or under state-adopted Right to Try laws. Charlie would probably not have been successful in obtaining access under the FDA's expanded access program because (1) authorization for distribution under the FDA's Expanded Access Program is ultimately contingent upon pharmaceutical companies who are generally fearful of incurring legal liability from injuries that can be unknown;<sup>157</sup> and (2) the overall process is rather slow and costly such that patients with quickly deteriorating conditions, such as Charlie, might not receive the treatment before it would become futile to pursue it.<sup>158</sup> Therefore, he probably would have had a better chance of obtaining pre-approved experimental treatment in the states that have adopted Right to Try laws.<sup>159</sup> Under these laws, parents have successfully been able to obtain experimental treatment for their terminally ill children.<sup>160</sup> Thus, if Charlie had been in the United States, there would have been a good

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<sup>153</sup> See *id.* at 420; see also U.S. DEP'T HEALTH & HUMAN SERVS., *supra* note 64.

<sup>154</sup> See discussion *supra* Section I.A; see also *Parham v. J.R.*, 442 U.S. 584, 604 (1979).

<sup>155</sup> See *supra* sources cited note 37; *Carbone*, *supra* note 114, at S115.

<sup>156</sup> See *supra* sources cited note 141 and accompanying text.

<sup>157</sup> *Pear & Kaplan*, *supra* note 95; see also *Flatten*, *supra* note 95, at 4 (“[D]rug companies rarely do anything that could raise their risk of failure, or draw the ire of the FDA. That especially includes giving their treatment to a dying patient, whose death could be counted against the company seeking approval [for that drug].”).

<sup>158</sup> See *Flatten*, *supra* note 95, at 4 (“[T]he entire regulatory and financial structure of the drug industry is so loaded with disincentives that treatment under compassionate use is rare by design.”).

<sup>159</sup> Right to Try laws have been passed in the following states: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. FAQ, *supra* note 99. But see *Alison Bateman-House et al., Right-to-Try Laws: Hope, Hype, and Unintended Consequences*, 163 ANNALS INTERNAL MED. 796, 797 (2015) (“The cruelest aspect of right-to-try laws is their creation of the false belief that experimental drugs and devices will be available to dying patients in states with these laws. In fact, the laws create no right for patients to obtain anything; rather, they state that patients have a right not to be barred from seeking access to experimental products. ‘Right to try,’ however, implies an entitlement: If a person asks, someone or some entity has a duty to provide. But right-to-try laws create no duty on the part of industry to provide anything.”).

<sup>160</sup> See *Right to Try is Working*, RIGHT TO TRY, <http://righttotry.org/right-to-try-is-working> [<http://perma.cc/6TJK-HXF3>] (last visited Sept. 3, 2018).

chance he could have received the experimental nucleoside treatment in a Right to Try state instead of relying on FDA approval or a serendipitous acceptance into a clinical trial.<sup>161</sup>

On April 11, 2017, the High Court judge denied the request of Charlie's parents to allow him to have experimental treatment and ruled that life support should be withdrawn against his parents' wishes, as his condition was deemed medically futile.<sup>162</sup> The concept of futility is inherently subjective and, thus, influences the best interest analysis.<sup>163</sup> The value Charlie's parents placed on his life led them to conclude that withdrawal of life-sustaining treatment was not in Charlie's best interest, as it could cause him pain and would not respect his personhood.<sup>164</sup> Moreover, as a family unit, parents should be able to be with their son and treat him until the very end.<sup>165</sup> Contrastingly, physicians value beneficence in conjunction with their duty to do no harm.<sup>166</sup> Therefore, if continuing life-sustaining treatment would have no empirical benefit to the patient and would be ineffective in treating or improving the patient's condition, the physician, in his professional capacity, would not be obligated to continue administering such treatment.<sup>167</sup> In Charlie's case, the physicians felt that they could not do anything that would improve his condition, as he had deteriorated to the point such that any life-sustaining treatment was futile and would only prolong his death.<sup>168</sup> The conflicting values of Charlie's parents and

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<sup>161</sup> See Flatten, *supra* note 95, at 4.

<sup>162</sup> Heffer, *supra* note 13; see Scutti, *supra* note 12.

<sup>163</sup> See Fleming, *supra* note 110.

<sup>164</sup> See Rachels, *supra* note 147 (explaining that sometimes, letting a patient dehydrate and starve to death by withdrawing life support—passive euthanasia—is worse than active euthanasia).

<sup>165</sup> See Fleming, *supra* note 110; Carbone, *supra* note 114, at S117, S119 (“A child has an interest in being part of a family, of continuing relationships with those who will provide support during medical treatments, and contributing in turn as a full member of the ongoing community that constitutes the family.”).

<sup>166</sup> See *supra* sources cited note 65 and accompanying text; *Greek Medicine*, *supra* note 129.

<sup>167</sup> Deborah L. Kasman, *When is Medical Treatment Futile? A Guide for Students, Residents, and Physicians*, 19 J. GEN. INTERNAL MED. 1053 (2004). However, whereas treatment can be deemed futile, medical care can never be: “[t]he patient must be guaranteed palliation, pain control, respect of her dignity, and reassurance that the medical team will never abandon her care even when specific treatments are deemed futile.” *Id.* at 1054–55; see Mary S. McCabe & Courtney Storm, *When Doctors and Patients Disagree About Medical Futility*, 4 J. ONCOLOGY PRAC. 207 (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2793955/pdf/jop207.pdf> [<https://perma.cc/HN2X-AT3Q>] (“The AMA Code of Ethics says physicians have an affirmative obligation to transition a patient to palliative care when other treatments have no reasonable chance of providing benefit.”).

<sup>168</sup> See Ashley Sweet, *Exploring the Futility of Care for Charlie Guard*, IMPAKTER (Sept. 6, 2017, 1:00 PM), <https://impakter.com/exploring-futility-care-charlie-guard> [<https://perma.cc/X3MJ-3P58>] (“In [the hospital’s] assessment, the underlying damage that Charlie had sustained was irreversible. . . . [Therefore,] Charlie’s treating physicians’ goal of care was to provide Charlie with a peaceful and comfortable death in the face of a tragic terminal illness. With little hope for benefit from an unproven experimental treatment, [due to his poor and fatal

physicians produced different views of what was in his best interest, causing a medical futility dispute.<sup>169</sup> In the United States, the resolutions of a futility dispute diverge as states have enacted different futility statutes that have varied deferential stances towards parental rights.<sup>170</sup>

## B. *Futility Statutes*

This Section explores the three types of futility statutes in the United States—red light, yellow light, and green light—in order to assess what would have happened to Charlie had he been treated in those respective jurisdictions. Furthermore, an analysis of the critiques of these approaches exemplifies the problem with a broad and ambiguous definition of futility.

### 1. Red Light

In states that have adopted a red light approach to futility, physicians cannot withdraw or withhold life-sustaining treatment without the consent of the surrogate decision-maker.<sup>171</sup> These substantive red light statutes dictate that in situations in which a surrogate requests life-sustaining treatment, the physician must comply even if in his professional capacity he ethically and morally objects.<sup>172</sup> Moreover, in procedural red light states, guidelines allow for surrogates to resort to the judicial process to get temporary restraining orders and

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prognosis] they believed that the burdens of prolonged invasive interventions, such as remaining on a ventilator and receiving tube feeds, while Charlie's underlying condition continued to worsen, were simply too great. Charlie's invasive treatments, they thought, could potentially have been causing him unnecessary suffering.”). This was corroborated by Dr. Hirano's assessment of Charlie's condition. Gina Shaw, *Grappling with Hope and Futility in Mitochondrial Disease*, 17 *NEUROLOGY TODAY* 14, 15 (2017), [https://journals.lww.com/neurotodayonline/Citation/2017/09070/The\\_Lessons\\_of\\_Charlie\\_Gard\\_\\_Grappling\\_with\\_Hope.8.aspx](https://journals.lww.com/neurotodayonline/Citation/2017/09070/The_Lessons_of_Charlie_Gard__Grappling_with_Hope.8.aspx) [http://perma.cc/9NHJ-JTQQ] (“After examining Charlie personally in the UK, and reviewing his scans, Dr. Hirano determined that his condition had deteriorated to the point that he was unlikely to benefit from the treatment.”).

<sup>169</sup> Medical futility disputes generally occur when the surrogate decision-maker requests aggressive treatment interventions for the chronically ill or imminently dying patient, but the physician refuses to administer such a treatment, as, in his professional view, it is medically or ethically inappropriate. Pope, *supra* note 22, at 351.

<sup>170</sup> *Id.* at 359. The foregoing analysis assumes that Charlie's condition had progressed to the point where the administration of experimental therapy would produce no benefit, i.e., it would be medically futile, and his death would be inevitable.

<sup>171</sup> *Id.* at 359–60.

<sup>172</sup> *Id.* at 360; see N.Y. PUB. HEALTH LAW § 2994-f (McKinney 2018) (“[I]f a surrogate directs the provision of life-sustaining treatment, the denial of which in reasonable medical judgment would be likely to result in the death of the patient, a hospital or individual health care provider that does not wish to provide such treatment shall nonetheless comply with the surrogate's decision . . .”).

injunctions.<sup>173</sup> In determining whether to grant such requests, judges will generally preserve the status quo of continuing life-sustaining treatment until adjudication; however, since the judicial process is slow, the patient often dies before the court can reach the merits.<sup>174</sup> Almost by default, then, the surrogate decision maker wins.<sup>175</sup> If Charlie was treated in a red light state,<sup>176</sup> the physician would have had to follow to his parents' wishes to continue administering life-sustaining treatment, even though Charlie's condition was deteriorating, there was no possibility of recovery, and the treating physicians felt that prolonging his life, and thus his suffering, was medically and ethically inappropriate.

Although this approach takes a highly deferential stance toward the parental right to make important and personal decisions on behalf of children, one of the major critiques of it is that the elimination of physicians' discretion of what is medically and ethically appropriate eliminates the identification of futile treatment.<sup>177</sup> This allows for the prolongation of the patient's suffering and leads the physician to be morally and ethically distressed, as the administration of treatment would go against his duty to do no harm.<sup>178</sup> Moreover, this undercuts

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<sup>173</sup> Pope, *supra* note 22, at 360.

<sup>174</sup> *Id.* at 360–61.

<sup>175</sup> *Id.*

<sup>176</sup> Such states include Idaho, Minnesota, New York, and Oklahoma. Thaddeus M. Pope, *Medical Futility Statutes*, BIOETHICS, HEALTH L. NORMATIVE JURIS., <http://www.thaddeuspope.com/futilitystatutes.html> [<http://perma.cc/R9Y3-MJ32>] (last visited Sept. 3, 2018).

<sup>177</sup> Pope, *supra* note 22, at 366 (“[The red light approach] is an unwelcome development because it mandates the continuation of life-sustaining treatment even when it is medically and ethically inappropriate. This might be characterized as a ‘false negative’ error. By eliminating clinician discretion, red light states eliminate the option of positively identifying the treatment as ‘futile.’ Patients continue to suffer. Clinicians continue to experience moral distress. Other patients are exposed to increased risks. And scarce health care resources are wasted.”).

<sup>178</sup> *Id.*; see *supra* sources cited note 117 and accompanying text. In fact, Hippocrates discouraged doctors from treating patients who are “overmastered by their disease.” Leigh Page, ‘Doctor, Don’t Give Up on Me!’, MEDSCAPE (Mar. 16, 2016), [https://www.medscape.com/viewarticle/857725\\_4](https://www.medscape.com/viewarticle/857725_4) [<http://perma.cc/DND2-NF9D>] (citing John D. Papadimitriou et al., *Euthanasia and Suicide in Antiquity: Viewpoint of the Dramatists and Philosophers*, 100 J. ROYAL SOC’Y MED. 25 (2007), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1761665/pdf/0025.pdf> [<https://perma.cc/TG73-GG9W>]); see also Oren Faircloth, *Mediation and End-of-Life Futility Decisions for Newborns*, 19 QUINNIPIAC HEALTH L.J. 153, 169 (2016) (“By enacting a ‘red light’ futility statute, the New York legislature has implicitly endorsed the notion that, in certain circumstances, a parent must have the right to set the standard of care for their child, despite the recommendations from the provider. If a provider recommends that LSMT be withdrawn because it is only prolonging suffering and death, and the parent refuses, the parent’s standard of care that ‘everything be done’ effectively trumps the provider’s professional responsibility to ‘first do no harm.’”). *But see* Rachels, *supra* note 147 (explaining that the alternative, the withdrawal of life-sustaining treatment, is characterized as passive euthanasia. The rationale of passive euthanasia is that it is the underlying pathology that causes death, not the withdrawal of life support, and therefore the doctor is not doing any harm. However, there is an argument that withdrawal of life-sustaining treatment is not the option that minimizes

the state's interest in protecting both the well-being of a minor child and the integrity of the medical profession: continuing life-sustaining treatment—if considered to be outside the standard of medically appropriate care—prolongs inevitable suffering and death, which would not only compromise the physicians' integrity in their role as healers, but would also permit state intervention in its capacity as *parens patriae* to prevent such protracted harm.<sup>179</sup> Therefore, this approach does not adequately balance the interests of both parties.

## 2. Yellow Light

Most states adopt a yellow light approach to futility disputes in which there is uncertainty surrounding the determination of whether physicians may stop treatment without the consent of the surrogate.<sup>180</sup> These statutes neither expressly permit nor forbid physicians from unilaterally ceasing the administration of life-sustaining treatment and leave the physicians uncertain as to the legal consequences of stopping such treatment without consent.<sup>181</sup>

The California statute is a noteworthy example of the inherent ambiguity in the yellow light futility statutes.<sup>182</sup> In California, physicians can refuse to comply with the surrogates' requests to provide life-

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harm. Using a consequentialist approach, we must then ask, what are the actions a physician, in their role as healers, can take that would achieve the best consequences in trying to alleviate a terminally ill patient's suffering? There are three possibilities: active euthanasia, passive euthanasia, and physician-assisted suicide. James Rachels argues that passive euthanasia, letting the patient die by withdrawing life-sustaining treatment, is sometimes worse for the patient and has the possibility to cause more prolonging harm and suffering, than killing them. Moreover, he argues that in some cases, letting someone die is as morally reprehensible as killing them. Therefore, it appears that this concept can also be inconsistent with the physician's obligation to do no harm).

<sup>179</sup> *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997); see *supra* sources cited note 37.

<sup>180</sup> Pope, *supra* note 22, at 363. Examples of such states include California, Delaware, and Connecticut. Pope, *supra* note 176.

<sup>181</sup> Pope, *supra* note 22, at 363. Even though they seem to provide legal immunity for physicians who stop life-sustaining treatment without consent, it is not clear whether such immunity is actually obtained. *Id.* (“[T]his immunity depends upon the satisfaction of standards and conditions that clinicians cannot be sure are really satisfied.”).

<sup>182</sup> As stipulated in the California Probate Code, a physician “may decline to comply with an individual health care instruction or health care decision that requires medically ineffective health care or health care contrary to those generally accepted health care standards applicable to the health care provider.” *Id.* at 364 (explaining that the physician “will not be ‘subject to civil or criminal liability or to discipline for unprofessional conduct’” if he acted in good faith when refusing to comply with the surrogate's request) (citing CAL. PROB. CODE § 4735 (West 2018)). However, the statute does not expressly set forth how the conditions can be satisfied so as to obtain legal immunity from the consequences of their actions. *Id.* This is in stark contrast to the green light approach, where the statute's conditions are “concrete and measurable,” as the physicians must “give forty-eight hours' notice of the ethics committee meeting, and (b) wait ten days.” *Id.*; see TEX. HEALTH & SAFETY CODE ANN. § 166.046 (West 2017).

sustaining treatment if such requests are “medically ineffective” or “contrary to generally accepted healthcare standards.”<sup>183</sup> These guidelines base legal immunity on a standard that is undefined due to the inherent and significant variability in medical practice.<sup>184</sup> Accordingly, if Charlie was treated in a yellow light state, the result of his futility dispute would be uncertain, as it would depend on how the treating physician interpreted the “generally accepted healthcare standards” as applied to Charlie’s unique situation.

While yellow light futility statutes incorporate oversight and accountability into the proposed standard of care, it is so uncertain, and physicians are so fearful of litigation, that the statute is more often than not interpreted as a red light.<sup>185</sup> Taking into account this understanding, the yellow light approach does not afford the proper constitutional balance between the parent’s fundamental right to make decisions about child-rearing and the state’s interest in protecting both children from harm and the integrity of the medical profession. It leaves physicians with essentially no rights<sup>186</sup> and gives parents too much power to make decisions for their own personal reasons, which can ultimately worsen the harm and suffering of their child, thereby justifying state intervention.<sup>187</sup>

### 3. Green Light

Lastly, green light futility statutes allow clinicians to stop treatment without the consent of the surrogate decision-maker.<sup>188</sup> These statutes, such as the Texas Advance Directives Act, set forth clear guidelines regarding legal immunity.<sup>189</sup> Abiding by the statute’s procedures,

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<sup>183</sup> Pope, *supra* note 22, at 364 (citing CAL. PROB. CODE § 4735).

<sup>184</sup> *Id.* at 363.

<sup>185</sup> Thaddeus M. Pope, *More on the H.B. 3520 Hearing and the Texas “Futility” Law*, MED. FUTILITY BLOG (Apr. 16, 2011), <http://medicalfutility.blogspot.com/2011/04/more-on-hb-3520-hearing-and-texas.html> [<http://perma.cc/M458-PW25>]; *see also* Faircloth, *supra* note 178, at 169 (“While physicians in ‘yellow light’ states are permitted to withdraw LSMT, the uncertain outcome of any subsequent litigation is enough to prevent risk-adverse providers from withdrawing LSMT unilaterally, without parental consent.”).

<sup>186</sup> *See* Page, *supra* note 178.

<sup>187</sup> *See generally* Carbone, *supra* note 114.

<sup>188</sup> Pope, *supra* note 22, at 361; *see* Page, *supra* note 178 (“[A]dministering ineffective interventions goes against the most basic ethical obligations of clinicians to benefit individual patients and to avoid harm.”).

<sup>189</sup> Pope, *supra* note 22, at 361–62; *see* Pope, *supra* note 176. (“Most states have some statutory provisions that (purport to) permit healthcare providers to refuse to comply with instructions or decisions for treatment that are contrary to the provider’s professional judgment and/or the professional’s conscience. Most are ineffective, because they condition immunity on compliance with the standard of care. Texas law includes no such condition.”); *see also* TEX. HEALTH & SAFETY CODE ANN. § 166.044 (West 2017) (“(a) A physician or health care facility that causes life-sustaining treatment to be withheld or withdrawn from a qualified

physicians who cease life-sustaining treatment after a hospital committee agrees with their classification of treatment as futile, then wait ten days to allow the surrogate decision-maker time to find a facility who will provide the requested treatment, will be civilly, criminally, and disciplinarily immune from legal action.<sup>190</sup>

This approach most resembles that of the United Kingdom. In the United Kingdom, the courts appointed a *guardian ad litem*<sup>191</sup> to represent the best interests of Charlie,<sup>192</sup> who had to agree with the physician's determination for the withdrawal of treatment to proceed.<sup>193</sup> Similarly, pursuant to the green light approach, an institutional committee must agree with the physician's determination before unilaterally withdrawing treatment.<sup>194</sup> If a hospital committee agreed with the physician's assessment of Charlie's futile condition, and his parents could not, within ten days, find a facility that would provide the life-sustaining treatment they requested, the treating physicians would have the unilateral right to withdraw such treatment without the consent of his parents.<sup>195</sup> Therefore, if Dr. Hirano could not have accepted Charlie's case within that short timeframe, and if Charlie was treated in a state with a green light approach, such as Texas, the result would most likely have been the same as it was in the United Kingdom.

One criticism of the green light approach is that it can cause life-sustaining treatment to be incorrectly identified as futile.<sup>196</sup>

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patient . . . is not civilly liable for that action unless the physician or health care facility fails to exercise reasonable care when applying the patient's advance directive. . . . (c) A physician, or a health professional acting under the direction of a physician, who participates in withholding or withdrawing life-sustaining treatment from a qualified patient . . . is not criminally liable or guilty of unprofessional conduct as a result of that action unless the physician or health professional fails to exercise reasonable care when applying the patient's advance directive. (d) The standard of care that a physician, health care facility, or health care professional shall exercise under this section is that degree of care that a physician, health care facility, or health care professional, as applicable, of ordinary prudence and skill would have exercised under the same or similar circumstances in the same or a similar community.”).

<sup>190</sup> Pope, *supra* note 22, at 361.

<sup>191</sup> “A guardian . . . appointed by the court to appear in a lawsuit on behalf of an incompetent or minor party.” *Guardian ad litem*, BLACK'S LAW DICTIONARY (10th ed. 2014).

<sup>192</sup> Because the physicians believed Charlie's parents' decision would lead to more, unnecessary suffering. See *Great Ormond Street Hospital v. Yates*, [2017] EWHC (Fam) 1909 [18] (Eng.) (“In circumstances where there is a dispute between parents and the hospital, it was essential that Charlie was himself independently represented and a guardian was therefore appointed to represent Charlie so that there was someone who could independently report to the court as to what was in his best interests.”).

<sup>193</sup> The guardian was appointed to represent the interests of Charlie as he lacked decision-making capacity. See Arthur L. Caplan, *Should Doctors Decide When It's Futile to Keep Charlie Gard Alive?*, MEDSCAPE (July 27, 2017), <https://www.medscape.com/viewarticle/883366> [http://perma.cc/8WEP-7FF3].

<sup>194</sup> Pope, *supra* note 22, at 361.

<sup>195</sup> See *id.*

<sup>196</sup> *Id.* at 366; see Judith F. Daar, *Medical Futility and Implications for Physician Autonomy*, 21 AM. J.L. & MED. 221, 222 n.10 (arguing that the debate surrounding whether a physician

Additionally, it does not afford the opportunity to seek appellate review in front of an independent and neutral decision maker, which is a cornerstone of procedural due process,<sup>197</sup> and which is necessary in addressing the fundamental parental rights at stake.<sup>198</sup> Moreover, these statutes do not reduce the risk of error in withdrawing life-sustaining treatment, as they do not prevent a physician's "corruption, bias, carelessness, and arbitrariness" from seeping into this extremely significant decision.<sup>199</sup> Because of the value-laden characterization of medical futility, "[c]linicians and ethics committees may inappropriately determine that the burdens of treatment outweigh the benefits, because they judge the patient's quality of life to be far lower than the [parent or surrogate decision maker] would judge it to be."<sup>200</sup> This allows for physicians to treat their patients in an overly paternalistic way when unilaterally deciding to cease treatment.<sup>201</sup> Consequently, this limits parents' decisional autonomy and substantive due process rights in making decisions that are essential to their children's personal bodily dignity.<sup>202</sup>

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ethically can unilaterally refuse to provide, or withdraw, treatment "revolves around fundamentally irresolvable moral conflicts concerning our most deeply held beliefs about the value of life." Therefore, a surrogate (who believes that life is precious) and a physician (who believes that life-prolonging, aggressive treatment should not be given to an irreversibly ill patient) will never agree on one definition of medical futility) (citing E. Haavi Morreim, *Profoundly Diminished Life: The Casualties of Coercion*, 24 HASTINGS CTR. REP. 33 (1994)).

<sup>197</sup> U.S. CONST. amend. XIV; see also Douglas B. White & Thaddeus M. Pope, *The Courts, Futility, and the Ends of Medicine*, 307 J. AM. MED. ASS'N 151, 151-52 (2012) (explaining that there are three potential benefits of preserving the possibility of appeal to the courts in futility disputes: (i) "[t]o [e]ncourage [i]ntensive [c]ommunication" between the patient's surrogate decision maker and clinician; (ii) "to obtain guidance on how to balance conflicting interests involved in futility cases;" and (iii) "[t]o [s]hine a [s]potlight on an [u]nresolved [s]ocial [i]ssue").

<sup>198</sup> Pope, *supra* note 22, at 366.

<sup>199</sup> *Id.*

<sup>200</sup> *Id.*; see White & Pope, *supra* note 197 ("[P]atients, physicians, and society have important interests at stake. Patients have an interest in receiving care consistent with their values. Physicians have an interest in not being compelled to act against their beliefs about how to best respect human dignity near life's end. Society has important interests in protecting individual rights and ensuring the fair allocation of scarce medical resources. When the interests of each party are correctly understood, it is clear that such decisions are not purely 'medical' decisions; thus, unilateral clinician decision making is problematic.").

<sup>201</sup> Paternalism is defined as "the interference of a state or an individual with another person, against their will, and defended or motivated by a claim that the person interfered with will be better off or protected from harm." Gerald Dworkin, *Paternalism*, STAN. ENCYCLOPEDIA PHIL., <https://plato.stanford.edu/archives/spr2017/entries/paternalism> [<http://perma.cc/8TWJ-CPAV>] (last updated Feb. 12, 2017). An act is paternalistic when an actor interferes with the decisional autonomy or liberty of another by making a decision for him, either against his consent or without his consent, because the actor believes that doing so would improve his welfare or promote his best interest. *Id.*

<sup>202</sup> See generally discussion *supra* Section II.A.

## III. PROPOSAL

Decisions surrounding medical futility are ultimately centered around principles of child-rearing, a fundamental right protected under liberty and privacy of the Due Process Clause.<sup>203</sup> Therefore, state futility statutes must properly balance parental rights and the state's interests in determining who is in the best position to properly assess an infant's quality of life and best interests in end-of-life treatment and care. However, the current state statutes are unable to attain this constitutional balance because the ambiguous interpretation of futility is embedded in its provisions—in these futility statutes, the states rarely define what constitutes medically futile care.<sup>204</sup>

Labeling a patient or a treatment as “medically futile” is inherently problematic because it invites subjective, value-laden judgment about quality of life or medical prognosis.<sup>205</sup> The lack of uniformity in defining futility, therefore, often leads to overly paternalistic, physician-centered decisions<sup>206</sup> regarding the administration, withholding, and withdrawal of treatment. Consequently, this undermines parents' right to make

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<sup>203</sup> See *supra* Section I.A (discussing that child-rearing is a fundamental right protected by the Fourteenth Amendment of the Constitution. Included in that is the ability of parents to speak on behalf of their minor children, which inevitably occurs within the context of medical decisions. There is a presumption that parents have their children's best interests in mind when making those decisions, and thus, they should be respected.); see also *supra* Section II.A.

<sup>204</sup> McCabe & Storm, *supra* note 167, at 207.

<sup>205</sup> Bosslet et al, *supra* note 27, at 1327 (explaining that such characterization is “problematic because [it] often hinge[s] on controversial value judgments about quality of life or require[s] a degree of prognostic certainty that is often not attainable.” Thus, each doctor is expected to come up with his own working definition of futility); see Kasman, *supra* note 167, at 1054 (explaining that scholar Griffin Trotter has attempted to clarify the definition of futility, arguing that it occurs when “(1) [t]here is a goal, (2) [t]here is an action and activity aimed at achieving this goal, and (3) [t]here is virtual certainty that the action will fail in achieving this goal.” But, it is nearly impossible to obtain “virtual certainty,” as there are always exceptions and small chances that a patient could survive against all odds. Moreover, “[m]odern medical knowledge and progressive technologies have dramatically altered our ability to sustain life. Discerning when medical interventions merely prolong dying is a distinctly modern challenge.”); see also James L. Bernat, *Medical Futility: Definition, Determination, and Disputes in Critical Care*, 2 NEUROCRITICAL CARE 198 (2005) (“Medical futility remains ethically controversial for several reasons. Some physicians summarily claim a treatment is futile without knowing the relevant outcome data. There is no unanimity regarding the statistical threshold for a treatment to be considered futile. There is often serious disagreement between physicians and families regarding the benefits to the patient of continued treatment. Medical futility has been conceptualized as a power struggle for decisional authority between physicians and patients/surrogates.”).

<sup>206</sup> Kasman, *supra* note 167, at 1054 (“Opponents of using medical futility for ethical arguments worry that physicians have a trump card to overpower families with less knowledge, thereby delivering paternalistic care. . . . These [opponents] state futility should never be evoked in medical decision making and prefer using *standards of care* combined with the *best interest* of the patient to solve end-of-life dilemmas.”); see also Bernat, *supra* note 205, at 198 (“Physicians may employ the concept of medical futility to justify a decision not to pursue certain treatments that may be requested or demanded by patients or surrogates.”).

autonomous decisions with respect to the bodily integrity of their children. This is illustrative of the green light approach, which gives a physician unilateral authority to withdraw life-sustaining treatment, even though there is inevitably variability—rooted in the subjectivity of ethical and medical judgment—among physicians in what constitutes appropriate care in the face of futility.<sup>207</sup> This poses a concern of undue variability in making decisions about treatment, dissuades physicians from fully engaging in challenging conversations that often help support surrogates through this painful process, and hinders physicians from working with surrogates to achieve mutually agreeable decisions.<sup>208</sup> A physician-centered futility statute in conjunction with an overbroad characterization of futility is problematic.<sup>209</sup> In comparison, although the red light approach is most deferential to parental rights, as it gives the decision-making authority to the parents or surrogates, it is problematic because parents do not have a positive right to request and demand treatment that is contrary to accepted medical practices.<sup>210</sup> The strong emotional and psychological factors that are involved in assessing end-of-life decisions may alter the parents' perception of whether their child's condition is truly futile and thus may dissuade them from genuinely considering a physician's professional recommendations.<sup>211</sup>

A statute that narrowly characterizes “futile” conditions or treatments, and that provides a more workable definition, would enable a collaborative approach that would respect a proper constitutional balance between state and parental rights.<sup>212</sup> It would also help remove the value judgment attached to futility.<sup>213</sup> The Society of Critical Care Medicine, the AMA, and the Texas Advance Directives Act have individually published statements regarding how to manage disputes between surrogates who request interventions and physicians who believe such interventions should not be administered.<sup>214</sup> However, their

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<sup>207</sup> See *supra* Section II.B.3.

<sup>208</sup> Bosslet et al., *supra* note 27, at 1323.

<sup>209</sup> See *id.* at 1322.

<sup>210</sup> *Id.*; see Clark, *supra* note 1, at 77 (“As a matter of justice, patients/surrogates cannot be given the absolute right to demand any medical treatment. To do so would create a system that would irrationally allocate health care to socially powerful people with strong preferences for immediate treatment to the disadvantage of those with less power and less immediate needs.”).

<sup>211</sup> Bosslet et al., *supra* note 27, at 1322.

<sup>212</sup> See generally *id.*

<sup>213</sup> FRANÇOISE BAYLIS ET AL., HEALTH CARE ETHICS IN CANADA 410 (3d ed. 2012) (explaining that “[p]hysiologic futility, understood in narrow terms, comes close to providing a value-free understanding of futility”).

<sup>214</sup> Bosslet et al., *supra* note 27, at 1320–21. The Society of Critical Care Medicine states that “[t]reatments should be defined as futile only when they will not accomplish their intended goal . . . i.e., treatments that have no beneficial physiologic effect.” *Id.* at 1321. The AMA has not endorsed any substantive definition. *Id.* The Texas Advance Directives Act endorses the use of “medically inappropriate” instead of futile. *Id.*

guidelines offer substantially different and conflicting definitions of “futile,”<sup>215</sup> which further blurs this already confusing concept.<sup>216</sup> In response to a need for clear guidance, in 2015, the ATS promulgated guidelines that are structured in such a way that narrow the ambiguity in futility and force surrogates and physicians to work collaboratively to make treatment decisions.<sup>217</sup> The guidelines remedy the shortcomings of the current futility statutes, enabling an adequate constitutional balance.<sup>218</sup> Its language should therefore be adopted by all states. This would respect the states’ roles as laboratories of experimentation, as it would merely clarify the central concept of the statutes while preserving the respective approaches.

The ATS recommends that “potentially inappropriate,” instead of “futile,” should be used to characterize a treatment that has a minimal chance of accomplishing the desired result of the surrogate, but for which a physician cannot ethically justify its administration.<sup>219</sup> This is because “inappropriate” more accurately and clearly conveys that the determinations being made by the physician depends on both technical medical expertise and technical judgment rather than just value-laden determinations.<sup>220</sup> Additionally, “potentially” suggests that these judgments are preliminary and thus require review before they can be acted upon.<sup>221</sup> In situations in which requests for potentially inappropriate treatment remain burdensome or demanding, despite the fact that the physician has communicated<sup>222</sup> with the surrogate about

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<sup>215</sup> See *id.* at 1321.

<sup>216</sup> *Id.* at 1320–21.

<sup>217</sup> *Id.* at 1320 (explaining that “collaborative decision making is a fundamental aspect of good medical care and is therefore a valuable ethical goal to foster.”).

<sup>218</sup> The guidelines unify the interests of patients, doctors, and the state:

Clinicians have an interest in not being compelled to act against their best understanding of their professional responsibilities. Society has important interests in protecting individual rights, fostering clinician professionalism, and ensuring the fair allocation of medical resources. Because of these complexities and the need for clear guidance . . . the American Thoracic Society (ATS) convened a multisociety working group to [ ] provide [guidelines that reflect the various perspectives].

*Id.* at 1320.

<sup>219</sup> *Id.* at 1318. Examples of which include when:

(ii) [a] clinician believes it is inappropriate to initiate dialysis in a patient in a persistent vegetative state; (iii) [a] clinician believes it is inappropriate to continue mechanical ventilation in a patient with widely metastatic cancer; (iv) [a] clinician believes it is inappropriate to place a tracheostomy tube in a child with prolonged respiratory insufficiency and severe irreversible neurological impairment.

*Id.* at 1324.

<sup>220</sup> *Id.* at 1322.

<sup>221</sup> *Id.*

<sup>222</sup> “Existing evidence suggests that most clinician–surrogate disputes can be resolved through ongoing communication or with the help of expert consultants, such as ethics or palliative care consultants.” *Id.* at 1320. Moreover:

the proposed treatment plan, the ATS suggests that there should be fair, process-based dispute resolution.<sup>223</sup>

In comparison, “futile” should only be used when a medical intervention cannot accomplish the intended physiological goal, which is a rare occurrence.<sup>224</sup> This narrow definition distinguishes cases in which the requested treatment cannot, under any circumstances, produce a benefit, from those that might be able to accomplish the desired goal.<sup>225</sup> In the infrequent cases in which the intended psychological effect cannot be accomplished, physicians should not

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[C]linicians should listen closely to surrogates; provide emotional support and establish a trusting relationship; discuss the patient’s prognosis in clear, jargon-free language; elicit the patient’s values and preferences; and explain principles of surrogate decision making. Based on this conversation, clinicians should discuss which treatment options fit with patient’s goals . . . [and] need not offer treatments that are outside the boundaries of accepted medical practice. If surrogates request treatments that clinicians believe are not consistent with a patient’s values or interests, or are outside the boundaries of accepted practice, clinicians should not simply acquiesce to these requests. Instead, clinicians should seek to understand the surrogate’s perspective, correct any misperceptions, and share the clinician’s perspectives with the surrogate. If the surrogate continues to advocate for treatments that the clinician believes are ill advised, the clinician should respectfully advocate for an alternative treatment course. This is important, because clinicians are obligated to advocate for good medical practice as part of their professional role, and their judgments about the boundaries of good medical practice deserve careful consideration in decisions regarding life-prolonging treatments.

*Id.*

<sup>223</sup> This includes:

(1) Enlist[ing] expert consultation to continue negotiation during the dispute-resolution process; (2) Giv[ing] notice of the process to surrogates; (3) Obtain[ing] a second medical opinion; (4) Obtain[ing] review by an interdisciplinary hospital committee; (5) Offer[ing] surrogates the opportunity to transfer the patient to an alternate institution; (6) Inform[ing] surrogates of the opportunity to pursue extramural appeal; [and] (7) Implement[ing] the decision of the resolution process.

*Id.* at 1319. Note that this mirrors some of the guidelines of the green light approach but preserves the right for an appeal. Additionally:

A process-based approach to conflict resolution is also recommended because the cases in question are ethically controversial, have important interests at stake, and do not have explicit rules that can be mechanically applied to resolve disputes. It is ethically important to incorporate multiple perspectives to minimize the risk that the values of any one individual will carry undue weight. In addition, process-based approaches better fulfill democratic ideals for resolving conflicts involving fundamental interests . . . .

*Id.* at 1323.

<sup>224</sup> *Id.* at 1319. Examples of which include: (i) “[a] clinician refus[ing] to perform CPR on a patient with signs of irreversible death (rigor mortis, dependent lividity)”); or (ii) “[a] clinician refus[ing] to administer antifungals as treatment for an acute myocardial infarction.” *Id.* at 1325.

<sup>225</sup> *Id.* at 1326–27 (“This distinction is important because, although there is general agreement that clinicians need not provide strictly ineffective interventions, there is controversy regarding how to resolve conflicts about treatments that might produce effects of controversial benefit.”).

provide futile care because, in these situations, the state's interest in protecting the medical profession and the welfare of children, in conjunction with the physician's ethical obligation to do no harm, outweigh parental interests in demanding a treatment that is contrary to acceptable medical care.<sup>226</sup> However, such determinations should not automatically defer to the physicians, and an expert consultation should assist with the conflict resolution process.<sup>227</sup>

This distinction between "potentially inappropriate" and "futile" treatment would have better allowed for a proper assessment of Charlie's options. At the point when Charlie's parents initially requested experimental treatment, it might have been "potentially inappropriate" because of the countervailing ethical considerations, but the constitutionally protected parental rights to determine what is in the best interest of their child would have prevailed. At the point at which it was determined that no treatment, including life-sustaining interventions, would work towards accomplishing the physiological goal of improving Charlie's condition, it would have forced his parents to assess what in fact their goal was and whether that goal would be truly consistent with what was in his best interest. Here, keeping Charlie alive was the intended physiological goal. Therefore, even though continuing life support might ethically be "potentially inappropriate," as it is prolonging his death, it would be consistent with the physiological goal of keeping him alive. However, since a disagreement between the parents and the treating physicians persisted regarding the administration of life support, per the ATS's guidelines, a dispute resolution process would have taken place that would have helped balance the parents' interests with those of the physician.<sup>228</sup> An expert consultant would have empathetically communicated the medical reasoning behind the refusal to administer treatment and would have provided the emotional and psychological support that Charlie's parents desperately needed during this painful time.<sup>229</sup>

#### A. *Counterarguments*

It can be argued that the state should not have authority to enter into this private and deeply personal realm of decision-making and allow physicians to act contrary to parental wishes, as this undermines decisional autonomy on issues essential to the bodily dignity of their

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<sup>226</sup> *Id.* at 1327.

<sup>227</sup> This will help "provide intensive psychosocial support to the surrogate." *Id.*

<sup>228</sup> *Id.* at 1319.

<sup>229</sup> *Id.* at 1320.

children. However, parental rights are not absolute.<sup>230</sup> Parental authority should be carefully examined when there is a fundamental disagreement about medical facts, prognoses, risks and benefits of a proposed treatment, and likelihood of suffering.<sup>231</sup> State intervention is justified when (1) the parents' decision would pose a risk of significant and preventable harm; (2) the harm is imminent, requiring immediate action to prevent it; and (3) the physician's treatment plan is both supported by proven medical evidence and is the least intrusive alternative that would minimize harm.<sup>232</sup> Without state intervention, parents would have free reign to make medical decisions for their children that could amount to abuse or neglect.<sup>233</sup> That is why states, pursuant to their police powers, can, and must, be able to promulgate their own futility statutes that protect the health, safety, and welfare of minor children in end-of-life treatment and care.

Moreover, while commentators have accepted that there is no workable definition of futility, they have nevertheless proposed that more states should either adopt a green light, process-based approach,<sup>234</sup> or a yellow light, multi-institutional ethics committee approach<sup>235</sup> to medical futility disputes. It can be argued, therefore, that there is no need to constrict the definition of futility or attempt to define it in a more particularized manner, as the chosen dispute resolution process ensures fair procedural and substantive due process. However, the core

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<sup>230</sup> See *Prince v. Massachusetts*, 321 U.S. 158, 167–68, 170 (1944) (“The right to practice religion freely does not include liberty to expose the . . . child to . . . ill health or death. . . . Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.”); see also *Custody of a Minor*, 393 N.E.2d 836, 843 (Mass. 1979) (holding that “family autonomy is not absolute, and may be limited where, as here, it appears that parental decisions will jeopardize the health or safety of a child.”); *In re Sampson*, 317 N.Y.S.2d 641, 671 (N.Y. Fam. Ct. 1970), *aff’d*, 323 N.Y.S.2d 253 (N.Y. App. Div. 1971) (holding that when a parent refused to allow her son to get a blood transfusion because they were Jehovah’s Witnesses, the court had “wide discretion to order medical or surgical care and treatment for an infant even over parental objection, if in the Court’s judgment the health, safety or welfare of the child requires it.”).

<sup>231</sup> Canadian Paediatric Soc’y, *Treatment Decisions Regarding Infants, Children and Adolescents*, 9 PAEDIATRIC CHILD HEALTH 99, 102 (2004), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2720471/pdf/pch09099.pdf> [<http://perma.cc/P5CT-46QT>].

<sup>232</sup> Douglas S. Diekema, *Parental Refusals of Medical Treatment: The Harm Principle as Threshold for State Intervention*, 25 THEORETICAL MED. 243, 250–54 (2004) (arguing that “[t]he ethical basis for the exercise of these police powers lies in . . . ‘the harm principle’ [which is rooted] [i]n *On Liberty* [by] John Stuart Mill[, where he] argued that ‘The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others.’”).

<sup>233</sup> Carbone, *supra* note 114, at S114–18 (explaining that an overview of cases “involving Jehovah’s witnesses who refuse to consent to blood transfusions for their children on religious grounds” demonstrates “why the courts are particularly willing to intervene . . . as a matter of institutional allocation of decision-making responsibility”).

<sup>234</sup> Faircloth, *supra* note 178, at 176.

<sup>235</sup> Pope, *supra* note 22, at 350, 368.

issue in these “traffic light” futility statutes is that the word futility is used without further clarification. This inherently ambiguous, value-laden term causes an imbalance between parental rights and state interests, which becomes evident during the dispute resolution process. Therefore, in order to truly ensure fair procedural and substantive due process, the definition of futility in these statutes must be narrowed according to the guidelines of the ATS.

#### CONCLUSION

An analysis of the Charlie Gard case within the U.S. legal framework demonstrates the complexities of trying to define futility and the implications of such an ambiguous term in state statutes. Limiting the use of the term futility to describe situations in which the requested treatment would not serve the intended physiological goal better balances the interests of parents, physicians, and states. This narrow definition diminishes the degree to which subjective values and beliefs contribute to a determination of futility. Therefore, the guidelines proposed by the ATS should be adopted and implemented by all states in their current futility statutes. As laboratories of experimentation, states have the power to adopt their own respective “traffic light” statutes regarding disputes surrounding end-of-life care. The implementation of the ATS’s guidelines will preserve that power while providing a better constitutional balance to those statutes by ensuring a holistic and particularized approach and reserving the classification of futility for extremely rare scenarios. This will result in more effective and less burdensome dispute resolution proceedings for cases involving futility disputes.