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Does Research with Children Violate the Best Interests Standard? An Empirical and Conceptual Analysis

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Does Research with Children Violate the Best Interests Standard? An Empirical and Conceptual Analysis

Seema Shah*

ABSTRACT

Even as research with children has increasingly been recognized as urgently needed for generating effective treatments for childhood diseases, drug formulations for infants and young children, and dosages appropriate for children, it has remained controversial. Scholars have engaged in heated debates over whether non-beneficial research with children is morally and legally justified. On one point, however, there has been agreement: Whether they support or criticize pediatric research, commentators generally assume that pediatric research should be justified under the "best interests of the child" legal standard. This assumption not only threatens important research and public health interventions, but it is also incorrect. This Article challenges conventional wisdom by arguing that research does not have to be in a child's best interests to be legally permissible.

The best interests standard is generally understood as the governing principle for legal decisions about children, particularly in the medical context. Nevertheless, the best interests standard operates in two different ways that have very different implications—treating a child's best interests as paramount versus as a primary consideration. Both versions of the standard fail to account adequately for the interests of others. Yet, the history of best interests standard reveals that the child's best interests were rarely considered in isolation of other the interests. In a variety of contexts, moreover, legal scholars have criticized the best interests standard for failing to take account of the interests of people other than the child. This concern applies with special urgency to certain medical and public health decisions. An empirical analysis reveals that the history and criticisms have not been effective in changing how courts oversee medical decision making involving children.

Insofar as it places the interests of the child above all other interests, the best interests standard is a legal fiction that should not be applied to public health decisions in general and pediatric research in particular. Attempts to fix the current standard are unlikely to work, largely because of the confusion already engendered by the different

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versions of the standard. Instead, legislators should adopt a new legal standard, the "secure child standard," for public health decision making: Parents should be given discretion to make decisions for children unless their decisions are likely to cause unjustified harm to the child. The secure child standard will lead to more transparency and prevent poor decision making in the contexts of public health and biomedical research, and is also a legal standard that may have broad applicability to decisions and policies involving children.

TABLE OF CONTENTS

INTRODUCTION……122
I. BACKGROUND: PEDIATRIC RESEARCH……126
A. Critiques of pediatric research for violating the best interests standard……129
1. Cases……129
2. Commentators……134
II. THE BEST INTERESTS STANDARD……137
A. Historical development……137
B. Criticisms of the best interests standard……145
1. Criticisms of the best interests as paramount consideration……145
2. Criticisms that apply to both versions of the best interests standard……147
III. EMPIRICAL ANALYSIS OF THE BEST INTERESTS STANDARD……153
A. Methodology……155
B. Results……156
C. Discussion of results……158
1. Why do judges use the best interests as paramount standard?……158
2. Does the best interests standard lead to problematic results in particular cases?……160
a. Organ or tissue donation……160
b. Cases involving public health considerations……163
IV. RESEARCH SHOULD NOT HAVE TO ABIDE BY THE BEST INTERESTS AS PARAMOUNT STANDARD……165
V. UNDERSTANDING THE BEST INTERESTS AS PARAMOUNT STANDARD……167
VI. AN ALTERNATIVE: THE SECURE CHILD STANDARD……170
CONCLUSION……173

INTRODUCTION

A recent class action lawsuit claims that a prestigious research institution treated children from low-income minority families as "guinea pigs." The lawsuit alleges that research on varying levels of lead paint removal unduly exposed young children in Baltimore to risk,[1] reviving past controversy over a 2001 decision that the same lead paint study was contrary to law for violating the "best interests of the child" legal

[1] Complaint at 1–2, Armstrong v. Kennedy Krieger Inst., Inc., No. 1:11-cv-03380 (N.D. Md., filed Nov. 22, 2011).

standard.[2] It is perhaps no surprise that the court applied the best interests standard to the context of research with children since this standard is widely considered to be the default legal standard in many situations involving minors.

Similar examples of recent controversy over pediatric research abound. For instance, a U.S. government advisory panel recommended that an anthrax vaccine be tested on children, justifying the research as being in the best interests of children, their parents, and the U.S. government.[3] This recommendation was hotly contested and criticized in the media as unlikely to benefit the children involved in the research, and only likely to help other children in the (perhaps unlikely) event of a widespread anthrax attack in the future.[4] The Presidential Commission for the Study of Bioethical Issues was asked by the Secretary of Health and Human Services to render an opinion on whether research on countermeasures to an anthrax attack can proceed.[5] Applying the existing risk/benefit balance in the U.S. Federal regulations to the case at hand, the Presidential Commission determined that before a bioterrorism attack occurs, research can only proceed if it poses minimal risk (except under extraordinary circumstances).[6] If designing a minimal risk study is impossible, research prior to a bioterrorism attack can proceed if it involves no more than a minor increase over minimal risk, undergoes review by a special panel, and satisfies additional ethical protections specified in the report.[7] The Commission opined that parental permission for research requires that parents determine what is in the child's "best or essential interests," but did not directly address whether a best interests requirement would preclude non-beneficial research.[8] Concluding that its report was not the final word, the Commission stated that pediatric research involving medical countermeasures to potential terrorist attacks "warrants an ongoing national conversation in order to ensure the highest standards of protection for children that reflect an unwavering commitment to safeguard all children *from* unacceptable risks in research and *through* research that promotes their health and well-being."[9]

Notwithstanding these and other controversies over pediatric research, there has been one area of consistent agreement: unless research is in a child's best interests, it cannot be legally justified. Because the primary aim of research is to generate new knowledge for the benefit of society and future patients, research may directly conflict with the "best interests of the child" legal standard. An unstated reality is that research

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[2] Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 853 (Md. 2001).

[3] NATIONAL BIODEFENSE SCIENCE BOARD, DRAFT REPORT: CHALLENGES IN THE USE OF ANTHRAX VACCINE ADSORBED (AVA) IN THE PEDIATRIC POPULATION AS A COMPONENT OF POST-EXPOSURE PROPHYLAXIS 1, 18–19 (2011), *available at* http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/ava-pediatric-execsum.pdf.

[4] Lisa Schnirring, *HHS Anthrax Vaccine Advisors Weigh Pediatric Use*, CENTER FOR INFECTIOUS DISEASE RESEARCH & POLICY (Sept. 22, 2011), http://www.cidrap.umn.edu/cidrap/content/bt/anthrax/news/sep2211anthrax.html.

[5] Letter from Kathleen Sebelius, Sec'y of Health and Human Serv., to Amy Gutmann, Ph.D., Chair of the Presidential Comm'n for the Study of Bioethical Issues., Pediatric Countermeasures Letter (Jan. 11, 2012), *available at* http://bioethics.gov/cms/node/633.

[6] PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, SAFEGUARDING CHILDREN: PEDIATRIC MEDICAL COUNTERMEASURE RESEARCH 56 (2013).

[7] Id. at 87.

[8] Id. at 26.

[9] Id. at 105.

participants are often exposed to risk in order to produce knowledge that can be used to help others in the future. This means that in many cases, research participants incur the risks of experimental treatments but are unlikely to personally benefit. When research is non-beneficial for the participants, individual consent to take on risk is very important. Yet, this ethical protection applies imperfectly to pediatric research. Children cannot legally give their own consent, and it is widely accepted that parents can only consent to activities that are in their children's best interests.

Because of the tremendous confusion the best interests standard has sown, and its rhetorical appeal, the standard has been reflexively applied by the courts to cases involving pediatric research. Some courts describe the principle as "paramount" or "the overriding concern" throughout the law governing children, and particularly so in medical decision making.[10] Courts applying the "paramount interpretation" of the best interests standard often understand the best interests standard to require that the best interests of the child determine the outcome in any case in which a child is a primary actor.[11] Within debates over the legality of pediatric research, scholars have largely accepted this same premise.

Yet legal scholars in constitutional and family law have criticized the best interests standard (and the paramount interpretation in particular) for a number of years for its complete inability to account for the interests of others. In fact, over fifteen years ago the U.S. Supreme Court explained that:

> "The best interests of the child," a venerable phrase familiar from divorce proceedings, is a proper and feasible criterion for making the decision as to which of two parents will be accorded custody. But it is not traditionally the sole criterion—much less the sole constitutional criterion—for other, less narrowly channeled judgments involving children, where their interests conflict in varying degrees with the interests of others.[12]

Although this statement seeks to clarify the place of the best interests standard in a broader range of decisions, it has not been effective. Courts apply two inconsistent interpretations of the best interests standard. In the most common interpretation, some

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[10] *See, e.g.*, Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 853 (Md. 2001) ("We have long stressed that the 'best interests of the child' is the overriding concern of this Court in matters relating to children."); In re Willmann, 493 N.E.2d 1380, 1389–90 (Ohio Ct. App. 1986) ("[T]he court has the right, in law, to order the treatment prescribed for David because the court stands *in loco parentis* and possesses the authority to preserve David's well-being and best interests. . . . Adults are ordinarily free to make choices denied to those of less than full age, but when those choices threaten the welfare of a child, the state must intervene."); Dietrich v. Anderson, 43 A.2d 186, 191–92 (Md. 1945) (describing the welfare of the child as being "of transcendent importance" and noting that the "paramount purpose of securing the welfare and promoting the best interests of the children" is something that "not only applies in cases of dispute between parents as to the custody of their children, but applies to all cases where those interests are in jeopardy.").

[11] *See* Loretta M. Kopelman, *The Best Interests Standard as Threshold, Ideal, and Standard of Reasonableness*, 22 J. MED. & PHIL. 271, 277 (1997) (defining the best interests standard as "acting so as to promote maximally the good of the individual") (citing ALAN E. BUCHANAN & DAN W. BROCK, DECIDING FOR OTHERS: THE ETHICS OF SURROGATE DECISION MAKING 88 (1989)).

[12] Reno v. Flores, 507 U.S. 292, 303–04 (1993).

courts consider a child's best interests to be paramount and to trump all other interests (the "paramount interpretation"). Alternatively, other courts make decisions more along the lines of what the Supreme Court recommended and evaluate the child's interests as a primary, but not *sole* consideration (the "primary interpretation").[13]

Notwithstanding the confusion engendered by different versions of the standard, both interpretations of the best interests standard are problematic as applied to a range of public health decisions. The paramount interpretation is too strict to permit reasonable decisions involving public health decision making, including but not limited to pediatric research. The paramount interpretation is also hard to apply to particular cases. Furthermore, the paramount interpretation might be better thought of as a legal fiction because courts often claim to be applying the paramount interpretation of the best interests standard while truly applying a different standard. The primary interpretation is more flexible, but still inadequate for good public health decision making. Although the primary interpretation does not prohibit pediatric research in the way that a literal interpretation of the paramount interpretation might, it is still poorly suited to capture the complex trade-offs involved in advancing the public's health and the interests of others.

Pediatric research that poses net risk therefore appears to conflict with the best interests standard. At the same time, the importance of pediatric research in developing therapies is now widely acknowledged. Most of the debate from the scholarly community has therefore focused upon the narrow question of whether parents have the legal authority to enroll their children in research that poses risks and is designed to help others. Yet the larger issue—whether the best interests standard is the appropriate legal test for pediatric research—has rarely been questioned. Jurisprudence and scholarship focusing on pediatric research have both failed to ask the essential question of whether the best interest standard should govern. Instead, the conventional approach is to try to reconcile the best interest standard with the need to conduct research to advance the public's health. This conventional approach is fundamentally misguided.

The primary thrust of this Article is that participation in pediatric research should not have to be legally justified as being in a child's best interests.[14] It is a mistake to apply the "best interests" standard to the context of pediatric research because it is ill-suited to contend with the trade-offs involved, and such an approach is likely very costly to the public. Despite the recognition of the problems with the best interests standard in some quarters, empirical analysis demonstrates that judges persist in applying the paramount interpretation of the best interests standard in medical decisions involving children.

Although one approach might be to clarify the best interests standard at a theoretical level, this approach is unlikely to succeed. Rather, pediatric research should

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[13] David William Archard, *Children's Rights*, STANFORD ENCYCLOPEDIA OF PHILOSOPHY (2010), http://plato.stanford.edu/entries/rights-children/#BesInt.

[14] This Article provides a legal analysis of non-beneficial research and proposes a new legal standard, with a more limited discussion of the ethical justifications for non-beneficial pediatric research. The argument is descriptive as to what the current legal standard for pediatric research is and normative with respect to what that legal standard should be, but it would require much more space to comprehensively address the ethical justification for pediatric research as well. For a thorough treatment of the ethical justifications for non-beneficial pediatric research, *see generally* DAVID S. WENDLER, THE ETHICS OF PEDIATRIC RESEARCH (2010).

be measured under an altogether different legal standard. This Article argues for a new legal standard, the "secure child standard," to govern legal rules and decisions involving children.

In Part I of this Article, I provide background on pediatric research and the debate over its moral and legal justifications. I discuss the historical development of the best interests standard in Part II, draw out modern-day implications, and examine criticisms of the best interests standard from legal and ethical scholars. Part III provides results of an empirical analysis of the use of the best interests standard in medical decisions involving children in the past forty years. In Part IV, I explain that the paramount interpretation of the best interests standard is a legal fiction, and argue that we should not retain the best interests standard. In Part V, I propose the "secure child standard" as an alternative approach to legal decision making involving children in research and other interventions that are needed to further public health. Under the secure child standard, parents are given discretion to make decisions for their children unless they pose unjustified risks of significant harm to the child. When there is evidence that children are being exposed to a risk of significant harm, courts should determine whether parents have appropriately balanced the competing considerations. Courts should not allow children to be exposed to unjustified harm or harm that is unacceptably high. I conclude that the secure child standard will better explain courts' decisions and that adopting the secure child standard can improve the clarity and soundness of future court decisions, prevent courts from reaching the wrong conclusions in nascent legal areas, and ensure that our policies concerning children have a sound foundation.

I. BACKGROUND: PEDIATRIC RESEARCH

The importance of pediatric research has only been recognized relatively recently. In 1973, one survey found that 78% of prescription drugs did not have enough data or information in their labeling about their use in children.[15] By 1991, this number had grown to 81% of drugs.[16] Many commentators have pointed out several reasons to be concerned about lacking information on how medical interventions work in children. Some have succinctly noted that "children are not just small adults."[17] Others have argued that: (1) children are physiologically different from adults; (2) children often process drugs differently in their bodies (and sometimes process them differently at different stages of childhood); (3) some diseases occur only in children or behave very differently in children; (4) infants and very young children are generally unable to take medication in solid form, unlike most adults; (5) infants are exposed to unique modes of disease transmission through birth or breastfeeding; and (6) at various stages of development, children may be at risk of developmental problems as side effects of

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[15] American Academy of Pediatrics Committee on Drugs, *Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations*, 95 PEDIATRICS 286, 286 (1995).
[16] *Id.*
[17] Terry P. Klassen, Lisa Hartling, Jonathan C. Craig & Martin Offringa, *Children Are Not Just Small Adults: The Urgent Need for High-Quality Trial Evidence in Children*, 5 PLoS MED. 1180,1180 (2008).

medication.[18] These theoretical concerns have been borne out by the results of recent pediatric research in drugs that were already approved for use in adults, which have shown unexpected safety findings related to neurological side effects, a failure to achieve reliable amounts of the drug in the body, and even increased mortality.[19]

Because of these differences, research does not always mean exposing patients to greater risk. In fact, there are some fields where almost all patients are enrolled in research, such as the field of pediatric oncology,[20] and this fact is what many consider responsible for improvement in survival rates over time.[21] For multiple reasons, studying a particular treatment in adults cannot give the full picture of how that same drug will work in children. And without data to establish how a drug works in children, the result is that physicians conduct ad hoc experimentation on their patients—treating a child without knowing whether a drug will work, what the risks of giving it might be, or which dose is the right one.

Although the importance of pediatric research is clear, one important justification for conducting research in adults does not apply to children. Adults typically give their own consent to take on risk for the sake of others. Adults who can consent can protect their own interests by deciding to participate in research only when they think the risks are acceptable. In general, children cannot legally give consent for themselves; parents or legal guardians give permission for children to be in research. The fact that parents must decide whether their children can enroll in research has given rise to concern that parents have conflicts of interest that may prevent them from making decisions that appropriately weigh their children's interests.[22]

Recognizing the complex ethical issues arising in pediatric research, Congress created the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research in 1974, making one of its charges to write a report on the ethics of

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[18] Christopher-Paul Milne & Jon B. Bruss, *The Economics of Pediatric Formulation Development for Off-Patent Drugs*, 30 CLIN. THERAPEUTICS 2133, 2139 (2008).

[19] Daniel K. Benjamin, et al., *Safety and Transparency of Pediatric Drug Trials*, 163 ARCH PEDIATRICS ADOLESCENT MED. 1080, 1082 (2009).

[20] Yoram Unguru, Annie M. Sill & Naynesh Kamani, *The Experiences of Children Enrolled in Pediatric Oncology Research: Implications for Assent*, 125 PEDIATRICS e876, e876 (2010).

[21] There is a common view that pediatric patients enrolled in clinical trials have higher rates of survival and show greater improvement than those who are not involved in research. *See* Jeffrey M. Peppercorn et al., *Comparison of Outcomes in Cancer Patients Treated Within and Outside Clinical Trials: Conceptual Framework and Structured Review*, 363 LANCET 263, 263 (2004) ("The belief that clinical trials offer the best treatment for patients with cancer is widespread in the oncology community."). There is some evidence to support this claim. *See* S.P. Hunger et al., *Improved Survival for Children and Adolescents with Acute Lymphoblastic Leukemia between 1990 and 2005: A Report from the Children's Oncology Group*, 30 J. CLINICAL ONCOLOGY 1663, 1666 (2012); Paul S. Gaynon et al., *Long-term Results of the Children's Cancer Group Studies for Childhood Acute Lymphoblastic Leukemia 1983–2002: a Children's Oncology Group Report*, 24 LEUKEMIA 285, 291 (2010). There may not be sufficient evidence, however, to be certain of its validity. Peppercorn, et al., *supra* note 21, at 267. ("In our review of the published work, we found little high quality evidence to support the pervasive belief that cancer trial participation leads to improved outcomes.").

[22] Holly Fernandez Lynch, *Give Them What They Want? The Permissibility of Pediatric Placebo-Controlled Trials Under the Best Pharmaceuticals for Children Act*, 16 ANNALS HEALTH L. 79, 87–88 (2007); Efi Rubenstein, Comment, *Going Beyond Parents and Institutional Review Boards in Protecting Children Involved in Nontherapeutic Research*, 33 GOLDEN GATE U.L. REV. 251, 252 (2003).

research with children.[23] The National Commission relied on the work of many scholars but two in particular, Paul Ramsey and Richard McCormick.[24] Based on its analysis of the literature, the National Commission issued recommendations that research with children is important to conduct and that with additional protections and limitations on the risks and benefits to which children can be exposed, research with children can be ethical.[25] These recommendations were subsequently codified into federal regulations governing research with children in 1983, and have not been revised since that time.[26]

The federal regulations governing research with children permit research with children in four categories: (1) research that is not likely to benefit a child and poses minimal risks, (2) research that may benefit the child directly and poses risks that are outweighed by the benefits, (3) research that will not benefit the child directly, but poses a minor increase over minimal risk and is likely to generate knowledge about the child's disorder or condition, and (4) research that cannot be approved in the first three categories but that is approved by a special panel convened by the Secretary of the Department of Health and Human Services.[27] The first three categories of research are to be approved by Institutional Review Boards (IRBs).[28] The least controversial categories are research that offers a prospect of direct benefit that outweighs the risks, which is sometimes referred to as "therapeutic" research,[29] and minimal risk research that offers no prospect of direct benefit.[30] The importance of research in these first two categories is widely, though not completely, recognized.[31]

This Article will focus on the more controversial categories of research that pose net risk to children. For instance, the third category of research permitted under the U.S. federal regulations is non-beneficial research that poses a minor increase over minimal risk.[32] The regulations require that this slightly riskier category of research be justified only when it offers benefit to other children in the future who suffer from the condition being studied in the research.[33] Finally, the fourth category of research is a catch-all category of not otherwise approvable research that can only be approved by a special panel.[34] The regulations do not specify a limit on the risks that this category of research

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[23] *Ethical Conduct of Clinical Research Involving Children*, COMMITTEE ON CLINICAL RESEARCH INVOLVING CHILDREN, INST. OF MED. OF THE NAT'L ACAD. 40 (Marilyn J. Field & Richard E. Behrman eds., 2004).
[24] *Id.* at 43.
[25] NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, RESEARCH INVOLVING CHILDREN: REPORT AND RECOMMENDATIONS 1 (1977).
[26] Douglas S. Diekema, *Conducting Ethical Research in Pediatrics: A Brief Historical Overview and Review of Pediatric Regulations*, 149 J. PEDIATR. 1, S3, S5 (2006).
[27] 45 C.F.R. § 46.401–46.409 (1983).
[28] *Id.*
[29] *See id.* § 46.405.
[30] *See id.* § 46.404.
[31] *See* Deborah Weimar, *Beyond Parens Patriae: Assuring Timely, Informed, Compassionate Decision Making for HIV-Positive Children in Foster Care*, 46 U. MIAMI L. REV. 379, 379– 80 (1991) (describing a case where a child in foster care in need of treatment that was only being provided in research experienced legal barriers in enrolling in the study).
[32] 45 C.F.R. § 46.406 (1983).
[33] *Id.*
[34] *See id.* § 46.407.

can involve.[35] This category of research could therefore include research that poses relatively high risks and no prospect of direct benefit. Although these regulations have been in place for almost thirty years, non-beneficial research remains very controversial.[36]

Notwithstanding the persistence of some controversy over pediatric research, the government has done a great deal in recent years to incentivize research in children. Making pediatric research legally permissible was not enough to ensure that pediatric research would be conducted as needed. Realizing this, the Food and Drug Administration (FDA) began a program in 1994 to encourage more pediatric research, but had limited success.[37] Congress acted in 1996 by adding an economic incentive for conducting pediatric research. Under the Pediatric Exclusivity Provision of the U.S. FDA Modernization Act, Congress gave sponsors of research six additional months of patent life if they performed pediatric studies requested by the FDA.[38] When this act was set to expire in 2002, Congress passed the Best Pharmaceuticals for Children Act, which continued the provision of pediatric exclusivity for conducting research specified by the FDA.[39] Some have argued that encouraging the conduct of pediatric research is not enough without attending to the need to publish the results.[40] Nevertheless, the need for pediatric research has been made even clearer by the research that has been disseminated as a result of these incentives.[41]

A. Critiques of pediatric research for violating the best interests standard

Even though the importance of pediatric research is now widely recognized, many scholars and commentators have questioned whether pediatric research can be legally or ethically justified. Shortly before ascending to Chief Justice of the Supreme Court, Warren Burger published an article arguing that "no rational social order will or should tolerate" pediatric research that does not offer net benefits to children.[42] Paul Ramsey forcefully argued that individuals should only be subjected to risk in research if they have given consent. Because children cannot give their own consent, he maintained that pediatric research that poses net risks could not be justified.[43] These arguments have found their way into the limited case law addressing research with children.

1. Cases

Only two state courts appear to have addressed the issue of when children can be enrolled into research. The paucity of cases can in part be explained by the fact that it is

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[35] *See id.* § 46.407.
[36] WENDLER, *supra* note 14, at 31–32.
[37] *See* 21 C.F.R. § 201.57 (2002).
[38] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105–115, 111 Stat. 2296 (1997).
[39] Best Pharmaceuticals for Children Act, Pub. L. No. 107–09, 115 Stat. 1408 (2002).
[40] Daniel K. Benjamin, Jr., et al., *Safety and Transparency of Pediatric Drug Trials*, 163 ARCH PEDIATR. ADOLESCENT MED. 1080, 1082 (2009).
[41] *Id.*
[42] Warren E. Burger, *Reflections on Law and Experimental Medicine*, 15 UCLA L. REV. 436, 438 (1968).
[43] Paul Ramsey, *The Enforcement of Morals: Nontherapeutic Research on Children*, 6 HASTINGS CENTER REPORT 4, 21–30 (1976); Paul Ramsey, *Children as Research Subjects: A Reply*, 7 HASTINGS CENTER REPORT 2, 40–42 (1977).

hard to imagine who would have both standing and the desire to bring suit. In 1973, James Nielsen, who served on the University of California at San Francisco's (UCSF) Committee on Human Experimentation brought suit against UCSF, objecting to a proposed pediatric study by arguing that parents and guardians lacked legal authority to consent to expose their children to risks.[44] The suit was dismissed for a lack of standing.[45] Parents or children are likely to be the only parties who might have standing to sue if a child participates in pediatric research, and it is not likely that they will often have the desire to bring suit. Only in rare circumstances would a parent consent to his or her child's involvement in a research study and subsequently bring suit against the researchers and sponsors, and children rarely bring suit against their parents' will. Of the courts that have addressed the legal permissibility of pediatric research, one court considered the welfare of the research subjects as the primary concern, and the other attempted to determine when to permit medical research by applying the best interests standard.[46]

The first case to address whether pediatric research is legally permissible was *T.D. v. N.Y. State Office of Mental Health.* Although both of the cases discussed herein appeared to prioritize the welfare of individual research subjects above all else, the court in *T.D.* did recognize that the state has important interests in conducting research. In particular, the court explained that the state has important policy reasons "to conduct research and to develop programs which further prevention and early detection of mental illness."[47] Thus, it appeared that the fundamental issue at stake in the case was balancing the societal benefit from medical research against the risks to subjects who cannot give their own consent.[48] The court determined that the New York state regulations in question were overbroad and exceeded the authority of the agency (but explicitly chose not to address the federal regulations), and limited its holding to non-beneficial research that poses greater than minimal risk.[49]

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[44] Nielsen v. Regents of the University of California et al., No. 665–049, Civ. 8–9 (Super. Ct. Cal. Aug. 23, 1973).
[45] WENDLER, *supra* note 14, at 44.
[46] *See* T.D. v. N.Y. State Office of Mental Health, 228 A.D.2d 95 (1996); *Compare Grimes* , 782 A.2d at 853 ("We have long stressed that the 'best interests of the child' is the overriding concern of this Court in matters relating to children.").
[47] *T.D.*, 228 A.D.2d at 101 (citing New York Mental Hygiene Law § 7.01).
[48] *Id.* at 100. Notably, some provisions of these regulations made them unique and less protective of subjects than the U.S. federal regulations and many international guidelines. For instance, if no parent or legal guardian is available to consent for the child, the regulations provide that consent may be obtained from an adult family member who is involved in making treatment decisions for the child. *See id.* at 123 ("We also find unacceptable the provisions that allow for consent to be obtained on behalf of minors for participation in greater than minimal risk nontherapeutic research from the minor's parent or legal guardian, or, where no parent or guardian is available, from an adult family member involved in making treatment decisions for the child."). The U.S. federal regulations have strict provisions for when a child can be involved in research if no parent or guardian is available to provide consent. *See* 45 C.F.R. § 46.408(d) (2011) (requirements for permission by parents or guardians and for assent by children); 45 C.F.R. § 46.409 (2011).
[49] *T.D.*, 228 A.D.2d at 123–124.

The second court to rule on pediatric research viewed it more harshly in the case of *Grimes v. Kennedy Krieger Institute*.[50] In this case, the Kennedy Krieger Institute, a research institute associated with Johns Hopkins, conducted a non-therapeutic research program testing the effectiveness of varying degrees of lead paint abatement in housing inhabited by young children.[51] The Maryland Court of Appeals decided that non-beneficial research involving children should not be permitted when it fails to meet the best interests standard.[52] This ruling was widely criticized and seemed to suggest that the federal regulations governing research with children conflicted with the laws governing children.[53] This had the potential to shut down a great deal of research.

The Maryland high court was concerned about the behavior of the researchers in inducing parents with young children to live in conditions that could be harmful to those children:

> [I]n our view, parents, whether improperly enticed by trinkets, food stamps, money or other items, have no more right to intentionally and unnecessarily place children in potentially hazardous nontherapeutic research surroundings, than do researchers. In such cases, parental consent, no matter how informed, is insufficient.[54]

The Kennedy Krieger Institute was testing different levels of removal of lead paint in a research study. The study "required certain classes of homes to have only partial lead paint abatement modifications performed . . . [and] encouraged, and in at least one of the cases required, the landlords to rent the premises to families with young children."[55]

Although the court did not think that the parents were responsible for the harm because they had failed to give informed consent,[56] the court reasoned that these parents did not have the authority to enroll their children in non-beneficial research that poses risks.[57] Interestingly, however, some commentators have noted that the pediatric research subjects in *Grimes* were better off than they would have been otherwise as a result of their participation in the research because approximately 95% of the homes in the areas where they lived contained hazardous levels of lead.[58]

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[50] *Grimes*, 782 A.2d at 807.
[51] *Id.* at 811–812.
[52] *Id.* at 858.
[53] *See* Diane E. Hoffmann & Karen H. Rothenberg, *Whose Duty is it Anyway?: The Kennedy Krieger Opinion and its Implications for Public Health Research*, 6 J. HEALTH CARE L. & POL'Y 109, 109–10 (2002); *see also* Doriane Lambert Coleman, *The Legal Ethics of Pediatric Research*, 57 DUKE L.J. 517, 575 (2007).
[54] *Grimes*, 782 A.2d at 814.
[55] *Id.* at 811–812.
[56] *Id.* at 849 (explaining that the "consent forms did not directly inform the parents that it was possible, even contemplated, that some level of lead, a harmful substance depending upon accumulation, might contaminate the blood of the children.").
[57] *Id.* at 852 ("What right does a parent have to knowingly expose a child not in need of therapy to health risks or otherwise knowingly place a child in danger, even if it can be argued it is for the greater good?").
[58] Anna C. Mastroianni & Jeffrey P. Kahn, *Risk and Responsibility: Ethics,* Grimes v Kennedy Krieger*, and Public Health Research Involving Children*, 92 AM. J. PUB. HEALTH 1073, 1075 (2002).

The *Grimes* court chose not to rule that the federal regulations were an unlawful extension of parental authority, primarily by taking pains to determine that the research was not consistent with the federal regulations.[59] Yet, the court had harsh words for many of the protections surrounding research. For instance, it called IRBs "in-house organs"[60] and said they were not sufficiently independent to protect the interests of children.[61] The court assumed that the best interests standard was the correct standard for judging research and concluded that parental and societal interests cannot overcome the concern for the particular child.[62] The court stated, "It is, simply, and we hope, succinctly put, not in the best interest of any healthy child to be intentionally put in a non-therapeutic situation where his or her health may be impaired, in order to test methods that may ultimately benefit all children."[63]

The court was correct that non-beneficial research that poses some degree of risk cannot be shoehorned into the best interests standard. The more important question the court failed to grapple with sufficiently was whether the best interests standard is the right standard to apply in the context of non-beneficial pediatric research.

The opinion did acknowledge that there are cases in which parents were allowed to consent to procedures even though the child's best interests were not the most important factor in the decision. Specifically, the court examined cases where parents consent for their children to serve as organ donors for other family members.[64] The court attempted to distinguish these cases in two ways. First, it noted that the parents or guardians involved obtained prior court approval before proceeding with the donations.[65] Second, it explained that the procedure was therapeutic for at least one of the children involved.[66]

Both of these arguments are flawed for several reasons. The argument that pediatric research is something parents can consent to without prior oversight mischaracterizes both research and the process of live organ donation. The *Grimes* study was approved by an IRB, which has regulatory authority to approve research. IRBs oversee all federally funded research and have the authority to disapprove research.[67] Therefore, it is not the case that parents can merely consent to whatever studies research sponsors choose to make available. Second, some parents make decisions about sibling donations without obtaining prior approval from a court,[68] and many more would be likely to do so since the

[59] *Grimes*, 782 A.2d at 860 ("The research did not comply with the regulations. There clearly was more than a minimal risk involved. Under the regulations, children should not have been used for the purpose of measuring how much lead they would accumulate in their blood while living in partially abated houses to which they were recruited initially or encouraged to remain, because of the study.").

[60] *Id.* at 817.

[61] *Id.* at 860.

[62] *Id.* at 853 ("this Court's concern for the particular child and particular case, over-arches all other interests."); *see also id.* at 858 ("We hold that in Maryland a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in non-therapeutic research or studies in which there is any risk of injury or damage to the health of the subject.").

[63] *Id.* at 853.

[64] *Id.* at 853–854.

[65] *Id.* at 855.

[66] *Id.*

[67] 45 C.F.R. §§ 46.103, 109 (2011).

[68] Curran v. Bosze, 566 N.E.2d 1319, 1342 (Ill. 1990) (three of the witnesses testifying in this case were parents who had made the decision for one child to donate an organ to a sibling, and it is clear in at least

law has become fairly settled that parents have the authority to consent for live organ or tissue donation. Third, one of the cases the court cites is not about a parent consenting for a child to donate to a sibling, but for a child to donate to a cousin.[69] This is not a direct conflict of interest for a parent who has the same duty to both children, and does not seem to be justified as the only way a parent can fulfill his or her duty to one of his or her children. Finally, the fact that a sibling donation is therapeutic for *one* child does not eliminate the conflict of interest faced by a parent in making the decision. Although the court determined that IRBs face significant conflicts of interest and are therefore not sufficiently independent to evaluate research, it was completely untroubled by the conflict of interest that a parent faces when deciding whether one child should donate an organ or tissue to another.

After *Grimes* was decided, commentators were concerned about its implications for the federal regulations.[70] In particular, although the court did not attempt to challenge the federal regulations themselves, and it is unclear that the court would have had authority to do so, its ruling appeared to forbid any non-beneficial research that poses risk, which would imply that research that is approvable under the federal regulations could not be conducted in Maryland. The Kennedy Krieger Institute filed a motion of reconsideration that the court denied. Nevertheless, the court took this decision as an opportunity to clarify its previous opinion and indicated the following:

> As we think is clear . . . by 'any risk,' we meant any articulable risk beyond the minimal kind of risk that is inherent in any endeavor. The context of the statement was a non-therapeutic study that promises no medical benefit to the child whatever, so that any balance between risk and benefit is necessarily negative.[71]

Unfortunately, this clarification did not help resolve the question of whether non-beneficial research that poses more than minimal risk might be acceptable. Furthermore, it still fails to acknowledge the complexity of the law governing the decisions that parents can make for children that do not benefit them. This case has been subjected to a great deal of criticism and its holding has not been followed by any other court.[72] Legal

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one case that the mother did not obtain prior court approval first—she stated that "[n]o one questioned her right to make that decision.").

[69] *Grimes*, 782 A.2d at 854 (citing Bonner v. Moran, 126 F.2d 121 (1941)).

[70] There is a paucity of case law on what research risks children can be exposed to for the benefit of others. One barrier to further legal treatment about children's participation in research is who would have standing to bring lawsuits to settle the open questions. The plaintiffs in *Grimes* were parents who initially provided consent for their children's participation in research. If anyone other than the parents were to sue, it may be difficult to establish standing and a right to interfere with parental authority to consent for children to engage in various activities. This suggests that future cases can only be brought in particular ways: (1) if parents claim they did not provide adequately informed consent; (2) if one parent sues for what another has agreed to; or (3) if prosecutors bring a case against a particular research study (in which case, they may also decide to sue the parents for agreeing to research participation).

[71] *Grimes*, 782 A.2d at 862.

[72] Cases that have cited and followed its analysis have done so in regard to procedural points about the standard of proof, summary judgment, or negligence. *See, e.g.*, Shastri Narayan Swaroop, Inc. v. Hart, 854 A.2d 269, 273 (Md. App. 2004); Ross v. Am. Iron Works, 834 A.2d 962, 967 (Md. App. 2003); Sadler v.

commentators have argued that the *Grimes* decision has the potential to shut down a great deal of valuable research, and inappropriately holds researchers responsible for risks that may be unrelated to research.[73] Thus, the persuasive ability and legal force of *Grimes* is still somewhat unclear, but seems of limited value.

2. Commentators

Following *Grimes*, a number of commentators have attempted to determine whether non-beneficial research with children is legally permissible. Some have argued that non-beneficial research is in the best interests of children. Others have concluded that non-beneficial research is not in a child's best interests, and that parents therefore do not have the authority to enroll their children in research. All of these commentators have assumed that parents can only consent to what is in their child's best interests.[74]

Karen Thiel argues that in deciding that research with children had to follow the best interests standard, "*Grimes* followed the common law rule that parents may be authorized to promote the best interests of their own children, but not children in general."[75] Thiel concludes that it is unclear from the *Grimes* ruling whether minimal risk research would be permitted under the best interests standard.[76]

Doriane Coleman contends that parents are given authority to consent for their children "because they are the most likely to make decisions in their children's best interests."[77] She agrees with the court in *Grimes* in many respects, stating: "the court was correct that the law of parents' consent authority (as it is defined by child protection law)

Dimensions Healthcare Corp., 836 A.2d 655, 669 (Md. 2003); Dehn v. Edgecombe, 834 A.2d 146, 158 (Md. App. 2003); Sterling v. Johns Hopkins Hosp., 802 A.2d 440, 444 (Md. App. 2002); Muthukumarana v. Montgomery County, 805 A.2d 372, 389 (Md. 2002); Megonnell v. United States Auto. Ass'n, 796 A.2d 758, 763 (Md. 2002); Md. Dep't of the Env't v. Underwood, 792 A.2d 1130, 1136 (Md. 2002); Coleman v. Anne Arundel County Police Dep't, 797 A.2d 770, 780 (Md. 2002). Four cases that involved questions about research have distinguished *Grimes* or used it as a reference for a factual point about the Nuremberg Code. *See* Abney v. Amgen, Inc., 443 F.3d 540, 550 (6th Cir. 2006) (finding dissimilarities between the facts of the case before it and *Grimes*); Suthers v. Amgen Inc., 441 F.Supp.2d 478, 487 (S.D.N.Y. 2005) (distinguishing *Grimes*); Abdullahi v. Pfizer, Inc., 2005 U.S. Dist. LEXIS 16126, at *31–32 (S.D.N.Y. Aug. 9, 2005) (citing *Grimes* for the fact that "the United States has not ratified or adopted the Nuremberg Code."); Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F.Supp.2d 1064, 1069 (S.D.Fla. 2003) (citing *Grimes* and describing the law regarding a duty of informed consent for research subjects as "unsettled.").

[73] Diane E. Hoffmann & Karen H. Rothenberg, *Whose Duty is it Anyway?: The Kennedy Krieger Opinion and its Implications for Public Health Research*, 6 J. HEALTH CARE L. & POL'Y 109, 109–111, 131 (2002).

[74] Importantly, some commentators have acknowledged that the interests of others in the family should be allowed to trump the best interests of an individual child, but few, if any, have clearly argued that the best interests standard itself should be questioned for this reason, in order to accommodate others' interests more generally, and for public health considerations as I do here. *See, e.g.,* 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, 390 (2008); Lainie Friedman Ross, *Health Care Decisionmaking by Children: Is it in their best interest?,* 27 HASTINGS CENTER REP. 41, 41 (1997).

[75] Karen Smith Thiel, *Research with Children: The New Legal and Policy Landscape: Note: Parental Consent for Children's Participation in Biomedical Research: The Ethical, Regulatory, and Judicial Framework of* Grimes v. Kennedy Krieger Institute, Inc., 6 J. HEALTH CARE L. & POL'Y 169, 191 (2002).

[76] *Id.* at 192–193.

[77] Doriane Lambert Coleman, *supra* note 53, at 548.

concerns itself exclusively with the best interests of 'the particular child in the particular case.'"[78] Coleman argues on this basis that the legal framework for pediatric research needs to be completely overhauled to reconcile it with the best interests standard and child custody law.[79]

Efi Rubenstein similarly takes the best interests standard to be the correct standard for evaluating pediatric research, and therefore contends that non-beneficial research should be limited and only allowed when a child advocate decides to enroll a child in research.[80] Rubenstein argues, "In the United States, federal regulations for nontherapeutic research with children require parental permission for child participation in nearly all research activities. This requirement is rooted in the assumption that parents will always act in the best interests of their children. . . . [T]his assumption is invalid and exposes children to unnecessary risks."[81] Rubenstein proposes that a child advocacy program should be created where an independent advocate has to decide whether a particular child can enroll in a research study—not that child's parents and not Institutional Review Boards—in order to eliminate possible conflicts of interest.[82]

On the other hand, some commentators assume a stringent version of the best interests standard should apply to research, but that the best interests standard would still permit research that poses net risks to children. For instance, David Smolin seems to argue that research can be justified under the best interests standard as a general rule. He does, however, acknowledge that the best interests standard is a problem for research that poses risks:

> Parental authority to subject children to situations and acts that are significantly harmful and indisputably contrary to the child's self interests may have existed in prior historical eras, but seems unlikely to have survived contemporary emphasis on the child's best interests. Although it could be argued that sacrifice for the sake of others is virtuous and thus good for the child, contemporary courts would generally be inclined to view significant risk-taking for others as clearly contrary to the child's best interest, and therefore beyond parental authority.

Smolin concludes that we are in a state of legal uncertainty about the status of research with children, and that we could remain in this state indefinitely so long as other state courts do not follow the lead of the *Grimes* court.

Loretta Kopelman argues that the best interests standard is less stringent than is often assumed, and that under this standard, "[t]he best interest of the child standard does not mandate that one always do what is literally best or ideal for the child. That would be an impossible duty for parents or investigators. Rather, it requires that some reasonable or

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[78] *Id.* at 584.
[79] *Id.* at 610–11.
[80] Efi Rubenstein, Comment, *Going Beyond Parents and Institutional Review Boards in Protecting Children Involved in Nontherapeutic Research*, 33 GOLDEN GATE U. L. REV. 251, 290 (2003).
[81] *Id.* at 252.
[82] *Id.* at 290.

minimal threshold duty of care must be met."[83] She further explains that "[t]he goal of many research rules for children, such as the U.S. regulations, is to balance the best interests of children as a group in having needed research conducted with the best interests of potential subjects."[84] Arguing that the best interpretation of the best interests standard is a "standard for reasonableness" that takes into account the interests of others, Kopelman contends that this version of the best interests standard can easily accommodate non-beneficial research.[85] It is not clear from Kopelman's analysis, however, whether courts actually use the best interests standard as a "standard for reasonableness." Furthermore, as shown in Part III *infra*, there is empirical evidence that courts routinely apply the best interests as paramount standard, rather than the interpretation Kopelman proposes.

Paul Litton proposes to reconcile research and the best interests standard in a novel and interesting way. He contends that it is in the best interests of each individual child to participate in low-risk, non-beneficial research, because the alternative is just as or more risky. He argues that the "slight risks" of being in this kind of research "would be transferred to medical care if non-beneficial pediatric research were prohibited altogether."[86] Litton appears to make this argument both to provide an ethical justification for pediatric research and also as guidance for courts, legislators, and regulators applying the best interests standard to determine whether individual children can participate in research.[87]

As an ethical justification for pediatric research that poses net risks to children, Litton acknowledges that his argument rests on an empirical claim.[88] Though this claim may be correct, there are some important caveats. First, there are some children who are relatively healthy throughout childhood and who only suffer from illnesses that are not difficult to treat with existing knowledge. Participating in research exposes those children to risks that are greater than they would experience otherwise. There is reason to believe that it may not be in the best interests of an individual child to be enrolled in research that is not for his or her direct benefit. Although most children might be worse off if non-beneficial research were not permitted, it does not follow that any particular child will be at all better off if he or she is permitted to participate in research. It would always be better for that child if some other child ran the risk of research participation. Additionally, some healthy children are exposed to a (likely very small) risk of death from participation in a research study. Although there it may be true *ex ante* that the child's risk of participation in a research trial is similar to the risk of being treated for some future

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[83] Loretta M. Kopelman, *Pediatric Research Regulations Under Legal Scrutiny:* Grimes *Narrows Their Interpretation*, 30 J. L. MED. & ETHICS 38, 48 n.18 (2002).
[84] Loretta M. Kopelman, *Children and Bioethics: Uses and Abuses of the Best-Interests Standard*, 22 J. MED. & PHIL. 213, 214 (1997).
[85] *Id*. at 216.
[86] 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, 409–10 (2008).
[87] *Id.* at 366 ("[I]n thinking about the best interests of each child, a court (or legislator or regulator) must also consider that from the perspective of each child (including each child enrolled in non-beneficial research), it is in her best interests for the state to permit such research where there is an appropriately low ceiling on the acceptable level of risk.").
[88] *Id.* at 367.

disease the child might contract without a solid evidence base, this argument would be difficult to make after a child has died. Nevertheless, to the extent that Litton's account is aimed at providing an ethical justification for the policy of permitting pediatric research, his work makes a valuable contribution, though one that differs from the aim of this Article.

Litton may also intend to provide guidance to courts about how to apply the best interests standard to pediatric research, which is the aim of this Article. The empirical analysis in Part III, *infra*, suggests that adding a new version of the best interests standard is unlikely to help clarify the confusion that characterizes courts' decision making. Additionally, though Litton's argument helps illustrate why the policy of pediatric research is justified, it seems to provide limited guidance to courts in particular cases when they have to decide whether a parent is justified in exposing their child to a certain amount of risk.

In sum, from the perspective of the best interests of the child alone, research that poses net risks is impermissible. However, the assumption made by many courts and commentators that the child's best interests should take precedence over all other interests is flawed. Looking at the historical development of the best interests standard will reveal that this narrow interpretation is not the only way to understand the best interests standard, and that the interests of others have been taken into account almost since the inception of the standard.

II. THE BEST INTERESTS STANDARD

A. *Historical development of the best interests standard*

The historical development of the best interests standard can be traced back to early English law. From the end of the thirteenth century, the English sovereign exercised a type of wardship over "natural fools and idiots" to protect them; this power was vested in the courts in 1540.[89] This exercise of protection over adults who lacked the mental capacity to protect themselves seems to have been the origin of the *parens patriae* doctrine and ultimately led to the ability of the state to regulate the treatment of children.[90] Nevertheless, in feudal England, the law considered children to be the property of their fathers, and the "father had the supreme right to the guardianship of his infant heirs" just as he did over his property.[91] Child labor was an important economic

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[89] Lawrence B. Custer, *The Origins of the Doctrine of Parens Patriae*, 27 EMORY L. J. 195, 195–96 (1978); *see also* 1 WILLIAM BLACKSTONE, COMMENTARIES *463 ("For the lord chancellor is, by right derived from the crown, the general and supreme guardian of all infants, as well as idiots and lunatics; that is, of all such persons as have not discretion enough to manage their own concerns. In case therefore any guardian abuses his trust, the court will check and punish him; nay, sometimes will proceed to the removal of him, and appoint another in his stead.").

[90] Custer, *supra* note 89, at 196; *see also* Daniel B. Griffith, *The Best Interests Standard: A Comparison of the State's Parens Patriae Authority and Judicial Oversight in Best Interests Determinations for Children and Incompetent Patients*, 7 ISSUES L. & MED. 283, 287 (1991–92).

[91] Sarah Abramowicz, *English Child Custody Law, 1660–1839: The Origins of Judicial Intervention in Paternal Custody*, 99 COLUM. L. REV. 1344, 1366 (1999); *see also* 1 WILLIAM BLACKSTONE, COMMENTARIES*453 ("The legal power of a father—for a mother, as such, is entitled to no power, but only to reverence and respect; the power of a father, I say, over the persons of his children ceases at the age of

asset for the family. For these reasons, courts generally did not interfere with a father's decisions about the guardianship of his property or his children.

Courts gradually gained increasing jurisdiction over decisions involving children. The idea that the king should serve as a father protecting all of his people was suggested in the scholarly literature in the mid 1500s, and in 1610, James I spoke before Parliament and referred to himself as "*parens patriae*, the political father of his people."[92]

Courts first began overseeing some decisions involving children directly with the passage of the Tenure Abolition Act in 1660, which did away with traditional forms of assigning guardianship, and granted fathers the right to appoint guardians for their children (either while the father was still alive or after his death).[93] Guardians had authority over marriage, education, and the religious upbringing of the ward, but the Court of Chancery had power over guardians.[94] Once courts were in the business of overseeing guardians, questions arose about what to do if a father died without appointing a guardian, or if a guardian became incapacitated during the child's life. The Court of Chancery was given the power to appoint guardians in such cases and to resolve disputes between guardians and children.[95] The basis for review of a guardian's decision was a nascent version of the best interests standard: the decision was judged based on whether it was "for the benefit of the infant."[96] At the time, this typically meant that the court made decisions to ensure the child could obtain increased fortune and rank, or because one course of action was considered more "proper" than another.[97] Yet a different standard was used in cases involving children who would eventually become members of the House of Lords. In these cases, courts' decisions were determined by the interests of the general public.[98] Thus, even from the early origins of the best interests standard, the interests of other parties and the public was a part of judicial decision making.

Although the tradition of fathers having absolute rights over their children was not immediately threatened by court jurisdiction over guardians,[99] the ability to regulate

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twenty-one: for they are then enfranchised by arriving at years of discretion, or that point which the law has established, as some must necessarily be established, when the empire of the father, or other guardian, gives place to the empire of reason. Yet, till that age arrives, this empire of the father continues even after his death; for he may by his will appoint a guardian to his children.").

[92] Custer, *supra* note 89, at 201 (citing W. STAUNFORD, AN EXPOSICION OF THE KINGES PREROGATIVE 37 (London 1567); P. HUGHES & R. FRIES, CROWN AND PARLIAMENT IN TUDOR-STUART ENGLAND 167 (1959).

[93] Abramowicz, *supra* note 91, at 1369. Fathers could appoint anyone as a guardian as long as the man was a property owner and was not Catholic.

[94] *Id.* at 1372–76.

[95] *Id.* at 1370.

[96] *Id.* at 1378–79. The Court of Chancery's earliest assertions of its *parens patriae* power over infants may have been consistent with the spirit of earlier legal decisions, but was likely to have arisen from a typographical error. *See also,* Custer, *supra* note 89, at 202–04.

[97] Abramowicz, *supra* note 91, at 1379.

[98] *Id.* at 1379–80.

[99] MARY ANN MASON, FROM FATHER'S PROPERTY TO CHILDREN'S RIGHTS 46 (1994) ("The mutual obligations of a master-servant relationship, rather than a parent-child relationship in the modern sense, best describes the legally enforceable bonds between the adult, who held custody and control over the child, and the child, who held rights similar to those of an employee.").

guardians paved the way for courts to regulate fathers.[100] In the 1756 case *Butler v. Freeman*, a child whose father was still living but had appointed a guardian was seduced away from the guardian.[101] The seducer tried to raise the defense that because the father was still alive, any enforcement of the guardian's wishes by the court would be an improper interference with the father's rights.[102] The court denied the legal distinction between testamentary guardians and fathers, proclaiming that the law treated the two equally.[103]

Two days after *Butler* was decided, *Blake v. Leigh* took this logic a step forward. There, the court found that fathers could waive their rights over their children and thereby relinquish their control over them.[104] In that case, a father was found to have waived his paternal rights by accepting an inheritance from the grandfather because a condition of the inheritance was that a guardian other than the father be appointed for the child.[105] The interests of the child were found to trump the interests of the father.

Courts also began to allow exceptions to recognize that the interests of children might sometimes require that their mothers retained custody over them. In *Blisset's Case*, decided in 1774, Lord Mansfield considered the rights of a father who was bankrupt, had not contributed to his family, and had committed adultery.[106] Lord Mansfield granted custody to the mother and explained that "if the parties are disagreed, the court will do what shall appear best for the child."[107] This was the first clear indication that the best interests of a child could take precedence over a father's rights, but more dramatic changes to the law did not occur for years to come.

In *Powel v. Cleaver*, decided in 1789, a father was found to forfeit his rights over his children when he refused a legacy for his child that would require transferring parental authority to a guardian.[108] The idea was that denying one's child access to wealth was a breach of paternal duty.[109] *Powel* brought about significant change in the law. *Powel*'s holding was explained by a later case that noted that the *Powel* court's exercise of jurisdiction was based on the duty "which upon a tender, just, and legitimate deliberation the parent owed to the true interests of the child . . . ."[110] Additionally, *Powel* was cited to support several other decisions where a court took away a father's parental rights where the father was bankrupt and the child had a sizeable inheritance.[111] These cases demonstrate an increasing willingness by courts to intervene to protect a child's interests. They also show that in the late 1700s, a child's best interests were thought to be served by the acquisition of wealth.

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[100] Abramowicz, *supra* note 91, at 1381.
[101] *Id.* at 1382 (citing 27 Eng. Rep. 204 (Ch. 1756)).
[102] *Id.*
[103] *Id.*
[104] *Id.* at 1383 (citing 27 Eng. Rep. 1009 (Ch. 1732)).
[105] *Id.*
[106] Blisset's Case, 1 Lofft 748, 98 Eng. Rep. 899 (K.B., 1774).
[107] Griffith, *supra* note 90, at 292 (citing *Blisset's Case*, 1 Lofft 748 (Mansfield, C.J.)).
[108] Abramowicz, *supra* note 91, at 1384.
[109] *Id.* at 1385 (quoting *Powel*, 29 Eng. Rep. 274 (Ch. 1789) ("[T]he Court will take care that the child shall be properly educated for his expectations.")).
[110] *Id*. at 1385 (quoting R. v. De Manneville, 5 East 221 (1804)).
[111] *Id.*

Two subsequent decisions significantly expanded the English Court of Chancery's jurisdiction over and ability to interfere with the traditional rights given to fathers. In *De Manneville*, a French father and a British mother were entangled in a custody battle, and the court decided the case by saying it would "do what is for the benefit of the infant, without regard to the prayer."[112] The court, clearly feeling ambivalent about its role,[113] weighed the relevant considerations and decided that the father would retain custody but would have to raise the child in England.[114] In another case, a father who had committed adultery with a married woman had breached the duty granted to him as a father, and the Court explained its role as a very active one—it noted that fatherhood is a trust that courts oversee.[115]

The presumption that the father was automatically the custodial parent was finally eliminated in 1817, when the "Rule in *Shelley*'s case" was adopted. This rule explicitly allowed courts to choose which parent was more fit to be a parent.[116] England began to formally recognize the importance of maternal rights in 1839, with the passage of the Custody of Infants Act that granted mothers rights over children for custody or for visitation.[117] Thus, English common law set the stage for American judges to recognize the best interests of children as well as the rights of mothers.

There is some debate about when the best interests standard was first used in the United States. The earliest published decision which defied the traditional focus on a father's rights appears to be *Prather v. Prather*, which was decided in 1809. In that case, the father forced his wife, the child's mother, to leave their home and he then began living with another woman. A South Carolina judge was clearly troubled by the father's actions and chose to award custody to the mother.[118] Another very early case that invoked the best interests of the child was *Commonwealth v. Addicks*, decided in 1813.[119] In this case, the mother had committed adultery; at that time, the mother's actions would usually have been grounds for granting custody to the father. Nevertheless, the court focused on the needs of the children and chose to award custody to the mother:

> It is to [the children], that our anxiety is principally directed; and it appears to us, that considering their tender age, they stand in need of that kind of assistance, which can be afforded by none so well as a mother. It is on their account, therefore, that exercising the discretion with which the law has invested us, we think it best, at present, not to take them from her.[120]

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[112] *Id.* at 1387 (quoting *De Manneville*, 5 East 221).
[113] *Id.* ("In the situation of this child it is extremely difficult not to interpose; and it is also extremely difficult to say, how the Court is to interpose.").
[114] *Id*.
[115] *Id.* at 1388–90.
[116] Shelley v. Westbrooke, 37 Eng Rep. 850 (Ch. 1817).
[117] *See* Robert C. Brown, *The Custody of Children*, 2 IND. L.J. 325, 325 n.3 (1927) (citing 2 & 3 Vict. c. 54 (Talfourd's Act)).
[118] MASON, *supra* note 99, at 60 (citing Prather v. Prather, 4 SC Eq. (4 Des.) 33 (1809)).
[119] Commonwealth v. Addicks, 5 Binn. 520 (Pa. 1813).
[120] *Id.* at 521–22.

Notably, the shift in legal focus to the best interests of the child did not immediately lead to a best interests standard. In *Commonwealth v. Addicks*, the court was focused on the child's interests. Nevertheless, it based its decision not entirely on what was in the interests of the individual children in front of them, but on a proxy for the child's best interests—the principle that young children, especially females, do best with their mothers. Moreover, the degree of change was not uniform across the country, and some courts still placed utmost importance on a father's natural right to custody up until the beginning of the twentieth century.[121]

When courts began to consider a child's interests more routinely, this led to a proxy of promoting the best interests of young children under the tender years doctrine.[122] The tender years doctrine was a presumption that the mother should retain custody of young children.[123] As Mary Ann Mason describes it:

> The colonial view of children as helping hands in a labor-scarce economy gave way to a romantic, emotional view of children, who were no longer legally akin to servants, under the complete control of their fathers or masters, but instead deemed to have interests of their own. Increasingly, these interests became identified with the nurturing mother.[124]

This presumption could be overridden upon a showing that the mother was unfit to raise the child, which was often accomplished by demonstrating that she had committed adultery or left the father without "just cause."[125]

Considering a child's welfare became more central to and more directly a part of legal decision making in 1886. At that time, the Guardianship of Infants Act was passed and required judges to consider a child's welfare when deciding the outcome of custody disputes.[126] Courts and legislatures began to focus on the best interests of the child in a manner independent of the tender years doctrine.

Perhaps the earliest reported case that used the best interests standard to judge a parent's medical decision making was *Heinemann's Appeal*, a case decided by the Pennsylvania Supreme Court in 1880.[127] This case involved a father with five children.[128] The father did not support his children financially—they were "supported out of their own estates."[129] When the children and their mother became ill with diphtheria, the father treated them himself by administering something called the Bannscheidt system, which involved pricking the patient's skin on different parts of the body with a instrument that

[121] MASON, *supra* note 99, at 50.
[122] *Id.* at 61.
[123] *See id.* at 53 (noting a shift among the judiciary during the nineteenth century in which "[j]udges . . . gave custody to [mothers] based on the growing judicial view that placing children in their mothers' care was in the best interests of children.").
[124] *Id.* at 50.
[125] *Id.* at 63. Notably, custody disputes did not often arise as they do today—as part of a divorce proceeding. They were more commonly brought by a writ of habeas corpus, with the noncustodial parent bringing suit after divorce, claiming that their child was being "wrongfully held or imprisoned**."** *Id.* at 58.
[126] Sarah Abramowicz, *Childhood and the Limits of Contract*, 21 YALE J.L. & HUMAN. 37, 50 (2009).
[127] Heinemann's Appeal, 96 Pa. 112 (1880).
[128] *Id.*
[129] *Id.* at 113.

had thirty needles and then rubbing these parts of the body with an irritating oil.[130] He believed that this treatment was sufficient for their medical care and refused to call a physician.[131] After being sick for several days, his oldest child died.[132] The father called for a physician only when his wife and other children were very near death; his wife and two more of his children also died.[133] The court determined that the father was so convinced of the utility of this unorthodox treatment that he was unlikely to call a physician for his other children, and, in addition to his inability to provide for his children, decided that this meant his natural custodial rights over the children were secondary to the interests of the children.[134] The Pennsylvania Supreme Court upheld the lower court's decree that dissolved the father's guardianship and appointed other guardians for the two surviving children.[135] This case followed in the tradition of cases finding that a father's rights over his children were not absolute and that guardians could be appointed for children when a father was found to be guilty of a dereliction of duty.

Courts began to consider the best interests standard outside the context of divorce when considering whether to allow children to stay with families of limited means that had difficulty meeting their children's needs.[136] This was part of a broader movement of progressive reform that occurred in the early twentieth century.[137] A White House Conference on the Care of Dependent Children was convened in 1909 by President Theodore Roosevelt. Its agenda was to address the following types of questions:

> Should children of parents of worthy character, but suffering from temporary misfortune, and the children of widows of worthy character and reasonable efficiency, be kept with their parents—aid being given to parents to enable them to maintain suitable homes for the rearing of the children? Should the breaking of a home be permitted for reasons of poverty, or only for reasons of inefficiency or immorality?[138]

Although their conclusion was by no means universally held, the attendees at the conference sensibly decided against removing children from their parents strictly because the parents were poor.[139]

Additionally, over the years, many commentators criticized the tender years doctrine for violating the equal protection rights of men and further argued that the generalization that children are better off with their mothers is simply untrue in many

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[130] *Id.* at 112–13.
[131] *Id.* at 112.
[132] *Id.* at 115.
[133] *Id.*
[134] *Id.* at 112, 115.
[135] *Id.* at 115.
[136] MASON, *supra* note 99, at 86.
[137] *Id.* at 87.
[138] *Id.* at 91 (citing *Proceedings of the Conference on the Care of Dependent Children*, *in* 2 CHILDREN AND YOUTH IN AMERICA 358, 359 (Robert Bremner ed., Harvard Univ. Press 1970).
[139] *Id.* at 91.

cases.[140] One court even stated the following: "The simple fact of being a mother does not, by itself, indicate a capacity or willingness to render a quality of care different from that which the father can provide."[141] The Guardianship of Infants Act was revised in 1925 to instruct judges that the child's welfare was the "first and paramount consideration" in custody battles.[142]

The movement towards no-fault divorce and subsequent increase in divorce rates in the second half of the twentieth century meant that divorce cases, not cases on assigning custody of children whose parents had died or could not provide care, dominated the legal landscape.[143] The best interests standard was clearly articulated as a standard for assigning custody after divorce and is now the leading principle applied to most, if not all, decisions involving children.[144]

There are a number of lessons we can draw from the historical development of the best interests standard. This history demonstrates that court intervention for the best interests of children has existed in some form for the last 350 years. At times, indirect proxies for the best interests of children have been used as the governing standard. Focusing on a child's best interests has led to different outcomes depending on the historical context. For instance, in the late 1600s, the best interests standard required courts to attend to advancing the rank and increasing the wealth of a child. Under the tender years doctrine of the first half of the twentieth century, the best interests standard was interpreted to mean that young children should be cared for by their mothers upon the dissolution of a marriage. Today, state legislatures have uniformly adopted the best interests standard for resolving custody disputes, and modern day biases may similarly be folded into the decisions that are made.[145] It is undoubtedly the case that court

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[140] *See id.* at 126 ("It was not only feminist rhetoric promoting equal treatment that persuaded legislators and judges to abandon the maternal presumption; equal treatment arguments were combined with the reality that great numbers of women had abandoned full-time housekeeping for the workplace, moreover, most of these new workers were mothers.").

[141] State *ex rel.* Watts v. Watts, 350 N.Y.S.2d 285, 289 (1973).

[142] Abramowicz, *supra* note 126, at 50.

[143] MASON, *supra* note 99, at 121.

[144] Daniel B. Griffith, *The Best Interests Standard: A Comparison of the State's Parens Patriae Authority and Judicial Oversight in Best Interests Determinations for Children and Incompetent Patients*, 7 ISSUES L. & MED. 283, 283, 293–94 (1991).

[145] Julia H. McLaughlin, *The Fundamental Truth About Best Interests*, 54 ST. LOUIS U. L. J. 113, 117 (2009) (citing ALA. CODE §§ 30–3–1 (LexisNexis 2009); ALASKA STAT. § 25.20.060 (2009); ARIZ. REV. STAT. §§ 25–403 (LexisNexis 2009); ARIZ. LEGIS. SERV. 25,403, 25,409 (West 2009); ARK. CODE ANN. § 9–13–103 (West 2009); CAL. FAM. CODE §§ 3000, 3080, 3100(a) (West 2009); CAL. FAM. CODE §§ 3102–3104 (Deering 2009); COLO. REV. STAT. §§ 14–10–123.5, 14–10–124, 19–1–117 (2009); CONN. GEN. STAT. ANN. § 46b–59 (West 2009); DEL. CODE ANN. tit. 13, §§ 727–728 (2009); D.C. CODE ANN. §§ 16–911 (a)(5), 16–914 (LexisNexis 2009); FLA. STAT. ANN. §§ 61.13(2), (6–7) (West 2009); GA. CODE ANN. § 19–9–3(A)–(D) (West 2008); HAW. REV. STAT. §§ 571–46.1, 571–46.2 (2009); IDAHO CODE ANN. §§ 32–717B, 32–719 (2009); 750 ILL. COMP. STAT. ANN. 5/601, 5/602, 5/602.1, 5/607, 5/607(b)–(e) (2009); IND. CODE ANN. §§ 31–17–1–1–5, 31–17–2–8 (LexisNexis 2009); IOWA CODE ANN. § 598.41 (West 2009); KAN. CIV. PRO. CODE ANN. § 60.1610 (West 2009); KY. REV. STAT. ANN. §§ 403.270, 405.021 (West 2008); ME. REV. STAT. tit. 19A, § 1651–1654 (2009); MD. CODE ANN. FAM. LAW §§ 5–203, 5–203(D)(2) (West 2009), 9–102 (LexisNexis 2009); MASS. GEN. LAWS ANN. ch. 119, § 39D (West 2009), MASS. ANN. LAWS ch. 208, § 28, 208, § 31, 209C, § 10 (LexisNexis 2009); MICH. COMP. LAWS ANN. §§ 722.26(a), 722.27(b) (West 2009); MINN. STAT. ANN. §§ 518.17, 518.175, 257C.08 (West 2009); MISS. CODE ANN. §§ 93–5–24, 93–16–1 (West 2009); MO. REV. STAT. § 452.402 (West 2009); MONT. CODE ANN. §§ 40–4–212,

interpretations of the best interests standard today reflect modern-day values. A final lesson is that the rights of others—particularly the rights of parents and the interests of the public—have been considered by courts in the earliest development of the best interests standard, and to the extent the modern interpretation departs from considering the interests of others, it departs from historical precedent. This is not to say that the departure is not merited in particular cases; it may well be. The point to draw from the history of the best interests standard is that it is only relatively recently that the standard has been stated as one that considers the interests of individual children to the exclusion of all other parties, and this development may merit further scrutiny.

Finally, it is also important to note that although the dominant view in family law is that "the law of parenthood is now structured around children's interests" and that child custody decisions are made under the best interests standard,[146] this statement of current law has been called into question.[147] Jill Hasday argues that parental property rights still play a significant role in modern family law.[148] For instance, she cites the example of child custody law and the fact that parental rights are terminated only if there is clear and convincing evidence that the parent is unfit—and not terminated solely because doing so would be in the child's best interests.[149] Additionally, all states recognize parental authority to conduct corporal punishment, and parents have substantial rights over their child's labor, which allows parents much more power than another employer would have.[150] Thus, although the emphasis on a child's best interests as trumping all other interests dominates the majority of case law, there are many elements of historical doctrines that continue to shape current law governing decisions about children. It is not entirely clear whether these are elements that are purely vestigial, appropriate recognitions of the limits of court interference into family life, or designed to allow children's interests to be balanced against the interests of others.

40–9–102 (2009); NEB. REV. STAT. §§ 42–364, 43–1802 (2009); NEV. REV. STAT. ANN. §§ 125C.050, 125.465, 125.480, 480.490 (West 2009); N.H. REV. STAT. ANN. § 461–A:6 (2009); N.J. STAT. ANN. §§ 9:2–1, 9:2–4(c), 9:2–7.1 (West 2009); N.M. STAT. ANN. §§ 40–9–1, 40–9–2, 40–9–3, 40–9–4 (West 2009); N.Y. DOM. REL. LAW § 240 (McKinney 2009); N.C. GEN. STAT. §§ 50–11.2, 50–13.2 (2009); N.D. CENT. CODE § 14–09–06 (2009); OHIO REV. CODE ANN. §§ 3109.04, § 3109.051 (LexisNexis 2009); OKLA. STAT. ANN. tit. 43 § 112 (West 2009); OR. REV. STAT. ANN. §§ 107.105(1), 107.169; 109.119 (West 2009); 23 PA. CONS. STAT. ANN. §§ 5301, 5303–5304, 5311–5312 (2009); R.I. GEN. LAWS §§ 15–5–16, 15–5–24.1 to 24.3 (2009); S.C. CODE ANN. §§ 20–3–160, 20–7–420 (2008); S.D. CODIFIED LAWS, §§ 25–4–45, 25–4–52, 25–5–7.1 (2009); TENN. CODE ANN. §§ 36–6–101, 36–6–106 (West 2009); TEX. FAM. CODE ANN. §§ 153.005, 153.007 (Vernon 2009); UTAH CODE ANN. § 30–3–10 (West 2009); VT. STAT. ANN. tit. 15, § 665 (2009); VA. CODE ANN. §§ 20–107.2, 20–124.3 (West 2009); WASH. REV. CODE ANN. §§ 26.09.050, 26.09.002 (West 2009); W. VA. CODE ANN. § 48–9–101 (West 2009); WIS. STAT. ANN. §§ 767.41, 767.451 (West 2009); WYO. STAT. ANN. § 20–2–201 (2009).

[146] Jill Elaine Hasday, *The Canon of Family Law*, 57 STAN. L. REV. 825, 848 (2004).

[147] *Id.* at 850.

[148] *Id.* at 849.

[149] *Id.* at 850.

[150] *Id.* at 851–52.

B. Criticisms of the best interests standard

There are various conceptions of the best interests standard, and one difficulty in evaluating the standard is that it can mean very different things. Before discussing the criticisms of the standard, it would therefore be helpful to clarify the different versions of the standard that are worth analyzing. One scholar has argued that there are two important ways to consider a child's interests: as (1) the paramount consideration or (2) a primary consideration.[151] The difference between these two is that if a child's best interests are the paramount consideration, a child's interests trump all other interests and considerations. If a child's best interests are a primary consideration, other interests may trump the child's interests, depending on the circumstances.[152] An additional clarification is that the best interests standard is typically understood to govern decisions made by parents or guardians that are later subject to judicial review. Some of the criticisms of pediatric research and the best interests standard take issue with the primary role that parents are meant to play and the amount of discretion that parents generally receive, rather than the standard itself, and therefore do not relate to the arguments herein.

1. Criticisms of best interests as the paramount consideration

The strict version of the best interests standard, where a child's interests are paramount, has been heavily criticized. As Robert Mnookin has explained, "[t]he very words of the best-interests-of-the-child principle suggest that the judge should decide by choosing the alternative that 'maximizes' what is best for a particular child."[153] It may be relatively easy to consider a child's best interests as paramount when choosing between two (or a few) options. For instance, in custody disputes, the question before a court is typically which parent should get primary or sole custody, or whether both parents should have joint custody. Choosing the option that best serves the child's interests might be relatively straightforward. However, aside from emancipating minors who seek judicial approval to care for themselves, judges do not have the power to simply take the child out of his or her parents' care and place that child into the care of other people the judge knows would be better parents for that child. So even if applying the best interests standard in this case is a little more straightforward, the best interests standard is not being applied to all aspects of the decision—it only applies to a small set of choices that are available to the judge.

In more general decisions in which there are numerous options, the best interests standard as a paramount consideration becomes very difficult and demanding. Jon Elster calls the standard "unfeasibly demanding of agencies charged with the care of children."[154] For instance, Elster points out, "[i]t might be in the best interests of a child

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[151] Archard, *supra* note 13.
[152] *Id.* ("[T]he real contrast is between a paramount consideration that trumps all others and a primary one that need not."). When the United Nations Convention on the Rights of the Child was convened, there was a debate over which version of the best interests standard should be incorporated into the final document. The U.N. Convention on the Rights of the Child ultimately adopted the weaker formulation—that the best interests of the child are a primary consideration. *Id.*
[153] Robert H. Mnookin, *Child Custody Adjudication: Judicial Functions in the Face of Indeterminacy*, 39 L. & CONTEMP. PROBS. 226, 255 (1975).
[154] Archard, *supra* note 13.

that her guardian give up every waking minute to her care. But no adult should have to sacrifice her own welfare for that of her child."[155] Promoting a child's best interests above all other considerations would require a great deal of resources devoted to each and every child, which would prevent parents from acting in ways that benefit people who are not children. Even if a child were to be slightly inconvenienced in order to allow a parent to spend time writing a novel, talking with a friend, or helping elderly parents, the best interests as paramount standard would not permit these kind of trade-offs, and it is not clear why these should be impermissible.

There are many other examples of the potentially overwhelming implications of the best interests standard. Consider all of the things that courts could require parents to do to improve their children's lives. Because of financial constraints, lack of time, or even other competing projects, parents frequently fail to give their children much of what would be in their best interests. For instance, children are routinely deprived of music lessons, the ability to learn a second or third language, organic food, their own bedrooms, a stay-at-home parent or a nanny, a parent's undivided attention, exposure to artistic and cultural activities, the ability to live in a relatively hazard-free environment, the best educational opportunities, ownership of a pet, parents who live together, and much more. Part of the important work of parenting involves setting limits on a child's demands in order to raise a child who can function socially and cooperate with others. There are many reasons that parents may not be able to provide certain goods for their children (or may not want to), but being a parent is incredibly hard work as it is. If courts required parents to do as much as possible to serve their children's best interests, parents would not be able to do much else. Furthermore, no matter why parents fail to abide by the best interests standard to this extent, it is not clear that the state has the power to enforce the best interests standard in this way. As Justice Stewart expressed:

> If a State were to attempt to force the breakup of a natural family, over the objections of the parents and their children, without some showing of unfitness and for the sole reason that to do so was thought to be in the children's best interest, I should have little doubt that the State would have intruded impermissibly on 'the private realm of family life which the state cannot enter.'[156]

If the state was able to disrupt family life at a moment's notice, the state would interfere significantly with constitutional guarantees of privacy and reproductive freedom. The state would have to develop a general policy of extensive interference into the assignment of parental rights in order to enforce this version of the best interests standard. As Jon Elster explains:

> If the best interest of the child is indeed the value guiding the law, one might wonder why courts or welfare agencies are not allowed to remove a

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[155] *Id.*

[156] Smith v. Org. of Foster Families for Equal. & Reform, 431 U.S. 816, 862–63 (1977) (Stewart, J., concurring) (quoting Prince v. Massachusetts, 321 U.S. 158, 166 (1944)).

> child from perfectly fit biological parents when other parents are available who would provide even better for the child.[157]

It is also unclear that government agencies are competent to assign children to their best parents. Finally, systematic and significant state involvement in parenting would disrupt the emotional attachments parents form with children, generate a great deal of uncertainty about the law, and create disincentives for having children.[158] If children could be taken from parents whenever it was in their best interests, this "would create so much uncertainty among parents, with subsequent lack of emotional attachment to their children, that the net effect would be to harm children in general."[159] Elster therefore concludes that a "paramount" best interests standard would actually undermine its own goals.[160]

2. Criticisms that apply to both versions of the best interests standard

The flaws with the paramount interpretation of the best interests standard discussed above are fairly clear, but both the paramount and primary interpretations share a number of additional limitations. Both interpretations are problematic because the best interests of the child are often difficult to discern as they rely on a narrow conception of what counts as being in a child's interests, and fail to take account of the budding autonomy that children have and interests of others.

Nevertheless, it is important to point out that some commentators have endorsed the primary interpretation of the best interests standard. For instance, recognizing that the best interests standard would be "incoherent or self-defeating" if it required every child to have the best, Loretta and Arthur Kopelman have argued that the best interests standard can be understood to take account of the interests of others.[161] Loretta Kopelman explains the use of the best interests standard in the law as follows: "Judges focus upon the needs and interest of particular children, but not to the exclusion of others' rights or interests, to determine which of the available options is best, assuming some option is minimally acceptable."[162] Kopelman explains that choices consistent with the best interests standard "are usually less than ideal but better than barely tolerable."[163] The problem with this version of the best interests standard is that it is not a very clear standard. In particular, the standard does not expressly indicate which trade-offs are acceptable and which are not.

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[157] Jon Elster, *Solomonic Judgments: Against the Best Interest of the Child*, 54 U. CHI. L. REV. 1, 22 (1987).
[158] *Id.*
[159] *Id.*
[160] One might argue that this version of the best interests standard is so problematic that it cannot be defended, and could even be considered a "straw man." In the empirical analysis provided below, however, I provide evidence that courts continue to cite this version of the best interests standard and even attempt to apply it in cases involving medical decision making for children.
[161] Loretta M. Kopelman & Arthur E. Kopelman, *Using a New Analysis of the Best Interests Standard to Address Cultural Disputes: Whose Data, Which Values?*, 28 THEORETICAL MED. BIOETHICS 373, 385 (2007).
[162] Loretta M. Kopelman, *The Best Interests Standard as Threshold, Ideal, and Standard of Reasonableness*, 22 J. MED. & PHIL. 271, 273 (1997).
[163] *Id.*

Even if the best interests of a child are only a primary consideration or something more like a "standard for reasonableness," it may be very difficult to apply in practice because it is hard to know what is actually in a child's best interests. Robert Mnookin has been a prominent critic of the best interests standard for its indeterminacy. He argues that the standard is very difficult to interpret because it requires predicting the future outcomes of various options for that child, and because there is no societal consensus on what values are most important with regard to how children are raised and what best promotes a child's welfare over time.[164] He also points out that judges have to find some way to figure out which values will promote a good life, or the best life, for that child, and there is no clear way to do that in our pluralistic society.[165] Furthermore, he argues that determining what will be in a child's best interests requires predicting that child's future.

Finally, Mnookin points out that the best interests standard is easier to apply in contexts like dispute resolution in custody battles, where the parents have invited courts in to help them resolve the dissolution of a marriage. But it may be harder to apply in other cases, and defining the scope of this function requires addressing "profound questions of political and moral philosophy concerning the proper relationship of children to their family, and the family to the state."[166] For custody disputes in which courts have a less problematic role to play, Mnookin concludes that the best interests standard is not perfect, but is the best of the available alternatives.[167] For child protection decisions or other types of cases, Mnookin recommends more determinate standards and protections against excessive state intrusion.[168]

The best interests standard has also been criticized for taking a narrow view of what is in a child's interests. In their seminal book, *Beyond the Best Interests of the Child*, Goldstein, Freud, and Solnit argue that the best interests standard does not give sufficient weight to psychological well-being.[169] They propose a "least detrimental alternative" approach, which involves ensuring that the child spends a maximal amount of time with the parent who promotes the child's psychological well-being (or, as they describe it, the "psychological parent").[170]

Another problem with the best interests standard is that it assumes that a child's welfare is always the most significant consideration as far as that child is concerned. However, children develop increased autonomy over time, and courts sometimes take the autonomy interests of children into account in a way that contravenes the best interests standard. Simply put, respecting an individual's autonomy sometimes requires allowing that individual to act against his or her interests. In rare cases, courts have allowed minors to refuse lifesaving treatment under the mature minor doctrine. States have allowed minors to refuse treatment if the minor is close to the age of eighteen, or if the minor and

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[164] Mnookin, *supra* note 153, at 264.
[165] *Id.* at 260–61.
[166] *Id.* at 265.
[167] *Id.* at 282.
[168] *Id.* at 277–79.
[169] *Id.* at 247.
[170] JOSEPH GOLDSTEIN, ANNA FREUD & ALBERT J. SOLNIT, BEYOND THE BEST INTERESTS OF THE CHILD 99 (1979).

parents are in agreement about the refusal of medical treatment, and that something important values are at stake. For example, the case of *In re E.G.* involved a seventeen-year-old girl who was a member of the Jehovah's Witnesses, a faith that forbids the use of blood transfusions.[171] She was likely to die within a month without the transfusions, but would have an 80% chance of achieving remission with the transfusions, and a 20%–25% chance of cure.[172] The Illinois Supreme Court determined that E.G. had the right to make her own decisions.[173] First, the court explained: "Although the age of majority in Illinois is 18, that age is not an impenetrable barrier that magically precludes a minor from possessing and exercising certain rights normally associated with adulthood. Numerous exceptions are found in this jurisdiction and others which treat minors as adults under specific circumstances."[174] The court balanced the maturity of the minor against the state's interests in preserving life, protecting third parties, preventing suicide, and maintaining the ethical integrity of the medical profession.[175] The court's opinion spoke to the ability mature minors have to make their own decisions about their medical care under the law. The Illinois Supreme Court explained that mature minors had the legal authority to refuse treatment,[176] even in life and death decisions. Of course, there may be ways to consider decisions like these as in the broader interests of the children involved. Based on their own religious beliefs, it is in the interest of a Jehovah Witness to refuse blood transfusions. Yet a legal standard that allows for a very broad interpretation of one's interests may not provide sufficient guidance for courts and thereby lead to considerable variability in its application.

For the purposes of analyzing the legal treatment of research, perhaps the most significant concern about the best interests standard is that it does not clearly allow for other people's interests to be taken into account. The paramount version of the best interests standard fails to account for the other interests that also matter—the interests of people other than the child. Taking the best interests of a child to be a primary consideration does not solve this problem. This approach still suggests we should focus our attention on the individual child, and does not provide a clear explanation of when we can legally deviate from that focus or when a child's interests might be less important than the interests of others. The interests of other children and of other adults should also count in decisions that affect one particular child. Parents have duties to others, including duties to their other children and the family as a whole, that may often conflict with the interests of a particular child.[177] There is no reason to think that in every conflict, the interests of one individual child can trump all others. The best interests standard fails to resolve what a parent should do if the interests of one child conflict with those of another.

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[171] *In re* E.G., 549 N.E.2d 322, 323 (Ill. 1989).
[172] *Id.*
[173] *See id.* at 326.
[174] *Id.* at 325 (noting the emancipated minor exceptions for children who are married or pregnant and that children under the age of eighteen can be tried as adults).
[175] *Id.* at 328.
[176] *Id.* The lower courts involved in this case had found the parents to have committed neglect, and the Illinois Supreme Court directed the lower courts to expunge this finding.
[177] *See* Robin S. Downie & Fiona Randall, *Parenting and the Best Interests of Minors*, 22 J. MED. & PHIL. 219, 222–23 (1997).

Outside of the family context, there are many other ways in which the interests of others seem to have greater weight than the interests of children. Children can be required to go to school to fulfill the state's need to have an educated citizenry, even if they are talented artists who would benefit much more from having time to explore the world and to engage in art. To promote the public health, schools can require children to be vaccinated, even when the vaccine poses risks and the chance that the child would have contracted a disease that is almost eradicated is slim to none. Children with communicable diseases are typically required to stay home from school, rather than infect others, even if they will miss out on important lessons. Some children volunteer their time to help others in various ways, including participating in activities like Habitat for Humanity or other charitable pursuits. This is thought to be a good way to instill in children the importance of helping others, and is not an activity for which a parent would have to get court authorization, even if it does not directly promote the child's interests. Parents also often try to instill in their children a sense of obligation to their families and communities by asking them to make contributions for others.

Elster also argues that the best interests standard is unjust towards parents because it does not factor in their interests. In particular, he notes that the standard would be unfair if it required "small gains in the child's welfare achieved at the expense of large losses in parental welfare."[178] Courts are in fact sometimes prevented from applying the standard when it conflicts with parental religious rights.[179] The state and federal constitutional guarantees to free exercise of religion bind courts to disregard the best interests standard in some cases.[180] In one California case where a parent's religious rights trumped the interests of the child, a dissenting judge was so troubled by the majority opinion that he stated the following:

> I must confess my complete inability to reconcile the concession made in the majority opinion that as a consequence of awarding the custody of the child to appellant he will be subjected to a teaching which "obviously is not for the best interests of the child" with a profession of obedience to the unquestioned dictate of the law that "the best interests of the child is the polestar of decision in custody cases."[181]

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[178] Elster, *supra* note 157, at 20.
[179] *See* Joanne Ross Wilder, *Resolving Religious Disputes in Custody Cases: It's Really Not About Best Interests*, 22 J. AM. ACAD. MATRIMONIAL L. 411, 421–423 (2009). One difficulty that courts rarely deal with is how the parent's right to free exercise of religion extends to a right to control the religious upbringing of their children. It is clear that some additional right must be operating here, or else parents would only have rights over their own religious practices, and not the religious beliefs of their children. Courts appear to combine the parental right to free exercise of religion, a concern for family privacy, and the state's interest in pluralism to reach the conclusion that parents can develop their children's religious beliefs. If, however, a teenager were to reject his parent's religious beliefs, it is not clear that courts would endorse parental action that favor the parent's religious views over the teenager's. Determining when parental authority arising from free exercise rights no longer extends to children (even if it does not cause them harm) is a challenging task that may require some theoretical treatment.
[180] *See id.*
[181] Quiner v. Quiner, No. 29840, 1967 Cal. App. LEXIS 2452, at *83 (Cal. App. 2d. May 25, 1967) (Herndon, J., dissenting).

Parental religious rights are often given greater weight than the best interests standard, and some commentators have argued that when parental religious rights are at stake, the best interests standard is replaced by something like a "substantial harm" standard.[182] There are also situations in which parents' own exercise of religious preferences will affect the children. The starkest way to put this is: What happens when a parent's decision based on religious preferences might threaten his or her own life, which would in turn have a detrimental effect on his or her children? If parents are expected to make decisions that are in their child's best interests, presumably the child's interests could override the parent's ability to make decisions about his or her own life.[183] In the case of *Public Health Trust of Dade County, Florida v. Norma Wons*, the court was asked to balance a woman's right to free exercise of religion against her children's interests in being raised by both of their parents.[184] The woman was a practicing Jehovah's Witness who suffered from "dysfunctional uterine bleeding," a recurring and potentially fatal condition that could be treated successfully with blood transfusions.[185] She had two young children.[186] A circuit court had previously ordered a blood transfusion for Mrs. Wons against her wishes.[187] The Florida Supreme Court declared: "While we agree that the nurturing and support by two parents is important in the development of any child, it is not sufficient to override fundamental constitutional rights."[188] The court was reluctant to interfere with Mrs. Wons' right to refuse treatment and exercise her religious beliefs for the sake of her children. In general, it seems unlikely that any court would bar a competent adult from exercising a fundamental liberty interest in order to protect the best interests of his or her children by continuing to care for them.

The interests of people outside the family unit may also be relevant to decisions involving children. Rachel Dufault has argued that the best interests standard is problematic because, as a general matter, it does not allow children to act altruistically:

> Unfortunately, the best interests of the child standard, as it now exists, suffers from an additional flaw: it imposes self-seeking values upon children. It permits children to act only when it is in their best interest, thereby foreclosing the possibility of altruistic or humane behavior. Such an impoverished vision of children based on net benefits fails to recognize the human element of childhood. Perhaps, then, what is most objectionable about the standard as it now exists is not that it imposes values on children, but that the values it imposes are the 'wrong' ones, i.e.

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[182] Wilder, *supra* note 179, at 421.
[183] *See* Rosamund Scott, *Autonomy and Connectedness: A Re-evaluation of Georgetown and its Progeny*, 28 J. L. MED. ETHICS 55, 55 (2000).
[184] Pub. Health Trust v. Norma Wons, 541 So. 2d 96, 97 (Fla. 1989).
[185] *Id.*
[186] *Id.*
[187] *Id.*
[188] *Id.* at 97–98 (citing St. Mary's Hosp. v. Ramsey, 465 So. 2d 666 (Fla. Dist. Ct. App. 1985); *In re* Osborne, 294 A.2d 372 (D.C. 1972); *In re* Estate of Brooks, 32 Ill. 2d 361 (1965); Mercy Hosp. Inc. v. Jackson, 489 A.2d 1130, 1130 (1985); *In re* Brown, 478 So. 2d 1033 (Miss. 1985)) (holding "that the state's interest in maintaining a home with two parents for the minor children does not override Mrs. Wons' constitutional rights of privacy and religion.").

> they are too narrow. A better judicial approach to the best interests test would be one that nurtures altruistic tendencies and recognizes that children, as well as adults, enjoy giving for the sake of giving, and not just for some tangible reward.[189]

Other commentators, drawing on Dufault's argument, have similarly argued that the best interests standard fails to capture the fundamentally altruistic nature of certain decisions.[190] These authors proposed a solution: restructure the standard such that a minor's wishes to be altruistic would count in deciding whether donating bone marrow or an organ would be in that child's best interests.[191] Of course, this could only be used if the child understands what it means to donate an organ or bone marrow. These authors also emphasized that altruism should be given additional weight in the process of determining whether minors can donate organs or tissue to others.[192] This issue will be discussed at greater length in subpart III(C), *infra*.

Elster argues that the best interests standard must in some cases be overridden by the public interest.[193] He points out that this occurs in cases like *Palmore v. Sidoti*, a custody dispute.[194] In this case, the Supreme Court asserted the importance of the state's interest in not becoming a party to unconstitutional racial discrimination.[195] The Court determined that it could not consider the effects of racial prejudice in deciding whether a custody arrangement would be in a child's best interests.[196] The Court explained:

> The question, however, is whether the reality of private biases and the possible injury they might inflict are permissible considerations for removal of an infant child from the custody of its natural mother. We have little difficulty concluding that they are not. The Constitution cannot control such prejudices but neither can it tolerate them.[197]

Even though the Court stated that the best interests standard was the correct standard,[198] it concluded that the likelihood that other parties would discriminate against the child could not be given effect by courts. Therefore, in some child custody cases, the state's interest in not being a party to racial discrimination outweighs the child's best interests. Elster describes cases like these as situations where the "child's welfare must, to put it crudely,

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[189] Rachel M. Dufault, Comment, *Bone Marrow Donations by Children: Rethinking the Legal Framework in Light of* Curran v. Bosze, 24 CONN. L. REV. 211, 237 (1991).
[190] Jennifer K. Robbennolt, Victoria Welsz & Craig M. Lawson, *Advancing the Rights of Children and Adolescents to be Altruistic: Bone Marrow Donation by Minors*, 9 J. L. & HEALTH 213, 229 (1994).
[191] *Id.* at 243–244.
[192] *Id.* at 244–245.
[193] Elster, *supra* note 157, at 26.
[194] *Id.*
[195] Palmore v. Sidoti, 466 U.S. 429, 433 (1984).
[196] *Id.*
[197] *Id.*
[198] *Id.* ("In common with most states, Florida law mandates that custody determinations be made in the best interests of the children involved.").

be sacrificed for the greater good."[199] He also argues that it is similarly a reasonable policy to think financial status should not be taken into account in custody determinations, even if one parent's greater wealth could be beneficial to a child.[200]

Finally, Elster worries that if the best interests standard is subject to so many problems in different contexts, "one might expect courts to find it difficult to apply it literally."[201] He concludes that judges do not acknowledge this difficulty overtly, and instead contort the best interests standard by fitting other interests into it and considering them instrumental to promoting the child's interests.[202]

In sum, a standard that takes the best interests of the child as paramount is self-defeating and difficult, if not impossible to implement. A standard that considers a child's best interests to be primary is less obviously problematic, but still presents serious difficulties because of its limited ability to take account of the interests of others. What is unclear from the existing literature is which version of the best interests standard is predominantly used in medical decision making.

The only way to be certain how the best interests standard is applied in medical cases is to survey the available medical cases and see whether the criticisms that have been articulated are real concerns. Do courts consider a child's interests in a narrow sense (i.e., health-related interests), or do they also factor in a child's psychological, emotional, and other interests? Are a child's best interests typically understood to be the paramount consideration, or are they more often considered to be a primary consideration? And if courts use one interpretation or another more frequently, how often do they fail to account for relevant considerations because of the use of the standard? The next section contains an empirical analysis of the best interests standard to help answer these questions and determine whether the best interests standard is operating as it should in the medical context, including but not limited to clinical research.

III. EMPIRICAL ANALYSIS OF THE BEST INTERESTS STANDARD IN MEDICAL DECISION MAKING INVOLVING CHILDREN

It is not entirely clear how the best interests standard operates in medical decisions involving children. One of the clearest statements about the law applying the best interests standard to medical treatment was included in a 1983 report from a presidential commission, and subsequently quoted in a 1986 Supreme Court opinion:

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[199] Elster, *supra* note 157, at 26.

[200] *Id*. at 27. Notably, this differs from the interpretation of a ward's best interests in the early days of jurisdiction over guardians, when financial considerations were determinative.

[201] *Id.* at 28.

[202] *Id.* at 29 ("Instead of arguing that parental interests or the interests of children in general come into play when the child's particular interest is indeterminate, they take account of these interests by making them part of the particular child's interest. I am not suggesting that judges consciously reason in this manner, only that their reasoning may be influenced by interests other than the particular child's, interests that are irrelevant under existing law but that they feel are morally pertinent or will lead to socially desirable behavior. Judges, no less than others, are vulnerable to self-deception, wishful thinking, and other forms of motivated irrationality. Although they are somewhat subject to reality control since their decisions can be appealed and reversed, their mistakes are less strongly sanctioned than those of a soldier or businessman.").

> The paucity of directly relevant cases makes characterization of the law in this area somewhat problematic, but certain points stand out. First, there is a presumption, strong but rebuttable, that parents are the appropriate decisionmakers for their infants. 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. In the exercise of this authority, the state not only punishes parents whose conduct has amounted to abuse or neglect of their children but may also supervene parental decisions before they become operative to ensure that the choices made are not so detrimental to a child's interests as to amount to neglect and abuse.
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> . . . [As] long as parents choose from professionally accepted treatment options the choice is rarely reviewed in court and even less frequently supervened. The courts have exercised their authority to appoint a guardian for a child when the parents are not capable of participating in the decisionmaking or when they have made decisions that evidence substantial lack of concern for the child's interests.[203]

The President's Commission did not, however, conduct an empirical analysis of the relevant legal cases to support its description of the legal landscape. One helpful insight from their report was to provide several structural reasons that there are so few cases in this area. The Commission explained that "health care professionals and institutions are reluctant to become enmeshed in legal proceedings."[204] It also noted that the U.S. healthcare system has few provisions for intervening with parental decision making. Child welfare agencies and courts are the actors most empowered to intervene, but they have limited reach. In fact, "the American legal system ordinarily relies upon the private initiative of individuals, rather than continuing governmental supervision, to bring the matter to the attention of legal authorities."[205] Although these features of the American legal system are structural and not substantive, they do have an important substantive effect on the law governing parental authority. They suggest that the law is simply unable to reach many decisions that parents make, and this fact effectively and dramatically extends parental authority. What courts do when they are faced with individual cases can still help us understand how the best interests standard is applied in practice, which version is applied most frequently, and whether applying the best interests standard keeps courts from being able to address the interests of others when those interests are relevant.

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[203] *Deciding to Forego Life-Sustaining Treatment: Ethical, Medical, and Legal Issues in Treatment Decisions*, PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMED. AND BEHAV. RESEARCH 212–13 (1983).
[204] *Id.* at 212.
[205] *Id.* at 214.

A. Methodology

To begin answering these questions, I undertook an empirical analysis examining the application of the best interests standard by courts reviewing medical decision making on behalf of children. I first searched the federal and state cases database on LexisNexis and Westlaw in January 2012 to identify the cases in the sample, and each database identified 259 cases.[206] This first search was supplemented with targeted searches on blood transfusion cases[207] and bone marrow donation[208] cases.

The next part of the analysis involved culling the results of cases that were not relevant, based on the following inclusion criteria: (1) the case was decided after 1960; (2) the case involved a medical decision (including abortion, bone marrow or organ donation, medical treatment, preventative intervention, cosmetic procedures); (3) the court was deciding whether to intervene, order a procedure to be performed, remove custody based on the decision, or provide guidance on how medical decisions should have been made in a particular case; (4) the case involved minors. The exclusion criteria were as follows: (1) the case involved decision making for an incompetent adult; (2) the case involved consideration of a fetus, embryo, or child who was not yet born; (3) the case was a criminal matter about whether a parent should be charged with neglect, abuse, or murder; (4) the procedure at issue was a paternity test; (5) the case was dismissed on procedural grounds; and (6) the court was involved in creating or adjudicating a custody agreement. Cases before 1960 were excluded because time could be a significant confounder. Reporting before 1960 appeared to be much less consistent; there was approximately one case each decade before 1960, but many per decade after that time period. Therefore, to advance the goal of this project—to study a finite population and capture the full universe of cases within a particular time—cases before 1960 were eliminated from the sample.

Snowball sampling was employed to ensure that the sample was complete. Each case that was found in the original search was shepardized[209] to identify more cases, and the results of these searches were subjected to the inclusion criteria listed above. Cases

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[206] For this search, I used the following search string: “best interest!” w/s standard OR test & medic! w/s deci! w/p child w/s parent!. Although these initial search terms may seem somewhat restrictive, the general approach of using a broad search based on the best interests standard was markedly inefficient. Fewer than 9% of the cases identified by this general search were relevant. The bulk of the cases that were identified involved custody disputes. Broader searches were even less efficient. Conducting a search on Westlaw yielded slightly different results than the LexisNexis search. The Westlaw search added eight new cases to the sample, but merely duplicated some results by identifying fifteen cases that had already been identified with the LexisNexis search. The bulk of the cases were identified through cases cited in the opinions identified, finding cases that the cited the cases identified, and more targeted search strings like the ones described below.

[207] This search used the following search terms: “best interest!”AND (child! OR minor) AND (blood w/s transfus!) and yielded 279 initial results.

[208] This search used the following search terms: “best interest!” AND (child! OR minor) AND (“bone marrow” w/s transplant) and yielded 28 initial results. A third search was performed on cases involving vaccines, but proved too overinclusive to be useful (“best interest!” AND (child! OR minor) AND health! AND (vaccin! OR immuniz!) AND NOT “Vaccine Act”).

[209] “Shepardizing” is a method to locate decisions that are based on previously identified prior precedent from *Shepard's Citations*, which are books listing published reports of appeals court decisions that cite a particular prior case.

that met the inclusion criteria were also shepardized, and so on. Finally, cases cited within the body of judicial opinions that were part of the sample were also included and evaluated according to the inclusion and exclusion criteria listed above. The final sample consists of 101 cases.

For each case in the sample, the following data were collected: year decided; question before the court; what the treatment or procedure was; whether the treatment or procedure in question was lifesaving; whether there were alternatives to the treatment or procedure; whether the issue involved abortion, bone marrow donation, vaccines, or surgery; whether the definition of the best interests standard was that the child's interests are a primary consideration or the paramount consideration (separated into considering only interests that were narrowly related to the physical health of the individual child versus considering broader interests, such as the interest in having a sibling survive), or whether there was no standard articulated; whether religion was at issue; what the age of the child was; and the holding.

The limitations of this strategy are that it is unclear whether all of the cases on medical decision making on behalf of children have been included in LexisNexis or Westlaw, and whether the strategies employed herein were successful at identifying all of the relevant cases in these databases. It is possible that state cases in particular are underreported, and that controversial cases may be over-reported.

B. Results

The cases that have invoked the best interests standard in medical decision making involve a variety of interventions. The largest category of cases (16/101) involved decisions about blood transfusions, but the rest of the cases spanned interventions ranging from cardiac surgery to sterilization to psychiatric medication. Although the National Commission assumed that most cases invoking the best interests standard in medical decision making were likely to involve life-or-death decisions, more than half of the cases (61/101) did not involve potential lifesaving interventions.

With regard to the definition of the best interests standard that was used by courts, forty-three considered the child's best interests as paramount with a narrow conception of what counts as the child's interests; twelve considered the child's best interests to be paramount, but with a broad conception of the child's interests; and forty-four considered the child's interests to be a primary consideration. Thus, in more than half of the cases (56/101), the court considered the child's interests to be paramount. And in a majority of those cases (44/56), courts considered the child's interests in a narrow sense, and only weighed considerations about the child's health.

In cases involving potentially lifesaving blood transfusions to which parents had religious objections, in all but two cases, courts found it acceptable to order the transfusion over the parent's objection. Only in two cases where the child involved was seventeen years old and expressed the same religious view as the parents did the courts allow the decision to stand. In cases in which courts ordered the transfusion to take place, the courts used a variety of different standards. Two courts did not use the best interests standard at all, and instead used a standard of what was in the state's or public's interest. Eight courts used a nuanced version of the best interests standard that took other's interests into account (best-interests-as-primary), three courts used a narrow conception

of the child's best interests as paramount and only referred to health interests, and one court used a broad conception of the child's interests but still held the child's interests to be paramount. In this category of cases, the best interests standard therefore seemed to provide limited, if any, guidance to courts in reaching the outcome.

Another interesting set of cases involved sterilization of mentally disabled children. Of the eight cases in the sample, six used a best interests as paramount standard with a narrow conception of the child's interests and placed the child's welfare above all else. Even though these courts ostensibly used the same standard, in two of those cases, the courts permitted the sterilization, and in four of those cases, the courts did not. In one case, the court used the best interests standard but considered the child's interests in a broad way (beyond merely medical interests), and remanded for further consideration in proceedings in which the child would be represented by counsel. Finally, in one case, a court declined to pick a standard and simply permitted sterilization because it had been permitted in similar cases.[210]

One interesting example comes from the sample in which the court treated the child's best interests as paramount, and considered only narrow health interests of the child.[211] In the case of *In re A.W.*, the court noted that sterilization is a special and fraught issue and that parents should not be allowed to make the decision without court intervention. The court required evidence showing that there was a need for sterilization and that sterilization was in the child's best interests. The court did not think it was permitted to consider the parental interests involved. It is possible that there are important historical reasons that the sterilization of mentally disabled people should be handled very carefully. Yet, a parent who is responsible for raising a mentally disabled child who cannot protect herself adequately or make sound decisions may have a very legitimate concern about that child being sexually active (or, more troublingly, sexually assaulted), and about the subsequent responsibility for a grandchild that would fall on the parents. Whether these kinds of considerations should be taken into account or not, the court in this case felt prohibited from doing so because of the best interests standard.

These sterilization cases illustrate three concerning features of the use of the best interests standard. First, it is not clear that the standard is used consistently to determine the outcome. Even though two courts cited the best interests of the child as paramount and only considered a child's health interests, these courts still felt they could authorize sterilization. The four other courts that used the same standard did not reach the same conclusion. Given that the facts of the cases were not significantly different, it seems that some courts applied the standard incorrectly. Second, the paramount version of the best interests standard may seem to prevent consideration of relevant information, like the burden on caretakers who might have to care for a developmentally disabled child and his or her children. Last, the best interests standard likely obscures some of the bases for particular decisions reached by judges. There is vast literature on the sterilization of incompetent persons, and at various points in our history, mass sterilization campaigns

[210] Ruby v. Massey, 452 F. Supp. 361 (D. Conn. 1978).
[211] *See generally In re* A.W., 637 P.2d 366 (Colo. 1981).

have been carried out in an incredibly troubling fashion.[212] As the court expressed in *In re A.W.*, "This record of past abuses necessitates governmental protection of a mentally retarded person's rights. . . . [S]terilization is a special case which requires more than parental consent. Rather than parents or guardians, a court, using uniform criteria, must be the ultimate arbiter on this matter."[213] This history likely informed the decisions reached by the judges in these cases, and may have constrained some of them from ordering sterilizations in particular cases for fear of abuse of that power by the state. The best interests standard makes it difficult to account for these considerations, and thereby contributes to decision making that is insufficiently transparent.

A final point to draw from these data is that they are consistent over time, and the use of the best interests as paramount standard by courts is not a relic of the past. Since the year 2000, there have been twenty-six medical cases that involved the best interests standard. In seventeen of those cases, judges considered the child's best interests to be paramount, and fifteen of those cases also took a narrow view of the child's interests. Despite considerable criticism of this impoverished approach to a child's interests in the literature and case law, courts are still applying a problematic version of the best interests standard.

C. Discussion of results

These results raise two important questions that will aid in their interpretation. First, why are judges invoking a version of the best interests standard that has been subject to sharp criticism? Second, is the use of the paramount best interests standard largely rhetorical, or is it leading courts to worrisome conclusions in particular cases?

1. Why do judges use the best interests as paramount standard?

There are a number of possibilities that could explain why judges are commonly invoking the best interests as paramount standard. An obvious reason is that the literature about the best interests standard has not had much of an impact on judicial decision making or the statutes that inform particular cases. Even if that is true, however, the fact remains that there are obvious problems in using and applying the best interests as paramount standard. Other parties, including parents, are likely present when these decisions are being made, and it seems unlikely that courts are willing to disregard their interests entirely. In some cases, such as the sterilization cases discussed above, courts applying the paramount version of the best interests standard reached different outcomes, even with similar facts. What is it about the paramount standard that makes it so attractive for judicial decision making?

Perhaps judges are merely applying the best interests as paramount standard as a legal fiction. A legal fiction is a statement that is treated as true for some legal purpose, even if it is not actually true in fact or in its application to a particular case.[214] Legal

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[212] Paul A. Lombardo, *Three Generations, No Imbeciles: New Light on Buck v. Bell*, 60 N.Y.U. L. REV. 30, 32 (1985) (discussing the "eugenics craze" of the Progressive Era and subsequent passage of sterilization laws).
[213] *In re* A.W., 637 P.2d at 370.
[214] LON L. FULLER, LEGAL FICTIONS 9 (1967).

fictions have many different motivations. With regard to the best interests standard, perhaps courts, like most actors, strive to describe their actions in the best light possible. Protecting children's interests and privileging them above other considerations sounds like a worthy goal to which courts should aspire. The court may set its sights on an approach that would be the most desirable, all else being equal. The court may not be able to reach that idealistic goal, however, because there are important and competing considerations to weigh in the balance.

As Lon Fuller explained, judges create legal fictions not so much out of "some instinct for self-deceit, as to an impulse toward harmony and system. By giving to the new law the verbal form of the old it facilitated its absorption into the existing corpus of rules."[215]Another related purpose behind legal fictions can be an aspirational goal—the desire to put the court's decision in the best light possible. Legal fictions can be intended to set the court's sights on an approach that would be desirable in the abstract. All things considered, however, the court may not be able to reach that idealistic goal if there are competing considerations the court also has to weigh. Peter Smith has argued that "judges' factual assumptions often reflect their aspirations for society and the law, even if those aspirations are unlikely to be realized."[216] For example, he argues that the common practice of using limiting instructions is a legal fiction.[217] It is premised on the assumption that even if jurors hear damning testimony that should not be entered into evidence, limiting instructions can correct the error.[218] Rather than confront the fallibility of jurors, who serve a critical role in our justice system, courts pretend that jurors understand and obey limiting instructions.[219]

More generally, aspirational fictions can be created when people confronted with conflicts of interest resolve the conflict by pretending it does not exist. For instance, the Declaration of Helsinki declares that, "[i]n medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests."[220] This language is prominent in its ethical guidance despite the fact that research is different from medical care, and the goal of research is to produce generalizable knowledge, not individual benefit. When it feels uncomfortable to acknowledge the true conflict between competing and important interests, it can be much easier to pretend that one of the interests clearly trumps. The best interests as paramount standard does just that with regard to decision making about children. Instead of acknowledging that parents, siblings, and society have interests that may sometimes trump the interests of a particular child, courts may often feel more comfortable declaring that nothing can trump the child's interests, regardless of whether this standard is ultimately reflected in the decision reached.

Aspirational fictions make sense when they set a legal decision maker's sights on an important goal to aim toward, even if it cannot be realized. Aspirational fictions put forth a decision making principle with broad appeal, like the idea of protecting children's

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[215] LON L. FULLER, ANATOMY OF THE LAW 52 (1968).
[216] Peter J. Smith, *New Legal Fictions*, 95 GEO. L.J. 1435, 1440 (2007).
[217] *Id.* at 1488.
[218] *Id.*
[219] *Id.*
[220] *Ethical Principles for Medical Research Involving Human Subjects*, WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI (2008), http://www.wma.net/en/30publications/10policies/b3/.

interests and privileging them above other considerations. These fictions help courts and other actors describe their actions in the best light possible.

Aspirational fictions are problematic when they hide the true character of the decisions judges are making, fail to give notice to the public about what the law says, or may make judges less attentive to other considerations that cannot fit neatly under the rubric of the fiction. As I have argued with a colleague elsewhere, when legal fictions are unacknowledged, courts that fail to realize a legal construct is a fiction may make inconsistent or incorrect decisions.[221] The use of the best interests as paramount standard as a legal fiction is dangerous because it is so obscure. Many courts may not realize that the best interests standard is a legal fiction because it is unacknowledged. Failing to realize that they are dealing with a legal fiction, courts can apply the best interests standard strictly and neglect other important interests, as possibly illustrated by the transplant cases discussed above.[222] Additionally, without transparency, courts will reach different conclusions about whether to consider the interests of people other than the child in very similar decisions, leading to unfairness in the judicial system.

Along with concerns about generating contradictory rulings in similar cases, another important question is whether the best interests as paramount standard leads courts to ignore relevant considerations. If there were no competing interests at stake, or the child's interests are so weighty that they effectively are paramount (they do in fact trump all other interests, even if they would not in theory), then these results are of much less concern. In the next section, I demonstrate that there are specific categories of cases in the sample, however, that have problematic outcomes when the best interests of the child are considered to be paramount.

2. Does the best interests standard lead to problematic results in particular cases?

The best interests standard led to problematic results in particular cases such as: (a) cases involving organ or tissue donation to a sibling; and (b) cases raising public health considerations.

a. Organ or tissue donation

Four cases involving organ or tissue donation to a sibling were included in the empirical analysis herein. In these cases, there are important questions about the sibling's welfare that may be relevant for parents to consider in making their decision. When courts consider the best interests of the donating child as paramount and take a narrow view of that child's interests, however, there is little room to consider the interests of the sibling in need of the donation.

Some commentators argue that the best interests standard rightly would not permit children to serve as organ donors because the psychological and physiological damage of donating an organ or tissue can be significant and bone marrow donation should only be

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[221] Seema K. Shah & Franklin G. Miller, *Can We Handle the Truth? Legal Fictions in the Determination of Death*, 36 AM. J. L. & MED. 4 (2010).

[222] *See generally*, Curran v. Bosze, 566 N.E.2d 1319 (Ill. 1990); Little v. Little, 576 S.W.2d 493 (Tex. Civ. App. 1979); *In re* Richardson, 284 So. 2d 185, 186 (La. Ct. App. 1973); Hart v. Brown, 289 A.2d 386 (Super. Ct. 1972).

allowed from legally competent donors.[223] Nevertheless, it is a minority position in the literature that bone marrow donation should not be permitted, and many transplants are currently happening. The United Network for Organ Sharing has published national data indicating that there were 361 organ transplants from pediatric living donors in 2011.[224] Because organ transplants are generally riskier and more complicated, they are likely to be rarer than bone marrow transplants. Thus, children are serving as organ and tissue donors in significant numbers, and there appear to be few court cases challenging these actions.

It is possible that some versions of the best interests standard could accommodate organ donation. One could argue that a child who grows up in a family that has not experienced the death of a child is better off psychologically. Nevertheless, given the considerable physical risks of organ donation, the value of growing up in an intact family has to be balanced against the risk of harm or even death from serving as a donor. Although it is possible that the balance lies in favor of donation in most cases, it is likely to be a close enough call in some cases that court intervention would make sense.

Courts could use the best interests as paramount standard along with a broad conception of the *donor* child's interests, as the court did in the case of *Little v. Little*.[225] In that case, the court considered the benefits to the donor of serving as a donor and continuing to have a relationship with his or her sibling.[226] Depending on the physical risks to the donor child, it might be in the child's best interests to obtain the psychological benefit of having his or her sibling survive. Although this might be true in particular cases, it is not straightforward to weigh this potential psychological benefit against the risks to that child. It is certainly possible that the child's life could be better if the sibling was not around to take the parent's attention. This kind of reasoning would require a cold calculation of the interests of the children and an understanding that these interests might actually compete. And something about this reasoning seems flawed. From a parent's perspective, it would seem better if a parent were to be primarily motivated by the benefit to one child and the lack of significant harm to other. But the best interests as paramount analysis does not allow for balancing the interests of multiple children in its focus on only one child, even though making family decisions in that way seems artificial and even incorrect.

When the risks of serving as a donor are minimal, and the chance that the donation will save the life of one's sibling is very high, it seems eminently reasonable for one sibling to help the other. For example, if one child needed blood to save his or her life, and a sibling could donate the blood at minimal risk of harm, the parents could and should be able to consent for one child to donate blood to the other. When the interests of

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[223] Cara Cheyette, Note, *Organ Harvests from the Legally Incompetent: An Argument Against Compelled Altruism*, 41 B.C. L. REV. 465, 513 (2000).
[224] UNOS, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, 2010 ANNUAL REPORT (2010), *available at* http://optn.transplant.hrsa.gov/latestData/rptData.asp (to access online, Click on Build an advanced report, for Step 1 (Choose a data category), select Donor; for Step 2 (Choose report columns), select Age - Pediatric/Adult; for Step 3 (Choose report rows), select Donation Year (2010–2011); for Step 4 (Choose your style), select Counts in the display box and Portrait in the format box. Under Optional, select Living donor; then under Submit Request, click Go).
[225] 576 S.W.2d 493, 498–99 (Tex. Civ. App. 1979).
[226] *Id.* at 498.

one's siblings are sufficiently weighty, such as when a life is at stake, then it would seem particularly troubling if a child who was able to make decisions could simply disregard his or her siblings' interests. In most families, the interests of one's siblings are expected to be a relevant consideration. If children were raised in such a way that they refused to consider how their actions would affect their siblings, many would consider these children selfish and uncaring.

Significantly, the paramount standard with a narrow interpretation of interests actually places parents in an untenable position when one child needs an organ or tissue donation from another. The parents would be required by the standard to authorize the donation on behalf of the child whose life could be saved, but would simultaneously be required not to authorize the donation on behalf of the child who would be serving as the donor. Although some commentators argue that the way to resolve this conflict is to take the decision making out of the hands of the parents altogether,[227] this solution would take the decision away from those who know the children best and would make it even more difficult to think about the interests of the family as a unit. Identifying a decision maker who is free of any conflict of interest may mean choosing a person who lacks the relevant information to make a good decision. Moreover, the conflict could not be entirely eradicated, as the decision maker would likely have to rely on the people who are considered to have a conflict for some of the information needed to make a sound decision. The existence of a conflict may in fact be relevant to the decision. Parents know the needs of their children and the family as a whole, and they are therefore best placed to balance competing interests when there is a conflict. Some have even argued that requiring separate donor advocates "under cuts the primacy of parents as the principal protectors of their children and communicates that clinicians and policy makers do not consider parents trustworthy in this most intimate setting."[228]

The best interests standard seems to have led to problematic decision making in at least one case in the sample—the case of *In re Richardson*.[229] In this case, a husband sued his wife to prevent her from consenting for one of their children to serve as an organ donor for the other.[230] Their daughter needed either a kidney transplant or dialysis to prevent her death, and their 17-year-old son Roy was by far the best match.[231] Roy had a mental disorder that gave him the mental capacity of a 3- or 4- year-old child, and a life expectancy of 25 years.[232] The court applied the paramount version of the best interests standard to the case and a narrow conception of the interests of the child. As a result, the court found that "surgical intrusion and loss of a kidney would clearly be against Roy's best interest," so it could not be permitted.[233] The court also rejected the argument that Roy would benefit from the transplant because his sister would be able to care for him if

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[227] Lainie Friedman Ross, *The Ethics of Hematopoietic Stem Cell Donation by Minors*, 163 ARCH PEDIATR. ADOLESCENT MED. 1065, 1065 (2009).
[228] Jennifer C. Kesselheim, et al., *In reply: The Ethics of Hematopoietic Stem Cell Donation by Minors*, 163 ARCH PEDIATR. ADOLESCENT MED. 1065–66, 1065 (2009).
[229] 284 So. 2d 185, 186 (La. Ct. App. 1973)
[230] *Id.* The court described the husband's act as a "procedural vehicle" to obtain a judgment on whether the parents had the legal authority to consent to the transplantation.
[231] *Id.* at 186–7.
[232] *Id.* at 186.
[233] *Id.* at 187.

his parents passed away, finding that argument too speculative.[234] The court consistently applied the best interests standard but in a way that arguably discounted the interests of the family as a whole and did not allow for consideration of other important interests. Freed of the constraint of the best interests standard, the court likely would have more carefully considered the interests of the family as a whole and the relationship between Roy and his sister, as later courts addressing similar questions did.[235]

The court failed to consider relevant family interests in this case. As Mark Cherry has explained, "families accept a wide range of choices that are in the best interests of the family, but not necessarily in the best interests of any particular child (such as moving to accept a better paying job in a city with greater pollution or an increased crime rate)."[236] Trade-offs and compromise are a natural result of living together. For this reason, valuing the institution of family may require that courts refrain from intervening, even when the choices made are inconsistent with the best interests of each individual child.

b. Cases involving public health considerations

Another category of cases where the best interests standard leads to problematic results involves public health considerations, which perhaps raises more important questions about the application of the best interest standard to pediatric research. Public health is "the societal approach to protecting and promoting health."[237] In general, public health measures seek to improve population health in a manner that may require individuals to bear risks or burdens, and thereby are inconsistent with the best interests standard. The values behind public health are different from the values that define other areas of medicine.[238] Vaccination may be the most obvious example of a public health measure that applies to children, and one in which there are other important interests at stake, including the public's health and parent's rights to free exercise of religion. All states have laws requiring vaccination against various diseases as a condition of enrollment into public school.[239] There has been a great deal of controversy about vaccination and a number of anti-vaccination groups have risen to prominence at different times in American history. However, political challenges to vaccination policies were rarely successful and became much less frequent as overall childhood health noticeably improved in a manner that was attributed to vaccination.[240] In fact, "[b]y the

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[234] *Id.*
[235] *See e.g.*, Curran v. Bosze, 566 N.E.2d 1319, 1336 (Ill. 1990).
[236] Mark J. Cherry, *Parental Authority and Pediatric Bioethical Decision Making*, 35 J. MED. & PHIL. 553, 561–62 (2010). *See also* Coleman, *supra* note 53, at 576 (arguing that "research cannot satisfy the law's requirement that the procedure be either in the best interests of the healthy child or when that standard is impossible to meet, in the best interests of the family on balance.").
[237] Nancy E. Kass, *An Ethics Framework for Public Health*, 91 AM. J. PUB. HEALTH 1776, 1776 (2001).
[238] *Id.*
[239] James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 833 (2001). Boston was the first city to make vaccination a requirement for attending school in 1827. *Id.* at 851.
[240] *Id.* at 867–68.

mid-1950s, it was arguably settled law that school vaccination mandates were presumptively valid."[241]

More than a century ago, the Supreme Court addressed whether states have the authority to mandate vaccination more broadly—not merely as a requirement for enrolling in public schools—in the case of *Jacobson v. Massachusetts*.[242] In this case, the Court reviewed a Massachusetts law that required the people living in a city or town be vaccinated when the Board of Health determined it was necessary to safeguard the public health.[243] The Court found that requiring vaccination is one of the "manifold restraints to which every person is necessarily subject for the common good,"[244] analogizing to quarantine or the military draft.[245] The Court determined that it could only intervene if the state's exercise of power was arbitrary and unreasonable or far beyond what was needed.[246]

There were six cases involving vaccination in the sample, and four of them explicitly weighed societal interests in their decision making even while referencing the best interests standard. Significantly, some courts dealing with the difficulties of applying the best interests as paramount slipped from a best interests of the individual child standard to a standard considering the best interests of children as a group. For example, in one case in the sample, the court found requiring smallpox vaccination was reasonable and a proper exercise of authority when the school board, "recognizing that smallpox is an acute and highly contagious disease necessitating strict measures of treatment and control, determined it was for the *best interests* of the children in its school district that vaccination against smallpox be compulsory."[247]

The reason the court used the best interests standard in such a strained way is clear. Whether to mandate vaccination is not an individualized decision but a public health decision. For an individual child, vaccination is sometimes not in that child's best interest.[248] The goal of vaccination is to create herd immunity to reduce the number of infections that occur and spread in a community.[249] It may not make sense for an individual to take on the risks of being vaccinated if a large proportion of people in the community have been inoculated against the disease. The risks of contracting a particular illness at that point are often negligible. In attempts to eradicate diseases, this risk-to-

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[241] Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL'Y L. & ETHICS 39, 52 (2012).
[242] 197 U.S. 11, 12 (1905).
[243] *Id.*
[244] *Id.* at 26.
[245] *Id.* at 29.
[246] *Id.* at 28.
[247] Pierce v. Bd. of Educ. of City of Fulton, 219 N.Y.S.2d 519, 521 (1961) (emphasis added). This approach resembles approaches that have been suggested in the literature to rename the best interests standard as "the best interests of everyone," and to "maximize known benefits and minimize known harms for all parties concerned." *See* Kopelman, *supra* note 162, at 280.
[248] *See* Holland, *supra* note 241, at 75 (noting the low incidence of Hepatitis B in the United States in questioning the justification for mandating vaccination for the disease).
[249] John P. Fox, et al., *Herd Immunity: Basic Concept and Relevance to Public Health Immunization Practices*, 141 AM. J. EPIDEMIOLOGY 187, 188 (1995).

benefit ratio becomes even less favorable as vaccines are administered when the chances of being infected are extremely low, in order to reduce those chances to zero.

Vaccination can raise the concern that parents who opt-out act as "free riders." There is a danger that some parents may take advantage of the goodwill of others by avoiding the risks associated with vaccination for their children but may still reap the benefits of herd immunity if most other parents opt in. Courts and schools struggle to coordinate collective action in these situations. Rather than acknowledging the collective action problem, these courts have appealed to the best interests standard, even though vaccination is likely not in the best interests of an individual child in many cases. These courts are departing from the best interests standard while using the best interests language to reach a very different outcome.

Invoking the best interests standard at a group level is not only confusing, but also dangerous. By using the language of the best interests standard, courts hope to make public health decisions seem more familiar and acceptable. This means that states could simply conduct a utilitarian calculus and expose some children to great risk if it resulted in sufficient benefit to others. Yet all states make exceptions for individual children for whom the vaccine is considered too risky.[250] These exceptions accord with the common intuition that there is some unacceptably high level of risk to which children cannot be exposed, no matter how great the benefit to others. For example, if one child in fifty was likely to face an almost certain risk of death from a vaccine, and the other forty-nine children would face a substantial risk of a non-fatal illness if they did not receive the vaccine, the best interests of the group of children could be used to justify an action that is not in the best interests of that one child. Yet this seems to be an unacceptable way to treat that child. This is one instance in which the terminology of best interests is being used to make public health decisions sound like individualized decisions. This imprecision is dangerous because it fails to put the right constraints on public health decisions. This tendency is even more problematic in the context of pediatric research.

IV. RESEARCH SHOULD NOT HAVE TO ABIDE BY THE BEST INTERESTS AS PARAMOUNT STANDARD

In many medical (and other) decisions involving children, interests other than those of the children may be relevant. Good examples of when these interests should be considered arise in domains that require some individuals to take on burdens for the common good. This is generally the case in public health and particularly the case in research.

Research is an important instance of public health decision making in which larger societal interests shape existing policy. Research that poses net risks should not be conducted if all we care about is maximizing the best interests of individual children in particular cases. However, research is a domain in which society benefits from generating

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[250] *States with Religious and Philosophical Exemptions from School Immunization Requirements*, NATIONAL CONFERENCE OF STATE LEGISLATURES (December 2012), http://www.ncsl.org/issues-research/health/school-immunization-exemption-state-laws.aspx; *see also* Christine S. Moyer, *Medical Vaccine Exemptions for Children not Always Justified*, AMEDNEWS.COM (Sept. 10, 2012), http://www.ama-assn.org/amednews/2012/09/10/hlsa0910.htm.

new knowledge to help people in the future, and this benefit may justify exposing children to some risk of harm. As discussed above in Part I, without systematic medical research, all children suffer from ad hoc experimentation by their physicians who have limited guidance for what drugs to give children or what dosages will work for them. Research enables practitioners to make informed and responsible decisions in treating children in the future. There may be times when the lack of evidence for how to treat a particular pediatric disease or what dose to give means that, absent research participation, children would be exposed to the same risks that they would be in research. In such cases, children may be made no worse off by their participation in research. But there are also times when healthy children need to be studied so medical practitioners have a better understanding of normal childhood development, or to serve controls to compare the effect of an intervention in a child with a disease to a child who is developing normally. There are also cases where there is so much uncertainty about benefit that it does not clearly outweigh the risks. Pushing past the boundaries of existing knowledge through research is a critical part of the medical enterprise. This necessitates exposing some children to increased risk for the benefit of others. This is why the U.S. Department of Health and Human Services allows children to be subjects in medical research—to benefit people other than the subjects themselves.[251]

One critic of the current oversight system of pediatric research, Doriane Coleman, acknowledges that parents are granted discretion to expose children to some risk for the benefit of others in contexts other than research. She argues that parents would not be able to raise children without risk, and their intent is not to expose their children to harm—the harm is incidental to their intent to accomplish some other goal.[252] It is highly unlikely that a parent who enrolls his or her child in research that involves net risks does so with the intent to cause harm to the child. The parent is more likely to be motivated by a desire to understand more about the child's condition or to help others by contributing to the production of new scientific knowledge. Intent is also not the critical factor—what matters is whether the potential harm involved is reasonable and justified. Parents who have the arguably noble intent to help their child reach eternal salvation are not legally permitted to deny their child access to a life-saving blood transfusion. What should and does matter to courts is the amount of harm to which the child is being exposed that could easily be avoided.

Given the tremendous need to conduct research in children, and the potential harmful consequences of allowing the best interests as paramount standard to govern public health decisions in general, there are two possibilities. Either the best interests standard can be rehabilitated to accommodate public health decisions and pediatric research, or legislators should enact a different standard governing public health decision making for children.

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[251] *See* 45 C.F.R. §§ 46.404, 46.406, 46.407 (2011).

[252] Coleman, *supra* note 53, at 574.

V. REHABILITATING THE BEST INTERESTS AS PARAMOUNT STANDARD?

The fact that the best interests as paramount standard is an unacknowledged legal fiction does not determine what we should do about it. The next question to ask is whether the best interests standard can be rehabilitated. The following section presents several reasons why it does not make sense to retain the best interests standard.

First, perhaps the version of the standard that considers children's interests to be a primary consideration can accommodate the various exceptions discussed herein. As noted earlier, Loretta Kopelman has argued that the best interests standard should be understood as a "standard of reasonableness," and that it actually means the following: "Judges focus upon the needs and interests of individual children, but not to the exclusion of others' rights or interests, to determine which of the available options is best, assuming some option is minimally acceptable."[253] She also describes the duty to protect the best interests of the child as a *prima facie* duty that can be overridden by other considerations.[254] Another way of describing this approach would be to suggest that the child's best interests are the primary consideration for judges, but other important rights and interests serve as constraints on what judges can do to advance a particular child's interests. Although Kopelman's approach is much more nuanced and reasonable than many others, it has several limitations.

The first limitation, as demonstrated by the empirical analysis in this Article, is that Kopelman's approach is not how judges currently interpret the best interests standard. This means that even if she is right about how the best interests standard *should* be interpreted, her theory does not accurately describe the state of the law and would require some implementation process to change the way that judges function. There may be such confusion about the best interests standard that there is no good way to clarify which version is the correct one. Kopelman's attempt to rehabilitate the best interests standard but retain the name is one way to respond to the many misinterpretations and confusions that currently exist about how decisions regarding children should be made. A better approach is to abandon the best interests standard in favor of a more accurate description of the standard that should be applied. Attempting to rehabilitate an existing standard that is easily misunderstood would be difficult and would lend itself to further imprecision. It is much cleaner theoretically to develop a better theory of what courts should be doing, and it also seems more likely that abandoning the standard will clarify the law.

Second, the "standard of reasonableness" view still fails to adequately or transparently account for the interests of others. In particular, it does not account for cases when the interests of another party are primary, such as cases in which the religious rights of a parent trump a child's interests,[255] or where the interests of a sibling in need of bone marrow trump the interests of a child who could serve as a donor. Courts do not choose the best option for a particular child while also accounting for other interests in those situations, nor is it necessarily what they should do. Third, it is not clear how the standard for reasonableness accommodates developing autonomy. Kopelman's standard does not clearly allow for situations in which children are able to make autonomous

[253] Kopelman, *supra* note 162, at 273.
[254] *Id.* at 282.
[255] Pub. Health Trust v. Norma Wons, 541 So. 2d 96, 97 (Fla. 1989).

decisions on their own, or for the possibility that some children might be able to have enough budding autonomy that their voices should be part of the decision-making process.

Another related approach would be to retain the best interests standard but expand the definition of what counts as being in the best interests of a particular child. Many of the competing interests that I have identified, such as parental interests, might be deemed to be promoted to the extent that they are indirectly in the best interests of children. Respecting parental rights and interests allows parents to do the difficult work of helping children develop so that they are someday able to function as adults. This provides an instrumental justification for parental rights as a way to promote the interests of children, so is seemingly consistent with applying the best interests standard but at a policy, rather than individual family, level. In support of this view, the Supreme Court has explained that deference to parents can be consistent with the best interests standard because "historically it has recognized that natural bonds of affection lead parents to act in the best interests of their children."[256]

As noted at the start of this Article, however, the Court has also recognized that many other important considerations are also relevant when decisions are about children or for children:

> "The best interests of the child," a venerable phrase familiar from divorce proceedings, is a proper and feasible criterion for making the decision as to which of two parents will be accorded custody. But it is not traditionally the sole criterion—much less the sole constitutional criterion—for other, less narrowly channeled judgments involving children, where their interests conflict in varying degrees with the interests of others.[257]

Trying to rehabilitate the best interests standard as Kopelman has suggested is unlikely to resolve the existing confusion, and cannot accommodate all cases that matter. There are some things that are not indirectly in the best interests of particular children, but that pose reasonable risks and burdens and greatly advance the public interest. Using a broad notion of "indirect interests" may fail to capture some very important trade-offs that should be made. It may also prevent the trade-offs from being made in a careful way that ensures that individual children are not exposed to unacceptable or unjustified risks. Consider situations that pose significant risk but offer considerable psychological benefit. For instance, if a child was very committed to the environment and a parent wanted the child to participate in a hunger strike in order to save a section of the woods in the neighborhood that had a lot of meaning to that child, it is highly unlikely that a court would or should consider participating in the hunger strike to be within the child's best interests.

Perhaps another approach to keeping the best interests standard could be to imagine the best interests standard as a standard that sets initial duties that are later subject to side constraints. This is again something like what Kopelman suggests and may also be close

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[256] Parham v. J.R., 442 U.S. 584, 602 (1979) (citations omitted).
[257] Reno v. Flores, 507 U.S. 292, 303–04 (1993).

to Paul Litton's view. Thus, the child's best interests are generally what drive decisions, but other considerations place important limits on how far we can go to promote or maximize a child's interests. This approach has some virtues, but it is still an insufficiently transparent standard for providing guidance for particular court decisions. We need at least some sense of which considerations are legitimate and can be balanced against the interests of the child. It would be better to be clear that the interests of others, the interests of the family, and the budding autonomy of children are the types of considerations that should count. Presumably, the profits of drug companies would not be enough for a court to override the best interests of a particular child, but it is not clear whether allowing for side constraints would allow for drug company profits to trump in particular cases or not, and the standard provides limited guidance for what should count. We also need to know how much we can sacrifice with regard to the child's interests. Suppose a child's sibling needs a bone marrow transplant. Are the potential donor's preferences a relevant side constraint? What about the needs of the sibling? Would the needs of another child who could also use the transplant be relevant? It is not at all clear how to determine what counts as a relevant side constraint, let alone how to apply the relevant side constraints to this case.

A fourth possible way to remedy the problems with the best interests standard is to consider it the correct standard, but to require courts to consider best interests of any individual child as a subjective matter that has to be evaluated on a case-by-case basis. Under this argument, any standard would operate at a very general level, and courts would then have to do the hard work of applying it to individual cases. This would explain the wide variation in case law to some degree, and would make it clear that the best interests standard could not be made more accurate, because it requires so much discretion in applying it to a particular case. It is likely true that the best interests of most children vary dramatically, and that it is very difficult for courts who know very little about the children affected by the decisions to know what is actually in the best interests of those children. The fact that a child's best interests really depend on that child's nature is a good reason to think that a great deal of discretion should be vested in people who know the child best—most often the child's parents. Yet, as evidenced by many cases discussed herein, courts are frequently faced with decisions that require considering interests other than the child's best interests. In those cases, courts sometimes defer to parents, while at other times take account of parental interests, state interests, or family interests. When courts balance competing interests, they often do so not because of the subjective nature of a child's interests—they do so because the child's interests are not the only ones that matter.

More fundamentally, all of these potential solutions depend on the ability to educate judges that the best interests of the child should not be the paramount consideration. The question then becomes whether courts could somehow be educated on the difference between the two different standards and required to apply the best interests as primary standard to most cases without some more dramatic change in the law. In this vein, Jill Hasday argues forcefully that the canon of family law has promulgated the view that the child's best interests are the determinative factor in cases involving children.[258] Noting that "[t]he academic community's scholarship . . . helps to create, shape, and

[258] Hasday, *supra* note 146, at 849.

perpetuate the family law canon," she proposes that family law scholars and casebook writers in particular endeavor to correct the errors in the family law canon and challenge conventional wisdom by clarifying how the law actually works.[259]

This strategy may be one important way to change the inaccurate and widespread perception that a child's best interests are the deciding factor for any case involving children, and allow us to recognize the fact that decisions involving children affect other parties in important ways, including parents, siblings, extended family, and even society at large. The problem with this strategy is that despite decades of criticism about the best-interests as paramount standard, courts continue to apply that standard. Given the amount of criticism about the best interests standard in the existing literature, it seems unlikely that further clarification in the literature will ameliorate this problem.

Even if the standard were improved, it is hard to see how the best interests standard could help us answer the crucial question of when courts should permit children to be exposed to risk, and how we can best balance the interests of children with the interests of others in policy decisions. One reason for this may be that the terminology of the best interests standard itself is confusing. If the child's best interests are the subject of the standard, it is very difficult to know how to incorporate the interests of others. Finally, failure to remedy this problem could have dramatic consequences. It may take just a few misguided decisions to have a chilling effect on pediatric research that could have disastrous implications.

For these reasons, it seems much more useful to develop a new, clearer standard that more explicitly accounts for the relevant considerations, and to have this new standard implemented by legislators. This standard, if carefully calibrated, could be applied to an even wider variety of cases. Below, I propose the "secure child standard" to remedy the deficiencies of the best interests standard that so many have identified. The secure child standard better captures the complexity of legal decision making involving children.

VI. AN ALTERNATIVE: THE SECURE CHILD STANDARD

Abandoning the best interests standard is only advisable if there is a better way to understand how the law should treat decision making about children. As an alternative, I propose the "secure child standard," under which courts should defer to parental decision making unless the child is exposed to some unjustified risk of significant harm. When courts review parental decisions, the secure child standard requires that they take into account the relevant parental, child, and state interests to determine whether the risk is justified. The secure child standard permits exceptions in certain cases. For instance, when children are able to make autonomous decisions of their own, parents may have to cede authority for decision making to children. Courts should also retain some power to intervene if children seek to undertake unjustified risks of significant harm. Unless children are deemed capable of making decisions for themselves, however, the secure child standard would not permit parents or the state to expose an individual child to harm above a certain threshold.

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[259] *Id.* at 899.

An important contribution of the secure child standard is to account for harms courts themselves may cause. When there is no significant harm to prevent, courts may cause greater harm to the child by interfering with the family. The threshold for court intervention should take this potential harm into account.

When there is some chance of significant harm to the child, the secure child standard recognizes particular times in which independent review of parental decision-making is important. Where the probability of significant harm is very low, parents should balance the risks of harm against the potential benefits for the child, the family, and society. Courts may still intervene if there is reason to suspect the decision is being made without good reason justifying the risk of harm. When there is a reasonable chance of serious harm, parents again decide whether there is good and sufficient reason to permit the harm. If the trade-off is between a benefit for the child and a risk of harm to that child, courts should give parents fairly wide latitude to make decisions. In areas where people other than the child have important interests at stake, such as public health, research, or when a sibling is in great need, courts may permit parents to make decisions that may expose a child to some risk of significant harm, but independent scrutiny should serve as a protection to ensure that parents do not expose their children to risk without sufficient reason. Courts should acknowledge that under the U.S. Federal regulations, pediatric research is subject to limitations on risk and prior review by IRBs,[260] and the protections specified in the regulations and IRB review may serve as a sufficient check on parental decision-making in most cases. Defining what counts as significant harm and when the likelihood of harm is sufficiently high to be concerning may be difficult, but the standard at least provides more explicit guidance for judges about what they should be focusing on, and greater transparency in judicial decision making, than the best interests standard. Additionally, determining what justifies exposing children to risk will likely require more work, and may be something that is developed further through the accumulation of precedent over time. The need for an exercise of judgment cannot be eliminated entirely, but the advantage of the secure child standard is that the correct criteria are made explicit.

Finally, even with justification, there are some risks that are unacceptably high under the secure child standard. Specifying when risks are unacceptably high is a difficult task and will require some additional work to generate useful guidance for courts making these determinations. Clearly, exposing one child to an almost certain risk of death for the benefit of others should never be tolerated by parents or courts, but it is likely that the threshold of risk that can be legally tolerated is much lower than that. One way to specify levels of acceptable risk would be to analyze the data about what risks are considered justifiable in the routine decisions parents and policymakers make, which is an effort in which some scholars are currently engaged.[261]

Besides its greater fidelity to what courts actually do, as has been shown previously, the secure child standard is preferable to the best interests standard for several reasons. First, courts can enforce the secure child standard while taking into account other relevant interests. These other interests include important competing considerations

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[260] 45 C.F.R. § 46.401–46.409 (1983).

[261] *See* Annette Rid & David Wendler, *A Framework for Risk-Benefit Evaluations in Biomedical Research*, 21 KENNEDY INST. ETHICS J. 141, 165–66 (2011).

like religious beliefs, a minor's growing autonomy, other family interests, and important societal interests (e.g., education, medicine, public health). This standard better captures the careful balancing in which courts should be, and often are, engaged.

The secure child standard also does a better job of allowing courts to incorporate respect for a child's developing autonomy than the best interests standard does. During adolescence, children mature and develop abilities that are recognized in the law. These abilities allow children to make decisions for themselves in ways that may or may not promote their own best interests. The secure child standard simply does not apply in situations where teenagers should be treated as competent adults who are free to exercise their autonomy to make decisions that may be good or bad for them. Although parents typically retain considerable authority to make many decisions for their adolescents, parental authority is much more easily overridden or may not be required in certain circumstances. Parental authority to provide permission for an adolescent for a wider range of activities may not be required when the minor is deemed to be emancipated or mature.[262] Emancipated minors are able to make their own decisions in ways that may not be in their best interests.[263]

The secure child standard is especially useful to account for societal interests that are at stake in legal decisions involving children. Public health and medical research are two areas where courts have struggled to factor in societal interests and harmonize them with the best interests standard. The secure child standard recognizes that there are times when children should be permitted to do things for the benefit of others, or for the greater good. However, it also acknowledges that there should be legal limits on the amount of sacrifice an individual child can take on for the benefit of others. Using the best interests standard as applied to children as a group, as courts have tried to do in vaccine cases, fails to place the important limit on the amount of risk an individual child can be exposed to for the benefit of others. Rather than referring to best interests at all, it would be better to acknowledge the trade-off more directly. In the areas of medical research or public health, courts should recognize that there are important societal interests at stake that may justify exposing individual children to some risk of harm. One especially valuable contribution of the secure child standard is to place a limit on the amount of harm that

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[262] Jessica A. Penkower, Comment, *The Potential Right of Chronically Ill Adolescents to Refuse Life-Saving Medical Treatment — Fatal Misuse of the Mature Minor Doctrine*, 45 DEPAUL L. REV. 1165, 1177 (1996) (Minors are considered emancipated who are below the age of consent but "whose parents have completely surrendered care, custody, and control of the child, have no involvement in the child's earnings, and have renounced parental duties.") (quoting Elizabeth J. Sher, Note, *Choosing for Children: Adjudicating Medical Care Disputes Between Parents and the State*, 58 N.Y.U. L. REV. 157, 158 n.5 (1983)). *See also* Lambert v. Wicklund, 520 U.S. 292, 293 (1997) (noting that married minors are determined to be emancipated, and courts can grant emancipation for other reasons.)

[263] By contrast, under the "mature minor" doctrine, adolescents can consent on their own behalf for interventions like contraception or treatment for sexually transmitted infections in cases where the treatment would be likely to benefit them. These laws were created in recognition of the fact that minors were increasingly vulnerable to sexually transmitted infections, that requiring parental consent may not be a protection because it may prevent adolescents from getting needed treatment or preventative measures, and in part because the state has a strong interest in ensuring that sexually transmitted infections are treated and controlled. The primary justification appears to be to protect the welfare of adolescents, so these laws are consistent with the application of the best interests standard. Penkower, *supra* note 262, at 1178–80.

children can be exposed to, so as to avoid the consequentialist conclusion that it would be acceptable to severely compromise the interests of some children for the greater good.

CONCLUSION

In this paper, I have shown that courts use the best interests standard in two major ways. They consider it the paramount consideration or a primary consideration. The best interests as paramount standard is an unacknowledged legal fiction that has implausible consequences and fails to account for relevant interests. The best interests as paramount standard neglects many other interests at stake, which does not fit with the historical development of the standard and is especially poorly calibrated for public health decision making. The primary version of the standard is less problematic, but still fails to capture the importance of the interests of others.

The best interests standard should be understood as an unacknowledged, aspirational legal fiction. Protecting children's interests and privileging them above other considerations sounds like a worthy goal to which courts should aspire. However, the use of the best interests standard as a legal fiction is dangerous because it can obscure the sometimes illegitimate considerations that are taken into account in cases involving children. In particular, courts that take the best interests of the child as the paramount consideration write opinions that are internally inconsistent, difficult for others to understand, that do not give appropriate notice to the public about which activities are permissible and which are not, and that may sometimes even reach the wrong result. Thus, ridding ourselves of the best interests standard would enable courts and policy-makers to reason clearly and correctly, without the constraint of a hidden legal fiction.

Abandoning the best interests standard requires a more coherent theory about how decisions for children should be made. To that end, I propose the secure child standard: in legal decisions involving children, parents should have discretion to make decisions for their children, and courts should intervene to prevent unjustified risks of significant harm to the child. When there is a risk of significant harm, courts should determine whether parents have appropriately balanced the competing considerations, and should not allow children to be exposed to unjustified harm or harm that is unacceptably high. Under the secure child standard, courts can begin to acknowledge the tough decisions they make involving children. This increased transparency will allow the law to grow without tortured or confusing reasoning. Abandoning the best interests standard will also help to develop sound standards for pediatric research and public health more generally that appropriately balance the interests of children with the interests of everyone else. The secure child standard has the potential to ensure that courts, parents, and the state are able to act in concert to protect children as they should.