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Non-Beneficial Pediatric Research and the Best Interests Standard: A Legal and Ethical Reconciliation

Paul Litton *

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INTRODUCTION

In 1966, Henry Beecher, a professor at Harvard Medical School, published an article in the *New England Journal of Medicine* describing twenty-two cases of unethical medical research, some of which involved children.¹ In the infamous Willowbrook study, for example, researchers deliberately exposed children who were wards in a state facility to hepatitis to study preventive measures.² Public attention to research tragedies led to the passage of federal regulations governing human subjects research, including special protections for children.³ The regulations restricted the participation of children in research, and, in that sense, they have protected children. However, this effort to protect children “may partly explain the underfunding and understudy of . . . health issues unique to children” that followed.⁴ Consequently, the vast majority of medications prescribed to children today have not been adequately studied in pediatric populations.⁵

Since the late 1990s, deploying an array of carrots and sticks, the federal government has sought to increase pediatric research, particularly with respect to pharmaceuticals, to address our lack of knowledge regarding the safety and efficacy of pediatric therapies.⁶ Its efforts have worked. Between 1990 and 1997, researchers completed eleven pediatric studies of marketed drugs; since 1997, the Food and Drug Administration (FDA) has requested approximately 800 studies involving 45,000 children in clinical trials.⁷ Pediatric research will continue to expand as the President recently signed into law measures to encourage pediatric

1. Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966).

2. *Id.*; Ezekiel J. Emanuel et al., *Scandals and Tragedies of Research with Human Participants: Nuremberg, the Jewish Chronic Disease Hospital, Beecher, and Tuskegee*, in ETHICAL AND REGULATORY ASPECTS OF CLINICAL RESEARCH: READINGS AND COMMENTARY 1, 3-4 (Ezekiel J. Emanuel et al. eds., 2003). As two commentators have described it, the history of pediatric experimentation at the time of Beecher’s article was “largely one of child abuse.” Susan E. Lederer & Michael A. Grodin, *Historical Overview: Pediatric Experimentation*, in CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW 3, 19 (Michael A. Grodin & Leonard H. Glantz eds., 1994) [hereinafter CHILDREN AS RESEARCH SUBJECTS].

3. LAINIE FRIEDMAN ROSS, CHILDREN IN MEDICAL RESEARCH 12 (2006) [hereinafter ROSS, CHILDREN IN MEDICAL RESEARCH]. The federal regulations governing human subjects research are codified at 45 C.F.R. § 46 (2007); the regulations pertaining to pediatric research are found within Subpart D.

4. ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 24.

5. *See infra* notes 42-46 and accompanying text.

6. *See* ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 24-28; *see also infra* note 60 and accompanying text.

7. SENATE DEMOCRATIC POLICY COMM., LEGISLATIVE NOTICE: S. 1082 – THE FOOD AND DRUG ADMINISTRATION REVITALIZATION ACT (2007), http://www.democrats.senate.gov/dpc/dpc-new.cfm?doc_name=lb-110-1-68.

research regarding medical devices.⁸

Any assessment of this expansion in pediatric research must carefully distinguish the purpose of research from the purpose of medical care. Medical care aims to promote an individual patient's well-being.⁹ Research aims to produce generalizable knowledge.¹⁰ Though the medical benefits of research participation sometimes outweigh its risks, much research inevitably exposes subjects to risks that are uncompensated by health benefits to the individual subjects; for such research to be worthwhile, the potential benefits to society must outweigh the risks to subjects.

Non-beneficial pediatric research aims to improve the general health and well-being of all children by exposing individual pediatric subjects to risks uncompensated by any health benefit to the subjects derived from participating in the study. For example, researchers often expose children to medical procedures, such as blood draws, biopsies, and x-rays, that carry some risk of pain and more serious harm—even though these procedures provide no potential benefit to the pediatric subjects.¹¹ They are performed only to learn more about a particular disease or to discover possible therapies. Research subjects do not include only ill children; researchers also enroll healthy children in protocols, exposing them to the risks of non-beneficial procedures, as a comparison group. Essentially, a non-beneficial pediatric protocol places some children at risk (very low risk, but nonetheless risk) purely for the good of children in the future. Is it ethical—and should it be legal—to conduct such research?

These issues have received scholarly attention over the past forty years, even before the passage of our current federal regulations, which permit some non-beneficial pediatric research.¹² This increased attention is due to 1) the exponential increase in pediatric research, and 2) the 2001 *Grimes* decision of the Maryland Court of Appeals (the state's highest court), which declared that parents have no legal authority to consent to enroll their children in non-

8. Pediatric Medical Device Safety and Improvement Act of 2007, Pub. L. No. 110-85, 121 Stat. 824. See *infra* note 64 for further discussion.

9. Franklin G. Miller & Howard Brody, *What Makes Placebo-Controlled Trials Unethical?*, 2 AM. J. BIOETHICS 3, 4 (2002); accord Trudo Lemmens & Paul B. Miller, *Avoiding a Jekyll-and-Hyde Approach to the Ethics of Clinical Research and Practice*, 2 AM. J. BIOETHICS 14 (2002) (agreeing that the aim of clinical care is to optimize a patient's welfare while the purpose of research is to produce generalizable knowledge).

10. 45 C.F.R. § 46.102(d) (2007) (stating that goal of research is to “develop or contribute to generalizable knowledge”); Emanuel et al., *supra* note 2, at 1.

11. David Wendler, *The Personal Significance of Helping Others: Implications for Non-Beneficial Pediatric Research* 5 (unpublished manuscript, on file with author) [hereinafter Wendler, *Significance*].

12. The federal regulations governing human subjects research with children, codified at 45 C.F.R. § 46.406 (2007), were enacted in 1983.

beneficial pediatric research.¹³ The court based its conclusion on the “best interests of the child” standard,¹⁴ concurring with both then-Judge Warren E. Burger’s view that experimentation on a child, unless for her benefit, is simply “indefensible,”¹⁵ and with Justice Wiley Rutledge’s famous sentiment in *Prince*:¹⁶ “Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.”¹⁷

Most commentators on pediatric research, however, disagree with *Grimes* and maintain that at least some non-beneficial pediatric research is ethically justifiable.¹⁸ A legal ban on all non-beneficial pediatric research would prove costly to the overall welfare of children, prohibiting pursuit of important medical knowledge and greatly slowing improvement of pediatric care.¹⁹

13. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 852-58 (Md. 2001).

14. For a discussion of the history of the best interests standard, see MARY ANN MASON, FROM FATHER’S PROPERTY TO CHILDREN’S RIGHTS: THE HISTORY OF CHILD CUSTODY IN THE UNITED STATES 121-60 (1994).

15. Warren E. Burger, *Reflections on Law and Experimental Medicine*, 15 UCLA L. REV. 436, 438 (1968).

16. *Prince v. Massachusetts*, 321 U.S. 158, 170 (1944). The petitioner in *Prince* had been convicted for violating state child labor laws after she had provided her nine-year-old niece, to whom she was guardian, with religious literature to distribute on public streets while preaching. She challenged the constitutionality of her convictions, arguing that they violated her First Amendment right to free exercise, her parental rights under the Fourteenth Amendment’s Due Process Clause, and her right to equal protection under the Fourteenth Amendment. The Court, however, upheld her convictions, affirming that “[t]he state’s authority over children’s activities is broader than over like actions of adults.” *Id.* at 168.

17. *Id.* at 170; see also *Grimes*, 782 A.2d at 856 (quoting *T.D. v. N.Y. State Office of Mental Health*, 626 N.Y.S.2d 1015, 1020-21 (App. Div. 1996) (quoting *Prince*, 321 U.S. at 170)).

18. E.g., NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, RESEARCH INVOLVING CHILDREN: REPORT AND RECOMMENDATIONS (1977) [hereinafter NAT’L COMM’N]; LAINIE FRIEDMAN ROSS, CHILDREN, FAMILIES, AND HEALTH CARE DECISION MAKING (1998) [hereinafter ROSS, CHILDREN, FAMILIES]; Wendler, Significance, *supra* note 11; Dan W. Brock, *Ethical Issues in Exposing Children to Risks in Research*, in CHILDREN AS RESEARCH SUBJECTS, *supra* note 2, at 81, 91-92; Loretta Kopelman, *What Conditions Justify Risky Non-therapeutic or “No Benefit” Pediatric Studies: A Sliding Scale Analysis*, 32 J.L. MED. & ETHICS 749 (2004) [hereinafter Kopelman, *Conditions*]; Richard A. McCormick, *Experimentation in Children: Sharing in Sociality*, 6 HASTINGS CENTER REP. 41 (1976) [hereinafter McCormick, *Experimentation*]; Lainie Friedman Ross, *In Defense of the Hopkins Lead Abatement Studies*, 30 J.L. MED. & ETHICS 50 (2002); Jack Schwartz, *The Kennedy Krieger Case: Judicial Anger and the Research Enterprise*, 6 J. HEALTH CARE L. & POL’Y 148 (2002).

19. NAT’L COMM’N, *supra* note 18, at 23-26; ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 19.

Because of the overall benefits to children provided by pediatric research, its practice appears clearly justified on consequentialist grounds. Consequentialism represents a family of views within moral theory that maintains that the right action or policy in a given context is that which produces the best consequences, the most overall net good.²⁰ Consequentialist theories can differ in how they define the good (i.e., what is to count as a good and bad consequence), but all have the same structure in advocating that morality requires us to maximize good consequences. Utilitarianism, for example, is a form of consequentialism that equates the good with pleasure and the absence of pain, and thus maintains that morality requires us to maximize overall net pleasure. In contrast, non-consequentialist (or deontological) accounts of morality maintain that “there are right- and wrong-making considerations other than good and bad effects.”²¹ To illustrate, a non-consequentialist would maintain that punishing innocent persons wrongs them, and is thereby wrong, even if punishing them would optimize good consequences.²² There are different versions of non-consequentialism, but the non-consequentialist idea that is most relevant for our purposes at this point is Kant’s famous conclusion that we must never treat any person merely as a means to an end, but always as an end-in-herself.²³ Others may serve as means to our ends, as I might hire an electrician to fix a faulty circuit. But I do not thereby use the electrician *merely* as a means to my ends, given that he has freely agreed to fix my circuit. To punish an innocent person to deter crime, on the other hand, treats that person merely as an instrument and not as a person.

We can now see why the justification for pediatric research, if one exists, has been described as “frankly and inevitably utilitarian.”²⁴ We conduct pediatric research because of the good consequences it produces for the health of children as a group; yet pediatric research often requires exposing children to risks contrary to their best interests, though children cannot provide binding consent. It appears, on its face, that pediatric research treats pediatric subjects merely as a means to an end when it exposes them to risk for the good of others without their informed consent.

20. STEPHEN DARWALL, *PHILOSOPHICAL ETHICS* 81 (1998). More specifically, an *act*-consequentialist takes right action to be that which maximizes good consequences in the particular circumstances. *Id.* A *rule*-consequentialist takes right action to be determined by *rules* which, if followed, would produce the best consequences (compared to other possible rules). *Id.*

21. *Id.* at 82.

22. *Id.*

23. IMMANUEL KANT, *GROUNDING FOR THE METAPHYSICS OF MORALS* 36 (James W. Ellington trans., Hackett Publ'g Co. 1993) (1785) (“Act in such a way that you treat humanity, whether in your own person or in the person of another, always at the same time as an end and never simply as a means.”).

24. Randall Baldwin Clark, *Speed, Safety, and Dignity: Pediatric Pharmaceutical Development in an Age of Optimism*, 9 U. CHI. L. SCH. ROUNDTABLE 1, 3 (2002).

An amicus brief submitted by research universities to the Maryland high court, asking it to reconsider its virtual ban on non-beneficial pediatric research, reflects the idea that this research is based on utilitarian considerations and conflicts with non-consequentialist moral principles: “The overall cost of [prohibiting non-beneficial pediatric research] in terms of lost advances in medical and health knowledge (and ultimately lost opportunities to cure diseases and prevent suffering and the loss of life) will far outweigh the asserted advantage of protecting individual rights.”²⁵

Though most commentators conclude that at least some non-beneficial pediatric research is morally permissible, they are unwilling to condone its practice on utilitarian or other consequentialist grounds, uncomfortable endorsing the use of children to improve others’ health when those children cannot provide binding consent. Thus, the fundamental ethical question raised by the pediatric ethics literature is whether a non-consequentialist justification exists for exposing pediatric subjects to research risks compensated only by the potential benefits to others. Alternatively, in Kantian terms, can we treat a pediatric subject, incapable of providing informed consent, as an end-in-herself and not merely as a means when we expose her to risks that are not in her best interests to face? Although these questions have received attention, a persuasive account has yet to appear.

The legal question addressed in this Article regarding the *Grimes* court’s reliance on the best interests standard in the research context has not received adequate attention. In determining researchers’ duties to children and parents’ legal authority to enroll their sons and daughters in research, should courts be guided by the best interests standard?²⁶ Are there legal grounds to which courts may turn to avoid invoking that standard? And if courts should, in fact, rely on the best interests standard, how should they interpret and apply that standard to research? Does the best interests standard preclude non-beneficial pediatric

25. Brief for Ass’n of Am. Med. Colls., Ass’n of Am. Univs., Johns Hopkins Univ. & Univ. of Md. Med. Sys. Corp. as Amici Curiae Supporting Appellee’s Motion for Reconsideration, *Grimes v. Kennedy Krieger Inst. Inc.*, 782 A.2d 808 (2001) (No. 128), available at <http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/briefs.htm> [hereinafter Amici].

26. Bioethics scholar Loretta Kopelman commented:

This [best interests] standard is so engrained in the law that the *Grimes* court made it clear that if the “best interests of the child” standard is incompatible with the federal pediatric regulations and practices, then the pediatric regulations and practices would have to change, and if federal agencies do not clarify the regulations, the courts will.

Loretta Kopelman, *Children As Research Subjects: Moral Disputes, Regulatory Guidance, and Recent Court Decisions*, 73 MT. SINAI J. MED. 596, 603 (2006). Kopelman is mistaken in implying that any state court could require a change in, or announce a clarification of, federal regulations. And the *Grimes* court did not make any such statement. But the *Grimes* decision and Kopelman’s commentary evidence a need to discuss the relationship between the law’s best interests standard and non-beneficial pediatric research, particularly for non-legal bioethics commentators.

research which seems, by definition, to be contrary to the best interests of each pediatric subject?

The legal questions are important for Maryland and for other states. First, even though the Maryland legislature passed a statute specifying standards for research that accord with the federal regulations, the *Grimes* ruling on parental authority remains law. It remains unclear whether *Grimes* prohibits minimal risk, non-beneficial pediatric research. If researchers in Maryland continue conducting minimal risk, non-beneficial pediatric research and a child is injured or dies, as may be inevitable, litigants will dispute whether the best interests standard prohibits even minimal risk, non-beneficial pediatric research in Maryland. Second, the number of research-related lawsuits filed in other states has increased over the past few years,²⁷ making it “likely that the courts will play a growing role in the future evolution of the law relating to research,”²⁸ and forcing these courts to consider non-beneficial pediatric research in light of the best interests standard. Third, discussion of the legal questions helps shed light on a persuasive non-consequentialist justification for non-beneficial pediatric research.

This Article answers two related questions: 1) What is the appropriate legal relationship between non-beneficial pediatric research and the best interests standard?; and 2) What is the fundamental ethical justification for this research, if not utilitarian or otherwise consequentialist? With regard to the legal question, this Article considers two possible approaches not taken by the *Grimes* court: first, that the best interests standard should not solely determine whether non-beneficial pediatric research should be legally permissible, but rather that the standard should be weighed against the overall good consequences produced by such research. Upon rejecting this approach, this Article advocates a second legal avenue: *Grimes* correctly invoked the best interests standard as controlling whether parents should have legal authority to enroll their children, but the court misapplied that standard. *Grimes* limited the relevant facts to the potential burdens and benefits to individual pediatric subjects presented by a non-beneficial protocol. As described below, in 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.

The second approach illuminates one compelling non-consequentialist justification for non-beneficial pediatric research. The justification for a child’s

27. See, e.g., Michelle M. Mello et al., *The Rise of Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40 (2003); E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL’Y 1 (2003).

28. CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 106 (2005).

participation does not rest on the greater good, but rather appeals to the benefits of the practice *for each child*. For each child, including those exposed to risk in a non-beneficial protocol, the benefits of such a policy outweigh the risks of being harmed in research.²⁹

Though I argue for that empirical claim, it may turn out to be false, in which case the research would require a different justification. This Article articulates an additional, potentially more controversial justification, appealing to the reason each person, including each child, has to help others when one can do so at little to no cost to oneself. The argument presented attempts to interpret and vindicate the work of Richard McCormick, whose debates in the scholarly literature with Paul Ramsey represent the classic departure for the pediatric research ethics literature.

In this Article, Part I presents background on the importance of pediatric research and recent federal attempts to expand it. Part II describes the tension between the federal regulations and *Grimes*. Part III defends *Grimes* against accusations that it failed to respect parental rights or failed to appreciate non-medical benefits that might accompany a child's research participation. Part IV considers, but ultimately rejects, the argument that *Grimes* should have treated the best interests of pediatric subjects as one consideration to be weighed against others, such as the benefits of research to future children. Part V presents both the proper best interests legal analysis of the issue and a non-consequentialist ethical justification. Finally, Part VI discusses a second non-consequentialist justification, attempting to revive McCormick's arguments.

29. One might ask whether the arguments presented are applicable to all phases of research or only to Phase II and later stages. The arguments do not presume any particular phase of research. I presume that the ethical standard and justification for non-beneficial pediatric research is the same regardless of the phase. As any commentator on pediatric research ethics would agree, ethically justifiable pediatric research places a very low ceiling on acceptable risk, whether that low ceiling is defined as "minimal risk" or "a minor increase over minimal risk," or by some other standard. A separate question—one that requires separate treatment—is how the fact of unknown risks, including the unknown risks of Phase I trials, should be considered when assessing protocols under the proper standard defining that ceiling on acceptable risk.

However, it is important to note that non-beneficial research on children is ethically justifiable only when it is scientifically necessary to conduct research on children. If it is not scientifically necessary to include children in safety tests because reliable results can be achieved through research on adults, then children should not be used as research subjects. *See* Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?*, 283 JAMA 2701, 2705 (2000) (noting that fair subject selection is an ethical requirement in research, which implies that "it may be appropriate to include [children in research testing a therapy] only after the safety of the drug has been assessed in adults[,] given that it is "not necessary to include children in all phases of research").

I. BACKGROUND

A. Importance of Pediatric Research

According to the Institute of Medicine,³⁰ biomedical research conducted over the past few decades has “helped change medical care and public health practices in ways that, each year, save or lengthen the lives of tens of thousands of children around the world, prevent or reduce illness or disability in many more, and improve the quality of life for countless others.”³¹ New vaccines, therapies, and discoveries regarding unexpected risks of accepted therapies have contributed to great improvements in children’s welfare.³²

It would be ethically preferable if this kind of medical progress could result from research on adults only, with findings then extrapolated to apply in the pediatric setting. Competent adults can provide informed consent, while young children cannot. However, research on adults cannot improve children’s lives nearly as much as pediatric research.³³

The Institute of Medicine discusses at least five reasons “why medicines must be studied in research with children to ensure their safe and effective use.”³⁴ First, some diseases and conditions affect children only (such as premature birth and phenylketonuria³⁵) or affect children differently than adults (such as arthritis and some forms of cancer).³⁶ Second, children often require forms of oral medicines, such as good-tasting liquids or chewable tablets, different than what is appropriate for adults. It is crucial to test the substances in which the active medication is dissolved or otherwise administered. Third, the ways in which medicines are absorbed, distributed to organs, and excreted depend on an

30. The Institute of Medicine is a private, non-governmental organization and component of the National Academies of Science. It was created by the federal government to provide “science-based advice on matters of biomedical science, medicine, and health.” About the Institute of Medicine, <http://www.iom.edu/CMS/AboutIOM.aspx> (last visited Sept. 7, 2007).

31. INST. OF MED., *ETHICAL CONDUCT OF CLINICAL RESEARCH INVOLVING CHILDREN* 25-26 (2004).

32. *Id.* at 26.

33. *See id.* at 66-72.

34. *Id.* at 66-67. For a similar discussion of the reasons to conduct research on children, highlighting the differences between children and adults, see Ralph E. Kauffman, *Scientific Issues in Biomedical Research with Children*, in *CHILDREN AS RESEARCH SUBJECTS*, *supra* note 3, at 29.

35. Phenylketonuria (PKU) is a genetic disorder that causes a buildup of a particular amino acid in the blood due to the lack of a specific enzyme, which causes mental retardation and other neurologic and psychiatric problems. Newborns are screened for the disorder and its effects can be controlled with diet. THE MERCK MANUAL OF MEDICAL INFORMATION 1618-19 (Mark H. Beers et al. eds., 2d Home ed. 2003).

36. *See* INST. OF MED., *supra* note 31, at 58-59.

individual's stage of development.³⁷ Because absorption depends on development, and because the relative size of children's organs does not match the relative size of adults', danger of over- or under-dosing arises when calculating a pediatric dose by extrapolating from adult studies. A trial and error approach to dosing based on adult studies sometimes works, but has also led to tragedy.³⁸ Fourth, we know that some medicines act differently in children (e.g., antihistamines may make an adult sleepy but a child hyperactive) or do not act at all because the necessary receptor has not yet developed in children.³⁹ Finally, some adverse effects of medicines are relevant only to children. For example, corticosteroids, inhaled to control asthma, can affect a child's growth.⁴⁰ Thus, pediatric studies, even more than similar adult studies, may require long-term tracking of outcomes.

Despite its importance, pediatric research has constituted an extremely small portion of medical research. The lack of knowledge regarding the safety and efficacy of therapies for children led Harry Shirkey in 1968 famously to describe children as "therapeutic orphans."⁴¹ Most medications prescribed for children have not actually been tested in children,⁴² and many labels for drugs used in children provide little information specific to pediatric patients.⁴³ Even some of the most-widely used drugs for children have labels that state explicitly that

37. *Id.* at 67-70; Margaret P. Sullivan, *Children as Therapeutic Orphans*, in RESEARCH ON CHILDREN: MEDICAL IMPERATIVES, ETHICAL QUANDARIES, AND LEGAL CONSTRAINTS 27 (Jan van Eys ed., 1978).

38. Michelle Meadows, *Drug Research and Children*, FDA CONSUMER MAG., Jan.-Feb. 2003, at 13, available at http://www.fda.gov/fdac/features/2003/103_drugs.html (discussing infant deaths caused by chloramphenicol, used in adults to treat penicillin-resistant infections).

39. INST. OF MED., *supra* note 31, at 71.

40. *Id.* at 71; Alessandro Salvatoni et al., *Inhaled Corticosteroids in Childhood Asthma: Long-Term Effects on Growth and Adrenocortical Function*, 5 PEDIATRIC DRUGS 351 (2003).

41. Harry Shirkey, *Therapeutic Orphans*, 72 J. PEDIATRICS 119 (1968), reprinted in 104 PEDIATRICS 583 (1999).

42. Meadows, *supra* note 38, at 13.

43. Jane E. Henney, Comm'r, Food & Drug Admin., *Increasing Pediatric Access to Medical Therapies*, Talk Given to Joint Meeting of Pediatric Academic Societies and American Academy of Pediatrics: Pediatrics in the New Millennium: Compelling Issues in Public Policy, May 15, 2000, available at <http://www.fda.gov/oc/speeches/2000/pediatricacademic.html> (stating that "for far too long, we haven't had enough scientific data to support [using therapies off-label] in the pediatric population[,] . . . a population made up of distinct subgroups, from infants to teenagers, each with its own biological and physiological characteristics"); see also Regulations Requiring Manufactures To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,632 (Dec. 2, 1998) (codified as amended in scattered sections of 21 C.F.R.) ("[P]roduct labeling frequently fails to provide directions for safe and effective use in pediatric patients.").

“safety and effectiveness in pediatric patients have not been established.”⁴⁴ In 2001, Congress noted that “only 20 percent of prescription medications on the market have been tested and approved for use in children.”⁴⁵

B. Federal Efforts to Increase Pediatric Research

In recent years the federal government has responded to this lack of pediatric information with multiple initiatives designed to increase pediatric research.⁴⁶ In the FDA Modernization Act of 1997 (FDAMA),⁴⁷ Congress enticed pharmaceutical companies with the promise to extend the patent life on specified drugs for six months in exchange for conducting clinical trials to determine appropriate pediatric dosing and safety information.⁴⁸ Concerned that this incentive would not adequately increase pediatric research,⁴⁹ the FDA promulgated what is known as the “Pediatric Rule.” It required pediatric safety and effectiveness data in applications for new drugs and biologic licenses,⁵⁰ barring exceptional circumstances,⁵¹ and it asserted the FDA’s authority to

44. FOOD & DRUG ADMIN., THE PEDIATRIC EXCLUSIVITY PROVISION, JANUARY 2001 REPORT TO CONGRESS 2 (citing C.J. Cote et al., *Is the Therapeutic Orphan About To Be Adopted?*, 98 PEDIATRICS 118, 118, 119 tbl. (1996)).

45. S. REP. NO. 107-838, at 1 (2001).

46. For discussions of the federal government’s efforts to promote pediatric therapies and drug safety prior to the most recent years, see I. Glenn Cohen, *Therapeutic Orphans, Pediatric Victims? The Best Pharmaceuticals for Children Act and Existing Pediatric Human Subject Protection*, 58 FOOD & DRUG L.J. 661, 661-63 (2003); Holly Lynch Fernandez, *Give Them What They Want? The Permissibility of Pediatric Placebo-Controlled Trials Under the Best Pharmaceuticals for Children Act*, 16 ANNALS HEALTH L. 79, 91-97 (2007).

47. Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified as 21 U.S.C. § 355a.).

48. The financial incentive of another six months of market exclusivity is significant. Schering-Plough, for instance, had an additional \$975 million in sales from Claritin during this bonus period. COLEMAN ET AL., *supra* note 28, at 531 (2005) (discussing *User Fees, Pediatric Exclusivity Keys in FDAMA Reauthorization*, FOOD & DRUG LETTER, June 22, 2001). For a more detailed account of how the incentive program functioned, see Cohen, *supra* note 46, at 663-67.

49. Regulations Requiring Manufactures To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,632 (Dec. 2, 1998) (codified as amended in scattered sections of 21 C.F.R.); *id.* at 66,639. In *Association of American Physicians and Surgeons v. FDA*, 226 F. Supp. 2d 204, 207 (D.D.C. 2002), the District Court for the District of Columbia struck down the rule as exceeding the FDA’s statutory authority. In 2003, Congress provided the agency with the necessary authority. 21 U.S.C.A. § 355c (Supp. 2006). See *infra* notes 57-58 and accompanying text.

50. Regulations Requiring Manufactures To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. at 66,632.

51. An applicant was able to request a waiver by certifying that 1) the drug did not present a “meaningful therapeutic benefit over existing treatments” and was not likely to be given to a

require manufacturers of already-marketed drugs and biologics to conduct pediatric studies.⁵²

FDAMA and the Pediatric Rule stimulated pediatric research⁵³ but also reflected shortcomings. Drug companies continued to lack an incentive to study 1) off-patent drugs, which was significant because “six of the ten drugs most widely prescribed to children were older antibiotics”,⁵⁴ and 2) drugs commanding a small market, especially drugs intended for newborns.⁵⁵

To address these concerns, as well as to renew FDAMA’s expiring market exclusivity provision, Congress passed the Best Pharmaceuticals for Children Act of 2002 (BPCA).⁵⁶ For high-priority drugs that lacked pediatric testing and that were no longer under patent, BPCA directed the National Institutes of Health to fund the needed research. Finally, because a federal district court struck down the FDA’s Pediatric Rule as exceeding the FDA’s authority,⁵⁷ Congress passed the Pediatric Research Equity Act (PREA) in 2003 to grant the FDA authority to require manufacturers to conduct pediatric studies.⁵⁸

The federal government’s efforts have significantly increased the amount of pediatric research. Since 1997, the FDA has requested approximately 800 studies, resulting in pediatric labeling for 119 drugs, whereas only eleven such studies had been completed in the previous seven years.⁵⁹ The medical research director at one children’s hospital estimated that “more studies [were] conducted

substantial number of children, 2) necessary studies would be “impossible or highly impractical,” or 3) strong evidence showed the drug would be “ineffective or unsafe in all pediatric groups.” *Id.* at 66,634. An applicant could also obtain a partial waiver by showing that “reasonable attempts to produce a pediatric formulation” necessary for that age group had failed. *Id.* at 66,634.

52. *Id.* at 66,632.

53. A status report to Congress prepared by the FDA in January 2001 conveyed that “[a]s a result of [FDAMA’s exclusivity provision], the FDA ha[d] issued over 157 Written Requests, asking for 332 studies that would potentially involve well over 20,000 pediatric patients. In less than three years [since FDAMA’s passage], over 58 pediatric studies ha[d] been conducted, study reports submitted, and exclusivity granted to 25 drugs.” FOOD & DRUG ADMIN., *supra* note 44, at ii.

54. COLEMAN ET AL., *supra* note 28, at 532; *see also* S. REP. NO. 107-79, at 2 (2001) (reporting FDA analysis of 1994 data finding that “6 of 10 drugs most commonly prescribed for children were off-patent”); FOOD & DRUG ADMIN., *supra* note 44, at iii.

55. COLEMAN ET AL., *supra* note 28, at 532; FOOD & DRUG ADMIN., *supra* note 44, at iii.

56. Best Pharmaceuticals for Children Act of 2002, Pub. L. No. 107-109, 115 Stat. 1408 (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.). Due to a concern for the welfare of children enrolled in research, as part of this Act Congress commissioned the Institute of Medicine to review the federal regulations and to make “recommendations about desirable practices in clinical research involving children.” INST. OF MED., *supra* note 31, at 2.

57. Ass’n of Am., Physicians & Surgeons v. FDA, 226 F. Supp. 2d 204 (D.D.C. 2002).

58. Pub. L. No. 108-155, 117 Stat. 1936 (2003) (codified as amended at 21 U.S.C. § 355c).

59. SENATE DEMOCRATIC POLICY COMM., *supra* note 7.

in children [between 1998 and 2003] than in the previous 30 years combined.”⁶⁰ As a result, many more children are participating in research.⁶¹ The 800 FDA-requested studies would potentially enroll 45,000 children.⁶²

The amount of pediatric research, and consequently the number of children involved in research, may increase beyond these numbers in the near future. President Bush recently signed into law a bill that, in addition to renewing both BPCA and PREA,⁶³ aims to increase pediatric research on medical devices.⁶⁴ With tens of thousands more children involved in research than when the federal regulations were passed, the time is ripe to revisit whether it is respectful of a child to enroll her in a protocol that is intended only to benefit children in the future.

C. Non-Beneficial Pediatric Research

The discussion above reviewed mostly familiar territory regarding the importance of, and efforts to increase, pediatric research generally. Much of this research exposes pediatric subjects to risks uncompensated by potential medical benefit to them individually. To produce reliable, generalizable data, researchers often perform medical procedures on pediatric subjects that carry some risk but do not benefit the participants in any way.⁶⁵

60. Meadows, *supra* note 38, at 13-14 (quoting Ralph Kauffman, M.D., Dir. of Med. Res. at Children's Mercy Hosp., Kansas City, Mo.). Philip Walson, then-Professor of Pharmacology and Pharmacy at The Ohio State University, made a similar statement: "I have been doing pediatric research for twenty-five years . . . [a]nd I can honestly say that there has been more research done in the past three years than in all the others combined." Stacey Schultz, *Drug Trials Are Clamoring for Kids, But Scrutinize the Study Before Signing Up*, U.S. NEWS & WORLD REP., Apr. 9, 2000, at 62. The FDA also provided a report to Congress in January 2001, as required by FDAMA, stating that the Act was "highly effective in generating pediatric studies of many drugs and in providing useful new information in product labeling." FOOD & DRUG ADMIN., *supra* note 44, at i (2001).

61. INST. OF MED., *supra* note 31, at 92.

62. SENATE DEMOCRATIC POLICY COMM., *supra* note 7.

63. Pediatric Research Equity Act of 2007, Pub. L. No. 110-85, § 402, 121 Stat. 866; Best Pharmaceuticals for Children Act of 2007, Pub. L. No. 110-85, § 502, 121 Stat. 876 (to be codified at 21 U.S.C. § 355 *et seq.*).

64. Pediatric Medical Device Safety and Improvement Act of 2007, Pub. L. No. 110-85, 121 Stat. 824. For example, this law requires the Director of the National Institutes of Health to designate an office as a contact point to help researchers "identify sources of funding available for pediatric medical device development." *Id.* § 304(a)(3). The Act also directs the Secretary of Health and Human Services, relying on the National Institutes of Health, Food and Drug Administration, and the Agency for Healthcare Research and Quality, to submit to Congress within six months of enactment a "plan for expanding pediatric medical device research development." *Id.* § 304(b)(1).

65. Many Phase I pharmacokinetic pediatric studies test drugs that will hopefully one day

As we will see below, some courts and commentators have posed the relevant ethical and legal questions at hand with respect to *non-therapeutic*, as opposed to *non-beneficial*, pediatric research. *Therapeutic* research usually refers to research intended or designed to benefit the enrolled subjects; *non-therapeutic* research aims primarily to produce generalizable knowledge.⁶⁶ This terminology has been persuasively criticized elsewhere, and I will not rehearse all the arguments.⁶⁷ Briefly, much research is intended to benefit enrolled subjects *and* produce generalizable knowledge, making the terminology difficult to apply.⁶⁸

But more importantly, labeling some research as “therapeutic” obfuscates the important, ethically-relevant distinctions between research (including “therapeutic” research) and actual therapy.⁶⁹ Therapy aims to optimize the well-being of each patient. A medical care physician owes primary loyalty to her patient: the potential benefits *to the patient* must outweigh the risks from any

provide treatment for a childhood cancer that has no present treatment. For many of these studies it is debatable whether they should be classified as non-beneficial or not. Many physicians see themselves as trying to treat pediatric oncology patients by recommending enrollment in such protocols. On the other hand, the odds that enrolling in a Phase I pharmacokinetic study will prove beneficial to a pediatric oncology patient are so small that it is difficult to understand such research participation as beneficial, given that participation comes with great opportunity costs regarding other ways in which a child might live out the rest of his or her life. For a very helpful discussion on this topic and for other examples of non-beneficial pediatric research, I thank Benjamin Wilfond, M.D., Chief of the Division of Pediatric Bioethics in the University of Washington’s Department of Pediatrics.

66. See ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 8-9 (2d ed. 1988).

67. See, e.g., *id.*

68. *Id.*

69. As Franklin Miller and others have argued, it is morally worrisome if all parties to research—both researchers and the subjects—do not grasp the essential difference between research and therapy. Subjects are prone to believe that procedures are administered to them for their benefit when, in reality, they are for purely research purposes. Franklin G. Miller et al., *Professional Integrity in Clinical Research*, 280 JAMA 1449, 1450 (1998) (citing Paul S. Appelbaum et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 17 HASTINGS CENTER REP. 20 (1987) (discussing the “therapeutic misconception”)). For example:

Insofar as investigators conflate the context and language of medical care with that of research, they not only reinforce the therapeutic misconception for patient volunteers, they also fall prey themselves to the seduction of the therapeutic misconception. In doing so, they can undermine informed consent and contribute to the potential for patient volunteers to be exploited for the sake of science and the benefit of future patients and present researchers.

Id. at 1451; see also Franklin G. Miller & Howard Brody, *A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials*, 33 HASTINGS CENTER REP. 19, 25-26 (2003) (arguing similar points); Franklin G. Miller & Donald L. Rosenstein, *The Therapeutic Orientation to Clinical Trials*, 348 NEW ENG. J. MED. 1383, 1384-85 (2003) (same).

prescribed diagnostic and therapeutic interventions.⁷⁰ However, the purpose of research is fundamentally different—to produce generalizable knowledge that will contribute to the welfare of future patients.⁷¹ Research subjects often face risks that are outweighed by potential benefit to *future patients*, not by potential benefits to the subjects.

Research methods used to produce such generalizable knowledge, even in many “therapeutic” protocols, are inconsistent with the best interests of individual research subjects. Researchers “seek[] to learn about disease and its treatment in *groups* of patients, with the ultimate aim of improving medical care”;⁷² thus, in contrast to the medical setting, “dosages and timing of drugs and other interventions”⁷³ are determined by the protocol, not based on or amended to suit individual characteristics of subjects.⁷⁴

Moreover, even research intended to provide a direct benefit to subjects may involve interventions—which carry risk—solely to produce generalizable knowledge without in any way benefiting the subjects.⁷⁵ For example, researchers are currently trying to find a treatment for a serious renal disease affecting children by giving some subjects a standard (though not adequately effective) therapy and other subjects an experimental therapy thought to be at least as effective as the standard one.⁷⁶ Thus, the group receiving the experimental intervention is put at no more risk than the children receiving

70. See National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. 23,192 (Apr. 18, 1979), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>; Paul Litton & Franklin G. Miller, *A Normative Justification for Distinguishing the Ethics of Clinical Research from the Ethics of Medical Care*, 33 J.L. MED. & ETHICS 566, 566 (2005).

71. See *supra* note 10 and accompanying text.

72. Miller & Brody, *supra* note 69, at 21.

73. Carl H. Coleman, *Shifting the Debate on Research with Decisionally Incapacitated Human Subjects: An Argument for a Systemic Approach to Risk-Benefit Assessment*, 83 IND. L.J. (forthcoming 2008) [hereinafter Coleman, *Decisionally Incapacitated*].

74. Carl H. Coleman, *Duties to Subjects in Clinical Research*, 58 VAND. L. REV. 387, 398 (2005) (citing JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 282 (2d ed. 2001)).

75. *Id.* at 399; Benjamin Freedman et al., In Loco Parentis: *Minimal Risk As an Ethical Threshold for Research upon Children*, 23 HASTINGS CENTER REP. 13 (1993); Miller & Rosenstein, *supra* note 69, at 1383.

76. See FSGS Clinical Trial, FAQs for Potential Patients, <http://www.fsgstrial.org/faqspatients.html> (last visited Apr. 1, 2008) (discussing Focal Segmental Glomerulosclerosis (FSGS)); Interview with Ted Groshong, M.D., Chairman, Dep’t of Child Health, Univ. of Mo. Sch. of Med., in Columbia, Mo. (Aug. 15, 2007). I thank Dr. Groshong for taking the time to explain and discuss this and other pediatric trials with me.

standard therapy. However, all pediatric participants will be subject to a regimen of blood draws that are not clinically-indicated; these blood draws are for research purposes only, conducted to monitor changes in the chemical values within the participants' blood, as well as to monitor their compliance with the protocol. Though associated risks may be minimal,⁷⁷ they are risks of harm nonetheless⁷⁸ and do not medically benefit the subjects.

Ethically, then, there is no relevant difference between non-therapeutic protocols and non-therapeutic interventions used within the context of a protocol that might, overall, be described as therapeutic.⁷⁹ Both need ethical justification, especially with regard to children. Thus, I focus on the ethical and legal acceptability of non-beneficial, not non-therapeutic, pediatric research.

77. See Seema Shah et al., *How Do Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research?* 291 JAMA 476 (2004) (finding that a single blood draw was the only research procedure that a majority of IRB chairpersons deemed to be minimal risk for pediatric subjects).

78. At the least there is risk of pain, and it cannot always be eliminated. See Susan Jane Fetzer, *Reducing Venipuncture and Intravenous Insertion Pain with Eutectic Mixture of Local Anesthetic: A Meta-Analysis*, 51 NURSING RES. 119 (2002) (finding that popular topical anesthetic does not significantly decrease pain during venipuncture and intravenous insertion for 15% of the population); Brigitte Lemyre, *How Effective Is Tetracaine 4% Gel, Before a Venipuncture, in Reducing Procedural Pain in Infants: A Randomized Double-Blind Placebo Controlled Trial*, 7 BMC PEDIATRICS 27 (2007), available at <http://www.biomedcentral.com/1471-2431/7/7> (noting that pain relief from venipuncture is "sub-optimal in neonates" and that the topical gel under study failed to significantly decrease pain). There are now topical anesthetics to reduce the risk of pain for older children, but some children still experience pain and anxiety due to venipuncture. Kim Cavender et al., *Parents' Positioning and Distracting Children During Venipuncture: Effects on Children's Pain, Fear, and Distress*, 22 J. HOLISTIC NURSING 32 (2004). Moreover, these anesthetics come with at least some risk of adverse effect. Janice Lander et al., *EMLA and Amethocaine for Reduction of Children's Pain Associated with Needle Insertion*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS, July 19, 2006, http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004236/pdf_fs.html.

79. It is also commonly thought that the technique of randomization in clinical trials—in which some subjects receive the experimental intervention while others receive another therapy or placebo—has the potential to compromise the welfare of patients, given that treatment decisions are based on random chance instead of any reasons related to each patient's needs or characteristics. However, a recent study concluded that "randomized treatment assignment as part of a clinical trial does not harm research participants." Cary P. Gross, *Does Random Treatment Assignment Cause Harm to Research Participants?*, 3 PLOS MED. 800, 800 (2006), http://medicine.plosjournals.org/archive/1549-1676/3/6/pdf/10.1371_journal.pmed.0030188-S.pdf.

II. LEGAL TENSION BETWEEN THE FEDERAL REGULATIONS AND EXISTING CASE LAW

A. Federal Regulations

Federal regulations govern all medical research conducted or supported by the federal government, conducted by institutions that have agreed to comply with the regulations, or conducted on any product intended to obtain FDA approval.⁸⁰ Subpart A of the regulation requires institutions to assure that their research is reviewed and approved by institutional review boards (IRBs) composed of persons with requisite knowledge to assess the ethical acceptability of proposed protocols.⁸¹ Subpart D specifies criteria that IRBs must use to evaluate pediatric protocols, depending upon their assessment of the protocol's risk/benefit profile.⁸²

According to these criteria,⁸³ a pediatric protocol must satisfy one of four sets of criteria regarding the potential risks and benefits of research participation before the protocol may be conducted.⁸⁴ First, under § 404, an IRB may approve "minimal risk research;" that is, § 404 authorizes IRB approval of protocols that pose "no greater than minimal risk" to the pediatric subjects, even if they do not stand to benefit from research participation.⁸⁵ The regulations define "minimal risk" as equivalent to or less than the risks "ordinarily encountered in daily life" or during routine health exams.⁸⁶ This standard is notoriously difficult to apply in

80. 45 C.F.R. § 46.101 (2007).

81. *Id.* §§ 46.103(b), 46.107. According to the regulations' criteria for assessing research, IRB approval requires first that "[r]isks to subjects are minimized," *id.* § 46.111(a)(1); second that such risks are "reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result," *id.* § 46.111(a)(2); third that subjects are selected on a fair basis, *id.* § 46.111(a)(3); and finally that researchers will obtain informed consent from each research subject or legally authorized representative according to the specifications for informed consent established by the regulations, *id.* §§ 46.111(a)(4), 46.116.

82. *Id.* §§ 46.401 to 46.409.

83. The FDA has also adopted these protections, with some changes. 21 C.F.R. §§ 50.51 to 50.56, 56.102, 56.107, 56.109, 56.111 (2007).

84. In addition to the provisions described above, regarding level of risk and potential benefits, Subpart D also prescribes that IRBs must "determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent." 45 C.F.R. § 46.408(a) (2007). IRBs must also determine that adequate provisions are made for obtaining the informed consent of one or both parents, depending on the circumstances, unless there is good reason to waive that consent requirement. *Id.* § 46.408(b)-(c). In this Article I will not address issues relating to the consent or assent of children in research.

85. *Id.* § 46.404.

86. *Id.* § 46.102(i).

practice and leads to varied judgments among IRB members;⁸⁷ nonetheless, it is the regulatory standard.

Second, § 405 permits “direct benefit” research. An IRB may approve a protocol that presents greater than minimal risk if it “present[s] the prospect of direct benefit to the individual subjects.”⁸⁸ The risks of an approved protocol must be “justified by the anticipated benefit” to the pediatric subjects, and “the relation of the anticipated benefit to the risk [must be] at least as favorable to the subjects as that presented by available alternative approaches.”⁸⁹ Research approvable under § 405 is most analogous, ethically, to clinical care, in that the direct benefits of research participation must counterbalance the risks for IRB approval.

Third, under § 406, an IRB may approve a protocol presenting up to a “minor increase over minimal risk” if the protocol is likely to yield vitally important knowledge about the subjects’ disorder or condition, even if the risks are not compensated by any potential benefit to the subjects.⁹⁰ The regulations do not define a “minor increase over minimal,” but the Institute of Medicine, commissioned by Congress to review the regulations, recently recommended interpreting the phrase as “a slight increase in the potential for harms or discomfort beyond minimal risk.”⁹¹

Finally, § 407 is a “catch-all” provision. If an IRB finds that a protocol fails to satisfy one of the first three sets of criteria but represents “an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children,” the Secretary of the Department of Health and Human Services may approve the protocol after consulting with a “panel of experts in pertinent disciplines” and providing “an opportunity for public review and comment.”⁹² However, § 407 does not provide any criteria to guide the panel of experts or the Secretary in assessing a proposed protocol. The regulations provide only the vague requirement that “the research will be conducted in accordance with sound

87. See Shah et al., *supra* note 77, at 476; see also INST. OF MED., *supra* note 31, at 5, 113 (noting that one of the tasks requested of authoring committee, writing for the Institute of Medicine and commissioned by Congress to review regulations regarding pediatric research, was to consider the “regulatory definition of ‘minimal risk’”). For an intriguing proposal for using empirical data to help interpret “minimal risk,” see David Wendler et al., *Quantifying the Federal Minimal Risk Standard: Implications for Pediatric Research Without a Prospect of Direct Benefit*, 294 JAMA 826 (2005).

88. 45 C.F.R. § 46.405 (2007).

89. *Id.* Note that IRBs do not consider financial payment as a benefit of research participation. Alex Rajczi, *Making Risk Benefit Assessments of Medical Research Protocols*, 32 J.L. MED. & ETHICS 338, 344 (2004).

90. 45 C.F.R. § 46.406 (2007).

91. INST. OF MED., *supra* note 31, at 128.

92. 45 C.F.R. § 46.407 (2007).

ethical principles.”⁹³

Evidently, the regulations permit non-beneficial pediatric research. Sections 404 (“minimal risk” research), 406 (“minor increase over minimal risk” research), and 407 (“catch-all” provision) clearly allow pediatric subjects in regulated research to be exposed to risks uncompensated by any benefit. Indeed, § 407 does not place any explicit ceiling on the level of risk to which a child may be exposed.

B. Existing State Case Law: Grimes

Very little state case law deals with pediatric research or even human subjects research more broadly. In 1996, an intermediate New York appellate court invalidated regulations promulgated by the state’s Office of Mental Health (OMH) which sanctioned the exposure of minor and incapacitated research subjects to “more than minimal risk” without compensating benefit.⁹⁴ The court cited two grounds: 1) OMH lacked authority under state law to publish these regulations;⁹⁵ and 2) the regulations violated the constitutional due process rights and common-law right to personal autonomy of subjects and potential subjects of OMH research.⁹⁶ The court found that by permitting greater than minimal risk, the regulations struck an improper balance between the “interests of researchers and the rights of the subjects.”⁹⁷ However, the New York Court of Appeals vacated that latter holding as an “inappropriate advisory opinion” once the lower court found OMH to lack the requisite authority.⁹⁸

The Maryland Court of Appeals’ 2001 *Grimes* opinion remains the sole major opinion addressing the propriety of pediatric research. The controversial research under scrutiny aimed to assess different methods of partial lead abatement in low-income housing in order to find an economically feasible means for landlords to make their units safe for rental.⁹⁹ Many landlords were choosing to abandon their units because the lead levels were not legally compliant and the cost of complete lead abatement exceeded the worth of many of the properties.¹⁰⁰ The ultimate purpose of the study, conducted by the Kennedy Krieger Institute (KKI), was to help increase the supply of housing for low-income Baltimore families.¹⁰¹

93. *Id.* § 46.407(b)(2)(ii).

94. *T.D. v. N.Y. State Office of Mental Health*, 650 N.Y.S.2d 175, 194 (App. Div. 1996).

95. *Id.* at 182.

96. *Id.* at 177.

97. *Id.*

98. *T.D. v. N.Y. State Office of Mental Health*, 690 N.E.2d 1259, 1260 (N.Y. 1997).

99. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 808 (Md. 2001).

100. *Id.* at 815 n.6.

101. *Id.*

The study involved over one hundred homes, divided into five groups: three groups of homes, which had significant lead dust levels, received varying degrees of lead abatement; a fourth group received complete lead abatement; and a fifth group of homes, built more recently, never had lead paint at all.¹⁰² Children lived in many of these homes, and landlords agreed to rent unoccupied units to families with at least one young child;¹⁰³ in exchange, at least in some cases, KKI helped landlords obtain public grants or loans to pay for the abatement procedures.¹⁰⁴ Investigators tested the lead levels in both the houses and the children's blood over a two-year period to determine whether any partial lead abatement method proved adequately safe.¹⁰⁵

Before the research concluded, two parents, on behalf of their respective children, sued KKI for breaching duties owed to the children to protect them from foreseeable harms inherent in the research.¹⁰⁶ Plaintiffs argued that KKI neglected to obtain the parents' truly informed consent by failing to disclose the dangers of lead poisoning, the fact that their homes contained high levels of lead dust, the particularly hazardous areas of the homes, the purpose of the study, and other pertinent facts.¹⁰⁷ Plaintiffs also charged that KKI failed to fulfill its duties under the signed consent; namely, that KKI broke its promise to inform plaintiffs of any new findings during the research that could impact plaintiffs' willingness to continue participation.¹⁰⁸ According to plaintiffs, KKI was unreasonably slow to inform them that the lead dust levels in their homes remained high even after intervention, and that the lead levels in their children's blood were elevated.¹⁰⁹

The trial court granted KKI's motion for summary judgment on the grounds that it owed no duty to the minor research subjects on which to base any civil liability.¹¹⁰ The children were living in their homes with elevated dust levels, and KKI was, in the trial court's view, an "institutional volunteer" trying to improve conditions for the community.¹¹¹ Accordingly, the trial court found neither a contract nor special relationship between KKI and the children that gave rise to any duty to protect the children from harm.¹¹²

102. *Id.* at 820.

103. *Id.* at 812. Researchers were interested in families with at least one child between five and forty-eight months old. *Id.* at 823.

104. *Id.* at 812, 821.

105. *Id.* at 812.

106. *Id.* at 818.

107. Brief for Appellant at 8-9, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 1177), 2001 WL 34552913.

108. *Id.* at 11-13.

109. *Id.* at 14-15; *Grimes*, 782 A.2d at 843.

110. *Grimes*, 782 A.2d at 832.

111. *Id.*

112. *Id.*

The court of appeals vacated the trial court's grant of summary judgment and remanded for trial.¹¹³ It held on a number of grounds that the relationship between KKI and the minor subjects could give rise to a duty to protect them from harm. Briefly, that duty could be based on the informed consent document (representing a contract),¹¹⁴ on KKI's act of recruiting the children to participate in non-therapeutic research,¹¹⁵ on the federal regulations governing human subjects research,¹¹⁶ and/or on the Nuremberg Code.¹¹⁷

Although the court remanded for trial, it addressed an issue that was neither essential to its reversal nor briefed by the parties:¹¹⁸ namely, the more general question of whether parents should have legal authority to consent to enroll their children in "non-therapeutic research."¹¹⁹ The court acknowledged that the federal regulations bound KKI because it received federal funding,¹²⁰ and that the regulations permit parents to enroll their children in some non-therapeutic research. However, the court held that it could bind researchers to more stringent standards in order to provide protections to human subjects greater than those provided by the regulations.¹²¹

113. *Id.* at 858.

114. *Id.* at 843. But as Jack Schwartz points out, the court "did not elaborate on how the existence of this contract gives rise to a duty enforceable in tort, as distinct from a cause of action for breach of contract." Schwartz, *supra* note 18, at 153.

115. *Grimes*, 782 A.2d at 845-46. The court stated:

[T]he trial courts appear to have held that special relationships out of which duties arise cannot be created by the relationship between researchers and the subjects of the research. While in some rare cases that may be correct, it is not correct when researchers recruit people, especially children whose consent is furnished indirectly

Id.

116. *Id.* at 846-49 (citing 45 C.F.R. §§ 46.101, 46.116, 46.407 (2007)).

117. *Id.* at 849. The Court also discusses and quotes the Nuremberg Code at length earlier in the opinion. *Id.* at 835-37.

118. *Id.* at 852.

119. *Id.* at 852-58. The court discussed *non-therapeutic*, as opposed to *non-beneficial*, research. For the difference between these terms, see *supra* notes 66-79 and accompanying text. That the court used "non-therapeutic" is not important, though, as it clearly had in mind pediatric research that poses risks uncompensated by benefit to the individual subjects.

120. The research was funded by the Environmental Protection Agency and Maryland's Department of Housing and Community Development. *Grimes*, 782 A.2d at 820.

121. The court noted that the regulation, 45 C.F.R. § 46.116(e) (2007), specifically states that the federal regulations' informed consent requirements "are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective." *Grimes*, 782 A.2d at 820. Subpart A of the regulations, though, contains even greater support for the court's position. It specifically states: "This policy does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects." 45 C.F.R. § 46.101(f) (2007). Subpart D does

And the court did, declaring that Maryland parents lack legal authority to enroll their children in research that would expose them to risk without potential benefit.¹²² Thus, even if the informed consent was adequate and KKI had lived up to its terms, the court condemned the research insofar as it exposed children to risks for the good of others.¹²³ It based its decision on the best interests standard:

We have long stressed that the “best interests of the child” is the overriding concern of this Court in matters relating to children. Whatever the interests of a parent, and whatever the interests of the general public in fostering research that might, according to a researcher’s hypothesis, be for the good of all children, this Court’s concern for the particular child and particular case, over-arches all other interests. 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.¹²⁴

Concluding that participation in non-beneficial pediatric research is not in the best interests of any child, the court effectively prohibited all pediatric research exposing a pediatric subject to “any risk” uncompensated by potential benefit to him or her.¹²⁵

The court’s ruling greatly distressed the research community as it prohibited a vast amount of critically important research. The Association of American Medical Colleges, along with the Association of American Universities, Johns Hopkins University, and the University of Maryland, filed an amicus brief in support of KKI’s motion for reconsideration, urging the court to rescind its

not contain any such proviso, but it also “does not purport to preempt any state laws.” Jack Schwartz, *Oversight of Human Subjects Research: The Role of the States*, in NAT’L BIOETHICS ADVISORY COMM’N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS M-1, M-6 (2001).

122. *Grimes*, 782 A.2d at 858.

123. *Id.* at 849-58.

124. *Id.* at 853. Earlier in the opinion, the court stated: “[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 non-therapeutic research surroundings, than do researchers. In such cases, parental consent, no matter how informed, is insufficient.” *Id.* at 814. This pronouncement is not contrary to the law and ethics of pediatric research, which agree with the court that “parental consent, no matter how informed,” can never be sufficient to justify enrolling a child in research. Parental consent would not be sufficient to justify exposing a child to unreasonable risks, for example. But the court later clarified its view, demonstrating its break with the federal regulations and commentators who support some non-beneficial pediatric research. The court described parental consent as never sufficient because it declared that *no conditions* could justify non-beneficial pediatric research.

125. *Id.* at 858.

prohibition of non-therapeutic pediatric research.¹²⁶ The court's standard disallows the use of placebos—given their non-therapeutic nature—in any trial carrying any risk whatsoever. Without placebo controls, amici argued that Maryland researchers would no longer be able to find cures or treatments for childhood illnesses for which there is no effective treatment, and would be unable to test new important vaccines for safety and efficacy.¹²⁷ The court's prohibition of non-therapeutic research carrying *any* risk would even rule out critically important research that exposes children only to minimal risks.¹²⁸ For example, under the ruling, “the ability to do skin biopsies . . . of disease-affected children and their non-affected siblings is necessary to determine the association of abnormal genes with disease.”¹²⁹ Skin biopsies represent very minimal risk to children, but nevertheless *some* risk, and thus would be prohibited under the *Grimes* ruling.¹³⁰

The court denied KKI's motion to reconsider,¹³¹ but did attempt to clarify its ruling on research that carries “*any* risk” without compensating benefit, stating: “As we think is clear from . . . the Opinion, by ‘any risk,’ we meant any articulable risk beyond the minimal kind of risk that is inherent in any endeavor.”¹³² We will discuss this “clarification” below.

C. Incompatibility of *Grimes* and the Regulations

After *Grimes*, the Maryland legislature enacted a statute requiring all research conducted in the state, regardless of funding or institution, to conform to “the federal regulations on the protection of human subjects.”¹³³ Nevertheless, *Grimes* remains law. Is *Grimes* inconsistent with the federal regulations and, if so, to what extent? Of course, this question is important to Maryland researchers, who must know what standards govern their practice. Looking beyond Maryland to possible future litigation, it is important to ask whether the best interests standard necessarily conflicts with federal regulations.

Most plainly, §§ 406 (“minor increase over minimal risk” research) and 407 (the catch-all provision) are inconsistent with *Grimes*. Section 406 allows “risk beyond the minimal kind . . . that is inherent in any endeavor,” as it authorizes IRB approval of research presenting a minor increase over minimal risk.¹³⁴

126. Amici, *supra* note 25.

127. *Id.* at 5-6.

128. *Id.*

129. *Id.* at 6.

130. *Id.*

131. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 861 (Md. 2001).

132. *Id.* at 862.

133. MD. CODE ANN., HEALTH-GEN. § 13-2002 (West 2005).

134. Some commentators disagree, maintaining that § 406 is consistent with *Grimes*. See, e.g.,

Section 407 is unmistakably inconsistent with *Grimes*, placing no ceiling at all on the level of risk to which children may be exposed. The only remaining question is whether *Grimes*, by forbidding “any articulable risk beyond the minimal kind that is inherent in any endeavor,” permits non-beneficial, *minimal risk* research

Loretta M. Kopelman, *Pediatric Research Regulations Under Legal Scrutiny: Grimes Narrows Their Interpretation*, 30 J.L. MED. & ETHICS 38, 43 (2002) [hereinafter Kopelman, *Pediatric Research Regulations*]; Kopelman, *Conditions*, *supra* note 18, at 755-56 (2004); John D. Lantos, Editorial, *Pediatric Research: What Is Broken and What Needs To Be Fixed?*, 144 J. PEDIATRICS 147, 148 (2004) (stating that the *Grimes* clarification “makes clear that investigators should not be held liable if they did, in fact, abide by federal regulatory standards. . . . In short, the decision strengthens, rather than undermines, the authority of the current federal regulations.”). Loretta Kopelman begins by highlighting that a protocol presenting a minor increase over minimal risk is approvable only if its interventions expose subjects to experiences “reasonably commensurate” with what the subjects normally experience due to their particular disorder or condition. Kopelman, *Pediatric Research Regulations*, *supra*, at 38; Kopelman, *Conditions*, *supra* note 18, at 755-56. This commensurability requirement is related to the rationale for § 406. The National Commission, on whose recommendations the regulations are based, stated that “commensurability is intended to assure that participation in research will be closer to the ordinary experience of the subjects.” NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, DEP’T OF HEALTH, EDUC. & WELFARE, PUB NO. (OS) 77-0004, REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN 9 (1977).

Given the commensurability requirement, Kopelman argues that § 406 authorizes studies whose interventions present no more than minimal risk to the pediatric subjects (who have the disorder or condition under study), though the interventions *would* present a minor increase over minimal risk for healthy children (who, as such, would not be enrolled in the study). Kopelman, *Pediatric Research Regulations*, *supra*, at 47; Kopelman, *Conditions*, *supra* note 18, at 755-56. Because the everyday experiences of the ill children under study may include exposure to interventions similar to those involved in the protocol, a study itself might represent only minimal risk to these children. Thus, on Kopelman’s account, § 406 could be construed to permit only research that exposes pediatric subjects to minimal risk and thus could be consistent with *Grimes* (on the assumption that *Grimes* would permit minimal risk, non-beneficial research). Kopelman, *Pediatric Research Regulations*, *supra*, at 47; Kopelman, *Conditions*, *supra* note 18, at 755-56.

Kopelman’s argument lacks merit, though. The fact that *some* studies would present a minor increase over minimal risk to a healthy child, but only minimal risk to children with a particular condition, does not imply that *all* or even most studies representing a minor increase over minimal risk to healthy children would expose sick children to only minimal risk. Some interventions may expose sick children to only minimal risk given their everyday experiences, but other interventions that would expose healthy children to a minor increase over minimal risk may expose sick children to a risk *greater* than a minor increase over minimal risk, precisely because of their weakened or otherwise highly vulnerable condition. Kopelman might argue, as the title of her article suggests, that *Grimes* “narrows” what the federal regulations mean; perhaps *Grimes* implies that § 406 should be read to authorize research on sick children only when the risks are no greater than minimal. But, *Grimes* in no way interprets the regulations, and, of course, it is not within the authority of state courts to determine the ultimate meaning of the federal regulations.

approvable under § 404. Generally commentators have maintained that it does.¹³⁵

However, neither the reasoning of the opinion nor the plain language of the court's subsequent clarification supports such a reading. *Grimes* places a risk ceiling at the level of risk inherent in *any* endeavor, suggesting, on its face, endeavors carrying the very lowest levels of risk. The level of risk inherent in all endeavors is the level of risk we cannot escape. But § 404 of the regulations does *not* restrict non-beneficial research to risks that low, but rather to the levels of risk associated with children's common, everyday activities. And as Dave Wendler points out,¹³⁶ the risks associated with children's everyday activities are greater than the risk inherent in all endeavors. The risks of riding in a car, of playing contact sports, or even of walking on a sidewalk are necessarily greater than, say, the risks of listening to a parent read a children's story.¹³⁷ Non-beneficial pediatric protocols that carry risks equivalent to those associated with riding in a car would be approvable under § 404 (as posing minimal risk), but not under the plain language of *Grimes*. The risks of riding in a car are "ordinarily encountered in daily life," and thus acceptable for research under the federal regulations, but they certainly are greater than the level of risk that is inescapable. Perhaps the court was not sufficiently careful and did not intend its

135. See Coleman, *Decisionally Incapacitated*, *supra* note 73, at 23 (characterizing *Grimes* as precluding parents from enrolling children in studies "involving more than minimal risk[,]” implying the permissibility of non-beneficial, minimal risk studies); Rupali Gandhi, *Research Involving Children: Regulations, Review Boards, and Reform*, 8 J. HEALTH CARE L. & POL'Y 264, 288 (2005); Kopelman, *Pediatric Research Regulations*, *supra* note 134, at 47; 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, 1073-74 (2002); David M. Smolin, *Non-therapeutic Research with Children: The Virtues and Vices of Legal Uncertainty*, 33 CUMB. L. REV. 621, 641 (2003).

136. David Wendler, *Risk Standards for Pediatric Research: Rethinking the Grimes Ruling*, 14 KENNEDY INST. ETHICS J. 187, 190-91 (2004). I follow Dave Wendler in arguing that *Grimes* is inconsistent with § 404.

137. Riding in a car is certainly an activity "ordinarily encountered in daily life," and carries a risk of dying at "approximately 0.06 per million trips for children aged 0 to 14 years and approximately 0.4 per million trips for children aged 15 to 19 years." Wendler et al., *supra* note 87, at 828 (conveying data adapted from U.S. DEP'T OF TRANSP., NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., TRAFFIC SAFETY FACTS: 2003 DATA (2004), available at <http://www-nrd.nhtsa.dot.gov/pdf/nrd-30/nscsa/tsf2003/809774.pdf>, and U.S. DEP'T OF TRANSP., NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., TRAFFIC SAFETY FACTS 2002 (2004), available at <http://www-nrd.nhtsa.dot.gov/pdf/nrd-30/nscsa/tsfann/tsf2002final.pdf>).

That statistic just quantifies the risk of dying. The risk of visiting an emergency room from car riding is about 3 per million trips for children younger than one; 8 per million trips for children between 1 and 4 years old; 13 per million trips for children 5 to 9; 18 per million trips for minors between 10 and 14; and 32 per million trips for those between 15 and 19. *Id.* We can confidently say that the risks of reading or being read to, or even of taking a family stroll, are not as great.

decision to have such implications, but the decision by its plain language has them nonetheless.

Furthermore, even if the court's plain language were ambiguous, its reasoning speaks against an interpretation consistent with § 404. As mentioned, the court stated that the best interests of the child are its overriding concern, and it took that standard to imply that no child should be used in research "where his or her health *may be impaired*" or "which *might possibly be*, or which proves to be, hazardous to [the child's] health," in a protocol aimed to "benefit all children."¹³⁸ The court's reasoning implies that no child should be exposed to any intervention that is not clinically indicated and poses some risk beyond what is inescapable.

It is worth noting *how* the court applied the best interests standard. Its analysis was based solely on the potential risks and benefits to a child of participating in a particular non-therapeutic protocol.¹³⁹ The court did not deem relevant any risks or benefits to a child that result from the ongoing practice of non-beneficial (or non-therapeutic) research. In that sense, it construed the relevant facts quite narrowly in applying the best interests standard. The court thereby assumed that non-beneficial protocols could be justified only by their benefits to the greater good, on a utilitarian basis which it ruled inconsistent with the law. The remainder of this Article explains that, while the court was right to reject a utilitarian justification, it erred in concluding that no other valid justification could be offered.

III. PEDIATRIC RESEARCH AND THE PARENT-CHILD RELATIONSHIP

In *Grimes*, neither party briefed, and the plaintiffs did not even raise, the issue of whether parents should have legal authority to enroll their children in non-therapeutic research.¹⁴⁰ There was no dispute to settle. Implicitly, and in quite an unusual way, the Maryland Court of Appeals invoked the state's *parens patriae* authority to limit the scope of parental authority. Under the Fourteenth Amendment, parents have the substantive due process right to direct the upbringing of their children and make decisions for them. However, Maryland and other states have received the English common law,¹⁴¹ which grants the state *parens patriae* authority to protect children in appropriate cases.¹⁴²

138. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 853 (Md. 2001) (emphasis added).

139. Coleman, *Decisionally Incapacitated*, *supra* note 73, at 48 (explaining two levels at which to assess best interests, in context of discussing research on incompetent adults).

140. *Grimes*, 782 A.2d at 852.

141. *See, e.g.*, MD. CODE. ANN., CONST., art. 5 (West 2007) (receiving the common law unless in conflict with constitutional or statutory law).

142. *In re Adoption/Guardianship of Victor A.*, 872 A.2d 662, 669 (Md. 2005) ("[The] fundamental interest [in raising a child] . . . is not absolute and does not exclude other important

The Maryland court's implicit invocation of the state's *parens patriae* authority was unusual because it was not stepping into a specific parent-child relationship to protect the interests of a child, as courts do when, for example, they are asked to approve a blood transfusion over a parent's objection. Rather, the court announced an absolute rule limiting the scope of parental authority in Maryland.

This Section highlights some legal support for the court's implicit invocation of the state's *parens patriae* powers in stripping parents of the power to enroll their children in non-beneficial research. I discuss two possible rationales for parents' presumptive legal authority to make decisions for their children, and argue that they are inapplicable to non-beneficial research; thus, the court's intrusion into the parent-child relationship, limiting the power of parents, is unproblematic on these grounds. Some commentators disagree, however; their views entail that the court failed to properly respect parental authority and, specifically, the interests that parents have in teaching their children altruism through research participation. I argue that the court was right not to grant weight to such views.

A. Parental Rights Protecting Parental Interests

First, one might argue that parental rights are based on the interests of *parents*, in light of the importance that parents attach to raising their children. This argument finds considerable support in judicial opinions. For example, in the well-known line of constitutional cases including *Meyer*,¹⁴³ *Pierce*,¹⁴⁴ *Yoder*,¹⁴⁵ and more recently *Troxel*,¹⁴⁶ the U.S. Supreme Court has affirmed that

considerations. Pursuant to the doctrine of *parens patriae*, the State of Maryland has an interest in caring for those, such as minors, who cannot care for themselves.”); see also *Koshko v. Haining*, 921 A.2d 171, 191 (Md. 2007) (citing the state's compelling interest as *parens patriae* “to ensure the well-being of Maryland's children”). An Illinois appellate court explained:

The [court], through the doctrine of *parens patriae*, has an inherent plenary power, independent of any authority given to it by the legislature, to act solely in the best interests of the child and for his own protection. It is not a justiciable matter because the authority does not derive from statute. The court's power to interfere with and control the persons and custody of all minors within its jurisdiction existed in the common law, prior to and independent of the Juvenile Court Act, by inheritance from the English courts of chancery.

In re O.H., 768 N.E.2d 799, 804 (Ill. App. 3d 2002) (citations omitted). For a discussion of the history of the *parens patriae* doctrine, see John Seymour, *Parens Patriae and Wardship Powers: Their Nature and Origins*, 14 OXFORD J. LEGAL STUD. 159 (1994).

143. *Meyer v. Nebraska*, 262 U.S. 390 (1923).

144. *Pierce v. Soc'y of Sisters*, 268 U.S. 510 (1925).

145. *Wisconsin v. Yoder*, 406 U.S. 205 (1972).

146. *Troxel v. Granville*, 530 U.S. 57 (2000).

parents have a fundamental liberty interest, protected by the Fourteenth Amendment, “in the care, custody, and control of their children.”¹⁴⁷

One prominent pediatric ethics commentator, Lainie Friedman Ross, attempts to provide a non-consequentialist defense of non-beneficial pediatric research in part by arguing that parents have a right to make decisions for their children, where that right is protective of the parents’ own interests. Her view is rooted in the idea that under a liberal political constitution, a primary function of government is to protect the freedom of competent adults to live according to their own conception of the good life; and a person’s conception of the good life may include “the freedom to form and raise a family” according to that conception.¹⁴⁸ Thus, according to Ross, parental rights are fundamental to parents, protective of their interests. Parent rights are not, in her view, derivative of children’s interests or justified as a means to protecting the interests of children.

Despite the support from case law and some commentators, the very idea that parents have rights over their children to protect *parents’* interests, and not to promote *children’s* interests, should have no role in showing how a child’s participation in non-beneficial pediatric research is consistent with treating her as an end-in-herself. The notion that parental rights are justified as protective of parents’ interests (and not derivative from children’s interests) quintessentially depicts children as a means and not as ends-in-themselves. It is the view that children are like property, the object of others’ rights. As Professor James Dwyer argues, parental rights are necessary only to allow a parent to treat his children in ways that he wants but are in serious conflict with the children’s interests.¹⁴⁹

147. *Id.* at 65. I am not suggesting that there is a plausible constitutional argument against the *Grimes* ruling; only that the idea that parents have rights that are protective of their own interests has support in the Court’s language.

148. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 3. At one point she does seem to suggest that parental rights are grounded at least in part by the welfare interests of children: “Parents [should be] given wide latitude in balancing the risks and benefits among family members because of the importance to a family’s well-being to the parents’ and the child(ren)’s well-being.” *Id.* at 95. But nevertheless, even in making that suggestion, she makes clear that on her view, parental rights are justified, in part, as protective of interests inherent to the parent.

149. See James G. Dwyer, *Parents’ Religion and Children’s Welfare: Debunking the Doctrine of Parents’ Rights*, 82 CAL. L. REV. 1371, 1439-40 (1994). Dwyer continues, explaining why a denial of parental rights does not imply unacceptably low barriers for justified state intervention into the family:

Given the costs of state intervention to the child, the child’s negative claim-rights would preclude state intervention where parents’ actions are in the child’s interests, have no clear effect on the child’s interests, or negative affect the child’s interests to a lesser extent than would the intervention. Given this assumption, parental rights would be necessary only to raise the threshold of harm to children that must be reached before the State may intervene.

Though court decisions, especially those interpreting the Free Exercise Clause,¹⁵⁰ endorse the idea that parents have rights to control their children, that fact implies neither that those decisions are morally justified nor that they are consistent with “a proper understanding of the limited purpose of rights in our legal system.”¹⁵¹ Invoking parental autonomy to show how exposing a child to non-beneficial research is respectful of that child’s moral status is, indeed, a strange way to argue that enrolling the child does not treat her merely as a means.

B. Parental Rights as Protection for Children’s Interests

Thus, we conceive of parental rights more plausibly as derivative and protective of children’s interests.¹⁵² That is, we should ascribe rights of control and custody to parents if that ascription is generally in the best interests of children. Children require the care, direction, and protection of adults, and “[c]onventional wisdom . . . holds that parents are in the best position to know what is best for their children and are likely to care more than any other adult about their children’s well-being.”¹⁵³

1. Case Law: Parents Act in Their Children’s Interests

This justification for ascribing parental rights also finds support in judicial

Id. at 1440 n.284. Ross reaches a somewhat similar conclusion in arguing that the state should not hold parents to the best interests standard in determining when state intervention is appropriate, but rather should interfere with the family only when children are being deprived of their basic needs. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 24, 90-93. The bases for their respective conclusions differ, as explained above.

150. These decisions are discussed in Dwyer, *supra* note 149, at 1379-1405.

151. *Id.*

152. In addition, in ascribing rights or interests to parents in controlling the lives of their children, courts, including the U.S. Supreme Court, have appealed to tradition, or historical practices. For example, to support the proposition that parents have a substantive due process liberty interest, the Supreme Court recently cited with approval its prior claim in *Yoder*: “The history and culture of Western civilization reflect a strong tradition of parental concern for the nurture and upbringing of their children. This primary role of parents in the upbringing of their children is now established beyond debate as an enduring American tradition.” *Troxel v. Granville*, 530 U.S. 57, 66 (2000) (citing *Wisconsin v. Yoder*, 406 U.S. 205, 232 (1972)); *see also* *Moore v. City of E. Cleveland*, 431 U.S. 494, 503 (1977) (“Our decisions establish that the Constitution protects the sanctity of the family *precisely because* the institution of the family is deeply rooted in this Nation’s history and tradition.”) (emphasis added). However, as James Dwyer rightly argues, the fact that a practice or rule has long been observed and part of tradition cannot serve, by itself, as a justification for the ascription of a right. Dwyer, *supra* note 149, at 1424. A longstanding tradition can be, of course, unjust. *Id.*

153. Dwyer, *supra* note 149, at 1427.

language, including the Supreme Court's. In describing its past recognition of "the family as a unit with broad parental authority over minor children," the Court in *Parham* elaborated:

The law's concept of the family rests on a presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions. More important, historically it has recognized that natural bonds of affection lead parents to act in the best interests of their children.¹⁵⁴

Accordingly, the Supreme Court and other courts presume that:

[F]it parents act in the best interests of their children. . . . [S]o long as a parent adequately cares for his or her children (i.e., is fit), there will normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent's children.¹⁵⁵

The Maryland Court of Appeals follows this line of reasoning, recently stating that in the context of parental disputes between a parent and a third party, the best interests standard does not govern the matter unless the parent is deemed unfit.¹⁵⁶

In the medical research context, a parent's decision to expose a child to, say, a venipuncture or other minimal risk procedure for the good of others would not provide reason to deem that parent unfit to care for her child. Thus, there would seem to be no reason for a state agent, such as a court, to intervene in the parent-child relationship by limiting parental authority regarding pediatric research. Nevertheless, one sympathetic to *Grimes* could respond persuasively that the "presumption that parents act in their children's best interests, while applicable to most child-rearing decisions, is not applicable in the [non-beneficial research] context."¹⁵⁷ The risks presented by a non-beneficial protocol are, by definition, not in the best interests of the children enrolled. Therefore we do not even need to ask whether a parent who enrolls a child in non-beneficial pediatric research is unfit; the decision to enroll is not within parental authority from the outset because the presumption that parents act in their children's best interests is

154. Troxel, 530 U.S. at 68 (quoting *Parham v. J.R.*, 442 U.S. 584, 602 (1979)).

155. *Id.* at 68-69.

156. *In re Roberto d.B.*, 923 A.2d 115, 128-29 (Md. 2007) (discussing *McDermott v. Dougherty*, 869 A.2d 751 (Md. 2005)).

157. *Parham*, 442 U.S. at 632 (Brennan, J., concurring in part and dissenting in part). The context of this quote was not a discussion of medical research, but of parental decisions to commit their children to mental hospitals.

inapplicable.

The argument in support of *Grimes* is not that any parental decision contrary to a child's best interests is outside the scope of parental authority; we do not require parents to sacrifice all their own interests to promote constantly the best interests of a child every hour of the day. Moreover, it is impossible to promote the best interests of each child in every situation when there are siblings who have competing interests. Parents must have authority to make many decisions (that do not constitute neglect or abuse) that are not in a child's best interests. However, we generally take this *policy* of permitting a wide scope of parental decision-making to be in the best interests of children. It is in the best interests of children to have parents who are able to pursue their own interests: to have content parents and to see their adult role models pursuing worthwhile activities. But the interests of children served by this general policy are irrelevant to a parental decision to enroll a child in non-beneficial research. Parents do not have a strong interest in exposing their children to non-beneficial risk, and a policy prohibiting non-beneficial pediatric research appears to be a negligible intrusion into the parent-child relationship.

2. Moral Education and Research Participation

Some commentators,¹⁵⁸—most notably, Ross—disagree, and would argue that the *Grimes* court failed to appreciate both the interests of parents in inculcating their children with their values and the interests of children in learning altruism through research participation. In Ross' view, the presumption that parents act in their children's best interest should be applicable in the research context because even if non-beneficial research is not in a child's best *medical* interests, research participation can be in the child's best *overall* interests by morally educating a child.¹⁵⁹ Because it "is likely that [a] child will come to share in some, if not most, of [her parent's] values,"¹⁶⁰ like altruism, Ross argues

158. See, e.g., HENRY K. BEECHER, RESEARCH AND THE INDIVIDUAL: HUMAN STUDIES 63 (1970); William G. Bartholome, *Parents, Children, and the Moral Benefits of Research*, 6 HASTINGS CENTER REP. 44 (1976).

159. With regard to the law, Ross might draw on a famous passage from *Pierce* for support: "The child is not the mere creature of the State; those who nurture him and direct his destiny have the right, coupled with the high duty, to recognize and *prepare him for additional obligations.*" *Pierce v. Soc'y of Sisters*, 268 U.S. 510, 535 (1925) (emphasis added). The context of the statement, in that case, might imply religious obligations, but it is reasonable to suppose that it also includes moral obligations more generally. See, e.g., *Michael H. v. Gerald D.*, 491 U.S. 110, 118-19 (1989) (citing California family law statute using similar language, stating that legal status of parenthood implies duty "to prepare the child for additional obligations, which includes the teaching of moral standards").

160. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 92.

that enrolling a child in non-beneficial research (at least with a minimal risk ceiling)¹⁶¹ can be consistent with treating the child as an end-in-herself and not merely a means.¹⁶² Even if the child does not adopt altruistic goals, Ross argues that parents respect children by teaching them the value of altruism.¹⁶³

The problem with Ross' argument, though, is that it is completely inapposite to research on children who are too young to learn any lesson of altruism.¹⁶⁴ An infant's or toddler's future moral character will not be affected by being told that she is helping others by taking a needle.¹⁶⁵

But even with regard to children who are somewhat older, Ross does not provide support for the conclusion that participating in medical research is an effective way to engrain altruistic dispositions. Generally, research participation is a passive activity and not something that a child will regularly engage in. We might question the judgment of a parent who regularly enrolls her child in research in order to teach altruism. But regardless, we are not concerned with justifying the regular enrollment of a child in non-beneficial pediatric research. We need to know whether any justification exists for enrolling a child even once in a non-beneficial protocol, and it seems doubtful that a one-time enrollment, perhaps in a protocol that involves one venipuncture or allergy skin testing, will have any importance for a child's long-term moral development. Furthermore, one should wonder whether any anxiety and fear that children experience when enduring physical discomfort or brief pain in a medical setting are conducive to learning moral lessons. Perhaps the anxiety and fear do not interfere with moral education; but if moral education is the justification for research, then we need some reason to believe participation effectively teaches altruism.

161. Ross asserts that children incapable of assenting should not be enrolled in any non-beneficial pediatric research that carries more than minimal risk, but that children who can assent may be enrolled if the risk is no "more than a minor increase over minimal." *Id.* at 98.

162. *Id.* at 90-93.

163. *Id.*

164. Cf. Jennifer K. Robbennolt et al., *Advancing the Rights of Children and Adolescents To Be Altruistic: Bone Marrow Donation by Minors*, 9 J.L. & HEALTH 213, 225 (1994-1995) (arguing that the mature minor doctrine is insufficient as a justification for most organ donation procedures involving young family members).

165. Perhaps if there is any benefit to the child from giving blood for research purposes it is that the experience may be helpful the next time she has to give blood or see a doctor or dentist in the future. See Y-L Lau & C-Y Yeung, *Parental Perception of the Effect of Venepuncture in Preschool Children in Non-Therapeutic Research*, 28 J. PAEDIATRICS & CHILD HEALTH 294 (78% of parents felt experience would benefit their child for future blood draws; 40% felt their child would be more confident for their next doctor or dentist visit).

3. *Interests of Children in New Experiences*

Benjamin Freedman and colleagues also defend non-beneficial pediatric research by appealing to the interests of parents and children in allowing parents to expose their children to a low level of risk.¹⁶⁶ They begin by arguing that the purpose of the IRB in protecting pediatric subjects is to “backup” parental decisions “by filtering out those studies that would impose an unacceptable level of risk.”¹⁶⁷ That is, on the authors’ view, the IRB is supposed to permit only those studies that an “informed and scrupulous parent[.]” could consent to.¹⁶⁸ As research would normally present a “new” experience for a child, a scrupulous parent would ask, “Is [my] child ready for this? . . . Are the risks sufficiently similar to those in my child’s everyday life that I should allow this experience at this time?”¹⁶⁹ In answering those questions, parental decisions about new risks are anchored to the risks of everyday life, and the regulations reflect that fact.¹⁷⁰ Thus, the authors contend that the “risks of everyday life” standard has normative force, “reflecting a level of risk that is not simply accepted but is deemed socially acceptable.”¹⁷¹

The problem with this view, though, is that it ignores one crucial fact about the risks that parents generally allow their children to face: Parents usually understand those risks as outweighed by the potential benefits to their children.¹⁷² Playing organized sports presents risks to children, but parents allow and frequently encourage or even cajole their children to play, not because the risks of injury are “deemed socially acceptable” in the abstract, but because the parents think the risks are outweighed by the benefits of participation to the child’s physical and emotional development. Even attending school carries risks of harm (e.g., children can be cruel to one another, traveling to school may carry risks); but we still send our children because it serves their best overall interests. The risks of these activities are justified by the benefits to the individuals incurring the risk. However, with non-beneficial pediatric research, we must ask what justifies exposure to the risk of research interventions when they offer *no* benefit to the individual child.

Freedman and colleagues suggest another role for the minimal risk standard in a justification for non-beneficial pediatric research, but it, too, suffers from the

166. Freedman et al., *supra* note 75, at 16-17.

167. *Id.* at 16.

168. *Id.*

169. *Id.*

170. *Id.* at 17.

171. *Id.*

172. For a thorough discussion of why we accept or ignore some risks and not others (and our irrationality with regard to the judgments implicit in our actions and beliefs), see Wendler, Significance, *supra* note 11, at 45-47, 80-81.

same shortcoming. They write: “[t]he risks of research are to a degree substitutive, rather than additive: research risks are undergone, but the risks of alternative activities are forgone.”¹⁷³ The problem is that the risks of forgone activities are most likely accompanied by benefits to the child, unlike non-beneficial pediatric research.

The authors helpfully stress that defining “minimal risk” without any reference to the ethical rationale behind it “is incapable of capturing anything significant by the term.”¹⁷⁴ But what they miss is that the ethical rationale behind any definition must be based on the ethical justification for exposing children to research risks. The purpose of exposing children to the risks of everyday life is very different from the purpose of exposing them to the risks of non-beneficial research, and thus, the minimal risk standard cannot justify non-beneficial pediatric research.

IV. “BEST INTERESTS” AS ONE FACTOR AMONG OTHERS

Our discussion thus far supports *Grimes*’ implicit invocation of the state’s *parens patriae* power and its limitation of parental authority based on the best interests standard. The court’s decision, however, is arguably vulnerable to the charge that it unwisely treated the best interests standard as an absolute bar to weighing other important considerations. This section first discusses legal support for treating the best interests standard as one factor among many. However, I then defend the court’s decision to determine the parental consent issue in light of the best interests standard. The court’s error was in how it *applied* the best interests standard to the issue at hand.

One tactic to take against *Grimes* is to argue that the best interests standard should not be dispositive in the research context. In many legal contexts the best interest of the relevant child is one consideration to be weighed among many.¹⁷⁵ One can then argue that with respect to research, the overall welfare of children must be considered along with the best interests of individual children who could be enrolled in research. This particular legal avenue is not optimal for reasons presented below, but it is still preferable to the *Grimes* ruling and is supportable by legal precedent.

173. Freedman et al., *supra* note 75, at 17.

174. *Id.* at 15. The authors point out that some procedures, like a splenectomy, are described in some contexts as “minimal risk” because of their necessity in the circumstances in which they are performed. Thus, what is to count as “minimal risk” is context-dependent. *Id.*

175. For an excellent and comprehensive assessment of the extent to which children possess legal rights with regard to their personal relationships, noting when state decision-makers do and do not appeal to a child’s best interests, see James G. Dwyer, *A Taxonomy of Children’s Existing Rights in State Decision Making About Their Relationships*, 11 WM. & MARY BILL RTS. J. 845 (2002-2003) [hereinafter Dwyer, *A Taxonomy*].

Recall that the *Grimes* court justified its reliance on the best interests standard by stating that it has “long stressed that the ‘best interests of the child’ is [its] overriding concern . . . in matters relating to children.”¹⁷⁶ As illustrated below, that statement is far-fetched, even as a description of the court’s own jurisprudence. No court, including the Maryland high court, settles *all* matters relating to children by a best interests analysis.¹⁷⁷ The Maryland Court of Appeals, in fact, recently acknowledged that context matters in determining whether the best interests standard is applicable: Though “the controlling factor in adoption and custody cases is . . . what serves the interest of the child, . . . it is clear that the context in which [an] issue arises is significant in determining the standard by which to evaluate the situation.”¹⁷⁸

Making the same point, the Supreme Court characterized the role of the best interests consideration within legal precedent:

“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 . . . for other, less narrowly channeled judgments involving children, where their interests conflict in varying degrees with the interests of others.¹⁷⁹

In fact, the reason that the best interests standard is generally dispositive in custody disputes is because other legally relevant interests neutralize each other.¹⁸⁰ When two legal parents compete for custody of a child, each comes to court with a fundamental, constitutionally protected liberty interest “in the care, custody, and control of their child[.]”¹⁸¹ With their interests in equipoise, the child’s is supposed to prevail. But in custody disputes between a legal parent and a third party, the best interests standard does not govern because of parental rights. Even where a third party (e.g., a grandparent) has raised a child for considerable time while a parent was “off pursuing other interests or wallowing in addiction,”¹⁸² most jurisdictions grant the parent a legal right to resume

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

177. As an obvious example, see earlier portions of the *Grimes* opinion itself. The court had to decide whether any evidence supported the claim that KKI owed a duty to the plaintiffs, and the court did not decide *that particular* children-relating matter according to a best interest analysis. Other considerations were relevant, such as whether the consent form created a contract between KKI and the parents. *Grimes*, 782 A.2d at 843.

178. *In re Roberto d.B.*, 923 A.2d 115, 126 (Md. 2007).

179. *Reno v. Flores*, 507 U.S. 292, 303-04 (1993).

180. *McDermott v. Dougherty*, 869 A.2d 751, 770 (Md. 2005).

181. *Troxel v. Granville*, 530 U.S. 57, 65 (2000).

182. Dwyer, *A Taxonomy*, *supra* note 175, at 942.

custody “absent proof of willful abandonment or present unfitness.”¹⁸³ Under law, an adult’s interest in raising his or her child may trump the child’s best interests.¹⁸⁴

But sometimes the best interests of a child must compete with other societal interests even in the context of a custody dispute between two fit legal parents. Consider the Supreme Court’s decision in *Palmore v. Sidotti*.¹⁸⁵ In that case, a Caucasian father petitioned in state court to modify a prior judgment granting custody of his son to the child’s mother, also a Caucasian, on grounds that the mother had begun cohabitating with an African-American man, whom she later married. The Florida state court awarded custody to the father, stating that the child, upon reaching school age, will be “more vulnerable to peer pressures [and] suffer from . . . social stigmatization” because of her mother’s interracial relationship.¹⁸⁶ The U.S. Supreme Court reversed, holding that state courts may not consider that the child may eventually suffer from existing racial prejudice: the law cannot control such prejudice, but it must not give it effect.¹⁸⁷ Regardless of whether the Florida court accurately assessed the child’s best interests, the point should be clear: although the fact that a child will eventually suffer from such racist bias is relevant to assessing her best interests, that consideration shall not control because of other important societal interests.

The Maryland Court of Appeals, which decided *Grimes*, handed down a similar opinion in *Griffin v. Crane* in 1998.¹⁸⁸ In that case, the trial court modified a prior judgment of custody for a father, awarding custody of two girls to their mother on grounds that the older girl had “reach[ed] an age where [she] at the very least exemplifies a need for a female hand.”¹⁸⁹ The state’s highest court reversed, holding that the Maryland Equal Rights Amendment to its state

183. *Id.*

184. *Id.* at 943. The Maryland Court of Appeals has stated:

[T]he non-constitutional best interests of the child standard, absent extraordinary (i.e., exceptional) circumstances, does not override a parent’s fundamental constitutional right to raise his or her child when the case is between a fit parent . . . and a third party who does not possess such constitutionally-protected parental rights. . . . In the balancing of court-created or statutorily-created ‘standards,’ such as ‘the best interest of the child’ test, with fundamental constitutional rights, in private custody actions involving private third parties where the parents are fit, absent extraordinary . . . circumstances, the constitutional right is the ultimate determinative factor; and only if the parents are unfit or extraordinary circumstances exist is the ‘best interest of the child’ test to be considered, any contrary comment in . . . our cases notwithstanding.

In re Roberto d.B, 923 A.2d 115, 130 (Md. 2007) (quoting *McDermott*, 869 A.2d at 808-09).

185. 466 U.S. 429 (1984).

186. *Id.* at 431.

187. *Id.*

188. 716 A.2d 1029 (Md. 1998).

189. *Id.* at 1033.

constitution forbids consideration of a parent's sex in determining parental rights.¹⁹⁰ Like the U.S. Supreme Court, this Maryland decision maintains that even if in reality the sex of a parent were relevant to discerning the best interests of a child in a custody dispute, a distinct societal interest, protected by law, prohibits consideration of that fact.

More recently, the Maryland high court had to decide whether a gestational mother, who was not genetically related to the fetuses she carried, had to be listed as the mother of the children when born on the birth certificate, even where the gestational mother had no intention of raising the twins. To the dismay of the dissent,¹⁹¹ the majority held that the best interests of the children were irrelevant.¹⁹² The court deemed dispositive that a state statute grants a man the opportunity to avoid legal parentage by demonstrating a lack of genetic link to a child, and, under the state's Equal Rights Amendment, concluded that a woman must have that same opportunity.

Maryland courts recognize and give weight to other interests—including interests not protected by the state constitution—that compete with the best interests of individual children in other contexts. For example, in cases in which parents disagree about a child's surname, "best interests" govern only sometimes, according to Maryland courts. In cases in which a child has "no initial surname"—in which the parents disagree at birth and continue to do so—courts should apply a "pure best interests" analysis.¹⁹³ However, if a father delays in seeking a paternity determination or objecting to the name given by the mother, the best interests standard does *not* govern. Rather, the father must demonstrate "extreme circumstances" that justify the name change because, in this "matter of . . . equity, . . . the doctrine of laches applies."¹⁹⁴

In other matters faced by courts, the interests of some child or children conflict with the interests of other children. For example, the Supreme Judicial Court of Massachusetts had to decide whether posthumously conceived children—conceived by a woman whose husband's sperm had been frozen before he died—should enjoy inheritance rights under its state intestacy statute.¹⁹⁵ That statute provided that posthumous children could inherit from a deceased parent, but it did not define "posthumous children."¹⁹⁶ The court stated that it should interpret the statute in light of "three powerful State interests: the best interests of

190. *Id.* at 1037.

191. *In re Roberto d.B.*, 923 A.2d 115, 142 (Md. 2007) (Harrell, J., dissenting).

192. *Id.* at 130.

193. *Id.* at 127.

194. *Id.* (quoting, with approval, *Schroeder v. Broadfoot*, 790 A.2d 773, 784-85 (Md. Ct. Spec. App. 2002)).

195. *Woodward v. Comm'r of Soc. Sec.*, 760 N.E.2d 257 (Mass. 2002).

196. *Id.* at 264.

children, the State's interest in the orderly administration of estates, and the reproductive rights of the genetic parent."¹⁹⁷ Notably, the court recognized that in considering the best interests of children, it could not focus solely on the best interests of posthumously conceived children: Granting "succession rights . . . to posthumously conceived children may, in a given case, have the potential to pit child against child" because that could "reduce the intestate share available to children born prior to the decedent's death."¹⁹⁸ Thus, in addition to the interests of genetic parents and other state interests, the court recognized that the best interests of some children had to be weighed against the interests of other children.

Arguably, a similar line of reasoning is applicable to research: A court or other agent of the state, in addition to focusing on the best interests of those children enrolled or to be enrolled in research, must also weigh the best interests of all children, generally. And a prohibition on all non-beneficial research is not in the best interests of children.

Given that the *Grimes* court's intervention into the family-child relationship was based on its *parens patriae* powers, it only makes sense that the court (or any other agent of the state) should consider the best interests of all children. The state, as *parens patriae* to all children, has a duty to "guard the general interest in youth's well-being,"¹⁹⁹ and thus must consider the implications of any policy or court holding on all children. As any parent of multiple children knows, it is not always possible to do what is in the best interests of one child in a particular situation without impacting the other children. It might be in the best interests of one child to be driven one hour away to play in some sporting event, though that might require exposing a sibling to the risks of highway driving without any compensating benefits awaiting at the end of the drive.

Nonetheless, case law exists supporting the court's heavy emphasis on the best interests standard in a context in which children are intentionally exposed to medical risks. Organ and bone marrow donation from a child or other incompetent person presents a similar ethical and legal issue: whether it is justified to perform an invasive medical procedure on a child or other person who cannot give binding consent where that procedure's sole medical purpose is to benefit a different person.²⁰⁰ Generally, when courts have been asked to authorize

197. *Id.* at 264-65.

198. *Id.* at 266.

199. *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944).

200. The *Grimes* court also discussed organ donation in a section denying the legal authority of parents to enroll their children in non-therapeutic research. However, the court discussed these cases to the extent that they support the view that judicial permission should be sought before non-therapeutic procedures are performed upon a child. The court was strongly dissatisfied with the IRB review of KKI's protocol and emphatically stated that Maryland courts "will not defer to

such procedures upon a guardian's request, they have not treated the best interests of the donor child as merely one factor among many.²⁰¹ They do not weigh the donor's interests against the interests of the recipient and of the parents who petitioned for court approval. Courts basically ask whether undergoing the procedure, with its attendant risks, is in the best interests of the donor child. Because donating confers no *medical* benefit to donors, courts look principally to the relationship between donor and donee, assessing the benefit to the donor of a

science to be the sole determinant of the ethicality or legality of such experiments." Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 855 (Md. 2001).

201. See, e.g., Curran v. Bosze, 566 N.E.2d 1319, 1331 (Ill. 1990) (holding that a parent "may give consent on behalf of a minor [child] for the child to donate bone marrow to a sibling, only when to do so would be in the minor's best interest"); Little v. Little, 576 S.W.2d 493, 500 (Tex. Civ. App. 1979) (upholding the trial court's decision to authorize the donation of a kidney by a fourteen-year-old sibling with mental retardation to her brother because of "strong evidence . . . that she will receive substantial psychological benefits" from the donation); see also *In re Doe*, 481 N.Y.S.2d 932 (N.Y. App. Div. 1984) (stating that a court's power to authorize a surgical intervention for an incompetent person to help a third party is confined by its *parens patriae* power, permitting authorization only where it is in the incompetent person's best interests); Robbenolt et al., *supra* note 164, at 214 (reporting that most courts deciding whether to authorize bone marrow donation from minor child have relied on "best interests" standard); Lisa K. Gregory, Annotation, *Propriety of Surgically Invading Incompetent or Minor for Benefit of Third Party*, 4 A.L.R.5th 1000 (2006) ("When considering whether an incompetent should undergo a surgical invasion for the benefit of a sibling, the cases [discussed herein] indicate an attempt by the courts to determine from an objective point of view what . . . will confer the incompetent the greatest net benefit, that is, what will be in the 'best interests' of the incompetent.").

In a widely cited Connecticut case, *Hart v. Brown*, the court declared that the parents of seven-year-old twins had the right to consent for one twin to donate a kidney to her sibling, holding that "natural parents . . . should have the right to . . . consent to an isograft kidney transplantation procedure when their motivation and reasoning are favorably reviewed by a community representation which includes a court of equity." 289 A.2d 386, 391 (Conn. Super. Ct. 1972). When will a court favorably review parents' reasoning? Here the court emphasized that the risks to the donor were very low and that the expected success of the surgery would be "of immense benefit to the donor" given that it would relieve stress on her family and prevent her from losing her sister. *Id.* at 389.

Some courts have appealed to the doctrine of substituted judgment—asking what the incompetent would choose to do if competent—instead of the best interests standard. However, putting aside whether it is appropriate to appeal to substituted judgment with persons who have never been competent, these courts basically engage in the substituted judgment analysis by examining what would be in the best interests of the incompetent. See, e.g., Strunk v. Strunk, 445 S.W.2d 145 (Ky. Ct. App. 1969) (authorizing a kidney donation from an incompetent person to his brother based on the importance of the donee to the donor's well-being); see also *Little*, 576 S.W.2d at 498 ("It is clear in transplant cases that courts, whether they use the term 'substituted judgment' or not, will consider the benefits to the donor as a basis for permitting an incompetent to donate an organ.").

continued relationship with the donee, as well as to any psychological benefit derived from helping to save the donee's life.²⁰²

Furthermore, ethically, concluding that the health benefits to all children should be weighed against the health risks imposed on some children does not explain how intentionally risking pediatric subjects avoids treating them merely as a means to an end. Weighing different interests and values along with the interests of individual children does not, in itself, imply consequentialist moral reasoning. However, if we take the consequences to children's health as the only relevant metric for assessing non-beneficial pediatric research, then we are essentially engaged in consequentialist reasoning without explaining how non-beneficial protocols respect the worth of their subjects. Indeed, if our only concern is health outcomes for all children, then, in principle, we cannot rule out the possibility that good consequences could justify exposing some small subset of children to significant risk for the good of others. Dave Wendler raises the example of testing vaccines: Perhaps that best way to maximize health benefits for all children would be to give, say, an experimental HIV vaccine to a small set of children and then test it by deliberately exposing them to HIV.²⁰³ But that, of course, would be unacceptable.

One might respond by arguing that, in reality, a policy permitting such high risk would not actually maximize good consequences, perhaps because of the outrage many would experience or a lack of trust the public would have in the ethics of research. But even if that response has the empirical facts correct, and even if a policy seeking to maximize health benefits to children should place an extremely low ceiling of acceptable risk on non-beneficial pediatric research, a consequentialist approach is inadequate. A consequentialist justification for any practice of human subjects research is unpersuasive because it cannot capture what would be wrong with a system that does unjustifiably expose some people to risks. If a researcher knowingly exposes a child to very serious risk without compensating benefit to her, we take the researcher's action to be wrong precisely because it *wronged the child*. The child's inherent value was disregarded. But on consequentialist diagnoses of what, if anything, would be wrong with such action, no sense can be made of the idea that the child was wronged. The action would be wrong on consequentialist grounds if a different course of action would have maximized overall welfare (act-consequentialism) or if the act contravened a rule which, if followed, would maximize overall welfare (rule-consequentialism). Neither consequentialist diagnosis makes reference to the value of the individual child or to the idea of wronging the child.

Thomas Nagel helpfully explicates this aspect of consequentialist moral reasoning. Consequentialist justifications are directed toward the "world at

202. Gregory, *supra* note 201, at 1000.

203. Wendler, *Significance*, *supra* note 11, at 97.

large,”²⁰⁴ meaning that the “object of justification . . . is everyone taken together”²⁰⁵ and not any particular individual. The interests of individuals matter to the consequentialist, but only as components of the overall state of the world, and are to be summed together to discern what act or policy is morally justified. Our researcher’s action might be unjustifiable to the child, but that moral fact would be an afterthought: It would be unjustifiable to the child—and to anyone else—primarily because it would not be justifiable to the world at large by failing to maximize overall welfare.²⁰⁶ Consequentialist moral reasoning cannot account for our firm commitment that some actions are wrong because the value of an individual has not been properly respected.

V. NON-CONSEQUENTIALISM, THE BEST INTERESTS STANDARD, AND PEDIATRIC RESEARCH

Nagel contrasts consequentialism with a non-consequentialist form of justification that is directed towards an individual person *as a distinct individual*.²⁰⁷ The essential idea in a non-consequentialist account is that an action or policy that affects a person in some way must be justifiable to her in light of reasons related to the “importance for [that] individual”²⁰⁸ of being related to in the way proposed by the considered act or policy. The justification for any act or policy must be assessed by comparing the reasons of *each individual, taken separately* (and not aggregated), for endorsing or rejecting that act or policy. This notion that acts (or omissions) or government policies must be justified to each individual *as an individual* conveys our common sense idea that we must treat and relate to each person in a way that expresses a respectful attitude toward *her* and not just to the overall state of the world. That our conduct

204. Thomas Nagel, *War and Massacre*, 1 PHIL. & PUB. AFF. 123, 137 (1972), *reprinted in* THOMAS NAGEL, *MORTAL QUESTIONS* 53, 68 (1979).

205. John Oberdiek, *The Morality of Risking: On the Normative Foundations of Risk Regulation* (2003) (unpublished Ph.D. dissertation, University of Pennsylvania) (manuscript at 93, on file with Van Pelt Library, University of Pennsylvania).

206. Oberdiek helpfully clarifies the distinction:

Under justification to the world at large, behavior is justified to persons *via* the world at large, or only after first being justified to the world at large; under justification to [an individual person], behavior is justified to the world at large *via* persons, or only after being justified to every individual taken separately.

Id. at 95.

207. Nagel, *supra* note 204, at 135.

208. Rahul Kumar, *Defending the Moral Moderate: Contractualism and Common Sense*, 28 PHIL. & PUB. AFF. 275, 281 (1999) [hereinafter Kumar, *Defending*]; *see also* T.M. SCANLON, *WHAT WE OWE TO EACH OTHER* 229 (1998) (stating that “the justifiability of a moral principle depends only on various *individuals’* reasons for objecting to that principle and alternatives to it”).

and policies must be justifiable to each individual, taken separately, characterizes a specific form of relationship among persons: that of mutual recognition of each individual's status as a person.²⁰⁹

To see the difference between consequentialist accounts and this non-consequentialist account of moral reasoning, consider a policy that seriously burdens some individuals, without their consent, to bring about slight benefit to many, such that the policy maximizes overall welfare.²¹⁰ A consequentialist would maintain that the burdened individuals have reason to endorse the policy because it maximizes welfare. But on the non-consequentialist account described, the slight benefits accrued to the many are not aggregated and offered to the burdened individuals as justification. Rather, the reasons that each individual has, *taken separately*, to endorse or reject the proposed policy are compared with one another, on a one-on-one basis. That is, what matters morally on this non-consequentialist view is whether any individuals "have personal reasons to reject this [policy] which are stronger than anyone's reasons to reject some alternative."²¹¹

We have discussed so far a non-consequentialist moral framework that expresses a commitment to the intrinsic worth of each individual person, requiring actions and policies to be justifiable to each person, not as a mere component in the general welfare of the world, but as an individual. In this sense

209. SCANLON, *supra* note 208, at 162; see also Kumar, *Defending*, *supra* note 208, at 284 ("[T]he aim [of moral reasoning] is to find principles that can serve as the basis for a shared understanding of the kind of consideration, in a person's practical deliberations, that persons may legitimately expect of one another, as a matter of mutual respect for one another as persons.").

210. See Derek Parfit, *Justification to Each Person*, 16 *RATIO* 368, 372 (2003).

211. *Id.* T.M. Scanlon provides a compelling example that illustrates the intuitive appeal of this account of moral reasoning. SCANLON, *supra* note 208, at 235. Imagine that Jones works in the transmitter room of a television station that is broadcasting a World Cup match being watched by millions of soccer fans. Electrical equipment falls on Jones' arm, crushing it and continually sending painful electric shocks through him, though his life is not endangered. Rescuing Jones from the pain would require shutting down the equipment—stopping the broadcast—for fifteen minutes, causing a great deal of displeasure to millions. Scanlon asks whether we should save him now or wait an hour until the game is over, and whether our answer depends on how many people's lives would be made slightly worse off should the broadcast be interrupted. Intuitively, it seems that Jones' co-workers should save him regardless of how many people's lives would be made slightly worse off by stopping the broadcast. Even if the displeasure aggregated across the entire world would be greater than the pain Jones was suffering, it seems clear that there is more reason to save Jones than to avoid interrupting the broadcast. That conclusion makes sense in light of a commitment to justification to each individual based on a comparison of the reasons that each affected person, taken individually, has to support or reject a principle requiring Jones to be saved. As Scanlon remarks, no individual in the class of persons watching the game could offer reasons regarding his own life that are as strong as the reasons Jones could provide to argue in favor of rescuing him. *Id.*

it is Kantian, though it does not follow the details of Kant's own theory. But it represents a way to understand Kant's Formula of Humanity, to treat each person as an end-in-herself and never merely as a means to an end.²¹² Demonstrating to an individual that she is treated in a manner justifiable to her on grounds she has reason to accept "is like reminding [her] that she was consulted before hand on what the appropriate course of action [or policy] would be."²¹³ She is treated as an end-in-herself, and not merely as a means, because she has reason to perceive the way in which she is treated by others or a government's policy as not merely something that has happened to her, but as what she has authorized herself.²¹⁴

Some commentators have assumed that non-consequentialist moral principles require the *actual* consent of research subjects in order for such research to be ethically justifiable. Critics have tended to assume that unconsented experimentation (including experimentation on young children) necessarily fails to treat research subjects as ends-in-themselves. Unsurprisingly, then, *Grimes* assumes that the central justification for non-beneficial pediatric research must be utilitarian. I will argue that this assumption is incorrect and that there is both a non-consequentialist ethical justification and a corresponding legal argument, invoking the best interests standard, for non-beneficial pediatric research. Before turning to those arguments, let us examine other non-consequentialist analyses of this research, not already discussed above, and see why they are unpersuasive.

A. Ramsey's Objection to Non-Beneficial Pediatric Research

Let us begin with Paul Ramsey's well-known, passionate objection to enrolling children in non-beneficial research.²¹⁵ Ramsey writes unequivocally that neither children nor incompetents should ever be exposed to research risks for the good of others.²¹⁶ Non-beneficial pediatric research, in Ramsey's words, is a form of "barbarism."²¹⁷

Ramsey's argument rests on the claim that ethically permissible research

212. IMMANUEL KANT, *GROUNDING FOR THE METAPHYSICS OF MORALS* 35-37 (James W. Ellington trans., Hackett Pub'g Co. 1993) (1785).

213. RAHUL KUMAR, *CONSENSUALISM IN PRINCIPLE: ON THE FOUNDATIONS OF NON-CONSEQUENTIALIST MORAL REASONING* 14 (2001) [hereinafter KUMAR, *CONSENSUALISM*].

214. *Id.*

215. PAUL RAMSEY, *THE PATIENT AS PERSON: EXPLORATIONS IN MEDICAL ETHICS* (1970) [hereinafter RAMSEY, *PATIENT AS PERSON*]; Paul Ramsey, *Children as Research Subjects: A Reply*, *HASTINGS CENTER REP.*, Apr. 1977, at 40; Paul Ramsey, *The Enforcement of Morals: Non-therapeutic Research on Children*, *HASTINGS CENTER REP.*, Aug. 1976, at 21 [hereinafter Ramsey, *Enforcement*].

216. RAMSEY, *PATIENT AS PERSON*, *supra* note 215, at 11.

217. *Id.* at 12.

requires the “reasonably free and adequately informed consent” of the human subject.²¹⁸ Ethical research has other requirements (e.g., protocols must be of “good experimental design”), but such requirements, according to Ramsey, also apply to research on animals. Humans are distinct in having the capacity to be “joint venturers” in the quest to better their own individual and collective health, and respecting each potential subject entails asking for her consent to join in that quest. Given that children cannot consent, it follows logically, according to Ramsey, that they must never be enrolled in non-beneficial pediatric research.²¹⁹

However, that conclusion does not follow. That informed consent is an ethical requirement for enrolling capacitated adults does not imply that it is a prerequisite for enrolling children in research. Duties to rational adults differ from duties owed to children because, in part, the former have the capacity to make decisions for themselves. Researchers must respect rational adults’ capacity to be or not to be “joint venturers.” Whether it is ethical to perform research on those who cannot be joint venturers is a separate question.

We need look no further than Ramsey’s own text for an obvious illustration. After stating that informed consent is a requirement for enrolling an adult in research, he states: “This holds without exception for ordinary medical practice.”²²⁰ Doctors commit a battery where they provide therapy to a capacitated adult without consent. That fact does not imply that doctors may not treat a young child. Indeed, hedging his absolute pronouncement, Ramsey acknowledges at least one exception to the rule that medical therapy requires informed consent: the case in which “consent may properly be assumed or implied when [someone is] in extreme danger and cannot [herself] consent explicitly,”²²¹ such as an unconscious accident victim in an emergency room. In stating that we may assume an unconscious victim’s consent, Ramsey is basically stating that the victim has very good reason to authorize the doctor’s treatment though the victim cannot actually consent. Those reasons are the basis for concluding that the victim *would* consent.

Furthermore, despite explicitly recognizing only one instance in which consent may be inferred, Ramsey implicitly acknowledges others. First, he rightly notes that informed consent cannot require that a prospective patient or subject be told of *every* possible consequence or risk associated with a proposed procedure. The consent process would be overwhelming in numerous ways.²²²

218. *Id.* at 2, 3.

219. *Id.* at 11.

220. *Id.* at 7.

221. *Id.* at 7.

222. *Id.* at 3. As the Court of Appeals for the District of Columbia stated in the leading case on informed consent, to require *full*, as opposed to reasonable, disclosure of every risk, “no matter how small or remote” is “obviously prohibitive and unrealistic to expect.” *Canterbury v. Spence*, 464

Many jurisdictions take a patient to have provided informed consent, despite not knowing the remote unknown risks, if the physician disclosed what a *reasonable* person in the patient's situation would consider relevant.²²³ A physician must consider what information a patient or subject has good reason to know and not to know. Adequate informed consent is consent to the entire procedure or intervention: The consent is *explicit* with regard to what the patient knows and it is *implicit* with regard to what the patient has good reason *not* to know.²²⁴

Second, Ramsey highlights that "consent is a continuing and repeatable requirement."²²⁵ But that fact, of course, does not imply that a physician must constantly ask a research subject for consent to continued participation. Some events do require a researcher to present newly learned information to a subject where that information would be material to a decision whether to continue. But generally, the researcher does not have a duty to ask constantly for the ongoing consent. Consent is implied: that is, there are good reasons from the perspective of each research subject not to require such a rule. It would provide no extra protection for research subjects and it would be ridiculously burdensome, not to mention annoying.

Thus, we can ask whether children have good reason to authorize a policy permitting non-beneficial pediatric research and/or being enrolled in a minimal risk protocol. Like unconscious patients, young children cannot give actual consent, but, as with unconscious patients, we can ask whether they have good reason to endorse the practice of non-beneficial research and their participation in it. Answering the fundamental ethical question may involve an inquiry into the reasons that have importance from the perspective of each child that speak in favor of non-beneficial pediatric research.

B. Brock's Rawlsian Argument

Dan Brock takes this promising approach to defending non-beneficial pediatric research, asking whether young children would, hypothetically, consent to participate in research.²²⁶ The ethical justification I offer is indebted and similar to Brock's, but differs in detail because Brock's argument, as formulated,

F.2d 772, 786 (D.C. Cir. 1972).

223. *Canterbury*, 464 F.2d at 787. Most states do not follow *Canterbury*, instead requiring physicians to provide the information that a reasonable *physician* would provide under the circumstances. However, a "majority of the population and doctors now reside in jurisdictions that have rejected [the physician-centered] standard of disclosure." PATRICIA A. KING ET AL., *LAW, MEDICINE, AND ETHICS* 149 (2006).

224. As Ramsey states, the informed consent document contains both explicit and "implied" permissions. RAMSEY, *PATIENT AS PERSON*, *supra* note 215, at 6.

225. *Id.*

226. Brock, *supra* note 18.

is problematic.

Brock aims to establish that it is morally permissible to enroll children in non-beneficial research because children have a moral obligation to participate in research.²²⁷ The basis of the alleged obligation is the benefit conferred upon children by medical progress due to *past* human subjects research. The underlying moral principle is one of fairness:

If one has freely participated in and accepted the benefits of a practice in which others have freely assumed burdens required by the practice for the benefit of others besides themselves, then one has a duty of fairness to do one's part by assuming similar burdens when one's turn comes in the practice to do so.²²⁸

As children do not “freely participate[] in and accept[] the benefits” of medical care and research,²²⁹ it does not follow from this principle that children have a duty of fairness to assume some burdens of medical research. To accommodate that fact, Brock suggests that it is reasonable to assume each child *would* consent to participate in and accept the benefits of research, given that it would be in each child's rational self-interest to do so.²³⁰ Thus, on Brock's reformulation, each child has a duty of fairness to children of different generations to contribute to research given that each hypothetically consents to the benefits of the practice.

But Brock first recognizes another obstacle to the argument: if one knows when in time that she exists—i.e., she knows that she already benefits from past research on children and will continue to do so—then she has no self-interested reason to agree to take on any burdens of research.²³¹ To address this problem, Brock suggests that we think of each child as giving hypothetical consent to the practice of non-beneficial pediatric research behind a Rawlsian veil of ignorance that blinds each party to knowledge of the generation to which she belongs.²³² If one does not know whether one belongs to a past, present, or future generation, but does assume that “the expected benefits of such research over time exceed[] its burdens,” each party behind the veil would agree to accept the benefits and burdens of the practice.²³³

Before assessing whether Brock's argument represents a promising strategy,

227. *Id.* at 91-92.

228. *Id.* at 92.

229. As Brock mentions, adults, like children, have never had the choice to live in social conditions which include the benefits of past medical research. We cannot ask our physicians to treat us without appeal to any knowledge that is based on past human subjects research. *Id.*

230. *Id.*

231. *Id.*

232. *Id.*

233. *Id.*

note that it would have to be supplemented if it is to be distinguished from a consequentialist view. Brock states that parties behind the veil would consent to a research policy if, over time, the benefits of the practice outweigh the burdens, presumably in relation to other alternative policies. But that is, in essence, how policies would be evaluated from a consequentialist perspective. As it stands, then, the argument does not offer an alternative to a consequentialist justification. What the argument needs is a non-consequentialist explanation as to why the parties would not consent to a policy that would allow some small set of children—say, wards of the state—to be exposed to serious risk when that exposure would bring about great overall benefit in comparison to the burdens placed on those few.

Instead of attempting to differentiate Brock's approach from a consequentialist analysis, I suggest rejecting the appeal to an underlying moral principle based on fair reciprocity *applied across generations*. As Brock recognizes, a principle of fair reciprocity is inapposite to the relations between generations, and the inappropriateness of applying it in this context cannot be solved by blinding parties to knowledge of their generation. The fair reciprocity principle is relevant to determining a morally acceptable division of advantages and burdens of a practice. In Brock's view, a present-day prohibition on non-beneficial pediatric research would not simply fail in furthering the interests of children in the future, but also would *wrong* past subjects by violating a duty of fairness owed to them. But research subjects of past generations cannot reap any of the advantages produced after their time; they could never have expected to reap benefits from the continuation of medical research into the future. I do not deny that we have good reason to honor and be grateful to past research subjects for their sacrifices; I deny that we must expose children to research risks now in order to be *fair* to past research subjects.

Similarly, Brock's argument implies that a prohibition on non-beneficial pediatric research would be unfair to future children. Let's put aside concerns related to Parfit's non-identity problem²³⁴ and stipulate that it is possible to wrong future persons by choosing one policy rather than another, including by failing to enhance medical knowledge for their benefit. It still seems implausible

234. DEREK PARFIT, REASONS AND PERSONS 351-79 (1984). The non-identity problem poses a challenge for thinking about duties to future persons. If a person can be harmed only by an action or policy that makes that person's life worse off than it otherwise would have been, then it follows that a person is not harmed by an act or policy that was a but-for cause of that particular person's coming into existence. If we adopt policy *A* now (say, with regard to conserving resources or conducting medical research) instead of policy *B*, even if policy *A* were disastrous and policy *B* would produce far better outcomes, future persons would not be harmed by our adoption of policy *A* if they, themselves, would not have existed had we adopted policy *B*. For an argument that we can *wrong* future persons even where we have not harmed them (based on the "non-identity" consideration), see Rahul Kumar, *Who Can Be Wronged?*, 31 PHIL. & PUB. AFF. 99 (2003).

that we would wrong future children *by acting unfairly* toward them because future children do not bestow a benefit on today's children. An explanation for any wrongdoing would have to be different.

The problem with the view, so far, is that it takes fairness to be connected to the idea of reciprocity across generations. However, to defend the appeal to Rawls, one might argue for *different kinds* of fairness. One kind of fairness is based on an idea of reciprocal relations among participants in a practice; but, perhaps, there is a different sense of fairness that is applicable across generations. Indeed, Rawls himself seems to endorse this possibility in his discussion of duties to future generations in *A Theory of Justice*. He begins by stipulating that the parties in the original position do not know the generation to which they belong: they do not know their "stage of civilization."²³⁵ But because they are contemporaries (a fact that they do know), they lack reason to endorse any policy of saving capital for future generations. As Rawls states, "[e]arlier generations will have either saved or not; there is nothing the parties can do to affect that."²³⁶ Thus, "to achieve a reasonable result," Rawls states that we should understand the parties in the original position to care about their immediate descendants and that they would wish their predecessors to have followed any principle they adopt.²³⁷ The parties proceed to ask how much wealth they are willing to save at each stage of civilization, presuming that each prior generation saved according to the same standard and keeping in mind the objective to maintain a material base adequate to realize just institutions in which basic liberties are protected.²³⁸

Rawls argues that the just savings principle is based on the idea of each generation doing its fair share to preserve a just society, each generation saves for the next in return for what it received from the past.²³⁹ Brock's argument might be construed as analogous. No reciprocal relationship exists among the generations, but nevertheless each generation has a duty of fairness to maintain some good—like a just society or the health of its citizens—through time.

The argument is flawed, though. As Rawls states, because the parties in the original position know they are contemporaries, "unless we modify our initial assumptions, there is no reason for them to agree to any saving whatever."²⁴⁰ Thus, Rawls modifies the assumptions built into the original position "to achieve a reasonable result": The parties now are to choose a principle of just savings based on what they wish past generations had saved despite the possibility that past generations might have saved nothing or insufficiently. But assumptions

235. JOHN RAWLS, *A THEORY OF JUSTICE* 254 (rev. ed. 1999).

236. *Id.* at 255.

237. *Id.*

238. *Id.* at 255-56.

239. *Id.* at 256-57.

240. *Id.* at 254-55.

cannot be built into the original position for the sake of achieving a result deemed reasonable before determining the outcome of the procedure. The original position is supposed to define a decision procedure that yields an outcome we have good reason to believe reflects moral principles because the assumptions that shape the original position reflect our firm moral commitments. The assumptions that shape the original position cannot be totally unmotivated (or motivated only to reach a result predetermined to be the reasonable one), or else we should not see any outcome as a moral requirement.

To clarify, recall that for the purpose of discerning the principles of justice for the basic structure of society, Rawls argues that the parties in the original position should be blinded to facts about themselves—such as their race, social class, or natural assets—that “seem arbitrary from the moral point of view.”²⁴¹ These moral constraints on the parties reflect our firm moral conviction that some “information is not morally relevant in arguments for principles of justice”²⁴² precisely because it is morally arbitrary. Because the conditions under which principles of justice are chosen reflect our commitments regarding fairness, we have good reason to conclude that the outcome of the agreement is also fair.²⁴³ The fairness of the bargaining position “transfers” to the principles chosen.²⁴⁴

The question, then, with regard to the argument for the just savings principle (and any analogous argument to justify non-beneficial pediatric research) is this: In applying the original position decision procedure at the legislative stage, what independent moral basis supports stipulating that the parties should decide on a just savings principle (or policy on pediatric research) in light of their wishes about their predecessors’ policies, regardless of the actual policies adopted by their predecessors? For any agreement to reflect a moral requirement of fairness, the constraints on the parties must reflect widely-shared and non-controversial convictions about what information is morally irrelevant to the decision procedure. The built-in assumption that the parties should consider the principle they wish their predecessors followed does not reflect widely shared, firm moral convictions. Without anchoring that built-in assumption in our shared moral convictions, we might nevertheless conclude that the parties in the original position would agree to a just savings principle or a policy authorizing non-beneficial pediatric research, but we would have no reason to view that outcome as morally binding, conveying a requirement of intergenerational fairness.²⁴⁵

241. *Id.* at 14.

242. SAMUEL FREEMAN, RAWLS 143 (2007).

243. FREEMAN, *supra* note 242, at 142; RAWLS, *supra* note 235, at 11.

244. FREEMAN, *supra* note 242, at 142.

245. I owe this point to very helpful discussions with Rahul Kumar.

C. A Non-Consequentialist Proposal

We begin by asking whether each child has reason to endorse a *policy* permitting non-beneficial pediatric research. We must assess and compare the benefits and burdens to individual children of living under the alternative policies we might adopt. Let's consider three options: a complete prohibition on non-beneficial research; a policy permitting non-beneficial pediatric research but with an extremely low ceiling on acceptable risk; and a policy allowing non-beneficial pediatric research with a higher risk ceiling. In this general discussion, I leave open whether the extremely low risk ceiling for the second option equates with minimal risk or allows a "minor increase over minimal" risk, as the federal regulations permit.²⁴⁶

The second option appears preferable to the first. This claim rests on the empirical assumption that the practice of non-beneficial pediatric research does, in fact, provide more net benefit to each child than that child would receive in a regime that bans non-beneficial pediatric research. This assumption is supportable.

First, most obviously, medical knowledge leads to new, safer, more effective treatments. Each child benefits from medical advancement by either receiving a treatment that otherwise would not have been available, or "from the availability of the treatment and the assurance that should the child need it, it would be available."²⁴⁷ If "newer[,] more effective[] medication . . . has not been subjected to rigorous study in pediatric populations," pediatricians "sometimes prescribe . . . less effective, but well-tested medication."²⁴⁸ The need to withhold possibly superior treatments due to a lack of research "keeps children from benefiting from state-of-the-art medication."²⁴⁹

Second, a prohibition on a child facing non-beneficial yet minimal (or minor increase over minimal) risk will only increase the risks the child will face in the medical care setting. Experimentation on children would not decrease; it would be transferred to the clinical setting where effects may not be as closely

246. Furthermore, how the appropriately low ceiling on acceptable risk should be precisely defined is a complicated topic unto itself. I am not defending or criticizing the definition of "minimal risk" in the federal regulations, and I do realize that I am not offering any alternative definition for the acceptably low ceiling on risk. One hope of this article is that a persuasive justification for non-beneficial pediatric research can help shed light on how we should define that level of risk, although I am unsure that it will.

247. Brock, *supra* note 18, at 91.

248. Ass'n of Am., Physicians & Surgeons, Inc. v. FDA, 226 F. Supp. 2d 204, 207 (D.D.C. 2002) (discussing Regulations Requiring Manufactures To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,632 (Dec. 2, 1998) (codified as amended in scattered sections of 21 C.F.R.)).

249. *Id.*

monitored and where medical knowledge gained will not be generalizable. According to the American Academy of Pediatrics, “the shortage of pediatric research creates an ethical dilemma for physicians, who ‘must frequently either not treat children with potentially beneficial medications or treat them with medications based on adult studies or anecdotal empirical experience in children.’”²⁵⁰ Inadequate pediatric labeling not only deprives children of optimal treatment, but also “exposes [them] to the risk of unexpected adverse reactions” in the clinical setting.²⁵¹

Third, the extremely low ceiling on risk to which we may permissibly expose children in research also contributes to the empirical assumption that permitting non-beneficial pediatric research is in the best interests of each child. The slight risks appear outweighed by the risks that would be transferred to medical care if non-beneficial pediatric research were prohibited altogether.

Inevitably, some children will be severely harmed in minimal risk research. But even these children could not reasonably object to a policy permitting non-beneficial pediatric research in favor of the *Grimes* prohibition. Were non-beneficial pediatric research prohibited, the risks they would have faced in the medical care setting would have been even worse than the risks they faced under a policy permitting minimal risk research.

Next, the third option, which would allow a high ceiling on risk, is unacceptable. Any policy that every child has good reason to endorse must place a very low ceiling on permissible risk exposure. First, we generally do not impose the moral duty on adults to help strangers when helping will come at a significant cost or risk. There is reason to be even more cautious with the risks we impose on children, and the risks that we allow their parents to impose, given their vulnerability and their inability to consent. Second, it is impossible to quantify the benefits that each child actually accrues from the practice of medical research. Given that impossibility, extreme caution warrants setting a very low limit on risk to ensure that the benefits of the practice do outweigh the risks for each child. Third, given that most children will not participate in the system and not take on any burdens, it is unfair if a few children take on very serious risks, bearing a very heavy burden for the practice. Fourth, allowing more risk will make it practically impossible to enroll any child in research whose parent comprehends that her child may be exposed to more than minimal (or more than a minor increase over minimal) risk, such that the system will not benefit each child. More importantly, we would have to suspect that children placed in such risky research were enrolled only because their parents did not comprehend the

250. INST. OF MED., *supra* note 31, at 60.

251. Regulations Requiring Manufacturers To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 62 Fed. Reg. 43,899, 43,900-01 (Aug. 15, 1997) (codified in scattered section of 21 C.F.R.).

risks involved.²⁵²

One might suppose that a system that allows at least *some* trials that are more risky—or even very risky—could produce even more benefits for children generally. Let's return to Wendler's example of testing an HIV vaccine by giving it to a small number of children and then deliberately exposing those children to the virus.²⁵³ Perhaps, from the perspective of each child the risk of contracting HIV would be higher during his life than the risk of being one of the few randomly chosen subjects, and therefore there would be reason to endorse a policy allowing such a study.

That conclusion is false, though. Any child potentially chosen to be a guinea pig for the vaccine has very good reason to reject such a policy, which would obviously treat any such child arbitrarily. Reasons exist to reject a proposed policy besides those related to the policy's prospects for improving one's well-being.²⁵⁴ The fact that a policy will intentionally inflict harm on some people on an arbitrary basis provides reason to reject such a policy.²⁵⁵ We would condemn on similar grounds any secret government policy of holding public executions of persons who are, unbeknownst to the public, actually innocent, even if those executions reduced each individual's risk of being a crime victim by deterring potential criminals.

Two interrelated questions remain: 1) Even if each child has reason to endorse a policy permitting non-beneficial pediatric research, do we nonetheless treat any child as merely a means by placing the child at (low) risk in a specific protocol? 2) Does a government policy permitting such research invite parents to violate their parental duties by asking them to treat their children contrary to their best interests?

Whether parents have a general duty to advance their child's best interests is irrelevant. Even if they do, that duty does not entail the obligation to advance their children's interests by making sure their children are free riders on a practice from which they benefit. A parent may have good reason to decline enrolling her child in a minimal risk, non-beneficial study; perhaps her child is particularly vulnerable physically or especially anxious or fearful (these are some of the reasons why we require parental consent for research).²⁵⁶ But to accept the

252. I am obviously assuming that any acceptable policy allowing pediatric research would require, as the federal regulations do, the consent of a child's guardian prior to research participation. 45 C.F.R. § 46.408 (2007).

253. Wendler, *Significance*, *supra* note 11, at 97.

254. SCANLON, *supra* note 208, at 206-13.

255. *Id.*

256. If minimal risk research does benefit all children, one might argue that a policy requiring parents to enroll their children at least once in research could be justified, at least under certain circumstances. However, if researchers generally are able to recruit a sufficient number of pediatric

benefits of a practice for one's child while taking the child to have no reason to participate in research expresses a disrespectful attitude toward other children who sustain the research. It is to say that one's child is special in a way that others are not, that it is acceptable to view others as merely a means to one's own ends.

One might object that accepting the benefits of the practice does not imply that one necessarily expresses a disrespectful attitude toward participants. A parent may think it is wrong for *any* child to be enrolled in research, but may nevertheless let her child accept the benefits of the practice reluctantly. After all, what is a parent to do when her child is ill? Refuse medical attention? But this response is not compelling. Once we understand that pediatric research, including non-beneficial pediatric research, benefits each child, including each pediatric subject, on what basis could a parent maintain her condemnation of the practice? As we have seen, the problem with *Grimes* is that the court failed to consider how its prohibition, if strictly obeyed, would make each child worse off. Upon acknowledgement that the *policy* is justifiable to each child, it becomes disrespectful to refuse to allow one's child to participate in the practice without any overriding considerations (e.g., one's child is particularly vulnerable). The fundamental ethical question raises concern that enrolling a child in non-beneficial pediatric research treats her solely as a means; but as it turns out, it is a principled refusal to let one's child participate in the practice that treats *other* children as merely a means to one's ends.

We now see that the *Grimes* court correctly appealed to the best interests standard to determine whether parents should have legal authority to enroll their children in research, but it misapplied the standard to the facts. What is needed is a lens to view the facts more broadly than that usually employed in a best interests analysis. *Grimes* narrowly looked to the risks and potential benefits presented to each subject by a non-beneficial protocol and, given that there is risk but no benefit, found that research participation could never be in a child's best interests. But though the court acknowledged the potential detrimental effect of its holding on the interests of children generally—aggregated across all children—it failed to consider that its rule could make *each* child worse off, *including any child who is or might be enrolled in research*. The underlying idea of this argument is that a *policy* allowing at least some non-beneficial pediatric research *is* in the best interests of each and every child, even though the policy itself puts some children at risk of being enrolled, at some point, in non-beneficial research.²⁵⁷

subjects to conduct important research, then it seems best to allow parents to decide whether or not to enroll their children, knowing whether their children are, for example, particularly anxious or fearful in medical settings.

257. The legal argument in this Section and the related ethical argument presented in Section

D. Implications

One practical implication of the preceding argument is that the informed consent process, involving children's guardians, should be amended. Because informed consent requires researchers to inform potential subjects of all information material to the guardian's decision, parents should be informed of the basic justification for exposing their child to research risk. For any non-beneficial protocol or one involving non-beneficial interventions, parents should be informed that the research interventions are not, themselves, in the best interests of the child. But it is also appropriate to inform parents that all children who have access to medical care do benefit from research and the contributions made by research subjects.²⁵⁸

One might object that it would unduly induce parents to consent if we tell them that their child benefits from other research and that they should consider that fact: it might make them feel guilty if they do not consent. But why would this be *undue* inducement? If it is *true* that parents should be willing to enroll their children in minimal risk research, it is not unduly coercive to tell parents that their child benefits from the research participation of others.

Indeed, a strength of the view is that it suggests a plausible amendment to current informed consent practices. Consider the other proposed justifications for non-beneficial pediatric research. Should parents be informed that a non-beneficial protocol is actually justified by the best interest of their three-year-old child because the parents could use research participation to teach altruism to the child? Or might we suggest to parents that enrolling their children is a good idea because their children would otherwise be doing something else carrying at least minimal risk? Or that the parent's child owes a duty to children long gone who contributed to research? None of these suggestions is plausible. But it seems appropriate to inform parents of the importance of medical research to each child.

My account also makes good sense of our significant moral concern over whether underprivileged children—particularly children underserved by the healthcare system—are overrepresented in research.²⁵⁹ The data is equivocal regarding whether the medically underserved are overrepresented in research,²⁶⁰ but the matter morally requires attention. If the justification for enrolling a child in a non-beneficial protocol is tied to the benefits the child accrues from the practice, then we ought to ensure that pediatric subjects do benefit from the

V.B, are in accordance with the approach to risk assessment that Carl H. Coleman has recently advocated with regard to incapacitated adults. Coleman, *Decisionally Incapacitated*, *supra* note 73.

258. *See id.* at 53 (making a similar suggestion with regard to decisions made for incapacitated adults).

259. *Cf. id.* at 48 (arguing that the justification for a policy permitting research enrollment of incapacitated adults requires that such adults have access to state-of-the-art health care).

260. ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 80.

healthcare system.²⁶¹ One might observe that even the underserved benefit from the advancement of medical knowledge, but even so, it would be unfair if those who derive the least benefit from the practice are those most burdened by it.²⁶²

Another strength of the view is that it explains why the ceiling on acceptable research risk can vary depending on the state of medicine at a specific time or during an exceptionally dangerous epidemic. As I argued, the fact that children would face increased risks in the clinical setting without non-beneficial pediatric research plays a role in justifying non-beneficial pediatric research. Therefore, the degree of risk in the medical care setting carries implications for the amount of acceptable research risk. The National Commission offered similar reasoning:

In exceptional situations, dangers to children or the community resulting from a failure to involve children in research might exceed whatever risk is presented by that research. For instance, the threat of an epidemic that could be offset by developing a safe and effective vaccine might justify research involving greater than otherwise acceptable to establish safety, efficacy, and dosage levels for children of different ages.²⁶³

If children generally face very severe risks in the medical care setting, this circumstance speaks in favor of allowing somewhat more risk in the research setting if exposing children to somewhat increased research risks will help significantly reduce the risks they face from medical care.

This implication of the view represents an advantage over other proposed justifications. For example, if non-beneficial pediatric research is justified because of its alleged *non-medical* benefits for enrolled children (such as benefits associated with moral education), then an increase in allowable research risk is justifiable only to the extent that those non-medical benefits would increase under the circumstances. Thus, in Ross's view, an increase in research risk would be permissible only if the circumstances permit more effective training in altruism. Though I am skeptical, perhaps the moral educative benefit from research participation will increase in very dangerous times. Nonetheless,

261. The right solution is not to limit the research participation of the underserved, but to ensure universal access to good medical care—but that is a separate topic, of course.

262. One might also suggest, perhaps, that it is the lack of informed consent that explains our moral concern for any overrepresentation of the underserved on the grounds that the underserved's parents are less educated and more prone to misunderstanding the purpose of research. See ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 80 (suggesting that the process of informed consent serves as a "social filter" because research, at the time, concluded that "[b]etter educated and wealthier individuals are more likely to refuse to participate and are underrepresented in most research"). But while that is a concern, an overrepresentation of the underserved in research would be morally problematic even if informed consent were perfect because they would be bearing more of the burden of a practice from which they benefit least.

263. NAT'L COMM'N, *supra* note 18, at 127.

undoubtedly any increased in permissible research risk would be justified publicly by appeal to the increased health risks children would face outside the research context during such times, rather than to any increase in moral educative benefit children might receive by research participation.

Despite these strengths, the view has at least one possible drawback: it rests on an empirical assumption that may turn out to be false for some children who are or may be enrolled in research, or, even if true now, may one day cease being true. That empirical assumption is, of course, that each child is better off under a policy permitting non-beneficial pediatric research than under the *Grimes* prohibition. If the empirical assumption is or turns out to be false, does that imply that it is unethical to do non-beneficial research on a child who is not made better off by a policy permitting non-beneficial research? Perhaps. But in the next section I present a second possible justification for non-beneficial pediatric research, one that does not rest on the empirical assumption.

VI. REASON TO HELP OTHERS

A. Reviving McCormick

My argument thus far has appealed to the benefits to each child of a policy that permits non-beneficial research, with a low ceiling on risk, over a policy in line with the *Grimes* prohibition. I now present an additional reason associated with any person's point of view, including each child's, to reconcile non-beneficial pediatric research and the respect due each child. This argument focuses on the duty each person has to help others when one has the opportunity to do so at little to no cost to herself. I am not presenting an entirely novel argument. Rather, it coincides with my interpretation of Richard McCormick's work. The literature reveals that McCormick's arguments have not won the day among commentators.²⁶⁴ The additional justification for non-beneficial pediatric research I offer builds on the best, most charitable interpretation of McCormick's work, and on the non-consequentialist framework presented above.

As mentioned, Paul Ramsey argues against non-beneficial pediatric research because of children's inability to consent. McCormick counters that enrolling a child in non-beneficial pediatric research can be respectful of her status as a person because each child *would* consent based on the fact that she *ought* to consent.²⁶⁵ Describing what he means by "ought," McCormick states that it is

264. See, e.g., ROSS, CHILDREN, FAMILIES, *supra* note 18, at 77-79 (rejecting McCormick's view); Wendler, Significance, *supra* note 11, at 66-70; Brock, *supra* note 18, at 81-101 (presenting justifications for pediatric research but not discussing McCormick's or any similar view).

265. Richard A. McCormick, *Experimental Subjects: Who Should They Be?*, 235 JAMA 2197 (1976) [hereinafter McCormick, *Experimental Subjects*]; see also McCormick, *Experimentation*,

“not based on the fact we [or the child] will derive any benefit from such experiments . . . , but because others will derive benefit at no cost or minimal cost”²⁶⁶ As McCormick argues, “[t]here are things we *ought* to do for others simply because we are members of the human community,” which are “not works of charity or supererogation . . . but our personal bearing of our share that all may prosper.”²⁶⁷

One might interpret as *empirical* McCormick’s claim that a child *would* consent because she ought to.²⁶⁸ That is, on one reading of McCormick, he argues that most competent adults actually do help others when they can at little to no cost to themselves (or that most do, in fact, consent to minimal risk research when invited to) because they ought to. Thus, on this reading, McCormick is merely predicting what each child will do in the future based on what most adults do. If this interpretation reflects McCormick’s argument, then one might question whether any empirical data support the claim; McCormick would have to concede if the data are unresponsive.

However, this interpretation does not capture the essence of McCormick’s view and is in tension with his text. He articulates how we should decide what a child *would* choose, but nowhere does he discuss what most adults actually do choose, and he explicitly recognizes the possibility that not enough people actually do volunteer.²⁶⁹ Rather, in claiming that a child *would* consent because she *ought* to consent, McCormick is making a normative, not empirical, claim about what each person has *good reason* to do. He states that the criterion for a parent’s proxy consent is not any predictive factor, but “its reasonableness,”²⁷⁰ regarding the “goods definitive of [the child’s] well-being” that he has reason to choose or “at least . . . could not reasonably object to.”²⁷¹ Being a member of the human community and helping others are “goods definitive” of a person’s well-being, on McCormick’s account, and thus each person has good reason to help others when one can do so “at no cost or minimal cost to [oneself].”²⁷²

There is no need to address the controversial question of whether one’s own well-being is advanced by helping others. It is sufficient to recognize that each person does have reason to help others when one can do so at little or no cost to oneself. Furthermore, the fact that it is legitimate to associate this reason with the perspective of children, as well as adults, is reflected by how we live, implicit in

supra note 18.

266. McCormick, *Experimental Subjects*, *supra* note 265, at 2197.

267. *Id.*

268. See, e.g., Wendler, *Significance*, *supra* note 11, at 66-67.

269. See McCormick, *Experimental Subjects*, *supra* note 265, at 2197.

270. *Id.* at 2197.

271. *Id.*

272. *Id.*

our firm moral commitments. Just imagine that your neighbor has suffered a bad injury and needs emergency medical attention. You can drive your neighbor to the hospital, but you would have to take your child with you. For the good of another person you would be putting the child at some risk. (This assumes the child is safer and better off playing at home, under your care and supervision, than riding in a car. Let's even stipulate that it is raining, so driving conditions are less safe than usual.) I submit that it is morally permissible to put the child in the car and go—and even morally problematic not to. In fact, it seems morally problematic even to consider *not* putting the child in the car on ground that it is not in your child's best interests. Yet imagine someone challenging your decision because it was not in your child's best interests to face the risks of car-riding. The objection seems out of place. You and your child drove your neighbor because you both had good reason to—it was the beneficent thing to do. One might be able to offer a story explaining how it is in the child's best interests that we do these things for one another. But that story does not seem necessary to justify putting the child at minimal risk for the good of another.

Without empirical data, I suspect that this argument resonates with many parents who do consent to enroll their children in non-beneficial, minimal risk research after fully comprehending that the research is solely for the good of others. I doubt parents consider that they are morally educating a young child through research participation, or that they are trying to be fair to past and future generations, or that their children would otherwise be facing the risks of daily life, etc. If we do not think that a parent wrongs a child by putting her in a car to drive an injured neighbor to the hospital, we should not think a parent wrongs a child by enrolling her in minimal risk research for the reason that it is good for others.

B. Objections and Replies

Ramsey and Ross have criticized McCormick on the ground that his argument would “justify compulsory altruism[,] . . . requir[ing] the participation of adults in research projects to which they do not give their consent.”²⁷³ This criticism, though, is misguided. That each person has good reason to help others when one is especially situated to do so at very little to no cost to oneself does not imply that the state may compel research participation or enforce that duty in any other way. Other reasons and values matter, such as those related to the importance of obtaining informed consent from persons capable of making decisions for themselves.²⁷⁴ Indeed, neither McCormick's position nor the

273. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 78-79; *see also* Ramsey, *Enforcement*, *supra* note 215, at 22.

274. *See supra* notes 234-237 and accompanying text.

arguments I have presented justify the state forcing children into research without parental consent.²⁷⁵

Ramsey raises a second objection. He agrees with McCormick that a parent asked to provide proxy consent for her child should consider what the child *would* choose, but Ramsey argues that it is a “violent and false presumption” to assume a child *ought* to consent.²⁷⁶ He argues that McCormick asks what a child would choose in light of what would be good for an adult to choose. In contrast, Ramsey argues that the question should be answered in light of what would be good for a child to choose. For adults and children, both Ramsey and McCormick think we need to look to the “natural tendencies” of persons to discern their good, on the assumption that they are naturally inclined toward their good. They depart in that Ramsey argues that we should determine the good of children by looking to *their* natural tendencies, not to those of adults. Because a young child is naturally inclined only toward preserving his own life, health, and growth,²⁷⁷ according to Ramsey, a parent may weigh only considerations related to those self-interested goods in exercising proxy consent; moral considerations are off limits.

But, of course, we do not actually make decisions for children that are consistent with their natural inclinations—thankfully for them and us. Children naturally may be inclined to preserve themselves, but they are also naturally inclined to act irrationally. Should we then treat them in ways that promote their irrationality? Of course not. This observation illustrates the ultimate problem with Ramsey’s (and McCormick’s) reliance on a natural law conception of the good: the conception is guilty of what G.E. Moore termed the “naturalistic fallacy.”²⁷⁸ Ramsey does not recognize that deeming something “natural” leaves open the question of whether that thing is good. We make decisions for children in light of what we think they have reason to do and care about. Most of those decisions focus on their best self-interest. But their “best self-interest” does not require us to promote their *actual* wants and inclinations as children. We try to

275. Ross argues that McCormick “realized” that his argument justified compulsory altruism. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 78-79 (citing McCormick, *Experimentation*, *supra* note 18, at 42-43). But McCormick did no such thing. He explicitly stated, “Even though it can be argued that we all have duties in this area [related to research participation], duties of readiness and willingness, it is understandable, even desirable, that informed consent accompany the fulfillment of these duties. For consensual community is something to be promoted whenever possible.” McCormick, *Experimentation*, *supra* note 18, at 43 (quoting McCormick, *Experimental Subjects*, *supra* note 265, at 2197). He argues that it might not be unjust for the government to recruit subjects by lottery if “not enough volunteers are available for minimal risk experimentation and the research seems of overriding importance to the public health.” *Id.*

276. Ramsey, *Enforcement*, *supra* note 215, at 22.

277. *Id.*

278. G.E. MOORE, *PRINCIPIA ETHICA* 58-69 (Thomas Baldwin ed., 1993).

shape their desires, thinking about their long-term interests. If we make decisions for them in light of good reasons, it is not a mistake to consider reasons that are other-regarding. As I noted, we put the child in the car in order to aid our injured neighbor because we all have reason to help others.

A final objection is directed toward both justifications I have offered. One might argue that the non-consequentialist moral framework employed in both justifications—based on the idea of justifying an action or policy *to* an individual *as* an individual by giving reasons that have importance from that person's point of view—is inappropriate for thinking about children's issues. The purported problem is that the motivating idea behind the framework is that the property in virtue of which persons morally matter is our capacity for rational self-governance.²⁷⁹ That is, on this view of moral reasoning, what matters most morally about persons is that we have the capacity to direct our own lives in light of the reasons we take ourselves to have. Justification to an individual (as opposed to the world at large) is related in that a person has reason to view the way that others treat her as respectful of her capacity for rational self-governance if their actions are justified in light of reasons that have importance from her own perspective. She can, in a sense, view their actions and their consequences "as *not* just things that *happen* to her, but as a result of what she herself has authorized."²⁸⁰ But this framework, then, seems inapposite to young children, who are not capable of rational self-governance. If they are not capable of rational self-governance, why should we ask whether each child has reason to endorse a policy permitting some non-beneficial pediatric research? The final point of the objection would be that we must take a child's welfare—and not reasons—as fundamental in thinking how we may treat her, given that young children do not respond to reasons.

The moral status of children within Kantian, non-consequentialist moral theory is a difficult topic. Possible lines of response would need development to be persuasive: Perhaps the potential of young children to become rational self-governors grounds a general duty to treat each one as an end and not merely a means, requiring us to justify ourselves to each on grounds that she could not reasonably reject. Alternatively, perhaps we have good reason to endorse that general duty to young children because we cannot make fine distinctions regarding the point at which children become sufficiently rational.²⁸¹

Regardless, scholars, policy makers, and courts have sought a justification for this research based on Kantian or non-consequentialist moral reasoning. I have not attempted to provide a full account of why we must treat each child as an end-in-herself. I begin with that assumption. If we reject the Kantian

279. See KUMAR, *CONSENSUALISM*, *supra* note 213, at 13-14; SCANLON, *supra* note 208, at 268.

280. KUMAR, *CONSENSUALISM*, *supra* note 213, at 14.

281. See *id.* at 22 (discussing reason to treat the sub-rational as being owed duties).

framework as inapplicable to children, on what basis are we under a duty to resist appealing to the aggregated benefits to all persons (or all sentient creatures) when justifying our decision to expose children to uncompensated research risks? A consequentialist, of course, would respond by saying that there *is no* basis. However, scholars and government agents have searched for a non-consequentialist justification, dissatisfied with defending the research on consequentialist grounds.

CONCLUSION

This Article has addressed three related questions regarding non-beneficial pediatric research: 1) Should the best interests standard determine whether non-beneficial pediatric research is ethically and legally permissible? 2) If it should, did the *Grimes* court correctly conclude that the standard precludes exposing a child to “any articulable risk beyond the minimal kind of risk that is inherent in any endeavor”?²⁸² In essence, was *Grimes* correct in essentially prohibiting non-beneficial pediatric research? 3) Finally, can non-beneficial pediatric research be justified only by appeal to utilitarian or otherwise consequentialist considerations? Does enrolling a child in a non-beneficial protocol necessarily treat the child merely as a means to our end of improving children’s health, or is there a non-consequentialist justification for the research?

A court, invoking the state’s *parens patriae* authority, should appeal to the “best interests” standard in assessing the permissibility of non-beneficial pediatric research. Though the *Grimes* court properly relied on that standard, it wrongly concluded that the standard precludes all non-beneficial research on children. Courts and other state decision-makers must consider that a policy permitting some non-beneficial pediatric research is in the best interests of *each* child, including children enrolled or potentially enrolled in research. Non-beneficial research and interventions help lead to newer, safer pediatric therapies, thereby lowering the risks children face in the medical care setting, while exposing pediatric subjects to extremely low risk.

Thus, a child’s participation in a non-beneficial pediatric protocol can be respectful of that child. Each child has reason to endorse both a policy permitting non-beneficial pediatric research and to participate in a practice from which she benefits. This proposed justification offers a plausible amendment to informed consent practices and helps explain shared intuitions regarding the conditions under which it is appropriate to conduct pediatric research.

282. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 862 (Md. 2001).