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The Legal Ethics of Pediatric Research

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THE LEGAL ETHICS OF PEDIATRIC RESEARCH

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ABSTRACT

Since the mid- to late 1990s, the scientific and medical research community has sought to increase its access to healthy children for research protocols that involve harm or a risk of harm. This move reverses longstanding policy within that community generally to exclude healthy children from such protocols on the grounds that the research as to them is nontherapeutic, that they are particularly vulnerable to research-related abuses, and that they are unable themselves to give informed consent to their participation. The research community's new posture has been supported by prominent pediatric bioethicists who have argued that unless healthy children are included as research subjects in harmful or risky research, the pediatric population will continue to suffer relative to the adult population in the extent to which it benefits from modern advances in science and medicine. In their view, it is possible for the research community to self-administer a rule that strikes a balance between protecting healthy children from research-related abuses and allowing their inclusion in cutting-edge pediatric research. In this scheme,

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parental consent is central to the research community's claims about child protection.

This Article explores the flaws inherent in this ethics of pediatric research. Specifically, it challenges the view from ethics that the law permits parents to consent to their children's inclusion in harmful or risky research to the extent that related invasions would meet legal maltreatment standards. More broadly, it challenges the movement to increase access to healthy children for harmful and risky research on the ground that it risks two important regressions: First, in its willingness to risk harm to individual children in the interests of the group, it threatens the progress the law has made in its development of the concept of the child as an individual worthy of respect in his or her own right, a concept that imagines parents as fiduciaries and that includes strong protections against invasions of bodily integrity. Second, in its failure to assure that the burdens of nontherapeutic research are not placed disproportionately on children of lower socioeconomic and minority status, it violates the antidiscrimination principle, which has only begun to make good on its promise of equal treatment for all children. Ultimately, this Article argues that harmonization of the rules governing pediatric research with the law of child protection and parents' consent authority is the best way to assure that children are protected in the research setting in these respects and to the same extent they are otherwise in the society.

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INTRODUCTION

A preeminent research institution enrolls a group of infants and young children in a study designed to measure the effects of varying degrees of lead abatement on lead levels in the blood, including by encouraging particular landlords to rent their properties only to families with young children and by encouraging the tenants in those properties to consent to their children's use as research subjects. The study is designed to determine whether the government can reduce current lead abatement requirements and still protect children from neurological injury. If a different standard can be developed, it will increase the availability of low-income housing in the city and help to restore blighted communities. At some point, researchers learn of, but do not warn parents about, risky lead levels in their children's blood; any warning would compromise the study midcourse.[1]

Ethicists have long debated whether and in what circumstances healthy children ought to be used as research subjects. Ethical codes and principles have emerged from those debates (and the history and developments that tend to spawn them) to govern the practices of clinicians, investigators, and the institutions of which they are a part. Central to these codes and statements of principles is the requirement that informed consent be obtained from subjects if they are legally competent to give it or from their legal representatives or "legal proxies" if they are not. Regardless of the value and propriety of the intervention otherwise, it cannot be undertaken unless this requirement is met.[2]

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1. This scenario is derived from the facts of *Grimes v. Kennedy Krieger Institute*, 782 A.2d 807, 811–13 (Md. 2001).

2. *See, e.g.*, NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1978), *available at*

Despite the provision for a proxy decisionmaker when the proposed subject is incapable of consent, the prevailing view among bioethicists and regulators from the late 1970s through the mid- to late 1990s favored excluding healthy children from pediatric research protocols. This view was largely driven by lingering concerns about the morality of subjecting nonautonomous individuals to research-related harm and risk, and about children's particular vulnerability to exploitation in the research setting.[3] Beginning in the late 1990s, however, the central commitment of this community began to shift from protection to access, so that the prevailing view favors including healthy children in nontherapeutic research, including in protocols that involve higher than minimal risk.[4] Both beneficence and distributive justice are believed to be better served by allowing, rather than disallowing, such interventions. Specifically, the prevailing view holds that including healthy children in higher-risk research will maximize the gains that can be obtained from the research, and that it is otherwise fair and just to distribute the burdens of this research across the population of children (both ill and healthy) who would potentially benefit from its results.[5] This view was ensconced in

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http://ohsr.od.nih.gov/guidelines/belmont.html; World Med. Ass'n, World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2004) (originally drafted in 1964), *available at* http://www.wma.net/e/policy/pdf/17c.pdf; 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181–84 (William S. Hein & Co. 1997) (1949), *available at* http://ohsr.od.nih.gov/guidelines/nuremberg.html [hereinafter NUREMBERG CODE]. Although the *Nuremberg Code*'s informed consent requirement does not sanction proxy consents, later codes do. *See infra* note 56.

3. *See infra* notes 87–89 and accompanying text.

4. *See infra* notes 90–110 and accompanying text. "Minimal risk" is a term of art defined in the federal regulations governing pediatric research. For a recitation of this definition and a description of the controversy over its interpretation, see *infra* notes 75–78 and accompanying text. The use of healthy children as subjects is "nontherapeutic" because the research "does not normally benefit the research subject directly, but is done to provide information about future treatments to others." Beth Newbury Whitstone, *Medical Decision Making: Informed Consent in Pediatric Research*, Congenital Heart Information Network, Mar. 26, 2004, http://www.tchin.org/resource_room/c_art_18.htm. Ill children may also be used as controls in nontherapeutic research. *See* MEDICAL RESEARCH WITH CHILDREN: ETHICS, LAW, AND PRACTICE 26–33 (Richard H. Nicholson ed., 1986) (discussing the history and the distinction between therapeutic and nontherapeutic research).

5. The book, *Beyond Consent*, provides an especially thorough treatment of this research ethics, which its authors apply not only to the pediatric context, but also to other contexts involving vulnerable subpopulations, including women, minorities, and subjects in the international context. BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH (Jeffrey P. Kahn, Anna C. Mastroianni & Jeremy Sugarman eds., 1998). Notably, the prevailing view may not necessarily reflect the majority or consensus position. *See* Seema Shah et al., *How Do*

national legislation that provides incentives for those who would engage in pediatric research and encourages the inclusion of children especially in trials of new and existing pharmaceuticals.[6] Most important, this view is influential in the interpretation of the federal regulations that govern the conduct of pediatric research on a day-to-day basis.[7]

As a result of these developments and a burgeoning investment in pediatric research, parents are increasingly being asked to allow their healthy children to be participants in experiments that may involve harm or more than minimal risk. According to the Institute of Medicine (IOM), "the number of industry-sponsored pediatric clinical trials and the number of child participants in such trials [between 1997 and 2001] increased by an estimated three-fold."[8] Correspondingly, the pediatric research budget of the National Institutes of Health (NIH) reflected "a growth rate of 82.4 percent in nominal terms."[9]

The widely held assumption among researchers who want to include children in their protocols is that satisfaction of their ethical and regulatory obligations—including the requirement that they afford parents "the consent process" and obtain their signatures on consent forms—fully assures the lawfulness of their work. Specifically, these researchers assume either that the law is not otherwise implicated in the transaction, or if it is, that it does not

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Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research?, 291 JAMA 476, 478 (2004) (describing the failure of polled IRB chairs to classify certain risks according to the authors' interpretation of the applicable regulatory standards).

6. For a description of this legislation, see *infra* notes 104–06 and accompanying text.

7. For further discussion, see *infra* notes 68–111 and accompanying text, which set out the relevant terms of these regulations, describe both the federal government's prior position with respect to the use of children as research subjects and these new inclusive policies, and note the policies' influence on the research community's interpretation of the regulations.

8. COMM. ON CLINICAL RESEARCH INVOLVING CHILDREN, INST. OF MED. OF THE NAT'L ACADS., ETHICAL CONDUCT OF CLINICAL RESEARCH INVOLVING CHILDREN 246 (Marilyn J. Field & Richard E. Behrman eds., 2004) [hereinafter IOM]; *see* Telephone Interview with Jennifer Li, Professor, Duke Univ. Sch. of Med. (Mar. 1, 2007) (explaining that both healthy and ill children are included in these protocols, and that because there are not always enough ill children to conduct a proper study, it is useful to be able also to access healthy children as subjects).

9. Daniel P. Gitterman et al., *Did a Rising Tide Lift All Boats? The NIH Budget and Pediatric Research Portfolio*, HEALTH AFFAIRS, Sept.–Oct. 2004, at 113, 116 (noting also that "[a]lthough funding for pediatric research increased from FY 1998 to FY 2003, its proportion of total NIH spending went down . . . from 12.3 to 11.3 percent"). For further description of the increased use of children in research, see *infra* notes 102–11 and accompanying text.

circumscribe parents' authority to give legally valid consent to nontherapeutic interventions involving their children any more than it circumscribes the right of competent adults to consent to such interventions on their own behalf.[10] From the standpoint of the research community, this assumption makes perfect sense. Its informed consent process was established to assure that physicians and scientists show appropriate respect for their patients and subjects, particularly for the latter's right to autonomous decisionmaking. (A more comprehensive perspective on the concept of respect for the person—and correspondingly, on the goals of the informed consent process—that would also include protection of an individual's right to bodily integrity is not prominent in the prevailing ethics of pediatric research.)[11] Thus, when individuals or their legal proxies are "consented" through this process, a signature on the consent form is proof that due respect was shown.[12]

The legality of parental consent in these circumstances is not so easily settled, however. And as a result, so long as valid parental consent remains a prerequisite for ethical and lawful research, the legality of some harmful and higher-risk uses of healthy children—and thus the viability of the movement to increase access to healthy children for such research—is also in doubt. Specifically, the federal

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10. *See* Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 852 (Md. 2001) ("Most of the relatively few cases in the area of ethics of protocols of various research projects involving children have merely assumed that a parent can give informed consent for the participation of their [*sic*] children in nontherapeutic research."); GEORGE J. ANNAS, LEONARD H. GLANTZ & BARBARA F. KATZ, INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA 54 (1977) (noting that "[i]nformed consent is a process" and that "[t]he signing of a consent form can be evidence that this process took place"). Early writings in the bioethical literature reflected an understanding of the law of parents' consent authority as a relevant boundary; at the same time, however, their authors—who were ultimately advocates for using healthy children as research subjects—generally argued in favor of a permissive interpretation of that law. *See, e.g.*, ANGELA RODDEY HOLDER, LEGAL ISSUES IN PEDIATRICS AND ADOLESCENT MEDICINE 146–60 (2d ed. 1985) (analyzing the legal boundaries of parents' consent authority and arguing that this authority is sufficient to permit research interventions that risk less harm "than that to which [the child] is reasonably likely to be exposed in normal daily life"). When modern commentators and researchers assume the lawfulness of parental consent to harmful and risky nontherapeutic research, it is likely because they (want to) believe in these older analyses, and/or because prior to *Grimes*, the courts did not have occasion to review a related issue.

11. For a description of the *Belmont Report*'s view of respect for the person, see *infra* text accompanying note 64.

12. For a description of this position, see *infra* notes 64, 84–86, and accompanying text.

scheme that primarily governs pediatric research does not preempt[13] state laws that otherwise define informed consent doctrine. As applied to parents as proxy decisionmakers, this doctrine—which has its origins in battery law and is thus motivated mainly by a commitment to respecting the individual's physical integrity—does not contemplate medical or scientific interventions involving healthy children. Rather, it assumes that the proposed intervention is in the best interests of an ill child.[14] Nor do the federal pediatric research rules supercede federal and state child protection laws or the boundaries inherent in the constitutional doctrine of parental autonomy. Established child protection law prohibits parents from acting intentionally to cause or to risk causing physical harm to their children unless it is to obtain a direct offsetting benefit; indeed, when they take such action, the traditional response is that they are guilty of child abuse.[15] Notably, although the definitions of "harm" and "risk" common to child protection law appear to overlap somewhat with definitions used by the research community, the two are not coterminous. The U.S. Supreme Court has generally accepted that the standards set out in child protection law also establish the constitutional boundaries of parents' decisional authority.[16] Thus, contrary to assumptions prevalent among bioethicists and the research community,[17] there will be procedures that are appropriate according to the standards of that community, but that cannot be authorized legally by a child's parents.[18]

Despite the apparent surprise and clear consternation of many bioethicists and researchers,[19] this integrated doctrine appropriately

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13. Preemption has special meaning in the law. In this context, it signifies the absence of an express or implied intention of the federal government to have its law supercede otherwise relevant state law. For a more detailed discussion of preemption doctrine, see ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 390–419 (3d ed. 2006).

14. *See* DAN B. DOBBS, THE LAW OF TORTS 54–62, 654 (2000) (outlining elements of the battery claim and discussing the informed consent doctrine as it concerns operations).

15. For a description of these rules, see *infra* notes 127–47 and accompanying text.

16. For a discussion of this doctrine, see *infra* notes 116–26 and accompanying text.

17. *See, e.g.*, HOLDER, *supra* note 10, at 152 (reflecting this misimpression); Loretta M. Kopelman, *What Conditions Justify Risky Nontherapeutic or "No Benefit" Pediatric Studies: A Sliding Scale Analysis*, 32 J.L. MED. & ETHICS 749, 754–56 (2004) (identifying the misimpression).

18. For an analysis of parents' consent authority in the research setting, see *infra* Part II.C.

19. *See, e.g.*, 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 (2002) (noting the fear of researchers in the wake of *Grimes* "that valuable public health research that complied with long-standing federal standards . . . would be halted

governed the outcome in *Grimes v. Kennedy Krieger Institute*,[20] the case from which the introductory illustration is derived and one of only two judicial decisions squarely to address the boundaries of parents' consent authority in the context of pediatric research.[21] In *Grimes*, the Maryland Court of Appeals—the state's highest court—concluded that parents cannot lawfully authorize researchers to use their healthy children in experiments that risk more than a minimal amount of harm.[22] In doing so, it flatly rejected the notion, based on modern ethical interpretations of the federal pediatric research regulations, that the harms associated with the lead abatement study were "minimal" or otherwise legally inflicted.[23] Focusing on the interests of the individual research subjects, the court also flatly rejected the more general view that these harms were worth risking because the research could eventually yield important benefits for the

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altogether"). Part II.C.5 discusses *Grimes* and the reactions of the bioethics and research communities.

20. Grimes v. Kennedy Krieger Inst., 782 A.2d 807 (Md. 2001).

21. *Id.* at 852. The only other case to have addressed this issue was *T.D. v. New York State Office of Mental Health*, 626 N.Y.S.2d 1015, 1018 (Sup. Ct. 1995), *aff'd*, 650 N.Y.S.2d 173 (App. Div. 1996). The *T.D.* decision invalidated state regulations that allowed "more than minimal risk" research on children and others incapable of giving consent, because they did not adequately protect the children's common law personal autonomy and constitutional due process rights. T.D. v. N.Y. State Office of Mental Health, 650 N.Y.S.2d 173, 176 (App. Div. 1996). In the words of the appellate court when affirming the district court's decision, "a parent or guardian, let alone another adult who may be a member of the child's family, may not consent to have a child submit to painful and/or potentially life-threatening research procedures that hold no prospect of benefit for the child . . . ." *Id.* at 192; *see also* Lainie Friedman Ross, *Children in Medical Research: Balancing Protection and Access: Has the Pendulum Swung Too Far?*, 47 PERSP. BIOLOGY & MED. 519, 526 (2004) (describing Complaint, *Nielsen v. Regents of the University of California*, No. 665-049 Civ. 8–9 (Cal. Super. Ct. Aug. 23, 1973), which sought a declaration that "parents and guardians ha[ve] no legal authority to consent to the participation of a child or a ward in nontherapeutic research irrespective of the degree of risk"). The *Nielsen* case was filed but never decided; nevertheless, according to Duane Alexander, director of the National Institute of Child and Health Development, merely addressing this issue in a judicial forum "'left investigators and research regulators shivering in their boots, and the shock waves it sent through the research community and the reaction and response it engendered in terms of regulations for protecting children in research cannot be overestimated.'" Ross, *supra*, at 526 (quoting Duane Alexander, *Regulation of Research with Children: The Evolution from Exclusion to Inclusion*, 6 J. HEALTH CARE L. & POL'Y 1, 4 (2002)).

22. *Grimes*, 782 A.2d at 848. The court also held that researchers have a tort law–based special relationship with their subjects, which imposes a duty to warn of known risks and dangers. *Id.* at 846. Like the court's analysis of parents' consent authority, its analysis in this respect is also strictly consistent with "black letter" law. *See* DOBBS, *supra* note 14, at 875–76 (describing the special relationships–based duty to aid).

23. *Grimes*, 782 A.2d at 848.

larger community of which they were a part.[24] Although there is no reason to believe that the particular research at issue in *Grimes* is typical of the sorts of interventions contemplated by the movement to increase access to healthy children for higher-risk experiments, it is nevertheless difficult to overstate the significance of this decision for the research community. Not only is the decision consistent with the law across the states on the boundaries of parents' consent authority, but there is also no question about the applicability of this law to research conducted in the state of Maryland. Among other things, it implicates both ongoing and contemplated research at such premier institutions as the NIH and Johns Hopkins University.[25] More generally, the decision puts the research community on notice that an ethics of pediatric research and an interpretation of the corresponding federal regulations that permit the use of healthy children in potentially harmful and higher-risk experiments will find itself on a collision course with the law of child protection and parents' decisional authority.

The research community could seek to avoid this collision by soliciting legal reforms that would exempt harmful and higher-risk

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24. *See id.* at 851 (quoting the National Bioethics Advisory Commission saying that "no matter how important the research questions, it is not ethical to use human participants without appropriate protections").

25. *See, e.g.*, Appellee's Motion for Partial Reconsideration and Modification of Opinion at 2, *Grimes*, 782 A.2d 807 (No. 128), *available at* http://www.aau.edu/research/Paint9.17.01.pdf (warning among other things of the dire implications of the decision for the "hundreds of fully accredited medical research projects now conducted in Maryland" and "the damage done to the institutions as a result of terminating these projects"). These implications were so important that the defendants and others allied with their interests lobbied Maryland state lawmakers to develop legislation that would abrogate the court's holdings. Tom Pelton, *Groups Target Study Limits*, BALT. SUN, Sept. 30, 2001, at 1B. The reforms that were ultimately enacted represent a compromise between the research community, which initially sought state adoption of the federal regulations, and those seeking greater or more definitive protections for research subjects. *See* Tom Pelton, *Draft Focuses on Subjects in Experiments*, BALT. SUN, Jan. 26, 2002, at 1B (describing the attempt to abrogate the court's holding); Tom Pelton, *Tests Bill Toned Down*, BALT. SUN, Jan. 31, 2002, at 1B (reporting on the compromise); H.B. 917, 2002 Gen. Assem., Reg. Sess. (Md. 2002), *available at* http://mlis.state.md.us/2002rs/billfile/hb0917.htm; MD. CODE ANN. HEALTH-GEN. §§ 13-2001 to -2004 (West 2006) (providing for limited public access to IRB minutes; subjecting all human subjects research to the federal regulations, even that to which the regulations are not otherwise applicable; and providing authority to the state's attorney general to seek injunctions to stop unethical studies). Although the legislation is certainly helpful to the research community in the sense that its work is now primarily subject to one set of essentially favorable rules—that is, the federal regulations—it did not abrogate either of *Grimes*'s holdings. That is, the common-law special relationships duty to warn is still on the books, as is the rule that parents may not consent to subject their healthy children to anything more than minimal risk as defined by the court.

pediatric research from the limitations inherent in this law. Given how entrenched its terms are in American society, and also the skepticism that still exists outside of the research community about its ability adequately to protect human subjects in light of its sometimes conflicting progress goals, it is questionable whether such reforms would be feasible. Nevertheless, if such reforms could be adopted, they would secure researchers' ability to use healthy children for at least some problematic interventions.

This Article advocates the opposite approach: reform of the federal pediatric research regulations, and in particular of their rules on harm and risk, according to the terms of the law of child protection and parents' decisional authority. The nontherapeutic research setting is fraught with conflicts of interest, including between the prospect of developments in science and medicine (for the good of mankind and the private sponsors and administrators of research), and the protection of healthy human research subjects (for the good of the particular individuals enrolled in experiments). Although advocates of the prevailing ethics of pediatric research often describe their project as developing an acceptable balance between protection and access, they have not managed to arrive at an interpretation of the rules on harm and risk that would accomplish this goal.[26] On the other hand, a central aim of the law of child protection and parents' decisional authority is precisely to protect individual children from unnecessary harms caused by adult caretakers with conflicting interests.[27]

Moreover, although the movement to increase access to healthy children for higher-risk research and to provide consistent interpretations of the federal rules purports to be progressive, in fact for children, it is regressive in two important respects.

First, the theoretical foundations underlying the law of child protection and parents' decisional authority imagine the parent as fiduciary of his or her child, who is deserving of respect as a person in the liberal tradition. The fact that children are pre-autonomous

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26. *See* Jeffrey P. Khan et al., *Changing Claims About Justice in Research: An Introduction and Overview*, *in* BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH, *supra* note 5, at 5; *see also infra* Part III.A.

27. Thus, for example, this law restricts parents' ability to require their children to work to contribute economically to their own and/or their family's welfare because doing so would cause them educational and potentially also physical harm. *See* SAMUEL M. DAVIS ET AL., CHILDREN IN THE LEGAL SYSTEM: CASES AND MATERIALS 16–17, 32 (Robert C. Clark et al. eds., 3d ed. 2004).

persons has reduced but not eliminated the benefits that inure to individuals within that tradition. This account, which only recently has replaced the historical concept of the child as property, allows for parental rights not as payment for bearing the burdens of parenthood, but rather as the best way to ensure that decisions affecting the child are made consistent with his or her interests.[28] This law is also firmly grounded in a commitment to individuals' physical integrity and a concomitant aversion to intentional invasions of that integrity, both of which permeate modern American jurisprudence, but which have only recently begun to be viewed as fully applicable to children.[29] Finally, this law reflects continued fealty to the harm principle, which provides the basis for the government to regulate conduct (and thus to curtail liberty) when that conduct threatens the individual's right to be free from harm.[30] The central aims of the movement to increase access to healthy children for higher-risk research—elimination of the presumption that children need the strongest possible protection from exploitation in the research setting, advancement beyond a singular concern for the protection of the individual to a more broad-based concern for the welfare of the group, and an interpretation of the federal regulations that allows for increasingly harmful and risky nontherapeutic interventions—threaten the progress represented by the application of these principles to individual children.

Second, the movement to increase access to healthy children for higher-risk research violates the antidiscrimination principle, which has only begun to have a real influence on the law's approach to the treatment of underprivileged children.[31] Although the risk of exploitation in the research setting exists for all children, it is most immediate for low-income and minority children. These children are the best source of large numbers of pediatric research subjects because, among other reasons, their parents are most likely to be lured by the ancillary benefits of participation (generally money and sometimes also free medical services) and (where socioeconomic

28. See *infra* notes 382–402 and accompanying text for a description of the modern legal theory of parental rights.

29. The most obvious examples of this aversion reside in the tort law of battery and in Fourth Amendment law. For further discussion of this aversion in the law of child protection and parents' decisional authority, see *infra* notes 132–39, 386–90 and accompanying text.

30. See *infra* note 390 and accompanying text for further discussion of the harm principle.

31. *Cf.* Leandro v. State, 488 S.E.2d 249, 255 (N.C. 1997) (holding that the North Carolina Constitution requires the state to provide every child, including those from poorer communities, with "an opportunity to receive a sound basic education").

status tracks education) least likely to understand the risks and burdens involved.[32] This group is also a principal source of otherwise healthy subjects who might be involved in research that poses more than a minimal risk of harm because unlike their more privileged counterparts, low-income and minority children are often perceived to be already at risk from, if not damaged by, their existing circumstances.[33] Consistent with these assumptions, research shows that poor African-American children are disproportionately represented among the population of healthy pediatric research subjects.[34] The irony that the new ethics of pediatric research is creating distributive justice problems for poor and minority children to advance the different distributive justice goal that is assuring all children—but primarily children whose parents can afford top-of-the-line health care—access to better medicines and conditions should not be lost on those who evaluate its merits.

There is an abundance of writing on the boundaries of permissible pediatric research in the ethical and bioethical literatures. On the other hand, there is precious little on the subject in the legal literature, and that which does exist was written primarily in the wake of *Grimes* and from an ethical rather than legal perspective.[35] It is safe

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32. *See infra* notes 357–60 and accompanying text. Of course, depending on its contents, one could be well educated and still not understand an informed consent form.

33. Part II.A discusses and examines the argument that healthy children who are at risk of harm or illness in the future might be characterized as having a "condition" justifying their inclusion in higher-risk research under the corresponding federal regulations.

34. LAINIE FRIEDMAN ROSS, CHILDREN IN MEDICAL RESEARCH: ACCESS VERSUS PROTECTION 44 (2006); *see also infra* note 358 (discussing this problem and contrasting it with the problem that these children are underincluded in research involving ill children).

35. *See* Randall Baldwin Clark, *Speed, Safety, and Dignity: Pediatric Pharmaceutical Development in an Age of Optimism*, 9 U. CHI. L. SCH. ROUNDTABLE 1 (2002); Rupali Gandhi, *Research Involving Children: Regulations, Review Boards and Reform*, 8 J. HEALTH CARE L. & POL'Y 264 (2005); Anna Gercas, *The Universal Declaration on Bioethics and Human Rights: Promoting International Discussion on the Morality of Non-Therapeutic Research on Children*, 27 MICH. J. INT'L L. 629 (2006); Clifton R. Gray, *The "Greater Good" . . . At What Cost?: How Nontherapeutic Scientific Studies Can Now Create Viable Negligence Claims in Maryland After* Grimes v. Kennedy Krieger Institute, Inc., 32 U. BALT. L. REV. 73 (2002); William G. Kelly, *Ericka and Myron: Canaries in the Mines*, 13 ALB. L.J. SCI. & TECH. 173 (2002); Loretta M. Kopelman, *Children as Research Subjects: Moral Disputes, Regulatory Guidance, and Recent Court Decisions*, 73 MOUNT SINAI J. MED. 596, 599 (2006) [hereinafter Kopelman, *Children as Research Subjects*]; Loretta M. Kopelman, *Minimal Risk as an International Ethical Standard in Research*, 29 J. MED. & PHIL. 351 (2004) [hereinafter Kopelman, *Minimal Risk*]; Loretta M. Kopelman, *Pediatric Research Regulations Under Legal Scrutiny:* Grimes *Narrows Their Interpretation*, 30 J.L. MED. & ETHICS 38 (2002) [hereinafter Kopelman, *Pediatric Research Regulations Under Legal Scrutiny*]; Kopelman, *supra* note 17, at 754–56; Symposium, *Research with Children: The New Legal and Policy Landscape*, 6 J. HEALTH CARE L. & POL'Y 1 (2002);

to assume that the absence of relevant legal analysis has played a major role in creating the disjunction in language, doctrine, and theory that is the subject of this Article. Indeed, as Dr. William J. Wenner has already noted,

> [t]he dearth of [relevant] judicial opinions, the findings of the court in *Grimes*, the response of the research and regulatory community to *Grimes*, the ambiguities of current regulations, and the continuing evidence of adverse effects on children in scientific experiments[,] all suggest a need to re-evaluate the legal protections offered to children involved in human experimentation.[36]

This Article intends exactly that.

It proceeds as follows: Part I describes the evolving ethics of pediatric research involving healthy children, focusing on the shift in national policy from the presumption that healthy children normally would be excluded from research designs to the presumption that they normally will be included in such designs, even when participation involves harm or more than minimal risk. Part II explores the legal boundaries of parents' consent authority, and it examines the degree of overlap and disjunction between those boundaries and prevailing assumptions, language, and practice in the research community. The Maryland Court of Appeals decision in *Grimes v. Kennedy Krieger Institute* is examined in this context. Part III develops a normative argument in favor of an ethics of pediatric research—and a corresponding reform of the federal pediatric research rules—that tracks the law of child protection and parents' decisional authority. The leading proposals to balance protection and access are critiqued in this discussion. The Article concludes that the suggested reforms ought to be undertaken despite the likelihood that they would preclude some potentially useful interventions. Although scientific and medical progress are often privileged in American society, absent more, such progress is an insufficient basis upon which

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Jennifer Rosato, *The Ethics of Clinical Trials: A Child's View*, 28 J.L. MED. & ETHICS 362 (2000); Lainie Friedman Ross, *In Defense of the Hopkins Lead Abatement Studies*, 30 J.L. MED. & ETHICS 50 (2002); Efi Rubinstein, *Going Beyond Parents and Institutional Review Boards in Protecting Children Involved in Nontherapeutic Research*, 33 GOLDEN GATE U. L. REV. 251 (2003); David M. Smolin, Address, *Nontherapeutic Research with Children: The Virtues and Vices of Legal Uncertainty*, 33 CUMB. L. REV. 621 (2002); William J. Wenner, *Does the Legal System Provide Adequate Protection for Children in Scientific Experiments? The Unanswered Question of* Grimes v. Kennedy Krieger Institute, 8 U.C. DAVIS J. JUV. L. & POL'Y 243 (2004).

36. Wenner, *supra* note 35, at 245.

to claim the right to subject healthy children to otherwise inappropriate harm and risk.

I. THE EVOLVING ETHICS OF PEDIATRIC RESEARCH USING HEALTHY CHILDREN

The history of pediatric experimentation begins well before the twentieth century, at a time when there was little apparent concern for the moral, ethical, or legal implications of this practice.[37] In this earlier period—from approximately the 1700s through the mid-1900s—healthy children were injected (sometimes by a curious physician parent) with, among other things, the measles, cowpox, and "crude extract of endocrine glands," in efforts to understand aspects of human biology and to develop vaccines against diseases.[38] They were subjected to lumbar punctures (spinal taps) to determine the safety of that procedure.[39] And their diets were altered to gauge the effects on the etiology of such diseases as scurvy and rickets.[40] According to Dr. Lainie Friedman Ross,

> [C]hildren [at that time] were frequently subjects in research because they were convenient: researchers would often experiment on their children, servants, or slaves. Children could also be recruited from institutions. In 1914, Alfred Hess, the medical director of the Hebrew Infant Asylum in New York City, explained the scientific advantage of enrolling institutionalized children: it permitted "conditions which are insisted on in considering the course of experimental infection among laboratory animals, but which can rarely be controlled in a study of infection in man." Children were also "cheap" in the sense of non-valued; in fact, one researcher explained that he used child subjects because they were "cheaper than calves."[41]

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37. *See* Ross G. Mitchell, *The Child and Experimental Medicine*, 1 BRIT. MED. J. 721, 721–22 (1964) (providing a "[h]istorical [b]ackground to [e]xperimental [r]esearch in [c]hildren").

38. *Id.* at 722. *See generally* Susan E. Lederer & Michael A. Grodin, *Historical Overview: Pediatric Experimentation*, *in* CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW 4 (Michael A. Grodin & Leonard H. Glantz eds., 1994) (setting out the history of pediatrics and pediatric experimentation).

39. Lederer & Grodin, *supra* note 38, at 4, 11.

40. *Id.* at 13.

41. Ross, *supra* note 21, at 520 (citations omitted). Dr. Ross's article is an extremely useful and concise primer on the history and evolution of ethical views on pediatric experimentation. It is reprinted in updated form in ROSS, *supra* note 34, at 12; *see also* ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, U.S. DEP'T OF ENERGY, FINAL REPORT OF THE

Although this view has become anathema, at the time "infant and child mortality was still very high[,] . . . methods of therapy were often drastic," and there was otherwise little "doubt about the morality of the work."[42] Indeed, researchers in this era were often successful, developing procedures and medicines that continue to benefit mankind.[43]

A series of controversial nontherapeutic experiments involving healthy children, beginning in the United States after World War I[44] and in Nazi Germany,[45] generated the first substantial ethical debate on the subject. Of particular relevance to this Article were experiments conducted from 1956 through 1971 at the Willowbrook State School, an institutional facility for mentally retarded children on Staten Island, New York.[46] The Willowbrook experiments, involving the feeding of hepatitis-infected feces to healthy children specifically recruited by the school to serve as subjects, were designed to permit researchers to study the course of the disease in the hope of developing an effective vaccine.[47]

The Willowbrook researchers, including the pediatricians on staff, defended the propriety of these experiments on the bases that

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ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS 196–226 (1996), *available at* http://hss.energy.gov/healthsafety/ohre/roadmap/achre/chap7.html (discussing nontherapeutic research on children and noting that institutionalized and "hospitalized patients were often viewed by physician-investigators as a convenient source of research subjects").

42. Mitchell, *supra* note 37, at 722.

43. *See* Gandhi, *supra* note 35, at 264 (describing aspects of this history using the example of the development of the smallpox vaccine).

44. *E.g.*, Ross, *supra* note 21, at 519–24 (describing some of the controversial studies conducted in this period); s*ee* Robert M. Nelson, *Children as Research Subjects*, *in* BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH, *supra* note 5, at 47, 51–52 (describing experiments at the Walter E. Fernald School, an institutional facility for children in Massachusetts, involving the deliberate exposure of healthy children to radioactive iron and radioactive calcium as part of a federally funded experiment to determine safe and acceptable levels of radiation).

45. *See* Eva Mozes-Kor, *The Mengele Twins and Human Experimentations: A Personal Account*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE 53, 55–56 (George J. Annas & Michael A. Grodin eds., 1995) (describing the Mengele twin studies in which one twin was injected with a deadly germ and monitored until death, and the other twin was killed for an autopsy comparison); Christian Pross, *Nazi Doctors, German Medicine, and Historical Truth*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra*, at 32, 36 (describing German scientists who intentionally infected healthy Jewish children with serum from hepatitis patients and then performed liver punctures on them).

46. Nelson, *supra* note 44, at 49–50. *See generally* DAVID J. ROTHMAN & SHEILA M. ROTHMAN, THE WILLOWBROOK WARS (1984) (reviewing the history of the Willowbrook State School and the push to close it down).

47. *See* ROTHMAN & ROTHMAN, *supra* note 46, at 263.

> (1) all the children would eventually contract hepatitis, (2) hepatitis was mild in this age group, (3) the deliberate infection may have induced immunity to the endemic strain, (4) the children would be isolated from other infections by being admitted to a special ward, and (5) only children whose parents consented would be included.[48]

Willowbrook researchers also emphasized that their work had been "sanctioned by the authorities of the New York State Department of Mental Hygiene, and by the Armed Forces Epidemiological Board, Office of the Surgeon General."[49]

Critics of the Willowbrook experiments, and of nontherapeutic pediatric research more generally, took the strong position that using healthy children as research subjects is wrong. Among other things, they argued that pediatricians have a duty to protect the welfare of children in their charge and that to subject healthy children to risky and harmful research primarily in the interests of science or in the interests of children more generally is a violation of that duty.[50] They argued that nontherapeutic research cannot be justified on the ground that healthy children are already at risk of harm from an unhealthy environment when it is possible for responsible adults to remedy the conditions that pose the harm; thus, at Willowbrook, the lead researcher, Dr. Saul Krugman, "could have insisted that hygienic measures be introduced to decrease the spread of the virus," and in any event, he "had at hand an antidote of some efficacy" as "[h]is own [earlier] findings demonstrated that gamma globulin provided some protection" against infection.[51] Ultimately, however, the debate

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48. Nelson, *supra* note 44, at 50; *see also* ROTHMAN & ROTHMAN, *supra* note 46, at 265 (explaining that the lead researcher at Willowbrook, Saul Krugman, rationalized his feeding of hepatitis-laden feces to the children on the grounds that even "if he had not infected the children, they still would have contracted hepatitis . . . . Thus . . . feeding them the virus did not really change anything and was an experiment in nature"). The original debate among Krugman, his associates, and their critics is found at Stephen Goldby, Letter to the Editor, *Experiments at the Willowbrook School*, THE LANCET, Apr. 10, 1971, at 749; Saul Krugman, Letter to the Editor, *Experiments at the Willowbrook State School*, THE LANCET, May 8, 1971, at 966; Edward N. Willey, Letter to the Editor, *Experiments at Willowbrook*, THE LANCET, May 22, 1971, at 1078; Benjamin Posamanick, Letter to the Editor, *Experiments at Willowbrook*, THE LANCET, May 22, 1971, at 1078–79; Geoffrey Edsall, Letter to the Editor, *Experiments at Willowbrook*, THE LANCET, July 10, 1971, at 95.

49. Robert Ward et al., *Infectious Hepatitis: Studies of Its Natural History and Prevention*, 258 NEW ENG. J. MED. 407, 412 (1958).

50. *See* Goldby, *supra* note 48, at 749 ("The duty of a pædiatrician in a situation such as exists at Willowbrook . . . is to attempt to improve that situation, not turn it to his advantage for experimental purposes.").

51. ROTHMAN & ROTHMAN, *supra* note 46, at 266.

about the propriety of nontherapeutic research centered on the issue of consent, specifically whether it is ethical for parents to authorize the use of their children in such research.[52]

Those who argued that healthy children should not be used as research subjects because they lack the capacity to give informed consent to participate believed that informed consent is required not merely out of a respect for individual autonomy—which can be substituted for by a legal representative if the subject lacks capacity—but also out of a broader respect for the person.[53] One of the most forceful and widely cited proponents of this view was the theologian and ethicist Paul Ramsey, who wrote that

> [t]o experiment on children in ways that are not related to them as patients is already a sanitized form of barbarism; it already removes them from view and pays no attention to the faithfulness-claims which a child, simply by being a normal or sick or dying child, places upon us and upon medical care. We should expect no morally significant exceptions to this canon of faithfulness to the child.[54]

For these reasons, Professor Ramsey concluded that "no parent is morally competent to consent that his child shall be submitted to hazardous or other experiments having no diagnostic or therapeutic significance for the child himself."[55] In other words, "[p]roxy approval

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52. *See id.* at 265–66 (explaining the critique of the consent process at Willowbrook, which was premised on the fact that parents of children who had previously been accepted into Willowbrook but were still awaiting placement could either "[s]ign the [consent] form or forgo the placement").

53. *E.g.*, Robert M. Nelson & William W. Reynolds, *We Should Reject Passive Resignation in Favor of Requiring the Assent of Younger Children for Participation in Nonbeneficial Research*, AM. J. BIOETHICS, Fall 2003, at 11, 12 ("[T]he analysis of assent should begin with the principle of respect for children (i.e., persons) and not respect for subject autonomy.").

54. PAUL RAMSEY, THE PATIENT AS PERSON: EXPLORATIONS IN MEDICAL ETHICS 12–13 (2d ed. 2002). The first edition of this book is dated 1970, and it is based on a series of lectures Professor Ramsey gave in 1969. Later in the same essay, Ramsey writes that "[t]o attempt to consent for a child to be made an experimental subject is to treat a child as not a child. It is to treat him . . . as if he were an adult person who has consented to become a joint adventurer in the common cause of medical research." *Id.* at 14; *see also* Ross, *supra* note 21, at 524 (describing a letter of protest published in *The Lancet* in which the author criticized studies using "normal children (or children suffering from some irrelevant disease) as controls in clinical research," because the author felt that "children should not be exposed to any risk in medical research 'unless there is a reasonable chance, or at least a hope, that the child may benefit [directly] thereby'").

55. RAMSEY, *supra* note 54, at 13. *See generally* Angela R. Holder, *Constraints on Experimentation: Protecting Children to Death*, 6 YALE L. & POL'Y REV. 137, 140–41 (1988) (describing this view in general).

for [nontherapeutic] research is not permissible because it constitutes a breach of [the parent's] fiduciary duty."[56]

The opposing view—that healthy children can be included in otherwise ethical nontherapeutic research—was and continues to be rationalized on the basis that the informed consent requirement exists to protect individual autonomy, and presumably no more, and thus that adequately informed consent can be provided by a child's legal representative.[57] Catholic theologian Richard McCormick famously opposed Professor Ramsey on this basis, arguing that "parental consent is . . . morally valid precisely insofar as it is a reasonable presumption of the child's wishes."[58] Professor McCormick's view was that it is reasonable for a parent to presume that a child would want to participate in experimental procedures "not because they are of benefit to himself, but because at little or no cost to himself he could contribute benefit to others."[59] Nevertheless, even within this camp significant questions remained concerning the morality of nontherapeutic research involving more than a minimal risk of harm and whether parents can consent to enroll their healthy children in such research.[60]

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56. Patricia Keith-Spiegel, *Children and Consent to Participate in Research*, *in* CHILDREN'S COMPETENCE TO CONSENT 179, 188 (Gary B. Melton et al. eds., 1983) (discussing Professor Ramsey's position); *see also* RAMSEY, *supra* note 54, at 14 ("No child or adult incompetent can choose to become a participating member of medical undertakings, and no one else on earth should decide to subject these people to investigations having no relation to their own treatment. That is a canon of loyalty to them."). Whereas later codes clearly envisioned the possibility of substituted consent by parents or guardians, the *Nuremberg Code* itself appeared to take this most absolute position. Jeffrey R. Botkin explains that "[o]n its face, [the *Nuremberg Code*'s first] principle precludes . . . research with children or anyone else without full decision-making capacities. While subsequent codes of research ethics permitted nontherapeutic research with young children, some scholars thought this original principle had it right." Jeffrey R. Botkin, *Preventing Exploitation in Pediatric Research*, AM. J. BIOETHICS, Fall 2003, at 31, 31; *see also* Keith-Spiegel, *supra*, at 183 ("Most commentators agree that a strict application of the Code would have resulted in a complete moratorium on research utilizing minor participants since they fail to meet the various tests and no provision for proxy consent is provided.").

57. *See* Nelson & Reynolds, *supra* note 53, at 11–12 (describing this alternative position).

58. Richard A. McCormick, *Experimentation in Children: Sharing in Sociality*, HASTINGS CENTER REP., Dec. 1976, at 41, 42.

59. *Id.*

60. *See, e.g.*, Richard A. McCormick, *Proxy Consent in the Experimentation Situation*, PERSP. BIOLOGY & MED., Autumn 1974, at 2, 14–15; Mitchell, *supra* note 37, at 724 (noting this debate in 1964, and describing his own view that "an experiment on a [healthy] child is permissible provided that the risk does not exceed the ordinary risks of daily living"). The definition of "minimal risk" that governs agencies and their benefactors in the United States is set out *infra* notes 75–83 and accompanying text.

This debate, set in the larger context of human subjects research generally, resulted in a series of codes, beginning in 1949 with the *Nuremberg Code*[61] and culminating in the United States in 1978 with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Science Research's *Belmont Report*,[62] which established the parameters of ethical experimentation.[63] As finally described in the *Belmont Report*, human subjects research must reflect (1) a respect for persons, which translates into the practical requirement that before research can begin, the investigator must assure that informed consent is provided by participants;[64] (2) beneficence, which translates into the requirement that research be justified on the basis of a favorable risk-benefit assessment;[65] and (3) justice, which translates into the requirement that "the benefits and burdens of the research be fairly distributed across the population."[66] With respect to pediatric experimentation in particular, the *Belmont Report* concluded that children deserve special protections because they are unable to give informed consent and are thus a particularly vulnerable population at risk of exploitation.[67]

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61. NUREMBERG CODE, *supra* note 2.

62. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, *supra* note 2.

63. This debate predates the exchanges between Professor Ramsey and Professor McCormick that I have just described. Nevertheless, their exchanges are representative of those that took place in the context of human subjects research in the aftermath of the Holocaust and in connection with the proceedings at Nuremberg. I use them here in lieu of the earlier iterations because they speak specifically to the problem of including healthy children (as a subset of the human subjects population) in human subjects research.

64. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, *supra* note 2, at 4, 10.

65. *Id.* at 6–8, 14–18.

66. *Id.* at 8–10, 18–20.

67. Specifically, the *Belmont Report* urges that the "respect for persons incorporates . . . [the] ethical conviction[] . . . that persons with diminished autonomy [including the immature] are entitled to protection." *Id.* at 4. Although it does not specifically define what "protection" means in this context, it does suggest that there might be "an order of preference in the selection of classes of subjects (e.g., adults before children)." *Id.* at 18. More generally, though, it finds that the degree of protection required in any given research setting "depend[s] upon the risk of harm and the likelihood of benefit." *Id.* at 5. And it cautions that although "[e]ffective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children—even when individual research subjects are not direct beneficiaries," *id.* at 7–8 (discussing the principle of beneficence), a "difficult ethical problem remains . . . about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved," *id.* at 8. *Cf.* IOM, *supra* note 8, at 2 (explaining that children are vulnerable and in need of special protection because "[u]nlike most adults, children usually lack the legal right and intellectual and emotional maturity to consent to research

On its face, the federal regulatory scheme promulgated in 1983, and based on the *Belmont Report* and an earlier published report *Research Involving Children*,[68] resolved the debate about the propriety of using healthy children in nontherapeutic research by adopting a restrictive but nevertheless compromise position.[69] Specifically, the regulations permit the use of healthy children in research when the study design involves no more than "minimal risk"[70] and informed consent is obtained "from each prospective subject or the subjects' legally authorized representative."[71] Typically, research "involving greater than minimal risk and no prospect of direct benefit to individual subjects" is permitted, *inter alia*, only if it is "likely to yield generalizable knowledge about the subject's disorder or condition";[72] in other words, the plain language of the regulations suggests that such research can be conducted only using children with relevant illnesses. There is an exception to this presumption for "research involving children that entails more than a minor increase over minimal risk and offers no prospect of direct therapeutic benefit, if the research is designed to promote generalizable knowledge, and if it is reviewed and approved by a

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participation on their own behalf"). At least one commentator has added that children are also vulnerable because "[t]he parent, guardian, or the person conducting the experiment may be motivated by rewards rather than the child's best interest." Wenner, *supra* note 35, at 244.

68. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, RESEARCH INVOLVING CHILDREN: REPORT AND RECOMMENDATIONS OF THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, at xvii–xix (1977). This report was published by the National Commission in 1977, one year prior to the publication of the *Belmont Report*. IOM, *supra* note 8, at 52–53.

69. Additional Protections for Children Involved as Subjects in Research, 45 C.F.R. pt. 46 subpt. D (2007); *see also* Basic HHS Policy for Protection of Human Research Subjects, *id.* pt. 46 subpt. A ("This policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research."); Ross, *supra* note 21, at 528 (explaining that "Subpart A of these regulations . . . [is] known as the Common Rule because it has been adopted by 16 federal agencies and departments of the U.S. government"). Ross explains that "[a]lthough [Professor Ramsey's particular] position did not receive wide support, it stimulated and stirred debate in the ethics community that brought the issue of children in research to the forefront." Ross, *supra* note 21, at 526 (quoting Alexander, *supra* note 21, at 2).

70. 45 C.F.R. § 46.404.

71. *Id.* § 46.111(a)(4) (setting out informed consent as a precondition to approval of research by designated institutional review boards).

72. *Id.* § 46.406. Some proposals, however, suggest including in this category healthy children who, because of their environment or genetic background, for example, are at risk of serious harm in the future. *See infra* notes 313, 320–24, 335–37, 344 and accompanying text.

panel of experts."[73] Yet, consistent with the notion that protecting children generally means excluding them from involvement in risky research, this provision has tended to be "invoked quite infrequently."[74]

As defined in the regulations, minimal risk "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[75] There is an important ongoing debate about whether this standard is absolute (pegged to the harms and discomforts ordinarily encountered in the "daily life of healthy children in the general population") or relative (pegged to the harms and discomforts ordinarily encountered in the daily life of children in the circumstances pertaining to the research).[76] For example, are the risks of experimental lead exposure the same for healthy children who live in middle-class neighborhoods with newer, lead-free homes as they are for healthy children who live in poor communities with some newer but many more variably abated homes?[77] As the influential Committee on Clinical Research Involving Children of the IOM has explained,

> A relative interpretation theoretically allows high-risk studies to be approved as "minimal-risk" studies if members of target research

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73. Ross, *supra* note 21, at 531 (summarizing the terms of 45 C.F.R. § 46.407). For a discussion of the varied interpretations of these standards, see *infra* notes 77–78 and accompanying text.

74. Ross, *supra* note 21, at 531; *see also* Holder, *supra* note 55, at 147 ("HHS did not renew the charter or funding of the panel of experts in related fields, known as the Ethics Advisory Board, when they expired in 1980. As a result, no mechanism exist[ed] [still in 1988] for approval of federal funding for studies involving more than minimal risk, and no such studies [were at that time being] funded."). *But see infra* note 109 and accompanying text.

75. 45 C.F.R. § 46.102(i) (2007); There are inherent ambiguities in this definition, resulting in malleability of the standard. *See infra* notes 76–83 and accompanying text.

76. *See* OFFICE FOR HUMAN RESEARCH PROTS., OFFICE OF THE U.S. SEC'Y OF HEALTH & HUMAN SERVS., PROTECTIONS FOR CHILDREN IN RESEARCH: A REPORT TO CONGRESS IN ACCORD WITH SECTION 1003 OF P.L. 106-310, CHILDREN'S HEALTH ACT OF 2000, at 7 (2001), *available at* http://www.hhs.gov/ohrp/reports/ohrp502.pdf.

77. *See* Kopelman, *Pediatric Research Regulations Under Legal Scrutiny*, *supra* note 35, at 42 (critiquing the "relativistic interpretation" of the minimal risk rules in the context of her examination of the *Grimes* lead abatement study); *see also* Holder, *supra* note 55, at 146 (setting out this dilemma in the context of bone marrow aspirations and spinal taps, and noting that, in the period around 1988, Yale's Institutional Review Board (IRB) would approve these diagnostic interventions in the context of pediatric research when the subjects had previously undergone similar interventions because of their conditions, but not when the subjects were healthy).

> populations experience high risks in their daily lives, including in their homes, schools, sports activities, or neighborhoods. In addition to such environmental risks, some potential target research populations may, by virtue of their medical condition or its treatment, experience substantial everyday risks, distress, and uncomfortable medical examinations that are, for them, routine but *not* minimal in burden or discomfort. A relative interpretation of minimal risk would permit comparably high risks in research for these already high-risk children. In contrast, more fortunate research populations that experience low levels of risk in daily life would have a correspondingly low risk threshold for assessing whether a study presented minimal risk.[78]

Despite congressional demands for clarification of this standard,[79] and despite an apparent consensus among commentators (including the IOM) that it ought to be absolute to protect particularly vulnerable subgroups within the pediatric population from exploitation,[80] NIH's Office of Human Research Protection (OHRP) has declined to act on that consensus, describing as "premature" any resolution of this issue.[81] As a result, the interpretation of minimal risk (including its variants, "a minor increase over minimal risk" and "more than a minor increase over minimal risk") is generally left to

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78. IOM, *supra* note 8, at 121.

79. *See* Wenner, *supra* note 35, at 261–62 (describing this mandate in the Children's Health Act of 2000). The response is discussed *infra* note 106.

80. *See, e.g.*, IOM, *supra* note 8, at 17 (Recommendation 4.1, rejecting relative interpretation of the harms and risks children experience in their daily lives); NAT'L HUMAN RESEARCH PROTS. ADVISORY COMM., CLARIFYING SPECIFIC PORTION OF 45 C.F.R. § 46 SUBPART D THAT GOVERNS CHILDREN'S RESEARCH 1 (n.d.) (interpreting "the definition of minimal risk to be that level of risk associated with the daily activities of normal, healthy children"); Nelson, *supra* note 44, at 60 ("It is unacceptable to place dependent persons in situations where the risk to them is increased and then use that increased risk as reason for redefining what constitutes a minimal risk to them." (quoting Loretta M. Kopelman, *When Is the Risk Minimal Enough for Children to Be Research Subjects?*, *in* CHILDREN AND HEALTH CARE: MORAL AND SOCIAL ISSUES 89, 91 (Loretta M. Kopelman & John C. Moskop eds., 1989))); *id.* at 58–60 (challenging the conclusion by Professor Kopelman and others that some subjectivity in defining minimal risk is acceptable); Shah et al., *supra* note 5, at 481 (noting, *inter alia*, that any relative interpretation of risk "conflicts with the general consensus that, to minimize potential for exploitation, the 'minimal' risk standard should be interpreted as referring to the risks in the daily lives of 'typical' children").

81. OFFICE FOR HUMAN RESEARCH PROTS., *supra* note 76, at iv. The effect of this ongoing impasse is that individual institutions and their IRBs continue to be permitted to interpret "minimal risk" according to an absolute or relative standard as they wish.

local Institutional Review Boards (IRBs),[82] which have tended to differ, in some cases substantially, in their related classifications.[83]

Under the federal regulations, research involving children also requires that "adequate provisions are made for soliciting the assent of the children" and "the permission of each child's parents or guardian."[84] Both must be obtained "in accordance with and to the extent that consent is required" of adult research subjects.[85] The relevant regulation in this respect provides that "no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative."[86]

As a result of these qualifications, especially because of a consensus within the bioethics and regulatory communities that the minimal risk rules were to be interpreted conservatively, most nontherapeutic research conducted from the late 1970s through the early 1990s involved the use of adult subjects, even when the research

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82. An IRB is "any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of . . . research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects." 21 C.F.R. § 56.103(g) (2007).

83. *See* Shah et al., *supra* note 5, at 479 (finding "substantial variability in IRB chairpersons' assessments of the risks of research procedures in children"). The implications of this arguably standardless rule and Professor Loretta Kopelman's particularly incisive critique in this respect are discussed *infra* notes 318, 353 and accompanying text. In this regard, Rupali Gandhi has noted that "[t]he definitional ambiguities leave an incredible amount of power in the hands of the IRBs." Gandhi, *supra* note 35, at 298.

84. 45 C.F.R. § 46.408 (2007). "Permission" and "assent" were designed "[t]o avoid the confusion associated with using the term 'informed consent' to mean two things," that is, the consent of the parent and the consent of the child. Robert J. Katerberg, *Institutional Review Boards, Research on Children, and Informed Consent of Parents: Walking the Tightrope Between Encouraging Vital Experimentation and Protecting Subjects' Rights*, 24 J.C. & U.L. 545, 551 (1998). Ethicists and child psychologists continue to debate whether young children, that is, children under fourteen, should be asked to assent in the context of nontherapeutic research. *See, e.g.*, Botkin, *supra* note 56, at 31–32 (arguing that because regulations were promulgated with an eye toward protecting children from exploitation in this research context, young children should be asked whether they want to participate, and their choice should be respected); Nelson & Reynolds, *supra* note 53, at 12–13 (arguing that assent is unrelated to autonomy and that a respect for persons requires that children be asked whether they assent to participation in nontherapeutic research); David Wendler & Seema Shah, *Should Children Decide Whether They Are Enrolled in Nonbeneficial Research?*, AM. J. BIOETHICS, Fall 2003, at 1, 1 (arguing that "the threshold for assent should be fixed at 14 years of age, and a dissent requirement should be adopted for all children in the context of nonbeneficial research").

85. 45 C.F.R. § 46.408(b).

86. *Id.* § 46.116.

implicated pediatric concerns.[87] It is noteworthy that the practice of using adult subjects in lieu of children whenever possible has its source in the *Belmont Report* itself, specifically in its discussion of the practical application of the principle of justice.[88] Thus, although justice requires that the benefits and burdens of research be distributed equitably across the population, the further admonition that vulnerable populations including children receive special protection means that

> it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.[89]

Since the mid- to late 1990s, however, some of "[t]hose who care about and for children" have recognized that protecting them from exploitation has had the ancillary effect of depriving them of the full "benefit [that is to be derived] from the dramatic and accelerating rate of progress in medical care that is fueled by scientific research."[90] This concern, shared by the IOM,[91] reflects the sense that the balance struck in the *Belmont Report* between assuring distributive justice and protecting vulnerable populations may have been skewed too far in favor of protection at the expense of doing justice by these same populations. For example, "pediatricians and others have argued that infants, children, and adolescents have not shared equally with adults in advances in biomedicine."[92] It has also been noted that "the health

87. Ross, *supra* note 21, at 528 (observing that the protections established by the regulations "effectively served to restrict participation of children in medical research"); Whitstone, *supra* note 4 (noting that "[u]ntil recent years, children were not included in research most of the time").

88. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, *supra* note 2, at 18.

89. *Id.* Ross characterizes this as the "children last" rule, based on the National Commission's position in its separate report *Research Involving Children*, that "[w]here appropriate, studies have been conducted first on animals and adult humans, then on older children, prior to involving infants." Ross, *supra* note 21, at 528; *see also* Rosato, *supra* note 35, at 362 ("Until a few years ago, the prevailing view was that children should not be participants in clinical research trials because children were incapable of consenting to such nontherapeutic interventions and are particularly vulnerable to abuse.").

90. IOM, *supra* note 8, at xiii.

91. *Id.*

92. *Id.* at 1. This concern is not brand new. Indeed, at least as early as 1964, the British academic pediatrician Ross Mitchell urged that a proper balance be struck between protecting

issues unique to children were underfunded and understudied" as a result of the government's protective stance.[93] Some have gone so far as to describe children as "therapeutic orphans" in this context.[94] Of special concern is the fact that

> many drugs with potential pediatric uses have not been tested in studies that include children. These drugs may still be prescribed for children based on physicians' judgment about how data from studies with adults might be extrapolated to children. Because children differ physiologically from adults in myriad ways that can affect how drugs work in the body, extrapolation based on adult drug doses and children's weight or age can be dangerous and lead to underdosing, overdosing, or specific adverse effects not evident in adults.[95]

In other words, the irony and "[t]he danger is that unless [drugs] are tested, every child remains an experiment because there are no data for safety or efficacy and no guidelines for dosing."[96] According to the American Academy of Pediatrics, there is thus "a moral imperative to formally study drugs in children so that they can enjoy equal access to existing as well as new therapeutic agents."[97]

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children from exploitation in the research setting and assuring that the benefits of this "era of apparently boundless technological advance, in medicine as in other fields," also inure to the children. Mitchell, *supra* note 37, at 721. And he was most explicit in his warning that the tendency to want to protect children from exploitation "may now be doing the advance of paediatric knowledge a disservice, since much that is known from clinical investigation of adults has not been applied to the child because the differences have been so heavily stressed." *Id.*; *see also* Holder, *supra* note 55, at 138–39 (making this same point in 1988).

93. Ross, *supra* note 21, at 529.

94. *E.g.*, Rosato, *supra* note 35, at 363 (using this expression in this context); Carol Tauer, *Children as Research Subjects: Guinea Pigs or Therapeutic Orphans?*, U. MINN. BIOETHICS EXAMINER, Fall 2003, at 1, 1 (describing this controversy).

95. IOM, *supra* note 8, at 1–2. According to Robert Nelson,

> [M]ost drugs used to treat children have never been tested formally in children, making off-label use of medications the de facto standard of care in pediatrics. Indeed, only 20 percent of drugs approved in the United States have been labeled for use in infants and children and only 37 percent of new drugs in 1996, with the potential for pediatric use, had some pediatric labeling at the time of approval.

Nelson, *supra* note 44, at 47.

96. Ross, *supra* note 21, at 530. Angela Holder made this same point much earlier when she noted that despite the de facto ban on using children in trials, "a pediatrician confronted by a sick child in a course of ordinary clinical practice is in effect conducting Phase Three drug trials if he prescribes such a drug, whether he considers himself a researcher or not." HOLDER, *supra* note 10, at 162.

97. *See* Rosato, *supra* note 35, at 367 (quoting American Academy of Pediatrics guidelines).

There is a more skeptical view of this shift in attitudes about protecting children. It is partly based in the enormous amounts of money that are available to researchers, particularly in the pediatric drug sector, and the corresponding institutional "pressures on investigators to quickly produce . . . results."[98] Using the Johns Hopkins Medical Center as an example, Vera Hassner Sharav of the Alliance for Human Research Protection describes a "climate at academic research centers in which considerations for the safety of research subjects has given way to commercial interests":[99]

> In 2001, about 50,000 persons participated as research subjects in clinical trials [there]; the medical school is consistently at or near the top in rankings of federal research support, not to mention the hundreds of millions of additional income from collaborations with industry. Between 1995 and 2000, Hopkins NIH grants climbed from $185 million to $305 million. In 2001, NIH grants rose to $334 million, while Hopkins expenditures for research and development exceed $1 billion. . . . [I]nvestigations . . . [have] found widespread noncompliance with multiple federal regulations . . . . The violations were so egregious and widespread throughout the university, that OHRP suspended "all federally supported research projects at the covered institutions." . . . [A]n external committee [subsequently issued] a stinging indictment of the research culture at Hopkins.[100]

According to Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania, "[t]he suspension of clinical research at Hopkins is [also] a symptom of a much deeper disease—the collapse of adequate protections for those involved in research at every American medical center, clinic, testing facility and hospital."[101]

However rationalized and perceived, and despite continuing resistance from some in the bioethical and research communities,

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98. Vera Hassner Sharav, *Author Response to Letter Regarding Children in Clinical Research: A Conflict of Moral Values*, AM. J. BIOETHICS, Summer 2004, at W35, W35 (quoting JOHNS HOPKINS UNIV., ANNUAL REPORT (2001)).

99. Vera Hassner Sharav, *Children in Clinical Research: A Conflict of Moral Values*, AM. J. BIOETHICS, Winter 2003, at W12, W16.

100. Sharav, *supra* note 98, at W35. Johns Hopkins was the institution responsible for the lead abatement study at issue in *Grimes v. Kennedy Krieger Institute*, 782 A.2d 807, 811 (Md. 2001), which is described in the introductory illustration.

101. *Id.* (quoting Arthur Caplan, *Research Ban at Hopkins a Sign of Ethical Crisis*, Bioethics on MSNBC, July 20, 2001, http://www.bioethics.net/articles.php?viewCat=2&articleId=43). For a description and analysis of the Hopkins situation including the steps the institution took to remedy the concerns expressed by the OHRP, see Robert Steinbrook, *Protecting Research Subjects—The Crisis at Johns Hopkins*, 346 NEW ENG. J. MED. 716, 716–20 (2002).

"social forces have shifted the core ethical question from *whether* children should be research subjects to *when* children should be research subjects,"[102] and "[o]verall, an approach of protectionism has given way to an approach of inclusion and access."[103] Thus, congressional legislation has sought to answer that ethical question by creating intellectual property–related incentives, such as patent-term extensions for drug manufacturers to include children in their studies,[104] educational and financial incentives for researchers to enter the field of pediatric research and to pursue related studies,[105] and requirements for agency reconsideration of the terms under which children were previously protected in the research setting.[106] The NIH

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102. Rosato, *supra* note 35, at 362.

103. *Id.* at 363.

104. 21 U.S.C. § 355a(a), (c) (2000) (including a "market exclusivity" provision that" gives drug manufacturers in certain cases an additional six months of patent protection when they test their products on children); 21 U.S.C. § 355c(a), (b) (Supp. V 2005) (codifying these FDA-promulgated regulations and thus providing as a matter of federal statutory law that, absent a waiver, new drugs cannot be approved and existing drugs cannot continue to be distributed in the pediatric population unless studies involving the safety and efficacy of the drugs in that population have been conducted); *see also* 21 C.F.R. § 201.23(a) (2007) (stating that drug manufacturers may be required to confirm the safety and efficacy of existing drugs in new pediatric studies when those drugs are likely to be used in pediatric medicine and when the absence of adequate labeling could pose significant risk to pediatric patients); 21 C.F.R. § 314.55(a) (2007) (supplementing and then replacing incentives in The Food and Drug Modernization Act of 1997, which expired in 2002, and requiring that new drug trials include pediatric subjects unless a waiver is obtained).

105. 42 U.S.C. § 284h(b)(3), (d) (2000) (establishing the Pediatric Research Initiative, the purpose of which is "to increase the development of adequate pediatric clinical trials and pediatric use information to promote the safer and more effective use of prescription drugs in the pediatric population," and which authorizes an initial fifty million dollars "and such sums as may be necessary" through 2005 to accomplish these ends); *id.* § 285g-10 (establishing an "Investment in Tomorrow's Pediatric Researchers," the purpose of which is "to ensure the future supply of researchers dedicated to the care and research needs of children" by supporting "an increase in the number and size of institutional training grants to institutions supporting pediatric training" and "an increase in the number of career development awards for health professionals who intend to build careers in pediatric basic and clinical research"); *id.* § 288-6(a) (establishing a loan repayment program, the purpose of which is to encourage the NIH to repay up to "$35,000 of the principal and interest of the educational loans" of pediatric research professionals).

106. Children's Health Act of 2000, Pub. L. No. 106-310, § 1003, 114 Stat. 1101 (expiring upon submission of required review) (requiring the Secretary of Health and Human Services to "conduct a review of the regulations under Subpart D of [45 C.F.R. pt. 46]" specifically to "consider any modifications necessary to ensure the adequate and appropriate protection of children participating in research," and listing among those terms needing reconsideration "(2) the definition of 'minimal risk' for a healthy child or for a child with an illness; . . . (4) the definitions of 'direct benefit to the individual subjects' and 'generalizable knowledge about the subject's disorder or condition'; . . . [and] (10) the appropriateness of current practices for

and its OHRP have also acted "to promote greater participation of children in research, despite general concerns regarding human subjects protections more generally."[107] Specifically, the NIH now requires that "[a]ll NIH-funded research . . . include a plan for the inclusion of children, unless there is good justification to exclude them,"[108] thus apparently reversing the government's longstanding "children last" rule.[109] And influential bioethicists continue to propose creative interpretations of the minimal risk and consent rules that (entirely apart from these initiatives) provide the scientific community with the basis to argue for and accept increased access to healthy children as research subjects, including in studies that involve more than a minimal risk of harm.[110] As a result of these efforts,

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recruiting children for participation in research"). The required review was submitted to Congress in May 2001. OFFICE FOR HUMAN RESEARCH PROTS., *supra* note 76, at ii. The review document agrees with many survey respondents who urged the development of additional guidelines in connection with the terms identified for review in the Children's Health Act, including the definitions of "minimal risk" and "minor increase over minimal risk." *Id.* at 7; *see also supra* notes 75–83 and accompanying text (setting out the regulatory definition and the debate over its interpretation). Nevertheless, it concludes that "[t]he current regulations under Subpart D of 45 CFR Part 46 are sound, effective, and well-crafted, and when implemented properly by IRBs and investigators, provide adequate and appropriate protections for children of all ages and maturity levels participating in research conducted or supported by DHHS." OFFICE FOR HUMAN RESEARCH PROTS., *supra* note 76, at iii.

107. Ross, *supra* note 21, at 531–32; *see supra* notes 95–98 and accompanying text.

108. Ross, *supra* note 21, at 531.

109. See *supra* notes 87–89 and accompanying text for a description of this policy and its origins. Consistent with this new mandate, since 2000 OHRP has "received over two dozen requests for [45 C.F.R. pt. 46, section] 407 panels . . . 11 panels have been convened since February 2001, and public comments were sought for six." Ross, *supra* note 21, at 531; *see also supra* notes 73–74 and accompanying text (describing the terms of section 407 and the infrequency with which it was invoked in the past). Ross uses these data and "disturbing evidence . . . that the new policies are encouraging the participation of children in research for which there are no plans to do pediatric subset analyses" as the basis for her concern that "the pendulum [may have] swung too far" away from the proper balance between protecting children and allowing them access to research participation in their best interest. Ross, *supra* note 21, at 519, 532. For an excellent description of this statutory and regulatory history, see Rosato, *supra* note 35, at 364–65.

110. *See, e.g.*, ROSS, *supra* note 34, at 211 (contending that children at higher levels of risk for lead poisoning should be considered as having a "disorder or condition" and arguing that the *Grimes* court could have found that researchers permissibly exposed the children to a "minor increase over minimal risk"); Kopelman, *supra* note 17, at 749 (arguing that healthy children at high risk of serious harm in the future should be considered as having a "condition" such that they would be eligible for "no benefit, higher hazard" research and criticizing the *Grimes* court for its conclusion that the children in that study were healthy and thus ineligible for such research); Nelson, *supra* note 44, at 62 (arguing that "the level of allowable risk" should be tied "to the assent of the child" or of a group of parents and older children in the event the child is too young to provide assent).

commentators predict "a dramatic increase in the number of future clinical studies involving children."[111]

II. THE LEGAL BOUNDARIES OF PARENTS' CONSENT AUTHORITY

The federal laws and policies described in Part I govern most aspects of pediatric research in the United States. Contrary to an analysis undertaken on behalf of the Institute of Medicine, this federal scheme does not exist in a vacuum.[112] In particular, its informed consent requirement is circumscribed by well-established constitutional doctrine concerning parental authority to risk or cause children harm and by related and equally well-established state law doctrines of informed consent and child maltreatment. Based on the premise that legally valid consent is a precondition to ethical human subjects research, this Part discusses the permissibility of pediatric research involving healthy children in the context of this broader legal landscape.

A. *The Doctrinal Boundaries of Parents' Consent Authority*

The boundaries of parents' consent authority are defined in part by the constitutional doctrine of parental autonomy and in part by

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111. Whitstone, *supra* note 4; *see* Tauer, *supra* note 94, at 4 (describing the evolution of pediatric research ethics and related regulatory and legislative developments, and concluding that "[w]e are undoubtedly seeing an increase in research involving children, encouraged both by the FDA and Congressional initiatives"); *see also supra* notes 8–9 and accompanying text (describing recent explosion in and spending on pediatric research).

112. *See* Amy T. Campbell, *Appendix* to IOM, *supra* note 8, app. B at 337 ("On the basis of a review of state law—statutory and case law—on this point (research with children and adolescents), there is little to go by in terms of the permissibility of and limits of such research."); *id.* at 326 ("[S]tate law—as specifically applied in the applied in the research setting—is a relative vacuum in terms of the regulation of research with children and adolescents."); *id.* at 328 ("Unfortunately, there is thus a great deal of uncertainty as to the extent of state regulations . . . . Perhaps this should be unsurprising given the particularly recent nature of calls to enhance the base of research with populations of this age."). The flaw inherent in this analysis is its assumption that, because the states have not specifically regulated the conditions under which researchers may conduct pediatric research, state law is silent on the issue. As I note throughout this Article, to the extent that parental and/or children's consent is a requirement of ethical research, well-established doctrine relating to consent and consent authority is directly relevant. Much to its credit, however, the IOM analysis—undertaken by Amy Campbell—is alone in understanding and then acknowledging the critical significance of some state law in this area, in providing fifty-state surveys on the law pertaining to children's capacity to provide lawful consent, and in suggesting the development of "uniform state guidelines" to minimize discrepancies in the states' treatment of pediatric research. *See id.* at 320–31, 337–39.

state law doctrines of informed consent and child protection. Thus, the threshold requirement in the federal pediatric research regulations that parents must consent to their children's involvement in related procedures cannot be met—or at least has no legal significance—unless parents actually have the right under those doctrines to subject their children to the risks or harms involved in the particular research.[113] Contrary to the assumption made by at least one prominent commentator, the federal regulations do not give parents this right.[114] They merely state that which is doctrinally obvious in both ethics and law: children cannot be used as research subjects (just as they cannot be treated medically) without their parents' consent.[115]

As a matter of federal constitutional law, parents are entitled to raise their children as they see fit, including to make most decisions for them until they reach the age of majority.[116] This doctrine of parental autonomy resides principally in the Fourteenth Amendment,[117] and is rationalized on the grounds of the following syllogism: children lack the "maturity, experience, and capacity for

113. Doctors may not treat, and researchers may not involve a child in research, without parental consent. Bonner v. Moran, 126 F.2d 121, 122 (D.C. Cir. 1941); *see* 45 C.F.R. § 46.116 (2007). As Dan Dobbs explains, however, "[t]here are limits . . . to the parent's power to give [legally] effective consent." DOBBS, *supra* note 14, at 229. In the absence of legally valid consent, doctors and researchers may be subject to liability in battery, whether or not the child suffers serious damage as a result of the treatment or research. *Id.* at 54 (explaining that battery law "vindicates the plaintiff's rights of autonomy and self determination, her right to decide for herself how her body will be treated by others, and to exclude their invasions as a matter of personal preference, whether physical harm is done or not").

114. *See* Ross, *supra* note 35, at 53. In this essay, Ross examines "whether parents have the moral and legal authority to expose their children to any degree of risk in non-therapeutic research." *Id.* She disposes of the legal aspect of this issue in this single line: "Legally, the federal regulations empower parents to consent to their children's participation in research that entails the risks" at issue in studies like the Hopkins lead abatement study featured in this Article's introductory illustration. *Id.* Over the course of a few paragraphs, she then proceeds to evaluate the moral basis for parental consent in this context, summarizing the historical debate and her own excellent work on the ethics of pediatric research. *Id.* at 53–54. Ross's selective focus on ethics at the expense of legal analysis is emblematic of the literature in this area.

115. *See Bonner*, 126 F.2d at 122 (setting out this rule in its classic context); *see also* DOBBS, *supra* note 14, at 229 (discussing this rule as a defense to battery).

116. Troxel v. Granville, 530 U.S. 57, 65 (2000) (plurality opinion); *see also* DOBBS, *supra* note 14, at 227 (describing limited exceptions to this presumption). Although *Troxel* is a plurality opinion, its description of the doctrine of parental autonomy is accurate. That is, to the extent the Justices disagreed, it was not about this aspect of the case. The doctrine is also described in relevant respects in the earlier case *Parham v. J.R.*, 442 U.S. 584, 600, 602–04 (1979).

117. *Troxel*, 530 U.S. at 64–65.

judgment" necessary to make good decisions for themselves.[118] Thus,

118. *Id.* at 69 (citing *Parham*, 442 U.S. at 602). As a factual matter, not all children are alike in these respects; depending on the issue, adolescents in particular can be highly capable decisionmakers. *Cf. infra* note 306 and accompanying text (exploring risk-related circumstances in which this is not necessarily the case). Nevertheless, the law has drawn the line at the age of majority and has stuck to it for most purposes, including for medical decisionmaking. *See Troxel*, 530 U.S. at 66 ("[I]t cannot now be doubted that the Due Process Clause of the Fourteenth Amendment protects the fundamental right of parents to make decisions concerning the care, custody, and control of their children."); *Parham*, 442 U.S. at 605 ("Most children, even in adolescence, simply are not able to make sound judgments concerning many decisions, including their need for medical care or treatment. Parents can and must make those judgments."); Commonwealth v. Nixon, 761 A.2d 1151, 1152–53 (Pa. 2000) (declining to adopt a mature minor rule on the grounds, *inter alia*, that to do so would absolve parents not only of their parental rights but also their responsibilities for the care of their older but still minor children); IOM, *supra* note 8, at 156 ("Although decisional capacity develops through childhood and even into adulthood, practical and policy considerations have led policymakers to require, in most cases, that individuals achieve a specified age (the 'age of majority') before they can enter into contracts, consent to medical care, and make other crucial decisions in their own right."). There are, of course, notable exceptions to this rule. For example, in *Hodgson v. Minnesota*, 497 U.S. 417 (1990), the Court discusses the constitutional right of adolescent girls to bypass their parents and get judicial approval for an abortion. *Id.* at 435. Furthermore, state laws may allow emancipated minors to make decisions for themselves, mature minors to make certain medical decisions, or minors to seek treatment without their parents' knowledge or permission for sexually transmitted diseases, pregnancy, or emotional problems. Alexander Morgan Capron, *The Competence of Children as Self-Deciders in Biomedical Interventions*, *in* WHO SPEAKS FOR THE CHILD: THE PROBLEMS OF PROXY CONSENT, at 57, 65–76 (Willard Gaylin & Ruth Macklin eds., 1982). For a summary of these exceptions, *see* IOM, *supra* note 8, at app. B.

Some prominent commentators have opined that the "mature minor exception" reflected in these laws ultimately provides for a general right of adolescents to make medical, and thus also research, decisions for themselves. *See, e.g.*, ANNAS, GLANTZ & KATZ, *supra* note 10, at 71–73 (suggesting the possibility of a broader mature minor exception); Clark, *supra* note 35, at 34 (arguing that the "doctrinal evolution suggests that . . . [the law is] eager to let those over fourteen act independently from their parents"); IOM, *supra* note 8, at app. B (suggesting much of the same in its analysis). These analyses are largely incorrect. The most common mature minor exceptions were not developed in recognition of the child's evolving capacity to make autonomous decisions; rather, they expressly sacrifice the value of an autonomous decisionmaker in limited instances to promote more important public policy goals. *See* Rosato, *supra* note 35, at 370 (noting that "existing exceptions to parental consent are narrow and based on public policy rather than the minors' competence"). Thus, older adolescents are permitted to consent to necessary and usually only limited medical treatment in the absence of their parents so that honest physicians can avoid battery claims and be paid for their work; emancipated minors are permitted to act in all respects on their own behalf because they no longer have legal guardians to act in their stead; adolescent girls are permitted to consent to abortions (generally subject to a judicial override) so that their developmental, educational, and other opportunities are not risked by unwanted pregnancies; and children can consent to treatment for certain diseases and emotional conditions so that, regardless of their parents' views, their individual and society's general welfare are protected. *See generally* Walter Wadlington, David C. Baum Memorial Lecture, *Medical Decision Making for and by Children: Tensions Between Parent, State, and Child*, 1994 U. ILL. L. REV. 311, 321, 323–24 (1994) (discussing emancipation and minor medical consent laws).

someone needs to make decisions for them. Parents are best suited for this purpose (as opposed to the state or another third party) because they are most likely to make decisions in their children's best interests.[119] Based on this rights and responsibilities framework—the Supreme Court most typically speaks of "the right, coupled with the high duty"[120]—the law formally presumes that whatever the parent's decision, it is in the child's best interests.[121] Among the many routine day-to-day decisions parents make, this doctrine protects their right to decide such fundamental questions as where their children go to school,[122] with whom they associate,[123] what treatment they receive in the event they become ill or injured,[124] and in general the values according to which they are raised.[125]

As between parents and third parties, including the state and other individuals, the presumption that parents act in their children's best interests is rebuttable only when there is evidence that a parent is causing or risking harm to a child.[126] State child protection laws

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119. *Troxel*, 530 U.S. at 68–69; *Parham*, 442 U.S. at 602.

120. *See, e.g.*, *Parham*, 442 U.S. at 602.

121. *Troxel*, 530 U.S. at 68–69; *Parham*, 442 U.S. at 602. As the U.S. Supreme Court affirmed in *Troxel*,

> [t]he law's concept of the family rests on a presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions. More important, historically it has recognized that natural bonds of affection lead parents to act in the best interests of their children.

530 U.S. at 68 (quoting *Parham*, 442 U.S. at 602). There are certainly other rationales for or theories of parental autonomy beyond this "fiduciary" theory. The most prominent of these is the "property" theory—that is, that children are the property of their parents and thus that parents are entitled to do with them as they wish. For a description of this evolution, see *infra* notes 382–402 and accompanying text. Contemporary doctrine prefers the fiduciary or best interests rationale, however, and thus it is the rationale that is most relevant to modern litigators and family law theorists.

122. Pierce v. Soc'y of Sisters, 268 U.S. 510, 529–35 (1925); Meyer v. Nebraska, 262 U.S. 390, 400–01 (1923).

123. *Troxel*, 530 U.S. at 78 (Souter, J., concurring).

124. *Parham*, 442 U.S. at 604; *see also* ANNAS, GLANTZ & KATZ, *supra* note 10, at 68 (setting out the parental consent requirement and its basis in law and legal theory).

125. *See Troxel*, 530 U.S. at 86 (Stevens, J., dissenting).

126. *Parham*, 442 U.S. at 602; Leonard H. Glantz, *The Law of Human Experimentation with Children*, *in* CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW, *supra* note 38, at 103, 106 (noting that "parents have broad discretion" in medical matters relating to their children, but that the state can intervene when parents "cross[] . . . boundaries constitut[ing] child abuse . . . ."). This high threshold for intervention is required because the law requires no more than adequate parenting; so long as the parent's decision or conduct does not cross the threshold into abuse or neglect, it will be considered adequate. *See, e.g.*, Santosky v. Kramer, 455 U.S. 745, 753 (1982) ("The fundamental liberty interest of natural parents . . . does not evaporate simply because they have not been model parents . . . ."); Bottoms v. Bottoms, 457

traditionally have defined the sorts of harm that will place a parent's decisions or conduct outside the scope of parental authority.[127] Among other things, these laws proscribe physical abuse,[128] emotional abuse,[129] and neglect.[130] Federal constitutional law generally embraces these boundaries on the ground that states have a compelling interest in protecting children from harm and risk that is intentionally inflicted by their parents.[131]

Consistent with society's particular aversion to unwanted and harmful invasions of physical integrity,[132] physical abuse in particular has come to be defined quite broadly. The definition promulgated by the U.S. Department of Health and Human Services (HHS) is typical,

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S.E.2d 102, 104 (Va. 1995) (requiring that "a parent's rights 'are to be respected if at all consonant with the best interests of the child'" (quoting Malpass v. Morgan, 192 S.E.2d 794, 799 (Va. 1972))). The legal presumption that parents act in their children's best interests is rebuttable on lesser grounds as between parents who may be separated or divorced and who have joint physical and legal custody of their children. *See, e.g.*, Hardin v. Hardin, 711 S.W.2d 863, 865 (Ky. Ct. App. 1986) (noting that the trial court is authorized "to make a determination" on the basis of its own evaluation when feuding parents cannot agree concerning an aspect of the care of their children).

127. All states have laws proscribing child maltreatment in its many forms. *See* CHILD WELFARE INFO. GATEWAY, DEFINITIONS OF CHILD ABUSE AND NEGLECT 1 (2007), *available at* http://www.childwelfare.gov/systemwide/laws_policies/statutes/define.pdf. These laws appear both in the states' penal codes and in their CPS provisions. Although some states' definitions are more broadly worded than others, a majority are consistent with one another. The definitions provided are representative of a majority of states' and the federal government's definitions.

128. For some typical definitions of physical abuse, see *infra* text accompanying notes 133–43.

129. Emotional abuse is typically defined as "injury to the psychological capacity or emotional stability of the child as evidenced by an observable or substantial change in behavior, emotional response, or cognition," or as evidenced by "anxiety, depression, withdrawal, or aggressive behavior." CHILD WELFARE INFO. GATEWAY, *supra* note 127, at 3.

130. Neglect is typically defined as the

> failure to provide for a child's basic needs. Neglect may be . . . [p]hysical (e.g., failure to provide necessary food or shelter, or lack of appropriate supervision)[,] [m]edical (e.g., failure to provide necessary medical or mental health treatment)[,] [e]ducational (e.g., failure to educate a child or attend to special education needs)[,] [e]motional (e.g., inattention to a child's emotional needs, failure to provide psychological care, or permitting the child to use alcohol or other drugs).

CHILD WELFARE INFO. GATEWAY, WHAT IS CHILD ABUSE AND NEGLECT? 2 (2006), *available at* http://www.childwelfare.gov/pubs/factsheets/whatiscan.pdf.

131. *See, e.g.*, Prince v. Massachusetts, 321 U.S. 158, 168–69 (1944) (upholding state law limits on parental authority under the First and Fourteenth Amendments on the ground that the state has an overriding interest in children's healthy development).

132. The society's aversion to invasions of physical integrity is in contrast to its treatment of invasions of emotional integrity, which do not receive nearly the same legal or cultural protection—as in, "sticks and stones will break my bones, but words will never hurt me." *See, e.g.*, DOBBS, *supra* note 14, at 822–24 (discussing this point generally in the context of tort law).

as it includes "physical injury (ranging from minor bruises to severe fractures or death) as a result of punching, beating, kicking, biting, shaking, throwing, stabbing, choking, hitting (with a hand, stick, strap, or other object), burning, or otherwise harming a child."[133] HHS regulations further provide that an "injury is considered abuse regardless of whether the caretaker intended to hurt the child."[134] In other words, under these rules parental motivation is irrelevant. It is noteworthy that HHS is also the federal agency responsible for the development and administration of the regulations governing human subjects research, including its pediatric provisions.[135]

Although the states obviously are most concerned with preventing and addressing the more serious instances of parentally inflicted harm, their laws typically also define abuse broadly, so that the boundary between permissible and impermissible conduct lies at the point at which—again however motivated[136]—a parent acts

133. CHILD WELFARE INFO. GATEWAY, *supra* note 130, at 3.

134. *Id.* Compare *infra* notes 144–65 and accompanying text, discussing doctrinal and de facto exceptions to the rules and to their embedded principle that motivation is irrelevant in the scheme. The prospects for nontherapeutic pediatric research to be considered among these exceptions is discussed *infra* notes 206–35 and accompanying text.

135. See *supra* notes 70–86 for the relevant terms of the Common Rule and of Subpart D, including the regulations' special provisions for research involving children.

136. *See, e.g.*, Gregory A. Loken, *Gratitude and the Map of Moral Duties Toward Children*, 31 ARIZ. ST. L.J. 1121, 1133–34 (1999) ("The very definitions of parental 'abuse' and 'neglect' are largely dependent on the results, not the motives, of the parents' actions . . . ."); Or. Dep't of Human Servs., What is Child Abuse and Neglect?, http://www.oregon.gov/DHS/children/abuse/abuse_neglect.shtml (last visited Nov. 27, 2007) ("Oregon law defines physical abuse as an injury to a child that is not accidental. Most parents do not intend to hurt their children, but abuse is defined by the effect on the child, not the motivation of the parents."). It is interesting to note that early legal definitions of child maltreatment tended to be centered on parental behavior and motivation. *See* Monrad G. Paulsen, *The Law and Abused Children*, *in* THE BATTERED CHILD 153, 154 (Ray E. Helfer & C. Henry Kempe eds., 2d ed. 1974) (providing as a typical example of this focus states that defined neglect as "subject[ing the child] to cruelty or depravity"); Michael Wald, *State Intervention on Behalf of "Neglected" Children: A Search for Realistic Standards*, 27 STAN. L. REV. 985, 1000 (1975) (arguing against broad definitions of neglect that focus "primarily in terms of parental conduct or home conditions"). The shift in the law—from basing definitions of abuse and neglect on parental motivation to basing definitions on harm to the child—occurred when experts began to argue that whether or not children suffer harm as a result of intentional parental conduct or neglect often has little to do with whether their parents are benevolently or malevolently motivated. Thus, a parent may act intentionally with malevolent intent but not cause any real harm to their child, just as they may act intentionally with benevolent intent and still cause them serious harm. Because of this, it was argued, a child protection scheme (as opposed to a parental rights scheme) more properly focuses on the child rather than the parent. *See, e.g.*, Wald, *supra*, at 1001–12 (making this point). Notwithstanding the modern motivation-free legal definitions of maltreatment, it is plausible to argue that parental motivation continues to drive much of the states' administrative

intentionally to cause "bodily harm greater than transient pain or minor temporary marks."[137] This standard is generally interpreted to mean pain, marks, or other adverse effects lasting for more than one day.[138] Importantly, "seeking unnecessary medical treatment" (for whatever reason) is a subcategory of physical abuse, sometimes described as medical abuse, which depending upon its severity, can result in a range of interventions from the provision of services to termination of parental rights.[139]

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practices. For example, it is plausible to consider interventions in the family in cases of physical abuse to be based in the view that a parent has no good reason to inflict such injury on a child, at least in addition to the view that the child ought to be protected against such harm. For additional discussion of the relevance of parental motivation to the definition and substantiation of maltreatment, see *infra* notes 154–65 and accompanying text.

137. WASH. REV. CODE ANN. § 9A.16.100 (West 2007); *see also In re* J.M.P., Nos. B184876, B185887, 2006 WL 1579562, at *1 (Cal. Ct. App. June 8, 2006) (listing the finding of "ant poison spread everywhere including on the children's toys and clothing and within reach of the girls" as one of several conditions endangering their welfare and justifying their removal from their mother's custody); Shay v. Rossi, 749 A.2d 1147, 1152 (Conn. 2000) (listing the ingestion of poison and Tylenol by a three-year-old as examples of incidents that would properly trigger suspicion of abuse).

138. *See, e.g.*, Hildreth v. Iowa Dept. of Human Servs., 550 N.W.2d 157, 159 (Iowa 1996) (defining "physical injury" and setting out this standard). This standard is typically used to govern the day-to-day practice of social workers involved in the reporting and investigation of child abuse cases. A few courts have rejected this standard in cases of alleged excessive corporal punishment. *See, e.g.*, *id.* at 160 ("[R]eddening of the skin lasting for twenty-four hours is [not] a physical injury per se. . . . [R]ather, [it is] evidence from which the existence of a physical injury can be found. . . . In applying this rule to petitioner's actions, [the alleged abuser] could not reasonably have foreseen that the rather limited striking of [the child's] buttocks would produce a physical injury."); *In re* C.B., 636 S.E.2d 336, 336 (N.C. Ct. App. 2006) (holding that notwithstanding child protective services (CPS) practice, bruises lasting for more than a day inflicted in a corporal punishment context were insufficient to meet the "serious physical injury" standard for physical abuse in North Carolina).

139. *See, e.g.*, Canter v. City of Bristol Dep't of Soc. Servs., No. 0507–05–3, 2005 WL 3369350, at *2 (Va. Ct. App. 2005) (terminating a mother's parental rights following felony child abuse conviction based on a number of abuse charges, including that she had given her three-year-old daughter Elavil "to calm her"); *see also* Becker v. Clark, 722 So. 2d 232, 233 (Fla. Dist. Ct. App. 1998) (noting the existence of Florida's "medical abuse/neglect" registry for parents and guardians found to have committed these violations against their children). Medical abuse is a term used in both law and medicine generally to connote the unnecessary and inappropriate use or provision of medicines or medical services. It has been used in a number of contexts. *See, e.g.*, *In re* Doe, 418 S.E.2d 3, 4 (Ga. 1992) (describing the aggressive but futile life-preserving efforts involving terminally ill patients including children as medical abuse); Shelby L. v. Shawna L., 699 N.W.2d 392, 399 (Neb. 2005) (describing as medical abuse the effects of Munchausen Syndrome by Proxy, that is, "the deliberate production or feigning of physical or psychological signs or symptoms in another person who is under the individual's care" (quoting AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 781 (4th rev. ed. 2000))); Charles O. Jackson, *The Amphetamine Inhaler: A Case Study of Medical Abuse*, J. HIST. MED. & ALLIED SCI. 187, 187–96 (1971) (describing the misuse of

The states also proscribe intentional parental conduct that merely risks physical abuse.[140] The degree of risk that is necessary to constitute actionable endangerment depends on the jurisdiction.[141] Regardless of the state's formal requirements, however, child protective services (CPS) are generally risk averse, especially at the intake and investigation stages of the process. Thus, depending upon the nature of the allegations, CPS will intervene on much less weighty evidence, including temporarily to remove children who are merely suspected of being in jeopardy.[142] Because many states' CPS departments are locally rather than centrally controlled, there is a patchwork of standards for risk-based interventions even within individual states; this, in turn, makes it difficult to predict the likelihood of such interventions.[143]

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amphetamines as medical abuse); Stephen N. Nelson, *"Do Everything!" Encountering "Futility" in Medical Practice*, 19 ETHICS & MED. 103, 112 (2003) (arguing that "medical abuse of patients in the name of science or love, grief or guilt is an indefensible use of patients as means to others' ends"); Therese Powers, *Race for Perfection: Children's Rights and Enhancement Drugs*, 13 J.L. & HEALTH 141, 146–49 (1999) (questioning the propriety of providing drugs such as human growth hormone and Ritalin to otherwise healthy children); John A. Robertson, *Reproductive Technology in Germany and the United States: An Essay in Comparative Law and Bioethics*, 43 COLUM. J. TRANSNAT'L L. 189, 217 n.141 (2005) (describing the misuse of medicine and medical procedures by Nazi doctors as medical abuse); Anne Tamar-Mattis, *Exceptions to the Rule: Curing the Law's Failure to Protect Intersex Infants*, 21 BERKELEY J. GENDER L. & JUST. 59, 63 (2006) (arguing that "gender normalizing surgery" is medical abuse).

140. *See, e.g.*, WASH. REV. CODE ANN. § 9A.16.100 (West 2007).

141. *Compare* CAL. PENAL CODE § 11165.6 (West 2007) (defining "child abuse" to include "willful harming or injur[ing] of a child or the endangering of the person or health of a child"), *and* TEX. FAM. CODE ANN. § 161.001(1)(D)–(E) (Vernon 2007) (terminating the parent-child relationship for "knowingly plac[ing] or knowingly allow[ing] the child to remain in conditions or surroundings which [will] endanger the physical or emotional well-being of the child . . . [and] engag[ing] in conduct or knowingly plac[ing] the child with persons who engage[] in conduct which endangers the physical or emotional well-being of the child"), *with* N.C. GEN. STAT. ANN. § 7B-101 (West 2007) (defining an "abused juvenile" as a child "whose parent, guardian, custodian, or caretaker . . . [i]nflicts or allows to be inflicted upon the juvenile a serious physical injury by other than accidental means," or who "[c]reates or allows to be created a substantial risk of serious physical injury to the juvenile by other than accidental means").

142. *See generally* Doriane Lambelet Coleman, *Storming the Castle to Save the Children: The Ironic Costs of a Child Welfare Exception to the Fourth Amendment*, 47 WM. & MARY L. REV. 413 (2005) (discussing this tendency and allowance especially in the context of the gateway phases of the child protection scheme).

143. *See id.* at 443 n.68 (noting, *inter alia*, this feature of North Carolina's child protection scheme).

B. *Exceptions to the Proscriptions against Physical Abuse*

There are both doctrinal and de facto exceptions to the proscriptions against maltreatment, and in particular to their incorporated rule that parental motivation is irrelevant in establishing abuse.[144]

The doctrinal exceptions are premised on the view that certain intentionally inflicted harms are necessary to secure the best interests of the child. Thus, even though it otherwise meets the definition of abuse, it is permissible to cut a child in the context of a surgical procedure when the intrusion is designed to alleviate the patient's own greater physical harm.[145] The cases that support this exception show that the nexus between the surgically inflicted injury and the benefit must be direct in the sense that the injury itself must be therapeutic, that the benefit must outweigh the injury, and that psychological or developmental benefit is generally disregarded as a sufficient basis to proceed with an injurious physical intervention.[146] In

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144. For an elaboration of the relevance of parental motivation in formal maltreatment law, see *supra* notes 134–36 and accompanying text.

145. ANNAS, GLANTZ & KATZ, *supra* note 10, at 75 ("[I]t is generally understood that the law allows a parent to consent to the invasion of his child's body only if such invasion is for the child's benefit or welfare."); Wadlington, *supra* note 118, at 331 ("[T]he underlying consideration is the child's welfare and whether his best interests will be served by the medical treatment.").

146. These features are all present in the reported cases involving a parent's decision to consent or not to surgery or other medical procedures on her child. The case, *In re Sampson*, 317 N.Y.S.2d 641 (Fam. Ct. 1970), *aff'd per curiam*, 278 N.E.2d 918 (1972), has been used as support for the proposition that courts will permit a parent to consent to a potentially or actually harmful physical invasion to obtain a psychological (rather than physical) benefit for the child. *E.g.*, ANNAS, GLANTZ & KATZ, *supra* note 10, at 69–70 (making this point). In *Sampson*, a New York State trial court held that a mother who had consented to plastic surgery on her son's face but who refused to consent to the blood transfusions that were necessary to the operation's success and the child's survival was guilty of child neglect, and ordered that the consent be given by a surrogate if and when the operation was to take place. *Sampson*, 317 N.Y.S.2d at 658. The surgery itself was deemed necessary to cure the child's apparently substantial cosmetic deformity so that he would have a chance to lead a more-or-less normal life. *Id.* at 644. A careful reading of the case reveals the flaw in the argument that the state intervened to protect the child's interests in psychological well-being. In fact, the child had been excluded by the state from school because he was considered too ugly to attend; and even though the school system had promised him at-home tutoring, it apparently did not hold up its end of the bargain. *Id.* As a result, the child entered his adolescent years virtually illiterate and still exiled from his peer group. *Id.* Everyone's interest at the time of the litigation was to fix his face so that this damage could be at least partially undone. *Id.* at 657. Although the opinion expresses an interest in the boy's psychological state, the court actually found that he was not emotionally disturbed. *Id.* at 645. Its focus was therefore on the fact of his physical deformity and its impact on his educational development. *Id.* at 657; *see also* Wadlington, *supra* note 118,

any event, it is impermissible to "sell" the right to maltreat a child for what might be characterized as an indirect benefit.

Along with medically indicated procedures, childhood vaccinations are most likely to be characterized as falling within this exception because they are intended to protect the child against particularly difficult diseases: a child vaccinated against polio is generally immune from its debilitating effects;[147] a child vaccinated against the human papillomavirus will, hopefully, be spared the possibility of cervical cancer.[148] Of course, the states' mandatory vaccination programs are also justified on the ground that they benefit the public health and thus society as a whole by containing the spread of infectious disease and, where inoculation is sufficiently widespread, by promoting the eradication of the disease from the human population.[149]

The right of a parent to use corporal punishment as a form of discipline is not typically considered an exception to the maltreatment rules because it is generally delimited by those rules. That is, it is generally the case that parents can only physically discipline their children so long as they do not inflict or risk serious physical injury.[150] California (among other jurisdictions worldwide) has begun to consider even stricter limits on parents wishing to engage in this form of discipline, particularly targeting the use of corporal punishment to correct the behavior of younger children.[151] A minority of states have set corporal punishment out as a formal exception to the maltreatment rules; even in those jurisdictions, however, parents'

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at 311 (discussing "the complex constitutional issues with which courts are presented when parental justification for declining life-saving treatment stems from the tenets of the parents' religion").

147. *See* Bonnie A. Maybury Okonek & Linda Morganstein, *Development of Polio Vaccines*, ACCESS EXCELLENCE CLASSIC COLLECTION, http://www.accessexcellence.org/AE/AEC/CC/polio.html (last visited Nov. 27, 2007) (describing history of polio as a disease, and the development and success of the polio vaccines).

148. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, HPV VACCINE QUESTIONS AND ANSWERS 1 (2006), *available at* http://www.cdc.gov/std/hpv/hpv-vaccine.pdf.

149. *See* ANGIE A. WELBORN, MANDATORY VACCINATIONS: PRECEDENT AND CURRENT LAWS 2–5 (2005), *available at* http://www.fas.org/sgp/crs/RS21414.pdf.

150. *See* CHILD WELFARE INFO. GATEWAY, DEFINITIONS OF CHILD ABUSE AND NEGLECT: SUMMARY OF STATE LAWS 5 (2007), *available at* http://www.childwelfare.gov/systemwide/laws_policies/statutes/defineall.pdf ("In 14 States, the District of Columbia, American Samoa, and the Northern Mariana Islands, physical discipline of a child, as long as it is reasonable and causes no bodily injury to the child, is an exception to the definition of abuse.").

151. *See infra* note 399 and accompanying text.

rights are circumscribed by the abuse standard.[152] Notwithstanding this general state of affairs, a few appellate courts in states that tend to be particularly protective of parents' rights have suggested (only implicitly) that parents will be given some leeway to transgress the boundaries of the abuse standard when they can show that they were engaged in physical discipline.[153]

Perhaps most important for purposes of this Article, there are also de facto exceptions to the proscription against physical abuse for harms and risks that are either explicitly or tacitly accepted in the culture. I characterize them as de facto exceptions because, although they are never set out as such in the doctrine and although they involve intentionally inflicted serious physical harm or risk that is not offset by a direct countervailing physical benefit, the government nevertheless routinely declines to intervene in the privacy of the relevant families.[154] On the harms side, these exceptions include relatively common procedures, such as ear piercing and male circumcision when these are done for other than medical reasons,[155] as well as relatively uncommon procedures such as removing an organ from a healthy child to give to an ill sibling[156] and gender reassignment

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152. *See* CHILD WELFARE INFO. GATEWAY, *supra* note 150, at 5 (emphasizing that even though it is set out as an exception in the relevant jurisdictions, corporal punishment is still required to be "reasonable" and not to "cause[] [any] bodily injury to the child").

153. See *supra* note 138 for a description of two of these cases.

154. There is no legal commentary directly on this subject, although the small literature on the use of culture in defining maltreatment comes somewhat close. *See, e.g.*, Roger J.R. Levesque, *Cultural Evidence, Child Maltreatment, and the Law*, 5 CHILD MALTREATMENT 146, 146–60 (2000); Alison Dundes Renteln, *Is the Cultural Defense Detrimental to the Health of Children?*, *in* 7 LAW AND ANTHROPOLOGY: INTERNATIONAL YEARBOOK FOR LEGAL ANTHROPOLOGY 27, 27 (René Kuppe & Richard Potz eds., 1994); Todd Taylor, *The Cultural Defense and its Irrelevancy in Child Protection Law*, 17 B.C. THIRD WORLD L.J. 331, 331 (1994). Professor Kathy Bradley and I treat these issues most directly in another project that discusses the practice of using healthy children as organ donors for their ill siblings as an example of a parenting practice that is at the same time formally unlawful and normatively accepted. Kathryn W. Bradley & Doriane Lambelet Coleman, The Boundaries of Family Privacy (unpublished manuscript, on file with the author).

155. *See, e.g.*, Doriane Lambelet Coleman, *The Seattle Compromise: Multicultural Sensitivity and Americanization*, 47 DUKE L.J. 717, 756–62 (1998) (comparing the apparently illegal practice of symbolically circumcising girls with the apparently legal practice of circumcising boys); J. Steven Svoboda, Robert S. Van Howe & James G. Dwyer, *Informed Consent for Neonatal Circumcision: An Ethical and Legal Conundrum*, 17 J. CONTEMP. HEALTH L. & POL'Y 61, 61–62 (2000) ("Numerous legal scholars have concluded that routine neonatal circumcision falls within the legal definition of child abuse and violates children's civil and human rights under national and international law.").

156. The practice of removing an organ from a healthy child to give to an ill sibling began with the first pediatric sibling kidney transplants in the late 1950s. *See generally* William J.

surgery.[157] On the risks side, the exceptions might be said to include any number of common but relatively high risk activities, the playing of physically stressful and contact sports being perhaps the most

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Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U. L. REV. 891 (1959) (describing this history). Since then, parents have consented to the use of their healthy children as bone marrow, kidney, and skin donors for their ill siblings, although other organs may also be at issue including "part of the pancreas, part of a lung, part of the liver, or part of the intestine." OrganDonor.Gov, What Can Be Donated, http://www.organdonor.gov/donation/what_donate.htm (last visited Nov. 27, 2007). Although there are no good data on the number and kinds of sibling transplant surgeries done annually in the United States, the widely held view is that bone marrow transplants are done most routinely. Indeed, children are sometimes conceived to be marrow donors for their ill siblings. *See, e.g.*, Robin Dawn Clark, John Fletcher & Gloria Petersen, *Conceiving a Fetus for Bone Marrow Donation: An Ethical Problem in Prenatal Diagnosis*, 9 PRENATAL DIAGNOSIS 329, 329 (1989). This family story is the subject of the popular novel JODY PICOULT, MY SISTER'S KEEPER (2004). I include sibling transplants here among the de facto exceptions to the maltreatment rules because it is a relatively common practice that is rarely interfered with by the state, and because none of the publicly available decisions authorizing parents to consent to sibling transplant operations were decided on the law; all were rendered by courts exercising their equity jurisdiction. *See, e.g.*, *In re* Cowan, Nos. 180564, 180565, slip op. at 2 (Ala. Jan. 6, 2003) (on file with the author) (authorizing parents and children to consent to transplant); Hart v. Brown, 289 A.2d 386, 378 (Conn. Super. Ct. 1972) (same); Nathan v. Farinelli, No. 74-87, slip op. at 11 (Mass. July 3, 1974) (on file with the author) (same); Foster v. Harrison, No. 68674, slip op. at 3–4 (Mass. Nov. 20, 1957) (on file with the author) (same); Huskey v. Harrison, No. 68666, slip op. at 2–3 (Mass. Aug. 30, 1957) (on file with the author) (same); Masden v. Harrison, No. 68651, slip op. at 4 (Mass. June 12, 1957) (on file with the author) (same); Little v. Little, 576 S.W.2d 493, 500 (Tex. Civ. App. 1979) (same). Although this skirting of maltreatment law has always been questionable—at common law, equity only attached when there was no adequate remedy at law—it is outright ultra vires in modern jurisprudence as the courts' equity jurisdiction has for the most part been relegated to guardianship and probate matters, and as the family and juvenile courts have assumed jurisdiction over all matters pertaining to the relationship between parents and their children. Jurisdictional and substantive contortions are necessary to fit a parental request for permission to consent to a sibling transplant in the modern era. This point is perhaps best illustrated by the moves made by the court in the declaratory judgment action, *In re Cowan*, No. 180564, 180565 (Ala. Jan. 6, 2003) (on file with the author). In that case, a probate judge, ruling on a petition filed by the parents of twin six-year-old girls seeking authorization to transplant skin from their healthy daughter to their burned daughter, found that (1) he had jurisdiction under the state's guardianship statute to decide the issue despite the statute's express inapplicability to children with parents because the conflict of interest inherent in the transplant situation meant that the girls were effectively parentless; (2) these same parents nevertheless were appropriate individuals to name as temporary guardians for the girls; and (3) the parents-as-guardians were entitled to distribute their healthy ward's assets—her skin—to benefit their other ward, her burned sibling. Thus, although there is precedent that suggests the lawfulness of parental consent in this context, the validity of that precedent is doubtful at best. *See* Bradley & Coleman, *supra* note 154 (discussing the sibling transplant cases in additional detail, and exploring the social norms at play in the view that the practice is acceptable and within the bounds of parental authority).

157. *See generally* Tamar-Mattis, *supra* note 139 (discussing this practice as akin to sibling transplants).

obvious.[158] (Some pediatricians would also include permitting children to play on a trampoline, to ride Razor scooters, and to wear shoes with wheels, as all three may be described as "serious accidents waiting to happen.")

Because these are only de facto exceptions, by definition there is no formal standard for determining whether other parenting practices or choices are or should be excepted from the maltreatment rules. Informally, however, one might derive such a standard based on what the existing de facto exceptions have in common. Thus, these existing exceptions are partly based in tradition and, at least to some extent, community acceptance. Beyond this, they appear to be based in a strongly held sense in society (or at least in important parts of society) that the associated harms and risks are worth suffering because the particular goods to be gained, for the child or for the child's family or cultural subgroup, outweigh those harms and risks. In other words, the exceptions appear to be based in society privileging certain goods in relation to the harms and risks that are necessary to achieve them.

According to this account, ear piercing, male circumcision, sibling transplants, gender reassignment surgery, and the engagement of popular but nevertheless high-risk activities may be said to contribute to constituting the child as a member of a family and cultural group, and to the survival and success of those collectives.[159] These practices and choices may also be said to be in the best psychological or developmental interests of the individual child—that is, without regard to group membership—although this is sometimes a more tenuous proposition. For example, the argument that it is in the child's interests to be a donor sibling has been criticized on several grounds, including most importantly because the analyses have tended to involve mere speculation by decisionmakers.[160] The

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158. *See* HOLDER, *supra* note 10, at 152 (positing this analogy in the context of Little League football).

159. *See, e.g.*, Bradley & Coleman, *supra* note 154 (describing this argument in the context of sibling transplants).

160. Since its first application in the sibling transplant setting, the best interests standard has been strongly criticized as begging both contrived pleadings and testimony, and mere speculation about both the benefits and risks of the transplant for the donor. *See, e.g.*, Charles H. Baron, Margot Botsford & Garrick F. Cole, *Live Organ and Tissue Transplants from Minor Donors in Massachusetts*, 55 B.U. L. REV. 159, 171 (1975) ("[T]he lack of genuinely adversary proceedings in most of these cases [results in] testimony [that] seems quite contrived. . . . [T]he sense of contrivance is strongest when the donor, as in some recent cases, is too young to have developed the kind of deep ties with his sibling that the testimony suggests."); *see also* Strunk v. Strunk, 445 S.W.2d 145, 150 (Ky. Ct. App. 1969) (Steinfeld, J., dissenting) ("Opinions

argument has also been criticized because it is believed in most cases to disguise the real motivation underlying the choice to engage and ratify the procedure: parents' overwhelming desire to make the decision that is right for themselves and the family as a whole, and others' normative sense that deferring to parents in these unusually difficult circumstances is—notwithstanding the law to the contrary—the right thing to do.[161] On the other hand, it seems easier to support the view that ear piercing, male circumcision, and contact sports are in the child's best psychological or developmental interests given their generally strong positive cultural connotations and the benefits that presumably flow to the child who is associated with those connotations.

In any event, what these exceptions suggest is that although parental motivation is formally irrelevant in maltreatment analysis, in certain circumstances it nevertheless influences the states' administration of the rules.[162] In fact, although some of these circumstances—sibling transplants being the most obvious example—tend to generate legal controversy, most involve parenting decisions and practices that are simply not thought of as harmful or abusive. As a normative matter, the notion that abuse might include ear and (more modernly) body piercing and high-level gymnastics, for example, would likely surprise most people—including CPS workers, who would more likely think of these as beneficial, innocuous, or at the very least a good idea on balance.[163] (The same would not be true,

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concerning psychological trauma are at best most nebulous."); *Farinelli*, No. 74-87, slip op. at 7 (Mass. July 3, 1974) (noting in the context of a request by parents for a declaratory judgment allowing them to consent to surgery to transplant bone marrow from their healthy child to their ill child that "[t]o require a finding of benefit to the donor, and particularly to accept a psychological benefit as sufficient, often seems to invite testimony conjured to satisfy the requirement by words but not by substance"); Tamar-Mattis, *supra* note 139, at 67–70 (making the same general point about "genital-normalizing surgeries"); *see also* Samuel J. Tilden, *Ethical and Legal Aspects of Using an Identical Twin as a Skin Transplant Donor for a Severely Burned Minor*, 31 AM. J.L. & MED. 87, 99 n.64, 101 n.87 (2005) (providing as evidence, the speculative nature of testimony offered to show that the transplant would protect a treasured sibling relationship and thus ensure the donor child's psychological well-being, the fact that the ill siblings at issue in *Huskey* and *Foster* died despite the transplants, and that the donor child in *Hart* had nightmares throughout her adolescence about having additional body parts removed and ultimately left the country and no longer communicates either with her twin or her parents).

161. *See* Bradley & Coleman, *supra* note 154 (setting out this critique).

162. See *supra* notes 132–49 and accompanying text for a description of the rules in this regard and the history of child maltreatment law, particularly as it pertains to the relevance of parental motivation to definitions of abuse and neglect.

163. The argument that allowing a child to participate in high-level competitive sports amounts to abuse has been made in the legal literature. *See, e.g.*, Jenna Merten, *Raising a Red*

for example, of the facial cuts and scarring that are part of traditional rites of passage and considered attractive in some other cultures, even though from an objective rather than culturally specific perspective they are no more harmful than the surgical reconstruction of a nose which also satisfies ritualistic and aesthetic goals.)[164] Ultimately, this reflects the fact that many parenting decisions and practices are judged according to majoritarian cultural norms and thus a "know it when you see it" test for child maltreatment.[165]

C. Parents' Consent Authority in the Research Setting

Whereas researchers are bound by ethical standards and the federal pediatric research regulations that codify them, parents' consent authority in the research setting depends on otherwise unrelated state and federal law. In particular, it depends on whether the research involves harm or risk that meets the maltreatment standard, and if so, whether the research fits within a doctrinal or de facto exception to the maltreatment rules. Although the child abuse analogy to pediatric research is anathema to the research community, which focuses on the beneficent intent underlying most research protocols,[166] it is inevitable to the extent that child protection law prohibits parents from giving legally valid consent to interventions and procedures that would amount to maltreatment.

Thus, there are four essential inquiries in this context: (1) whether there are research-related interventions that cause the sort of physical harm that is contemplated by typical abuse standards; (2) whether there are research-related interventions that pose a real risk of the sort of physical harm that is contemplated by typical abuse standards; (3) if there are research-related interventions that cause or

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Card: Why Freddy Adu Should Not Be Allowed to Play Professional Soccer, 15 MARQ. SPORTS L. REV. 205, 225 (2004). And concerns about the deleterious long-term consequences of athletic-related physiological stress and injuries led the American Academy of Pediatrics to suggest that children under fourteen not be permitted to play high-level competitive sports. *Id.* at 211. Nevertheless, the view that permitting a child to engage in these sports amounts to abuse has never caught hold in the law.

164. *See generally* Renteln, *supra* note 154 (discussing similar analogies).

165. *See* Doriane Lambelet Coleman, *The Role of the Law in Relationships Within Immigrant Families: Traditional Parenting Practices in Conflict with American Concepts of Maltreatment*, *in* IMMIGRANT FAMILIES IN CONTEMPORARY SOCIETY 287, 293 (Jennifer E. Lansford et al. eds., 2007).

166. *See, e.g.*, HOLDER, *supra* note 10, at 138, 156 (lamenting the equation of modern "pediatric research with abuse" and arguing that it has prevented the development of the field at the expense of children's health).

pose a real risk of causing the sort of physical harm that is contemplated by typical abuse standards, whether the child subject will derive a direct countervailing benefit from the research; and (4) when the latter is true except that there are no countervailing benefits, whether research might fit within the de facto exceptions to the maltreatment rules. Although this Article otherwise focuses exclusively on healthy children, this analysis holds whether the child at issue is healthy or ill.

1. *On Harmful Research*. Although many research-related interventions will fall within the category of risky rather than harmful research, some may be characterized as harmful from the outset. Thus, needle sticks, blood draws, and lumbar punctures can be described as harmful, as children tend to experience pain and sometimes also longer-term consequences—for example bruising, soreness, and severe headaches—in connection with their administration. Interventions designed to determine how harmful a known harmful condition or substance is, and in particular when it becomes toxic, will also fall in this category. Thus, for example, intentional exposure to or administration of chemical substances—including drugs, pesticides, and other environmental contaminants—may be treated from the outset as harmful rather than merely risky interventions. The closest non-research-related analogy in this context would be the intentional exposure to or administration of poisons, which is both initially harmful and risky as a consequential matter.

The critical question in this analysis is whether the harm caused by the procedure or intervention is sufficiently serious so that it meets the "serious bodily injury" requirement in typical abuse definitions. With respect to routine procedures such as needle sticks and blood draws, one might easily conclude that in most instances this requirement would not be met—because the harm is generally *de minimis*—so that parents could give legally effective consent to their engagement. This appears to be Professor Loretta Kopelman's position based on her reading of the minimal risk rule, and my sense is that it is correct.[167] On the other hand, procedures and interventions

167. Kopelman, *Children as Research Subjects*, *supra* note 35, at 599 (noting that she has "argued in detail . . . that we should drop the 'everyday risk' standard and simply understand minimal risk as no more than the sort of risks we all encounter in routine medical or psychological examinations or testing"); Kopelman, *Minimal Risk*, *supra* note 35, at 360–61

that are of such concern that a local anesthetic or conscious sedation is required are more likely to cross the line—because they are indicative of a heightened degree of pain and suffering—as are interventions that require children to be exposed to or ingest the equivalent of poisons in an effort to determine their toxicity or their effectiveness when their toxicity in the pediatric population has not been established.

The ethics of pediatric research and the federal pediatric research regulations focus on the risk of adverse events following or incidental to research-related interventions and procedures.[168] For example, they focus on the extent to which a lumbar puncture is likely to lead to a severe headache and dehydration. As a result, at least formally, they ignore the harms that may be inherent in the interventions and procedures themselves. That is, they ignore that the lumbar puncture itself may be harmful. The foregoing analysis reflects the fact that the law of child protection is formally focused *both* on those initial harms *and* on the risks inherent in parental decisions and conduct that may cause further or greater harm. Thus, the lumbar puncture itself, as well as the fact that it may cause a severe headache and dehydration, are of concern within this scheme. What this means is that researchers can expect the law of child protection to parse the facts differently than the federal regulations. Whether this difference results in a different classification of the propriety of a given intervention or procedure depends ultimately on whether the law is prepared to tolerate as much harm as the researchers and their IRBs.

2. *On Risky Research*. It is probably the case that most pediatric research will pose a risk of harm rather than or in addition to being harmful from the outset. The risk may be minuscule or it may be significant but, in all cases, there likely will be risk. Thus, to determine the extent of any disjunction between the research rules and the law of child protection, it is essential to clarify their respective treatment of risky interventions and procedures.

("The 'Everyday-risks' standard is . . . very vague, I have argued, because it can be understood in so many different ways . . . . Understanding the 'everyday-risks' standard as the sort of everyday risks all of us ordinarily encounter, means there is one standard for everyone.").

168. For a further discussion of this focus and its application in this context, see *supra* notes 75–83 and accompanying text and *infra* notes 169–90 and accompanying text.

As discussed in Part I of this Article, the pediatric research community relies on the federal regulations' minimal risk standard as the basis to judge the propriety of research-related interventions and procedures. For healthy children, the presumption is that only studies posing a minimal risk of harm are permissible; and minimal risk is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[169] This presumption can be rebutted—and research posing more than a minor increase over minimal risk can include healthy child subjects—if a panel of experts concludes that, on balance, taking into consideration both the risks of harm and the study's tendency "to yield generalizable knowledge," it makes sense to proceed.[170] In addition, some healthy children—for example, those who are at an increased risk of developing a serious disease like breast cancer in the future—might be considered to have a "condition" justifying their inclusion in research that poses a minor increase over minimal risk.[171]

Studies designed to determine how IRBs classify particular interventions and procedures reflect important variability, in part because people disagree about what is "minimal," "minor," and "more than minor,"[172] and in part because there is a dearth of data on the incidence of adverse effects in the pediatric population from even the most routine procedures and interventions.[173] As a result, there is no standard view within the research community about how these and less routine procedures should be classified. This state of affairs is further complicated by the fact that some researchers, regulators, and bioethicists hold the view that minimum risk is properly viewed relatively, according to the harms and discomforts ordinarily encountered in the daily life of children in the circumstances

169. 45 C.F.R. § 46.102(i) (2007).

170. *Id.* § 46.406–.407.

171. For a discussion of this interpretation of the minimal risk rules, see *supra* note 33 and accompanying text, and *infra* notes 313–14, 320–24, 335–37, 344 and accompanying text.

172. *See* Shah et al., *supra* note 5, at 478.

173. *Id.* at 479–80 (accepting that "data are needed on the risks of research procedures and the risks children face in daily life" so that IRBs can accurately categorize procedures according to the federal regulations' risk criteria); *id.* ("[V]ariation in IRB chairpersons' risk assessments of pediatric research may be caused by a lack of data, especially for nonphysical risks"); *id.* ("To ensure that the risk assessments made by IRB chairpersons are based on all the risks to children, it will be important to conduct research to systematically assess the risks of research procedures in children, including any psychological risks or risks of discomfort.").

pertaining to the research; this relative interpretation of the minimal risk standard allows for the classification of interventions as involving minimal risk in certain populations even if the interventions would not meet this standard in others.[174]

At bottom, what these circumstances reflect is a generally held view within the research community that taking on risk—including in some cases a risk of serious injury—is both necessary and acceptable given the societal and knowledge-related goods to be gained from the enterprise. From the perspective of the research community, there is such value in these goods that especially slight risks of serious harm to individuals are risks worth taking.[175] To the extent there is disagreement within the community, it is not so much about this proposition as it is about how to classify particular interventions and procedures within risk categories, and then about which risk categories are acceptable given the particular subject population at issue.[176] Although there may be different ways to think about this last problem, the pediatric research regulations reflect the view that the most important distinction is between healthy and ill children,[177] the latter being potentially subject to more risk than the former.

In contrast, the law of child protection and parents' consent authority does not contemplate risk according to the standards applicable under the federal regulations—that is, minimal risk, a minor increase over minimal risk, and more than a minor increase over minimal risk. Rather, it speaks in some instances simply of "a risk" of serious injury, and in others of "a substantial risk" of serious injury.[178] (One might consider child protection law to be less

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174. *See supra* notes 76–83 and accompanying text.

175. By "serious injury" and "serious harm," I mean the kind of harm that would qualify as abuse according to child protection law. See *supra* notes 132–43 and accompanying text for a definition of the terms in that context, and see *supra* notes 167–68 and accompanying text for suggestions of some research-related interventions that might meet this standard. Almost by definition, of course, the research community is also willing to take the slight risk that subjects will suffer the ultimate injury, as this is always a possibility, especially when the nature and degree of risk of adverse events is not known. When a healthy research subject dies in an experimental setting, it is typically required that the death be reported to the regulatory authorities and that the circumstances surrounding the death be investigated. Telephone Interview with Michael Waitzkin, Partner, FoxKiser (Mar. 22, 2007) (notes on file with the *Duke Law Journal*). The research may or may not be halted, depending upon the outcome of the investigation and the nature of the study. *Id.*

176. *See supra* notes 75–83 and accompanying text; Shah et al., *supra* note 5, at 479–81; *infra* notes 310–22 and accompanying text; *infra* notes 335–44 and accompanying text.

177. *See supra* notes 68–74 and accompanying text.

178. *See* discussion *supra* notes 140–43 and accompanying text.

sophisticated in this respect, and thus that it could benefit from an examination of the more nuanced risk classifications in the pediatric research setting.) In any event, applications of the risk rules in classic child protection contexts reveal the government's tendency to take little to no chances, that is to accept very little risk when the stakes are very high, but to require a showing of substantial risk in circumstances involving less important stakes.[179] Thus, for example, if the risk contemplated is of death, serious bodily injury, or sexual assault, the state is likely to intervene even when the chances of these consequences are slim.[180] On the other hand, when the risk contemplated is of neglect that could eventually lead to more serious consequences, the state is likely to intervene only when the chances for a negative outcome are substantial.[181] Finally, child protection law does not distinguish among healthy and ill children, or dissimilarly situated children—privileged and underprivileged children, for example—as it applies maltreatment standards.[182]

This approach to risk is different from that of the research community in two respects that are particularly important to this Article. First, although both child protection law and the pediatric research rules use a sliding scale characterized by degree of risk, child protection law tends to focus more on small risks when the consequences would be serious, whereas the pediatric research regulations assume the permissibility of small risks even of important consequences. (Child protection law's approach in this respect is not unfamiliar in the law more generally; for example, in negligence law a person who fails to guard against a small risk of large damages is often assumed to be acting unreasonably and imprudently.[183]) Second,

179. *See* Coleman, *supra* note 142, at 426–58 (describing the states' approach to child maltreatment reports and providing illustrations from the case law).

180. *See id.* at 414–15, 426–58.

181. *See, e.g.*, *In re* Stumbo, 582 S.E.2d 255, 261 (N.C. 2003) (providing that a single instance of a naked child apparently unsupervised in a driveway is insufficient to establish neglect).

182. Some have argued that the poor and minorities do not have the same legal rights as those who are more privileged. *See, e.g.*, William J. Stuntz, *Race, Class, and Drugs*, 98 COLUM. L. REV. 1795, 1824 (1998) ("[P]eople with money enjoy more privacy than people without. They live in freestanding houses and own more land; they conduct less of their lives in public places like the neighborhood streets. Fourth Amendment law accordingly gives them greater protection."). However true this may be in practice, it does not reflect formal law or the legitimate aspirations of poor and minority members of the society to equal treatment under that law.

183. *See, e.g.*, *In re* Kinsman Transit Co., 338 F.2d 708, 725 (2d Cir. 1964) (holding that defendants were responsible for damages that were only slightly foreseeable given their

the pediatric research rules are read by many to provide researchers with the flexibility to consider the characteristics of the subject population in evaluating the level of acceptable risk, whereas the law of child protection formally assumes the equality of all children. A cut is a cut and a risk of serious bodily injury or death is just that, regardless of whether the child who suffers it is healthy or ill, rich or poor, black or white.

These differences are the product of at least somewhat different orientations and objectives. Thus, whereas the research community is by definition inclined to balance risk against knowledge and then to some extent to privilege knowledge, child protection law is inclined to balance harm and risk against the privacy of the family and then to some extent to privilege protecting the child. What this means in general is that although there is bound to be substantial overlap between what child protection law and pediatric research ethics and rules permit in terms of risk, differences are also likely.

Not surprisingly, these differences will be situated in the middle, between what Professor Angela Holder once described as "harmless research" and "clearly dangerous interventions where an effective and demonstrably safer therapy exist[s]."[184] Thus, there is little doubt that research-related interventions and procedures that involve only *de minimis* harm and that pose no real risk of death or very serious bodily injury in the healthy child subject are lawful regardless of the analysis engaged; again, needle sticks and blood draws likely fall in this category.[185] There is also little doubt that research-related interventions and procedures that pose an important risk of death or very serious bodily injury will be prohibited under both schemes. On the other hand, it is entirely foreseeable that research posing only a slight or unknown but acknowledged risk of death or very serious bodily injury would be classified as unlawful by those responsible for applying child protection law, even though the same risk might be classified as lawful by those responsible for applying the rules

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tendency to cause significant harm); Overseas Tankship (U.K.) Ltd. v. The Miller Steamship Co. Pty. (The Wagon Mound No. 2), 1 A.C. 617, 643 (P.C. 1967) (same). Even though the latter is a foreign legal decision, it is very much part of the canon of American tort law. *See, e.g.*, GEORGE C. CHRISTIE ET AL., CASES AND MATERIALS ON THE LAW OF TORTS 307–33 (4th ed. 2004) (setting out these cases to illustrate the courts' analysis of proximate cause).

184. HOLDER, *supra* note 10, at 152, 164 (providing as illustrations of these extremes the snipping of a hair sample and the deliberate exposure to hepatitis).

185. See *supra* notes 167–68 and accompanying text for a discussion of these examples in an analysis of harmful, as opposed to risky, research-related interventions.

governing research. (This is most likely to happen when researchers and regulators rely on the first part of the minimum risk definition, which compares research risks to those "ordinarily encountered in daily life," because unlike child protection law, this standard does not distinguish between intentional and incidental risks, or between risks that are generally accepted in the culture and those that are not.[186]) Depending upon the particulars, trials that contemplate exposing healthy children to environmental toxins and potentially poisonous drugs are among those research-related interventions and procedures that might well fall within this category of disagreement.

Given the dearth of data about the degree of risk inherent in common and contemplated research-related interventions and procedures,[187] the related tendency of those in the research community to disagree with one another about the acceptability of particular procedures and interventions,[188] and the flexibility inherent in child protection law's risk rules,[189] it is difficult to be more specific with respect to the research-related interventions that are likely to fall within this middle category of potential disagreement among those responsible for administering child protection law and those responsible for administering the research rules. Nevertheless, it is entirely predictable that child protection law's risk-averse nature will collide with the research rules' risk-taking nature in this context. This equation is not altered by the fact that the regulations may be already too constraining for some in the research community, or by the fact that much of what researchers want to know relates to risk, and thus that it is necessary, if the information is to be acquired, to proceed in the face of uncertain or even unknown risk.[190] Whereas researchers may see in this situation an obligation to make individual sacrifices for the greater good, the child protection community may hope that there are other ways to solve the problem, but in any event, that

186. See *supra* notes 154–65 and accompanying text for a discussion of the de facto exceptions to child maltreatment rules, and see the discussion *infra* Part II.C.4 for analysis of the case for including pediatric research among those exceptions.

187. *See supra* note 173.

188. Shah et al., *supra* note 5, at 478–80.

189. See *supra* notes 140–43 and accompanying text for a discussion of this point.

190. *See* Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 213 (1998) ("Because experimentation takes place in the realm of the unknown, or at least the 'scientifically unproven,' several aspects distinguish it from treatment: risks may be unforeseeable; assumptions are not supported by scientific evidence and expertise is therefore more vulnerable than it is in clinical practice; a subject's consent cannot be based on anticipated benefits; and researchers and subjects may have conflicting interest.").

community's inclination (based on its mandate to act in the interests of the individual child) will be to sacrifice the greater good for the protection of that child.

3. *On the Benefit the Child Derives from Research*. To the extent that a research-related intervention or procedure falls within child protection law's prohibitions, it may still pass muster within that scheme if it can be characterized as providing a benefit to the individual child subject that outweighs the harm or risk inherent in the research. The issues that arise in this context are much discussed in the bioethics literature without regard to their implications for child protection law. Specifically, do indirect benefits count, and if not, what constitutes a direct benefit?

Within the bioethics and research communities, there are advocates on both sides of the debate about whether indirect benefits can be used to offset the risks inherent in research.[191] Money, gifts, and in-kind services such as free medical care, are discussed in this context.[192] For those who believe that indirect benefits count or should count to offset research-related harms and risks—because, as a policy matter, it is wrong to patronize children or because, as a practical matter, this is the only way to get the necessary participation—the critical questions involve whether it is permissible to pay valuable compensation, and if not, how to set the amount of money or the nature of the gift or in-kind service so that it does not cause parents to act against what they otherwise believe to be their children's interests.[193] In the latter instance, the concern is how to set the amount

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191. For a general overview of this debate, see, for example, IOM, *supra* note 8, at 226; ROSS, *supra* note 34, at 130–53; Robert A. Burt, *On Gnats, Camels, and Payment to Research Subjects: A Comment*, 9 J. MED. & L. 25, 27–29 (2005); Christine Grady, *Payment of Clinical Research Subjects*, 115 J. CLINICAL INVESTIGATION 1681, 1683–85 (2005); Michael B. Kimberly et al., *Variation in Standards of Research Compensation and Child Assent Practices: A Comparison of 69 Institutional Review Board-Approved Informed Permission and Assent Forms for 3 Multicenter Pediatric Clinical Trials*, 117 PEDIATRICS 1706, 1708 (2006); Bonnie W. Ramsey, *Appropriate Compensation of Pediatric Research Participants: Thoughts from an Institute of Medicine Committee Report*, 149 J. PEDIATRICS S15, S16–S18 (2006).

192. *See* Ramsey, *supra* note 191, at S16–S18; IOM, *supra* note 8, at 122, 134, 213; text accompanying notes 338–40; *infra* notes 357–60 and accompanying text (discussing the IOM report's analysis of the benefits issue in these respects).

193. *See, e.g.*, Partners Human Research Comm., Partners Healthcare Sys., Remuneration for Research Subjects, http://healthcare.partners.org/phsirb/remun.htm (last visited Nov. 27, 2007) (discussing these tensions). As described in this article:

> Most often healthy volunteers who will derive no medical benefit from their participation in the research study are compensated reasonably for the time they

of money or kind of gift or service so that it is an appropriate token of appreciation, but no more: fifty dollars for participating in a vaccine study might be a token for a middle-to-high income parent and child who might imagine spending the money on a new video game. The same sum might be quite significant for a low-income parent and child who might imagine spending it on groceries or clothing.[194]

These are extremely important issues that ought to continue to receive substantial attention from ethicists, researchers, and their regulators. On the other hand, the law of child protection is only concerned with the debates to the extent that a research-related harm or risk qualifies as maltreatment. When it does, the law requires a direct benefit; more specifically, the case law indicates that the harm or risk must itself be therapeutic. A relevant analogy to non-research-related interventions would be to the provision of medicine or a surgical procedure intended to benefit the child by, for example, regulating a dysfunction or repairing an injury.[195] Thus, because the

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> devote to research projects. Monetary compensation is not intended to be the only motivating force to induce subjects to participate. The goal of IRB oversight of research subject compensation is to ensure that stipends paid to research subjects provide fair compensation without undue pressure (coercion) to participate. Excessive monetary compensation may cause subjects to undertake risks or discomforts that they otherwise would not assume. This unfairly targets subjects of lower socioeconomic groups and places more of the "risk burden" of medical research on these groups. In the case of healthy volunteer studies, the IRB is often in the position of suggesting decreased compensation over that suggested by investigators, in an effort to decrease the element of financial coercion.

Id.

194. Interview with Catherine Fisk, Professor of Law, Duke Univ. Sch. of Law, in Durham, N.C. (Mar. 1, 2007) (noting that this sum was offered to her and her son in connection with a meningitis vaccine study at Duke University); Telephone Interview with Jennifer Li, *supra* note 8 (noting that this is a common sum in the context of vaccine studies at Duke University).

195. For a discussion of this exception and the *Grimes* court's application of the rule, see *supra* notes 146–49 and *infra* text accompanying note 257. *Cf.* Kopelman, *Pediatric Research Regulations Under Legal Scrutiny*, *supra* note 35, at 44 (contrasting the *Grimes* researchers' assessment of benefits with that of the court, which "understood direct benefit to subjects in terms of their individual best interest and discounted social utility"). Legal analysis is based in large part on the use of relevant analogies. Some commentators operating within a bioethics rather than legal paradigm have suggested that the harms and risks inherent in a research-related blood draw, lumbar puncture, or pharmaceutical study might properly be analogized to the harms and risks inherent in driving across town or in playing football. HOLDER, *supra* note 10, at 152 (analogizing some research risks to the risks inherent in Little League football); Shah et al., *supra* note 5, at 479 (analogizing some research risks to the risks inherent in "a single car trip across town during rush hour"). Depending on the facts, this may be correct, because both categories of harm and risk might be more-or-less equivalent. Unlike the first clause of the minimal risk rule, however, the legal method encourages if not demands more precise analogies, especially when they are available. *See supra* text accompanying note 75 (setting out the language of the minimal risk rule). Thus, as a practical matter, it is difficult to get around case

use of healthy children as research subjects does not contemplate a therapeutic offset—indeed, by definition, this research is nontherapeutic—it probably cannot be fit within this doctrinal exception.[196]

Some commentators have resisted this conclusion, arguing, for example, that psychological, developmental, and educational benefits are sufficiently direct so that they are the equivalent of more conventional (physical) therapeutic benefits. The development of an altruistic personality or of altruism as a character trait is often discussed in this regard, although there are others.[197] (For example, researchers at one prominent research institution gave child subjects laptops which were loaded with an educational program concerning their condition; they were permitted to keep the laptops when the study was complete.)[198] This is not an implausible position given the fact that parents sometimes place their children at risk of harm when

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law dealing directly with the scope of parental consent authority in the medical setting as one considers such procedures as blood draws, lumbar punctures, and the provision of drugs that are otherwise intended to be diagnostic or therapeutic. This is why I believe that if harmful and risky research-related interventions and procedures are to avoid child protection law's strictures, it is not likely to be within this exception.

196. The fact that healthy children may be ill in the future, and thus that the development of certain pharmaceuticals may eventually be therapeutic for them, does not alter this analysis. *Cf.* Rosato, *supra* note 35, at 366–67 (describing the view of the FDA's Pediatric Advisory Subcommittee that because healthy children benefit personally and therapeutically from relevant drug development, they are appropriately included in related drug trials).

197. *See, e.g.*, HOLDER, *supra* note 10, at 152 (taking the position that pediatric research benefits child subjects because they "may be learning something about altruism and empathy"); *see also* Kimberly et al., *supra* note 191 (documenting results of study of "variation in standards of research compensation," which showed wide variation among IRBs overseeing three multicenter pediatric clinical trials); Shah et al., *supra* note 5, at 478 (noting that 60 percent of IRB chairs polled "considered added psychological counseling not necessary for research purposes to offer a prospect of direct benefit to the participating children," that 51 percent of IRB chairs polled considered "[a]dded medical examinations and medicines not necessary for research purposes . . . to offer a prospect of direct benefit," and that 10 percent of IRB chairs polled considered "payment for participation . . . to offer a prospect of direct benefit to the participating children"); *cf.* Cara Cheyette, Note, *Organ Harvests from the Legally Incompetent: An Argument Against Compelled Altruism*, 41 B.C. L. REV. 465, 482–83 (2000) (describing the donor's "euphoria of having done something utterly selfless and good"); Jennifer K. Robbennolt, Victoria Weisz & Craig M. Lawson, *Advancing the Rights of Children and Adolescents to Be Altruistic: Bone Marrow Donation by Minors*, 9 J.L. & HEALTH 213, 245 (1995) (discussing psychological benefits to a child donor).

198. Telephone Interview with Jennifer Li, *supra* note 8 (describing a hypertension study at Duke University).

it is thought that they will learn valuable lessons from the experience.[199]

The problem is that courts have traditionally resisted the use of psychological, developmental, or educational benefits to offset what would otherwise be abusive interventions and procedures.[200] Indeed, the notion that an important physical injury or risk is justified only by an offsetting physical benefit is very much ingrained in the law, which generally privileges protection against physical intrusions and is also otherwise disinclined toward arguments about emotional welfare.[201] Moreover, although some parents may act for altruistic reasons, the sense among clinicians and researchers is that parents of such children are more often motivated by the indirect benefits at issue, that is, by the money, gifts, or in-kind services offered by researchers to induce participation in the study. This may be particularly true when the indirect inducements are important.[202] What this means is that even if the courts were to become amenable to the view that physical injuries and risks could be offset by psychological, developmental, or educational benefit—a move which would make sense at least in certain circumstances[203]—available evidence tends to negate the view that most healthy children enrolled in harmful or risky research will benefit from the experience in one or more of these respects.[204] If their parents are not enrolling them for this reason, it is unlikely that

199. For example, parents have enrolled their children in boarding schools and camps that mimic boot camp and/or that involve deprivations that either border on or else cross the line of abuse. *See, e.g.*, Scott Thomsen, *Boy, 14, Dies at Boot Camp Amid Abuse Allegations*, ATLANTA J.-CONST., July 4, 2001, at A3.

200. See *supra* note 146 and accompanying text for a discussion of this point. The de facto exceptions to the maltreatment rules are uniquely different in this respect. For a discussion of the prospects for including nontherapeutic research within the exceptions, see *supra* notes 154–65 and accompanying text and *infra* notes 206–11 and accompanying text.

201. *See* DOBBS, *supra* note 14, at 821–24 (describing the general hesitation of courts to accept stand-alone claims of emotional distress and harm in relation to more traditional claims relating to physical injuries).

202. Telephone Interview with Jennifer Li, *supra* note 8; Interview with Phil Rosoff, Director of Clinical Ethics, Duke Hosp., in Durham, N.C. (Feb. 18, 2007); s*ee also infra* note 360 and accompanying text (describing empirical evidence on this point); *cf.* Partners Human Research Comm., *supra* note 193 (explaining concern that remuneration may particularly encourage individuals from "lower socioeconomic groups" and "place[] more of the 'risk burden' of medical research on these groups").

203. *See, e.g.*, Bradley & Coleman, *supra* note 154 (arguing that in some specific cases, serious physical injury may be justified by psychological and/or developmental benefit to the child in issue). Some of the de facto exceptions to the maltreatment rules demonstrate a similar equation. *See supra* notes 154–65 and accompanying text.

204. *See supra* note 202 and accompanying text.

this will be the take-home message from the child's perspective. In any event, such benefit is particularly unlikely when the healthy child subject is developmentally unripe for lessons of this kind.[205]

4. *On Research as a "De Facto Exception" to Maltreatment.* To the extent that a research-related intervention or procedure falls within child protection law's prohibitions but fails to be excepted under the traditional benefit standard, it may still pass muster within that scheme if it can be brought within the de facto exceptions to the maltreatment rules.[206] The issues that arise in this context are also familiar to the research community: On the harms side, the question is the extent to which research-related interventions are like ear piercing, male circumcision, sibling transplants, and gender reassignment surgery, so that they might properly be considered alongside these procedures as normative exceptions to laws proscribing child abuse. On the risks side, the question is the extent to which research-related interventions and procedures are like engaging in physically stressful and contact sports, or—assuming one accepts the view that these are "accidents waiting to happen"—like playing on a trampoline or riding a Razor scooter. Bioethicists and researchers have discussed both sets of analogies, although they are probably most comfortable with those relating to risk.[207]

Thus, for example, it has been argued that typical research-related interventions such as pharmacokinetic or toxicity studies are likely no more risky than activities "ordinarily encountered in [children's] daily life" such as playing football,[208] driving across town

205. Within the bioethics community, the issue of when children are developmentally capable of altruism is frequently tied to the issue of when children are developmentally capable of assent, and it is hotly contested. *See, e.g.*, Nelson & Reynolds, *supra* note 53, at 12 (arguing that the capacity for altruism is closely linked with the capacity for empathy, and that some children under the age of ten and as young as two or three appear to be capable of altruism); Wendler & Shah, *supra* note 84, at 2–6 (suggesting that fourteen is the age at which researchers can be comfortable that children are capable of altruism).

206. *See supra* notes 154–65 and accompanying text.

207. Because they do not tend to think about research-related interventions and procedures as harms in and of themselves, their practice is to think in terms of risk from the outset. This is both inherent in and reinforced by the minimal risk rule, which defines permissible study designs according to the risks they pose. *See supra* notes 167–68 and accompanying text.

208. For a description of Angela Holder's original use of this analogy, see HOLDER, *supra* note 10, at 152.

during rush hour,[209] or playing in traffic,[210] none of which (it has been suggested) are outside parents' consent authority. Although the comparability of these risks to typical research-related interventions and procedures is not entirely clear, because researchers often do not know or else may only be able to make an educated guess about those risks,[211] it is certainly true that children are harmed in the context of these "everyday activities" to an extent and in ways that may not be an issue in many research designs. In other words, if (as the minimal risk rule suggests) what matters most to the de facto exceptions analysis is the equivalence of risk, there is arguably a strong case to be made for the authority of parents to consent to their children's participation in at least some higher-risk research designs.

It has also been argued that parents should have the right to consent to their healthy children's participation in nontherapeutic research because the law allows parents to consent to the use of their healthy children as organ donors for their ill siblings.[212] The notion underlying this view is that both interventions or procedures are nontherapeutic, that research is mostly less harmful and less risky than organ transplant surgery, and that both can be justified on altruistic grounds.[213] I would add that both are at least to some extent ordinary, in that within the spheres in which they are engaged there seems to be a general consensus that they are acceptable; in the transplant setting, this is particularly true of bone marrow transplants, but less so of kidney and other similarly invasive and impacting transplants.[214]

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209. *See* Shah et al., *supra* note 5, at 479 (developing this analogy).

210. Kopelman, *Children as Research Subjects*, *supra* note 35, at 598 (describing a study in which the infusion of insulin into healthy children was justified on the basis that it was "safer than the everyday risk of playing in traffic").

211. See *supra* notes 172–74 and accompanying text.

212. *See* Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 853–55 (Md. 2001) (discussing the relevance of the sibling transplant cases to nontherapeutic research); ANNAS, GLANTZ & KATZ, *supra* note 10, at 1 (describing a very early donation decision as involving "experimentation in the nontherapeutic setting"); *id.* at 76–87 (describing this same decision as a "nontherapeutic procedure," and setting out the scholarly debate about the significance of the sibling transplant cases to the research setting).

213. *Cf.* ANNAS, GLANTZ & KATZ, *supra* note 10, at 86–87 (arguing that parents are better able to make a voluntary decision to consent to nontherapeutic research than to a transplant because parents are generally under duress in the sibling transplant context).

214. I derive this position from three facts: First, many hospitals publicly advertise their bone marrow transplant services, including in the pediatric context. *E.g.*, Pediatric Bone Marrow Transplant, Duke Comprehensive Cancer Center, http://www.cancer.duke.edu/pbmt (last visited Nov. 27, 2007); Pediatric Bone Marrow Transplant, Seattle Cancer Care Alliance,

Whether or not these analogies are apposite, the bioethics and research communities can argue that research-related interventions and procedures ought to be brought within the de facto exceptions to the maltreatment rules because they have the potential to be of tremendous benefit both to society in general and to children in particular. For example, unless some harmful and higher-risk research involving healthy children is permitted, well-intentioned studies cannot be conducted to assure that children benefit along with adults from advances in knowledge and medicine in particular.[215] The fact that the federal government has signed on to this project speaks to its acceptability, to the related point that many in the society do not conceive of pediatric research as abuse, and otherwise at least in general to its significance as a public policy matter.[216] Given this landscape, it is plausible to argue that, to the extent it is flexible, the law of parents' consent authority ought not to be read so as to thwart the success of this critical project.

The argument on the other side rests both in its general outline and in its particulars on the view that the bioethics and research communities have misunderstood the law of parents' consent authority, including the social norms that underlie the existing de facto exceptions to the maltreatment rules. Thus, contrary to the view formally embedded in the minimal risk rule—that equivalence of risk is what matters in assessing the lawfulness of higher-risk research—child protection law considers risk along with whether parents are harming or risking their child's welfare intentionally or incidentally. And otherwise abusive interventions or procedures are only excepted if they provide a direct, therapeutic benefit to the particular child in question, or if they are generally accepted in the society as worthwhile for the child, or the child's family or cultural subgroup.

Mar. 2007, http://www.seattlecca.org/patientsandfamilies/pediatricCare/pediatricBoneMarrowTransplant. Second, at least one state has specifically legislated in favor of permitting children to donate bone marrow but not other organs. *E.g.*, ALA. CODE § 22-8-9 (LexisNexis 2006) (allowing minors, fourteen and older, to consent to a bone marrow transplant). Finally, although healthy children are used as organ donors in contexts not involving bone marrow, data on these practices appear to be either nonexistent or at least publicly unavailable. *See* Living Donors Recovered in the U.S. By Donor Age, The Organ Procurement and Transplantation Network, http://www.optn.org/latestData/viewDataReports.asp (follow "National Data"; then select "Donor" in "Choose Category"; then follow "Living Donors by Age) (report based on OPTN data as of Nov. 23, 2007, printout on file with the *Duke Law Journal*).

215. *See supra* notes 90–97 and accompanying text.

216. *See supra* notes 102–11 and accompanying text.

Sports and recreational activities pass muster, although research that poses an equivalent risk may not, because they fit the parameters of the de facto exception in this regard. Notwithstanding older federal regulations authorizing some higher-risk research involving healthy children,[217] and legislative and regulatory activity since that proposes to increase researchers' access to healthy children for this category of research,[218] this practice still lacks the level of general societal acceptance that typifies sports and recreational activities. Moreover, participation in sports and recreational activities is generally held to be a good thing for the individual children at issue: It helps them to stay fit or to gain fitness. It provides them with an inclusive peer group. It teaches them discipline and in many cases also the value of teamwork. And in most instances, they benefit from the strong positive connotations that flow from their association with these activities. For better or worse, the same cannot be said of participation in research. Although some parents may include their children in harmful or risky research as a way to teach them the value of altruism, the most prevalent rationale is access to indirect benefits such as monetary compensation, gifts, or in-kind services.[219]

For child protection law, driving across town during rush hour requires a different analysis because it poses an incidental rather than an intentional risk of harm; only the latter carries with it the possibility of a child abuse charge.[220] Whereas parents act intentionally and are conscious of their choice when they sign a consent form permitting their child's participation in a tackle football league, they act only incidentally, more often than not without real choice, when they bring their child along for the car ride across town during rush hour. Relatedly, unlike higher-risk research using healthy children as subjects which might (depending upon the study) be deemed important, this activity is widely accepted as necessary in a largely commuter society. The same cannot be said of participation in high-risk sports, recreational activities, or research.

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217. *See supra* notes 69–74 and accompanying text.

218. *See supra* notes 102–11.

219. *See supra* notes 202–04 and accompanying text.

220. Elsewhere in this Article, I emphasize that child abuse requires intentional action to hurt or risk injury to a child. *See supra* notes 136–37 and accompanying text; *infra* note 267 and accompanying text. Depending on the risk, neglect rather than abuse charges might be appropriate for incidentally caused injuries or risks. For a discussion of the problem of allowing children to play in traffic, see *infra* notes 221–23 and accompanying text.

Playing in traffic is a bad analogy in general because neither the law of parents' consent authority nor the minimal risk rule legitimately encompasses the activity within the category of permitted conduct. A child who plays in traffic can easily be characterized as neglected, and based on this, the state can intervene in the family to provide protection. This is particuarly true if the child is found doing so on more than one occasion.[221] And one would be hard pressed to characterize playing in traffic as an activity ordinarily encountered in the daily life of children as required by the minimal risk rule. The fact that this analogy was used by at least one set of researchers and their IRB regulators to justify infusing healthy children with insulin[222] as part of a "pediatric study on the causes of obesity" reflects the inherent malleability of the minimal risk rule, and the relatively free reign the community has within its regulatory structure to define the boundaries of permissible research.[223]

Finally, despite the surface appeal of the analogy, comparing nontherapeutic research using healthy children to using healthy children as organ donors for their ill siblings is also unhelpful. Both do involve the use of healthy children in interventions and procedures that are harmful and risky. Both are accepted as ordinary, at least

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221. *Cf. In re* Stumbo, 582 S.E.2d 255, 261 (N.C. 2003) (holding that an anonymous "report of a naked, unsupervised two-year-old in the driveway of her home does not trigger" a mandatory investigation, and suggesting that it is not a "report" of maltreatment but that multiple reports of a similar sort could meet the standard).

222. Kopelman, *Children as Research Subjects*, *supra* note 35, at 598.

223. *Id.* at 596. Kopelman criticizes this use of the "'everyday risk' part of the [minimal risk] definition" on the ground that "it allows too high a level of risk," and she uses this playing in traffic analogy to illustrate her point. *Id.* at 598–99. In this same context, she argues that "even if we know the probability and magnitude of the daily risks all of us encounter (which can include drive-by shootings, SARS, and terrorism) well enough to establish the 'minimal risk' standard for research, it is unclear why everyday risks are morally relevant or justified." *Id.* at 598. I would add that these would not withstand child protection law's strictures, in that parents could not intentionally subject their child to such risks and stay within the bounds of legitimate parental authority. For a discussion of the law's inherent risk averseness, and its different treatment of intentional and incidental exposures, see *supra* notes 137, 178–81 and accompanying text, and *infra* note 267 and accompanying text. Also, *infra* note 311 and accompanying text discuss Kopelman's suggestion that the minimal risk rule ought to be restricted to the terms of its second clause—that is, "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered . . . during the performance of routine physical and psychological examinations or tests." 45 C.F.R. § 46.102(i). Kopelman explains that the NIH's Office of Human Research Protection stopped this study midcourse on the ground that it involved more than minimal risk, and thus that it could not proceed without "special federal approval." Kopelman, *supra* note 17, at 596.

within the clinical and research communities, although the acceptability of using healthy children as donors of organs other than bone marrow may be relatively low.[224] And both are sometimes justified on altruistic grounds.[225] Yet research is unlike sibling transplants in their most important aspect, namely research cannot satisfy the law's requirement that the procedure be either in the best interests of the healthy child[226] or, when that standard is impossible to meet, in the best interests of the family on balance.[227] Relatedly, the courts have required a transplant recipient to be a member of the donor child's immediate family. The courts have not permitted parents to require their children to be altruistic outside of that unit.[228] The social norms underlying the sibling transplant decisions center on the sanctity of the family unit, and on the view that when the family is faced with the prospect of a preventable death, parents ought to be permitted to do what they can to keep all of their children alive.[229]

The research community's best argument for inclusion of nontherapeutic pediatric research among the de facto exceptions to the maltreatment rules is not based in these analogies, but in a more general appeal to the principles underlying the exceptions. It is based in the notion that pediatric research is accepted by many as

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224. *See supra* notes 156, 214 and accompanying text.

225. See *supra* note 197 and accompanying text for a description of the original analogy.

226. *See* Foster v. Harrison, No. 68674, slip op. at 3 (Mass. Nov. 20, 1957) (on file with the author) (requiring donation to be in best interest of donor child, and finding that this standard was met because he would suffer severe emotional and developmental harm as a result of the loss of his treasured ill sibling and of being unable to contribute to saving his life); Huskey v. Harrison, No. 68666, slip op. at 2 (Mass. Aug. 30, 1957) (on file with the author) (same); Masden v. Harrison, No. 68651, slip op. at 4 (Mass. June 12, 1957) (on file with the author) (same).

227. *See* Hart v. Brown, 289 A.2d 386, 391 (Conn. Super. Ct. 1972) (using a best interests of the family test and finding that the surgery was acceptable on balance, taking into consideration the interests of the ill child, the healthy child, and the parents); Nathan v. Farinelli, No. 74-87, slip op. at 11 (Mass. July 3, 1974) (on file with the author) (rejecting best interests of the child standard in favor of a best interest of the family approach, which requires parents to weigh competing interests within the family, and finding that the surgery was acceptable according to this analysis).

228. *See* Curran v. Bosze, 566 N.E.2d 1319, 1344–45 (Ill. 1990) (denying father's right to force testing of twins for purposes of determining their compatibility with ill half-brother in need of a bone marrow transplant); *cf.* McFall v. Shimp, 10 Pa. D. & C.3d 90, 91 (Com. Pl. 1978) (holding that the court had no authority to require a cousin of a person suffering from bone marrow disease to donate bone marrow because "[t]he common law has consistently held to a rule which provides that one human being is under no legal compulsion to give aid or to take action to save another human being or to rescue").

229. Bradley & Coleman, *supra* note 154 (discussing the social norms underlying the sibling transplant cases).

worthwhile and even important for children in general; and thus, although some protocols may formally qualify as abusive, they are not viewed as such, at least within the relevant communities.[230] This argument is not without significant problems, however.

For example, whereas the other de facto exceptions all involve an intervention or procedure that is designed to inure to the benefit of the child or to the child's family, nontherapeutic pediatric research only possibly inures to the benefit of children as a class.[231] Most important, harmful and risky nontherapeutic pediatric research involving healthy children is still not generally accepted within the society—as the other de facto exceptions are—as beneficial, innocuous, or at least a good idea on balance; indeed, many in society do associate research with abuse of human subjects.[232] In this respect, the researchers, bioethicists, regulators, and others within the federal government who have come to embrace the project to include healthy children in potentially harmful and risky pediatric protocols are in a different place than the community at large. This is reflected in the parallel legislative concern that this project not jeopardize child protection,[233] the tendency of those with means—that is, those who cannot be induced by indirect benefits such as money, gifts, or in-kind services such as free medical care—not to include their own children in such research,[234] and the sense of some important observers of the research enterprise that however well-intentioned researchers may

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230. *See, e.g.*, Rosato, *supra* note 35, at 363 (explaining that "[t]he positive results of research in [the AIDS] context . . . translated into a more positive view of research overall"). For a description of both these general principles and the argument based on them in favor of including research among the de facto exceptions, see *supra* notes 215–16 and accompanying text.

231. I say "possibly" here because a lot of research fails to yield any benefit and some research yields benefits for groups other than the study populations.

232. *See* Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 815 n.6 (Md. 2001) (describing this phenomenon as "replete" within "the literature on the law and ethics of human experimentation" and providing support for this view (quoting R. Alta Charo, *Protecting Us to Death: Women, Pregnancy, and Clinical Research Trials*, 38 ST. LOUIS U. L.J. 135, 135 (1993))); Rosato, *supra* note 35, at 364 ("Increased access to research facilitated by breakthroughs in AIDS treatments has been tempered in the last few years by evidence of research abuses in other contexts.").

233. *See supra* note 106 and accompanying text.

234. Interview with Philip Rosoff, *supra* note 202. Indirect benefits that might amount to compensation for participation in research are inherently problematic. *See supra* notes 191–94 and accompanying text.

be, the community is not well suited by nature to police itself.[235] Perhaps the best evidence of this view, however, is the Maryland Court of Appeals's decision in *Grimes v. Kennedy Krieger Institute.*

5. *The Significance of the* Grimes *Decision.* As described in the Introduction, the study at issue in *Grimes* had as its ultimate goals an increase in the number of low-income housing units in Baltimore and restoration of some of the city's most blighted areas.[236] The dearth of such housing had been tied to strict federal lead abatement standards designed to protect the health (particularly the neurological development) of young children. Specifically, it was believed that property owners were abandoning their units when the costs of lead abatement were greater than the value of the properties.[237] Based on this belief, the study sought to determine whether the government could require less lead abatement (and thus less costly renovations) and still protect children's health.[238] To these ends, the researchers solicited a group of property owners who agreed to permit the researchers to conform their units to one of five levels of lead abatement and to rent them only to families with young children.[239] The study contemplated that the children living in these units would be enrolled as research participants, with their parents' informed consent.[240]

The researchers and study sponsors understood that the study by design would subject some healthy young children to presumptively

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235. See *supra* notes 98–101, *infra* notes 274, 276–78 and accompanying text for a discussion of this concern, including as applied to pediatric research.

236. *Grimes*, 782 A.2d at 815 n.6.

237. *Id.* at 821; *see also* Brief of Appellee at 21, Higgins v. Kennedy Krieger Inst., No. 129 (Md. Feb. 27, 2001), *vacated sub nom.* Grimes v. Kennedy Krieger Inst., 782 A.2d 807 (Md. 2001) ("[T]he purpose of the study is to answer the very question of whether different remediation levels can be an effective means of limiting the potential for harm.").

238. *Grimes*, 782 A.2d at 815 n.6, 819. Specifically,

> [t]he purpose of this research study was to characterize and compare the short and long-term efficacy of comprehensive lead-paint abatement and less costly and potentially more cost-effective Repair and Maintenance interventions for reducing levels of lead in residential house dust which in turn should reduce lead levels in children's blood.

Id. (internal quotations omitted).

239. *Id.* at 821–23.

240. *Id.* at 820, 823. In addition to finding that researchers have a special relationships–based duty to aid their subjects who are endangered as a result of the study, *id.* at 851, and that parents cannot consent to involve their children in potentially harmful research, *id.* at 857–58, the court also found deficient the consent forms that parents were asked to sign in connection with their children's participation in the study, *id.* at 844.

harmful levels of lead exposure.[241] As Dr. Lainie Friedman Ross explained, "[t]he researchers encouraged landlords to rent the repaired premises to families with children despite the fact that [they] (1) suspected that some of these programs would not fully eradicate the problem; and (2) knew that the continued lead exposure was dangerous for the children."[242] Thus, the

> purpose of the study was manifestly not to reduce the level of lead in the blood of the children that were the subjects of the study, but to create a controlled research environment focusing on abatement of lead dust. The success of the various abatement procedures would be measured, in significant part, not by reducing the levels of lead in the children's blood, but by periodic measurements of the level of lead in their blood.[243]

Nevertheless, the researchers (and their IRB) concluded that this was not problematic: First, the children or at least other similarly situated children were already subject to the same risks by virtue of their impoverished circumstances,[244] so "the probability and magnitude of harm or discomfort anticipated in the research [were] not greater in and of themselves than those ordinarily encountered in [these disadvantaged children's] daily li[ves]."[245] Second, whatever harms and risks could be attributed to the research would be offset by the "direct" benefits of participation, including at least partially lead-abated housing—no small thing in a city that was alleged to be in crisis in this respect—and periodic testing for risky lead levels in their

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241. *Id.* at 812, 820 n.13. The researchers at least tacitly acknowledged this in the consent form. *Id.* at 819. Nevertheless, the principal investigator in *Grimes* claimed on appeal that the Institute was merely engaged in "passive data collection" regarding "risks that otherwise exist in the subjects' lives," and that it did not "subject[] [the children] to dangerous conditions." Brief of Appellee, *supra* note 237, at 23–24; *see also id.* at 14 ("The relationship [Kennedy Krieger Institute] had with Appellants was solely that of an observer. [Kennedy Krieger Institute] sought and received permission to collect information about an existing and evolving condition which [it] neither created nor controlled."); Brief of Appellee at 19–20, Grimes v. Kennedy Krieger Inst., No. 128 (Md. Feb. 27, 2001) (arguing that the principal investigator was not responsible for the creation of the lead hazards in the homes).

242. ROSS, *supra* note 34, at 207.

243. *Grimes*, 782 A.2d at 819 n.11.

244. As proponents of the study argued, "participation in this study did not involve any increase in risk of lead exposure over that experienced by other residents of similar housing in Baltimore City." Brief of Amicus Curiae, The National Center for Lead-Safe Housing at 8, Higgins v. Kennedy Krieger Inst., No. 129 (Md. May 8, 2001).

245. Katerberg, *supra* note 84, at 555 (quoting 45 C.F.R. § 46.102(i)).

blood.[246] For children placed in lead-free or relatively low-lead units, there was the added benefit of healthier housing than their parents or guardians might otherwise have been able to afford.[247] Finally, the researchers also believed that the harms and risks inherent in the study would be offset by the contribution their participation would make to the regeneration of their communities.[248]

The study in these respects was both well-intentioned and arguably ethical according to prevailing standards in the research community.[249] In the view of at least some commentators in the bioethics literature, because the federal regulations governing pediatric research codify those standards, the study was also lawful. For example, Dr. Ross has argued that because they provide for parental consent, the federal regulations at least implicitly authorize parents to enroll their healthy children in otherwise ethical pediatric research.[250] Ross has also argued that the research involved either minimal risk because (according to a relative interpretation of that rule) exposure to lead is an ordinary event in the lives of the children at issue, or else no more than a minor increase over minimal risk, in which case the children were lawfully enrolled because they could be characterized as having a "condition"—being at high risk of serious injury or illness in the future—justifying this increase.[251] The fact that

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246. *Grimes*, 782 A.2d at 824. The latter involved subjecting each child to five venipunctures, including to test for baseline lead levels, and then again at two, six, twelve, and eighteen months into the study period. *Id.* at 820.

247. Supp. Brief of Appellee at 9, Higgins v. Kennedy Krieger Inst., No. 129 (Md. May 21, 2001) (arguing that the Kennedy Krieger Institute "improved the health of the participants by ridding their homes of lead hazards and providing blood lead screenings").

248. *See* Brief of Appellee, *supra* note 237, at 20 (explaining the value of the research to "infants and young children in Baltimore City"); Brief of Appellee, *supra* note 241, at 21 (same). The appellees also argued more broadly that imposing additional obligations on researchers like them to protect research subjects from research-related harms would "deal[] a crippling, if not fatal, blow to [research to] the detriment of our society." Brief of Appellee, *supra* note 237, at 22; *see also* Brief of the University of Maryland at Baltimore as Amicus Curiae in Support of Motion for Reconsideration at 3, *Grimes*, 782 A.2d 807 (arguing that the court's original articulation of the boundaries of parents' consent authority jeopardizes a lot of "research that is vital to the promotion of children's health").

249. *Grimes*, 782 A.2d at 853 (noting that the "motives of all concerned . . . were, for the most part, proper").

250. *See supra* note 114 and accompanying text.

251. *See* ROSS, *supra* note 34, at 208–09 (suggesting that children were more properly classified as "at risk" than as "healthy"). Interestingly, Loretta Kopelman, who initially proposed this progressive interpretation of the minor increase over minimal risk rule, Kopelman, *supra* note 17, at 752–53, disagrees that it would have been appropriate to use it to justify the increased risk at issue in *Grimes*, *see* Kopelman, *Pediatric Research Regulations*

disadvantaged children and their families residing in Baltimore were statistically likely to suffer from exposure to lead was the basis for this latter conclusion, as well as the more general sense among many in the research community that the study involved merely passive observation of existing conditions, rather than the establishment of study conditions to which these individuals were subsequently exposed.[252] Finally, in the context of her initial discussion of *Grimes*, Professor Loretta Kopelman has argued that the law of child protection ought to be read to reflect the view common in the research and bioethics communities, that to protect the best interests of the child in the long run, it is sometimes necessary to act in the best interests of children generally.[253]

Reversing the trial court's decision to grant summary judgment to the defendant, the Maryland Court of Appeals ultimately rejected their version of these arguments. Specifically, it held as a matter of law that the parent of a healthy child "cannot consent to the participation of [that] child . . . in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject."[254] (The court later explained that "by 'any risk,' [it] meant any articulable risk beyond the minimal kind of risk that is inherent in any endeavor.")[255] As applied to the facts of *Grimes*, it was not

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Under Legal Scrutiny, *supra* note 35, at 45 (arguing that to permit approval of the research under this rule "because *some* of the children are at risk . . . . undercuts the intention of [the rule] if its goal is to allow certain exceptions when there is an opportunity to learn about a child's *actual* disorder or condition").

252. *See* ROSS, *supra* note 34, at 211 (describing the relevance of these circumstances); Gandhi, *supra* note 35, at 286–89 (discussing *Grimes* including in this respect).

253. *See* Kopelman, *supra* note 17, at 756. Two years after this initial discussion, in 2006, Kopelman offered a quite useful reconciliation of *Grimes* and the federal rules governing pediatric research, which suggests among other things that aspects of the research design in *Grimes* were insufficiently protective of the child subjects. *See* Kopelman, *Children as Research Subjects*, *supra* note 35, at 603; *cf.* Gandhi, *supra* note 35, at 286–89 (critiquing the *Grimes* opinion in part on the basis that the court improperly interpreted the federal regulations).

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

255. *Id.* at 862 (per curiam). This explanation was in response to vigorous argument by the appellees in the context of their motion for reconsideration. *See* Appellee's Motion for Partial Reconsideration and Modification of Opinion, *supra* note 25, at 4 ("The 'not *any* risk' rule formulated by the Opinion is extraordinary because of its categorical nature and because it is unprecedented. The formulation is extreme because it does not tolerate or contemplate even minimal or normal everyday risks."). Although some have suggested this was a clarification or retreat from the court's original "any risk" formulation, *see, e.g.*, ROSS, *supra* note 34 at 208, the court itself believed that it was merely restating the obvious, *see Grimes*, 782 A.2d at 862 ("As we think is clear from Section VI of the Opinion, by 'any risk,' we meant any articulable risk beyond the minimal kind of risk that is inherent in any endeavor.").

"legally acceptable" intentionally to "expose otherwise healthy children . . . to a nontherapeutic research environment that . . . might cause the children to ingest lead dust . . . that . . . can, in sufficient amounts, . . . cause serious or long term adverse health effects."[256] In the court's view, "parents, whether improperly enticed by trinkets, food stamps, money or other items, have no more right to intentionally and unnecessarily place children in potentially hazardous nontherapeutic research surroundings, than do researchers. In such cases, parental consent, no matter how informed, is insufficient."[257] Implicit in this ruling is that according to the law of child protection and parents' decisional authority—as well as the norms underlying that law, which are otherwise prevalent in the culture—parents cannot act intentionally to cause or risk serious harm to their children unless the harm is offset by a benefit that is recognized as sufficiently direct and weighty.[258] Thus, "[w]hatever 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, [the law's] concern for the particular child and particular case, overarches all other interests."[259] In this case, which involved healthy children, the "balance between risk and benefit is necessarily negative."[260]

Much to the dismay of the researchers and of some commentators,[261] the court also analogized the research in *Grimes* to historical cases of experimental abuse of vulnerable human subjects:

> The research project at issue here, and its apparent protocols, differs in large degree from, but presents similar problems as those in the

256. *Grimes*, 782 A.2d at 853 (majority opinion).

257. *Id.* at 814.

258. For a discussion of this aspect of the doctrine, see *supra* notes 145–49 and accompanying text. For a discussion of the cultural exception, see *supra* notes 154–65 and accompanying text.

259. *Grimes*, 782 A.2d at 853.

260. *Id.* at 862 (per curiam).

261. *See, e.g.*, ROSS, *supra* note 34, at 214 (expressing concern about the court's analogy of the lead abatement research to the "experiments at Tuskegee"); Barbara A. Noah, *Bioethical Malpractice: Risk and Responsibility in Human Research*, 7 J. HEALTH CARE L. & POL'Y 175, 217 (2004) (arguing that "[c]ommentators have correctly criticized the court for its overbroad approach to the legal questions presented and for its extreme rhetoric in comparing the lead paint research protocol with historical research atrocities such as the Nazi experiments and the Tuskegee Syphilis Study"); *infra* note 282 and accompanying text (noting this basis for the researchers' failed motion to reconsider); *cf.* Kopelman, *Pediatric Research Regulations Under Legal Scrutiny*, *supra* note 35, at 39 (describing as "stinging" the court's opinion in this respect).

> Tuskegee Syphilis Study conducted from 1932 until 1972 . . . the intentional exposure of soldiers to radiation in the 1940s and 50s . . . the tests involving the exposure of Navajo miners to radiation . . . and the secret administration of LSD to soldiers by the CIA and the Army in the 1950s and 60s . . . . [These] were also prior instances of research subject being intentionally exposed to infectious or poisonous substances in the name of scientific research. . . . These programs were somewhat alike in the vulnerability of the subjects . . . . In the present case, children, especially young children, living in lower socioeconomic circumstances, albeit not as vulnerable as the other examples, are nonetheless, vulnerable as well.[262]

Based on this analogy the court found it "clear . . . that the scientific and medical communities cannot be permitted to assume sole authority to determine ultimately what is right and appropriate in respect to research projects involving young children free of the limitations and consequences of the application of Maryland law."[263]

Viewing the decision purely from the perspective of doctrine, the Maryland Court of Appeals got it mostly right. There is nothing in the federal rules that indicates that they preempt otherwise applicable state law relating to research. In this case both negligence law and the law of parents' consent authority were at issue. And the court's articulation and application of that law was "textbook." Specifically with respect to parents' consent authority, the court was correct that parents generally do not have authority to consent to harming and endangering their children to the extent contemplated by the research design.[264] (I take this position for the same reasons I assume the court itself did, namely that the researchers intentionally exposed the

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262. *Grimes*, 782 A.2d at 816–17 (majority opinion).

263. *Id.* at 817; *see also id.* at 835–36 (discussing "the atrocities performed in the name of science during the Holocaust"; the fact that the *Nuremberg Code* "at least in significant part, was the result of legal thought and principles . . . and thus should be the preferred standard for assessing the legality of scientific research on human subjects"; the reasons why the Code was not adopted as the standard to govern researchers in the United States, including that "the Nazi experiments were considered so extreme as to be seen as irrelevant to" researchers in this country, even when they were engaged in "the testing of new polio vaccines on institutionalized mentally retarded children"; and "[u]tilitarianism was the ethic of the day").

264. For a discussion of these standards and their applicability to pediatric research, see *supra* notes 132–39 and accompanying text and Part II.C.1. One might argue that because of the procedural posture of the case, there is no way to tell whether the children were in fact harmed. This is correct if one assumes that the relevant harm is only consequential, that is, future developmental impairments. On the other hand, if—as the court apparently assumed—the harm was exposure to presumptively dangerous levels of lead, this fact was established by virtue of its inclusion in the research design.

children to presumptively harmful levels of lead, a known poison for young children.) It was correct about the exception to that rule, that parents' consent authority only extends to harming and endangering children to such an extent when "the balance between risk and benefit" is positive on the benefit side.[265] It was also correct that indirect benefits—from "trinkets, food stamps, money or other items" to "the good of all children"—cannot be recharacterized as "direct" and do not count toward this balance.[266] And it was correct to reject both the characterization of the study as involving mere passive observance of existing conditions,[267] and the effort to discriminate among children with respect to the risks to which they are properly subjected by their parents and researchers.[268] Finally, and perhaps most important, the court was correct that the law of parents' consent authority (as it is defined by child protection law) concerns itself exclusively with the best interests of "the particular child in the particular case."[269]

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265. See *supra* notes 145–49, 191–205 and accompanying text for a discussion of the benefits rule and its applicability to pediatric research.

266. For discussion of the benefits rule and its applicability to pediatric research, see *supra* notes 145–49, 191–205 and accompanying text.

267. Children will inevitably suffer incidental harms and risks as a result of their parents' choices and circumstances. For example, a young child may accidentally burn a hand on a hot stove reaching for the fire while his or her parent is doing laundry in another room. So long as it is not the result of neglect, such an accident incident to the parent's circumstances will not run afoul of the law. But of course it is another matter entirely when the parent intentionally places the child's hand in the fire. This distinction appeared to perplex the research community and bioethicists commenting in the aftermath of the decision. They struggled with the notion that the law would seek to punish the careful creation of conditions for study purposes that otherwise might or even likely would exist naturally for the same or similar individuals. The distinction is nothing new, however, either for the law or for pediatric ethicists. Maltreatment law, like criminal and tort law, distinguishes both in theory and in practice among levels of fault—that is, among intentionally, negligently, and incidentally-caused harms—and attaches significantly more moral opprobrium to (and exacts higher degrees of punishment for) higher degrees of fault.

268. For a discussion of the law's antidiscrimination theme, see *supra* note 182 and accompanying text. For a critique of the research community's overuse of healthy poor and minority children as research subjects in nontherapeutic protocols, see *infra* notes 357–60 and accompanying text.

269. See *supra* notes 117–26 and accompanying text for a description of the law's focus on the individual child and the best interests of that child. A few commentators have sought either to develop an interpretation of *Grimes* that can be reconciled with the federal regulations or to argue that *Grimes* was based not on common law principles but on a misunderstanding or misinterpretation of the federal rules. *See, e.g.*, Gandhi, *supra* note 35, at 286–89 (arguing that the court misapplied the federal regulations); Kopelman, *Pediatric Research Regulations Under Legal Scrutiny*, *supra* note 35, at 40–47 (describing the court's ruling and "seeming departures

To the extent the court may have been wrong on the doctrine, it was in its articulation of the level of allowable risk. Specifically, the court's holding that parents "cannot consent to the participation of [their] child . . . in nontherapeutic research or studies in which there is *any* risk of injury or damage to the health of the subject"[270] does not comport with even the relatively risk-averse provisions of child protection law.[271] The court's further explanation set out in response to the defendant's motion for reconsideration that "by 'any risk,' [it] meant any articulable risk beyond the minimal kind of risk that is inherent in any endeavor,"[272] did little to move its position closer to the standard—or if it did, its language was so ambiguous (particularly in light of the fact that the term "minimal risk" is laden with specific meaning in this context) that it left the matter entirely unclear. Although this does not alter the correctness of the rule as applied in the case—that parents cannot consent to the level of harm and risk implicated by the lead abatement study's design—it is problematic in terms of its potential to mislead those who would seek to apply its terms in the future.

The *Grimes* decision also has meaning beyond doctrine. Primarily this concerns the strong sense of the court that the research community's history of past abuses of individual human subjects—specifically notwithstanding the benevolent intent underlying much of this history—deprives it of any legitimate claim to trustworthiness or independence in establishing the boundaries of ethical and legal research.[273] And the decision concerns the equally strong sense that courts in this situation have an especially important role to play in monitoring the research community's work to assure the protection of human subjects.[274] As a practical matter, these views, together with

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from the federal regulations," and offering interpretations of the ruling that would minimize the collision between the regulations and the law as relied on by the court).

270. Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 858 (Md. 2001) (emphasis added).

271. In Part II.B, I discuss the reasons why parents are permitted, even intentionally and without transgressing the boundaries established by traditional child abuse laws, to expose their children to harm and risks of injury greater than those "inherent in any endeavor." *See supra* notes 140–43, 169–90 and accompanying text. The discussion includes an application of this rule to pediatric research. *Id.*

272. *Grimes*, 782 A.2d at 862 (per curiam).

273. *See id.* at 855 (majority opinion) (suggesting that because of this history, "[s]cience cannot be permitted to be the sole judge of the appropriateness of such research methods on human subjects, especially in respect to children").

274. *See id.* at 853 (suggesting that courts are important as an institution to check the scientific community's perspective on "human and legal ethical concerns," and that this

the facts in the case, made it impossible for the court to imagine that research in general, or even this study in particular, might qualify as a de facto exception to the maltreatment rules.[275] Theoretically, they exposed a continuing disjunction between the law and the research enterprise concerning the appropriate conception and treatment of individuals who would be research subjects.

These issues are not new. The role and power of the law to regulate science has historically been rejected by what has been called the "republic of science."[276] At the same time, courts have not

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community must be carefully monitored to ensure that researchers do not "embark[] on slippery slopes, that all to [sic] often in the past, here and elsewhere, have resulted in practices we, or any community, should be ever unwilling to accept").

275. By definition, the exception cannot apply if an intervention or procedure is generally believed to be abusive. *See supra* notes 154–65 and accompanying text.

276. *See* SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 93 (1995) (using this expression to denote the belief of the scientific community in its independence from the law). Charles McCarthy describes its particular prevalence in the period preceding the development of the federal regulations, among those who held on to the "enlightenment view that human progress was inextricably linked to advances in science and technology." Charles R. McCarthy, *The Evolving Story of Justice in Federal Research Policy*, *in* BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH, *supra* note 5, at 11, 14. Thus,

> [m]any persons, particularly those involved in medicine or medical research, held fast to the view that the moral integrity of each research investigator was both necessary and sufficient to provide safeguards for the rights and well-being of research subjects and for the well-being of science itself. Many of those in the research establishment held that ". . . a basic tenet of the philosophy upon which the scientific method rests [is]: the integrity and independence of the research worker and his freedom from control, direction, regimentation, and outside interference." Persons who held this view feared that attempts to regulate research would hobble scientific progress.

Id. (quoting C.J. Van Slyke, *New Horizons in Medical Research*, 104 SCIENCE 559 (1946)). The federal regulations were ultimately promulgated despite them, of course, and as McCarthy notes, "[g]radually there was an erosion of the view that the integrity of research investigators and reliance on remote peer review of the scientific merit of research protocols provided sufficient protections for research subjects." *Id.* at 15. In other words, researchers came to accept the inevitability and even the validity and merit of regulatory standards and the IRB as an institution. To the extent the scientific community has truly embraced regulation of its enterprise, however, it appears to be limited to a measure of self-regulation. The federal regulations governing human subjects research are a perfect illustration of this point because they are, in effect, the embodiment of the scientific (including the bioethics) community's own views about how it ought to go about its business. The federal regulations largely codify the right of the scientific community to govern itself within the boundaries established by their terms. For example, the "[p]rocesses that are crucial to [the] governing of the 'republic of science,' such as peer review, funding, teaching, publication, or the day-to-day administration of research projects and laboratories, ordinarily (and scientists would say properly) remain outside the purview of the courts." JASANOFF, *supra*, at 93. Regulation according to these rules permits the scientific community to operate to a great extent outside of or at least side-by-side with the law *writ large*. Indeed, as Jasanoff has written, "[s]cientists . . . actively patrol their boundaries against incursions by the law, citing the efficacy of their [modern] self-regulatory mechanisms." *Id.* at 111; *see also* Sharona Hoffman & Jessica Wilen Berg, *The Suitability of IRB Liability*, 67

hesitated to scrutinize that community's self-regulatory mechanisms when human subjects research is alleged to have violated fundamental legal norms ensconced in state or other federal law.[277] Indeed, courts may be particularly likely to intervene when, as in *Grimes*, they are faced with alleged mistreatment of child subjects.[278]

Ultimately, the critical policy question that arises out of *Grimes* is whether this inherent distrust of researchers and their enterprise is unfairly anachronistic, that is, unfairly based in a history that no longer has relevance in this new era of sensitivity toward and respect for individual human subjects, formal regulation, and previously unimaginable scientific and medical promise, including for children. Things have changed. *Grimes* itself acknowledges this when it describes as imperfect its analogy of the facts in the case to past research-related abuses.[279] And there are ample other indicia: the development and vitality of the field of bioethics in the wake of those abuses; the important compromises inherent in the pediatric research regulations between the pursuit of scientific knowledge and the protection of individuals who would be subjects; the reluctance within

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U. PITT. L. REV. 365, 412–26 (2005) (arguing that because they are disruptive of research, civil lawsuits filed against IRBs and their members should first undergo mandatory administrative review by HHS or the FDA to screen out frivolous lawsuits and to expedite resolution of others, and that when lawsuits are considered by courts, IRB members should have qualified immunity so long as they acted in good faith and in accordance with federal regulatory review requirements).

277. JASANOFF, *supra* note 276, at 112 (noting, for example, that "courts will insist on full observance of informed-consent requirements when asked to intervene, demanding if anything a higher standard of disclosure from researchers than from treating physicians. Moreover . . . the perception that a patient is being used for commercial gain may tilt the balance of judicial sympathy against researchers, even if the work itself promises to alleviate human misery"); *id.* at 93 ("Legal inquiries into research relationships promise special insights . . . because here perhaps more than in any other setting courts have to confront the discrepancies between science's idealized claims to special status and its actual social practices.").

278. According to one source,

> The State is concerned to protect the interests of children in most circumstances. This concern is the greater when another intends to invade the physical integrity of a child, or to expose the child to the risk of harm. Indeed, the interests of children in such circumstances are taken so seriously that it is thought proper to use the law as the appropriate means of protecting them. By having recourse to law, the State is indicating that it is not content to leave provisions for the protection and welfare of the child to less formal social regulation, whether by agreement among the medical profession or among any other professional group or, *a fortiori*, by agreement between parents or between parents and doctors.

MEDICAL RESEARCH WITH CHILDREN: ETHICS, LAW, AND PRACTICE, *supra* note 4, at 125.

279. *Grimes*, 782 A.2d at 816 ("The research project at issue here . . . differs in large degree from, but presents similar problems as those in" the historical cases.). For a discussion of this analogy, see *supra* notes 261–63 and accompanying text.

the community to open the doors to harmful and risky research involving healthy children without concomitant assurances that they will continue to be protected even as these doors are opened; and the very real concern for some children that if this balance is not struck right, they will inevitably lose out as science and medicine distribute their rewards. The *Grimes* researchers and commentators in the aftermath of the decision were frustrated that the court saw the researchers in that case as one (almost) with their historical counterparts, and that it did not either know of or acknowledge the paradigm shifts that are represented by these changes.[280]

To some extent this frustration is understandable. But it is understandable in the same way as the frustration of those who say that charges of discrimination are unfairly anachronistic, and who offer as proof of the disconnect that society has come a long way since the time of women's disenfranchisement or Jim Crow: Enormous progress has been made and there have been real paradigm shifts, but the problems also cannot be described as merely historical. In the case of research, and of research involving healthy children in particular, the inherent tensions between doing good by the group and doing right by the individual remain fundamentally unresolved, as does the basic point that benevolence of intent does not guarantee justice. The *Grimes* court may have been unfair to the research community in its failure expressly to couple its critique of the lead abatement study with a recognition of the very real differences that exist between its older and modern incarnations. And it may have been unfair in its relentless insistence—over fifty pages of opinion—that the researchers and their IRB had done only wrong. The court was not unfair, however, in its bottom line that the ties that bind modern researchers to their historical counterparts are ties that justify the law's continued oversight role.[281]

The best support for this point is surprisingly missing from the *Grimes* opinion—that is, how closely analogous the lead abatement study was to the almost universally condemned hepatitis experiments at the Willowbrook State School: the researchers in both cases were well-respected pediatric experts who were undoubtedly also well-

280. For citations to the researchers' failed motion to reconsider, see *infra* note 282, and see *supra* note 261 for citations to commentators after-the-fact.

281. *See* Gandhi, *supra* note 35, at 266–67 (arguing that "examples of unethical research involving children are not limited to the distant past," and that these demonstrate the need for improvements in the regulatory structure).

intentioned in their desire to solve an important public health crisis. At issue at Willowbrook was a longstanding institutional hepatitis infestation, and in *Grimes* a city-wide problem with lead-dust. In both cases, there were alternatives to solving the crises that did not involve using healthy children as research subjects. At Willowbrook, it was an existing hepatitis remedy, and in *Grimes* it was lead abatement, as the government already had mandated. The families in both cases were from vulnerable subpopulations. That is, the Willowbrook families had children in need of scarce institutional space, and the *Grimes* families had children in need of scarce safe housing. In both cases the parents were afforded access to these scarce resources because their children were the targets of researchers. The children in both cases were otherwise healthy before the researchers intervened. The researchers deliberately exposed some children in both cases to poisons with their parents' uninformed consent, monitored the effects on their bodies, and partially or totally deprived them of available information or treatment to preserve the integrity of the research. Finally, the researchers in both cases justified the research on the grounds that, because of their vulnerabilities, the children would likely have been harmed even without the intervention; it was potentially good for the child subjects—if the intervention was milder than what they would have suffered had they been left alone—and for children more generally because the body of scientific knowledge pertaining to their circumstances might be advanced; and their supervising agencies had approved the study designs.[282]

There are differences between the two studies, but these are differences in degree rather than substance, and in any event they are far fewer than their similarities. Thus, whereas the researchers at Willowbrook forced institutionalized and sequestered children to eat hepatitis-infested feces, the researchers in *Grimes* merely established the otherwise relatively good conditions in which at least some children would be exposed to presumptively harmful levels of lead dust. And whereas the Willowbrook researchers were almost entirely free from regulation, the *Grimes* researchers were more (although arguably not better) constrained.

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282. These similarities support the *Grimes* court's decision to reject the request to excise those portions of its original opinion reflecting on the research community's history. *Grimes*, 782 A.2d at 861–62 (per curiam); Appellee's Motion for Partial Reconsideration and Modification of Opinion, *supra* note 25, at 9–12.

Given these similarities, critics of *Grimes* are not likely to be successful in defeating the analogy to Willowbrook. Some, however, are likely to continue resisting the basic notion—underlying both *Grimes* and the condemnations of Willowbrook—that it is wrong for a researcher to manipulate an existing environment to ensure controlled study conditions when the study subjects are either at risk of or statistically likely to be exposed to those conditions in any event.[283] From the perspective of the research community, which constantly seeks to balance the imperative to gain useful knowledge against the protection of human subjects, proceeding in this way in these circumstances may be a good place to strike the balance; at least statistically, one can say that subjects are probably not going to be harmed or put at risk as a result of the research. It should be plain that this analysis is also irretrievably flawed from the different perspective of child protection law. This law has as its exclusive mandate the protection of "the particular child," who might well be the statistical anomaly, and as such, it is utterly unconcerned with most "'for the greater good' projects" to the extent they would require harming that child to achieve their ends.[284]

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It is not known how typical the research at issue in *Grimes* is in any of its respects, because there is no central database that describes the nature and numbers of protocols involving healthy children.[285] One could surmise that the case is likely not representative of typical protocols because, in the years since the *Belmont Report*, researchers and their institutions have learned to err on the side of excluding rather than including healthy children in pediatric research, and then to include them only in circumstances of truly minimal risk as this term might be interpreted colloquially. There are good anecdotal indicia that this atmosphere of caution still prevails in many places, including that *Grimes* as litigation is anomalous. On the other hand,

283. See *supra* note 241 and accompanying text for a discussion of this concern.

284. *See Grimes*, 782 A.2d at 815, 853 (majority opinion). The states' mandatory vaccination programs are the primary exception to this general rule. *See supra* notes 147–48 and accompanying text.

285. Telephone Interview with Jennifer Li, *supra* note 8. According to Dr. Li, to get this information, one would have to survey either each institution engaged in pediatric research or else a representative sample of such institutions. *Id.* Given the significance of the issues at stake, this would be a valuable empirical project.

one could surmise that it is likely to be increasingly representative of typical protocols because of the push—reflected in federal legislation and liberal reinterpretations of older regulatory standards—to include healthy children in higher-risk research, and because of the corresponding rise both in spending on pediatric research and in the numbers of new pediatric research trials. There are also good anecdotal indicia to support this view, including that prominent bioethicists have simultaneously urged reconsideration of the merits of the research in *Grimes* and provided a basis in the regulations to support its propriety as part of their project to increase researchers' access to healthy children for higher-risk research. The truth with respect to the typicality of the research in *Grimes* is likely to be a composite of both views, as local control of the research community's regulatory structure continues to prevail.[286]

In any event, *Grimes*'s significance is independent of its typicality, one way or the other. The case is significant because it demonstrates the linguistic, doctrinal, and theoretical disjunctions that separate the ethics of the research community from the law of child protection and parents' decisional authority as this law is implicated in the project to include healthy children in harmful or risky research.[287] In this respect, even though it is anomalous as litigation, it is not at all unique in its statement of the relevant law or of the principles that will govern future judicial examinations of this issue. Finally, it is representative of the courts' willingness to exercise their authority to check the research community's perspective on "human and legal ethical concerns," perhaps especially as these relate to the proper treatment of children.[288]

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286. *See* Gandhi, *supra* note 35 at 266–67 (noting that "[t]he current system relies heavily on IRBs to function appropriately and interpret the federal regulations with careful deliberation," that "reasonable people can and do disagree over how the regulations should be interpreted and what types of research protocols are ethically permissible," and that these "definitional ambiguities leave an incredible amount of power in the hands of the IRBs"); Telephone Interview with Michael Waitzkin, *supra* note 175 (explaining that private sponsors of research, for example drug manufacturers, gravitate toward institutions and IRBs that are less restrictive in their interpretations of the federal regulations).

287. *Grimes*, 782 A.2d at 852–53.

288. *Id.* Others have focused on *Grimes*'s significance in different respects. *See, e.g.*, Kopelman, *Pediatric Research Regulations Under Legal Scrutiny*, *supra* note 35, at 40–48 (describing the ways in which the opinion may impact decisionmaking within the research community); *id.* at 40 (describing "an impressive array of critics [who suggest that] the research and treatment gap between adults and children will widen significantly if the *Grimes* holding prevails"). For further discussion of the state's special interest in the protection of children, and thus the courts' special role in assuring their protection, see *supra* notes 277–78.

III. AN ARGUMENT IN FAVOR OF A LEGAL ETHICS OF PEDIATRIC RESEARCH

To the extent that the research community was unaware of the problem before, the Maryland Court of Appeals's decision in *Grimes* put it on notice that the ethics of pediatric research is on a collision course with the law of child protection and parents' decisional authority. On the surface, this collision is most clearly reflected in an apparent incompatibility of language: the notion of "more than a minor increase over minimal risk," for example, being foreign to the law of parents' consent authority notwithstanding that the federal regulations at least implicitly contemplate their compatibility. Beneath the surface, the collision reveals important differences in orientation and objectives: whereas the law of parents' consent authority privileges individual rights and interests by seeking to balance a respect for parental autonomy against a commitment to protect the individual child from harm, the ethics of pediatric research privileges a combination of group-based interests and child protection by seeking to balance the progressive goals of the scientific enterprise against a commitment to protecting children as a vulnerable subpopulation.

Because both approaches privilege child protection to some extent, these differences do not signify a complete disconnect in outcomes between what might be permitted according to research ethics and what might be permitted according to the law of parents' consent authority and child protection. As I described in Part II, there is substantial overlap between the two. At the same time, because they also privilege competing goods—individual rights and interests versus group-based interests—the overlap is not complete: there will be instances in which pediatric ethics will permit research-related interventions and procedures that are unlawful according to the law of parents' consent authority and child protection, and vice versa.[289]

To avoid this collision in all of its respects, the research community has three options: It can continue to litigate individual cases as they arise in the judicial context in hopes of influencing the eventual development of a common and constitutional law that is

289. For example, the ethics of pediatric research may be more protective with respect to nonphysical forms of harm and risk than the laws of child protection and parent's consent authority. *See infra* note 367 and accompanying text.

favorable to its enterprise.[290] It can work with state and federal officials to try legislatively to minimize the conflict.[291] Or, it can work with federal regulators to harmonize the ethics of pediatric research with the law of child protection and parents' consent authority. This Part argues in favor of this third option.[292] This argument is based in the view that the normative priors of and relationships within the research community make this community ill suited to resolving the inherent tension between protection and access, in the view that the law of child protection and parents' consent authority is itself well suited to do this difficult work, and in a normative preference for rules governing child protection that both privilege respect for the child as an individual and emphasize antidiscrimination principles.

A. The Problem with "Balancing Protection and Access"[293]

Part I of this Article explains that the ethics of pediatric research has undergone a fundamental shift away from a commitment to treat children, particularly healthy children, as a vulnerable subpopulation deserving of almost absolute protection from exploitation in the experimental setting to a commitment whenever possible to include both healthy and ill children in relevant human subjects research. The stated objective of the new ethics of pediatric research is not, however, a full pendulum swing away from protection to access; that

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290. For example, the research community can work to convince courts in the future to reject the analysis in *Grimes* and instead to base decisions squarely in the federal regulations, or to interpret *Grimes* so that it is consistent with those regulations. *See, e.g.*, ROSS, *supra* note 34, at 206–14 (arguing on behalf of the primacy of the federal regulations including as they concern parents' consent authority); Kopelman, *Pediatric Research Regulations Under Legal Scrutiny*, *supra* note 35, at 47 (proposing interpretations of *Grimes* and the regulations that would avoid much of the collision).

291. For example, the research community could replicate the work done in Maryland in the aftermath of the decision to develop state law rejecting *Grimes* and aligning with the federal regulations. *See supra* note 25; *see also* IOM, *supra* note 8, at app. B (suggesting the development of "uniform state guidelines" and adoption of those guidelines by states wishing to regulate aspects of pediatric research in ways consistent with the federal guidelines and research ethics).

292. These options do not preclude additional reforms, for example of the existing regulatory structure. For an interesting discussion and proposal along these lines, see Gandhi, *supra* note 35, at 299–311 (arguing that the system of local control by IRBs has largely precluded the development of effective ethical standards to govern pediatric research, and proposing revision of the existing regulatory structure that would provide for oversight of local IRBs analogous to the structure of the federal courts).

293. This expression comes directly from Lainie Friedman Ross. Ross, *supra* note 21; *see also* Nelson, *supra* note 44, at 47–49 (understanding this as the goal of the new ethics of pediatric research).

is, it is not the mere reverse of the prior "children last" rule.[294] Rather, recognizing that "[a] system that rejects an exclusive focus on the person most affected must include a method to prevent itself from becoming a way to legitimate imposition on underdogs,"[295] what is sought by the proponents of the new pediatric research ethics is an effective balance between protection and access.[296]

Thus, as the authors of the critical book *Beyond Consent: Seeking Justice in Research* wrote in 1998, the scientific community can and should "creat[e] opportunities for fair access to research and its potential benefits, while simultaneously developing mechanisms of protecting subjects from exploitation."[297] Among others, Dr. Robert Nelson (also writing in *Beyond Consent*) has applied this principle specifically to the pediatric context, arguing that because children have suffered both from experimental abuse and from the dearth of relevant medical and pharmaceutical development, it is essential to develop an ethics of pediatric research that would allow children to access the benefits and burdens of research in a context that assures their protection from the kinds of exploitation to which they were vulnerable prior to the promulgation of the federal rules.[298]

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294. Lainie Friedman Ross can be credited with both the pendulum metaphor, which works so well in this context, and the description of the standard (older) ethics as involving a "children last" rule. *See* Ross, *supra* note 21, at 519, 528; *see also supra* note 89 and accompanying text (providing citations to her work in this regard).

295. Roger B. Dworkin, *Medical Law and Ethics in the Post-Autonomy Age*, 68 IND. L.J. 727, 738 (1993).

296. *See* Rosato, *supra* note 35, at 368 ("[T]he paradigm for children has shifted from protectionism to access."). This approach is entirely consistent with the broader goals of bioethics as a field, which seeks to study and then whenever possible to reconcile tensions between scientific and medical progress and—in this context—the protection of human research subjects. *See, e.g.*, Alexander M. Capron, Dir., Dep't of Ethics, Trade, Human Rights, & Health Law, World Health Org., Fifth Rabbi Seymour Siegel Memorial Lecture in Medical-Legal Ethics: The Difficulties of 'Doing Bioethics' Globally: Ethics, Law and Human Rights in the UN System (Jan. 19, 2006) (PowerPoint slides on file with the author) (arguing that it is inaccurate to describe bioethics as "a branch of human rights" because unlike human rights, bioethics is informed by a combination of "[r]ights-based theories" and "principilist, consequential/ utilitarian & feminist theories.").

297. Jeffrey P. Kahn, Anna C. Mastroianni & Jeremy Sugarman, *Changing Claims About Justice in Research: An Introduction and Overview*, *in* BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH, *supra* note 5, at 1, 2–3.

298. *See* Nelson, *supra* note 44, at 47 (explaining that the inability under older interpretations of the federal regulations to conduct research on children means that children do not have equal access to the fruits of scientific and medical progress); *id.* at 49–52 (describing some of the history of the exploitation of children by researchers); *id.* at 52 (noting that "the current federal regulations governing research are designed to prevent" research like that which occurred in the past, including the Willowbrook experiments); *id.* at 57–59 (discussing accepted

This Article's argument in favor of harmonizing the ethics of pediatric research with the law of child protection and parents' consent authority rejects the view at the core of this new ethics that access to healthy children for harmful and higher-risk research is necessary and that it is possible within the prevailing regulatory and ethical scheme successfully to balance protection and access.

There is much that society would like to know about children that it does not know because it has been reluctant to involve healthy children in risky research.[299] There is also probably little doubt that some of this information could be quite useful as researchers and others think, for example, about new approaches to particular pediatric conditions. It is true that pediatricians would benefit, and thus presumably their pediatric patients would benefit, from the existence and availability of information about how children might respond to drugs designed for and tested exclusively in the adult population.[300] Because pediatricians share their experiences, much of this information is available for drugs that have been on the market for some time.[301] For newer drugs, however, there is a dearth of

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conceptual and applications problems with the minimal risk standards); *id.* at 57, 62 (suggesting ways to include healthy children in more than minimal risk research while at the same time safeguarding their interests in autonomy and respect).

299. *See supra* notes 90–97 and accompanying text.

300. I distinguish between the existence and availability of this information because there is some empirical evidence that suggests that permitting the use of pediatric subjects in pharmaceutical studies has resulted in new knowledge, but not necessarily in the public availability of that knowledge. In other words, it appears that in some situations, some pharmaceutical companies may be choosing not to disclose the results of their research, particularly when the findings are adverse. *See* Daniel K. Benjamin, Jr. et al., *Peer-Reviewed Publication of Clinical Trials Completed for Pediatric Exclusivity*, 296 JAMA 1266, 1269–70 (2006).

301. It has been argued that this information was obtained in the context of what were effectively Phase III drug trials—that is, as pediatricians experimented with their ill pediatric patients. *See, e.g.*, HOLDER, *supra* note 10, at 162. This is a legitimate critique. It is not obvious, however, that it provides good support for the argument to expose *healthy* children to risk that is unnecessary from their individual perspectives. One might argue, for example, that it is legitimate to take a chance with an ill child, because that child might well benefit, that is, the child might be healed of an illness or condition; but that it is entirely illegitimate to take this same risk with a healthy child because there is no such prospect. (Indeed, this is the argument bioethicists generally use to support the conventional interpretation of the federal regulations, that ill children can be subjected to higher risks in the research setting than healthy children). The fact that good research may not be feasible with the relatively small number of ill subjects that might be available in any given context does not necessarily fix this problem if one of the relevant perspectives is that of the healthy child.

relevant data.[302] Nevertheless, decisionmakers continue to be free, just as they were at the time of the drafting of the *Belmont Report*, to choose to forego the formal collection of some of this information on the basis that the costs of obtaining it are (from a normative perspective) too high. This gets to the crux of the matter: The costs are not too high, and thus it may be a good idea to permit the use of healthy children in higher-risk research settings, if there is a way also to protect those children from research-related abuse and exploitation. On the other hand, the costs will remain prohibitive if the project to "balance protection and access" cannot be accomplished.

This project has received significant attention from many thoughtful people. Nevertheless, it has largely failed because of the irreconcilable tension between access and protection: unless one defines child protection to mean the protection of children as a group, it is impossible simultaneously to harm and risk injury to individual child subjects and also to protect them against these same circumstances.[303] The efforts of the Institute of Medicine and of some prominent pediatric bioethicists (a few of whom are also members of the IOM) to reconcile increased access with continued child protection exemplify this quandary and emphasize the need for a new approach to determining when, if ever, it is permissible for researchers to use healthy children as subjects in harmful and higher-risk research.

For example, Dr. Nelson has proposed solving the problem of balancing protection with access to healthy children by tying "the level of allowable risk . . . to the assent of the child" and by providing that "parental permission can suffice for a child [incapable of assent] to participate in greater than minimal risk research provided that the research has been reviewed and approved by a representative panel of older children and their parents who are members of the intended research population."[304] In his view, this would allow researchers increased access to healthy children for higher-risk research and

302. The federal government has provided extended patent protection for pharmaceuticals that are tested on children precisely to address this problem. *See supra* note 104 and accompanying text.

303. This does not mean that the bioethics project in general is flawed, only that in some cases it may not be possible to reconcile the tensions at issue, and choices that privilege one or another side of the balance have to be made.

304. Nelson, *supra* note 44, at 62.

protect them at the same time—the latter because, in addition to the various adult decisionmakers in the equation, the child (or child proxies) also would be consulted. The assumption is that children are protected from exploitation and abuse in the research setting if their views generally are heard, and they are still inclined to participate. Consistent with his related work on assent, Nelson's proposal demonstrates real respect for what children have to say about their own circumstances, which is rarely a bad thing.[305] But defining protection in this way is enormously problematic because it ignores the substantial empirical, neurological, and anecdotal evidence that children (including adolescents) tend to make poor decisions regarding risk,[306] which is one of the principal rationales underlying the longstanding public policy to protect them with adult proxy decisionmakers.[307] As Professor Terrence Ackerman has noted, "We

305. *See, e.g.*, Nelson & Reynolds, *supra* note 53, at 13 ("We should not privilege research enrollment over moral harm to children but rather should solicit a child's 'yes' to research participation and respect both a child's dissent *and* silence.").

306. *See generally* Elizabeth S. Scott, Adolescence and the Regulation of Youth Crime, Keynote Address at the Temple Law Review Symposium: Law and Adolescence: The Legal Status, Rights, and Responsibilities of Adolescents in the Child Welfare, Juvenile, and Criminal Justice Systems (Mar. 18, 2006), *in* 79 TEMP. L. REV. 337 (2006) (summarizing this evidence); *see also id.* at 339 ("The capacities for reasoning and understanding improve significantly from late childhood into adolescence, and by mid-adolescence, most teens are close to adults in their ability to reason and to understand information—what you might call 'pure' cognitive capacities—at least in the abstract. The reality, however, is that they are likely less capable than are adults in *using* these capacities in making real-world choices, partly because of lack of experience and partly because teens are less efficient than adults in processing information."); *id.* at 340 ("[A]s compared to adults, adolescents are more likely to focus on the here and now and less likely to think about the long-term consequences of their choices or actions, and when they do, they are inclined to assign less *weight* to future consequences than to immediate risks and benefits."); *id.* at 343 ("[I]n calculating the risk-reward ratio that guides decision making, adolescents may discount risks and assign greater weight to the rewards of a choice than do adults. . . . What distinguishes adolescents from adults in this regard, then, is not the fact that teens are less knowledgeable about risks, but, rather, that they attach different value to the rewards that risk taking provides."). *But see* Rosato, *supra* note 35, at 369 (arguing in 2000 that "[t]he general consensus in the psychological literature is that most children over fourteen years can consent to their own treatment or to their participation in research").

307. *See supra* notes 116–25 and accompanying text; *see also* ROSS, *supra* note 34, at 92 (arguing that "respect for children entails some respect for their current autonomy, but also respect for the persons they are becoming . . . . parents and researchers show respect by deciding what activities are appropriate for a child"); Kopelman, *supra* note 17, at 754–55 (asserting that a child's "agreement lacks full authorization because minors generally lack capacity to assess the consequences of their actions. For the same reason, we do not allow minors to be soldiers, firefighters, or police, despite what the minors want"). *See generally* HOLLY BREWER, BY BIRTH OR CONSENT: CHILDREN, LAW, & THE ANGLO-AMERICAN REVOLUTION IN AUTHORITY (2005) (describing the evolution in the law of children's consent authority, from

fool ourselves if we think we fulfill our moral duties by standing aside and asking the child to decide."[308] Regardless of one's views on this moral question, the relevant adults will not have fulfilled their legal duty to the child unless they have at least mediated that decision.[309]

Professor Loretta Kopelman's proposal to balance protection and access contains a number of new approaches to the federal regulations governing pediatric research. Specifically, she has proposed that the use of healthy children as research subjects be limited to circumstances that involve only minimal risk;[310] that minimal risk be defined simply according to "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered . . . during the performance of routine physical and psychological examinations or tests";[311] that relative interpretations of this standard be rejected;[312] that children who are presently healthy but who are at high risk of developing serious problems in the future be characterized as having a "condition" justifying enrollment in higher-risk research;[313] that group-based stereotypes be rejected as a basis for establishing the existence of a "condition";[314] and that the best interests of the child standard be defined to include a focus on the best interests of children as a group.[315] Kopelman's proposals have been developed in a number of contexts, including in her discussions of the *Grimes* case. In those discussions, she strongly disagrees with

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the view that it emanated from inherited status to the view that it emanates from experience and the capacity to reason).

308. T.F. Ackerman, *Fooling Ourselves with Child Autonomy and Assent in Nontherapeutic Clinical Research*, 27 CLINICAL RES. 345, 346 (1979).

309. See *supra* notes 116–25 and accompanying text for a discussion of parents' legal responsibilities and of the circumstances in which children are permitted to be autonomous decisionmakers.

310. Kopelman, *supra* note 17, at 755–56.

311. Kopelman, *Children as Research Subjects*, *supra* note 35, at 597–99 (modifying the definition slightly by deleting the first prong but embracing the second, in contrast to the prevailing definition of minimal risk: "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests" (quoting 45 C.F.R. § 46.102(i) (2005))); *see* Kopelman, *Minimal Risk*, *supra* note 35, at 361–68.

312. Kopelman, *supra* note 17, at 751–52.

313. *Id.* at 752–56. The IOM's proposal in this regard is discussed *infra* notes 335–37, 344–46 and accompanying text.

314. Kopelman, *supra* note 17, at 751–53.

315. *Id.* at 756.

the *Grimes* court's characterization of the children in the case as healthy on the basis that, given the dearth of lead-free or properly lead-abated affordable housing in Baltimore, they were at risk of sustaining lead-related injuries. And she argues that it was therefore appropriate to characterize them as having a "condition" justifying their inclusion in the higher-risk lead abatement study.[316]

Professor Kopelman has been a leading voice for children within bioethics community, providing, among other things, accurate information about relevant legal rules, solid analysis of several issues arising under those rules, and provocative arguments about how the law might be interpreted or pushed to accommodate research-related interventions and procedures that may not pass legal muster.[317] She is particularly notable for her longstanding, thorough, and incisive critique of the definition of minimal risk, which—as subsequent empirical work has reinforced—affords individual IRBs altogether too much discretion in risk classification and thus continually begs arbitrary outcomes.[318] Her solution to this problem—to restrict the definition of minimal risk—should receive substantial attention because it would go far toward harmonizing the ethics of pediatric research involving healthy child subjects with the law of parents' consent authority and child protection.[319]

On the other hand, Professor Kopelman's solution to the problem of balancing child protection and increased access to healthy children for higher-risk research is troubling because it requires the reclassification of some healthy children as ill for purposes of

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316. *Id.* at 751.

317. *See, e.g.*, Kopelman, *Children as Research Subjects*, *supra* note 35, at 598 (arguing that the "everyday risk" standard of minimal risk in section 404 should be dropped because it is too open-ended and can be abused); Kopelman, *supra* note 17, at 751 (contending that dividing children into discrete categories as sick or healthy is not realistic and ignores the concerns of those at risk of developing a condition). *See generally* Loretta Kopelman, *Health Care and Research Issues*, *in* ENCYCLOPEDIA OF BIOETHICS 387 (Stephen G. Post ed., 3d ed. 2004) [hereinafter Kopelman, *Health Care and Research Issues*] (surveying the development of children's rights and providing an analytical framework for determining when research should be done on children).

318. Kopelman, *Health Care and Research Issues*, *supra* note 317, at 362; *see also* Jeffrey Janofsky & Barbara Starfield, *Assessment of Risk and Research on Children*, 98 J. PEDIATRICS 842, 843 (1981) (noting that data used by IRBs to assess "risk inherent in many pediatric procedures are limited to listings of complications and case reports, neither of which provide the frequency of morbidity and mortality associated with the procedures"); Shah et al., *supra* note 5, at 478 (providing empirical data on this point).

319. See *supra* note 167 and accompanying text for this point in the context of my analysis of the legality of harmful and risky research.

developing an adequate pool of pediatric research subjects.[320] It is plausible to challenge the merits of the traditional healthy/ill dichotomy and to reimagine health as being a continuum along which many people, who are otherwise considered healthy, might be reclassified, for example, as being at risk or as already having a possibly latent illness. Indeed, as a scientific or medical matter, a continuum theory of health may be closer to the truth than the traditional dichotomy. And it is not unprecedented to distinguish between "normal," "at risk," and "troubled" children as society develops relevant public policy.[321] But to use the intermediate "at risk" category to justify additional harms and risks rather than additional safeguards (as other programs for "at risk" children do) is counterintuitive to the extent that one of the goals is child protection.[322] This defect cannot be cured, as Kopelman would have it, by redefining the best interests of the child standard at the core of child protection law to include the best interests of all children. Aside from the fact that such an interpretation of the best interests standard is fundamentally at odds with its objectives, and thus unlikely to gain any traction in the law,[323] on its face there is nothing protective about an approach that would subject healthy individuals to risky research because that may benefit others in the future.[324] The fact that under Kopelman's approach some healthy children would be culled from the universe of prospective research subjects because they could not

320. Kopelman denies that healthy children would be subject to risky research under her approach. *See, e.g.*, Kopelman, *supra* note 17, at 756. But this requires a sleight of hand: She argues that "healthy" in some circumstances can mean "unhealthy" for research purposes. *Id.* at 751–54 (contending that a sliding scale based on likelihood of developing an illness would be more realistic than a healthy or unhealthy dichotomy). She suggests that society's moral duty to protect them would be met nevertheless because (as she conceives it) children "collectively" are protected. *Id.* at 756. Once again, however, it is only by redefining the essential terms of the debate that Kopelman can claim to have accomplished her objective.

321. Here I am thinking of special educational programs and opportunities that target at risk but otherwise healthy children, such as "pre-k" classes for at-risk four-year-olds.

322. Kopelman is correct that these differences might justify disparate treatment of the individuals at issue according to basic principles of antidiscrimination law. *See* Kopelman, *supra* note 17, at 755–56. Thus, for example, it justifies state funding of pre-k programs for at risk four-year-olds, funding that would not need to be provided on an equal basis to four-year-olds who were not at risk. As I argue, however, the notion that this principle would be used to justify additional harms rather than additional benefits is anathema to its foundations.

323. *See* discussion Part III.B.2.

324. To her credit, Professor Kopelman has recognized that this view is firmly entrenched in the law. Her suggestion that the best interests of the child standard be reimagined as a best interests of children standard is a response to this law. *See supra* text accompanying note 315.

be characterized as having a condition, or because researchers initially described the study group too generally, yields no additional protection for the individual healthy children who do make the cut.

Dr. Lainie Friedman Ross has sought to "ensure appropriate safeguards without compromising access unnecessarily"[325] by proposing that researchers be permitted to use both healthy and ill children in research that poses a minor increase over a minimal risk of harm;[326] that the concepts of minimal risk and minor increase over minimal risk be merged;[327] that permissible research—including what currently is characterized as minimal risk or as posing a minor increase over minimal risk—be redefined as Professor Terrence Ackerman earlier proposed, as when "the probability of [physical and psychological] harm is no more than that to which it is appropriate to intentionally expose a child for education purposes in family life situations";[328] and that the authorities restrict researchers' ability to conduct studies involving more than a minor increase over minimal risk.[329] Assuming that Ross intends for this to be an integrated approach,[330] this would mean that no child would be subject to discrimination based on his or her circumstances in terms of the acceptable amount of harm and risk, and that the amount of harm or risk to which any child could be exposed would be limited according to the terms set by Ackerman.

At first blush, this would seem to accomplish both a good measure of protection and also some access. Indeed, Dr. Ross generally appears to be more inclined than some of her colleagues to

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325. ROSS, *supra* note 34, at 32.

326. *Id.* at 78–81.

327. *Id.* at 83.

328. *Id.* As Dr. Ross explains, this "allows children to participate in novel experiences compatible with their development; and it provides the greatest parental latitude that is consistent with a liberal community's respect for parental autonomy." *Id.*; *see also id.* at 96–97 (explaining that parents can legitimately override a child's dissent so long as the proposed research does not involve abuse or neglect because they have the right to inculcate their values within these parameters). *But see id.* at 98 (suggesting that parents and researchers should not be permitted to override an adolescent's dissent).

329. See *supra* notes 73–74, 109 and accompanying text for a description of section 407 and its process, and its increased use. Dr. Ross does not propose eliminating the possibility that such studies might be approved by the Ethics Advisory Board, but she does appear to be concerned that this exception not become the vehicle to avoid the restrictions inherent in the regulations otherwise. *See* Ross, *supra* note 21, at 531–32.

330. I have derived Dr. Ross's approach from an examination of her different works.

sacrifice access when this is necessary to achieve protection.[331] Researchers would be able to use both healthy and ill children in their research, but on equivalent terms, and only so long as the harms and risks involved did not transgress commonly accepted boundaries, including those informed by the antidiscrimination principle and fiduciary theory.[332] (Ackerman's proposed parameters for permissible pediatric research can be read as incorporating these concepts.) This picture is complicated, however, by Ross's conclusion that the research in *Grimes* was both legal and ethical.[333] It may be the case that this particular analysis should be examined independent of her other views; it may reflect a fealty to the independence of the scientific enterprise and to the associated notion that the federal regulations governing pediatric research provide necessary immunity to researchers who might transgress other aspects of the law.[334] But if

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331. For example, she is concerned about the new and increased use of section 407 panels, and she questions whether the pendulum has swung too far away from protection. *See, e.g.*, *supra* note 109. Dr. Ross's approach appears to preclude the possibility of any research under section 407—that is, of any research that would pose what is now classified as "more than a minor increase over minimal risk."

332. Dr. Ross explains that she disagrees with the strictures of fiduciary theory, and so presumably would disagree with this characterization of her views. *See* ROSS, *supra* note 34, at 22. Fiduciary theory as it is used in this Article, however, is not nearly so restrictive. *See supra* notes 50–51 and accompanying text; *infra* notes 396–400 and accompanying text. This is because its articulation in the law is based not only on responsible adults' obligation to care for the welfare of the individual child, but also on the understanding that those adults have quite a lot of liberty to make decisions about how they will maximize that welfare in the context of their own lives. *See supra* notes 50–51 and accompanying text; *infra* notes 396–400 and accompanying text. At least on the surface, this view of fiduciary theory is consistent with Ross's approach. See, however, *infra* note 333 and accompanying text for discussion of Ross's approval of the research in *Grimes* despite its violation of even the law's more relaxed version of the fiduciary principle.

333. In Dr. Ross's view, "the research was ethically permissible because (1) it offered the prospect of direct benefit to the children who lived in the homes with lead paint; and (2) albeit nontherapeutic for the children in the control arm, it entailed no more than minimal risk." ROSS, *supra* note 34, at 212. The former proposition is difficult to accept given the researchers' position that the results of the periodic testing for lead poisoning should not be released to the families. The latter is disturbing in light of the fact that the lead plaintiff in *Grimes*, eighteen-month-old Ericka Grimes, was located in a unit designated as a control but nevertheless was exposed to sufficient lead dust allegedly to cause learning disabilities and cognitive impairments. *See* Manuel Roig-Franzia & Rick Weiss, *Md. Appeals Court Slams Researchers*, WASH. POST, Aug. 21, 2001, at B1. Ross also took the position that if the research did not qualify as "minimal risk," it could still be lawful according to a modern interpretation of the federal regulation that permits the use of healthy children in riskier research when these children can be said to have a "condition" worthy of study and "condition" is defined as being at risk. *See* ROSS, *supra* note 34, at 211.

334. Ross's initial reaction to the *Grimes* decision lends some credence to this possibility, as it was her view that the court was wrong to find that parents could not give lawful consent to

Ross's approach would permit the research rejected in *Grimes*, her conception of permissible harm and risk—"the probability of [physical and psychological harm] is no more than that to which it is appropriate to intentionally expose a child for education purposes in family life situations"—includes situations that likely few outside of the research community would defend. At the end of the day, this would bring society back full circle to quite a lot of access to healthy children for the benefit of others in the future, but little meaningful protection for the children actually enrolled in the research.

Finally, in its 2004 report entitled *Ethical Conduct of Clinical Research Involving Children*, the IOM implicitly proposed expanding access to healthy children for higher-risk research along the lines proposed by Professor Kopelman—that is, when the children can be described as having a "condition" that is useful for researchers to study.[335] In adopting this position, it rejected a narrow definition of the concept that would limit researchers to children with "an illness, disease, injury, or defect."[336] At the same time, it also rejected a broader definition that would allow researchers access to children according to an unlimited number of "social, developmental, or other characteristic[s]."[337] According to Dr. Ross, the IOM also

> recommended that payment be part of the consent process, although it should not be emphasized as a benefit of participating. While most have argued against payments that might be undue inducements, the IOM justified permitting payments "to reduce certain barriers to research participation" reflecting the change in focus from protecting children from research risks to promoting greater access to research participation. It rejected payments to parents beyond direct reimbursement . . . but supported the provision of reasonable

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their children's involvement in the research because the federal regulations (in her view) say they can. *See supra* note 114 and accompanying text.

335. IOM, *supra* note 8, at 130. The IOM proposal in this respect largely mirrors Loretta Kopelman's. For a description and critique of Professor Kopelman's proposal pertaining to what she calls "risky 'no benefit'" research, see *supra* notes 320–24 and accompanying text. Kopelman is a member of the IOM's Committee on Clinical Research Involving Children, which was responsible for drafting the IOM Report. *See* IOM, *supra* note 8, at v. The regulatory provision, 45 C.F.R. § 46.406 (2007), permits researchers to expose children with "disorders" and "conditions" to research that poses a minor increase over minimal risk. IOM, *supra* note 8, at 134–36 (discussing this provision and the definitional quandaries it poses).

336. IOM, *supra* note 8, at 129.

337. *Id.*

> age-appropriate compensation for children based on time involved when the research does not offer the prospect of direct benefit.[338]

The IOM report itself qualifies this recommendation with the caveat that

> no payment [for participation in research] should be so large or be timed in such a way as to unduly influence parents' or children's decisions about research participation. . . . Payments should not influence parents' or children's decisions to participate in research when such participation is not in a child's best interest.[339]

But as Ross notes, "If the IOM recommendations are adopted, then only in the U.S. would children involved in nontherapeutic research be eligible for an incentive payment beyond a token gesture."[340]

The IOM report contains an extremely thorough treatment of the history, ethics, and regulation of pediatric research. Its examination of the important issues raised by the prospect of increasing access to children for this research is equally thorough. Most important, its recommendations reflect its authors' commitment to balancing protection and access. Thus, alongside its proposals to justify and incentivize increased access to the pediatric population are proposals that would make an important contribution to child protection. For example, it proposes that access to healthy children continue to be limited to research posing no more than minimal risk; that "the interpretation of the concept [of minimal risk] should be 'indexed' to the experiences of the 'normal, healthy, average child'";[341] that "direct benefit" for purposes of permitting higher than minimal risk research be defined as "a tangible positive outcome (for example, cure of disease, relief of pain, and increased mobility) that may be experienced by an individual," and correspondingly that "collateral, indirect, or side benefits" be defined as benefits "that are not related to the research objectives";[342] and that "[r]esearch organizations and

338. ROSS, *supra* note 34, at 133 (citations omitted).

339. IOM, *supra* note 8, at 213. Note that there is no question that payment for participation is intended to influence parents' and children's decisions about research participation. Thus, what the IOM report seeks to avoid is *undue* influence.

340. ROSS, *supra* note 34, at 134.

341. IOM, *supra* note 8, at 122 (quoting the National Human Research Protections Advisory Committee interpretation of minimal risk).

342. *Id.* at 132. The IOM report provides as examples of such "collateral, indirect, or side benefits . . . the opportunity to learn more about their condition or develop social relationships with others in similar circumstances." *Id.* It also specifically notes that "although research

sponsors . . . pay the medical and rehabilitation costs for children injured as a direct result of research participation, without regard to fault."[343]

Even though the IOM report makes important contributions in these respects, it also potentially creates new problems in its recharacterization of healthy but at-risk children as having a condition so that they might be included as subjects in higher-risk, no-benefit research, and in its suggestion that children might be paid more than token sums when their parents agree to enroll them in such research. As noted in the earlier discussion of Loretta Kopelman's proposal to include some healthy children in higher-risk, no-benefit research, it is counterintuitive from the child protection perspective to expose at-risk children to an increased risk of harm—rather than, for example, a decreased risk of harm or additional protections—on the basis that they are at risk.[344] Moreover, although the IOM report restricts its approval of more than mere token payments to payments that would not "unduly influence" parents to enroll their children, it appears likely that the effect of its proposal would be to increase the use of relatively poor children in pediatric research.[345] As described, this population is already overrepresented in pediatric research involving healthy child subjects.[346]

Most important, however, the IOM report fails to propose or adopt a solution to the problem of how to define minimal risk and its variants.[347] Indeed, aside from its rejection of a relative interpretation of minimal risk, it is silent on the subject of uniform standards that would govern the definition of those rules. This is critical because the rules are the locus of the federal regulations' protections for

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participants may view gifts or payments for research participation as benefits, federal guidance makes clear that such payments should not be included by investigators or IRBs in their risk-benefit assessments." *Id.*

343. *Id.* at 21.

344. *See supra* notes 320–24 and accompanying text.

345. Part II.C.3 discusses the benefits issue.

346. See *infra* notes 357–60 and accompanying text for a discussion of this phenomenon.

347. This is in contrast with, for example, Loretta Kopelman and Lainie Ross Friedman, both of whom propose solutions to this critical problem. *See supra* notes 311, 328 and accompanying text.

children,[348] and they are effectively standardless.[349] (As Loretta Kopelman has noted, "the apparent consensus that children may participate in nontherapeutic research 'if the study is not too risky is illusory if we mean different things by "not too risky."'"[350]) Because the research community's regulatory structure is decentralized to a large extent, the rules at the core of the solution thus continue to be malleable according to the needs, interests, predispositions, and expertise of individual IRBs and researchers; individual children who are subject to a particularly conservative IRB review process will get more protection than those who are subject to a particularly liberal one; sponsors of pediatric research (including the drug sector) are likely to favor the latter over the former in their grant-making processes; and parents (in their ability to withhold consent) remain the only predictable source of protection for individual children who are of interest to researchers.

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348. See *supra* notes 68–89 and accompanying text for a description of these rules and their purpose in the federal scheme. *Cf.* Celia B. Fisher, Susan Z. Kornetsky & Ernest D. Prentice, *Determining Risk in Pediatric Research with No Prospect of Direct Benefit: Time for a National Consensus on the Interpretation of Federal Regulations*, AM. J. BIOETHICS, Mar. 2007, at 5, 5 ("During the 25 years since their adoption, [the minimal risk rules] have helped IRBs balance subject protections with the pursuit of scientific knowledge to advance children's welfare.").

349. *See* IOM, *supra* note 8, at 18, 117, 121, 134–36 (acknowledging this problem and recommending, *inter alia*, that HHS and the FDA "cooperate to develop and disseminate guidance and examples for investigators and [IRBs] to clarify important regulatory concepts and definitions (including definitions of minimal risk, minor increase over minimal risk, condition, and prospect of direct benefit)"); Fisher, Kornetsky & Prentice, *supra* note 348, at 5 (emphasizing that the "inconsistency in IRB application of [minimal risk rules and definitions] to pediatric protocols has been widespread, in part because of the ambiguity of the regulatory language," and calling for "a national consensus on recommended criteria"); *see also* Nelson, *supra* note 44, at 58 (describing the different ways one might interpret the minimal risk rule's "risks of everyday life" and arguing that "the apparent consensus that children may participate in nontherapeutic research 'if the study is not too risky is illusory if we mean different things by "not too risky."'" (quoting Kopelman, *Health Care and Research Issues*, *supra* note 317, at 362)). *See generally* Janofsky & Starfield, *supra* note 318, at 844–45 (finding considerable differences among pediatric department chairs and pediatric research center directors on estimates about whether the procedures such as venipuncture, arterial puncture, and gastric and intestinal intubation were regarded as risky); Shah et al., *supra* note 5 (describing a 2002 study of 188 IRB chairpersons whose views as to the procedures and interventions that constitute minimum risk and a minor increase over minimum risk varied widely). Both the Janofsky & Starfield and Shah et al. studies are described and the Shah et al. study is critiqued by the IOM. IOM, *supra* note 8, at 120. Despite its critiques of the Shah et al. study, however, the authors of this report conclude that "the results still point to the considerable subjectivity of risk assessments." *Id.*

350. Nelson, *supra* note 44, at 58 (quoting Kopelman, *Health Care and Research Issues*, *supra* note 317, at 362).

In theory, IRBs are intended to act as important barriers to inappropriate human subjects research by assuring the safety and integrity of studies conducted under their auspices.[351] And thus, in the context of pediatric research, they should effectively function as parents' adjuncts in the business that is child protection. There is no reason to doubt that IRBs in general do their jobs as defined by the federal rules and pediatric research ethics.[352] Nevertheless, the regulatory structure's failure to demand uniformity among IRBs with respect to what it means to do child protection,[353] coupled with its failure to require these institutions to evaluate the merits of particular research proposals before they permit researchers to begin their work,[354] assures that they are not necessarily effective partners in this respect.[355] This problem may be exacerbated when IRBs are inappropriately invested in the grant-related successes of their institutions.[356]

This situation is especially troubling because in the United States the pool of healthy children from which researchers most easily draw is characterized by their parents' low socioeconomic and minority status.[357] Whereas ill children of low socioeconomic and minority

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351. *See* Interview with Philip Rosoff, *supra* note 202 (arguing IRBs probably prevent gross abuses but otherwise are ineffective at protecting subjects).

352. *See id.* (explaining IRBs' focus on ensuring consent, not the merits of the research).

353. *See supra* notes 5, 75, 83, 347–50, and accompanying text. In addition, Jennifer Rosato explains that "when IRBs and others are seeking ethical guidance on children as research subjects, they must look to a patchwork of authorities that does not adequately address children's interests. . . . Reliance on these authorities creates some fundamental weaknesses in any resulting ethical framework." Rosato, *supra* note 35, at 365.

354. For example, IRBs are not required to ask whether there are other ways to arrive at the same information that do not involve risking the welfare of healthy child subjects. Their role is limited to ascertaining whether the federal rules governing pediatric research are being followed, including especially its consent provisions. Interview with Philip Rosoff, *supra* note 202.

355. There is a vast literature on the subject of IRBs, their deficiencies, and ways in which these could be remedied. For a sampling of this literature as it focuses on pediatric research issues, see generally Fisher, Kornetsky & Prentice, *supra* note 348 (describing inconsistency in IRB interpretations of minimal risk rules, and ethical issues that have arisen out of that inconsistency); Gandhi, *supra* note 35 (proposing structural reforms to address concerns about arbitrary decisionmaking with respect to the application of the minimal risk definitions); Rosato, *supra* note 35, at 362 (describing problems with the IRB system that diminish its reliability as adequate protectors of child research subjects).

356. See *supra* notes 99–101 and accompanying text for discussion of this as an issue in the context of the oversight authorities' review of Johns Hopkins's IRB processes.

357. *See* Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 815 n.6 (Md. 2001) (describing how "the literature on the law and ethics of human experimentation is replete with warnings that all subjects, but especially vulnerable subjects, are at risk of abuse by inclusion [as research

status are typically underrepresented in both therapeutic and nontherapeutic clinical trials, healthy children with these backgrounds are typically overrepresented in nontherapeutic research.[358] Dr. Lainie Friedman Ross has offered the view that the overuse of poorer, mostly African-American children in U.S.-based research involving healthy children may be attributable to the fact that "many academic medical centers [are located] in poor urban sites with a large minority

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subjects]," that among the vulnerable are "children and the elderly . . . and racial minorities, ethnic minorities, and women . . . whom history shows to be the most frequent victims of abuses in human experimentation," and that "[t]he failures in the informed consent process lead to serious inequities in research, specifically for the poor and less educated who bear most of the research burden" (citations omitted)); *id.* at 815–16 n.6 (enrolling primarily poor black children in lead abatement study); David D. Kirkpatrick, *E.P.A. Halts Florida Test on Pesticides*, N.Y. TIMES, Apr. 9, 2005, at A15 (federally- and industry-funded study put on hold and ultimately cancelled because researchers in pesticide exposure study allegedly avoided families from educated communities while seeking to enroll healthy infants and children to age three by offering their parents $970, a camcorder, and other incentives for their consent and cooperation); Deanna Fene, *Pesticide and Infant Study Halted*, FIRST COAST NEWS, Nov. 9, 2004, http://www.firstcoastnews.com/news/news-article.aspx?storyid=27370 (citing the "many parents, doctors and environmental groups who feel [the compensation] incentive targeted poor people"); News4Jax.com, Environmental Group Calls Local Pesticide Study 'Racist,' Nov. 8, 2004, http://www.news4jax.com/print/3900662/detail.html. This problem is exacerbated in the context of research conducted by U.S.-based institutions abroad. *See, e.g.*, Abdullahi v. Pfizer, Inc., No. 01 Civ. 8118 (WHP), 2002 U.S. Dist. LEXIS 17436, at *1–3 (S.D.N.Y. Sept. 17, 2002) (involving the injury and death of numerous Nigerian children who were recipients of an experimental antibiotic shown by prior animal testing to involve a risk of "significant side effects in children such as joint disease, abnormal cartilage growth . . . and liver damage"), *vacated as improvidently granting motion to dismiss on* forum non conveniens *grounds*, 77 F. App'x 48 (2d Cir. 2003). U.S.-based researchers may choose to conduct some aspects of their research in foreign settings as a way to get around relatively stricter U.S. rules concerning risk, benefit, and consent. Telephone Interview with Jennifer Li, *supra* note 8.

358. *See* ROSS, *supra* note 34, at 48 (noting based on empirical analysis of recent pediatric research data that "[b]lacks are overrepresented in the research compared to their proportion in the census"); *id.* ("Black children are overrepresented and Hispanic children are underrepresented in all studies and in each subcategory [of research, including in clinical trials, therapeutic research, and potentially stigmatizing research] when compared with the census data."); *id.* at 50 ("The most significant difference occurs in potentially stigmatizing research . . . where White subjects are significantly underrepresented, but Black and Hispanic subjects are significantly overrepresented."); *see also* Catherine Walsh & Lainie F. Ross, *Are Minority Children Under- or Overrepresented in Pediatric Research?*, 12 PEDIATRICS 890, 891–94 (2003) (reporting on an empirical study of minority children in pediatric research). Studies seeking to explain the dearth of low income and minority subjects in therapeutic and nontherapeutic research involving ill children tend to conclude that relatively wealthier families have greater access to clinicians who would enroll their ill children in this research, and that because of the Tuskegee Syphilis Experiment, educated African-American parents continue to distrust researchers' motives when their children are ill. *See, e.g.*, Giselle Corbie-Smith et al., *Attitudes and Beliefs of African Americans Toward Participation in Medical Research*, 14 J. GEN. INTERNAL MED. 537, 543–44 (1999).

population."[359] Consistent with the general understanding in the research community, however, she also acknowledges that "the limited research data that exist suggest that the main reason healthy subjects volunteer for research is the monetary incentive" and that this incentive is particularly "problematic for research on children because it may lead to the exploitation of some children by well-meaning but less educated parents who do not understand the purpose of the activity."[360]

Thus, in the end, although the proposals to balance protection and access share a deep commitment to assuring that children will benefit when science doles out the fruits of its endeavors, all fail to protect some healthy children from the more harmful and risky research they would permit. The common solution in all of the proposals is implicitly to leave to individual researchers and their IRBs the authority to choose the research that is worth doing, to decide how much harm and risk is too much, and to define child protection to mean protection of children as a group. So long as this group is respected, not exploited for its inherent vulnerabilities, and not used for "over the top" harmful or risky research, "children" are being protected, and an acceptable balance between protection and access has been struck. From the child protection perspective, the problems with this situation are evident: it potentially exposes healthy children—particularly poor and minority children—to too much harm and risk, and it eliminates almost entirely concern for the individual child.[361]

B. The Merits of Harmonizing the Ethics of Pediatric Research with the Law of Child Protection and Parents' Consent Authority

This Section argues that the ethics of pediatric research should be harmonized with the law of child protection and parents consent authority. Despite numerous well-intentioned efforts, the research community has not arrived at an appropriate and effective balance

359. ROSS, *supra* note 34, at 51–53.

360. *Id.* at 81. Notes 202–04 and accompanying text discuss this point in the context of the discussion about benefits in general.

361. In its admonition that researchers respect the assent of the older child and only permit proxy consent to suffice for younger children, Robert Nelson's proposal is a partial exception to this point. *See supra* notes 304–05 and accompanying text; *see also* Nelson & Reynolds, *supra* note 53, at 12 (separately discussing the value of respect for children's assent).

between protection and access.[362] On the other hand, the law of child protection and parents' consent authority is both applicable to and capable of resolving these tensions. In addition, because this law codifies progressive social norms about the child and his or her relationship to adults and the society, both the research community and children who would be research subjects would benefit from its use to set the standards also for the research enterprise.

1. *Resolving the Dilemma of Protection and Access.* The research and bioethics communities have long sought to balance their interest in increasing access to child subjects for higher-risk research against their interest in protecting children from the harms and risks inherent in research.[363] The pendulum swings that Dr. Lainie Friedman Ross describes so well in her related work—between the completely unregulated use of healthy children as research subjects in the period preceding the *Belmont Report*, to their almost complete exclusion in the following period, to their inclusion in increasing numbers and in increasingly risky research designs—exemplify the competing positions and the resulting quandaries at issue in this project.[364] As I argued in Section A, these quandaries remain unresolved in significant respects, particularly from the child protection perspective. The result is that although the project to access healthy children for increasingly risky research is well underway, the parallel project to assure the protection of these children as they are being used as research subjects has effectively stalled.[365]

On the other hand, the law of child protection and parents' consent authority is premised on the fact that children's interests will sometimes diverge from those of their parents and other relevant

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362. *See supra* Part III.A. This point is generally well understood within that community, which appears to be receptive to solutions to the problem.

363. See *supra* notes 294–98 and accompanying text for a description of this project.

364. *See supra* note 21.

365. See *supra* Part I and Part III.A for an examination of this disparity. As Jennifer Rosato has noted in the context of the modern push to increase the use of children in drug trials,

> [i]n promulgating the new FDA regulations, the FDA was aware of the myriad of serious ethical issues raised when children are research subjects. [Thus, it] initially . . . noted that 'because pediatric patients represent a vulnerable population, special protections are needed to protect their rights and to shield them from undue risk.' Nevertheless, it ultimately declined to adopt regulations that would guide a resolution of these issues.

Rosato, *supra* note 35, at 365 (citation omitted).

adults. This law is thus designed to identify the circumstances—both traditional and novel—that may result in a conflict of interest between children and adults, the institutions responsible for addressing conflicts, and the rules and procedures according to which they will be resolved. In addition, these rules and procedures specifically contemplate the existence of tensions between child protection and competing norms, including especially parental autonomy and the states' interest in the overall welfare of society.[366] Because of this, the law of child protection and parents' consent authority is both applicable to and capable of resolving the related tensions between the research community's child protection and scientific progress goals.

This law is applicable to the resolution of this problem because according to the federal regulations, among other things, parental consent is an essential—if not *the* essential—requirement of ethical research and because parents' ability to give lawful consent in all contexts is defined by its terms. Indeed, given this situation, it is difficult to understand why the research and bioethics communities have over the years sought to reinvent this wheel. Harmonization of research ethics with this body of law would go far toward relieving the research community of its *Grimes*-related concerns.

Importantly, the law of child protection and parents' consent authority is also capable of resolving the related tensions because this is precisely its business; it is designed to determine whose interests—children's or adults'—prevail on any given set of facts, and in particular when adults' choices and actions cross the line into prohibited territory. This framework contemplates two sets of circumstances: those in which children's and adults' interests are coterminous (either in fact or as a result of the legal fiction that parents act in the best interests of their children so long as they do not transgress the boundaries of maltreatment law) and those in which their interests diverge (because the adults at issue have or contemplate transgressing those boundaries). And it provides the tools—the maltreatment definitions and their exceptions—necessary properly to sort adult decisions and actions according to whether they are permissible or prohibited.

366. See *supra* notes 116–31 and accompanying text for a description of the doctrine of parental autonomy; and see *infra* notes 391–92 and accompanying text for a description of the states' interest in children as future citizens of the society.

These tools are not perfect. For example, I have criticized them in another context for their failure adequately to address nonphysical forms of abuse and neglect.[367] And in some cases, individuals responsible for implementing the rules take advantage of the breadth and vagueness built into the definitions to intrude on the privacy of the family in unhelpful and even harmful ways.[368] Finally, while the law of child protection has developed in tandem with the constitutional doctrine of parental autonomy, the included right to consent on behalf of the child has developed primarily in the tort law context as a defense to battery and in the context of medical neglect cases.[369] Given the history of pediatric research, it is no real stretch to imagine that certain study designs might qualify as child abuse.[370] Nevertheless, there would be some work to do to establish the sorts of research-related procedures and interventions that would qualify as abusive in the modern context.[371]

Although these are important flaws, they need not be obstacles to harmonization. Because the law of child protection and parents' consent authority merely establishes the minimum level of care and respect adults owe children, the research and bioethics communities are free and should continue to exercise leadership in recognizing emotional harms and risks as boundaries to permissible research.[372] Moreover, exposure to inappropriately broad definitions of abuse can be minimized, if not avoided entirely, through exclusive reliance on officials responsible for standardizing those definitions at the state rather than local level.[373] And because of their experience applying child protection law to diverse scenarios, for example to foreign and

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367. DORIANE LAMBELET COLEMAN, FIXING COLUMBINE: THE CHALLENGE TO AMERICAN LIBERALISM 131–32 (2002); *cf.* Taylor, *supra* note 154, at 339–40 (noting that emotional abuse is not always included in the states' definition of maltreatment, in part because of "its elusive and intangible nature").

368. Legal definitions of maltreatment are crafted in this way

> to assure that the state can exercise wide discretion in treating targeted parental conduct as maltreatment; and [to] ensure[] that the state is not precluded from addressing such conduct by the failure of the legislature or administrative officials to include all conceivable forms of abuse or neglect in its laws.

Coleman, *supra* note 142, at 428.

369. *See* discussion *infra* Part II.A.

370. See *supra* Part I for a description of some of this history.

371. I propose the beginnings of this analysis in Part II.C.

372. *See, e.g.*, IOM, *supra* note 8, at 246–50 (discussing this issue); Shah et al., *supra* note 5, at 478 (same).

373. *See infra* note 379 and accompanying text.

novel parenting practices,[374] these officials have the expertise to partner with the research community to develop protocols specifically appropriate to this setting.[375]

Harmonizing the ethics of pediatric research with the law of child protection and parents' consent authority would, at a minimum, require revising the federal regulations governing pediatric research to reflect the law's definitions of permissible harm and risk.[376] The language of "minimal risk" could be retained—this might be important for many reasons, including that it is commonly used in the global context—so long as its content is fully consistent with those definitions.[377] The regulations should also be made to reflect the legal boundaries of parents' decisional authority. Although these boundaries are already implicit in the regulations, it must be made clear that parental consent is not the same as respect for the child. Parents as proxies have authority to consent to their children's inclusion in research only when this exercise is consistent with the fulfillment of their legally defined fiduciary obligations. Incorporating these boundaries would also ensure the inclusion of any eventually applicable exceptions to the maltreatment rules should these be at issue.[378] Finally, the regulations should require review of pediatric study designs to ensure that they do not violate maltreatment law. This review might be conducted as part of or following the IRB process by an independent expert in the field of child protection—for example, the state agency responsible for supervising locally administered child welfare programs. This work could be done by a local child welfare agency. The research community, however, is more

374. *See* Coleman, *supra* note 165, at 290–93 (discussing the law's applicability to these settings).

375. *See* Coleman, *supra* note 142, at 428–29 (explaining that the definitions of maltreatment are usually purposefully broad so that officials on the ground can adapt them to novel situations that may involve abuse or neglect).

376. See *supra* Part II.C for a description of those rules and their application in the research setting. Because these rules are inherently nondiscriminatory, revising the ethics of pediatric research consistent with their terms would also solve the ongoing debate among bioethicists and regulators over the issue of an absolute versus relative interpretation of the harms and discomforts "ordinarily encountered in daily life" in favor of the consensus position. See *supra* notes 76–83 and accompanying text for a description of this debate. Within HHS, the easiest way to accomplish this harmonization would be to revise the federal rules governing pediatric research with its own maltreatment definitions. Notes 133–35 and accompanying text set out these definitions in relevant part.

377. *See* Kopelman, *supra* note 17, at 749–50 (describing this global context).

378. Parts II.A and II.B discuss this body of law.

likely this way to get correct and consistent interpretations of the relevant laws.[379]

Adopting these changes would strike the balance between protection and access somewhere between the conservative ethics of Paul Ramsey and his disciples and the progressive ethics of those who have reinvigorated this debate by calling for increasing the risk to which healthy children are properly exposed.[380] This particular balance or middle ground is probably consistent with the approach of many within the research community who would thus benefit from its formal adoption as the governing standard in the research setting. Even those who would approach the matter differently, however, would be getting a good measure of what they say they want: respect for individual child subjects in a form that is acceptable to those who would judge its terms, and respect for the scientific enterprise as an important countervailing concern. They would, of course, also lose something in the trade: the ability lawfully to expose healthy children to some higher-risk research, and any scientific progress that could be achieved only in this way. On the other hand, what they would gain would be immeasurable in the long run. Contrary to the skeptical views expressed by the *Grimes* court and by other unconvinced observers of the research enterprise, the society would come to know and trust in the research community as an institution that shares its particular commitment to child protection.[381]

2. *A Consistent Commitment to Child Protection*. A consistent commitment to the progressive view of child protection ensconced in the law of child protection and parents' consent authority is ultimately the most important reason to harmonize the ethics of

379. The general point that "IRBs should include experts on children, either as members or consultants," is not a new one. *E.g.*, Rosato, *supra* note 35, at 369 (making this argument); *id.* at 367 (noting that this recommendation comes also from the American Academy of Pediatrics). The difference between these proposals and the one I make here relates to the expert's qualifications and orientation. Thus, although Rosato and others have recommended the use of an expert "knowledgeable in 'pediatric ethical, clinical, and psychosocial issues,'" *id.* at 372, I am recommending someone with specific expertise in the law of child protection and parents' consent authority. The two are not the same.

380. See *supra* Part I, which sets out these competing positions.

381. See *supra* notes 254–63 and accompanying text for a description of the *Grimes* court's views in this respect. *Cf.* IOM, *supra* note 8, at 251 (discussing the concern that the research community not be perceived as insensitive to concerns about discrimination in the selection of research subjects). For a description of other skeptical views of the pediatric research enterprise, see *supra* notes 98–101 and accompanying text.

pediatric research with this law. Child protection as a concept and social commitment is on the ascendancy, entirely apart from the world of science and research. Much remains to be done—and also undone—to secure children's general welfare and the safety of individual children: nevertheless, American society stands at a high point in the history of the child.

In concept, the child is no longer as she was throughout much of Western history—the equivalent of property or else a mere extension of her parents who could do with her as they wished.[382] She is no longer "cheaper than a calf"[383] or otherwise of lesser value.[384] Rather, the child today is an individual, albeit a preautonomous one, to whom her parents and society owe basic obligations of nurture and respect.[385] An important aspect of this modern vision is that the child's body and mind are ultimately her own, not to be used to her detriment by the adults who are responsible for her care and development.[386] To the contrary, her parents' right to exercise

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382. *See* Elizabeth S. Scott & Robert E. Scott, *Parents as Fiduciaries*, 81 VA. L. REV. 2401, 2407 (1995) (noting that "[u]ntil the social reform movement at the beginning of this century . . . [a] parent's right to the custody of his children so approximated property ownership that it could be transferred by contract, and lost only by abandonment or unfitness"); Barbara Bennett Woodhouse, *From Property to Personhood: A Child-Centered Perspective on Parents' Rights*, 5 GEO. J. ON FIGHTING POVERTY 313, 313–15 (1998) [hereinafter Woodhouse, *From Property to Personhood*] (describing the evolving concept of the child in this respect); Barbara Bennett Woodhouse, *"Who Owns The Child?"* Meyer *and* Pierce *and the Child as Property*, 33 WM. & MARY L. REV. 995, 997 (1992) (explaining the Supreme Court's early cases involving children as moves to "constitutionalize[] a narrow, tradition-bound vision of the child as essentially private property").

383. See *supra* text accompanying note 41 for an example of this expression's use in the early 1900s to explain why children were particularly useful as research subjects.

384. *See* Keith-Spiegel, *supra* note 56, at 182 (explaining that the "[l]ack of legal status and the high mortality rate of minors also contributed to their lower perceived value and interest").

385. *See* Scott & Scott, *supra* note 382, at 2402–03 (describing a modified fiduciary approach to the parent-child relationship and a conception of the child based in that approach); Barbara Bennett Woodhouse, *Hatching the Egg: A Child-Centered Perspective on Parent's Rights*, 14 CARDOZO L. REV. 1747, 1855–58 (1993) (describing a child-centered view of parents' rights as emanating from the responsibility to nurture and respect the child, specifically from the formation of an attachment to the child based in the fulfillment of this responsibility). Arguably, the most developed articulation of this vision is found in the United Nations Convention on the Rights of the Child (UNCRC), which describes an individual with evolving capacities to whom parents and the state owe duties of care commensurate with those capacities. Convention on the Rights of the Child, Nov. 20, 1989, 1577 U.N.T.S. 3. Even though the United States has failed to ratify this treaty, its fingerprints are evident throughout the document as a result of the integral involvement of State Department officials and U.S.-based NGOs in its development. *See* Woodhouse, *From Property to Personhood*, *supra* note 382, at 313–18 (discussing the UNCRC).

386. *See* Anne C. Dailey, *Constitutional Privacy and the Just Family*, 67 TUL. L. REV. 955, 975–76 (1993) (noting that "[f]rom th[e] liberal belief in 'the intrinsic and ultimate value of the

discretion in the ways they guide her along the path to adulthood is directly tied to the fulfillment of their fiduciary obligations of nurture and respect,[387] including to the development of a relationship with her that honors these commitments.[388] As a result, although liberalism (with its almost singular focus on the rights of adults) often inures to the detriment of children,[389] describing the child and her relationship to her parents in this way accords her one of this ideology's central benefits: the protection of the harm principle.[390]

The modern relationship between parents and the state reflects this evolution in the concept of the child. Thus, although a relatively narrow sense of *parens patriae* caused the state mostly to stay out of the affairs of the family through the late 1800s to mid-1900s,[391] a much more expansive view of the state's role has since made it a forced, but also often embraced, junior partner with parents to guide the child's development and welfare. Mandatory school attendance requirements, child labor laws, civil and criminal maltreatment laws, the foster care system, and immunization requirements are at once

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human individual' comes the view that 'the concept of privacy embodies the moral fact that a person belongs to himself and not others nor to society as a whole'" (citations omitted)); *see also supra* notes 126–31 and accompanying text (applying this idea to child welfare law).

387. Parham v. J.R., 442 U.S. 584, 602 (1979) ("Parents generally 'have the right, coupled with the high duty, to recognize and prepare [their children] for additional obligations.'" (quoting Pierce v. Soc'y of the Sisters of the Holy Names of Jesus and Mary, 268 U.S. 510, 535 (1925))); *see also* Katharine T. Bartlett, *Re-Expressing Parenthood*, 98 YALE L.J. 293, 297–98 (1988) (describing the traditional view of "parenthood as exchange").

388. *See* Bartlett, *supra* note 387, at 295 (describing a new construction of the relationship between parent and child, away from parents' rights toward parents' responsibility for constructing a nurturing relationship with their child).

389. *See* COLEMAN, *supra* note 367, at 93–138 (describing some of the important ways in which liberalism has harmed children); Coleman, *supra* note 142, at 421 (noting the ways in which "children are 'the Achilles heel of liberalism'"); Dailey, *supra* note 386, at 987 ("By vesting parents with authority over their children, liberalism must find a way to resolve the apparent violation of its competing principle of individual sovereignty. Parental authority, in the form of family privacy, confronts the will of the individual child.").

390. *See* JOHN STUART MILL, ON LIBERTY (1912), *reprinted in* 2 THE GREAT POLITICAL THEORIES 186, 186 (Michael Curtis ed., Avon Books 1981) ("The only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others. . . . He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise, or even right.").

391. *See* Scott & Scott, *supra* note 382, at 2407 (explaining that "[u]ntil the social reform movement at the beginning of th[e twentieth century], the state took little interest in family governance").

the most prominent aspects of this partnership and the most reflective of the modern concept of the child.[392]

The institutions that have developed to support the modern concept of the child and the related relationship between parents and the state are now well entrenched in American society. Of particular relevance to this Article are the maltreatment laws and government agencies—the federal and state departments of health and human services, social services, and child protection—that enforce them.[393] Their overarching goal is the protection of the individual child from harm suffered either intentionally or as a result of neglect by parents or guardians.[394] To be sure, there is no dearth of criticism of these institutions, from those who believe they are not doing enough to those who believe they are doing too much.[395] But in general, their goals are widely accepted, as are the structures and protocols they have developed to achieve them.

The impact of these progressive developments on the lives of individual children has been stark. Although the fiduciary theory of parental authority and the modern view of *parens patriae* share common ground with the theological ethics of Paul Ramsey and his disciples, unlike that ethics, neither requires selfless dedication to the ideal best interests of the child. Both parents and the state have legitimate competing interests to balance and reality-driven circumstances to contend with, and thus, inevitably and lawfully will fall short of that ideal. This does not mean that the ideal can be ignored or discounted, however,[396] because it has been enormously

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392. *See generally* DAVIS ET AL., *supra* note 27 (describing these incursions into the parent-child relationship).

393. HHS describes minimum requirements for the states' child maltreatment laws and conditions related federal funding on compliance with those requirements. Child Abuse Prevention and Treatment Act of 1974, Pub. L. No. 93-247, 88 Stat. 4 (codified as amended at 42 U.S.C. §§ 5101–5116 (2000)); *see also* Wadlington, *supra* note 118, at 322–23 (describing how child maltreatment reporting statutes were "well received" despite the society's general aversion to "informer laws," reflecting "society's overwhelming concern with shielding children" from harm). The CPS function is administered at the state level by state departments of social services. *See* 45 C.F.R. § 233.90 (2006) (conditioning federal funding of state welfare for low-income families on adequate child maltreatment provision).

394. See *supra* notes 132–43 and accompanying text for a description of these rules.

395. *See* Coleman, *supra* note 142, at 416–20 (providing an analysis of this spectrum of criticism).

396. Some pediatric bioethicists have seized on this, and the unremedied, relatively poor life circumstances of many underprivileged children, to suggest that the best interests standard is a weak restraint on both parents' consent authority and (derivatively) researchers' ability to use healthy children in harmful or risky experiments. *See, e.g.*, Kopelman, *supra* note 17, at 755.

influential in establishing the boundaries of parental authority at a point that ensures continued respect for the child as a person: for example, not only can parents no longer lawfully beat a child to death for disrespecting them,[397] in most places they can no longer cause them more than transient pain or temporary bruising.[398] The view that spanking is an affront to the child's human dignity has even caused some jurisdictions legally to restrict this traditional parenting practice.[399] Possibly the most important impact of the best interests of the child ideal on the law is that, on its face and with only a few still very narrow exceptions, child maltreatment law in general no longer cares about a parent's reasons for causing harm. As a result, although the law in many states prior to the 1960s focused on parental motivation in defining abuse, its modern focus is on harm to the child.[400]

The fact that child maltreatment law formally does not take into account wealth or poverty, or whether the child is a member of a traditionally disenfranchised minority group, further promises that every child in this new tradition will be respected as a person on equivalent terms. Significant disparities continue to exist among these groups with respect to their circumstances and how they are treated by public and private institutions. Nevertheless, the antidiscrimination principle—which "guarantees that similar individuals will be dealt with in a similar manner by the

397. *See* Coleman, *supra* note 142, at 509 n.286 (explaining the absolute paternal ownership theory in history).

398. *See supra* text accompanying notes 136–37 for a description of this standard.

399. *See, e.g.*, CAL. WELF. & INST. CODE § 300 (West 2006) (excepting from California's definition of physical abuse only "age-appropriate spanking to the buttocks"); Op. Cal. Att'y Gen. No. 97-416 (July 21, 1997) (interpreting this exception narrowly to require that parents also demonstrate that a spanking was necessary and proportional); *see also* CBCNews Online, *To Spank or Not To Spank?*, CBCNEWS, Feb. 2, 2004, http://www.cbc.ca/news/background/spanking (reporting on the Canadian Supreme Court's decision to ban the spanking by parents of teenagers and children under the age of two).

400. *See* Monrad G. Paulsen, *The Legal Framework for Child Protection*, 66 COLUM. L. REV. 679, 681–86 (1966) (describing "cruelty to children" statutes). *Compare supra* notes 132–65 and accompanying text (providing illustrative definitions of abuse, explaining that in general, parental motivation is irrelevant to a finding of maltreatment, and setting out the exceptions to this policy), *with* MASS. ANN. LAWS ch. 119, § 42 (LexisNexis 1932), *repealed by* An Act Relative to the Care and Protection of Children, and Relative to the Advisory Board of the Department of Public Welfare, ch. 646, § 1, 1954 Mass. Acts 648, 648 (defining maltreatment according to the "vice of its parents").

government"[401] and which requires strict scrutiny of arguments that would rely upon distinctions made on the basis of suspect classifications[402]—works toward assuring that this promise eventually will be kept.

The movement to increase access to healthy children for higher-risk research poses a direct challenge to this theoretical, institutional, and real-world progress because it focuses on the interests of children as a group rather than on the individual child, overincludes healthy low-income and minority children in nontherapeutic research, and fails to require researchers to prove the merits of their proposals. Although others may disagree, in my view it is not worth compromising this progress so that other children in the future might possibly benefit.

This is a basic Kantian claim, but also an empirical one: each child, no matter his or her external circumstances, should be treated with the care and respect due to an individual in this society. In particular, no child's health and welfare should be discounted relative to the interests of others. The fact that some ill children will be harmed if drugs designed for adults are not also tested for safety and efficacy on children does not itself justify risking the well-being of the healthy child who would be used for this purpose. Risking a child's well-being so that scientists can test their theories in other respects—for example, about the level of lead abatement or pesticide use that is necessary to minimize the likelihood of related disabilities—is particularly unjustified when there are alternative ways to arrive at the same ends.[403]

Moreover, even assuming the cynics are wrong and that the push to increase access to healthy children for higher-risk research is only benevolently motivated,[404] overall children are more likely to be

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401. JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW 682 (7th ed. 2004). The antidiscrimination principle was initially developed in response to official racist policies including slavery and the black codes of the late 1800s, Doriane Lambelet Coleman, *Individualizing Justice Through Multiculturalism: The Liberals' Dilemma*, 96 COLUM. L. REV. 1093, 1129–33 (1996), and is most often applied to critique race- and gender-based differences in treatment or outcomes. It applies equally, however, to other circumstances in which institutions take advantage of the inherent vulnerabilities of certain human conditions to subject those who bear the burdens of those conditions to relatively poor opportunities.

402. CHEMERINSKY, *supra* note 13, at 694–96.

403. See *supra* note 357 for a description of these study designs.

404. For a discussion of the contrary view, see *supra* notes 98–101 and accompanying text, which explore the suggestion that calls for increased access to children for pediatric research are at least partly driven by economic, rather than altruistic, concerns. *Cf.* Abdullahi v. Pfizer, Inc.,

better off under a system with strong maltreatment laws that require parents and the society to respect their personhood and equality than under a system that sacrifices these for the general good that science can do, or even for the specific good of more and better pharmaceuticals tailored to the needs of the pediatric population. There is no doubt that children continue to benefit tremendously from drug development and other research-related advances. There also appears to be a general consensus that if individual healthy children are not included in higher-risk pediatric trials, children in general will continue to be deprived of some measure of these advances in relation to adults.[405] There is no minimizing this consequence. Nevertheless, a policy that sanctions some perfectly legitimate research, but also some of what is otherwise known to be child abuse, cannot be justified on these grounds. In this regard, very little has changed since the 1970s, when the nation was horrified to learn that emotionally disturbed but otherwise healthy institutionalized children were used as research subjects by ostensibly well-intentioned pediatricians seeking a better hepatitis vaccine.[406]

Finally, although not all pediatric research is connected to the pharmaceutical industry, this sector is clearly associated with the arguments to increase access to the pediatric population for

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No. 01 Civ. 8118 (WHP), 2002 U.S. Dist. LEXIS 17436, at *1–3 (S.D.N.Y. Sept. 17, 2002) (describing Pfizer study of new antibiotic alleged to have resulted in the injury and death of numerous Nigerian children; the company is alleged to have pursued the study for financial reasons, despite that the drug previously had been tested only on animals and had been shown in that context to involve a significant risk of harm), *vacated as improvidently granting motion to dismiss on* forum non conveniens *grounds*, 77 F. App'x 48 (2d Cir. 2003); Benjamin et al., *supra* note 300, at 1266 (noting that incentives created to encourage pediatric drug trials have resulted in a substantial increase in such trials, but that publication of their results in peer-reviewed journals is "limited"; as a result, some of the benefits the society and children were expected to gain from these incentives are not being realized); Kirkpatrick, *supra* note 357 (describing proposed EPA study of the effects of pesticides on children, which was to have been funded in part by the pesticides industry); Jennifer S. Li et al., *Economic Return of Clinical Trials Performed Under Pediatric Exclusivity Program*, 297 JAMA 480, 480 (2007) (concluding that the pediatric exclusivity program has resulted, among other things, in a disproportionate return for pharmaceutical companies that have agreed to conduct pediatric research concerning the safety and efficacy of their blockbuster drugs).

405. See *supra* notes 90–97 and accompanying text for an explanation of this view.

406. See *supra* notes 46–52 and accompanying text for a description of the experiments at Willowbrook and the outcry in the aftermath of their discovery.

research,[407] and with the growth in spending on pediatric research.[408] Thus, in comparing the merits of the competing arguments for increased access to healthy children for higher-risk research and for child protection law–based curbs on such access, it is worth noting that children are not actually "therapeutic orphans" as is claimed by some critics of particularly protectionist ethical rules.[409] Indeed, as any parent in the United States who can afford good health care for his or her child knows, this is hyperbole. Pediatricians do not always have a ready answer to every medical problem or precise information about how a child will respond to a particular drug they are interested in prescribing. Nevertheless, compared with parents who cannot afford good health care, parents in many other countries, and parents in other historical periods, parents in this era suffer from an embarrassment of treatment riches.

To the extent that there is still a disparity between children and adults in this respect, it deserves attention. But if justice is what motivates those who would seek a solution, the answer cannot be even a partial return to the time when society ignored the fact of children's infancy and attendant vulnerability. Indeed, the disparity exists in part because in 1978, the drafters of the *Belmont Report* decided that protecting children from research-related abuse was more important than assuring them parity with adults in the search for ever better treatment options.[410] Although it may be useful from time to time to challenge this conclusion, there is no compelling reason to believe in this period that anything has changed, and thus that this decision was or is wrong.

If there does come a time when it is more important to do science than child protection—for example, in the case of a national medical emergency—justice requires that the burdens of this choice be distributed across the society. The solution cannot be as it stands: the disproportionate use of poor and minority children as research

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407. See *supra* notes 95–97 and accompanying text for a description of these arguments.

408. Telephone Interview with Jennifer Li, *supra* note 8 (describing recent trials conducted under the pediatric exclusivity rule that included healthy child subjects); *see supra* notes 8–9 and accompanying text.

409. *See supra* text accompanying note 94.

410. *See supra* notes 62–68 and accompanying text. The distributive justice argument for increasing access to healthy children for higher-risk research was part of the discussions surrounding the development of the *Belmont Report* and the earlier-published report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Research Involving Children*. *See supra* notes 66–68.

subjects.[411] Regardless of whether this use is intentional or incidental as some have claimed,[412] there is no justice in a system in which those who primarily bear the burdens of research are most likely to come from especially vulnerable subpopulations which are also least likely to benefit from its successes.[413]

CONCLUSION

The question whether it is ever appropriate to involve healthy children in risky research is a hard one. It has perplexed philosophers, bioethicists, researchers, and others, at least since Nuremberg. On the one hand, if healthy children are off-limits for such research, there is much that society cannot learn about children in general, including how to improve their lives and prospects. On the other hand, permitting researchers to use healthy children in this context risks their health and welfare, in some cases to a point that otherwise would be considered intolerable. It also risks the perpetration of distributive injustices both domestically and internationally as researchers and institutions encounter difficulties in their effort to enlist sufficient subjects for their work: history and modern practice demonstrate that it is much easier to enlist children of vulnerable parents in risky research—particularly parents who are financially or

411. For a description of this disparity, see *supra* notes 357–60 and accompanying text. The movement to increase access to healthy children is motivated in large part by arguments about distributive justice. *See supra* notes 90–92 and accompanying text.

412. For example, see *supra* notes 359–60 and accompanying text, discussing Dr. Ross's theory that the disparity may be due to the location of some research institutions in poor, urban settings.

413. Existing data show important "disparities in health outcomes between minority children and their Caucasian counterparts, and between children of lower and higher-family socioeconomic status." ROSS, *supra* note 34, at 56 ("[T]here are serious and significant heath care disparities in medicine, including pediatric medicine, based on race and ethnicity . . . ."); *id.* at 51 ("Our data found that Black children are overrepresented in medical research overall. The overrepresentation of Black children in pediatric research stands in acute contrast with their decreased access to pediatric health services, even when they have the same health care insurance."); *id.* at 55–56 (suggesting that although "Black children do have fair access to the potential benefits that may accrue from participation in clinical trials," the same is not true of "therapeutic research more generally"); *see also* IOM, *supra* note 8, at 122 ("Allowing a relative interpretation of minimal risk . . . violate[s] the ethical principle of justice, which requires that the burdens and benefits of research be distributed equitably. As a political and practical matter, it could also create social dissension if those in disadvantaged communities or populations understood that their children would be exposed to a higher risk in research than better off children.").

medically needy, or who are relatively uneducated—than it is to assure that its burdens are spread fairly across the population.

The federal rules governing pediatric research largely ensconce prevailing ethical standards. Thus, as the ethical tide shifts, so too do permissible interpretations of those rules. Until the mid- to late 1990s, prevailing interpretations reflected the generally held view that it was inappropriate to involve healthy children in risky research. The notion was that whatever disparity existed between adults and children in terms of their access to the benefits of research was acceptable given the moral issues associated with the use of healthy children in this controversial setting. Since then, however, bioethicists have renewed the call to involve healthy children in risky research, relying primarily on the argument that increasing reliance on pharmaceuticals to treat illness and disease has caused the disparity in benefits between children and adults to grow to a point at which it is no longer acceptable. This argument has been largely successful. The use of healthy children in risky research settings is once again prevalent, as is the research community's recourse to particularly vulnerable subgroups within the pediatric population to fill out their protocols. Notably, although the argument in support of this result was built on the promise of new and better pharmaceuticals, the use of healthy children in this setting has not been limited to drug trials.

As it proceeds in this direction, society must not forget the lessons of the past that caused it to regulate pediatric research in the first place. These lessons taught that the research setting is fruitful ground for abuse and exploitation of pediatric subjects, notwithstanding the good intentions of researchers and regulators. It is thus essential to establish a boundary between permissible and impermissible uses of children that reflects the common understanding of what it means to abuse a child and to exploit a group of vulnerable individuals.

Prominent members of the research community have worked hard to develop just such a boundary. But they have largely failed for reasons that have nothing to do with their integrity or creativity and everything to do with their competing priorities. Indeed, the difficulty of crafting a rule that simultaneously includes a healthy child in, and protects a healthy child from, a high-risk study cannot be overstated.

The research community has a long history of self-regulation. It is therefore not surprising that its members would wish to solve this problem themselves, according to their own normative priors and without outside interference. But, in fact, a boundary between

permissible and impermissible uses of children already exists in the law of child protection and parents' consent authority: research is unethical and thus, according to the federal regulations, cannot proceed without legally effective parental consent. And parents cannot give legally effective consent when the research design would subject the child to the equivalent of maltreatment as defined by the governing state's law. Consistent with the antidiscrimination principle, this law does not distinguish among children in the measure of protection they are due.

This Article argues that the ethics of pediatric research should be harmonized with the law of child protection and parents' consent authority for both practical and normative reasons.

Practically, it makes sense for researchers and regulators to comply with the terms of the law that will ultimately govern their enterprise. Although law is sometimes malleable, so that those who resist often influence its contours, this is not likely to be the case with the law of child protection and parents' consent authority. It is firmly entrenched in the jurisprudence precisely because of the strength of social norms about protecting children from unnecessary harm and risk.

Normatively, it makes sense for researchers and regulators to conduct their work consistent with the law of child protection and parents' consent authority because this law draws the line of permissible harm and risk consistently, and in all cases, at child abuse. Although this would prohibit some (but not all) uses of healthy children as research subjects, it would do ample compensating good: children would be protected in the research setting to the same extent they are protected in other settings. And the research community would engender enormous goodwill in the larger society. This will be indispensable going forward, as the success of its enterprise is ultimately dependent upon the public's confidence that it is truly committed to the protection of its research subjects.