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The Kennedy Krieger Case: Judicial Anger and the Research Enterprise

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Notes

THE KENNEDY KRIEGER CASE: JUDICIAL ANGER AND THE RESEARCH ENTERPRISE*

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"One cool judgment," President Woodrow Wilson once remarked, "is worth a thousand hasty counsels. The thing to be supplied is light, not heat."[1] In *Grimes v. Kennedy Krieger Institute, Inc.*,[2] a well-intended but flawed critique of pediatric research ethics, the judgment of the Maryland Court of Appeals was anything but cool. The Court's rhetoric was heated, its historical comparisons inflammatory and unjust, and aspects of its decision ill-considered. Yet, from this heat comes a light of sorts: an illumination of the need for greater rigor in the procedures for protecting research participants, especially children and other vulnerable subjects.

This article, after summarizing the case as it came to the Court of Appeals, discusses the principal elements of the Court's opinion:

- *Holding on researcher's duty* - a decisive opinion on the question presented on appeal, whether researchers potentially have a duty of care toward subjects participating in the kind of research conducted by the Kennedy Krieger Institute (hereinafter "KKI");
- *Dictum stated as "holding" on parental authority* - an authoritative discussion, beyond that needed to decide the question presented, about the basis on which parents or other legal guardians may consent to the participation of children in research;
- *Commentary on research ethics* - a discursive analysis of the ethics of this KKI research, the ethical review that this research received, and the protection of subjects in the research enterprise generally, striking for its scathing tone and sweeping criticism.

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* The views expressed in this article are personal, not official.

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1. An Address in Pittsburgh on Preparedness (Jan. 29, 1916), *in* 36 THE PAPERS OF WOODROW WILSON 33 (Arthur S. Link ed.) (1981).

2. 782 A.2d 807 (Md. 2001). The decision of the Court of Appeals encompassed two separate appeals, *Grimes v. Kennedy Krieger, Inc.*, No. 128-2000, and *Higgins v. Kennedy Krieger, Inc.*, No. 129-2000. *See infra* text accompanying notes 16-28. The Court's main opinion was issued on August 16, 2001. On October 11, 2001, the Court supplemented its opinion with a brief explanation for its denial of a motion for partial reconsideration filed by the Kennedy Krieger Institute. *See infra* text accompanying notes 83-87.

The article concludes by addressing the implications of the decision for research involving children and other vulnerable subjects.

I. FACTS AND TRIAL COURT DECISION

A. Lead Abatement Study

The prevention of lead poisoning is an important public health goal.[3] KKI, a renowned pediatric research and treatment facility affiliated with the Johns Hopkins University, had long treated lead poisoned children.[4] Many of KKI's patients came from low-income neighborhoods in Baltimore, where 95% of the housing stock had lead paint.[5]

Researchers at KKI published a study in 1990 indicating that traditional methods of removing lead paint, such as scraping or burning, could potentially increase the risk to children through exposure to the lead dust produced by these methods.[6] Following up on that research, KKI obtained a grant from the Environmental Protection Agency to study various methods of lead abatement that were hypothesized to be more effective– that is, to provide a substantial reduction in lead exposure through nontraditional methods made affordable to inner-city landlords.[7]

This hypothesis, however, like countless other health-related hypotheses that are plausible in theory, finds solid support only if tested in empirical research. Consequently, researchers at KKI designed a study protocol as follows: Three groups of houses, all known to have lead paint, received prescribed but varying amounts of maintenance and repair.[8] Two additional groups of houses were included as controls: One group was deemed completely abated of its prior lead paint, and the other group consisted of more modern housing where lead paint had never been used.[9] The Court of Appeals explained:

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3. "Significant exposure to lead is a preventable environmental threat to optimal health and developmental outcomes for young children." COMM. ENVTL. HEALTH, *Screening for Elevated Blood Lead Levels*, 101 PEDIATRICS 1072, 1072 (1988).

4. KKI, *Lead-Based Paint Study Fact Sheet, at* http://www.kennedykrieger.org/whatsnew/newsreleases/latestnews/leadfactssheet.htm (hereinafter KKI Fact Sheet) (last visited July 7, 2002).

5. *Id.*

6. *See generally* Mark R. Farfel & J. Julien Chisolm, Jr., *Health and Environmental Outcomes of Traditional and Modified Practices for Abatement of Residential-Lead Based Paint*, 80 AM. J. PUB. HEALTH 1240 (1990).

7. KKI Fact Sheet, *supra* note 4.

8. *Grimes*, 782 A.2d at 820.

9. *Id.*

> The goal of the research was to determine the effectiveness of differing degrees of lead paint abatement in reducing lead dust levels in the houses. The ultimate aim of the research was to find a less than complete level of abatement that would be relatively safe, but economical, so that Baltimore landlords with lower socioeconomical rental units would not abandon the units.[10]

According to the Court, families with at least one young child were recruited for the study.[11] The children participating in the study had the lead levels in their blood periodically tested, and the results were compared to the testing results of lead in dust samples from the houses, exterior soil, and drinking water.[12] The Court determined these research protocols resulted in a research environment focused on abatement of lead dust.[13] The success of the various abatement procedures were largely measured, not by the reduction of lead levels in the children's blood, but by periodic blood lead level measurements.[14] KKI offered small inducements for parents to keep their children in the study– periodic payments of $5 and $15 for the time spent responding to questionnaires and what the Court characterized as "a stream of compensation flowing to the research subjects and the parents" in the form of gifts, trinkets, and food coupons.[15]

B. Litigation in Lower Court

Ericka Grimes was an infant, living in a supposedly fully abated house on Monroe Street, when her mother agreed that she would participate in the KKI lead abatement study.[16] In March 1993, testing of dust samples from the house:

> [R]evealed what the researchers referred to as 'hot spots' where the level of lead 'was higher than might be found in a completely . . . [abated] house.' This information about the 'hot spots' was not furnished to [Ericka's mother] until . . . more than nine months after the samples had been collected and . . . not until after Ericka Grime's blood was found to contain elevated levels of lead.[17]

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10. *Id.* at 820-21. According to KKI, "As expected, lead abatement measures resulted in significant reductions in the lead dust for all five types of property treatments. Overall the blood levels of most children residing in the study homes stayed constant or went down, even though in a few cases, they rose." KKI Fact Sheet, *supra* note 4.

11. *Grimes*, 782 A.2d at 823.

12. *Id.* at 822.

13. *Id.* at 819.

14. *Id.* at 819.

15. *Id.* at 843.

16. *Grimes*, 782 A.2d at 823.

17. *Id.* at 825.

After learning of Ericka's elevated blood lead levels, her mother sued KKI "for negligence for failing to warn of, or abate, lead paint hazards that KKI allegedly discovered in the Monroe Street property during the research study."[18] KKI filed a third-party complaint against the landlord, and Ericka filed an amended complaint to add the landlord as an additional defendant.[19] However, Ericka subsequently dismissed claims against the landlord.[20] In a motion for summary judgment, KKI argued that it did not breach any duty that it owed to Ericka.[21] Persuaded by this argument, the circuit court granted KKI's motion and entered judgment in its favor.[22]

Myron Higgins was four-years-old when his mother agreed to his participation in the KKI study.[23] Myron, his mother, and his siblings moved into a house on Federal Street with lead hazards that were partially abated under one arm of the KKI study.[24] After becoming aware that lead levels in Myron's blood were elevated, Myron and his mother sued KKI, the organization that had performed the abatement, and the landlord for several negligent acts,[25] including inadequate abatement methods and a failure to warn Myron and his mother of the lead hazard on the premises.[26] In its summary judgment motion, KKI argued that it owed no duty to Myron or his mother.[27] The circuit court granted the motion and entered judgment in favor of KKI.[28]

The plaintiffs in both cases appealed to the Court of Special Appeals, Maryland's intermediate appellate court. Prior to that court's consideration, the Court of Appeals took jurisdiction over the appeals on its own motion.[29] Because the cases were decided on summary judgment, the record on appeal was, as characterized by the Court, "not extensive."[30]

II. THE COURT'S CHARACTERIZATION OF THE RESEARCH

Every aspect of the Court's opinion was affected by its understanding of the nature of KKI's research. According to the Court, KKI's study was

18. *Id.* at 825-26.

19. *Id.* at 826.

20. *Id.* at 825-26.

21. *Grimes*, 782 A.2d at 825-26.

22. *Id.*

23. *Id.* at 827-28.

24. *Id.* at 827.

25. *Id.* at 828-29.

26. *Id.* at 829. As in *Grimes*, the plaintiffs alleged that KKI negligently failed to disclose information about lead dust levels found in the house. *Id.*

27. *Grimes*, 782 A.2d at 831.

28. *Id.* at 832.

29. *Higgins v. Kennedy Krieger Institute Inc.*, 766 A.2d 147 (Md. 2001).

30. *Grimes*, 782 A.2d at 820.

"nontherapeutic research using minors,"[31] as distinguished from what the Court termed "therapeutic research."[32]

The Court understood the nature of "therapeutic research" by reference to its supposed purpose, "to directly help or aid a patient who is suffering from a health condition the objectives of the research are designed to address – hopefully by the alleviation, or potential alleviation of the health condition."[33] "Nontherapeutic research," by contrast, generally uses subjects not known to have the condition the research is designed to address. [34] Additionally, nontherapeutic research is designed to produce benefits for the public at large, and is not designed to directly benefit the subjects utilized in the research.[35]

The Court's categorization of research into "therapeutic" and "nontherapeutic" is conceptually flawed and ignores more than two decades' criticism of this approach.[36] The term "therapeutic research" fails to give due account to the differences between research and clinical care, in terms of both goals and methods. Although a clinical trial might be conducted with a reasonable expectation that those who receive the test article will be therapeutically benefited, the primary goal of the trial, like all other research, is the acquisition of generalizable scientific knowledge, following research procedures that may not accord with the goals of therapeutic care for individual participants.[37] Moreover, in clinical care, treatment is determined by reference to the personal situation of the patient, whereas in research, treatment is determined by reference to the procedures specified in the research protocol.[38] Thus, even "studies with therapeutic components often have features that are not routine therapy, such as extra procedures, tests, or hospitalizations."[39]

As will be discussed later in this article, the Court's imprecise language, coupled with its restriction on parental authority, contributed to the confusion and dismay among researchers in the wake of the decision.[40] The Court might have markedly improved its analysis of the issues had it avoided the terms "therapeutic" and "nontherapeutic," and instead followed the more careful approach of the

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31. *Id.* at 811.

32. *Id.* at 811-12.

33. *Id.*

34. *Id.*

35. *Id.*

36. *See* Loretta M. Kopelman, *Pediatric Research Regulations Under Legal Scrutiny: Grimes Narrows Their Interpretation*, 30 J.L. MED. & ETHICS, 38, 41 (2002).

37. *See* 45 C.F.R. § 46.102(d) (2001) (providing the definition of "research" for purposes of federal regulations); Franklin G. Miller & Howard Brody, *What Makes Placebo-Controlled Trials Unethical?*, AM. J. BIOETHICS, Spring 2002, at 3, 6 ("[T]he intent or purpose of administering treatments in clinical trials is not to provide personalized therapeutic benefit but to test hypotheses concerning safety and efficacy of treatment in groups of patients.").

38. 45 C.F.R. § 46.102(d) (2001).

39. Kopelman, *supra* note 36, at 41.

40. *See infra* text accompanying notes 78-82.

federal regulations on the protection of human research subjects. These regulations simply identify the possibility that some research may provide direct benefits to the subjects.[41] This usage might have opened the Court's eyes to the possibility that, although the KKI research could not by any means be deemed therapeutic for the participants, who had no illness and therefore had no need for therapy, the research might well have held out a reasonable prospect of a direct, health-related benefit, at least for the children in the abated properties.[42]

III. THE COURT'S HOLDING ON RESEARCHER'S DUTY

The Court reviewed the elements of a negligence claim under Maryland law, including the element "that the defendant was under a duty to protect the plaintiff from injury."[43] Because the trial court had resolved the cases "solely on the grounds that there was no legal duty to protect the children," the only issue remaining was "whether KKI was under a duty to protect [the children] from injury."[44]

The Court quickly concluded that the relationship between KKI and the children was one in which "a duty or duties would ordinarily exist, and certainly could exist, based on the facts and circumstances of each of these individual cases."[45] As the Court viewed the facts of the two cases, a special relationship imposing a duty on the researchers could be inferred, and, indeed, ordinarily would be created in similar research programs involving human subjects.[46]

One possible source of the special relationship giving rise to a duty of care is the consent document, characterized by the Court as a "bilateral contract between the parties."[47] The Court did not elaborate on how the existence of this contract gives rise to a duty enforceable in tort, as distinct from a cause of action for breach of contract.[48]

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41. *See* 45 C.F.R. §§ 46.111(a)(2), 46.116(a)(3), 46.405 (2001).

42. KKI has asserted that the lead abatement study "would provide benefits to the Study participants since all participants would live in housing that had been improved or was new and would be monitored for blood lead levels on an ongoing basis." KKI Fact Sheet, *supra* note 4. One commentator has agreed that "all the children who lived in residences that received lead abatement could have potentially benefited from their participation." Lainie Friedman Ross, *In Defense of the Hopkins Lead Abatement Studies*, 30 J.L. MED. & ETHICS 50, 51 (2002).

43. *Grimes*, 782 A.2d at 841. (quoting Rosenblatt v. Exxon, 642 A.2d 180, 188 (Md. 1994) (internal quotations omitted)). The other elements of a negligence claim are that the defendant breached the duty of care, that the plaintiffs suffered actual injury or loss, and that the injury or loss proximately resulted from the defendant's breach of the duty. *Id.*

44. *Grimes*, 782 A.2d at 841.

45. *Id.* at 842.

46. *Id.* at 843.

47. *Id.*

48. "There is no single principle or simple test for determining when a defendant's breach of a contract will also breach an independent duty and give rise to a tort action." Mesmer v. Maryland Auto. Ins. Fund, 725 A.2d 1053, 1059 (Md. 1999). Presumably, the trial court might find on remand that KKI

A second possible source of duty is the nature of "nontherapeutic research" itself.[49] As the Court summarized, "the trial courts appeared to have held that special relationships out of which duties arise cannot be created by the relationship between researchers and the subjects of the research."[50] The Court conceded that the trial courts' view of "special relationships" may indeed hold true, but only "in some rare cases . . . ."[51] Instead, the Court stressed that the trial courts' limited view of "special relationships" does not govern instances in which researchers recruit subjects, "especially children whose consent is furnished indirectly, to participate in nontherapeutic procedures that are potentially hazardous, dangerous, or deleterious to their health."[52] Recruiting "otherwise healthy subjects to interact with already existing or potentially existing hazardous conditions, or both, for the purpose of creating statistics from which scientific hypotheses can be supported, would normally warrant or create such special relationships as a matter of law."[53] The Court suggested that a duty of care might also be grounded in the federal regulations "that impose standards of care that attach to federally funded or sponsored research projects that use human subjects."[54] The Court specifically cited the policy on protection of human research subjects adopted as regulations by the Department of Health and Human Services and a number of other federal agencies, known as Common Rule.[55]

The Court also identified the regulations applicable to pediatric research conducted or sponsored by that Department.[56] The Court concluded that a special relationship resulting in a duty of care is imposed by the federal regulation: "The question becomes whether this duty of informed consent created by federal regulation, as a matter of State law, translates into a duty of care arising out of the

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negligently performed its obligations under the consent document, which sounds in tort. *See* Matyas v. Suburban Trust Co., 263 A.2d 16, 18 (Md. 1970).

49. For a discussion of this terminology, see *supra* text accompanying notes 40-42.

50. *Grimes*, 782 A.2d at 845.

51. *Id.* The Court suggested that a relationship might not exist if all the researchers were doing was compiling "already extant statistics for purposes of studying human health matters." *Id.* at 846. The Court did not explain why this type of research using individually identifiable data, which if done negligently can result in the loss of privacy and other harms, might not give rise to a duty of care.

52. *Id.* at 845-46.

53. *Id.*

54. *Id.* at 846. *See also* Daum v. SpineCare Med. Group, Inc., 61 Cal. Rptr. 260 (Cal. App. 1997).

55. *See* 45 C.F.R. pt. 46, subpt. A (2001). The Court noted that EPA-sponsored research "presumably" is subject to the Common Rule. *Grimes*, 782 A.2d at 847. This presumption is correct, for the EPA has adopted the Common Rule in its own regulations. 40 C.F.R. pt. 26 (2001).

56. *See* 45 C.F.R. pt. 46, subpt. D (2001). There is no comparable EPA regulation; hence, there is no discernable basis for the Court's assumption that a regulation which, on its face, is not applicable to EPA-funded research nevertheless applied. One can speculate, however, that KKI had agreed with the Department of Health and Human Services (DHHS) to apply Subpart D to all of its research, regardless of funding source. *See* 40 C.F.R. § 26.103(a)-(b) (2001); 45 C.F.R. § 46.103(a)-(b) (2001).

unique relationship that is researcher-subject, as opposed to doctor-patient. We answer that question in the affirmative."[57]

Finally, the Court identified the Nuremberg Code as a potential source of the duty of care.[58] The Court held as follows: "The breach of obligations imposed on researchers by the Nuremberg Code, might well support actions sounding in negligence in cases such as those at issue here."[59] With this thoroughgoing rejection of the trial court's ruling that researchers owed no duty of care to their subjects, the Court of Appeals vacated the grant of summary judgment and remanded the cases for trial.[60] Had the Court acted as it normally does in cases involving a trial court's erroneous grant of summary judgment, it would have resolved the case and said no more.[61] Indeed, one judge, who concurred in the result only, would have limited the decision to "the narrow question" of whether the grant of summary judgment to KKI was erroneous "on the ground that, as a matter of law, it owed no duty to warn . . . [the] human subjects participating in its research study."[62] Had the Court done so, its decision would have been largely welcomed as a reasonable step to promote human research subject protection. It was the Court's venture beyond the issue presented that had the greatest potential impact on the conduct of research.[63]

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57. *Grimes*, 782 A.2d at 849.

58. *Id.* The Nuremberg Code is a set of precepts published by the Nuremberg Tribunal following the trials of the Nazi doctors found guilty of various atrocities in the course of experimentation on humans. The Court set out the entire test of the Nuremberg Code in footnote 31. *Id.* at 835.

59. *Id.* at 849. The Court did not discuss the importance of the Nuremberg Code's first provision: "[t]he voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent...." *Id.* at 853. Taken literally, it would preclude not only the KKI lead abatement study but also all other research involving children. Jonathan D. Moreno, *Regulation of Research on the Decisionally Impaired: History and Gaps in the Current Regulatory System*, 1 J. HEALTH CARE L. & POL'Y 1, 12 (1998). Because the Nuremberg Code was announced in the wake of experimental atrocities using coerced prisoners, however, its intended scope is likely narrower than its literal text suggests, and its first provision should not be applied out of context as a bar to all research in which the subjects themselves cannot give consent.

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

61. *See*, e.g., Schmerling v. Injured Workers' Ins. Fund, 795 A.2d 715 (Md. 2002); *see also* Hagerstown v. Hagerstown, 793 A.2d 579 (Md. 2002).

62. *Grimes*, 782 A.2d at 858-59 (Raker, J., concurring).

63. This is not to suggest that the Court's holding on duty is without interest or importance. To the contrary, the holding is rich with nuance and interpretive difficulties. Diane E. Hoffmann & Karen H. Rothenberg, *Whose Duty Is It Anyway?: The Kennedy Krieger Opinion and Its Implications for Public Health Research*, 6 J. HEALTH CARE L. & POL'Y 1, 109 (2003).

IV. "HOLDING" ON PARENTAL AUTHORITY

A. The Court's Strong Dictum

The Court began its analysis by pointing out "that the 'best interests of the child' is the overriding concern of this Court in matters relating to children."[64] The interests of a parent, the Court continued, and "the interests of the general public in fostering research, according to a researcher's hypothesis to be for the good of all children," are to be subordinated to the child's best interest.[65] The Court declared that "[i]t is not in the best interest of any healthy child to be intentionally put in a nontherapeutic situation where his or her health may be impaired, in order to test methods that may ultimately benefit all children."[66] Moving to the particulars of the lead abatement research, the Court opined: "One simply does not expose otherwise healthy children, incapable of personal [consent], to a nontherapeutic research environment that is known at the inception of the research, might cause the children to ingest lead dust . . . . Such a practice is not legally acceptable."[67]

In the Court's view, the core problem had nothing to do with any inadequacies in the informed consent process. The experiment *itself* could not be made legally or ethically permissible no matter what degree of parental consent or supplemental information was furnished to the parents involved, because "It was wrong in the first instance."[68]

Curiously, given this unyielding language, the Court discussed and distinguished three cases where other courts had approved parental decisions to subject one sibling to a medical procedure without therapeutic purpose for the benefit of another sibling.[69] The Court commented that the "primary importance" of these cases was "not that the parents or guardians consented to the procedures, but that they first sought permission of the courts and received that permission, before consenting to a nontherapeutic procedure in respect to some of their minor children, but that was therapeutic to their other children."[70] By contrast, the Court

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

65. *Id.*

66. *Id.*

67. *Id.* The Court's casual reference to children, who are "incapable of personal assent (consent), as if these terms are synonymous, blurs an important distinction. In the regulations governing pediatric research funded by federal DHHS, only parents or legal guardians may give consent (in the terminology of the regulations, "permission"). 45 C.F.R. §§ 46.402(b), 46.408(b). A child who lacks the legal capacity to give informed consent to research participation might nonetheless be capable of giving assent— that is, an affirmative agreement to participate in research. *See* 45 C.F.R. §§ 46.402(b), 46.408(a). The children who were plaintiffs in the litigation, however, were too young even for assent at the time of research participation.

68. *Grimes*, 782 A.2d at 857-58.

69. *See* Hart v. Brown, 289 A.2d 386 (Conn. Supp. 1972); Strunk v. Strunk, 445 S.W.2d 145 (Ky. 1969); Bonner v. Moran, 126 F.2d 121 (D.C. Cir. 1941).

70. *Grimes*, 782 A.2d at 854-55.

observed, "in the case sub judice, no impartial judicial review or oversight was sought by the researchers or by the parents."[71] If, however, the participation of children in this research was "not legally acceptable" and "wrong in the first instance," as stated by the Court, it is difficult to discern, even putting aside practical considerations, how the insertion of a judicial review mechanism into the consent procedures would conceivably lead to a different result.

The more direct precedent, in the Court's view, was a portion of a New York intermediate appellate court decision, *T.D. v. Office of Mental Health*.[72] The appellate court found "unacceptable" regulatory provisions that allowed parents to consent to the participation of their children in "greater than minimal risk non-therapeutic research."[73] The court held:

> We are not dealing here with parental choice among reasonable treatment alternatives, but with a decision to subject the child to non-therapeutic treatments and procedures that may cause harmful permanent or fatal side-effects. It follows therefore that a parent . . . 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 . . . .[74]

The Court of Appeals "concur[red] with that assessment."[75] The Court ended its discussion on the lack of parental authority with what it explicitly labeled a "holding," notwithstanding that the entire discussion was dictum:[76] "we hold that in Maryland a parent, appropriate relative, or applicable surrogate, cannot consent to the participation of a child or other person under legal disability in

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71. *Id.* at 812.

72. 650 N.Y.S.2d 173 (N.Y. App. Div. 1996), *appeal dismissed*, 680 N.E.2d 617 (N.Y. 1997), *leave to appeal granted*, 684 N.E.2d 281 (N.Y. 1997), *appeal dismissed*, 668 N.Y.S.2d 153 (N.Y. 1997).

73. *T.D.*, 650 N.Y.S.2d at 191.

74. *Id.* at 192.

75. *Grimes*, 782 A.2d at 856. The Court was unaware of, or indifferent to, the fact that the Appellate Division of the New York Supreme Court characterized this and similar portions of the intermediate appellate court's decision as "an inappropriate advisory opinion." *T.D.*, 668 N.Y.S.2d at 154.

76. Dictum "refers to a statement made by a court 'incidentally or collaterally, and nor directly upon the question before [it], or upon a point not necessarily involved in the determination of the cause." Holliday v. Sturm, Ruger & Co., Inc., 770 A.2d 1071, 1086 (Md. App. 2001) (quoting BLACK'S LAW DICTIONARY 1072 (6th ed. 1990)). Dictum "lacks the authority of adjudication... [and] is not entitled to the precedential weight afforded the holding because it does not receive the 'deliberate and considered judgment' used in phrasing the holding." Holliday, 770 A.2d at 1086 (quoting State v. Wilson, 664 A.2d 1, 7 (Md. App. 1995)). *See also, e.g.*, Stover v. Stover, 483 A.2d 783 (Md. App. 1984). Because the question before the Court was the correctness of the trial court's grant of summary judgment to KKI based on lack of duty, the Court's statements about parental authority meet the definition of dictum.

nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject."[77]

B. Reaction in the Research Community and the Court's "Explanation"

The Court's summary pronouncement appalled many researchers and their lawyers. They feared that the Court, by failing to clarify the scope of "nontherapeutic research," had foreclosed a wide swathe of research. For example, in its motion for partial reconsideration, KKI lamented, "On the day the mandate in this case issues, hundreds of fully accredited medical projects now conducted in Maryland will terminate."[78] Other proponents of pediatric research took the view that parents would no longer have authority to enroll children in a randomized controlled trial with a placebo arm, because "[f]or the placebo recipients, the research . . . in the language of the Court, is "nontherapeutic."[79] In addition, these proponents pointed out, the Court's prohibition of parental consent in nontherapeutic research involving "any risk of injury or damage to the health of the subject,"[80] taken literally, "is inconsistent with medical research. The blunt fact is that there is almost no research without risk."[81] As another research institution pointed out, "even a simple questionnaire, . . . depending on its subject matter, might pose the slight risk of temporarily upsetting a child."[82]

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77. *Grimes*, 782 A.2d at 858. It is inexplicable why the Court, piling dictum upon dictum, included this passing reference to an "other applicable surrogate" and an "other person under legal disability." The case was solely about pediatric research, and it is facile to assume that issues involving adults who lack decisional capacity are incidental. *See generally* NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING PERSONS WITH MENTAL DISORDERS THAT MAY AFFECT DECISIONMAKING CAPACITY (1998), *available at* http://bioethics.georgetown.edu/nbac/capacity/volumeii.pdf (last visited Sept. 15, 2002); *see also, e.g.*, Diane E. Hoffmann et al., *Regulating Research with Decisionally Impaired Individuals: Are We Making Progress?*, 3 DEPAUL J. HEALTH CARE L. 547 (2000); Evan G. DeRenzo, *Decisionally Impaired Persons in Research: Refining the Proposed Refinements*, 25 J. L. MED. & ETHICS 139 (1997).

78. Appellee's Motion for Partial Reconsideration and Modification of Opinion at 1, *Grimes* (No. 128) [hereinafter *KKI Motion*]. In its motion KKI explicitly abandoned its prior position that it owed no legal duty to the research subjects. KKI has elsewhere characterized its prior position as a "legalistic" and a "technical argument" that it now "regrets." KKI Fact Sheet, *supra* note 4.

79. Brief of Amici Curiae Association of American Medical Colleges et al., in Support of Motion for Reconsideration at 7, *Grimes*, (No. 128).

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

81. Brief of Amici Curiae Association of American Medical Colleges et al., *supra* note 79, at 11.

82. Brief of University of Maryland, Baltimore as Amicus Curiae in Support of Motion for Reconsideration at 11, *Grimes*, (No. 128). *See* Memorandum of the National Center for Lead-safe Housing as Amicus Curiae Urging Partial Reconsideration and Modification of Opinion, *Grimes* (No. 128), *available at* http://www.kennedykrieger.org/whatsnew/newreleases/latestnews/leadsafebrief.htm (last visited Sept. 30, 2002); *see also* Memorandum of Law of Public Justice Center in Partial Support of Appellee's Motion for Partial Reconsideration and Modification of Opinion, *Grimes*, (No. 128), *available at* http://www.kennedykrieger.org/whatsnew/newsreleases/latestnews/leadPJCmemo.htm (last visited Sept. 30, 2002).

The Court denied KKI's motion.[83] In doing so, the Court clarified the kind of research in which parental consent was prohibited and allayed the worst fears of researchers. "The context of the statement," the Court explained, "was a nontherapeutic study that promises no medical benefit to the child whatever, so that any balance between risk and benefit is necessarily negative."[84] Presumably, this explanation implies that parents are not prohibited from permitting their children to participate in research, like many randomized clinical trials, that holds out a reasonable prospect of direct medical benefit. In research of that kind, the "balance between risk and benefit" might turn out to be negative, but it is not "necessarily negative" a priori.[85]

Furthermore, the Court explained that when it said "any risk," it "meant any articulable risk beyond the minimal kind of risk that is inherent in any endeavor."[86] The phrase "minimal kind of risk that is inherent in any endeavor" appears to refer to the concept, set forth in the Common Rule, that minimal risk "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[87]

C. The Court as Self-Initiated Lawgiver: An Error of Good Intentions

"Absent exceptional circumstances," the Court of Appeals recently wrote in another case in which it reversed a trial court's grant of summary judgment, "an appellate court will review a grant of summary judgment only upon the grounds relied upon by the trial court."[88] As discussed above,[89] the trial court resolved the negligence claims by finding that KKI had no legal duty toward the plaintiffs; the trial court never ruled on the question of the parents' authority to enroll their children in this research.

So, what was the "exceptional circumstance" that caused the Court of Appeals to take up the issue of parental authority? Apparently, it was the Court's belief that it needed to rescue children from the danger presented by amoral scientists and compliant parents. The Court began this portion of its opinion with this declaration:

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83. *Grimes*, 782 A.2d. at 861.

84. *Id.* at 862.

85. *See* Robert M. Nelson, *Nontherapeutic Research, Minimal Risk, and the Kennedy Krieger Lead Abatement Study*, 23 IRB: ETHICS & HUMAN RES. 7, 10 (2001) (discussing the circumstances under which a placebo-controlled clinical trial may be deemed to hold out the prospect of direct benefits – that is, to be "therapeutic," in the Court's terminology).

86. *Grimes*, 782 A.2d. at 862.

87. 45 C.F.R. § 46.102(i) (2001).

88. *Hagerstown*, 793 A.2d at 588; *See also, e.g.*, Paine Webber Inc. v. East, 768 A.2d 1029, 1036 (Md. 2001); Bishop v. State Farm Mut. Ins., 757 A.2d 783, 787-88 (Md. 2000); Gresser v. Anne Arundel County, 709 A.2d 740, 745 (Md. 1998).

89. *See supra* text accompanying notes 16-25.

> The issue of whether a parent can consent to the participation of her or his child in a nontherapeutic health-related study that is known to be potentially hazardous to the health of the child raises serious questions with profound moral and ethical implications. What right does a parent have to knowingly expose a child not in need of therapy to health risks or otherwise knowingly place a child in danger, even if it is for the greater good?[90]

Given this view of what is at stake, the Court's venture into self-initiated lawmaking was both understandable and, in principle, justified. The Court was correct in discerning the importance of a clear delineation of parental authority to consent to a child's participation in research. The federal regulations governing human subject research defer to "any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects."[91] Well-crafted judicial limits on parental authority, to protect children against potentially hazardous research not justified by the reasonable prospect of direct medical benefit, would be a welcome common law protection.

Yet, it is folly for any court to venture into this contentious area without a solid basis on which to proceed. If a court is to sensibly balance the competing policy considerations –advancing scientific progress to improve the health of children, while protecting children against exploitation and genuine harm –it needs education about the issue that can only be provided by a full evidentiary record and focused argument. A court should also carefully consider the relationship between its legal pronouncements and other relevant law, especially the federal regulations governing most pediatric research.[92] Finally, a court needs to word its opinion with precision, so that researchers and their lawyers can understand the new limitations and apply them to a wide variety of research endeavors.

The Court of Appeals fell short on all of these criteria. The Court acknowledged with considerable understatement that the "issue of the parent's right to consent on behalf of the children has not been fully presented in either of

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90. *Grimes*, 782 A.2d at 852. The Court's suggestion that the mothers of Ericka and Myron had "knowingly" placed their children in danger was at odds with the Court's earlier description of the inadequacy of the consent document: "Nowhere in the consent form was it clearly disclosed to the mother that the researchers contemplated that, as a result of the experiment, the child might accumulate lead in her blood, and that in order for the experiment to succeed it was necessary that the child remain in the house as the lead in the child's blood increased or decreased, so that it could be measured." *Id.* at 824.

91. 45 C.F.R. § 46.101(f) (2001).

92. *See* 21 C.F.R. pt. 50, subpt. D (2001) (interim rule) (governing pediatric research regulated by the FDA); 45 C.F.R. pt. 46, subpt. D (2001) (governing pediatric research funded by the DHHS).

these cases."[93] Nowhere in its discussion of parental authority, including its explanation in denying KKI's motion for partial reconsideration, did the Court attempt to correlate its limitations to the categories in the federal regulations.[94] The Court's careless drafting of its summary holding led to justifiable alarm among researchers and the need for the later "explanation" by the Court, itself far from precisely stated, intended to allow most pediatric research in Maryland to proceed. That the Court's holding, as later explained, can be correlated with the federal regulations owes more to the insight of commentators than any mindful effort on the Court's part.[95]

This aspect of the Court's opinion may indeed, as one commentator put it, have "asked the right question about the moral authority of parents" and have come to a defensible answer, one consistent with mainstream ethical views.[96] Yet, the moral authority of the Court risks erosion when indignation blinds it to the "passive virtue" of judicial self-restraint.[97]

V. THE COURT'S COMMENTARY ON RESEARCH ETHICS

A. The Ethics of KKI's Research

In its denial of KKI's motion for partial reconsideration, the Court noted that "every issue bearing on liability or damages remains open for further factual development, and any relevant evidence not otherwise precluded under our rules of evidence is admissible."[98] Indeed, the Court protested, despite its discussion of "the various issues and arguments in considerable detail, the only conclusion that we reached as a matter of law, was that on the record currently before us, summary judgment was improperly granted . . . ."[99] This more cautious language retracted nothing, however, from the Court's denunciation of the ethics of the KKI research.

Evidence of judicial indignation is abundant. Despite the very limited record before it, the Court did not hesitate to declare that the KKI research protocols were

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93. *Grimes*, 782 A.2d. at 852 (Raker, J., dissenting). As the dissenting judge stated, more forthrightly: "Inasmuch as these issues were never raised by the pleadings or parties below, this Court had no basis [on which] to address these very complex issues...." *Id.* at 862.

94. *See* 45 C.F.R. §§ 46.404-46.406 (governing research not involving greater than minimal risk; involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects; and research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition).

95. *See* Kopelman, *supra* note 36, at 47.

96. *See* Nelson, *supra* note 85, at 11.

97. *See* Alexander Bickel, *Forward: The Passive Virtues*, 75 HARV. L. REV. 40, 79 (1961) (The Supreme Court, "in deciding whether, when, and how much to adjudicate," should rely on considerations that are not "predelictional, sentimental, or irrational."). *Id.*

98. *Grimes*, 782 A.2d at 861.

99. *Id.*

"not legally acceptable,"[100] "not appropriate,"[101] and "innately inappropriate."[102] Furthermore, the Court flatly stated that KKI had not complied with federal regulations regarding informed consent and the ethical conduct of research.[103]

Moreover, the Court's rhetorical flourishes about the KKI research were scathing. The children who were the subjects of the research were likened to "canaries in a mine," exposed to serious harm as a sentinel for the benefit of others.[104] The children, it is said, were "used as guinea pigs."[105] The Court could not resist adding: "Children, it should be noted, are not in our society the equivalent of rats, hamsters, monkeys, and the like."[106] The Court also described the children as having been "enticed into living in, or remaining in, potentially lead-tainted housing and intentionally subjected to a research program, which contemplates the probability, or even the possibility, of lead poisoning . . . ."[107] The parents were said to have been "improperly enticed by trinkets, food stamps, money or other items . . . ."[108] No form of parental consent and no consent process "could make the experiment at issue here, ethically or legally permissible. It was wrong in the first instance."[109]

The Court's indignation is further evidenced by its explicit comparison of the KKI research to the worst abuses in the history of human experimentation. In the Court's view, the KKI research:

> [D]iffers in large degree from but presents similar problems as those in the Tuskegee Syphilis Study . . . the intentional exposure of solders 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 . . . .[110]

As if this were not damning enough, the Court went on to identify other grossly unethical experiments that "were *also* prior instances of research subjects

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100. *Id.* at 853.

101. *Id.* at 855.

102. *Id.*

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

104. *Id.* at 813. "It can be argued that the researchers intended that the children be the canaries in the mines but never clearly told the parents." *Id.* It was a practice in earlier years, and perhaps even now, for subsurface miners to rely on canaries to determine whether dangerous levels of toxic gases were accumulating in the mines. Canaries were particularly susceptible to such gases. When the canaries began to die, miners knew that dangerous levels of gases were accumulating. *Id.*

105. *Id.* at 852.

106. *Id.*

107. *Id.* at 814.

108. *Id.*

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

110. *Id.* at 816.

[sic] being intentionally exposed to infectious or poisonous substances in the name of scientific research."[111] The Court then named the Tuskegee Syphilis Study, where effective treatment was deliberately withheld from patients affected with syphilis; the Jewish Chronic Disease Hospital Study, in which seriously ill patients were injected with cancer cells without their consent; the Japanese military's use of "plague bombs" in World War II; and typhus experiments by the Nazis at Buchenwald concentration camp.[112]

The similarity to these notorious examples of research abuse extended, in the Court's view, not only to KKI's research methodology but also to the type of subjects involved:

> These programs were somewhat alike in the vulnerability of the subjects; uneducated African-American men, debilitated patients in a charity hospital, prisoners of war, inmates of concentration camps and others falling within the custody and control of the agencies conducting or approving the experiments. In the present case, children, especially young children, living in lower economic circumstances, albeit not as vulnerable as the other examples, are nonetheless, vulnerable as well.[113]

In addition, the Court denounced the supervisory Institutional Review Board (IRB) at the Johns Hopkins University, which "abdicated [its] responsibility, instead suggesting to the researchers a way to miscast the characteristics of the study in order to avoid the responsibility inherent in nontherapeutic research involving children."[114] The Court chastised Hopkins' IRB, "whose primary function was to insure safety and compliance with applicable regulations," because it encouraged the researchers to misrepresent the purpose of the research in an effort to label the study 'therapeutic' and thus subject to a lower safety standard of regulation. The IRB's purpose was ethically wrong . . . ."[115] The Court also suggested that KKI acted without due regard for the well-being of the children because it was influenced by financial interests. The Court made a point of noting the lack of a:

> [C]omplete record of the specific compensation of the researchers involved . . . . Neither is there in the record any development of what pressures, if any, were exerted in respect to the researchers obtaining the

111. *Id.* (emphasis added).

112. *Id.* at 816-17.

113. *Id.* at 817.

114. *Id.* at 813. The Court was upset with IRB's suggestion that the children living in "control group housing" (that is, houses thought to be free of lead paint) be characterized as gaining some benefit from their participation in the study.

115. *Grimes*, 782 A.2d at 817.

> consents of the parents and conducting the experiments. Nor, for the same reason, is there a sufficient indication as to the extent to which [KKI] has joined with commercial interests, if it has, for the purposes of profit, that might potentially impact upon the researchers' motivations and potential conflicts of interest . . . .[116]

The dearth of information in the record did not stop the Court from terming the KKI researchers as "compensated."[117] In discussing one of the reasons why a researcher has a legal duty toward the subjects of research, the Court commented that these "legal duties, and legal protections, might additionally be warranted because of the likely conflict of interest between the goal of the research experimenter and the health of the human subject, especially, but not exclusively, when such research is commercialized."[118] The Court simply did not trust the researchers' capacity to act against scientific interest in order to protect subjects. For example, the Court took the view that the KKI researchers delayed disclosure of elevated lead dust levels in order to avoid loss of study subjects.[119]

B. The Ethics of Research Generally

Undoubtedly, factors peculiar to this case help explain the Court's rhetorical excess and condemnatory tone. It is apparent, for example, that an important reason for the Court's fury was KKI's dogged insistence that it owed no duty to the subjects.[120] In addition, the Court might have been influenced by the highly publicized death of a research subject in an unrelated study at Johns Hopkins and the brief suspension of federally funded research at Hopkins.[121] Despite these

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116. *Id.* at 840. The Court also mused about KKI's profit motive when the court rejected the trial court's characterization of KKI as "an institutional volunteer in the community." *Id.* at 846. As the Court put it, "it is not clear that the KKI was a mere volunteer in any event. It received funding for developing and conducting the research. Whether it recognized a profit is unknown from the record. The 'for profit' nature of some research may well increase the duties of researchers to ensure the safety of research subjects, and may well increase researchers' or an institution's susceptibility for damages in respect to any injuries incurred by the research subjects." *Id.*

117. *See id.* at 819, 823-24. Presumably, the Court was referring to the grant monies from the EPA. *See supra* text accompanying note 7.

118. *See id.* at 850.

119. *See id.* at 823-24.

120. The Court quoted at extraordinary lengths excerpts from oral argument in which KKI's counsel sought to defend the proposition that the trial court's decision on the absence of any duty of care was correct. *See id.* at 829-32. The only conceivable purpose for devoting more than three pages of small type in the Maryland Reports to this colloquy was to evidence the Court's astonishment at KKI's persistence. KKI disavowed this position after the issuance of the Court's initial decision. *See supra* note 79.

121. *See* Letter from Patrick J. McNeilly, Compliance Oversight Coordinator, Division of Compliance Oversight, Office of Human Research Protections & Michael Carome, Director, Division of Compliance Oversight, Office of Human Research Protections, to Edward D. Miller, Dean and Chief Executive Officer, Johns Hopkins Medicine et al., July 19, 2001, *available at*

specific motivations, however, the Court's critique extends more generally to the means for protecting subjects that are relied upon within the research community. The Court was scornful of the IRB's capacity or willingness to restrain overzealous researchers and suggested that this deficiency is "endemic to the research community as a whole."[122] These "in-house organs," the Court remarked, "are not designed, generally, to be sufficiently objective in the sense that they are as sufficiently concerned with the ethicality of the experiments they review as they are with the success of the experiments."[123]

The Court agreed with a commentator that the informed consent process affords insufficient protection, given that researchers are "under competitive pressure and also financial pressure from corporate backers."[124] In the Court's own words, "The conflicts are inherent. This would be especially so when science and private industry collaborate in search of material gains."[125] The Court's deep suspicion is evident in its infelicitously phrased remark: "to turn over human and legal ethical concerns solely to the scientific community, is to risk embarking on slippery slopes, that all too often in the past, here and elsewhere, have resulted in practices we, or any community, should be ever unwilling to accept."[126]

Given the Court's dismissal of the research community's commitment to ethical practices and the effectiveness of its self-regulatory apparatus, it is not surprising that the Court would deem the potential of tort liability a necessary deterrent of abusive research practices. Whatever else it does, the KKI opinion will encourage ongoing efforts by plaintiffs' lawyers to develop the tort of research negligence.[127]

C. The Court as Research Critic: A Failure of Self-Restraint

In the face of the Court's barrage, KKI protested that the Court not only assumed the truth of all of the plaintiffs' facts but also discussed broader propositions and historical comparisons about which, given the procedural posture

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http://ohrp.osophs.dhhs.gov/detrm_letrs/jul01a.pdf (last visited July 17, 2002). *See also* Dale Keiger & Sue DePasquale, Trials and Tribulations: A Special Report, JOHNS HOPKINS MAG., Feb. 2002, at 28.

122. *Grimes*, 782 A.2d at 813.

123. *Id.* at 817.

124. *See id.* at 839 (quoting Jeffery H. Barker, *Human Experimentation and the Double Facelessness of a Merciless Epoch*, 25 N.Y.U. REV. L. & SOC. CHANGE 603, 617-20 (1999) (internal quotations omitted)). In its characterizations of the ethics of the research enterprise, the Court relied extensively on literature critical of aspects of current practice. In addition to the Barker article, *see generally* Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157 (1998), and Richard W. Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW. 455 (1996).

125. *Grimes*, 782 A.2d at 817.

126. *Id.* at 853.

127. For a description of cases filed by the most active plaintiff's lawyer in this field, *see* Jennifer Washburn, Informed Consent, WASH. POST MAG., Dec. 30, 2001, at 8.

of the case, KKI had not been given any opportunity to respond.[128] The inflammatory historical comparisons, in particular, were "fundamentally unfair," KKI rightly argued.[129]

Just as KKI protested, with reason, at the Court's one-sided account of its research, so many others in the research community may bridle at the Court's thinly supported generalizations about deficiencies in the supervision of human subject research. As one commentator observed, "even a serious condemnation of the [Johns Hopkins] IRB at that time does not necessarily justify the court's sweeping condemnation of all IRBs and all intra-institutional attempts at human subject protection."[130]

Of course, there are valid reasons to worry about the effectiveness of informed consent, the adequacy of IRB oversight, and the potentially corrupting effect of money on the system for protecting human subjects. The Court, however, is institutionally disadvantaged in addressing these issues, for it has no inherent expertise in the area and necessarily views the issues through the lens of a particular case – here, a case that, owing to the inadequate record, actually clarified little, even about the particular research activity that resulted in the litigation, let alone research generally. Consequently, the Court's ethical critique, while forceful and in places credible, suffers badly from imprecision and superficiality. The Maryland Court of Appeals may be a sound court, but it has earned little credence as a bioethics commission.[131]

VI. CONCLUSION: IMPLICATIONS FOR RESEARCHERS

Grimes is a landmark in the history of human subjects protections. It is the most sweeping indictment of the current system of research protections ever written by an American appellate court. In many respects, the Court's opinion is also a landmark in judicial intemperance. For all of its flaws, however, the decision is a clear warning to the research community to take nothing for granted when conducting human subject research, especially research involving children or other vulnerable subjects. Indeed, it is the second such warning, following that of the Appellate Division of the New York Supreme Court in *T.D.*[132] If important research is not to be stymied by the prospect of successful litigation (or, more immediately, the inability to recruit subjects in a climate of mistrust), researchers

128. KKI Motion, *supra* note 78, at 1-2.

129. *Id.* at 8.

130. Ross, *supra* note 42, at 54.

131. A true bioethics commission, marshaling greater expertise and sophistication, has already offered a more measured and insightful critique of the current system of research regulation. *See* NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POL'Y ISSUES IN RES. INVOLVING HUM.. PARTICIPANTS (2001), *available at* http://bioethics.georgetown.edu/nbac/human/overvol1.pdf (last visited Sept. 18, 2002).

132. *See supra* text accompanying notes 72-74.

and academic institutions must adopt safeguards to convince even the most skeptical judicial observer of the ethical propriety of their research.

For the sake of both their ethical obligations and their pursuit of important knowledge, pediatric and other researchers should take heed of the KKI decision, surely not by abandoning their research but by redoubling their commitment to the highest ethical standards. Specifically, researchers should:

- Exercise scrupulous care in characterizing the existence or degree of potential benefit from participation in research.
- Exercise scrupulous care in characterizing the level of risk faced by research participants.
- Devote genuine attention to minimizing whatever risks the participants must bear for the sake of the scientific objective.
- Provide evidence within the research protocol of careful attention to these issues of benefit and risk.
- Exercise scrupulous care in conducting a genuine informed consent process, including the use of honest and understandable language in consent documents.
- Ensure that procedures are in place, and are monitored, so that information that has been promised to research participants, or that may be material to their decision whether to continue to participate, reaches the participants on time.

Research institutions, as well, should heed the warning of the KKI decision by improving their processes and taking steps to promote public confidence in the ethical conduct of their research. They should:

- Select IRB members who are capable of, and committed to, holding researchers accountable for the actions identified above.
- Ensure adequate financial and staff support for their IRBs.
- Provide meaningful educational programs for investigators and IRB members in the ethics of human subject research.
- Make the minutes of their IRBs available to members of the public upon request, after redaction of genuinely confidential or privileged information.[133]
- Consider the creation of a regional or consortium IRB for the review of protocols that have a higher than average risk profile, to diminish the concern that an IRB is inherently biased toward approval in order to promote the institution's cash flow.

133. Under recently enacted Maryland Law, and IRB "shall make the final minutes of a meeting available for inspection within 30 days of a receipt of a request for the minutes from any person," although the IRB "may redact confidential or privileged information." MD. HEALTH-GEN. CODE ANN. § 13-2003 (West Supp. 2002).

These actions by researchers and research institutions may be seen as defensive, in that they are partly aimed at deterring lawsuits and avoiding regulatory problems. In a more positive light, however, these improvements in the methods for protecting research subjects would reflect fidelity to ethical standards and would go some distance in restoring eroded public trust.