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Karen Smith Thiel

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# PARENTAL CONSENT FOR CHILDREN'S PARTICIPATION IN BIOMEDICAL RESEARCH: THE ETHICAL, REGULATORY, AND JUDICIAL FRAMEWORK OF *GRIMES V. KENNEDY KRIEGER INSTITUTE, INC.*

KAREN SMITH THIEL, PH.D.\*

For almost forty years, scholars, scientists, and ethicists have expressed concerns about the appropriate role for children in biomedical research. In the United States, civil litigation by the parents of two children who participated in a lead-based paint study conducted in Baltimore, Maryland, brought this issue to the fore and highlighted the fundamental tension between regulatory and judicial approaches to the participation of children in biomedical research.

The 1998 policy of the National Institutes of Health (NIH) mandates the inclusion of children in human subjects research.<sup>1</sup> Yet, the August 2001 opinion, and subsequent October 2001 clarification by the Court of Appeals of Maryland regarding parental consent for children's participation in biomedical research in *Grimes v. Kennedy Krieger Institute, Inc.*<sup>2</sup> has become judicial precedent in Maryland and may become persuasive authority in other jurisdictions. Whether *Grimes* will become the judicial equivalent of a "sentinel event" for children's participation in biomedical research on a national scale has yet to be determined.

This paper will focus on the issue of parental consent for children's participation in biomedical research. Following Baylis and Downie,<sup>3</sup> the paper

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\* The author is a juris doctor candidate at the University of Maryland School of Law. She holds a Ph.D. in Sociology, with interests in health law and children's advocacy.

1. NIH, NIH POLICY AND GUIDELINES ON THE INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS (1998) [hereinafter NIH POLICY & GUIDELINES]. The Food and Drug Administration (FDA) has developed policy based on the Food and Drug Modernization Act (FDMA) of 1997 that utilizes regulatory mechanisms to encourage the testing of proposed drugs in children. However, there are no specific standards for children's participation in these drug trials other than to refer researchers to the Department of Health and Human Services (DHHS) regulations on the protection of human subjects, Additional Protections for Children Involved as Subjects in Research, 45 C.F.R. pt. 46 subpt. D, and the American Academy of Pediatrics' "Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations." For an in depth discussion of the FDA regulatory provisions regarding children's participation in drug trials and a critical assessment of deficiencies in that regulation, see Jennifer Rosato, *The Ethics of Clinical Trials: A Child's View*, 28 J.L. Med. & Ethics \*362 (2000), WL 28 JLMEDETH 362.

2. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001), *reconsideration denied*, (Oct. 11, 2001).

3. See generally Françoise Baylis & Jocelyn Downie, *An Ethical and Criminal Law Framework for Research Involving Children in Canada*, 1 Health L.J. \*39 (1993), LEXIS, Law Reviews Combined. Baylis and Downie confine their discussion to newborns, infants, and children under the age of seven in

will confine its analysis to infants and young children, rather than to older children who possess the capability of assent, or adolescents, for whom "mature minor" or emancipated minor issues related to actual informed consent may arise.<sup>4</sup> The historical context for the federal regulatory approach and the judicial context for the decision in *Grimes* will be presented. The decision in *Grimes* will be analyzed, as well as arguments raised in a set of amicus briefs, which resulted in the court's subsequent clarification of the most controversial section of the opinion relating to parental consent for children's participation in research. Two persuasive authorities and one Maryland opinion will be used to further explore lingering constitutional and civil liability issues raised: the opinion of the Canadian Supreme Court in *E. (Mrs.) v. Eve*,<sup>5</sup> the opinion of the Appellate Division of the Supreme Court of New York in *T.D. v. New York State Office of Mental Health*,<sup>6</sup> and the opinion of the Court of Appeals of Maryland in *Wentzel v. Montgomery General Hospital, Inc.*,<sup>7</sup> The paper will conclude with a discussion of the implications of the decision in *Grimes* for biomedical research involving children.

### I. GRIMES V. KENNEDY KRIEGER INSTITUTE, INC.

Erika Grimes was a nine-month-old infant in March of 1993 when her mother was approached by representatives of the Kennedy Krieger Institute, Inc. (Institute) to participate in a research study designed to assess the efficacy of various methods of lead abatement in a set of homes in Baltimore City.<sup>8</sup> Erika's mother gave consent, indicating that she understood the purpose of the study was to "learn about how well different practices work for reducing exposure to lead in paint and dust."<sup>9</sup> Dust-lead levels in the homes assigned to three-lead abatement procedures and two control groups were to be measured eight to nine times over a two-year period.<sup>10</sup> In addition, the informed consent form stated: "We also are doing free blood lead testing of children aged 6 months to 7 years, up to 8 or 9 times over the next two years."<sup>11</sup> The consent form indicated that lead present in paint, house

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order to examine the legal and ethical status of parental/guardian consent on behalf of subjects who cannot now and have never been able to provide legally effective consent or ethically valid assent to participate in biomedical research. *Id.* at \*44-45.

4. For analyses of adolescent autonomy in decision making, see Rhonda Gay Hartman, *Adolescent Autonomy: Clarifying an Ageless Conundrum*, 51 Hastings L.J. \*1265 (2000), WL 51 HSTLJ 1265; and Elizabeth S. Scott, *The Legal Construction of Adolescence*, 29 Hofstra L. Rev. \*547 (2000), WL 29 HOF LR 547.

5. [1986] 2 S.C.R. 388.

6. 650 N.Y.S.2d \*173 (N.Y. App. Div. 1996), 1982 Md. LEXIS 282.

7. 447 A.2d 1244 (Md. 1982).

8. *Grimes*, 782 A.2d at 824. The factual narrative for this case is drawn from the plaintiffs' allegations as cited in the opinion of the Court of Appeals of Maryland. *Id.*

9. *Id.*

10. *Id.*

11. *Id.*

dust, and soil was a major source of lead exposure among children.<sup>12</sup> Erika's mother was informed that she would be provided with specific blood-lead results as well as steps to reduce any risks of exposure.<sup>13</sup> However, no further information was provided about the effects of lead poisoning in children, other than that it was "a problem in Baltimore City and other communities across the country."<sup>14</sup>

Erika's home was in the control group,<sup>15</sup> a property considered completely abated of lead paint prior to the start of the study, hence requiring no further abatement or maintenance procedures.<sup>16</sup> Yet, the day before Erika's mother signed the consent form, dust testing in their home revealed "hot spots," described by researchers as lead levels higher than anticipated in a completely abated house.<sup>17</sup> This elevated lead level in the home at baseline was not reported to Erika's mother until nine months later.<sup>18</sup> Although Erika's blood-lead results were normal in the first test, which was completed within the first month of her participation in the study, tests completed five and eleven months later both registered blood-lead levels in the "highly elevated" range.<sup>19</sup> The result of each of these blood-lead tests was communicated via letter to Erika's mother within either days or, at most, two weeks of the test.<sup>20</sup> Erika did not continue her participation in the full course of the study, as she and her mother moved from the property in the summer of 1994.<sup>21</sup>

Erika's mother filed suit in the Circuit Court of Baltimore City, alleging that the Institute was negligent in not warning her about or abating the lead paint in her home at the time it was first discovered in March of 1993.<sup>22</sup> The Institute filed a

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12. *Id.*

13. *Id.* at 825. It is not known at this time whether the Johns Hopkins University Institutional Review Board classified the Lead-Based Paint Study as having a direct benefit to children participating in the study based on lead-based paint exposure being a "problem in Baltimore City," because the Circuit Court's decision was based on the Institute's Motion for Summary Judgment. The trial record cited by the Court of Appeals of Maryland does not reflect arguments offered by the defendant in the civil litigation. However, in its Motion for Reconsideration, the Institute emphasized that the study conferred a direct benefit on the children who participated in the research, because they lived in housing that had been abated while they participated in the study and the researchers monitored the lead levels in their blood. Appellee's Motion for Partial Reconsideration and Modification of Opinion, *Grimes* (No. 128).

14. *Grimes*, 782 A.2d at 824.

15. *Id.* at n.21.

16. *Id.* at 822.

17. *Id.* at 825.

18. *Id.*

19. *Id.* The Court of Appeals' record notes that the categories of risk used for subjects in the Lead-Based Paint Study were based on a five-class scheme used by the Centers for Disease Control and Prevention (CDC). Readings of 10 to 19 micrograms of lead for every deciliter of blood were classified as "moderately elevated," and readings from 20 to 44 as "highly elevated." *Id.* at n.23.

20. *Grimes*, 782 A.2d at 825.

21. *Id.*

22. *Id.* at 825-26.

Motion for Summary Judgment arguing that, as a matter of law, it did not owe a duty to Erika or her mother, and the motion was granted.<sup>23</sup>

The Court of Appeals of Maryland reviewed the Circuit Court's judgment for the Institute.<sup>24</sup> The appellant contended that a duty of care was owed to Erika and her mother based on one or more of four separate theories.<sup>25</sup> First, a contract existed between the Institute and the appellant; second, the Institute had voluntarily assumed the risk; third, a "special relationship" existed between the Institute's researchers and the appellant; and fourth, the existence of 45 C.F.R. § 46 created a duty on the part of the researchers to the subjects in the study.<sup>26</sup> On appeal, this case was joined with that of another child who had participated in the same research study.<sup>27</sup>

Myron Higgins was a four-year-old child in May of 1994 when his mother rented a home, which had been partially abated as one of the homes in the moderate level of repair and maintenance "treatment group" for the Lead-Based Paint Study.<sup>28</sup> During that same month, Myron and his mother were recruited to participate in the study.<sup>29</sup> Myron's mother provided informed consent on behalf of her son.<sup>30</sup> Although the home had registered lead levels above accepted Maryland clearance levels just a week prior to the Institute obtaining consent from Myron's mother, she was not informed of the results either before or after she signed the consent form.<sup>31</sup> The Institute concluded that these elevated levels were due to an alternate method of dust collection, and chose instead to rely upon the results of the dust wipe method on which Maryland bases its clearance levels.<sup>32</sup> When the dust wipe method was used, lead levels were under the Maryland clearance level.<sup>33</sup> Myron's mother was informed, via letter sent the following month, that the dust wipe sample indicated that no areas in her home contained higher lead levels than would be found in a completely abated home.<sup>34</sup> Dust samples taken two and five months afterward yielded test results that were above the Maryland clearance

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23. *Id.* at 826.

24. *Id.*

25. *Grimes*, 782 A.2d at 826.

26. *Id.* The Court refers to Subpart A, Federal Policy for the Protection of Human Subjects, 45 C.F.R. pt. 46 subpt. A, and Subpart D, Additional Protections for Children Involved as Subjects in Research, 45 C.F.R. pt. 46 subpt. D.

27. *Id.*

28. *Id.* at 826-27, n.25.

29. *Id.* at 828.

30. *Id.*

31. *Grimes*, 782 A.2d at 828.

32. *Id.* at n.26.

33. *Id.*

34. *Id.* at 828.

level.<sup>35</sup> Myron's mother contends that the first time she was made aware of the elevated levels of lead in the home was in September of 1994.<sup>36</sup>

Tests of Myron's blood-lead levels conducted within the first month of the family's occupation of the home, and two and five months later, placed him in the moderately to highly elevated range.<sup>37</sup> These results were communicated to Myron's mother, and she was instructed to "provide the test result to child's primary health care provider right away."<sup>38</sup>

Myron's mother filed suit in the Circuit Court for Baltimore City in February of 1995 claiming negligence on the part of the property's landlord, and subsequently amended her complaint in April of 1999 to add both the Institute and the company that had performed the lead abatement at the property.<sup>39</sup> Again, the Institute filed a Motion for Summary Judgment arguing it did not owe any duty to Myron or his mother, and the court once again granted the motion.<sup>40</sup>

Both plaintiffs appealed the Circuit Court's decision, and the Court of Appeals of Maryland, hearing the cases together, issued its decision in August 2001.<sup>41</sup> On the issue of whether the Circuit Court had erred in granting the Institute's Motion for Summary Judgment in the consolidated cases, the court held, "[t]here was ample evidence in the cases at bar to support a fact finder's determination of the existence of duties arising out of contract, or out of a special relationship, or out of regulation and codes, or out of all of them, in each of the cases."<sup>42</sup> Both cases were remanded to the Circuit Court for further proceedings consistent with the opinion.<sup>43</sup>

Although the issue was not raised either by the appellant or the appellee, the court, in a scathing critique of the conduct of the Lead-Based Paint Study and the role of the Institutional Review Board (IRB) in approving its protocol, asked whether a parent could consent to the participation of his or her child in non-therapeutic research with known potential health hazards.<sup>44</sup> The court held, "in Maryland a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in non-therapeutic research or studies in which there is any risk of injury or damage to the health of the subject."<sup>45</sup>

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35. *Id.*

36. *Id.*

37. *Grimes*, 782 A.2d at 828.

38. *Id.* at 828-29.

39. *Id.* at 829.

40. *Id.* at 829-32.

41. *Id.* at 818-19.

42. *Id.* at 858.

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

44. *Id.* at 852.

45. *Id.* at 858.

This section of the opinion, with its implication for the future of children's participation in biomedical research, alarmed researchers, and research institutions throughout the state and nation. A number of amicus briefs were filed with the appellee's Motion for Reconsideration.<sup>46</sup> Although the motion was denied, the court issued a clarification of its holding with respect to parental consent.<sup>47</sup> The clarification, as well as the opinion itself, may have great import for the future of children's participation in biomedical research. An analysis of the historical, regulatory, and judicial context for this decision provides a framework for examining the arguments advanced by the court and considering the implications of the court's ruling.

## II. ETHICAL CONSIDERATIONS AND THE HISTORICAL CONTEXT FOR THE DEVELOPMENT OF A REGULATORY APPROACH TO CHILDREN'S PARTICIPATION IN BIOMEDICAL RESEARCH IN THE UNITED STATES

The historical context for the development of a regulatory approach to children's participation in biomedical research in the United States has its origins both in ethical guidelines developed by international tribunals and organizations, and in a series of rather shocking examples of biomedical research conducted with individual children or groups of institutionalized children.<sup>48</sup> Federal regulations for the protection of human subjects, which draw on both of these influences, are contained in 45 C.F.R. § 46 Subpart A, Federal Policy for the Protection of Human Subjects, and Subpart D, Additional Protections for Children Involved as Subjects in Research.<sup>49</sup>

Participation in biomedical research was first addressed in The Nuremberg Code,<sup>50</sup> a set of guidelines for human subjects research developed in 1947 by a panel of American justices at the conclusion of the war criminal trials held before the Nuremberg Military Tribunal.<sup>51</sup> Guidelines for infants and children were not directly addressed in the Code. However, the status of infants and children as research subjects was addressed by implication. The first principal, "The voluntary consent of the human subject is absolutely essential," refers to individuals who:

[S]hould have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice . . . and should have sufficient knowledge and comprehension of the elements of the subject

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46. See *infra* note 182.

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

48. Leonard H. Glantz, *Research with Children*, 24 Am. J.L. & Med. \*213, \*213 (1998), WL 24 AMJLM 213.

49. 45 C.F.R. § 46 (2001).

50. *Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law no. 10*, 181-82 (U.S. Gov't Printing Office, 1949) [hereinafter *The Nuremberg Code*].

51. Glantz, *supra* note 48, at \*213.

matter involved as to enable him to make an understanding and enlightened decision.<sup>52</sup>

The Code does not address the issue of subjects who are unable, due to immaturity or incapacity, to consent to their participation in research, but it does provide for human subjects to halt their participation in research.<sup>53</sup>

Children, other than emancipated minors or adolescents determined to be "mature minors," have neither the statutory nor common law capacity to give consent.<sup>54</sup> Nor is it commonly thought that they necessarily have the cognitive or psychological capacity to comprehend the subject matter of research, or engage in decision-making that would meet the Code's requirements of a voluntary, free power of choice, and enlightened decision-making.<sup>55</sup> Subsequent efforts to develop ethical guidelines for the conduct of research explicitly addressed these issues as they relate to the participation of children.<sup>56</sup>

Beginning in 1953, recommendations for children's participation in research were developed in the World Medical Association's Declaration of Helsinki.<sup>57</sup> The treatment of pediatric research has been traced in a series of declarations.<sup>58</sup> In 1964, "Helsinki I" distinguished between therapeutic and non-therapeutic research, calling for the level of risk in a research study to be proportional to the expected benefits.<sup>59</sup> Proxy consent was to be permitted for any subjects who were legally incompetent.<sup>60</sup> In 1975, "Helsinki II," called for independent review of research protocols, adding psychological and physical well-being as factors to be considered in the determination of risk.<sup>61</sup> Minor children were specifically addressed as a class of legally incompetent research subjects.<sup>62</sup> In 1983, "Helsinki III" suggested that children could participate in the consent process.<sup>63</sup> "Helsinki IV," adopted in 1989, included as part of its basic principles two explicit statements relating to

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52. The Nuremberg Code, *supra* note 50.

53. *Id.* "During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him impossible." *Id.*

54. Leonard H. Glantz, *The Law of Human Experimentation with Children*, in CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW 111-13 (Michael A. Grodin & Leonard H. Glantz eds., 1994).

55. The Nuremberg Code, *supra* note 50.

56. Ann E. Ryan, *Protecting the Rights of Pediatric Research Subjects in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use*, 23 Fordham Int'l L.J. \*848, \*869 (2000), WL 23 FDMILJ 848.

57. *Id.*

58. *Id.*

59. *Id.* at \*870.

60. *Id.*

61. *Id.*

62. Ryan, *supra* note 56, at \*872.

63. *Id.*



children.<sup>64</sup> The first stated, “[w]here physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.”<sup>65</sup> The second stated, “[w]henver the minor child is in fact able to give consent, the minor’s consent must be obtained in addition to the consent of the minor’s legal guardian.”<sup>66</sup>

In addition to the Helsinki Declarations, the World Health Organization’s (WHO) 1983 International Ethical Guidelines for Biomedical Research Involving Human Subjects addressed children’s participation in both therapeutic and non-therapeutic research and called for parental proxy consent, child consent to the extent that the child is able to provide it, and complete respect for the child’s refusal to participate in non-therapeutic research.<sup>67</sup> In 1996, the Council of Europe Convention (CEC) on Human Rights and Biomedicine adopted stringent requirements for children’s participation in non-therapeutic research.<sup>68</sup> Under the new requirements, children may only participate in non-therapeutic research if it involves minimal risk and burdens.<sup>69</sup> If research does not directly benefit the incompetent individual, it must contribute to a greater understanding of the medical condition of that individual or other subjects in the individual’s age group.<sup>70</sup>

Finally, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use’s “Guidelines for Good Practice” proposed that human subjects who are unable to provide informed consent should not participate in non-therapeutic research unless a set of conditions are met.<sup>71</sup> Such conditions included parental permission, low risks relative to benefits, IRB approval, and closely monitoring research so that individual subjects can be removed from a study if they show any signs of distress.<sup>72</sup> If at any point the child indicates that he or she does not wish to participate in the research, the child’s wishes should be respected.<sup>73</sup> The guidelines also recommend that IRBs engaged in reviewing protocols involving children should have a pediatrician member.<sup>74</sup>

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64. World Med. Ass’n, Declaration of Helsinki: Ethical Principles for Med. Research Involving Human Subjects, *available at* [http://www.wma.net/e/policy/17-c\\_e.html](http://www.wma.net/e/policy/17-c_e.html) (last visited Sept. 15, 2002) [hereinafter World Med. Ass’n].

65. *Id.* at §11.

66. *Id.*

67. Ryan, *supra* note 56, at \*875.

68. *Id.* at \*876-80.

69. *Id.* at \*880.

70. *Id.* at \*879.

71. *Id.* at \*920.

72. Ryan, *supra* note 56, at \*920-21.

73. *Id.* at \*926.

74. *Id.* at \*933.

The other factor that drove the domestic federal regulatory process with respect to children's participation was a series of incidents involving children as research subjects. Lederer and Grodin have chronicled the, sometimes disturbing, history of children's involvement in biomedical research in the United States.<sup>75</sup> These authors concluded that the history of pediatric experimental research "is largely one of child abuse."<sup>76</sup> In the late 1800s, children were injected with experimental infections of syphilis and gonorrhea.<sup>77</sup> With the development of the x-ray, researchers studied the infant stomach by exposing infants as young as two days old to a series of x-rays.<sup>78</sup> In the early 1900s, children in hospitals and orphanages were inoculated with experimental vaccines for measles and tuberculosis.<sup>79</sup> And, in the 1930s, clinical trials of untested polio vaccines were conducted on children.<sup>80</sup> Perhaps the most infamous study involved a group of severely retarded children living at the Willowbrook State School from the 1950s until the 1970s, who were experimentally infected with hepatitis and then observed over the natural course of the disease.<sup>81</sup>

Although the original version of the federal guidelines for the protection of human subjects did not specifically address children's participation in research, a federally funded national commission developed two other documents that provided such guidelines.<sup>82</sup> The National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research published its "Report and Recommendations: Research Involving Children" in 1977, and "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research" in 1978.<sup>83</sup> In 1983, "Additional Protections for Children Involved as Subjects in Research" was published as Subpart D to 45 C.F.R. § 46.<sup>84</sup>

The Commission recommended the dual provision of parental permission and child assent as the most effective way to ensure informed consent for the participation of the child in human subjects research.<sup>85</sup> The Commission also recommended that a child's refusal to participate in the research should preclude any participation by the child,<sup>86</sup> and children as young as seven years of age should

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75. Susan Lederer & Michael Grodin, *Historical Overview: Pediatric Experimentation*, in CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW 3-28 (Michael A. Grodin & Leonard H. Glantz eds., 1994).

76. *Id.* at 19.

77. *Id.* at 7.

78. *Id.* at 9.

79. *Id.* at 8.

80. *Id.* at 14.

81. Lederer & Grodin, *supra* note 75, at 17.

82. *Id.* at 19. The original guidelines were published in 1974 at 45 C.F.R. § 46.

83. *Id.*

84. 45 C.F.R. pt. 46 subpt. D.

85. Ryan, *supra* note 56, at \*886-87.

86. *Id.* at \*890.

be allowed to assent to their participation.<sup>87</sup> Neither of these latter provisions was adopted in the subsequent federal regulations.<sup>88</sup>

The Belmont Report identified three ethical principles for the conduct of human subjects research: respect for persons, beneficence, and justice.<sup>89</sup> These principles are to serve as “an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.”<sup>90</sup> The Belmont Report explicitly addressed research involving children in its discussion of the meaning of beneficence.<sup>91</sup> While commenting that children derive benefits from effective ways of treating childhood diseases, the authors noted that a difficult ethical issue arises when the children are involved in research that involves more than minimal risk with no direct benefit.<sup>92</sup>

The Belmont Report applied its ethical principles to three aspects of the research process: informed consent, the assessment of risks and benefits, and the selection of subjects.<sup>93</sup> The report notes that special provisions may need to be made for vulnerable populations whose ability to comprehend information provided in informed consent is severely limited.<sup>94</sup> These incompetent subjects, including infants and young children, should still be accorded the respect of having the opportunity to choose to participate in research, and any objection on their part should be honored.<sup>95</sup> The report notes that the principle of respect for incompetent subjects requires that consent of third parties be obtained in order to protect them from potential harm, and that “[t]he third parties chosen should be those who are most likely to understand the incompetent subject’s situation and to act in that person’s best interest.”<sup>96</sup> The description of the responsibilities of third parties is

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87. *Id.* at \*892. Weithorn and Scherer present research findings that school-aged children are cognitively and psychologically capable of providing assent. Nine-year-olds exhibited reasoning skills that were characterized by logical and practical problem solving strategies, but did not meet adult standards. The authors found that the cognitive functions of the fourteen-year-olds in the studies they reviewed met the legal criteria to consent to most types of treatment and research. Lois A. Weithorn & David G. Sherer, *Children’s Involvement in Research Participation Decisions: Psychological Considerations*, in CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS AND LAW 133-79 (Michael A. Grodin & Leonard H. Glantz eds., 1994).

88. Ryan, *supra* note 56 at \*890, \*892.

89. NAT’L COMM’N FOR THE PROTECTION OF HUM. SUBJECTS OF BIOMED. & BEHAV. RES., PUB. No. (OS) 78-0012-014, BELMONT REPORT: ETHICAL PRINCIPALS AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 4 (1977) [hereinafter THE BELMONT REPORT].

90. *Id.* at 3.

91. *Id.* at 5.

92. *Id.*

93. *Id.* at 6.

94. *Id.* at 7.

95. THE BELMONT REPORT, *supra* note 89, at 7.

96. *Id.*

important because it establishes a standard for parental consent for the participation of children in biomedical research, that is, the "best interests" of the child.<sup>97</sup>

### III. THE REGULATORY CONTEXT FOR CHILDREN'S PARTICIPATION IN RESEARCH

The mandate of 45 C.F.R. § 46 applies to human subjects research that is conducted or supported by any federal department or agency that takes administrative steps to apply the regulation to its research activities.<sup>98</sup> The regulation also applies to entities that receive federal funding for research, including universities.<sup>99</sup> Subpart D of the regulation, "Additional Protections for Children Involved as Subjects in Research," defines children as "persons, who have not attained the legal age for consent to treatment or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."<sup>100</sup>

The Lead-Based Paint Study was reviewed under Maryland law.<sup>101</sup> In Maryland, a minor has the same legal capacity as an adult to consent for medical treatment for substance abuse, sexually transmitted diseases, pregnancy and reproductive health.<sup>102</sup> Minors over the age of sixteen have the same legal capacity as an adult to consent for treatment for mental or emotional disorders.<sup>103</sup> Emancipated minors of any age may consent to their own medical treatment, and minors who are married or the parent of a child have the same capacity as an adult

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97. Dan W. Brock, *Ethical Issues in Exposing Children to Risks in Research*, in CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS AND LAW 81-101 (Michael A. Grodin & Leonard H. Glantz eds., 1994). Brock summarizes the two relevant ethical issues for children who lack the legal capacity to provide their own consent to participate in research as follows: "[w]ho should have authority to decide about children's participation in research?" and, "What standards should those deciding about children's research participation use for those decisions?" He argues that the three existing ethical standards for decision-making for those who do not have the capacity to make their own decisions are advanced directives, surrogate decision-making, and the best interests of the child, but since infants and young children have never had prior competence in decision-making, neither the advanced directives nor surrogate decision-making standards should apply to them. Brock states that children's best interests are served when their capacity to develop into autonomous adults is protected by the present choices made on their behalf. *Id.*

98. 45 C.F.R. § 46.101.

99. *Id.* at § 46.103 ("Each institution engaged in research which is covered by this policy, and which is conducted or supported by a federal department or agency, shall provide written assurance, satisfactory to the department or agency head, that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federal-wide use by that office."). *Id.*

100. *Id.* § 46.402.

101. Md. Code Ann., [Health-Gen. II] § 20-102 (2000).

102. *Id.* However, an abortion cannot be performed on a minor without the physician first having given notice to the minor's parent or guardian. *Id.* §20-103.

103. *Id.* § 20-104.

to consent to medical treatment.<sup>104</sup> Aside from these exceptions, parental consent would be required in Maryland for children's participation in both therapeutic and non-therapeutic research.

The regulation categorizes research into four categories: research not involving greater than minimal risk; research involving greater than minimal risk, but presenting the prospect of direct benefit to the subjects; 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;<sup>105</sup> and research not otherwise approvable, which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children.<sup>106</sup> The permission of the child's parents or guardian and provisions for obtaining the assent of the child are required for each research category.<sup>107</sup>

The IRB charged with reviewing the research protocol for compliance with the federal policy is responsible for making adequate provisions to solicit the assent of the child, when the child is deemed capable of providing that assent, and obtaining the permission of the child's parents or guardian.<sup>108</sup> The IRB considers the age, maturity and psychological state of the children involved in determining whether an individual child or all children involved in the research are capable of providing assent.<sup>109</sup> However, in cases involving infants and young children, assent is not necessary if the child's capacity is too limited for providing reasonable assent.<sup>110</sup> The IRB makes provisions for the permission of one parent or guardian in the first two categories of research and permission from both parents for research that falls into the latter two categories.<sup>111</sup>

In March 1998, the NIH issued its "Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects."<sup>112</sup> The policy was developed at Congress' direction.<sup>113</sup> NIH stated that its policy was that children "must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them."<sup>114</sup>

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104. *Id.* § 20-102.

105. Research in this category is contingent on an IRB finding that the risk to the child represents a minor increase over minimal risk. In addition, the experiences of the child in the research are to be "reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations." 45 C.F.R. § 46.406 (1994).

106. *Id.* §§ 46.404-46.407.

107. *Id.*

108. *Id.* § 46.408.

109. *Id.*

110. *Id.*

111. *Id.* ("[B]oth parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child."). *Id.*

112. NIH POLICY & GUIDELINES, *supra* note 1, at 1.

113. *Id.*

114. *Id.*

The foundation of the policy was the need for developing a scientific basis for medical treatments for children using information from clinical trials with children rather than merely extrapolating data obtained from adult clinical trials.<sup>115</sup> Included in the list of acceptable justifications for exclusions from the policy is the existence of "laws or regulations barring the inclusion of children in the research."<sup>116</sup> Presumably, if a state legislature were to pass statutory prohibitions or limitations on the inclusion of children in research, the NIH policy would then defer to the statutory provisions or to regulations designed to implement the statute.

The August 2001 opinion of the Maryland Court of Appeals in *Grimes* barred the participation of Maryland children from certain types of biomedical research by holding that a parent could not consent to the participation of a child in non-therapeutic research where there were known potential health hazards.<sup>117</sup> At the time of the decision, no law barring children from participating in biomedical research at either the federal or state level existed.<sup>118</sup> The subsequent October 2001 opinion clarified the court's previous holding with respect to parental consent, but still restricted the types of research to which parents may consent.<sup>119</sup> Furthermore, calls on the heels of this Opinion for a legislative solution to the issue of children's participation in biomedical research could establish more restrictions on children's participation in biomedical research.

#### IV. THE JUDICIAL CONTEXT FOR CHILDREN'S PARTICIPATION IN RESEARCH

There is a fundamental tension between societal goals and individual rights with respect to children's participation in biomedical research. Federal policy mandating the inclusion of children in biomedical research for the promotion of science that meets children's health needs may conflict with legal approaches to the role of individual children and their parents in decision-making related to their inclusion in research studies. This tension is best characterized by Dickens in his analysis of the impediments to an individual parent's legal authority to consent to his or her child's participation in health research: "Exclusion of young persons from participation in medical research necessary to protect and promote their health is an injustice to them as members of a community, but their inclusion as

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115. *Id.*

116. *Id.*

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

118. See *T.D.*, 650 N.Y.S.2d \*173. Although New York's Public Health Law article 24-A states, in part, "it shall be the policy of this state to protect its people against the unnecessary and improper risk of pain, suffering or injury resulting from human research conducted without their knowledge or consent," the court in *T.D.* noted that there is a provision in that statute which states that article 24-A does not apply when the research is in compliance with 45 C.F.R. § 46. *Id.* at \*182.

119. *Grimes*, 782 A.2d at 861-62.

individual participants in research may be an illegality to each of them.”<sup>120</sup> Promoting the health of children, in general, is not within the realm of an individual parent’s legal authority; parents only have the legal authority to promote the best interests of their own children.<sup>121</sup>

The “best interests” of a child may be compromised by his or her participation in biomedical research, particularly when the research is of no direct benefit to the individual child. Glantz describes a number of ways in which children participating in research are particularly vulnerable.<sup>122</sup> Children may be participating involuntarily since they are not capable of consenting themselves or the parent or guardian giving consent may not be acting in the best interests of the child.<sup>123</sup> Incentives offered to parents may inappropriately influence parental consent; researchers themselves may have interests that do not reflect the child’s welfare; special populations of children, such as institutionalized children, may not even have the natural protectiveness of parents; children with terminal diseases or rare illnesses may be placed at additional health risk; and the legal capacity of parents or guardians to consent for their children’s participation in research is still unclear.<sup>124</sup> The uncertainty of the legal capacity of parents and guardians to consent for children’s participation in biomedical research, coupled with the notion that consent should reflect a parent acting in the best interests of the child, are themes that run throughout what little judicial precedent exists on this issue.

There is no common law rule for children’s participation in biomedical research. The closest analogy is that of children’s medical treatment or children’s participation as donors in the medical treatment of family members.<sup>125</sup> The common law rule for consent for the medical treatment of children calls for parental consent.<sup>126</sup> However, exceptions which allow minors to consent to their own medical care for sexually transmitted diseases, substance abuse, or pregnancy and reproductive health, along with the concept of mature minors, which has been adopted by the Supreme Court in *Bellotti v. Baird*,<sup>127</sup> make the common law rule virtually inapplicable to late adolescents.<sup>128</sup>

The legal capacity for consent by children and younger adolescents is murkier. In *Cardwell v. Bechtol*,<sup>129</sup> the Tennessee Supreme Court adopted the

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120. Bernard M. Dickens, *The Legal Challenge of Health Research Involving Children*, 6 Health L.J. \*131, \*132 (1998), LEXIS, Law Reviews Combined.

121. *Id.* at \*133.

122. Glantz, *supra* note 48, at \*218-19.

123. *Id.*

124. *Id.*

125. *Id.* at \*227-28.

126. *Id.* at \*224.

127. Glantz, *supra* note 48, at \*226 (citing *Bellotti v. Baird*, 443 U.S. 662 (1979) and providing the U.S. Supreme Court’s definition of a mature minor as a minor that is able to give informed consent).

128. Glantz, *supra* note 48, at \*225-26.

129. Glantz, *supra* note 48, at \*225.

"Rule of Sevens," stating that when children between the ages of seven and fourteen are involved in research, there was a rebuttable presumption that they did not have the capacity to consent to their medical treatment.<sup>130</sup> But, for children over the age of fourteen, there was a rebuttable presumption that they did have the capacity to consent to their medical treatment.<sup>131</sup>

Parents have the legal right to make decisions for their minor children.<sup>132</sup> However, courts have not found this parental right to be an absolute right. In *Newmark v. Williams*,<sup>133</sup> the Delaware Supreme Court applied a "best interests" standard to deny the State of Delaware's custody petition to enable it to intervene, over the objections of his parents, in the medical treatment of a three-year-old boy with an advanced form of cancer.<sup>134</sup> Here, it was the State, rather than the parents, who argued that the medical treatment was in the "best interests of the child."<sup>135</sup> The court refused to remove the child from the custody of parents, who were loving and nurturing, in order to permit the State to supervise his medical treatment.<sup>136</sup> The court found that it was not in the best interests of the child to be subjected to highly invasive, painful chemotherapy with an unacceptably low chance of success.<sup>137</sup> However, the court stated in *dicta*:

We also recognize that parental autonomy over minor children is not an absolute right. Clearly, the State can intervene in the parent-child relationship where the health and safety of the child and the public at large are in jeopardy. Accordingly, the State, under the doctrine of *parens patriae*, has a special duty to protect its youngest and most helpless citizens.<sup>138</sup>

The issue of *parens patriae* was raised in a Canadian case regarding a third party's right to consent to a medical procedure on behalf of an incompetent individual. In *E. (Mrs.)*<sup>139</sup> the Canadian Supreme Court refused to grant a mother's petition for authorization to consent to the sterilization of her moderately mentally retarded adult daughter because the procedure would not directly benefit the

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130. Glantz, *supra* note 48, at \*225.

131. Glantz, *supra* note 48, at \*225. It should be noted that many jurisdictions adopt a similar scheme for children's criminal liability, and courts will consider a child as young as five culpable for civil tort liability. *See id.*

132. *Newmark v. Williams*, 588 A.2d 1108, 1115 (Del. 1991).

133. *Id.*

134. *Id.*

135. *Id.* at 1118.

136. *Id.*

137. *Id.*

138. *Newmark*, 588 A.2d at 1116.

139. [1986] 2 S.C.R. 388.



daughter.<sup>140</sup> The court refused to consider the benefit to the aged mother of not having to care for potential offspring of a daughter who was not competent to care for children.<sup>141</sup> The court held that its *parens patriae* jurisdiction “is to be exercised for the benefit of the person in need of protection and not for the benefit of others,”<sup>142</sup> and examined the issue of a non-therapeutic operation by asking whether allowing it would best protect Eve.<sup>143</sup> Extending this holding to the issue of a parent’s legal authority to consent for children’s participation in research with no direct benefit to the child, it could be argued that the court would prohibit children’s involvement in research to which parents consent based on a sense of altruism or due to financial incentives.

Basing its ruling on the best interests of the child, the Court of Appeals of Maryland in *Wentzel*,<sup>144</sup> refused to grant a guardian’s petition for a sterilization procedure on a thirteen-year-old severely retarded girl.<sup>145</sup> The court held that the procedure was not necessary for either the child’s medical or mental health.<sup>146</sup> Moreover, the court found that the concerns of the child’s guardian that her ward might become pregnant and give birth to a child who would then become the guardian’s additional responsibility did not justify the procedure.<sup>147</sup> The court noted that “in considering the best interests of an incompetent minor, the welfare of society or the convenience or peace of mind of the ward’s parents or guardian plays no part.”<sup>148</sup>

The Appellate Division of the New York Supreme Court considered the issue of children’s participation in research in a complicated case involving the existence of a state policy reflected in its public health statutes, a set of regulations developed by a state agency, and a motion for a declaratory judgment on the legality of decisionally impaired adults and children’s participation in research with no direct medical benefit to the subject.<sup>149</sup> *T.D.* involved a challenge to the State Office of Mental Health’s regulations that permitted decisionally impaired adult and child residents of state facilities to participate in non-therapeutic research with more than minimal risk.<sup>150</sup> The court held that the regulations violated both

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140. *Id.* at 389.

141. *Id.* at 434.

142. *Id.* at 427.

143. *Id.* at 397.

144. 447 A.2d \*1244.

145. *Id.* at \*1245, \*1254.

146. *Id.* at \*1254.

147. *Id.*

148. *Id.*

149. *T.D.*, 650 N.Y.S.2d \*173.

150. *Id.* at \*175. The regulations of the State Office of Mental Health appeared to conflict with statutory language in the state’s Public Health Law, enacted after the scandal of hepatitis experimentation on children residing in the Willowbrook State School. The provision of the Public Health Law stated, “it shall be the policy of this state to protect its people against the unnecessary and

state and federal due process rights and the common law right of personal autonomy.<sup>151</sup> The rationale for this decision was that the regulations failed to balance the interests of research with the rights of subjects.<sup>152</sup>

The court analogized parental consent for children's participation in non-therapeutic research having greater than minimal risk to that of a parent denying a child medical treatment.<sup>153</sup> The court found that by allowing an IRB to waive parental consent requirements, parents' or guardians' state and federal due process rights were violated because they could not contest the IRB's decision.<sup>154</sup>

Until *Grimes*, with the exception of *T.D.*, there appears to be no other case in the United States which deals with the issue of consent for children to participate in biomedical research. However, a 1944 opinion of the Supreme Court may be useful in speculating on how a court might use precedent from a case involving parental control and a due process claim to rule on the capability of a parent to consent to research with no direct benefit to the child, but only the altruistic benefit of promoting the development of knowledge to help other children. In *Prince v. Massachusetts*,<sup>155</sup> the Supreme Court affirmed a custodial aunt's conviction for violating a state child labor statute when she allowed her nine-year-old niece to preach religious doctrine in the street.<sup>156</sup> The court rejected the aunt's claim that her parental rights under the Due Process Clause of the Fourteenth Amendment had been violated, noting that the state, as *parens patriae* "has a wide range of power for limiting parental freedom and authority in things affecting the child's welfare; and that this includes, to some extent, matters of conscience and religious conviction."<sup>157</sup> In often quoted *dicta*, the court stated, "Parents may be free to become martyrs themselves, but it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."<sup>158</sup>

Extending this reasoning to parental consent for children's participation in biomedical research having no direct benefit to the child, a court might find that this, too, is a matter of conscience. Parents may be promoting altruistic behavior in their children and helping to advance scientific knowledge for the benefit of

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improper risk of pain, suffering, or injury resulting from human research conducted without their knowledge or consent." *Id.* There is no similar statutory provision in Maryland.

151. *Id.* at \*176.

152. *Id.* at \*177.

153. *Id.* at \*192. ("It follows therefore that a parent or guardian . . . 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 and that may have the same result as a denial of necessary medical treatment."). *Id.*

154. *Id.* at 124 (The case was dismissed on the grounds that a substantial constitutional question was not directly involved in the appeal).

155. 321 U.S. 158 (1944).

156. *Id.*

157. *Id.* at 167.

158. *Id.* at 170.

children in general. But a court might find that only children who are legally able to consent for medical procedures under statutory provisions of the relevant jurisdiction or children who meet some other criteria of maturity, such as the existing NIH criteria for child assent, may participate in these types of research studies. Clearly infants, young children, and perhaps children as old as seven, twelve, or even fourteen years of age, would not meet this standard for consent.

V. THE OPINION OF THE COURT OF APPEALS OF MARYLAND IN *GRIMES V. KENNEDY KRIEGER, INSTITUTE, INC.*, REGARDING PARENTAL CONSENT FOR CHILDREN'S PARTICIPATION IN BIOMEDICAL RESEARCH

The issue of whether a parent could consent to his or her child's participation in non-therapeutic research that is known to be potentially hazardous to the health of the child was not raised on appeal.<sup>159</sup> However, the Court of Appeals of Maryland chose to address the issue because of the "overriding importance of this matter and this Court's interest in the welfare of children."<sup>160</sup> Adopting a "best interests of the child" standard,<sup>161</sup> the court stated that it is not in the best interests of a child, otherwise healthy, to be placed in a non-therapeutic research setting in which there was a risk of harm to the child's health.<sup>162</sup> The court discounted both the societal interest in promoting scientific research to benefit children as a group and the interests of parents, and focused instead on the particular child and the children who were appellants in this case.<sup>163</sup> This approach is consistent with those taken by the courts in *Eve, Wentzel, T.D.*, and *Prince*. The court, by implication, rejected both the NIH policy on the inclusion of children in research and the altruistic purpose of any third party, including individual parents who volunteered their child for non-therapeutic research. The court found that the design of the Lead-Based Paint Study was not legally acceptable because it exposed otherwise healthy children, too young to provide assent for their participation in research,<sup>164</sup> to known potential long-term hazardous health effects.<sup>165</sup>

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

160. *Id.*

161. *Id.* at 853. The "best interests of the child" standard is used in child custody cases, and is also the Maryland standard in substituted judgments for estates of a disabled person. See Md. Code Ann., [Health-Gen. II] § 13-713 (2001). For standards pertaining to surrogate decision-making, see Md. Code Ann., [Health-Gen. I] § 5-605 (1993).

162. *Grimes*, 782 A.2d at 852-53.

163. *Id.* at 853.

164. *Id.* at 854 (citing *Bonner v. Moran*, 126 F.2d 121 (1941)) (noting that the doctrine of a "mature minor" could be used to find that some minors were mature enough to provide actual consent for a non-therapeutic medical procedure). It is possible the court in *Grimes* did not issue an opinion on whether mature minors could consent to their participation in non-therapeutic research, because the appellants were ages nine-months and four years, respectively, at the time they were enrolled in the Lead-Based Paint Study. Nor did the court address the issue of whether a child's capacity for providing assent

Focusing on the non-therapeutic nature of the Lead-Based Paint Study, the court stated:

When it comes to children involved in nontherapeutic research, with the potential for health risks to the subject children in Maryland, we will not defer to science to be the sole determinant of the ethicality or legality of such experiments . . . . Moreover, in nontherapeutic research using children, we hold that the consent of a parent alone cannot make appropriate that which is innately inappropriate.<sup>166</sup>

The court then concurred with the holding in *T.D.* and modeled its own holding on the language used by the New York court: “[a] parent or guardian . . . 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 . . . .”<sup>167</sup> In doing so, the court took an absolutist rather than a relativistic perspective; neither parental consent, nor improvement in the information provided as the basis for parental consent would have made the Lead-Based Paint Study either ethically or legally permissible.<sup>168</sup> The court found that the study “was wrong in the first instance.”<sup>169</sup> In a ruling that stunned the biomedical research institutions in the state, the court held that “in Maryland a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject.”<sup>170</sup>

The Johns Hopkins University interpreted the holding as prohibiting the conduct of most non-therapeutic research involving children in the State of Maryland unless researchers obtain court approval for the study.<sup>171</sup> Rather than obtain this type of court approval, the University stated that researchers would conduct their studies outside the state.<sup>172</sup> Studies likely to be affected by the court’s holding include vaccine research and investigational studies of new drugs seeking FDA approval.<sup>173</sup> The University also stated that the court’s ruling was

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would affect the legal authority of parents to consent to their child’s participation in non-therapeutic research.

165. *Id.* at 852-53.

166. *Id.* at 855.

167. *Id.* at 856.

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

169. *Id.* at 858.

170. *Id.*

171. Johns Hopkins University, Lead-Based Paint Study, *at*

<http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/leadfactsheet.htm> (last visited Oct. 10, 2002).

172. *Id.*

173. *Id.*

inconsistent with existing federal regulations, which had been developed with the input of scientists, ethicists, federal agencies, and representatives of patient advocacy groups.<sup>174</sup>

The Institute's Motion for Reconsideration argued that the court, in its treatment of the "ancillary" issue of parental consent, not only went beyond the relief sought by the appellant, but had far reaching consequences for hundreds of research studies involving children currently underway in the State of Maryland.<sup>175</sup> The Institute stated that this holding was the type of policy issue that was more appropriately the function of the legislature.<sup>176</sup> The Institute also pointed out that the use of the term "any risk" was both unprecedented and extreme in that it did not conform to more commonly used "minimal risk" criteria regarding research associated with risks to children inherent in everyday life.<sup>177</sup>

The Institute's motion focused on a definition of everyday life for residents of Baltimore City, and specifically children living in the types of housing included in the study.<sup>178</sup> The Institute argued that the children participating in the study benefited by being able to live in housing with safer lead content levels than those available in the rest of the community, and the children received monitoring of the lead levels in their blood during that time.<sup>179</sup> The Institute also argued that the court's holding violated the Supremacy Clause of the United States Constitution because it conflicted with existing federal policies concerning children in research and regulations for the protection of human subjects.<sup>180</sup>

Research institutions filed amicus briefs in an attempt to overturn the holding.<sup>181</sup> These institutions were also concerned that the effect of the holding would be to shut the door to all research involving children unless it had a direct health benefit to the child.<sup>182</sup> The NCLSH and the PJC asked the court to revise its opinion and not prohibit parents from consenting to the participation of their

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174. *Id.*

175. Appellee's Motion for Partial Reconsideration and Modification of Opinion, *Grimes* (No. 128), available at <http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/kennedykriegermotion.htm> (last visited Oct. 10, 2002).

176. *Id.*

177. *Id.*

178. *Id.*

179. *Id.*

180. *Id.*

181. The Association of American Medical Colleges (AAMC), Association of American Universities, Johns Hopkins University, University of Maryland Medical System Corporation (UMMSC), University of Maryland, Baltimore (UMB), National Center for Lead-Safe Housing (NCLSH), and the Public Justice Center (PJC) all filed amicus briefs [hereinafter AAMC et al.].

182. See AAMC Brief, *infra* note 184, at Argument ¶ 2; UMB Brief, *infra* note 193, at Interest of Amicus Curiae, Introductory Statement ¶ 7; PJC Motion, *infra* note 183, at Position of Amicus PJC ¶ 1.

children in research that meets existing federal regulations.<sup>183</sup> The university-based amicus briefs documented the consequences of the holding's prohibition on children's participation in research with "any risk" on the future of pediatric research in general and advocated for parental consent for research involving children that was conducted under the existing federal regulations.<sup>184</sup>

The AAMC et al. noted that the impact of the court's holding regarding parental consent would result in lost advances in medical and public health knowledge with the consequence that cures for diseases and the prevention of suffering and loss of life would be seriously hampered.<sup>185</sup> It pointed out that research involving children was conducted under the existing legal framework of federal regulations, IRB oversight, and the civil tort system.<sup>186</sup> The brief advanced two main arguments: 1) that "non-therapeutic research is an essential component of medical research,"<sup>187</sup> and 2) that "risk is an inevitable consequence of medical research."<sup>188</sup> Non-therapeutic research included the use of randomized, double-blind trials in which placebos are given to one set of participants. Yet, because there is no therapeutic value from the placebo, that type of research would be prohibited in Maryland.<sup>189</sup>

The AAMC et al. argued that, as risk was inevitable in medical research, to prohibit children's participation in studies with "any risk" would be "inconsistent with medical research."<sup>190</sup> The use of the "any risk" standard was contrasted with definitions used for the categories of "minimal risk" and "minor increase over minimal risk" in the existing federal regulations and found to be inconsistent with those regulations.<sup>191</sup>

The AAMC et al. further argued that the existing federal regulations permit research without benefit to each participant, and that, "[i]f the legal standard is that the research must be therapeutic for each and every individual involved who faces

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183. Motion by the National Center for Lead-Safe Housing for Leave to File Memorandum as Amicus Curiae Urging Partial Reconsideration and Modification of Opinion at Position of Amicus ¶ 4, *Grimes* (No. 128), available at <http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/leadsafebrief.htm> (last visited Oct. 10, 2002) [hereinafter NCLSH Brief]; Motion by the Public Justice Center for Leave to File Memorandum as Amicus Curiae in Partial Support of Appellee's Motion for Partial Reconsideration and Modification of Opinion at Position of Amicus PJC ¶ 2, *Grimes* (No. 128), available at <http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/PJcmotion.htm> (last visited Oct. 10, 2002) [hereinafter PJC Motion].

184. Brief of Amicus Curiae Association of American Medical Colleges et al. at Introduction ¶ 2, *Grimes* (No. 128), available at <http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/briefs.htm> (last visited Oct. 10, 2002) [hereinafter AAMC Brief].

185. *Id.*

186. *Id.*

187. *Id.*

188. *Id.*

189. AAMC Brief, *supra* note 184, at Argument ¶ 4.

190. *Id.*

191. *Id.*

any risk, a great deal of health research involving children, and other persons under legal disability . . . including research regarding the causes, progression, prevention, and treatment of conditions of high morbidity and mortality, could never be conducted.”<sup>192</sup>

The UMB brief took a different approach, asking the court to clarify the meaning and scope of its holding with respect to parental consent so that researchers and university administrators could apply the correct legal standard to their studies involving children.<sup>193</sup> UMB suggested the court’s holding be viewed in two ways: 1) that parents were prohibited from consenting to research with any risk to the health of the child, and 2) within the context of *Grimes*.<sup>194</sup> UMB argued that when the court’s reasoning is reviewed in the context of *Grimes*, the holding permitted parental consent for a child’s participation in “genuinely risky research without anticipated direct benefit to the subjects,” but permitted “research involving children which is authorized by existing federal regulations.”<sup>195</sup> The UMB brief invited the court to clarify its holding and tie it more specifically to the facts as presented by the appellants. Furthermore, the UMB brief gave the court a way to clarify its holding to remove inconsistencies with existing federal regulations and to provide clearer direction to researchers and their institutions for the conduct of future research.

In October 2001, the Court of Appeals of Maryland denied the appellee’s Motion for Reconsideration, but proceeded to clarify its holding with respect to parental consent for children’s participation in non-therapeutic research.<sup>196</sup> By “any risk,” the court stated that it meant “any articulable risk beyond the minimal kind of risk that is inherent in any endeavor.”<sup>197</sup> The court emphasized, in the manner advocated by UMB’s brief, that the context for this portion of its holding was a non-therapeutic study with no direct medical benefit to the child.<sup>198</sup> On remand, the court left to the circuit court the question of whether the Lead-Based Paint Study offered a benefit to the participating children.<sup>199</sup>

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192. *Id.*

193. Brief of Amicus Curiae University of Maryland, Baltimore at Interest of Amicus Curiae and Introductory Statement ¶ 6, *Grimes* (No. 128), available at <http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/Umbrief.htm> (last visited Oct. 10, 2002) [hereinafter UMB Brief].

194. *Id.*

195. *Id.*

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

197. *Id.* at 862.

198. *Id.*

199. Given the arguments advanced in its Motion for Reconsideration, it is anticipated that the Institute would argue that the Lead-Based Paint Study conferred a benefit on the children who participated in the study.

VI. IMPLICATIONS OF *GRIMES V. KENNEDY KRIEGER INSTITUTE, INC.* FOR CHILDREN'S PARTICIPATION IN BIOMEDICAL RESEARCH

The court's clarification of its holding on parental consent for children's participation in non-therapeutic research is regarded to some extent as being in conformity with 45 C.F.R. § 46 and its provisions for the participation of children in research involving minimal risks.<sup>200</sup> Although the court did not explicitly state that parental consent was permissible for research which conformed to existing federal guidelines, it appears that the court intended to permit research falling within the first two of the four categories of the existing federal regulation.<sup>201</sup> That is, parents can consent to their child's participation in research "that does not involve greater than minimal risk,"<sup>202</sup> and to research "involving greater than minimal risk but having direct benefits for the child."<sup>203</sup> However, parents cannot consent to their child's participation in research "involving greater than minimal risk and no direct benefit, but which has the possibility of developing generalized knowledge about the child's particular disorder or condition."<sup>204</sup> Additionally, parents cannot consent to research "which would not otherwise be approvable, but which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children."<sup>205</sup> The holding remains inconsistent with federal policy and existing federal regulations. Altruistic motivations of parents could no longer justify children's participation in biomedical research, unless the risk to the child is minimal, or unless the direct benefit to the child justifies his or her participation in research involving "greater than minimal risk."

The court followed the approach taken by the courts in *Eve, Wentzel, T.D.*, and *Prince*, and focused on the individual child's best interests and the direct benefit of the research for the child, while disregarding the altruistic interests of third parties, such as parents or guardians, and societal interests in promoting medical knowledge about conditions affecting children. *Grimes* followed the common law rule that parents may be authorized to promote the best interests of their own children, but not children in general.

Several components of the court's clarification are still unclear. The court does not define "articulable risk" and risk that is "inherent in any endeavor." By

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200. Press Release, Kennedy Krieger Institute, Johns Hopkins Response to Court of Appeals Ruling in Lead Paint Case, *available at* <http://www.hopkinsmedicine.org/press/2001/OCTOBER/courtfofappeals.htm> (last visited Oct. 10, 2002).

201. Author's recollection of class discussion, Law & Biomedical Sciences Seminar: Medical Research, University of Maryland School of Law (Fall 2001) (notes on file with author).

202. 45 C.F.R. § 46.404.

203. *Id.* § 46.405.

204. *Id.* § 46.406. The *Grimes* decision raises concern that genetic studies that involve children, which may fall within this third category, would no longer be permitted in Maryland.

205. *Id.* § 46.407.



“articulable risk,” the court is thought to mean “minimal risk,” defined in the federal regulations as “risk to children inherent in everyday life.” However, another court might interpret this term differently. When the court describes acceptable risk as that “inherent in any endeavor,” it may mean general levels of risk that children experience as a class. It could also mean the risk that is inherent in the experience of a subset of children, such as those living in housing stock that contains lead-based paint. Based on arguments advanced in its Motion for Partial Reconsideration and Modification of Opinion, it would appear that the Institute would adopt the latter interpretation.<sup>206</sup>

In addition, the court does not make it clear whether research having no direct benefit to the child would be permitted in Maryland if it were first subjected to judicial review and approval by the court. The court’s holding may mean that Maryland children are not allowed to participate in these types of research studies. The court left unanswered the issues of a court’s capacity to review cases involving complex research protocols, and what sorts of costs to the research institution and timelines this would involve.

The appropriate role of the IRB in assuring compliance with the court’s order was also left unanswered by the court’s holding. It is unclear whether the IRB can waive parental consent to enable a minor to consent to his or her own participation in research as permitted under the federal regulations. While the court’s holding states that a parent may not be able to consent to his or her child’s participation in research with “greater than a minimal risk,” and of “no direct benefit to the child,” it gives no indication to the consent capacity of a mature minor to participate in research that has “more than a minimal risk” and no “direct benefit.”

Furthermore, the status and breadth of research currently underway in Maryland that falls into the types of research to which parents cannot consent has not been determined by the court’s holding. In order to provide direction to researchers, IRBs, and research institutions in the State of Maryland, these issues need to be discussed further and a set of uniform procedures developed to provide consistency in research. The NIH, FDA and other agencies in the DHHS need to examine this clarification to determine how their policies for the inclusion of children in biomedical research and the existing regulations for research involving children are affected. The existing NIH policy for the inclusion of children as participants in research involving human subjects excludes from its mandate studies which take place in jurisdictions that bar the inclusion of children in research. Presumably, the court’s decision in *Grimes* would exempt certain types of studies conducted in Maryland from including children.

The court’s clarification appears to permit parental consent for children’s participation in research involving no greater than minimal risk. Yet, the court does not reconcile this category of risk with its “best interests of the child”

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206. Appellee’s Motion, *supra* note 175, at Section II ¶ 13.

standard. Because a research protocol does not involve greater than minimal risk, does that mean that procedures conducted under that protocol are something that an infant or young child would welcome, or that a court could justify as being in the best interests of the child? A simple procedure such as a venepuncture is likely to involve some level of discomfort and perhaps pain, or may induce fear in an infant or young child. An unwanted touching is a battery at common law. When these “no greater than minimal risk” procedures have no benefit to the child, does this mean that the court is permitting parents to consent to the battery of their child?<sup>207</sup>

In October 2001, prompted by the court's ruling in *Grimes* and an unrelated death of a research subject participating in a university-based asthma study, the Maryland General Assembly conducted a hearing on the issue of human subjects' participation in research.<sup>208</sup> Representatives of the legal and research community in the State testified, and legislators expressed concern both for the court's involvement in what they believed to be the purview of the legislature and for further oversight of protections for human subjects in the State of Maryland.<sup>209</sup>

## VII. CONCLUSIONS

The court's clarification of its opinion in *Grimes* allows research involving at least two categories of risk to children to continue in Maryland. Yet, provisions for judicial review of protocols with greater levels of risk, the role of the IRB in assuring compliance with this new state policy, and lingering issues related to the use of the best interests of the child standard as it relates to biomedical research still must be addressed. Legislative hearings may provide a forum for these and other issues related to children's participation in biomedical research. Although *Grimes* was a civil negligence case, with no constitutional issues raised by the plaintiffs, it may be regarded as the biomedical research equivalent of a “sentinel event,” sensitizing the courts, researchers, and federal agencies to constitutional issues involved in parental consent for children's participation in biomedical research.

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207. See Baylis & Downie, *supra* note 3, at 50-52 for a discussion of the way in which research protocols involving the breaking of children's skin may be considered aggravated assault under Canadian criminal statutes, even when the parent has consented to their administration. Procedures, which involve the breaking of children's skin, would include venepunctures and lumbar punctures.

208. Matthew Mosk, *Research Shield Discussed in Maryland: Law Sought to Protect Medical Studies*, WASH. POST, Oct. 24, 2001, at B7, available at 2001 WL 29164170.

209. *Id.*