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# WHOSE DUTY IS IT ANYWAY?: THE KENNEDY KRIEGER OPINION AND ITS IMPLICATIONS FOR PUBLIC HEALTH RESEARCH

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On August 16, 2001, the Maryland Court of Appeals issued its Opinion in *Grimes v. Kennedy Krieger Institute, Inc.*<sup>1</sup> The Court shocked the research establishment with its scathing characterization of researchers as untrustworthy individuals willing to inflict harm on vulnerable children or subjects for long-term gains. The Opinion resulted from two lawsuits alleging lead poisoning of children enrolled in a study conducted by Kennedy Krieger Institute, Inc. (KKI). The Court compared the actions of KKI, an internationally known pediatric treatment and research facility, to a long list of historical instances of exploitation and abuse of human research subjects including “the Tuskegee Syphilis Study, the international exposure of soldiers and Navajo miners to radiation, the secret administration of LSD to soldiers, the injection of chronically ill patients with cancer cells without their consent, [and] the typhoid experiment conducted by the Nazis at Buchenwald.”<sup>2</sup>

Moreover, in its 95-page slip Opinion, the Court appeared to hold that “in Maryland, a parent . . . cannot consent to the participation of a child or other person on legal disability in nontherapeutic research or other studies in which there is any risk of injury or damage to the health of the subject.”<sup>3</sup> This statement was particularly alarming to the research community because of its potential to halt virtually all research in the state involving children.<sup>4</sup> The statement, which the

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

2. Lisa Ohrin, *Children as Research Subjects: Grimes v. Kennedy Krieger Institute, Inc.*, MID-ATLANTIC ETHICS COMMITTEE NEWSL. (Law & Health Care Program, U. of Md. Sch. of Law and The Mid-Atlantic Ethics Committee Network, Baltimore, Md.), Fall-Winter 2001, at 4.

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

4. Appellee’s Motion for Partial Reconsideration and Modification of Opinion at 1, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 128) (“[O]n the day the mandate in this case issues, hundreds of fully accredited medical research projects now conducted in Maryland will terminate.”).

Court referred to as a holding, was also puzzling because the issue was raised by the Court rather than at the request of the parties.<sup>5</sup>

Understandably, these facets of the Court of Appeals' Opinion troubled the research community.<sup>6</sup> However, another aspect of the Court's decision may actually be more significant. Arguably, the Court's holding regarding the legal duty of researchers and the scope of that duty, breaks new legal ground and may have more long-term consequences for researchers and research subjects than either the statement on parental consent or the Court's harsh characterization of researchers. The case also raises important questions about where we, as a society, place legal obligations about who has the role to protect vulnerable citizens from harm in a country where individuals do not have safe places to live and access to adequate health and child care.

In this article, we focus on the Court's decision regarding the legal duty of researchers and the role of tort law in mediating between the need for advances in public health research and compensating injured research subjects. We begin by briefly describing the legal basis for establishing a duty of care and the broader policy and societal justifications for finding such a duty. In the second section of the article, we summarize the context of the Kennedy Krieger case focusing on the problem of lead paint poisoning, the objectives of the Kennedy Krieger research, and the experience of two of the children (the plaintiffs) enrolled in the study.

After describing the history of the case and the Court of Appeals Opinion, we discuss two possible interpretations of the Court's decision. In this section, we assert that as a result of confusion in the Opinion regarding the definition of the research study, the Court's decision may result in a significantly broader duty than has been imposed historically in the research setting. In particular, the Court's apparent view that the research risks in this case included the risks of living in lead

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5. See concurring opinion by Judge Raker in which she states that "the majority chooses to go far beyond the narrow question presented in these appeals and addresses a number of ancillary issues in dicta." *Grimes*, 782 A.2d 861. See also, Jack Schwartz, *The Kennedy Krieger Case: Judicial Anger and the Research Enterprise*, 6 J. HEALTH CARE L. & POL'Y 1, 148 (2002) (characterizing this statement of the Court as dicta).

6. As a result of a subsequent motion for reconsideration and modification of the original opinion, researchers were partially relieved. Although the Court denied the motion requesting reconsideration, it clarified its statement regarding the issue of parental consent. The Court noted that by "any risk" it meant "any articulable risk beyond the minimal kind of risk that is inherent in any endeavor." See Order Denying Appellee's Motion for Partial Reconsideration and Modification of the Opinion, *Grimes*, 782 A.2d 807 (Md. 2001) (Nos. 128 and 129). The clarification made the statement more consistent with, although not identical to, the federal rules on research with children. The holding would not permit parental consent for nontherapeutic research with children above minimal risk. The federal rules permit such research if it is a "minor increment" above minimal risk. See 45 C.F.R. § 46.406 (2001). And, while the Court's Opinion on this issue is arguably dicta, the clarification alleviated some of the concerns of researchers who saw the Court's statement as indicative of action the Court might take in the future, if given the opportunity, or as a recommendation to the legislature to take action on this issue.

painted housing is at odds with more traditional views of public health research which arguably would view the risks as those arising from the collection of dust and blood samples. This broader view has significant implications for the scope of the duty required of researchers in what might be described as observational public health studies.

The Opinion is particularly troubling because it can lead to a significant burden for researchers in two ways: 1) adoption of the Court's broad interpretation of what constitutes the research endeavor and its associated risks (a factually based view), or 2) adoption of the Court's articulated holding in conjunction with a narrow view of the research project and its associated risks (a legally grounded perspective). The holding, on its face and as applied to a traditional (narrow) view of the research, calls for the disclosure of risks that may not be a result of participation in the research project.

In addition to exploring the contrasting interpretations of the Court and the researchers regarding what constitutes the research project in this case, we "deconstruct" the scope of the duty as articulated by the Court and pose a series of questions as to how such a duty might be discharged and how realistic the Court's apparent expectations are regarding the duty of researchers. Finally, we discuss the implications of the Court's broad based duty requirement in the context of public health studies and raise the question whether the Opinion may ultimately have negative consequences for the future of public health research in Maryland and for the compensation of injured parties.

We argue that the ultimate result may lead to paralysis in similar public health studies and have negative consequences for such research in Maryland as well as for the compensation of victims of research harms or harms arising from exposure to public health risks. If, in fact, the Court's decision stifles public health research, society will suffer because we will not have the data on which to base needed public health reforms. Moreover, individuals who are harmed as a result of exposure to noxious substances in the environment or in their homes, whether or not as a result of participation in a research protocol, may suffer as well. Without the public health and epidemiological data generated by research studies individuals will be unable to prove causation and will not be compensated for their injuries.

## I. THE BASIS OF A LEGAL DUTY AND THE GOALS OF TORT LAW

The first element of a successful claim based on negligence requires a showing that the alleged "tortfeasor" had a legal duty of care to the plaintiff.<sup>7</sup> In

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7. The duty requirement is consistent with the traditional framework of tort law but arguably takes sides in an ongoing debate between legal scholars over the appropriateness of duty as an element in negligence cases. *Compare* RESTATEMENT (THIRD) OF TORTS § 7 (Tentative Draft No. 1, 2001) with RESTATEMENT (THIRD) OF TORTS § 7 (Tentative Draft No. 2, 2002). The other elements necessary for

general, the law holds that one has a duty to act reasonably to prevent physical harms to others that might result from one's affirmative acts but, as to inaction, the law provides that there is "no duty to act affirmatively for the benefit of others in the absence of some special relationship."<sup>8</sup>

In the case of affirmative acts, most often the duty is characterized as reaching to foreseeable risks of the conduct in question.<sup>9</sup> When A is injured as a result of B's failure to act, however, the law is much more forgiving and, absent certain narrow circumstances, the law provides that one does not have a duty to act to protect another, i.e., to rescue or be a Good Samaritan. While there may be a moral duty in such circumstances, our legal system has determined that "the law should not try to enforce unselfishness or make one person serve his fellows."<sup>10</sup> Those who support the "hands off" doctrine argue that it is justified by our strongly engrained societal beliefs in individual freedom of action along with the difficulty of implementing any "general duty to act for the benefit of others."<sup>11</sup>

The limited circumstances in which liability for failure to act can attach include cases involving a contractual relationship or other special relationship between the parties.<sup>12</sup> As regards a contractual agreement, an individual may be liable for harms based on actions he or she promised via contract to perform but failed to carry out.<sup>13</sup> A special relationship, beyond contract, has been

establishing negligence include: breach of the duty owed by the defendant to the plaintiff; harm to the plaintiff; and evidence that the harm resulted from the defendant's breach. *See* *Richwind Joint Venture v. Brunson*, 645 A.2d 1147, 1151 (Md. 1994).

8. DAN B. DOBBS, *THE LAW OF TORTS*, § 227, at 579 (2000). In actuality, this does not mean that one has no duty to others but that one has no duty to act or behave in an affirmative manner. *Id.*

9. *See* HARPER, JAMES & GRAY, *THE LAW OF TORTS* § 18.2, at 654 (2d ed. 1986). An exception, carved out of this general rule, occurs when an individual assumes the risk by virtue of consenting to it. In such cases, the defendant may have no duty to the plaintiff as regards that particular risk and as a result of the consent the responsibility for any harm is shifted to the plaintiff. DOBBS, *supra* note 8, § 212 at 540.

10. *See* HARPER, JAMES & GRAY, *supra* note 9, § 18.6, at 725. The authors assert that such a rule "represents an attitude of rugged, perhaps heartless, individualism." *Id.* at 719. However, they also state that courts and legislatures are making a number of exceptions to this rule. For example, "many states have statutes requiring motorists to stop and give first aid to those whom they have injured without regard to questions of fault, and a few courts have held a defendant liable for failure to furnish his victim reasonable help, though he was faultless in inflicting the original injury, or for failure to take protective steps to shield plaintiff from a danger that defendant has innocently created." *Id.* § 18.6, at 721 (footnotes omitted). Those who are critical of the general rule believe that the law should "reflect virtues like compassion as well as a central interest in liberty." *See* DOBBS, *supra* note 8, § 314, at 854.

11. *See* DOBBS, *supra* note 8, § 314, at 854 (*citing* Richard Epstein, *A Theory of Strict Liability*, 2 J. LEG. STUDIES 151, 198 ff. (1973)). Others assert that "a general duty of reasonable rescue would violate important legal process values and would be unmanageable." *Id.* (*citing* James A. Henderson, Jr., *Process Constraints in Tort*, 67 CORNELL L. REV. 901, 930 (1982)).

12. Other types of cases where nonaction can result in liability include situations where the defendant creates the risk of harm or the defendant undertakes "an affirmative action that is either cut short or performed negligently," e.g., a rescue attempt. *See* DOBBS, *supra* note 8, § 314, at 854.

13. While tort law may establish duties beyond what is required under contract, "where defendant's negligence ends merely in nonperformance of the contract and where defendant is not under

acknowledged by the courts in a number of specific formal relationships including common carriers and passengers, employers and employees, owners of land and persons invited on to their premises, innkeepers and their guests, and custodians and their wards.<sup>14</sup> While these relationships are well recognized and widely accepted as generating special duties, the list of special relationships that courts have acknowledged is much longer. It has included, for example, parent-child, school-student, and doctor-patient relationships.<sup>15</sup>

In determining whether a relationship outside of these recognized special relationships warrants a duty of care, courts have often considered the policy issues involved and have balanced a number of factors including:

[T]he burden it would put on defendant's activity; the extent to which the risk is one normally incident to that activity; the risk and the burden to [the] plaintiff; the respective availability and cost of insurance to the two parties; the prevalence of insurance in fact; the desirability and effectiveness of putting the pressure to insure on one rather than the other, and the like.<sup>16</sup>

The recognition of a duty as a result of any of the above criteria is not, in and of itself, determinative of liability. The court must also establish the scope of that duty—what specific actions the defendant was obliged to take given the circumstances. In cases involving strangers, the duty owed in most cases is to act as a reasonable person would in similar circumstances. However, when individuals are in a special relationship, courts have often imposed a different level of duty.<sup>17</sup> For example, in the case of health care providers and patients, the professional typically owes the duty of care established by his or her peers.<sup>18</sup>

The rules regarding duty and tort law, more generally, have been established to accomplish certain societal objectives, chief among them the compensation of injured parties and the deterrence of undesirable or risky behavior. These objectives are based on a set of larger societal goals including moral responsibility

any recognized duty to act apart from contract, the courts generally still see no duty to act affirmatively except the duty based on—and limited by—defendant's consent." See HARPER, JAMES & GRAY, *supra* note 9, § 18.6, at 727 (footnotes omitted).

14. See RESTATEMENT (SECOND) OF TORTS, §§ 314A-314B (1965).

15. See, e.g., *Myers v. Quesenberry*, 193 Cal. Rptr. 733 (1983), in which physicians were held subject to a duty to their patient to warn her not to drive in an uncontrolled diabetic condition, and were held subject to liability to a third person who was injured by the patient's car when it went out of control, on the theory that such injury was a foreseeable consequence of the breach of the doctors' duty to the patient.

16. See HARPER, JAMES & GRAY, *supra* note 9, § 18.6, at 730.

17. In some cases the standard has been lower; in others, higher. For example, courts traditionally held that "landowners owed only the duty to not wantonly or intentionally injure trespassers and licensees." See DOBBS, *supra* note 8, § 228 at 581.

18. This duty was sometimes of the highest quality but sometimes woefully unsafe . . . " *Id.*

and corrective justice between parties and societal welfare. With regard to corrective justice, the goal of tort law is to inculcate personal and institutional responsibility on the part of individuals and organizations for their harmful actions and to correct wrongs through some form of redress or compensation. This goal, however, can sometimes conflict with the goal of societal welfare. As a result, courts will often take into account the social utility of a particular outcome in terms of its costs and benefits to society when contemplating the need for corrective justice.<sup>19</sup>

## II. THE CONTEXT OF THE CASE

### A. *The Problem of Lead Paint Poisoning*

Lead paint continues to be a major public health problem today, despite the fact that its potential for harm was known as far back as the early 1900's.<sup>20</sup> According to the U.S. Department of Housing and Urban Development (HUD), almost one million children under the age of six suffer from elevated lead levels which, if untreated, could lead to lead poisoning and approximately "one in three households with young children has significant lead-based-paint hazards."<sup>21</sup> Lead contaminated house dust is a major contributor to lead exposure. The lead gets into the air when house dust becomes contaminated by lead-based paint inside a home and the paint peels, deteriorates, or flakes. Children typically ingest lead particles via hand to mouth contact.<sup>22</sup>

Authorities state that it is impossible to totally eliminate the risk of lead poisoning in such houses and that modern lead hazard control methods on average reduce levels of lead contaminated house dust by about 60%.<sup>23</sup> Those most at risk for lead poisoning are children from low-income families.<sup>24</sup> Lead poisoning can

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19. *Id.* § 8, at 12-13.

20. Gerald Markowitz & David Rosner, "Cater to the Children": *The Role of the Lead Industry in a Public Health Tragedy, 1900-1955*, 90(1) AM. J. PUB. HEALTH 36, 37 (Jan. 2000). During the first half of the century other countries restricted the use of lead in paint; however this was not the case in the United States. *Id.* at 37. In the 1950s the lead industry started limiting the amount of lead in interior paints. *Id.* at 44.

21. OFFICE OF LEAD HAZARD CONTROL, U.S. DEP'T OF HUD, NAT'L SURVEY OF LEAD AND ALLERGENS IN HOUSING: FINAL REPORT ES-5 (2001).

22. CDC AND PREVENTION, U.S. DEP'T OF HEALTH & HUM. SERVS., SCREENING YOUNG CHILDREN FOR LEAD POISONING: GUIDANCE FOR STATE AND LOCAL PUBLIC HEALTH OFFICIALS 13 (1997).

23. PRESIDENT'S TASK FORCE ON ENVTL. HEALTH RISKS & SAFETY RISKS TO CHILDREN, ELIMINATING CHILDHOOD LEAD POISONING: A FEDERAL STRATEGY TARGETING LEAD PAINT HAZARDS 4 (2000). In addition to exposure from their homes, children may also be exposed to lead outside of their homes as it exists in soil, dust and drinking water. See NAT'L SURVEY OF LEAD AND ALLERGENS IN HOUSING: FINAL REPORT, *supra* note 21, at 1-2.

24. For example, among low income children ages 1 – 5, 8.0% have a blood lead level greater than 10 µg/dL compared to 1.0% of high-income children and 1.9% of middle income children. In addition,

cause permanent brain damage and has been linked to behavioral problems and, in severe cases, can cause death.<sup>25</sup> The Centers for Disease Control (CDC) has classified blood lead levels in children into categories from “normal” to “moderately elevated,” “highly elevated” and “urgently elevated.” At levels considered moderately elevated, medical interventions include education to reduce exposure and absorption. At highly elevated levels, education along with a medical exam and case management are recommended. At urgently elevated levels, chelation therapy is recommended.<sup>26</sup>

Although there are several laws that currently affect the sale or rental of homes with lead paint,<sup>27</sup> at the time of the Kennedy Krieger study, there were few

11.2% of African American children have a blood lead level (BLL) greater than 10 µg/dL, compared to 2.3% of white children ages 1–5. SCREENING YOUNG CHILDREN FOR LEAD POISONING: GUIDANCE FOR STATE AND LOCAL PUBLIC HEALTH OFFICIALS, *supra* note 22, at 41.

25. Lead is a toxin that affects the central nervous system and is damaging to the developing nervous system of young children and fetuses. High levels of lead can result in convulsions, mental retardation, kidney damage, severe anemia, and, at times, death. Lower lead levels can result in reduced intelligence and short-term memory, damage to the reproductive system, poor hand-eye coordination, slow reaction times, reduced height, hearing problems, and numerous behavioral problems. *See* NAT'L SURVEY OF LEAD AND ALLERGENS IN HOUSING: FINAL REPORT, *supra* note 21, at 1-1. At a level as low as 10 µg/dL, reduced IQ, hearing, growth and behavioral problems can occur. *See* ELIMINATING CHILDHOOD LEAD POISONING, *supra* note 23, at 11.

26. The CDC classifies blood lead level concentrations in children as follows:

Class I (Normal) – less than or equal to 9 µg/dL

Class IIA (Moderately elevated)–10–14 µg/dL

Class IIB (Moderately elevated)–15–19 µg/dL

Class III (Highly elevated)–20–44 µg/dL

Class IV (Urgently elevated)–45–69 µg/dL

Class V (Critically elevated)–greater than or equal to 70 µg/dL

*See* Grimes, 782 A.2d 807, 825 n.23 (citing CDC, PREVENTING LEAD POISONING IN YOUNG CHILDREN (Oct. 1, 1991)). The American Academy of Pediatrics recommends that for a blood lead level (BLL) between 10–14 µg/dL, education should be provided to decrease blood lead exposure; between 15–19 µg/dL, education should be provided to decrease blood lead exposure and lead absorption and an environmental history should be taken; at levels of 20–44, µg/dL all the previous measures should be taken and, in addition, a full medical examination and case management should be provided. For any BLL greater or equal to 45 µg/dL, chelation therapy should be started. At levels of 70 µg/dL or above, hospitalization and immediate chelation therapy is required. *Am. Academy of Pediatrics, Screening for Elevated Blood Levels*, 101 PEDIATRICS 1072, Tbl. 3 (June 1998).

Chelation therapy involves using an agent to bind lead ions thereby removing them from circulation and lowering the blood lead level while forming a water soluble complex that can be excreted in urine. *See* Morri Markowitz, *Lead Poisoning: A Disease for the Next Millenium*, 30(3) CURRENT PROBLEMS IN PEDIATRICS 62, 67 (Mar. 2000).

27. The primary federal law that addresses lead paint abatement is the Residential Lead Based Paint Hazard Reduction Act (Title X) of 1992. 42 U.S.C. §§ 4851–4856 (2000). The Act, which became effective in 1994, applies to any housing constructed prior to 1978 if the owner applies for mortgage insurance or receives housing assistance payments under a program administered by the Secretary of HUD, or receives more than \$5,000.00 in project-based assistance under a federal housing program. Exceptions include zero bedroom units, housing leased for less than 100 days, housing for the elderly, housing for the handicapped, and rental housing inspected and determined to be free of lead-based paint. 15 U.S.C. § 2681(17) (2000).



applicable laws or regulations. At the state level, the relevant law was the Department of Environment's Procedures of Abating Lead Containing Substances from Buildings.<sup>28</sup> These regulations, in effect since 1988, do not require that any homeowner or landlord undertake any lead paint abatement, however, if the homeowner or landlord does undertake such abatement, the regulations specify the appropriate procedures and clean up methods. In order to meet the "clearance standards" for complete lead paint abatement under this law, lead levels in dust samples must meet the following criteria:

- Floor lead dust levels are below 200 micrograms per square foot;
- Windowsill lead dust levels are below 500 micrograms per square foot;
- Window well lead dust levels are below 800 micrograms per square foot; and

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Those covered must be given lead hazard information pamphlets and must undergo periodic risk assessments and interim controls in accordance with a schedule determined by the Secretary. Specific provisions of the Act include: i. disclosure of known lead-based paint and/or lead-based paint hazards by persons selling or leasing housing constructed before 1978, which is the phase out year of residential lead based paint use, and that buyers/renters receive specific information on lead-based paint as well as information on low-cost tips on identifying and controlling lead-based paint hazards, 42 U.S.C. § 4852d(a) (2000); ii. standards for lead-based paint hazards and lead dust cleanup levels in most pre-1978 housing and child-occupied facilities, *Id.*; iii. ensuring that individuals conducting lead-based paint abatement, risk assessment, or inspection are properly trained and certified, 15 U.S.C. § 2682(a)(1) (2000); iv. ensuring that owners and occupants of pre-1978 housing are provided information concerning potential hazards of lead-based paint exposure before certain renovations are begun. Under the Act, owners may also be given grants for lead-based hazard reduction. 42 U.S.C. § 4852. Grants must be made available to families below certain income levels and in all cases the landlord is to give priority in renting units that have undergone lead paint hazard reduction to families with a child under the age of six years. *Id.*

At the state level, current laws include the Maryland Reduction of Lead Risk in Housing Program and the Lead Hazard Reduction Grant Program and Lead Hazard Reduction Loan Program. MD. ENVIR. CODE ANN., §§ 6-801 – 852 (2002); MD. ANN. CODE Art. 83B, §§ 2-140 –1411 (1998 Repl. Vol.) Both were passed by the state legislature in 1994. The Reduction of Lead Risk in Housing Program requires owners of older residential properties to meet certain risk reduction standards upon each change in tenancy, including passing a lead dust "clearance test" or undertaking appropriate lead hazard reduction treatments. MD. ENVIR. CODE ANN., §§ 6-815 (2002). Owners, beginning in 1996, were also required to provide new tenants with informational pamphlets about how to protect their families from lead based paint in their home and tenant's rights regarding lead poisoning. § 6-820, §6-823. By 2001, owners were required to certify that 50% of their rental units received full risk reduction treatments, and by 2006, they must certify that 100% of their units have received full risk reduction treatments. § 6-817. Owners who comply with these and other requirements of the law may be protected by limited liability in cases against them for lead poisoning. §6-828.

The grant and loan programs were established to assist owners of residential property or child care centers fund lead hazard reduction activities with an emphasis on activities including the replacement of windows containing lead-based paint on friction surfaces. MD. ANN. CODE Art. 83B, §§ 2-1403 (1998 Repl. Vol.). Criteria for grants include location in an area of the State designated by the Department to be an area with a concentration of children who have been diagnosed with elevated blood lead, or residential property constructed before 1950 and families of limited income. MD. ANN. CODE Art. 83B, §§ 2-1406 (1998 Repl. Vol.).

28. MD. REGS. CODE 26, §§ 02.07.01-02.07.12 (1988).

- All abated surfaces and all floors have been treated to provide smooth and easily cleanable surfaces.<sup>29</sup>

### B. The R&M Study

Since the early 1980s, the KKI has been at the forefront of efforts to prevent and treat the harms associated with lead paint poisoning in children.<sup>30</sup> In an effort to evaluate the effectiveness of selected methods of lead paint abatement, KKI, with funding from the U.S. Environmental Protection Agency (EPA),<sup>31</sup> undertook the Lead Paint Abatement, Repair, and Maintenance Study (R&M Study).<sup>32</sup> Beginning in approximately 1992,<sup>33</sup> KKI recruited property owners to participate in the Study. If they agreed and their housing units met the criteria for participation,<sup>34</sup> their housing units were randomly assigned a lead abatement level of 1, 2, or 3 with “three being the most extensive and costly.”<sup>35</sup> Each of these

29. *Id.* § 12; *See also Grimes*, 782 A.2d at 820 n.13. These standards applied to complete lead paint abatements and were the basis on which an owner could receive a certificate of lead-free housing. *See MD. REGS. CODE* 26, §16.02.05 (1996). There were no standards for partially abated homes. In addition to these standards, the City of Baltimore had established abatement regulations for lead paint. These regulations define a lead-based paint violation and specify methods of abatement and cleanup for such violations. A violation is defined as, among other things: “the presence of lead-based paint on the interior or exterior surfaces of any property . . . that is easily accessible to a child; or that is cracking, peeling, chipping, blistering, or flaking or is in an otherwise deteriorated condition; or that is chalking so that the lead dust generated therefrom is determined by the Commissioner [of the Baltimore City Health Department] to pose a health hazard . . . .” BALTIMORE, MD., ABATEMENT REGULATIONS FOR LEAD PAINT § 5.1 (1987).

30. *See Joanne Pollak, The Lead-Based Paint Abatement Repair & Maintenance Study in Baltimore: Historic Framework and Study Design*, 6 J. HEALTH CARE L. & POL’Y 1, 91 (2002).

31. *See Grimes*, 782 A.2d at 819. KKI received a \$200,000 grant entitled “Evaluation of Efficacy of Residential Lead Based Paint Repair and Maintenance Interventions” from EPA in 1993. *Id.* The project was jointly sponsored by the EPA, the Maryland Department of Housing and Community Development (DHCD), the Baltimore City Health Department, and the Maryland Department of the Environment. *Id.* at 820. According to Joanne Pollak, “In 1990, the EPA, through its Office of Pollution Prevention and Toxics, issued a work assignment to Battelle Memorial Institute, who [sic] in turn subcontracted with Kennedy Krieger, directing the design of a “Lead Paint Abatement & Repair and Maintenance Study in Baltimore.” *See Pollak, supra* note 30 at 96.

32. In his deposition, Mark Farfel, Sc.D., principal investigator of the Study, stated that the reason for doing the Study was that there was “very little documentation for any type of lead hazard introduction short of full abatement.” Brief for Appellants at 4, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 1177).

33. Brief for Appellants at 4, *Grimes* (No. 1177).

34. Criteria for participation included having “been built before 1941, having documented lead-based paint in the unit and elevated levels of lead in dust in at least two sites in the house greater than the clearance criteria standard in Maryland.” *See* Brief for Appellants at 4-5, *Grimes* (No. 1177). *See also Grimes*, 782 A.2d at 822-23.

35. KKI described the levels of abatement as follows: “Level 1 intervention included scraping of peeling and flaking lead-based paint on interior surfaces; limited repainting of some surfaces, wet cleaning with a trisodium phosphate detergent; and vacuuming with a high efficiency particulate air vacuum to the extent possible in an occupied house; the provision of an entry way mat; and stabilization of lead-based paint on exterior surfaces to the extent possible. Level 2 intervention included two key additional elements: use of sealants and paints to make floors smoother and more easily cleanable, and

methods of abatement had previously “been demonstrated to reduce lead dust levels significantly” in affected homes.<sup>36</sup>

There were approximately 25 units assigned to each level. In addition, there were two “control groups”— one that included modern homes (post 1980), and another that included completely abated homes.<sup>37</sup> A total of 108 properties were enrolled in the study. Property owners received loans from the Maryland Department of Housing and Community Development to carry out the abatements.<sup>38</sup>

After the properties were selected, families were enrolled in the study. The enrollment procedures varied based on whether the properties were occupied or unoccupied, and whether the units had been abated prior to the initiation of the study. For occupied properties, Kennedy Krieger researchers interviewed families to determine if they met the criteria for enrollment. These included the presence of one or more children four years of age or younger and “the absence of certain health issues.”<sup>39</sup> If families agreed to participate in the study, the abatements were performed. During the abatement process, families were asked to leave the property for several days so as not to be exposed to lead dust.<sup>40</sup> For properties that had not been occupied, the abatements were completed prior to renting the units and families were approached to enroll in the study after agreeing to rent the unit. If homes had been abated prior to the initiation of the R&M Study, families were approached to determine their eligibility for participation and asked of their interest in participation.<sup>41</sup> In all cases, researchers obtained the consent of the parties to enroll in the study.

During the study period, researchers collected dust samples from the homes of residents living in the housing who agreed to participate in the Study in order to assess environmental lead levels. In addition, researchers monitored blood lead levels of children living in the participating households. According to a published description of the Study, “[e]levated blood lead levels in the children were to be

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in-place window and door treatments to reduce abrasion of lead-painted surfaces. Level 3 added window replacement and encapsulation of exterior window trim with aluminum coverings as the primary window treatment, encapsulation of exterior door trim with aluminum, and the use of coverings on some floors and stairs to make them smooth and more easily cleanable. Memorandum of Points and Authorities in Support of Motion to Dismiss at 2-3, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 1177). See also *Grimes*, 782 A.2d at 821-22.

36. Robert M. Nelson, *Nontherapeutic Research, Minimal Risk, and the Kennedy Krieger Lead Abatement Study*, 23 IRB ETHICS & HUM. RES. 7, 7 (2001).

37. Memorandum of Points and Authorities in Support of Motion for Summary Judgment at 2, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 01600); See also *Grimes*, 782 A.2d at 820.

38. *Grimes*, 782 A.2d at 821 n.15.

39. See Pollak, *supra* note 30 at 99.

40. *Id.* at 100.

41. For a more complete description of the enrollment process see Pollak, *supra* note 30 at 98-101.

reported to the family immediately; environmental lead levels were to be provided as well, but less promptly, allegedly due to delays caused by EPA testing specifications.”<sup>42</sup>

*C. The Experiences of Myron Higgins and Ericka Grimes*

On May 13, 1994, Catina Higgins, mother of Myron Higgins, leased an apartment at 1906 E. Federal Street in Baltimore City from Lawrence Polakoff. Polakoff had been approached by KKI and agreed to have his property undergo a level 2 abatement. The abatement, as described above, was completed prior to the unit being rented. Ms. Higgins learned of the unit from an ad in the paper and was interested in renting it because of the rental fee.<sup>43</sup> Prior to moving into the unit, Ms. Higgins was asked to review and sign a lease addendum which stated that “eating, chewing paint or plaster or household dust that contains lead, by children, especially under 6 years of age, may cause severe illness.”<sup>44</sup> The document also advised her to notify the owner or landlord if she found any “chipping or peeling paint throughout the property,”<sup>45</sup> and to include on the lease addendum any areas of the unit containing “loose, chipping, or flaking paint.”<sup>46</sup> Ms. Higgins signed the addendum and did not include any statement about the condition of the paint.<sup>47</sup>

Viola Hughes, mother of Ericka Grimes, moved into an apartment located at 1713 N. Monroe Street in Baltimore City in the summer of 1990. The unit had been “completely abated” as of October 15, 1990.<sup>48</sup> Ericka Grimes was born on May 30, 1992, approximately two years later.<sup>49</sup>

At the time Higgins and Hughes were approached by KKI to participate in the R&M Study, Myron Higgins was approximately four and one-half years old, and Ericka Grimes was ten months old. KKI researchers asked each parent to sign an informed consent form stating that lead poisoning in children was a problem in Baltimore City, that their housing unit had undergone or would undergo lead

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42. Robert M. Nelson, *supra* note 36, at 7. Nelson also reports that the “blood lead levels declined in nearly all the children involved in the study, significantly for some. Based on the demonstrated effectiveness of affordable lead abatement methods, the program has been replicated in 13 other cities.” *Id.* See Pollak, *supra* note 30 at 99, *citing* U.S. EPA, PUB. NO. 747-R-005, LEAD-BASED PAINT ABATEMENT AND REPAIR AND MAINTENANCE STUDY IN BALTIMORE: FINDINGS BASED ON TWO YEARS OF FOLLOW-UP 25 (1997).

43. The ad listed the property at a rental of \$315/month. Brief for Appellants at 3, *Grimes* (No. 1177). See also *Grimes*, 782 A.2d at 827.

44. See Memorandum of Points and Authorities in Support of Motion to Dismiss at 4, *Grimes* (No. 1177).

45. *Id.*

46. *Id.* at 5.

47. *Id.*

48. Plaintiffs disputed this fact. Memorandum in Opposition to Defendant’s Motion for Summary Judgment and In Support of Plaintiff’s Motion for Partial Summary Judgment, at E. 50, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 01600).

49. *Grimes* 782 A.2d at 824.

abatement in order to reduce exposure to lead but that the abatement would not completely eliminate exposure to lead.<sup>50</sup> Furthermore, KKI, through the form, sought permission to collect dust samples from their homes and blood samples from their children.<sup>51</sup>

As part of the study, KKI obtained dust samples from each unit on three to six separate occasions and collected blood samples from each child on three separate occasions.<sup>52</sup> Catina Higgins was informed after the second and third dust

50. Prior to asking Ms. Higgins to sign the consent form, a member of the research team was instructed to say: "I am here because your house had special repairs done before you moved here in order to reduce exposure to lead in paint and dust. We are interested in finding out how well the repairs worked. Can we talk about this study with you and/or the head of the household?" Memorandum of Points and Authorities in Support of Response by Kennedy Krieger Institute to Plaintiff's Opposition to KKI's Motion for Summary Judgment at 5, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 24C-95-066067).

51. The form explicitly stated:

As you may know, lead poisoning in children is a problem in Baltimore City and other communities across the country. Lead in paint, house dust, and outside soil are major sources of lead exposure for children. Children can also be exposed to lead in drinking water and other sources. We understand that your house is going to have special repairs done in order to reduce exposure to lead in paint and dust. On a random basis, homes will receive one or two levels of repair. We are interested in finding out how well the two levels of repair work. The repairs are not intended or expected to completely remove exposure to lead.

We are now doing a study to learn about how well different practices work for reducing exposure to lead in paint and dust. We are asking you and over 100 other families to allow us to test for lead in and around your homes up to eight times over the next two years, provided that your house qualifies for the full two years of study. Final eligibility will be determined after the initial testing of your home. We are also doing free blood lead testing of children aged 6 months to 7 years, up to eight times over the next two years. We would also like you to respond to a short questionnaire every 6 months. This study is intended to monitor the effects of the repairs and is not intended to replace the regular medical care your family obtains.

**BENEFITS:**

To compensate you for your time answering questions . . . we will mail you a check in the amount of \$5.00. In the future we would mail you a check in the amount of \$15 each time the full questionnaire is completed. The dust, soil, water, and blood samples would be tested for lead at the Kennedy Krieger Institute at no charge to you. *We would provide you with specific blood-lead results. We would contact you to discuss a summary of house test results and steps that you could take to reduce any risks of exposure* [emphasis added.] *Grimes*, 782 A.2d at 824-25.

52. The chart below indicates when the samples were taken and when each parent was notified of the results.

<b>Samples:</b>	<b>Dust</b>	<b>Dust</b>	<b>Blood</b>	<b>Blood</b>
<b>Plaintiff:</b>	<b>Date Taken:</b>	<b>Date Parent Notified:</b>	<b>Date Taken:</b>	<b>Date Parent Notified:</b>
<b>Higgins</b>	May 17, 1994	June 24, 1994	June 8, 1994	July 18, 1994**
<b>Higgins</b>	July 25, 1994	Sept. 14, 1994*	July 29, 1994	Aug. 2, 1994**
<b>Higgins</b>	Nov. 3, 1994	Feb. 7, 1995*	Nov. 9, 1994	Dec. 6, 1994**
<b>Grimes</b>	Mar. 9, 1993	Dec. 16, 1993*	Apr. 9, 1993	Apr. 9, 1993***
<b>Grimes</b>	Aug. 23, 1993	Dec. 17, 1993	Sept. 15, 1993	Sept. 29, 1993**
<b>Grimes</b>	Mar. 9, 1994	May 19, 1994	Mar. 25, 1994	Mar. 28, 1994**
<b>Grimes</b>	Sept. 19, 1994	Oct. 28, 1994		

samplings that several samples taken from her unit had lead levels above the clearance levels for lead in dust.<sup>53</sup>

The initial dust samples collected in the Hughes/Grimes household, on March 9, 1993, revealed elevated lead levels (above clearance levels for fully abated homes) in dust in the home but Ms. Hughes was not informed of these results until nine months later.

KKI informed Ms. Higgins and Ms. Hughes of the blood lead level results verbally and in writing. Myron Higgins' initial results were collected approximately 3–4 weeks after moving into the unit. At that time, his blood lead level was "moderately elevated" by CDC standards at 17.5 micrograms per deciliter of blood ( $\mu\text{g}/\text{dL}$ ). The results of his second test were "highly elevated" at 21 $\mu\text{g}/\text{dL}$ . The results of his third test, although still in the moderately elevated range, showed a decline in lead levels to 10.5  $\mu\text{g}/\text{dL}$ .<sup>54</sup> After the first elevated level, Ms. Higgins was told that she should contact her physician about the results. KKI also reported that the Baltimore City Health Department was notified of Myron's elevated lead levels.

Although Ericka Grimes' initial blood lead levels were normal, her second and third results were elevated.<sup>55</sup> On October 3, 1993, Kennedy Krieger informed the state Lead Registry of Ericka Grimes' elevated test results. The Registry then

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<b>Grimes</b>	Apr. 18, 1995	July 19, 1995		
<b>Grimes</b>	Nov. 13, 1995	Jan. 18, 1996		

\* Plaintiffs informed that home had "hot spots" where lead level was "higher than might be found in a completely renovated [abated] house." *Grimes*, 782 A.2d at 825-28.

\*\* Elevated blood lead levels found. *Id.* at 825-26, 828 (Md. 2001).

\*\*\* The exact date of the notification is unclear from the file. While, the Opinion states the date at April 9, 1993, Appellee's Brief states that Ms. Hughes received notice of the first result (placing Ericka Grimes' blood lead level in the "normal range") on September 29, 1993. *See id.* at 825. *See also* Brief of Appellee at 8, *Grimes* (No.128).

53. It later became apparent that there was a difference of opinion between Higgins and KKI as to whether the samples collected at the initial testing were above the clearance levels and plaintiffs were not informed of high levels at that time. According to Appellant's brief, "lead dust in the second level floor area of the home increased from 75 to 742 micrograms per square foot, the first story floor area increased from 65 to 1684 micrograms per square foot, the first story window well increased from 27 to 4470 micrograms per square foot, and the second floor window well increased from 110 to 8807 micrograms per square foot." Brief for Appellants at 7, *Grimes* (No. 1177). According to KKI, the "elevated" levels were based on a different dust collection method than the method used to establish the clearance levels. The higher levels were a result of an "experimental Cyclone vacuum dust collector. These samples all gave results, which indicated that the lead present therein was far above the accepted Maryland clearance levels . . . . However, according to KKI, the clearance levels are based on dust wipe collection not Cyclone collection. KKI presented evidence that additional samples were collected by the dust wipe technique and that these samples indicated a presence of lead below the Maryland clearance levels." *Grimes* 782 A.2d at 828 n.28.

54. Brief for Appellants at 12, *Grimes* (No. 1177).

55. Ericka Grimes' initial results were normal at 9  $\mu\text{g}/\text{dL}$ . Her second results were elevated at 32  $\mu\text{g}/\text{dL}$  and her third results were elevated at 22  $\mu\text{g}/\text{dL}$ . *See* Memorandum of Points and Authorities in Support of Motion for Summary Judgment at 4, *Grimes* (No. 01600). *See also Grimes*, 782 A.2d at 825.

notified the Baltimore City Health Department. The Department “inspected the property and obtained dust samples on October 13, 1993.” According to KKI, “no elevated levels of lead were found in these samples and the property was discharged from the Baltimore City Health Department on Nov. 3, 1993” with a notation that the property was “lead free.”<sup>56</sup>

### III. THE HISTORY OF THE CASE

#### *A. Initiation of the Law Suits*

Catina Higgins, on behalf of herself and her son, Myron Higgins, filed suit in the Circuit Court for Baltimore City in February, 1993, against Lawrence Polakoff, the owner of the apartment in which she and her son lived. She claimed that, as a result of Polakoff’s negligence in “maintaining, supervising and renting” the apartment, her son was lead-poisoned.<sup>57</sup> Approximately six years later, in April, 1999, Higgins amended her complaint to add KKI and Environmental Services, Inc., the contractor that performed the abatement, as defendants. In the complaint, Higgins alleged that KKI referred to the apartment as “lead safe housing” and that “both Kennedy and Environmental were negligent in undertaking to abate, paint, and repair the premises prior to and/or during the [minor plaintiff’s] occupancy, and [did] so in an unreasonable, incomplete, unworkmanlike, and/or illegal manner.”<sup>58</sup> Furthermore, Higgins alleged that “KKI was negligent in failing to warn her of the lead hazard which KKI and its agents knew or should have known, or had reason to know, existed in the premises.”<sup>59</sup> As a result of this negligence, Higgins claimed that her son suffered permanent brain damage which had caused a “learning disability, shortened attention span, impulsivity, hyperactivity, [and] extreme difficulty reading” and that these problems had led to behavioral and emotional difficulties.<sup>60</sup>

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56. Memorandum of Points and Authorities in Support of Motion for Summary Judgment at 5, *Grimes* (No. 01600). This fact was disputed by plaintiffs in their Memorandum in Opposition to Defendant’s Motion for Summary Judgment and in Support of Plaintiff’s Motion for Partial Summary Judgment, *Grimes* (No. 01600).

57. Amendment By Interlineation at ¶ 1, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 1177). “After discovery, the plaintiff added Chase Management, Inc. and CFOD-2 Limited Partnership to the lawsuit as additional owners and operators of the rental property.” Brief for Appellants at 1, *Grimes* (No. 1177). In 1992, prior to Ms. Higgins’ moving into the unit, Polakoff “transferred ownership of the property to CFOD-2, a limited partnership in which Chase was a general partner.” *Grimes*, 782 A.2d at 829.

58. Amendment By Interlineation ¶ 8, *Grimes* (No. 1177).

59. Memorandum of Points and Authorities in Support of Motion to Dismiss at 2, *Grimes* (No. 1177). Subsequently, Lawrence Polakoff filed a cross claim against KKI and Environmental Services, Inc. seeking indemnity and/or contribution. *Id.*

60. Amendment By Interlineation ¶ 15, *Grimes* (No. 1177).

The Grimes case was initiated on March 11, 1999, when Ericka Grimes, by her mother, Viola Hughes, filed suit in the Circuit Court for Baltimore City against KKI.<sup>61</sup> Grimes alleged that KKI “failed to inform and/or warn” her of lead paint hazards which it had discovered and “failed to take any action to abate said hazards” and that she suffered lead paint poisoning as a result of KKI’s negligence, which caused her “permanent disability, brain injury, and other physical mental and emotional injury.”<sup>62</sup>

### *B. Motions for Summary Judgment*

In response to the complaints and in the midst of discovery, KKI filed a Motion for Summary Judgment in both cases,<sup>63</sup> arguing that the plaintiffs had no cause of action against the defendant because it owed the plaintiff no duty to avoid the alleged injury.<sup>64</sup> Specifically, KKI asserted that it had no “special relationship” with the owner or independent contractor that would require it to exercise “reasonable control over them,”<sup>65</sup> had no duty to warn the plaintiffs of latent defects because such a duty only adheres to the landlord/tenant relationship,<sup>66</sup> and lastly, had no duty because this was not a doctor/patient relationship.<sup>67</sup> Finally KKI stated that if it owed any duty to the plaintiffs, it was a duty to inform them of “the nature of the study they were conducting, the purpose of the study and the

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61. Complaint and Election For Jury Trial, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 01600).

62. *Id.*

63. The Motion for Summary Judgment was filed on February 24, 2000 in the *Higgins* case and on April 19, 2000 in the *Grimes* case. Motions for Summary Judgment, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 1177) (No. 01600).

64. In support of its argument, KKI stated that “[a] duty can be created by contract, by statute, or pursuant to a special relationship that exists between the parties, such as a landlord/tenant relationship or physician/patient relationship” but that no contract or special relationship existed between KKI and the plaintiffs, nor any controlling statute. Memorandum of Points and Authorities in Support of Motion to Dismiss at 8, *Grimes* (No. 01600) (*citing to* *Schweitzer v. Brewer*, 280 Md. 430, 440-41, 374 A.2d 347, 353 (1977)). In response to KKI’s motion, plaintiff, Ericka Grimes, filed a motion for partial summary judgment arguing that she was entitled to judgment as a matter of law on the issue of whether the Defendant owed a duty to her. Plaintiff’s Motion for Partial Summary Judgment, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 01600).

65. Memorandum of Points and Authorities in Support of Motion to Dismiss at 8, *Grimes* (No. 1177). KKI made this argument in response to the plaintiff’s assertion, based on *Lamb v. Hopkins*, 303 Md. 236, 492 A.2d 1297 (1985), that KKI “took charge of the owner and the independent contractor” and was therefore under a duty to “exercise reasonable control over them.” Plaintiff’s Memorandum of Points and Authorities at 7, *Grimes* (No. 1177).

66. Plaintiff’s Memorandum of Points and Authorities at 7, *Grimes* (No. 1177) (*citing to* *New Summit Association v. Nissel*, 73 Md. App. 351, 533 A.2d 1350 (1987)).

67. *Id.*



extent of [their] involvement” and of any risks associated with their participation in the study. According to KKI, it fulfilled each of these requirements.<sup>68</sup>

### *C. The Trial Court Decision and the Appeal*

In April, 2000 and July, 2000, respectively, the Circuit Court for Baltimore City granted KKI’s motions in both cases. In *Higgins*, the judge concluded that KKI was an “institutional volunteer in that community trying to help citizens,” and thus owed no legal duty to the plaintiff or her son.<sup>69</sup> Subsequently, appellants filed appeals in the Court of Special Appeals.<sup>70</sup> On February 8, 2001, prior to consideration by the Court of Special Appeals, the Court of Appeals issued a Writ of Certiorari, thus bypassing a hearing before the Court of Special Appeals.<sup>71</sup>

## IV. THE COURT OF APPEALS DECISION

### *A. The Holding*

The Court of Appeals wrote its opinion in the context of reviewing the decisions of the two trial courts that granted KKI’s motions for summary judgment.<sup>72</sup> As a result, the factual record was not complete and the Court viewed all the evidence in the light most favorable to the appellants.<sup>73</sup> This procedural posture opened the door to the Court’s one-sided and arguably exaggerated fact presentation. By winning at the trial court level on summary judgment, KKI left itself vulnerable, to some extent to these skewed factual assumptions.

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68. Memorandum of Points and Authorities in Support of Response by Kennedy Krieger Institute to Plaintiff’s Opposition to KKI’s Motion for Summary Judgment at 10, Kennedy Krieger Inst., Inc., 782 A.2d 897 (Md. 2001) (No.1177).

69. *Grimes*, 782 A.2d. at 832 (citing to the trial court’s bench opinion). Approximately two months later, on May 4, 2000, Plaintiff Higgins filed a Motion for Reconsideration. See Plaintiff’s Motion for Reconsideration, *Grimes* (No. 1177). On May 25, 2000, the Circuit Court denied this motion without a hearing. Order, *Grimes* (No. 1177).

70. Catina Higgins filed her appeal on July 20, 2000 and Ericka Grimes filed her appeal on July 26, 2000. See Notice of Appeal, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 95066067/CL193461) and (No. 24-C-99-000925). In addition, both plaintiffs dismissed their claims against their respective landlords and owners of the property in order to take an immediate appeal.

71. *Grimes* 782 A.2d at 826. In addition to briefs prepared by appellants (*Grimes* and *Higgins*) and appellees (KKI), amicus briefs were prepared by the Public Justice Center (PJC), in collaboration with the National Health Law Program, and The East Harbor Village Center and by the National Center for Lead-Safe Housing. Brief of Amici Curiae The Public Justice Center, The National Health Law Program, and The East Harbor Village Center, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001)(No. 129).

72. In its Opinion, the Court of Appeals noted that this was a case of first impression and that it found only one case in state or federal courts that was “fairly close on one point” to the issues addressed in this case. *Grimes*, 782 A.2d at 811, 855 (referring to the case of *T.D. v. New York State Office of Mental Health*, 650 N.Y.S.2d 173 (N.Y. App. Div. 1996).

73. *Id.* at 821 n.12; See also *Ashton v. Brown* 660 A.2d 447, 452 (1995) (explaining the standard of review for decisions based on a motion for summary judgment).

Consistent with this posture, the Court adopted the question at issue as phrased by appellants in the Higgins case:

Was the trial court incorrect in ruling on a motion for summary judgment that as a matter of law a research entity conducting an ongoing non-therapeutic scientific study does not have a duty to warn a minor volunteer participant and/or his legal guardian regarding dangers present when the researcher has knowledge of the potential for harm to the subject and the subject is unaware of the danger?<sup>74</sup>

This phrasing is key in determining the significance of the Court's holding.

The Court concluded that the trial court erred in granting the defendant's Motion for Summary Judgment on the grounds that "a legal duty normally exists between researcher and subject and in all probability exists in the cases at bar,"<sup>75</sup> and that "the consents of the parents in these cases under Maryland law constituted contracts creating duties."<sup>76</sup>

While the issue of the existence of a duty was the focus of the Court's decision, this was not particularly significant. In fact, in a supplemental brief to the Court, appellees agreed that a duty did exist but disagreed as to the scope of the duty.<sup>77</sup> As a result of the Court's holding that a duty could exist in such circumstances, it remanded the cases to the Circuit Court for Baltimore City to determine whether "a special relationship, or other relationships arising out of agreements, giving rise to duties existed between KKI and both sets of appellants."<sup>78</sup> Because the Court found that a duty did exist as a result of the "contracts" between the parties and that a duty might exist as a result of a special relationship,<sup>79</sup> it would appear that the task of the lower court on remand is to determine whether a special relationship exists in these cases that gives rise to duties going beyond those established by the informed consent agreements, i.e., the contracts, or beyond the federal regulations regarding research with human subjects.<sup>80</sup>

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74. *Grimes*, 782 A.2d at 818. The Court also recounted appellants' contentions that KKI was negligent because KKI breached its duty to: "(1) design a study that did not involve placing children at unnecessary risk; (2) inform participants in the study of results in a timely manner; and (3) to completely and accurately inform participants of the research study of all the hazards and risks involved in the study." *Id.* at 841.

75. *Id.* at 818.

76. *Id.*

77. Supplemental Brief of Appellee at 1-2, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (No. 129).

78. *Grimes*, 782 A.2d at 819.

79. See *infra* text accompanying notes 102-103.

80. In fact, the court states that while federal or state "conditions or recommendations" may be relevant to whether a breach of contract or duty occurred, they "have no limiting effect on the issue

### B. The Court's Reasoning

In its legal analysis, the Court quoted extensively from Maryland case law that addresses the issue of duty<sup>81</sup> and focused predominantly on the relationship between the parties. In its consideration of whether a special relationship between the parties existed, the Court considered the consent agreement and the federal regulations governing research with human subjects. Before embarking on this analysis, however, the Court stated that although a special relationship between researcher and subject has not been recognized in the Maryland Code or in prior Maryland cases, "evidence in the record suggests that such a relationship involving a duty or duties would ordinarily exist, and certainly could exist, based on the facts and circumstances of each of these individual cases."<sup>82</sup>

With respect to the consent agreement, the Court appeared to say that it created all the elements of a contract (mutual assent, offer, acceptance and consideration) and as such imposed duties on each of the parties.<sup>83</sup> Furthermore, the Court found that the information provided in the consent agreement was inadequate and, in fact, that the consent was "not valid because full material information was not furnished to the subjects or their parents."<sup>84</sup> The Court suggested that full material disclosure in this case would have included a statement that "the researchers anticipated that, as a result of the experiment, it was possible that there might be some accumulation of lead in the blood of the children."<sup>85</sup>

As regards the relationship between the parties, the Court emphasized the role of KKI in creating and conceptualizing the study and contrasted it with a research study where data is collected retrospectively, stating:

As opposed to compilation of already extant statistics for purposes of studying human health matters, the creation of study conditions or protocols or participation in the recruitment of otherwise healthy subjects to interact with already existing, or potentially existing,

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whether, at law, legal duties, via contract or special relationships" are created in Maryland in experimental nontherapeutic research involving Maryland children." *Grimes*, 782 A.2d at 820.

81. *Grimes*, 782 A.2d at 842 (citing to Walpert, Smullian & Blumenthal, P.A. v. Katz, 762 A.2d 582, 589 (2000); Jacques v. First Nat'l Bank, 515 A.2d 756, 759 (1986)).

82. *Id.*

83. The Court describes the duties of KKI for example, as including: (1) financial compensation to appellants for their participation in the study; (2) the collection and analysis of lead dust samples from appellants' homes; (3) discussion of the results of the lead tests with appellants and steps that could be taken that could reduce exposure to lead; and (4) collection of blood samples from children in the household and provision of results to appellants. *Grimes*, 782 A.2d at 843. In exchange, appellants agreed to (1) allow KKI into their homes to collect dust samples; (2) periodically fill out questionnaires; and (3) allow the children's blood to be drawn, tested and used in the study. *Id.* Considerations, thus, included "money, food coupons, trinkets, bilateral promises, blood to be tested in order to measure success." *Id.*

84. *Id.* at 844.

85. *Id.*

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.<sup>86</sup>

The Court also discussed the role of the federal regulations on research with human subjects<sup>87</sup> in creating a special relationship.<sup>88</sup> The Court quoted from the regulations regarding informed consent emphasizing the provisions that state that “an investigator shall seek . . . consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence,”<sup>89</sup> and that each subject must be provided with any new findings “developed during the course of the research which may relate to the subject’s willingness to continue participation . . . .”<sup>90</sup>

The Court further pointed to the federal regulations that directly address research with children, in particular the provision regarding nontherapeutic research that presents greater than minimal risks, i.e., those beyond which a child confronts in every day life.<sup>91</sup> Such research requires approval by the Secretary of the Department of Health and Human Services (DHHS). The Court concluded that the research did not comply with the federal regulations as, according to the Court, “there clearly was more than a minimal risk involved,”<sup>92</sup> and there was no

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86. *Id.* at 846.

87. These regulations require, among other things, that any covered research be approved by an Institutional Review Board (IRB), a multidisciplinary committee often affiliated with an academic research institution and composed of researchers and outside volunteers established to ensure compliance with the federal rules regarding research with human subjects. 45 C.F.R. §§ 46.107- 45.109 (2001). Furthermore, informed consent must be obtained from all subjects. *See id.* § 46.116. In the case of children, their parent or guardian must give consent. *Id.* §§ 46.401- 46.409.

Covered research includes any research that is conducted or supported by a Federal Department or Agency, 45 C.F.R. § 46.101(a)(1); or subject to regulation by a federal department or agency, 45 C.F.R. § 46.101(a)(2); or research conducted by an institution that has a compliance assurance with a federal agency or department, 45 C.F.R. § 46.103(a). In order to approve a research protocol, an IRB must determine that risks to human subjects will be minimized “by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.” 45 C.F.R. § 46.111(a)(1). Moreover, an IRB must review the informed consent form that the researcher will use. 45 C.F.R. § 46.115(a)(1). The form, among other things, must include an adequate description of the research and its purpose, a description of the procedures to be followed, all “reasonably foreseeable risks,” and “any benefits to the subject or to others which may reasonably be expected from the research.” 45 C.F.R. § 46.116(a). The regulations also address research with children and provide more detailed rules regarding allowable risk and consent procedures. *See* 45 C.F.R. § 46.401-.409 (2001).

88. Given that EPA funded the study, it was subject to the federal rules. *See* 45 C.F.R. § 46.101 (2001).

89. *Grimes*, 782 A.2d at 847 (quoting 45 C.F.R. § 46.116 (2001)).

90. *Id.*

91. *Id.* at 848 n.38 (citing 45 C.F.R. § 46.407(b) (2001)).

92. *Id.* at 848.

indication in the record that KKI had sought approval from the Secretary.<sup>93</sup> The Court also concluded that under the federal regulations, a researcher has a duty to inform its subjects of all reasonably foreseeable risks.<sup>94</sup> The Court ended its analysis of the role of the federal regulations by stating that in Maryland, the duty of informed consent established by federal regulation may, depending on the facts, create a “duty of care [under state law] arising out of the unique relationship that is researcher-subject, as opposed to doctor-patient.”<sup>95</sup>

In a separate section, the Court addressed the “ethical appropriateness” of the research.<sup>96</sup> Here it relied on the Nuremberg Code, the Declaration of Helsinki, and a recent report of the National Bioethics Advisory Commission.<sup>97</sup> From these documents the Court concluded that “otherwise healthy children should not be the subjects of nontherapeutic experimentation or research that has the potential to be harmful to the child” and that it is “first and foremost, the responsibility of the researcher and the research entity to see to the harmlessness of such nontherapeutic

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93. *Id.*

94. The Court cited to *Whitlock v. Duke University*, 637 F.Supp. 1463 (M.D. N.C. 1986), *aff'd by*, 829 F.2d 1340 (4th Cir. 1987), in which the U.S. District Court of the Middle District of North Carolina “decided that in determining what duty a researcher owes to a subject of nontherapeutic experimentation, it would analyze a duty consistent with 45 C.F.R. § 46.116” and that a researcher has “a duty to inform the subject of *all* risks that are *reasonably foreseeable*.” *Grimes*, 782 A.2d at 848 n.38 (citing *Whitlock v. Duke University*, 637 F.Supp. 1463, 1471 (M.D. N.C. 1986), *aff'd by*, 829 F.2d 1340 (4th Cir. 1987)). The District Court in *Whitlock* held, however, that although “a heightened duty existed between a researcher and an adult research participant,” organic brain damage from decompression experiments was not foreseeable. *Id.* The decision was affirmed by the Court of Appeals for the Fourth Circuit. *See id.* The Court of Appeals distinguished this conclusion from the facts of the case at bar, asserting that the “risks associated with exposing children to lead-based paint were not only foreseeable but were well known by KKI, and, in fact, it had to have been reasonably foreseeable by KKI that the children’s blood might be contaminated by lead because the extent of contamination of the blood of the children would, in significant part, be used to measure the effectiveness of the various abatement methods.” *Id.*

95. *Id.* at 849. On this point, the Court also relies on the Nuremberg Code which “speaks strongly to the existence of special relationships imposing ethical duties on researchers who conduct nontherapeutic experiments on human subjects.” *Id.* The Court states that the Code was intended to “be applied internationally” and was “never expressly rejected in this country.” The Code “specifically requires researchers to make known to human subjects of research ‘all inconveniences and hazards reasonably to be expected, and the effects upon his health or person which may *possibly* come from his participation in the experiment.’ 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.” *Id.*

96. *Id.* at 849-52. The Court relied extensively in this part of its Opinion on the Amicus Brief prepared by the Public Justice Center. The brief focused on public policy and ethical reasons for establishing a duty on the part of researchers to protect their research subjects from unreasonable harm and argued that research subjects need legal protection because of (1) potential conflicts of interest between the goal of the researchers and the health of the human subject; (2) the superior position of the researchers in terms of expertise regarding potential research risks; and (3) the trust that subjects place in researchers. Brief of Amici Curiae The Public Justice Center, The National Health Law Program, and The East Harbor Village Center at 10-12, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001)(No. 129).

97. *Grimes*, 782 A.2d at 849-52 (citing NAT’L BIOETHICS ADVISORY COMMISSION, ETHICAL AND POL’Y ISSUES IN RES. INVOLVING HUM. PARTICIPANTS (2000)).

research.”<sup>98</sup> Moreover, “consent of parents can never relieve the researcher of this duty.”<sup>99</sup> The Court also attempted to clarify the relationship between consent and duty by stating that: “[a] researcher’s duty is not created by, or extinguished by, the consent of a research subject or by IRB approval. The duty to a vulnerable research subject is independent of consent, although the obtaining of consent is one of the duties a researcher must perform.”<sup>100</sup>

In concluding its discussion of duty, the Court stated that “[t]he study, by its design, placed and/or retained children in areas where they might come into contact with elevated levels of lead dust. Clearly, KKI contemplated that at least some of the children would develop elevated blood lead levels while participating in the study.”<sup>101</sup> As a result, it found that the potential harm to children subjects was “both foreseeable and potentially extreme” and that a “special relationship” exists in “circumstances where such experiments are conducted.”<sup>102</sup>

## V. INTERPRETING THE DECISION

### *A. A Groundbreaking Decision or Simply an Application of Existing Law?*

The Court was very clear in its holding that a duty of care may exist between researchers and subjects in nontherapeutic research studies and went to great lengths to elaborate on the different legal and ethical bases for such a duty. In sum, the Court held with respect to the legal underpinnings that:

[I]nformed consent agreements in nontherapeutic research projects, under certain circumstances, can constitute contracts; and that, under certain circumstances, such research relationships can, as a matter of law, constitute “special relationships” giving rise to duties, out of the breach of which negligence actions may arise [and that] normally, such special relationships are created between researchers and the human subjects used by the researchers. Additionally. . . governmental

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98. *Id.* at 850.

99. *Id.*

100. *Id.*

101. *Id.* at 852.

102. *Id.* The Court further asserts that a special relationship creating special duties between researcher and subject might also arise as a result of the potential conflict of interest that exists for researchers who want to ensure reliable research results and must also be concerned with the well being of their subjects and because of the superior knowledge of the researcher regarding the risks associated with the research. *Id.* at 851. According to the National Bioethics Advisory Commission, “[g]iven the gap in knowledge between investigators and participants and the inherent conflict of interest faced by investigators, participants cannot and should not be solely responsible for their own protection.” *Id.* (quoting NAT’L BIOETHICS ADVISORY COMM., ETHICAL AND POL’Y ISSUES IN RES. INVOLVING HUM. PARTICIPANTS 3-4 (Dec. 19, 2000)).

regulations can create duties on the part of researchers toward human subjects out of which “special relationships” can arise.<sup>103</sup>

While this holding and the Court’s rationale are not surprising, what is potentially groundbreaking is the scope of the duty the Court appears to endorse. It is clear under the federal rules regarding research with human subjects that researchers who fall within this regulatory framework, as KKI did, have a duty to: 1) design a study that minimizes the risks to subjects,<sup>104</sup> 2) obtain adequate informed consent from subjects,<sup>105</sup> and 3) tell their subjects of “any new findings developed during the course of the research which may relate to the subject’s willingness to continue participation.”<sup>106</sup> These duties are straightforward and widely accepted. However, duties going beyond these requirements, as implied in this case, have generally not otherwise been established.

The Court’s phrasing of the duty in the question presented as a “duty to warn [research subjects] regarding dangers present when the researcher has knowledge of the potential for harm to the subject and the subject is unaware of the danger,”<sup>107</sup> appears unique in its apparent inclusion of situations where the duty is not based on risks that have arisen as *a result of participation in the research*. As written, the statement seems to include preexisting risks to the individual subject, which the researcher discovers, that are not caused by participation in the research study. Rather, the risks become known by the researcher during the course of the investigation and may not be known by the subject. In fact, the Court stated that a study in which subjects will interact with “*already existing, or potentially existing hazardous conditions*” is one in which special relationships would normally be created.<sup>108</sup>

Imposing a “duty to warn” raises questions as to what the researchers should have told the subjects at the start of the study as well as whether the researchers had a duty to inform the subjects much earlier than they did of the results of the dust sample tests. A broad interpretation of such a duty would mean that the researchers: 1) had a duty to warn of risks not necessarily created by the study; and 2) had an obligation to inform subjects of the dust and blood sample test results as soon as possible so that subjects could act on the knowledge conveyed, similar to the obligation that would be imposed on a physician reporting clinical test results to a patient. If this broader duty is what the court had in mind, the case breaks new

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103. *Grimes*, 782 A.2d at 858. The Court stated that the question of whether such a relationship existed was a matter of fact for the trial court rather than a matter of law.

104. *Id.* at 841, 851-52.

105. *Id.* at 847 (citing 45 C.F.R. § 46.116(a) (2001)).

106. *Id.* (citing 45 C.F.R. § 46.116(b)(5) (2001)).

107. *Id.* at 818.

108. *Id.* at 846.

ground by imposing an obligation on researchers that has not clearly been established elsewhere.<sup>109</sup>

The holding apparently would require that researchers disclose risks related to a subject's living situation, not necessarily to the research study. This would mean, for example, in the case of researchers conducting a study on the impact of radon on children, that if the researchers found high levels of radon in or around the children's home that might be harmful, they would have a duty to inform, and perhaps educate, the children and their parents about the potential risks of exposure to radon. Arguably, they would further be required to "warn" the parents each time they obtained a radon reading that was considered potentially harmful to individuals/children living in the area. This set of facts is clearly different from a situation where the researchers are deliberately exposing children to a potentially harmful substance, for example, making them inhale oxygen mixed with different levels of lead dust or involving them in a study where they are testing the efficacy of a new drug.

While this interpretation of the Court's Opinion (that is, a duty to warn of harms arising outside the research protocol and in a timely manner) seems plausible simply by reading the text of the question posed, a different (less far reaching) interpretation is also possible depending on how one defines the research project and its related risks. If the research risks are defined to include the risks of living in housing with lead paint, as the Court appears to define them, the holding is not significant because the Court is simply requiring the researchers to inform subjects of the research-related risks. However, if the research is defined more narrowly, and the risks confined to those arising from collecting dust and blood samples, the holding would have considerable import because the required disclosure would include risks arising outside of the research protocol. In this case, however, the outcome (discharge of the duty) may be the same under either scenario—disclosure of the risks of living in housing with partially abated lead paint.

### *B. Conflicting Interpretations of the Research*

#### *1. The Court's View - A Different Paradigm?*

The ambiguity as to the significance of the holding lies in different perspectives on when the research protocol began and what constituted the research interventions. The Court seems to believe that the research commenced when KKI obtained the agreement of the non-profit entity that owned or managed low income housing in Baltimore City to participate in the project by seeing that

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109. In its brief to the Court of Appeals, KKI argued that appellants were asking the Court to "create an entirely new definition of duty which would dramatically change the landscape of tort law" and that this would not be "in accordance with Maryland law, common sense, or the best interests of our society." Brief for Appellee at 26, *Grimes* (No. 129).



different units received different levels of abatement.<sup>110</sup> The Court refers to “the very inappropriateness of the research itself,”<sup>111</sup> implying that KKI intentionally exposed young children to potentially harmful levels of lead dust, much as if they gave them a new drug to test for safety and efficacy. The Court does not view KKI as studying the impact of lead paint on families who voluntarily moved into a unit that had some level of lead paint abatement done or who lived in a unit that subsequently received some level of abatement. Under the Court’s broad view of the research, the families were part of the study when they moved into the units or when a decision was made to include a unit in the study. Furthermore, because KKI was the overall “designer” of the project and “orchestrated”<sup>112</sup> each of its various components, it had a duty to the subjects at a much earlier stage than that understood by the researchers. The Court adopted appellants view that

[A]lthough the plaintiffs unwittingly moved into the home not knowing it was part of experimental research, Kennedy set this experiment into motion, solicited this specific lead infested property to be a part of the experiment, initiated the limited and incomplete type of repair that was to be performed on the property, set up a Federal grant mechanism to pay for the repairs, encouraged the landlord to lease the property to a family with a young child, and then waited for the minor plaintiff to move into the home in order to solicit the child’s participation in the experiment. As a result of Kennedy’s actions, and in light of the apparent risk of its conduct, at a minimum it owed the plaintiffs a duty to fully warn of risks known to Kennedy and unknown to the plaintiffs.

<sup>113</sup>

As a result, KKI should have contacted the families before they moved into the units, or before they agreed to have any abatement performed if already living in the unit, and informed them of the risks of living in a home with any lead paint.<sup>114</sup> Appellants argued that KKI, based on its knowledge and the fact that it

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110. *Grimes*, 782 A.2d at 812.

111. *Id.* at 815.

112. Appellants argued that KKI “orchestrated the ... study that resulted in injury to the appellants,” and, as a result, appellee’s argument that duty in this case would be based on the existence of a special relationship is misplaced. Supplemental Brief for Appellants at 8, *Grimes* (No. 129). Instead, the appellants argued that the basis for establishment of a duty is foreseeability. *Id.* at 10.

113. Brief for Appellants at 25, *Grimes* (No. 1177).

114. In their Argument, appellants asserted that KKI had a legal obligation to protect the minor research subjects from “foreseeable harm which it knew was inherent in its experiment.” Brief for Appellants at 14, *Grimes* (No. 1177). More specifically, appellants argued that KKI owed a “duty of full disclosure as to all the risks associated with participation in its research experiment in order for the research subjects to make a reasonable and informed judgment as to whether they wanted to participate in the Study,” as well as a “continuing duty to warn them of additional risks and hazards when these risks came to the attention of Kennedy during the course of the research experiment.” *Id.* at 14-15.

“set into motion the act of making repairs to the property,”<sup>115</sup> should have foreseen the potential harms to the children living in the units and thus had “an obligation to inform them of all risks and hazards at the beginning and throughout the course of the study.”<sup>116</sup>

The terms “orchestrating,” “designing,” and “setting into motion” were significant in the description of KKI’s role. By adopting this characterization of KKI’s part in the broader effort of having landlords perform some level of lead abatement on their property, the researchers can be more easily thought of as the entity that placed the subjects at risk, thus justifying imposing on them a duty to warn.

Key to an understanding of the holding is the realization that the Court’s view of the research-related risks included exposure to lead in dust in the subjects’ homes. This view is conveyed in the way in which the Court refers to the research risks. The Court wholly adopted the appellant’s perspective that Kennedy owed plaintiffs a duty to explain in full and complete detail the “true” purpose of the study, and all foreseeable risks inherent in “the research.” This included all harm that might result to the children as a result of “the research,” and even the knowledge that “the research” was experimental and untested and that unforeseeable risks might occur, so that the subjects or their parents fully comprehended and appreciated the harmful situation in which they were potentially placing their young children.<sup>117</sup> Through this language, the Court implies that the researchers had a duty to inform the tenants of the risks of living in housing with moderately elevated lead levels.<sup>118</sup>

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115. Brief for Appellants at 16, *Grimes* (No. 1177).

116. Supplemental Brief for Appellants at 2, *Grimes* (No. 1177).

117. Brief for Appellants at 21, *Grimes* (No. 1177).

118. The subjects were told when they rented the units that they were living in houses that had been painted with lead based paint and to tell the landlord of any areas where paint was chipping. The Public Justice Center, et. al., stated in their amicus brief that:

[T]he family was not informed that the unit was part of a research project [until] after they had already moved into the test property. KKI did not disclose the level of abatement that had been done to the home, did not identify what was experimental about that abatement level, and did not warn about the specific areas that had not received any abatement (such as basements that had flaking and chipping lead paint.) KKI did not explain that it was unknown whether the experimental abatement level would prevent the child from developing lead poisoning. Indeed, KKI did not even inform the parents that their children ran the risk of being lead poisoned due to [sic] the presence of lead in the house or the experimental abatement level being tested. KKI did not explain the serious brain and health damage that lead paint could cause to preschool-aged children.

Brief of Amici Curae The Public Justice Center, The National Health Law Program, and The East Harbor Village Center at 27, *Grimes* (No. 129).

## 2. A Conspiracy Theory?

The Court's sweeping characterization of the research study and the role of KKI in designing the larger initiative is complemented by a harsh tone and highly skeptical view of the beneficent nature of the research enterprise. While the expansive view of the research may be due to review under the summary judgment standard, this does not explain the Court's highly critical view of the researchers. The language of the Court paints a picture of a conspiracy between the landlords and the researchers and is particularly telling of its distrust of the research establishment. For example, it states that the researchers "required" certain homes to have only partial lead abatement; that they "required" the landlords to rent the premises to families with young children; that they would be measuring the extent "to which the theretofore healthy children's blood became contaminated with lead."<sup>119</sup> Furthermore, they characterized the researchers as "enticing" the subjects to living in, or remaining in, "potentially lead-tainted housing," and "intentionally" subjecting them to a research program which contemplated "the probability, or even the possibility, of lead poisoning . . . ."<sup>120</sup>

Overall, the Court characterized the purpose of the study as finding a "less than complete level of abatement that would be relatively safe, but economical, so that Baltimore landlords with lower socio-economical rental units would not abandon the units,"<sup>121</sup> rather than a purpose of improving the safety of housing with lead paint. In describing the recruitment of subjects into the study, the Court also casts the researchers in a dark light stating that the researchers were motivated to enroll individuals in the study who were likely to remain in the rental unit because if they did not remain the study results would be of questionable value. Specifically, the Court states that it would "benefit the accuracy of the test [results], and thus KKI, the compensated researcher, if children remained in the houses over the period of the study even after the presence of lead dust in the houses became evident."<sup>122</sup> The Court, in fact, compares the use of children in the study to that of canaries used by coal miners in the 20<sup>th</sup> century to test for carbon monoxide.<sup>123</sup>

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119. *Grimes*, 782 A.2d at 812.

120. *Id.* at 814.

121. *Id.* at 821.

122. *Id.* at 823-24.

123. *Id.* at 813. See also DEP'T OF LABOR, MINE SAFETY AND HEALTH ADMIN., A PICTORAL WALK THROUGH THE 20<sup>TH</sup> CENTURY: CANARIES, at <http://www.msha.gov/century/canary/canary.htm> (last visited Oct. 21, 2002). According to the cite, before the availability of modern detection devices for carbon monoxide, miners used canaries: "Following a mine fire or explosion, mine rescuers would descend into the mine carrying a canary in a small wooden or metal cage. Any sign of distress from the canary was a clear signal that the conditions underground were unsafe, prompting a hasty return to the surface." *Id.*

### 3. The Researchers' View

In stark contrast to the Court's perspective of the research study, the researchers' view is much more circumscribed. From KKI's vantage point, at least in the cases at issue, the research did not begin and subjects were not part of a research protocol until after they moved into the units and agreed to let the researchers come into their homes to collect dust samples and to draw blood from their children to test for lead. The researchers viewed the risks of the study as those arising exclusively from taking the samples. They viewed the risks of lead poisoning, in contrast, as arising from living in the lead painted units. From their perspective, the families could have lived in the units whether or not they participated in the study and would have been exposed to the risks of lead poisoning whether or not they participated in the research.

Moreover, KKI argued that it did not have responsibility for the renovations or the rental of the units.<sup>124</sup> As a matter of law, neither KKI nor the property owners were required to do any renovations or abatement at all.<sup>125</sup> However, to the extent that renovations and abatements were performed, KKI stressed that it did not supervise or direct the independent contractors who performed the work.<sup>126</sup>

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124. In its Memorandum of Points and Authorities in Support of Response by KKI to Plaintiff's Opposition to KKI's Motion for Summary Judgment, KKI stated that it "approached property owners to ask that they volunteer their properties in Baltimore City for a research study," and that "[t]he owner of the property was free to collaborate or not collaborate in the study, free to rent or not rent his property at any time during the course of the study, and was free to rent to whomever he chose. KKI did not dictate to the owner to whom he should rent the property, nor did KKI refer prospective tenants to the owners of the properties involved in [the] study." Memorandum of Points and Authorities in Support of Response by Kennedy Krieger Institute to Plaintiff's Opposition to KKI's Motion for Summary Judgment at 2, *Grimes* (No. 1177).

125. In its brief to the Court of Appeals, KKI made clear that at the time the R&M Study began, "there were no Maryland statutes, regulations, standards, or protocols governing the method by which property owners had to reduce known lead hazards in their rental properties," [Brief for Appellee at 2, *Grimes* (No. 128)], with the exception of standards for complete abatement. *Id.* at n.1 ("[T]he Advisory Council on Lead Poisoning was still in existence, which the General Assembly had created in 1986 to, among other things, '[s]tudy the means of safe removal of lead paint from the interiors and exteriors of buildings and make recommendations to the Secretary.'"). Moreover, in 1992, the General Assembly created the Lead Paint Poisoning Commission to "study and make recommendations on means for inspecting and remediating rental dwelling units and property found to have lead paint on surfaces accessible to children." *Id.* at 2-3 (citations omitted). While the argument is true from a regulatory standpoint, under Maryland common law at the time, a landlord in Baltimore City was liable for harms resulting from lead poisoning of a tenant if he had reason to know of chipping, peeling or flaking lead paint and reasonable opportunity to correct the problem. *CITE aff'd by Richwind Joint Venture v. Brunson*, 645 A.2d 1147 (1994). It was not until 1996, however, under the statutory provisions of the Maryland Reduction of Lead Risk in Housing Program that landlords desiring limited liability were required to inform tenants of lead paint risks. *See supra* note 27 and *infra* note 127 and accompanying text.

126. Brief for Appellee at 5, *Grimes* (No. 128). KKI explained that CFOD-2, the owner of the Federal Street property, "volunteered it to be part of the R&M Study. The property was vacant at the time and randomly assigned to receive a Level 2 intervention." Moreover, "CFOD-2 hired ERI to

KKI's view of the research intervention was simply the taking of dust samples and drawing of blood. In fact, the research institution characterized its relationship with plaintiffs as one of "an observer" in which it "sought and received permission to collect information about an existing and evolving condition which KKI neither created nor controlled." From KKI's perspective, "it did nothing to introduce Appellants to any hazardous condition."<sup>127</sup>

Through this lens, the risks associated with exposure to lead were not part of the research study but were the risks of living in the apartments. To the extent that someone was responsible for those risks, it was the landlord, not the researchers.<sup>128</sup> In its legal argument, KKI stated that it had no common law or statutory duty to warn appellants of the lead hazard that existed on the premises that they rented. Regarding a common law duty, KKI argued that whether it owed any duty to appellants was "entirely dependent on the nature of the relationship between them," and that KKI and appellant "did not have a landlord-tenant relationship that would obligate KKI to inform appellants of hidden hazards in the property, irrespective of whether KKI knew of the hazards and could foresee harm from them."<sup>129</sup> KKI further argued that appellants were trying to impose a duty on KKI that exceeded that of landlords.<sup>130</sup>

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perform the intervention work which was done in May 1994." Brief for Appellee at 6, *Grimes* (No. 129).

127. Brief for Appellee at 14-15, *Grimes* (No. 129).

128. KKI argued that it was the responsibility of the owner, not KKI, to keep the rented premises in a "habitable condition," "free of chipping, flaking, and peeling paint." Memorandum of Points and Authorities in Support of Response by Kennedy Krieger Institute to Plaintiff's Opposition to KKI's Motion for Summary Judgment at 2, *Grimes* (No. 1177). But, in addition, KKI pointed out that the owner was "under no legal obligation to completely eliminate all lead-based paint from the premises, that there was "no law requiring a complete abatement before a property can be rented." *Id.* The owner is only required to remove all flaking, chipping and peeling paint before renting the unit which, according to KKI, they did. *Id.* After the owner agreed to have their property used in the research study, the owner obtained a loan from the Maryland DHCD to finance the cost of the abatement process. *Id.* at 3. The renovations were performed by an environmental consulting firm, ERI, through a contract with the owner. *Id.*

129. Brief for Appellee at 14, *Grimes* (No. 129). KKI further asserted that it "did not induce Appellants to move into the Federal Street property and was not involved in establishing Appellants' tenancy. KKI's relationship with Appellants began after Appellants signed a lease and moved into the Federal Street property." *Id.*

130. KKI pointed out that in Baltimore City, landlords may not "lease a dwelling with flaking, loose or peeling paint," and that no premises may be leased "for human habitation except those that are fit for human habitation, i.e. those that are kept in good repair and safe condition as defined by the Baltimore City Code." Brief for Appellee at 15, *Grimes* (No. 129) (citing *Brown v. Dermer*, 744 A.2d 47 (2000)). Consequently, KKI stated, "a landlord in Baltimore City has a duty to repair flaking, loose, or peeling paint of which the landlord knows or has reason to know." *Id.* However, a landlord in Baltimore City has no duty to disclose or repair the mere presence of lead paint in the premises that is not in a dangerous condition, i.e., flaking, loose, or peeling." Brief of Appellee at 15, *Grimes* (No. 129) (citing *Richwind Joint Venture v. Brunson*, 355 Md., 645 A.2d 1147 (1994); and *Scroggins v. Dahne*, 645 A.2d 1160 (1994)).

According to the researchers, the risks of exposure to lead in dust would have existed whether or not the plaintiffs agreed to participate in the research protocol.<sup>131</sup> KKI recognized its duty to provide adequate informed consent but argued that the “law requires informed consent before an actor does something to a person that the person would not otherwise have had done to them, or the actor withholds something from the person that the person would otherwise have had.”<sup>132</sup> That is, if KKI had given the subjects a new drug it would have had an obligation to tell them the risks of the new drug, but because it was not exposing them to new risks that they would not otherwise encounter by virtue of living in the units they rented, KKI did not have an obligation to inform them of the risks associated with their living situation.<sup>133</sup> In the words of KKI, “it was not the study that presented any risk of harm to Appellants, it was the circumstances in which Appellants found themselves completely independent of whether they participated in the study.”<sup>134</sup>

KKI further argued that, as a legal matter, outside of the landlord-tenant context or other special relationship, a person “has a duty to warn another of hazards known to the first person, not the second, only if the first person’s conduct exposed the second person to those hazards.”<sup>135</sup> Because KKI did nothing “to create or expose Appellants to any lead hazards” KKI argued that it had no duty to warn them of such hazards.<sup>136</sup> KKI characterized the duty that appellants would place upon it as a “duty to rescue,” that is, a duty to aid another in time of distress, and argued that no such duty exists unless the defendant placed the plaintiff in danger or had a “special relationship” with the plaintiff,<sup>137</sup> neither of which, it argued, was the case herein.<sup>138</sup>

131. In fact, KKI stated in a trial court memo that Ms. Higgins was free not to participate in the study in which case “the potential for exposure to lead still existed.” Memorandum of Points and Authorities in Support of Response by Kennedy Krieger Institute to Plaintiff’s Opposition to KKI’s Motion for Summary Judgment at 10-11, *Grimes* (No. 1177).

132. Brief of Appellee at 24, *Grimes* (No. 129).

133. *Id.* at 25.

134. *Id.* KKI further argued that because the entire purpose of the study was to evaluate the effectiveness of various abatement levels and there had been little research on the effectiveness of anything but full abatement, the risks of partial abatement were not known and KKI could not have adequately warned plaintiff of them. *Id.*

135. Brief for Appellee at 16, *Grimes* (No. 129) [*citing* B.N. v. K.K. , 538 A.2d 1175 (1988) (providing that a person may be liable for failing to warn another that he has a highly infectious disease before engaging in sexual relations with that person); *see also* *Faya v. Almaraz*, 620 A.2d 327 (1993) (holding that a surgeon may be liable for failing to warn his patients that he has AIDS prior to performing surgery upon them)].

136. *Id.*

137. *Id.* at 16-17.

138. KKI further relied on the Restatement’s limited list of special relationships and argued that the relationship between KKI and plaintiffs did not fit within any of these. Brief for Appellee at 17-18, *Grimes* (No. 129). These relationships include only 1) common carrier-passenger, 2) innkeeper-guest, 3) landowner-invitee, and 4) certain custodial relationships. RESTATEMENT (SECOND) OF TORTS § 314A (1965). KKI dismissed appellants’ argument that a special relationship existed between the

Throughout the Opinion there is considerable confusion about the risks associated with participation in the research study and the risks associated with the research subject's living situation. The fact that KKI participated in encouraging the landlords to secure the loans so that they could undertake the different levels of lead abatement and to recruit families with children muddies the water.<sup>139</sup> In addition, the fact that some families were recruited prior to the abatement process, although not the families who initiated this litigation, and some after, further complicates the question about when the research began and what constituted the research interventions.

### *C. Differences in Facts of the Two Cases*

The confusion about which risks were part of the research is further compounded because the facts of the two cases that were appealed are different and one seems to fit more neatly under the Court's perspective of the research project and the other under the researcher's perspective. In the *Grimes* case, Erika Grimes' mother moved into the unit in the summer of 1990. The unit was allegedly completely abated prior to October 1990, after she moved in. Erika Grimes was not born until May 1992 and Erika's mother agreed to be part of the study in March 1993. The facts of this case lend themselves more readily to the view of the researchers that they were simply testing children who already lived in abated or partially abated units—that is, the subject and her family had been living in the unit for a number of years prior to any research study and agreed to be part of the study when they consented to let KKI take dust and blood samples. Thus, they would have experienced risks as a result of their living arrangements whether or not they participated in the study. If they had not participated in the study, it is possible that they would not have known of the risks to their children.

In the *Higgins* case, in contrast, one could argue that the family was "recruited" to live in the unit immediately after a level two abatement had been performed. Ms. Higgins responded to an ad in the newspaper listing the property as a rental for \$315/mo. Under these facts, the Court's view is more plausible—that is, that she was recruited to participate in the research study rather than to live in the unit. Yet, the Court's view is not entirely persuasive given that Ms. Higgins could have rented the apartment and not participated in the study. Under these

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parties because KKI voluntarily assumed to perform a task for the benefit of the plaintiffs and the plaintiffs relied on such performance. In contrast, KKI argued that it neither expressly nor impliedly agreed "to undertake any actions that the Appellants were relying on to protect the health of the occupants of the premises," and therefore did not have a special relationship "created by voluntarily assumed duties." Brief for Appellee at 19, *Grimes* (No. 129).

139. If, in contrast, KKI simply identified houses that had had some level of abatement, without having spoken to the property owners and encouraged them to undertake some type of abatement, and subsequently contacted the residents about collecting dust samples and testing the blood lead levels in their children, the Court may have looked on the matter differently.

latter circumstances it would be difficult to argue that KKI owed any duty to her or her children.

The factual pattern that fits best with the Court's perspective is that of those study participants who were recruited prior to having their units undergo abatement procedures. Under this scenario, arguably, the intervention did include the abatement process itself and any associated risks. Yet, neither of the litigants in this case were part of this group. Moreover, the researchers would argue that these procedures did not impose any additional risks on those living in the units; rather, they reduced the pre-existing risks.

#### *D. Broad v. Narrow Interpretation of Duty*

The different perspectives on when the research was initiated and on the risks to which the subjects were exposed as a result of participation in the research, rather than as a result of living in the units, are significant in determining the implications of the Court's holding. If one views the research protocol broadly, i.e., as including the risks of living in moderately abated housing, as did the Court, then the holding is not groundbreaking for future research (although it may have a significant impact for this case). It would simply require that the researchers inform the subjects of harms resulting from participation in the research protocol—something required as part of the federal rules on research with human subjects. The factual dispute, moreover, would be about compliance with those rules and whether the researchers did what they said they would do in the informed consent agreement.<sup>140</sup> However, if one views the research protocol more narrowly, i.e., as limited to the risks of taking the dust and blood samples, as most researchers would, then the holding is much more significant. It imposes a greater responsibility on researchers than currently exists to inform subjects of harms to which the subjects may be exposed that do not necessarily arise from participation in the research protocol.

## VI. THE SCOPE OF THE DUTY

### *A. Deconstructing the Scope of the Duty*

In *Grimes*, the Court focused on two aspects of disclosure in considering the scope of the duty owed by the researchers: 1) disclosure prior to study enrollment, during the informed consent process, of the risks of living in housing containing lead paint and alternatives to living in such housing; and 2) disclosure of information gained during the course of the study, namely results of the dust and

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140. While this interpretation of the Opinion would not result in a significantly new legal rule, in this case, it could result in an obligation of disclosure of information not typically required because of the interpretation the Court gives to the research intervention.



blood sample tests, although the results of the dust sample tests appear to be primarily at issue.<sup>141</sup>

The potential breadth of the first of these duties was articulated by appellants in the Higgins case who argued that the consent form had numerous omissions. For example, it did not state that the unit in which Catina and Myron Higgins lived contained lead based paint and high levels of lead in dust and did not explain “the specific dangers and risks associated with lead poisoning.”<sup>142</sup> Nor was Higgins told that by living in the unit and participating in the Study her son could be exposed to lead-based dust and could suffer serious and permanent injury as a result of lead poisoning.<sup>143</sup> Furthermore, the family was not informed that the unit was part of a research project until after they had already moved into the test property.

Specifically, appellants alleged that KKI did not:

- disclose the level of abatement that had been done to the home, nor identify what was experimental about that abatement level, nor warn them about the specific areas that had not received any abatement (such as basements that had flaking and chipping lead paint);
- explain that it was unknown whether the experimental abatement level would prevent the child from developing lead poisoning;

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141. In regard to the disclosure of the dust sample results, appellants pointed out in their brief in the Higgins case that the researchers, in their consent form, promised to “share with [Ms. Higgins] any new findings that may develop while [she was] participating in [the] study.” Brief for Appellant at 11, *Grimes* (No. 1177). Instead, they argued that the first letter KKI sent to Ms. Higgins, with the results of the initial dust testing (post abatement), failed to warn her “of any areas containing lead dust and gave a misleading impression that the home did not contain any lead in the dust samples.” *Id.* Moreover, KKI did not provide the results of the second dust testing results, performed on July 25, 1994, which showed that the level of lead in the dust “increased in several areas throughout the home above the clearance criteria in Maryland,” until September 14, 1994. *Id.* By the time the letter reached Ms. Higgins, she argued, “Myron Higgins was already exposed to high levels of lead in dust and was found to have an elevated blood lead reading.” *Id.* Appellants further argued that the findings regarding the lead levels in the dust were relevant to Ms. Higgins’ willingness to continue to participate in the study and that KKI should have confirmed her informed consent to continue participation. As a result of her continued participation in the study, appellants allege that Myron Higgins developed elevated levels of lead in his blood. *Id.* at 12.

142. *Id.* at 8. The appellants described these risks as including “permanent cellular destruction and retardation of cellular development, permanent and severe brain damage, diminution in IQ, learning disabilities, extreme difficulty reading, shortened attention span, impulsivity, behavioral and hyperactivity disorder, visual and spatial motor control problems, diminution in stature,” etc. *Id.*

143. *Id.* at 9. Appellants further stressed the knowledge of Catina Higgins when she moved into the unit stating that she was unaware it “ever contained lead-based paint, and in general she was unaware that older homes contain lead-based paint.” *Id.* at 7. And, because her son had not been diagnosed with elevated blood levels until after he moved into the unit, she had “no experience with or knowledge of any of the specific dangers associated with exposure to lead-based paint and/or lead in household dust,” until after moving into the unit. *Id.* Moreover, she “never understood the real purpose of the study.” *Id.* at 10. In their brief, appellants reported that Catina was 21 years old when she moved into the unit and “had no more than obtained a high school education from Baltimore City public schools.” *Id.* at 3.

- inform the parents that their children ran the risk of being lead poisoned due to [the] presence of lead in the house or the experimental abatement level being tested;
- explain the serious brain and health damage that lead paint could cause to preschool-aged children;
- explain, in the consent form, the purpose of the “free blood lead testing” of the child—to monitor whether the child became lead poisoned while living at the test property.<sup>144</sup>

The underlying assumption in this series of omissions is that the research “intervention” was living in partially lead abated housing, along with the lead abatement procedure, and the risks were those associated with that intervention. The federal regulations regarding research with human subjects states that an intervention “includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.”<sup>145</sup> While it is clear, as a factual matter, that the blood tests and dust sample tests were interventions coming within the definition of the term in the federal regulations, it is less clear, as a factual matter, whether the abatement process was an intervention “performed for research purposes.”<sup>146</sup> While KKI may have encouraged some landlords to undertake the abatements for the overall design of the research, some of the units had been abated prior to the research study and, in those cases, the reason for the abatement was clearly not participation in the research protocol. In cases where property owners had not undertaken an abatement prior to the initiation of the study, it is likely that the reason they conducted the renovations was not because of the research project but rather so that they could get their properties back on the market and rented.

In addition to the problematic breadth of the initial disclosure requirement implied by the Court, the requirement raises issues related to the quality of the information to be disclosed. A duty to disclose the risks associated with living in housing containing lead paint and in housing that had undergone various levels of abatement may also have some risks. For example, providing the information too soon in the research project may result in the sharing of information that is inaccurate or incomplete and may be unduly alarmist. According to a 1995 report by the U.S. Department of HUD, intact lead-based paint on most walls and ceilings

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144. Brief for Amici Curiae The Public Justice Center, The National Health Law Program, and The East Harbor Village Center at 27-28, *Grimes* (No. 129).

145. 45 C.F.R. § 46.102(f)(2) (2002).

146. *Id.*

is not a hazard.<sup>147</sup> KKI asserted in its brief that there is no evidence that “the mere presence of lead” in homes will lead to lead poisoning. And, according to a fact sheet by the EPA, “lead paint is usually not a hazard if the paint [1] is in good condition, and [2] is not on an impact or friction surface (like a window, door or stair).”<sup>148</sup> Arguably, the purpose of the R&M Study was to develop data on whether partial abatement methods might preserve the intactness of the paint and prevent deterioration of painted surfaces leading to peeling, flaking or chipping and thus reduce the incidence of lead poisoning in minor residents.

The second requirement—timely disclosure of the lead dust sample results—might be compelling if it were clear that the dust levels were elevated to a level that was considered hazardous. There was disagreement among the parties, however, as to whether, as a factual matter, this was the case.<sup>149</sup> The parties were in dispute regarding the significance of several of the dust sample results. This is a factual matter that should be determined by the jury when the case is argued on remand and is key to a finding of liability.

Even if the levels were potentially hazardous, however, this does not resolve the question of *when* the researchers should have disclosed the dust sample results and exactly *what they should have told the subjects*. These questions raise issues about the role of researchers versus clinicians and public health authorities. KKI, assuming the tests were not to be used as a basis for clinical medical decision-making, pointed out that the dust samples were processed at its Trace Metals Lab, “which typically took several months” and that “the samples were processed for research purposes, only, with several research-related quality control steps, and done in large batches.”<sup>150</sup>

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147. Supplemental Brief for Appellee at 2-3, *Grimes* (No. 129) (citing U.S. DEP’T OF HUD, GUIDELINES FOR THE EVALUATION AND CONTROL OF LEAD-BASED PAINT HAZARDS IN HOUSING 1-8 (1995)).

148. *Id.* at 2. (citing U.S. DEP’T OF ENVTL. PROTECTION, FACT SHEET IDENTIFYING LEAD HAZARDS IN RESIDENTIAL PROPERTIES (PUB. NO. EPA 747-F-01-002) (2001) at <http://www.epa.gov/lead/leadinfo.html> (last visited Sept. 19, 2002)). KKI further argued that each of the study units was left with “paint in good condition and paint on friction surfaces encapsulated after the intervention.” Supplemental Brief of Appellee at 3, *Grimes* (No. 129).

149. In its brief, KKI attempted to clarify the results of the dust sample tests performed in the Higgins household. According to KKI, the “results of dust wipes collected in May were below the Maryland clearance levels,” whereas the results of samples collected in July and November “showed areas above the clearance levels.” Brief of Appellee at 8-9, *Grimes* (No. 129). KKI indicated this in its letter to Ms. Higgins. According to KKI, appellants were notified of the dust sample test results in writing. The written notification stated, in part: “The chart below will show the areas where dust was collected in your home. Remember there is no rule for how much lead is allowed in the dust from a house like yours. However, we have placed an \* next to areas where the amount of lead was higher than might be found in a completely renovated house.” *Id.* at 8. With respect to those areas with levels above the clearance levels, it suggested that Ms. Higgins “give those areas special attention” when cleaning the house. *Id.* at 9.

150. Brief for Appellee at 7 n.8, *Grimes* (No. 128).

Finally, at issue, is the duty of the researchers to disclose the results of the children's blood tests. That the researchers had a duty to disclose the blood test results is clear given that they represented, in the informed consent form, that they would disclose such findings. As in the case of the dust sample results, what is less clear is *when* the results should have been disclosed and *what* obligations the researchers had in disclosing the information.

*B. Discharging the Duty—What is Required?*

Under either interpretation of the Court's Opinion, that is, if one adopts the Court's broad view of the research study, or the broad articulation of the duty with a narrower view of the research, there is a significant question about how each of the disclosure requirements outlined above would be discharged. Under the Court's broad view of the research study, the consent form was not adequate because it did not inform parents that their child might ingest lead dust particles. This finding assumes that the ingestion was a result of participation in the study rather than living in the unit. If, on the other hand, one applies the Court's broad scope of the duty, requiring disclosure of risks which the researcher knows of by virtue of data he or she is collecting, whether or not the risk is generated by the research intervention, then one would also be required to disclose the risks to children of living in housing containing lead paint.

Whether or not this "quantity" of disclosure would be sufficient is also not entirely clear. Should the researchers also have told the subjects (or potential subjects) of alternatives to living in lead painted housing or urged them not to live in units that had not been fully abated? In their brief, appellants asserted that Ms. Higgins was "never informed [by KKI] that an alternative and scientifically proven form of treatment to reduce her child's lead exposure would be to remove her son from the lead infested property and move into a fully abated or lead free home."<sup>151</sup>

Such a requirement would undoubtedly mitigate this type of research. As appellees stated in their brief, "[i]f KKI and other researchers are precluded from observing others in different situations (which are not the creation of the research project) in order to learn how to minimize risk to others, then all research will be dealt a crippling, if not fatal, blow to the great detriment of our society."<sup>152</sup>

If the parties had, however, agreed to participate in the research (by living in one of the experimental units) after the disclosure regarding risks of lead paint to their children, there remain questions as to the duty of the researchers to inform the participants of the results of the dust level tests. For example, did the researchers have a duty to give the participants the results in a more timely manner or to explain what the levels meant? Did they have a duty to tell them if the dust levels were higher than what would be found in fully abated houses and, if they were, that

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151. Brief for Appellants at 9, *Grimes* (No. 1177).

152. Brief for Appellee at 21-22, *Grimes* (No. 129).

they should take their children to their physicians right away?<sup>153</sup> One might argue, under the type of duty advocated by the appellants, that researchers should have had someone come in to take more remedial action or encouraged plaintiffs to move and assisted them find alternative housing. This type of requirement would arguably put the researchers in the position of rescuers, placing on them a burden that our laws do not generally impose on individuals in our society— not even on our physicians.

Such a requirement is also insensitive to the possibility that the subjects and their families might not be able to move or to afford to hire someone to perform additional abatement or remedial action. Such information may actually be harmful to families if they are, in fact, powerless to change their situation.<sup>154</sup> The subjects' inability to provide better housing for their children may cause them extreme anxiety and guilt. Moreover, they could be at risk for a charge of child abuse or neglect for failure to take action once having the information about the potential risks to their child.

By creating a private right of action for research subjects, the Court is ultimately causing a transfer of income from the pockets of the researchers to the low income individuals who are often participants in research studies of this kind. With the income such subjects obtain from these judgments, perhaps they will be able to move to better housing that has no lead paint. Although this outcome seems right, the allocation of such sweeping responsibilities to the research community seems misplaced.<sup>155</sup>

## VII. IMPLICATIONS FOR PUBLIC HEALTH RESEARCH AND COMPENSATION OF INJURED PARTIES

If the Court's Opinion goes beyond informing research subjects of the risks imposed by the research protocol (narrowly defined) and requires a duty to warn of harms related to a subject's living conditions, or other factors not the result of

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153. KKI did not tell them to take their child to their physician at this point but when the blood test levels came back above normal the notice told the child's mother that she "should provide the test result to [her] child's primary health care provider right away." Brief for Appellee at 9, *Grimes* (No. 128). See also Brief for Appellee at 9, *Grimes* (No. 129).

154. MD CODE ANN. ENVIR §§ 6-839, 840(a)(2)(i). At the time of this case there was no significant monetary assistance available to families whose children were found to have elevated levels of lead in their blood so that they could relocate. Subsequently, as part of the Reduction of Lead Risk in Housing Act, 42 U.S.C. §§ 4851-4856 (2000), if a landlord has complied with the lead risk reduction requirements of the law, see *supra* note 27, but has notice that a child living in one of his units has blood lead levels above a certain threshold amount, the landlord may not be liable for negligence if he makes an offer to the occupants to assist them relocate their household to lead-safe housing either permanently or temporarily, while the affected unit is renovated, and to pay reasonable expenses for the medically necessary treatments of the affected child.

155. While the Opinion exposes researchers to liability, tenants may also still sue landlords for violation of Maryland common law or relevant statute. As a result, in similar circumstances, landlords and researchers could be jointly and severally liable.

participation in a research protocol, but about which the researcher may know or have expertise, then the holding would have far reaching consequences for many types of research. The holding would also affect the compensation of individuals harmed by participation in research or as a result of exposure to public health risks.

The holding is particularly relevant to public health and environmental studies. Consider, for example, research on malnutrition. Could a researcher study a population that exposes its children to a diet without certain nutrients or would the researcher be required to tell the subjects of the risks of such a diet and urge them to change their diet or see their physician? If families agreed to be part of the study, when the researchers found, each day, that the child's diet was deficient in essential nutrients, would they be required to tell the family immediately? If they did not tell the family, but later the child was found to have organ damage as a result of their diet, could the parents successfully sue the researchers for failure to tell them of their observational findings that the child's diet each day had been deficient in these essential nutrients? If the researchers had noted some harmful effects on the health of the children, would they have a duty to tell the parents and urge them to take the children to their family doctor? If the parents did not take the children to the doctor would the researchers have any obligation to report the parents for child neglect?

Alternatively, consider research on the effects of second-hand smoke on children living in housing with parents who smoke. Should it be the obligation of the researchers to inform the parents at the start of the research of the risks to children of second-hand smoke? Should they be required to tell them every time they find a level of smoke in the air that might be hazardous? If the parents do not change their smoking habits, should the researchers be required to report them for child abuse or neglect?

Much of our public health research is of the nature that we are studying the risks to health status of certain diets or life styles or environmental factors, e.g., living close to a nuclear power plant. This type of research is significantly different from clinical research trials by virtue of its focus and objectives. As articulated by public health experts, public health research and practice focus on:

- the health and safety of populations rather than the health of individual patients;
- prevention of injury and disease rather than treatment and care;
- relationships between the government and the community rather than the physician and patient; and
- population-based services grounded on the scientific methodologies of public health (e.g., biostatistics and epidemiology) rather than personal medical services.<sup>156</sup>

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156. Lawrence O. Gostin, *Public Health Law: A Renaissance* 30 J. OF L., MED. & ETHICS 136, 136 (2002).

These differences are significant for how we think about the obligations of public health researchers. It is ironic, for example, that the results of the R&M Study may have provided evidence of the need for changes in our laws and policies regarding lead paint abatement. A sweeping duty requirement could significantly inhibit this type of research.

Of course, the real danger of the Court's Opinion is the possibility that it will significantly reduce major public health studies that could be the basis for revising our public health and environmental laws and practices that would protect the very population the Court seems so concerned about in its Opinion.<sup>157</sup> A further negative consequence of an atrophied public health research enterprise is the difficulty it may impose on individuals seeking compensation for harms related to public health research or simply for harms resulting from exposure to unsafe environmental substances. Not only will plaintiffs have to show that defendants owed them a duty of care, in addition they will have to prove that the exposure to the harmful substance caused their injuries. Without the relevant epidemiological data to show causation such plaintiffs will leave the courtroom empty handed. This outcome undermines the primary societal goals of tort law—compensation of the injured party and deterrence of risky behavior.

Ideally, the holding in this case would lead to the conduct of safer research studies rather than significantly fewer studies. Instead, the indeterminacy of the meaning of the Court's decision coupled with greater and more costly research burdens and the potential for significant liability will arguably have a chilling effect on the conduct of future public health studies. This, in turn, will have a detrimental effect on progress in the field of public health and may, inadvertently, limit the ability of plaintiffs through the tort system to receive compensation for public health harms or to force changes in public health practices.

From our perspective, the Court's Opinion might have better achieved the goal of safer research if it had been clearer in its articulation of the duty required of the researchers. Such a duty would clearly include those established by the federal regulations on human subjects research. If the Court felt compelled to go beyond these well established duties and impose a duty to warn of harms that do not arise out of the research interventions, factors that would be relevant to the imposition of such a duty might include whether: 1) the researchers have an ongoing relationship with the subjects and the information is gained during the time that there is contact between researcher and subject; 2) the researchers, as compared to the subjects,

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157. As a matter of public policy, KKI argued that the obligation appellants were seeking to impose on it would "effectively end the worthwhile research being conducted to find cost-effective ways to minimize lead paint poisoning, as well as many other types of research." Brief of Appellee at 20, *Grimes* (No. 129). KKI further pointed to the General Assembly's statement that it is vitally important to "reduce the incidence of childhood lead poisoning, while maintaining the stock of available rental housing." MD. CODE ANN. ENVIR. § 6-802 (2000).

have the means to measure the risk at issue and have superior knowledge of that risk; 3) the risk poses a serious threat to life or health; 4) the potential harm is imminent and will occur without intervention; and 5) there is an effective intervention.

### VIII. CONCLUSION - A HOLLOW VICTORY?

It is too early to tell how the lower courts will interpret the Court of Appeals decision in the Kennedy Krieger case and perhaps we are raising the specter of consequences that are far beyond what the Court intended. Nonetheless, the Court seems to be raising the odds of liability for researchers, and in the end, it may be a hollow victory for research subjects. Although the Court has made clear that there will generally be a duty on the part of researchers, the fact that the duty is so unclear and difficult to understand may mean that much less research of this sort will be carried out. If this is true, for the research that is carried out, plaintiffs may be unsuccessful because although they have established a duty, they will not have the empirical data necessary to prove causation. By creating a legal environment in which it is perceived as too risky to engage in such research, we may be denied information that not only might help future generations, but also might help future plaintiffs.