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THE LEAD-BASED PAINT ABATEMENT REPAIR & MAINTENANCE STUDY IN BALTIMORE: HISTORIC FRAMEWORK AND STUDY DESIGN

JOANNE POLLAK, J.D.*

The tragedy of lead paint exposure for young children has continued in this country for over a century, despite widespread knowledge of the danger of lead additives. During the first half of the 20th century, while almost every other country in the western world was banning the use of lead in interior house paint, the paint companies in the United States were promoting its use.¹ The paint companies' promotion included advertising which made children a central element of their campaigns even though lead's potentially devastating effects on the development of young children were well known.²

The problem stems from the fact that although lead in interior house paint improves durability,³ when taken internally, it may affect the central nervous system leading to neurobehavioral problems and learning deficiencies in young children.⁴ The lead in paint gets to children in several ways: from chips of paint

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1. 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. OF PUB. HEALTH, 36, 36-37 (January 2000). As early as 1848 there was knowledge of the dangers of lead poisoning. *See id.* at 36, 44 n.8. In the first decade of the 20th century extensive "scientific literature on the subject accumulated in Australia, England and the United States." *Id.* at 36. In 1922, the Third International Labor Conference of the League of Nations recommended the banning of white lead for use in interior paints, and by 1931, most European countries had banned its use. *See id.* at 37. Although there were calls for the banning of the use of lead in interior house paint in the United States as early as 1913, the Lead Industries Association (LIA) conducted an extensive campaign to assure the public that lead in paint was safe and specifically made children a central focus of an extensive marketing campaign. *See id.* at 37-41. The LIA disparaged clinical research demonstrating the dangers of lead paint and convinced homeowners and local and state governments to expand the use of interior lead paint. *See id.* at 42-43. During the 1940's and 1950's, some local and state health departments sought to warn the public about lead's dangers, and even though California in 1945 and Maryland in 1949 passed statutes requiring labeling regulations for lead paint, the LIA was instrumental in securing the Maryland law's repeal in 1950. *See id.* at 43.

2. *See id.* at 38-40.

3. U.S. DEP'T OF HUD, COMPREHENSIVE AND WORKABLE PLAN FOR THE ABATEMENT OF LEAD-BASED PAINT IN PRIVATELY OWNED HOUSING: REPORT TO CONGRESS, at 1-1 to 1-2 (1990).

4. *See* U.S. DEP'T OF HHS, THE NATURE AND EXTENT OF LEAD POISONING IN CHILDREN IN THE UNITED STATES: A REPORT TO CONGRESS I, II I-7 and IV 1-25 (July 1988); and U.S. DEP'T OF HUD, *supra* note 3, at xvi-xvii, 2-1 to 2-5.

that fall on the floor from peeling wall paint or when windows are moved up and down,⁵ and from lead dust that falls from the painted walls to the floors and furniture where very young children crawl and play.⁶ These paint chip flakes and dust may make their way into children's mouths when they naturally put their fingers in their mouths.⁷ This flaking and dust problem is exacerbated when children live in poorly maintained homes, often located in low income areas, where the homes contain lead-tainted paint.⁸

It was not until 1978 that the Consumer Products Safety Commission prohibited the use of lead in house paint.⁹ Yet the overwhelming legacy of homes filled with lead paint remained in both large cities and small communities. Since the dangers of lead paint in existing old housing stock were well known, what would or could be society's response? Would or could all existing housing be torn down to build new homes? Or could society find ways to make existing houses safer?

This article explores an attempt at the second response and what happened to researchers at the Kennedy Krieger Institute (Kennedy Krieger), a non-profit institute, when they tried to evaluate ways to make existing houses with lead paint safer for young children living in those houses. Their 1992 research study, the Repair and Maintenance Study, became the subject of the recent Maryland Court of Appeals decisions in *Grimes v. Kennedy Krieger Institute*.¹⁰ The case consolidated the petitions of two plaintiffs who alleged that Kennedy Krieger had not been timely in reporting dust lead levels to the families or in warning them of

5. See U.S. DEP'T OF HHS, CTR FOR DISEASE CONTROL AND PREVENTION, PREVENTING LEAD POISONING IN YOUNG CHILDREN 17-19 (1991).

6. See generally U.S. DEP'T OF HUD, *supra* note 3, at xvi.

7. See U.S. DEP'T OF HHS, *supra* note 5, at 18.

8. U.S. DEP'T OF HUD, *supra* note 3, at 2-19, 3-10 and 3-15.

9. 16 C.F.R. § 1303.1 (2002). Although some cities adopted laws or regulations prohibiting the use of lead in paint prior to 1978 (such as Baltimore for public housing in 1951), between the 1950's and 1977, paints with lead in excess of the then voluntary limits for lead in paint were produced. See U.S. DEP'T OF HHS, *supra* note 4, at 1-26, IX-5 and IX-7.

10. *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807 (Md. 2001), *reconsideration denied*, (Oct. 11, 2001). The court had harsh criticism for the design of the study inferring that by allowing families with young children to live in homes that were not completely lead free and measuring the effects of living in those homes, Kennedy Krieger had engaged in unethical behavior. See *id.* at 848. This extraordinary conclusion, based on a very incomplete record, was coupled with a holding that parents may not consent to participation by their children in research if there is any risk in the study. See *id.* at 858. In the court's order denying the request for reconsideration, the court clarified that the only conclusion that it reached as a matter of law was that, on the record currently before it, summary judgment was improperly granted. *Id.* at 861. The court further clarified that any risk in the context of parental consent "meant any articulable risk beyond the minimal kind of risk that is inherent in any endeavor." *Id.* at 862. Therefore, although the court held that parents could not consent to a child's participation in research if there were any risk to the child, the statement of the court in its order makes it clear that this holding is dicta and that this dicta is amended to adopt, in substance, the minimal risk definition under 45 C.F.R. § 46.102(i) (2001).

the hazards of lead in paint.¹¹ The court heard the matter on appeal from a summary decision in Kennedy Krieger's favor in the lower court.¹² The only issue on appeal was whether that summary judgment had been properly granted.¹³ There had been no trial on the facts in the lower court, including no exploration of the study design, the consent documents or the nature of the repair and maintenance measures in the homes.¹⁴ Consequently, the record before the court was overwhelmingly incomplete. Notwithstanding this limited record, however, the court came to the conclusion that the study was flawed and placed children at risk for lead poisoning.¹⁵ What, in fact, was flawed was both the court's analysis and its rush to judgment on a thin record.

In the late 1980's and early 1990's, there was a national crisis in lead paint poisoning, and it was critical that researchers explore methods that could, in the absence of any national or local mandate to fully abate homes with lead paint, or build a sufficient supply of new homes, reduce lead in homes in a safe and effective manner.¹⁶ The Repair and Maintenance Study was such a study. Contrary to the conclusion in *Grimes* that the study put children at risk, the facts show that the children in the study were in housing environments that did not put them at increased risk for lead poisoning, and, in fact, the study offered the expectation of decreased risk of lead poisoning. This article outlines the factual basis for the study, including the historical framework in which the study was proposed and carried out.

I. THE LEAD PAINT SITUATION AFTER 1978

The banning of lead paint in 1978, although a positive development, did not by itself eliminate the reality of all existing housing stock in the United States containing lead paint. Lead paint poisoning continued, and still continues, to be one of the most significant environmental health problems for children in the United States.¹⁷ Children across the nation were poisoned by lead paint, and public health officials and federal agencies were anxious to find the best way to address

11. See *Grimes*, 782 A.2d at 818.

12. See *id.*

13. *Id.*

14. Court Order Granting Motion for Summary Judgment, *Grimes v. Kennedy Krieger Institute Inc.*, 782 A.2d 807 (Md. 2001) (No. 24-C-99-000925).

15. See *Grimes*, 782 A.2d at 848.

16. See generally U.S. DEP'T OF HHS, *supra* note 4, at XI-7.

17. PRESIDENT'S TASK FORCE ON ENVTL. HEALTH RISKS AND SAFETY RISKS TO CHILDREN, ELIMINATING CHILDHOOD LEAD POISONING: A FEDERAL STRATEGY TARGETING LEAD PAINT HAZARDS, 11-13 (2000); Steven Waldman, *Lead and Your Kids: Disturbing New Evidence about the Threat to Their Health: How to Protect Them*, NEWSWEEK, July 15, 1991, at 43.

this significant public health problem.¹⁸ Building new homes using paint manufactured after 1978 would create houses free of lead based paint, although children in cities would still be exposed to lead in soil, drinking water, and other homes and buildings where lead was present.¹⁹ The availability of new homes varied throughout the United States, particularly in the older inner cities of the country, like Baltimore, where approximately 95% of the housing stock was built before the 1978 ban on lead in house paint.²⁰ The shortage of post-1978 housing was more acute in low-income neighborhoods where housing with lead paint was often in poor condition, and thus, put children at high risk of lead poisoning from flaking paint and lead dust.²¹

Children in Baltimore in the early 1990's were at very high-risk for lead poisoning compared to the nation as a whole. This risk factor is measured by testing a child's blood lead elevation, which is reported as the number of micrograms of lead per deciliter of blood or $\mu\text{g}/\text{dL}$.²² The rate of blood lead elevations in Baltimore City at this time was 10-15 times higher than the national rate.²³ Also, the Maryland Department of the Environment (MDE) had identified certain high-risk neighborhoods in Baltimore City where as many as 60% of tested children had blood lead elevations that were above 10 $\mu\text{g}/\text{dL}$.²⁴ According to the

18. See U.S. DHMH, STRATEGIC PLAN FOR THE ELIMINATION OF CHILDHOOD LEAD POISONING, 38-44 (February, 1991). See generally U.S. DEP'T OF HUD, *supra* note 3, at 6-10 to 6-12; U.S. EPA, STRATEGY FOR REDUCING LEAD EXPOSURES, at 13, 18 (1991).

19. See generally U.S. DEP'T OF HHS, *supra* note 5, at 17-22.

20. See U.S. CENSUS BUREAU, QUICK TABLES, DP-5. HOUSING CHARACTERISTICS: 1990, GEOGRAPHIC AREA: BALTIMORE CITY, MARYLAND, at http://quickfacts.census.gov/cgi-bin/cty_QuickLinks?24510 (last visited Oct. 14, 2002); See generally U.S. DEP'T OF HUD, *supra* note 3, at 3-6, 3-32.

21. See U.S. DEP'T OF HUD, *supra* note 3, at 2-16, 2-24.

22. See e.g., U.S. DEP'T OF HHS, *supra* note 5, at 1.

23. MD. DEP'T OF THE ENV'T, CHILDHOOD BLOOD LEVELS SURVEILLANCE IN MD., 1997 ANNUAL REPORT, at tbl. 3 [hereinafter MDE 1997 ANNUAL REPORT]; MD. DEP'T OF THE ENV'T, CHILDHOOD BLOOD LEAD SURVEILLANCE IN MD. 1993-1999 SUMMARY, at tbl. 5, Children 0-72 mos. [hereinafter MDE SUMMARY]; MD. DEP'T OF THE ENV'T, LEAD POISONING PREVENTION PROGRAM: CHILDHOOD LEAD REGISTRY, NO. AND PERCENT OF CHILDREN 0-72 MOS. SCREENED FOR LEAD POISONING WITH BLOOD LEAD LEVELS ≥ 10 , ≥ 15 , and ≥ 20 $\mu\text{g}/\text{dL}$, BALT. CITY ZIP CODES 1992-1995 [hereinafter MDE 0-72 MOS.]; MD. DEP'T OF THE ENV'T, RESIDENTIAL ZIP CODES OF CHILDREN AGED 12-36 MOS. WITH BLOOD LEAD LEVELS ≥ 10 $\mu\text{g}/\text{dL}$, BALT. CITY, 1992-1995 [hereinafter MDE 12-36 MOS.].

24. MDE 0-72 MOS., *supra* note 23 at tbl. 3 ; MDE 12-36 MOS., *supra* note 23 at 1. See, e.g., MDE SUMMARY, *supra* note 23; MD. DEP'T OF THE ENV'T, BALT. CITY NEIGHBORHOODS AT HIGHEST RISK FOR CHILDHOOD LEAD POISONING, CHILDHOOD LEAD REGISTRY (1992) [Hereinafter MDE NEIGHBORHOODS]; MD. DEP'T OF THE ENV'T, LEAD POISONING PREVENTION PROGRAM, DISTRIBUTION OF CHILDREN AGE 6 AND UNDER BY BLOOD LEAD LEVEL (VENIPUNCTURE ONLY) BY CENSUS TRACT: BALT. CITY, 1992 [hereinafter MDE 6 AND UNDER]; MD. DEP'T OF THE ENV'T LEAD POISONING PREVENTION PROGRAM, BALT. CITY CENSUS TRACTS WITH THE HIGHEST PERCENTAGE OF KNOWN CASES OF CHILDHOOD LEAD POISONING 20 $\mu\text{g}/\text{dL}$ IN 1992 [hereinafter MDE HIGHEST PERCENTAGE]; MD. DEP'T OF THE ENV'T LEAD POISONING PREVENTION PROGRAM, BALTIMORE CITY CENSUS TRACTS HAVING SHOWN THE HIGHEST NUMBER OF KNOWN CASES OF CHILDHOOD LEAD POISONING 10 $\mu\text{g}/\text{dL}$ IN 1992 [hereinafter MDE HIGHEST NUMBER]; See also Balt. City Health Dep't,

Center for Disease Control and Prevention (CDC) 1991 guidelines, a blood lead level above 10 µg /dL could pose a risk to children.²⁵ The rate of blood lead elevations in these high-risk areas was 20-30 times higher than the national rate.²⁶

Not only did as many as 60% of tested children in identified high-risk neighborhoods have blood lead elevations above 10 µg/dL, the CDC's threshold level of concern, but 15% to 22% of tested children had blood levels at twice that level, i.e., above 20 µg /dL.²⁷ This rate was 30-45 times higher than the national rate.²⁸ In addition to the known levels of toxicity, a problem existed with identifying new cases. MDE data indicated that less than half of Baltimore City children were screened for lead levels by health care providers during the 1990's,²⁹ presumably including children in many of the highest-risk neighborhoods.

Thus, it was an accepted fact that children were being poisoned in older Baltimore housing neighborhoods. Yet despite this, the availability of affordable new housing or comprehensively lead-abated homes in the poor areas of the City was almost non-existent.³⁰ Given the high prevalence of lead painted houses and the slow pace of housing replacement, it was recognized that without a substantial subsidy for new or improved homes, children would continue to occupy older houses with lead hazards for decades to come.

Kennedy Krieger is a non-profit institute dedicated to the treatment of children with developmental diseases and disabilities. Over many decades, both before and after 1978, Kennedy Krieger's lead prevention and treatment program treated hundreds of lead exposed children who came to its clinical program for treatment after they were identified as lead poisoned.³¹ The data showed that these and other Baltimore City children had been poisoned in the same older, lead-painted houses in the same older neighborhoods and blocks of Baltimore City.³² Kennedy Krieger and society at large were faced with the reality that:

A New Housing Regulation, XXVII BALT. HEALTH NEWS 113, 114-115 (August-September, 1951) (showing the incidence of lead poisoning in Baltimore children from 1931-1951).

25. U.S. DEP'T OF HHS, *supra* note 5, at 1.

26. *See generally* MDE 1997 ANNUAL REPORT, *supra* note 23; MDE 0-72 MOS., *supra* note 23; MDE 12-36 MOS., *supra* note 23.

27. *Id.*

28. *Id.*

29. *See* MD. DEP'T OF THE ENV'T, CHILDHOOD LEAD REGISTRY, OCCURRENCE OF LEAD POISONING IN CHILDREN 0-72 MOS., REPORT FOR 1/94-12/94; MDE SUMMARY, *supra* note 23.

30. Telephone Interview with Barry Mankowitz, President, City Homes, Inc. (August 8, 2002).

31. E-mail from Dr. Gary Goldstein, President, Kennedy Krieger Institute, to Joanne Pollak, Vice President & General Counsel, Johns Hopkins Medicine (Nov. 1, 2002, 14:24:00 EST) (on file with author).

32. *See* Balt. City Health Dep't, *supra* note 24; MDE 6 AND UNDER, *supra* note 24; MDE HIGHEST PERCENTAGE, *supra* note 24; MDE HIGHEST NUMBER, *supra* note 24.

- there was an acute shortage of lead paint free housing, particularly for low income/high-risk populations;³³
- society had not committed the resources to abating lead paint hazards in these private, older homes;³⁴
- efforts to identify and reduce environmental sources of lead in the home were made only after children were found to be lead poisoned;³⁵
- there were no laws or regulations requiring landlord-initiated preventive maintenance to reduce lead hazards in rental units;³⁶ and
- because of these factors, children would continue to occupy high-risk lead painted houses for decades to come.³⁷

Dr. J. Julian Chisolm, Director of Kennedy Krieger's lead prevention and treatment program, and his colleague, Dr. Mark Farfel, understood the acute need to find safe, effective and practical ways to control residential lead exposures that could be applied on a widespread basis.³⁸ They understood that these ways were needed in order to help society prevent lead poisoning from occurring in the first place so that new generations of children would not become poisoned.³⁹ Their goal was to provide a scientifically sound basis for prevention policies and practices.⁴⁰

II. THE EARLY WORK OF DRs. CHISOLM AND FARFEL

Drs. Chisolm and Farfel conducted research to determine and document safe and effective methods for the control of lead paint hazards in homes. In the 1980's they secured research funding from various federal agencies, including the Environmental Protection Agency (EPA), to perform several studies, the goal of which was to document and evaluate the effectiveness of some commonly used

33. See U.S. DEP'T OF HUD, *supra* note 3, at 3-6, 3-32; LEAD-BASED PAINT HAZARD REDUCTION AND FINANCING TASK FORCE, PUTTING THE PIECES TOGETHER: CONTROLLING LEAD HAZARDS IN THE NATION'S HOUSING (June, 1995).

34. See U.S. DEP'T OF HUD, *supra* note 3, at xxi.

35. See U.S. DEP'T OF HHS, *supra* note 5, at 2-3.

36. Maryland's landlord law affecting preventive lead reduction activities was passed in 1994, with regulations effective in 1996. The Lead Poisoning Prevention Program Act, MD. CODE ANN., [ENVIR.], §§6-801-852 (2001); MD. REGS. CODE tit. 26 §16.02.03 (1996).

37. See U.S. DEP'T OF HUD, *supra* note 3, at 1-2.

38. See J. Julian Chisolm, Jr., M.D., *Removal of Lead Paint from Old Housing: The Need for a New Approach*, 76 AM. J. PUB. HEALTH 236, 236-37 (1986); Mark R. Farfel, Sc.D. & J. Julian Chisolm, Jr., M.D., *Health and Environmental Outcomes of Traditional and Modified Practices for Abatement of Residential Lead-Based Paint*, 80 AM. J. PUB. HEALTH 1240, 1243-44 (1990).

39. See Chisolm, *supra* note 38.

40. See Farfel & Chisolm, *supra* note 38, at 1240-44 (comparing abatement procedures and making recommendations for improvements).

lead abatement methods.⁴¹ Through Kennedy Krieger's work, and the work of others, it was discovered that certain methods of removing lead in paint and dust were actually dangerous to humans.⁴² For example, it was discovered that the use of do-it-yourself heat guns, open flame torches and sanding equipment for removing lead paint actually increased the level of lead dust, and consequently, lead poisoning in children and workers.⁴³ Documentation of these hazards was critical to the development of more protective practices and policies in this area.

Drs. Chisolm and Farfel and others also performed studies on homes to determine if alternative lead hazard reduction procedures worked to reduce lead levels in house dust.⁴⁴ They found that several methods such as encapsulating lead paint surfaces, replacing lead painted components (e.g., windows), removing deteriorated and chipped paint, making surfaces smooth and more easy to clean (e.g., floor coverings) and professional cleaning with special vacuums and wet washing methods were successful in significantly reducing lead dust levels in these homes.⁴⁵ The studies documented significant reduction, but not total elimination of lead dust through use of these methods.⁴⁶

Using the techniques identified by these and other research studies, Baltimore City began a lead reduction program in the late 1980's in consultation with Kennedy Krieger. Dozens of homes were improved through this City program.⁴⁷ Unfortunately, the cost of this comprehensive lead abatement often exceeded the market value of older houses in poor neighborhoods.⁴⁸

41. See generally Farfel & Chisolm, *supra* note 38; Evan Charney et al., *Childhood Lead Poisoning: A Controlled Trial of the Effect of Dust-Control Measures on Blood Lead Levels*, 309 *NEW ENG. J. MED.* 1089, 1089 (1983).

42. Chisolm, *supra* note 38, at 236; Farfel & Chisolm, *supra* note 38, at 1240, 1242-44; Press Release, U.S. Consumer Prod. Safety Comm'n, CPSC Warns About Hazards of Do-It-Yourself Removal of Lead-Based Paint (Feb. 1989) available at <http://www.cpsc.gov/CPSCPUB/PUBS/5055.html> (last visited Oct. 14, 2002). See generally, A. Fishbein et al., *Lead Poisoning from Do-It-Yourself Heat Guns -Removing Lead-Based Paint: Report of Two Cases*, 24 *ENVTL. RES.* 425 (1981); Y. Amitai et al., *Hazards of Deleading Homes of Children with Lead Poisoning*, 141 *Am. J. Diseases of Child.* 758 (1987).

43. Farfel & Chisolm, *supra* note 38, at 1243-44. See generally Fischbein et al., *supra* note 42.

44. See generally Mark R. Farfel & J. Julian Chisolm, Jr., *An Evaluation of Experimental Practices for Abatement of Residential Lead-Based Paint: Report on a Pilot Project*, 55 *ENVTL RES.* 199 (1991); Mark R. Farfel et al., *The Longer Term Effectiveness of Residential Lead Paint Abatement*, 66 *ENVTL RES.* 217 (1994).

45. Farfel & Chisolm, *supra* note 44, at 203-09; Farfel et al., *supra* note 44, at 217, 219-20.

46. Farfel & Chisolm, *supra* note 44, at 203-10; Farfel et al., *supra* note 44, at 219-20.

47. Farfel et al., *supra* note 44, at 218-20; See generally BALT. CITY DEP'T OF HOUS. AND CMTY. DEV. & CITY BUILDERS (Lead Paint Abatement Project: July 1, 1987-Dec. 31, 1990) (describing the abatement process and accomplishments of a pilot project) (on file with the Journal of Health Care Law & Policy).

48. LEAD-BASED PAINT HAZARD REDUCTION & FIN. TASK FORCE, PUB. NO. HUD-1547-LBP 3, 6 PUTTING THE PIECES TOGETHER: CONTROLLING LEAD HAZARDS IN THE NATION'S HOUSING (1995).

III. THE REPAIR AND MAINTENANCE STUDY

In the late 1980's and early 1990's, recognizing that full abatement of all housing with lead based paint was extraordinarily expensive and unlikely to be funded in the immediate future, several federal agencies called for research regarding the effectiveness of various lead reduction strategies.⁴⁹ Drs. Chisolm and Farfel proposed research regarding lead reduction methods that might yield commensurate reduction in lead dust in the homes, which could be applied on a widespread basis, and, which in turn, would prevent or reduce the risk of lead poisoning in children.⁵⁰ In 1990, the EPA, through its Office of Pollution Prevention and Toxics, issued a work assignment to Battelle Memorial Institute, which in turn subcontracted with Kennedy Krieger, directing the design of the Lead-Based Paint Abatement and Repair and Maintenance Study in Baltimore.⁵¹ The purpose of the study was to evaluate the short and long-term effectiveness of various levels of repair and maintenance in reducing exposure to lead in the home.⁵² The EPA's work assignment stated that:

Lead has been identified as a significant cause of neurobehavioral and learning deficits in young children which are long lasting, if not indeed permanent. The recent report to Congress by the Agency for Toxic Substances and Disease Registry (July, 1988) points out that lead in existing residential paint, household dust and soil now constitutes the major source of high lead exposure in U.S. children. This study would provide a means of evaluating new policies and practices in Maryland for abating lead in residential paint and dust.⁵³

49. U.S. DEP'T OF HUD, *supra* note 3, at xv, xvi, xxii; U.S. DEP'T OF HHS, *supra* note 4, at XI-3 - XI-5.

50. Letter from J. Julian Chisolm, Jr., M.D., Associate Professor, Johns Hopkins School of Medicine, & Mark Farfel, Sc.D., Director of Lead Poisoning Prevention, Kennedy Krieger Inst., Assistant Professor, Johns Hopkins School of Hygiene & Public Health, to Robert Elias, Ph.D., EPA (Sept. 28, 1989) (on file with the Journal of Health Care Law & Policy).

51. Contract for Design of LBP Abatement, R&M Study, Contract No. 68-D8-0115, May 14, 1990, U.S. EPA-Battelle Memorial Inst. (on file with the Journal of Health Care Law & Policy) [hereinafter EPA-Battelle Contract]; Subcontract for Design of Lead-Based Paint Abatement and R&M Study in Baltimore, Subcontract No. W-8300(1566)-1628, June 25, 1990, Battelle Memorial Inst.-Kennedy Krieger Inst. (on file with the Journal of Health Care Law & Policy) [hereinafter Battelle-KKI Subcontract].

52. BATTELLE & KENNEDY KRIEGER INST., FINAL QUALITY ASSURANCE PROJECT PLAN FOR KENNEDY KRIEGER INSTITUTE: LEAD-BASED PAINT ABATEMENT & REPAIR & MAINTENANCE STUDY I (July 22, 1992).

53. EPA-Battelle Contract, *supra* note 51 at 2.

With the EPA's supervision and approval, researchers at Kennedy Krieger designed a research study to investigate lead hazard reduction in existing homes.⁵⁴ The study included approximately 75 structurally sound homes in Baltimore's high-risk neighborhoods that had not received any lead reduction improvements (unimproved homes).⁵⁵ Through the efforts of the landlords of these homes who took advantage of a State loan program, these homes underwent various combinations of lead abatement improvements called repair and maintenance or R&M.⁵⁶ (The unimproved homes that received improvement under the State's loan program were called R&M homes and the study was called the R&M Study.) About two-thirds of the R&M houses were located in the top 20% of census tracts in Baltimore City in terms of risk of lead exposure.⁵⁷ The R&M Study was intended to measure the relative effectiveness of various combinations of prevention methods and strategies,⁵⁸ all of which had been shown to substantially reduce residential lead dust exposure in a safe manner, and, therefore, in turn, to reduce the risk of lead poisoning.⁵⁹

There were three types of R&M homes (Levels I, II and III) and each level received different types of lead reduction measures previously tested in occupied or vacant houses.⁶⁰ All R&M homes also received prescribed common measures, such as removal of deteriorated interior paint, professional cleaning, provision of resident education, cleaning kits, door mats, and ongoing house observation.⁶¹ Although each of the different preventive methods used in the three levels of houses had been used in one of the prior studies referenced above, and had been shown to significantly reduce lead dust levels, the exact combination of the methods used in each level had not been tested previously.⁶²

In addition to the R&M homes, the Study included two groups of homes to be used as comparisons to the R&M homes.⁶³ One group of homes had been

54. See BATTLE & KENNEDY KRIEGER INST., *supra* note 52.

55. See BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 2, §2.1.

56. See BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 1, §2.0; 55, tbl. 2.6; 58, tbl. 2.8; See generally Balt. City Dep't of Hous. & Cmty. Dev. & City Builders, *supra* note 47, at 1-2 (describing the process by which property owners applied for abatement funding).

57. E-mail from Dr. Mark Farfel, Associate Professor, Kennedy Krieger Institute and Department Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, to Joanne Pollak, Vice President & General Counsel, Johns Hopkins Medicine (Nov. 1, 2002, 16:36:00 EST) (on file with author).

58. MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy) [hereinafter Research Project Notification].

59. See Farfel & Chisolm, *supra* note 44, at 203-10; Farfel et al., *supra* note 44, at 219-20.

60. BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 53-59, §2.3.1.6. See also Farfel & Chisolm, *supra* note 44 at 203-210; Farfel et al., *supra* note 44 at 217, 219-20.

61. *Id.*; see also Research Project Notification, *supra* note 58, at attachment 1.

62. Farfel & Chisolm, *supra* note 44, at 203-10; Farfel et al., *supra* note 44 at 217, 219-20; See generally BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 50 (stating that procedural revisions would be made as needed in homes where treatments prove ineffective).

63. BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 66-67, §2.3.1.6.

comprehensively abated under a Baltimore City lead abatement program in the late 1980's before the R&M study was implemented.⁶⁴ The second group of homes had been built after 1978, the year when the federal government banned the use of lead in house paint.⁶⁵ Notably, and in direct contrast to the negative comparisons made in the *Grimes* case,⁶⁶ the study did not include a control group of unimproved homes where there were no interventions to reduce lead in dust and paint.⁶⁷

IV. ENROLLMENT OF FAMILIES IN THE R&M STUDY

To carry out the R&M Study in these five categories of homes, two different enrollment processes were followed, depending on whether the homes were occupied or not occupied.⁶⁸

A. Occupied R&M Homes:

From the prior studies, it was known that certain lead reduction measures could be performed safely so long as there were precautions in place to protect occupants, their belongings, and the workers.⁶⁹ Specifically, it was believed that the less intensive types of interventions that were going to be used in the study's occupied homes, such as the placement of textured floor mats, sealing floors with sealants, removal of loose and peeling paint, installing aluminum caps on window wells and other related treatments,⁷⁰ were safe to perform in occupied homes.⁷¹ The majority of the R&M homes included in the study were owned by City Homes, Inc.,⁷² a non-profit corporation whose mission was to operate and maintain decent and affordable rental housing in low income urban neighborhoods. City Homes and other private landlords who participated in the study identified what they believed to be structurally sound homes that might be candidates for the intervention.⁷³ City Homes also had a pre-existing lead poisoning prevention policy that included tenant education and making their improved units available to families with lead poisoned children.⁷⁴ As part of the pre-enrollment activities,

64. *Id.*

65. *See id.*

66. *See Grimes*, 782 A.2d at 816-17 (Md. 2001).

67. BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 50, §2.3.1.6.

68. *Id.* at 60-67.

69. Chisolm, *supra* note 38; Farfel & Chisolm, *supra* note 38, at 1244; Press Release, U.S. Consumer Prod. Safety Comm'n, CPSC Warns About Hazards of Do-It-Yourself Removal of Lead-Based Paint (Feb. 1989), available at <http://www.cpsc.gov/CPSCPUB/PUBS/5055.html> (last visited Oct. 14, 2002); Fishbein, *supra* note 42, at 428, 430; Amital, *supra* note 42, at 760.

70. *See* BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 53, tbl. 2.6; 55, tbl. 2.8.

71. *See generally* Research Project Notification, *supra* note 58 at 3 (explaining the steps that were taken to protect families during the R&M process).

72. Research Project Notification, *supra* note 58 at 2.

73. BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 60-61, §2.3.1.7.

74. Research Project Notification, *supra* note 58 at 2.

Kennedy Krieger research staff interviewed the families living in the identified homes.⁷⁵ The purpose of the interview was to determine whether the family and the home met the study's criteria, including the absence of certain health issues and the presence of one or more young children, *i.e.*, up to four years of age.⁷⁶ In addition, the interviewers assessed the family's interest in participating in the research study.⁷⁷

The structure of the houses was evaluated to determine if the houses met the State's loan requirement for structural soundness.⁷⁸ If the house was determined to be structurally unsound, the house and households were not eligible for participation.⁷⁹ During both the pre-enrollment outreach visit and the home visit, the Kennedy Krieger outreach team reviewed the procedures that would occur if the family participated in the study, including an explanation of the interventions to be performed in the home, family education about lead poisoning and lead dust control, provision of a cleaning kit with instructions on its use, observation of the home and surrounding for obvious defects, and regular dust and blood lead testing.⁸⁰ There was an extensive consent process.⁸¹ If a family expressed interest in the study and agreed to participate, the landlord could apply for a loan from the State to perform the R&M lead reduction interventions in the home.⁸² If the family did not agree to participate in the R&M Study, the landlord could still apply for State loan funds to conduct some form of lead hazard reduction work.⁸³

All of the R&M Level I homes and half of the R&M Level II homes were occupied when the enrollment process began.⁸⁴ Thus, all of these families were living in non-improved properties.⁸⁵ Absent the families' enrollment in the study, and the landlords' participation in the State's Loan Program, the R&M interventions and related active education and follow-up (including blood lead and dust lead testing) probably would not have occurred. Therefore, unless these families' landlords independently had accessed the State's Loan Program, the families would have continued to live in the non-improved properties.

Prior to the actual R&M interventions, the families were asked to leave the home for the day or two it took to have the interventions performed by an

75. See BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 63, §2.3.1.7.

76. See BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 47, §2.3.1.4.

77. See BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 60-67, §2.1.3.7.

78. See BATTLE & KENNEDY KRIEGER INST., *supra* note 52 §2.3.1.4.

79. See BATTLE & KENNEDY KRIEGER INST., *supra* note 52 §2.3.1.4.

80. See BATTLE & KENNEDY KRIEGER INST., *supra* note 52 at 60-67, §2.3.1.7.

81. See Farfel, *supra* note 58 (consent forms for study).

82. Letter from Md. Dep't of Hous. & Comm. Dev., in Research Project Notification, *supra* note 58, at App. A.

83. See MD CODE ANN. art. 83B, §2-307 (Repl. Vol. 1991).

84. U.S. EPA, LEAD-BASED PAINT ABATEMENT AND REPAIR AND MAINTENANCE STUDY IN BALTIMORE: FINDINGS BASED ON TWO YEARS OF FOLLOW-UP 25 (EPA No. 747-R-005) (1997).

85. *Id.* at viii.

experienced and state certified lead reduction contractor.⁸⁶ Thereafter, Kennedy Krieger research staff would visit the home on a regularly scheduled basis to perform study-related functions.⁸⁷ These included measurement of the dust lead levels, visual observations of the house, cleaning education, and discussion of lead dust reduction techniques.⁸⁸ Kennedy Krieger assisted families with transportation to the Kennedy Krieger Clinic where blood samples were collected from the young children at regular intervals to determine the blood lead level at the time of the test.⁸⁹

B. Unoccupied R&M Homes:

One group of homes, labeled R&M III, received the most intensive combination of lead reduction measures.⁹⁰ Level III lead reduction methods included the removal of old windows and the installation of new windows.⁹¹ This involved a greater degree of disturbance of lead paint and therefore was deemed safe only for application in vacant housing.⁹² Thus, none of the families involved in the R&M III homes were approached about participation in the study until after the family had rented a house in which the lead reduction measures had already been performed by the landlord and contractors.⁹³ This also was true for the families that moved into the vacant R&M II homes after the lead reduction measures had been performed by the landlords and contractors.⁹⁴ The research study procedure was that vacant homes in high-risk areas that fit the structural soundness criteria for the study would be identified, the landlords would apply for a State loan to do the work, qualified workmen would perform the work, and then the landlord would rent the home to families.⁹⁵ Thereafter, Kennedy Krieger

86. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 52-57, tbls. 2.5- 2.10.

87. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 52-57, tbls. 2.5- 2.10.

88. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 52-57, tbls. 2.5- 2.10.

89. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 1, §3.1.1.1 (Blood); 15-16, §4.2.2 (procedures); 15-17, §2.1.4 (times).

90. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at tbl. 2.10.

91. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at tbl. 2.10.

92. See *generally* Fischbein, *supra* note 42; Chisolm, *supra* note 42; Amitai, *supra* note 42; Consumer Prod. Safety Comm'n, *supra* note 42; Farfel & Chisolm, *supra* note 38.

93. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 60-65, §2.3.1.7.

94. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 60-65, §2.3.1.7.

95. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 64-65, §2.3.1.7. All the children in the R&M homes had reportedly spent most or all of their lives living in existing older, low-income rental housing and thus had been at risk of exposure to lead in dust and paint in their homes and environment. U.S. EPA, *supra* note 84, at viii. However, it was theoretically possible that an unoccupied R&M unit could have been rented to a family who had had no history of living in older, low-income rental housing. That home would have been rented to a family whether or not the family ultimately chose to participate in the study. If there was an ethical question of the propriety of allowing families to move into lead-reduced rather than lead-paint free homes, that ethical question existed for homes renovated through any lead paint reduction program, not just homes whose landlords accessed the City's lead reduction loan program.

contacted families in the rental homes to determine if they wished to participate in the study.⁹⁶ If the family agreed to participate, the family received all of the intervention strategies and active follow-up discussed above.⁹⁷

C. Previously Abated and New Homes (All Occupied):

The homes previously abated prior to the start of the R&M Study and the post-1978 newer homes were occupied at the start of the R&M Study, and thus families were contacted while living in the homes.⁹⁸ Kennedy Krieger followed the same consent procedures and primary prevention strategies as described above for the occupied R&M homes, including explaining steps that the family could take to reduce any risk of lead exposure.⁹⁹ For all study participants in the previously abated homes and the newer homes, the study involved active follow-up, including the provision of the MDE pamphlet, ongoing family education, monitoring of blood and dust lead levels at regular intervals, observation of the house for obvious defects, and any follow-up deemed necessary as a result of blood level changes or obvious house defects.¹⁰⁰

V. THE ENROLLEES WERE GIVEN NOTICE OF THE CONTINUING RISK OF LEAD PAINT EXPOSURE AND THE PURPOSE OF THE STUDY:

All families in the R&M Study were advised in discussions and in written consent documents that they were living in homes or environments that were not lead free.¹⁰¹ All the consent forms stated that:

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.¹⁰²

In addition, all the families who lived in or would live in the R&M homes were advised that the R&M repairs are not intended, or expected, to completely

96. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 65.

97. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 tbl. 2.5; 54, tbl. 2.7; 56 tbl. 2.10 (each providing that efforts would be made to increase awareness and knowledge of lead poisoning among property owners and occupants).

98. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 66-67, §2.3.1.7.

99. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 66-67, §2.3.1.7.

100. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at 66-67, §2.3.1.7.

101. Consent Forms for Study, in MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy).

102. Consent Forms for Study, in MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy).

remove exposure to lead¹⁰³ and that the special repairs were being done in order to reduce, not eliminate, exposure to lead in paint and dust.¹⁰⁴

All the families in the R&M Study also were advised as to the purposes of the study, including the fact that there were different levels of repair in the R&M homes.¹⁰⁵ Likewise, all families were advised that the study hoped to learn about how well these different practices worked for reducing exposure to lead in paint and dust.¹⁰⁶

The families in the R&M homes were advised that they would be in homes with different levels of repair, and the consent forms for both the occupied homes,¹⁰⁷ and for the unoccupied homes,¹⁰⁸ disclosed that two levels of repair and maintenance were involved. Both forms stated that one purpose of the Study was to see how well the two levels of repair worked.¹⁰⁹ The determination of which level of R&M would be used in occupied or unoccupied homes was done on a random basis.¹¹⁰ Because prior studies had not previously used the exact

103. Consent Forms for Study, in MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy).

104. Consent Forms for Study, in MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy).

105. Consent Forms for Study, in MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy).

The four consent forms included the following:

The consent form for the occupied homes that received R&M intervention stated that: We are interested in finding out how well the two levels [Levels I and II] of repair worked and we are now doing a study to learn about how well different practices work for reducing exposure to lead in paint and dust.

The consent form for the unoccupied homes that received R&M interventions stated that: We are interested in finding out how well the two levels [Levels I and III] of repair worked and we are now doing a study to learn about how well different practices work for reducing exposure to lead in paint and dust.

The consent form for the previously abated dwellings stated that: We are now doing a study to learn about how well these and other practices worked and the purpose of the blood lead level testing is to determine how well the abatement of the lead paint works in keeping young children's blood lead at low levels.

The consent form for the post-1978 urban dwellings stated that: We are now doing a study to learn about how well different practices work for reducing exposure to lead in paint and dust and the purpose of testing for lead in and around a house like yours, and in blood, is to determine the contribution of non-paint sources to total lead exposure. This will help us learn more about the role of outside lead sources and whether modern housing alone will keep blood lead levels at acceptable levels.

106. Consent Forms for Study, in MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy).

107. Consent Forms for Study, in MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy).

108. Consent Forms for Study, in MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy).

109. Consent Forms for Study, in MARK FARFEL, RESEARCH PROJECT NOTIFICATION 1 (No. 91-05-02-01) (1992) (on file with the Journal of Health Care Law & Policy).

110. See BATTTELLE & KENNEDY KRIEGER INST., *supra* note 52, at 15, §2.1.4.

combinations of methods for dust lead reduction as were used in the three R&M levels, the Study was designed to measure the effectiveness of those combinations.¹¹¹ What was known was that, based on prior research, all the methods applied in the R&M houses were expected to substantially reduce lead in dust.¹¹²

A. Alternatives to Participation in the R&M Study

The R&M Study involved blood lead testing for all children in the Study.¹¹³ Although it was not necessary to join the study to receive blood lead testing, blood lead testing for all children was not a requirement of the City, State or federal government at the time of the Study.¹¹⁴ In fact, only approximately one-third of at risk children in Baltimore City during this period were tested for blood lead levels.¹¹⁵ Thus, if a family decided not to participate in the R&M Study, blood lead level testing would be a matter between the family and the child's health care provider, if the family had one. Although it was not necessary to join the Study for a landlord to access the State's loan program, unless a particular landlord did so, the alternative to participation in the Study for those living in occupied homes (R&M Levels I & II) was to remain in the home without having the repair and maintenance improvements made. Since the R&M improvements had already been made to the vacant Level II and III houses before tenants moved in, the alternative for these families was to move into the homes but decline enrollment in the Study. The same was true for those occupying the previously abated dwellings and the newer (post-1978) homes. The only alternative was not to take part in the Study (thereby foregoing research related blood tests, environmental tests and family education sessions).

B. The R&M Study Did Not Expose Children to Increased Risk

The involvement of children in the R&M Study included drawing blood to determine blood lead levels; living in a dwelling that either would undergo or had undergone lead hazard reduction procedures expected to lower the risk of exposure to lead in dust and paint; education about lead dust control; and home observation for obvious structural defects.¹¹⁶ These activities did not put children at increased risk.¹¹⁷

111. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52, at 1.

112. See Farfel & Chisolm, *supra* note 44; Farfel et al., *supra* note 44.

113. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52 at §3.1.1.1. See also 52, tbl. 2.5; 54, tbl. 2.7; 56 tbl. 2.10.

114. U.S. DEP'T OF HHS, *supra* note 4, at 15.

115. MDE SUMMARY, *supra* note 23.

116. See generally BATTELLE & KENNEDY KRIEGER INST., *supra* note 52.

117. See generally Fischbein, *supra* note 43; Farfel & Chisolm, *supra* note 43; Farfel & Chisolm, *supra* note 44; Farfel et al., *supra* note 44.

The R&M interventions in the homes, based on prior research, were expected to lower the risk of lead poisoning for occupants of the R&M homes.¹¹⁸ (See for example, Drs. Farfel and Chisolm's Report on a Pilot Project where the experimental dust lead reductions to the floors, window sills and window wells were reported to be 89.3%, 91.1% and 96.6% respectively, over the follow-up test period.¹¹⁹ Based on the reported housing histories of the families in the R&M Study, all the children in the R&M homes had spent most or all of their lives living in existing older, low-income rental housing and thus had been at risk of exposure to lead in dust and paint in their homes and in their environment.¹²⁰ This is consistent with the fact that approximately ninety-five percent of the then available housing stock in Baltimore City had been built prior to 1978 and the fact that low-income housing was high-risk housing due to poor maintenance.¹²¹ Accordingly, any family living in an unimproved home was already at risk for lead poisoning and could expect to benefit from the R&M Study interventions. Likewise, any family moving into an improved home would be moving into safer housing than approximately 95% of the options then available to low income families in high-risk neighborhoods in Baltimore City.¹²² Because families would have moved into all of these homes, with or without the Study, the Study itself did not expose the children to an increased risk of exposure to lead.

As mentioned above, the Study included two comparison groups, *i.e.*, the families in the comprehensively abated homes, and the families in the post-1978 homes.¹²³ A control or a comparison group could be included in the Study because monitoring children living in the previously abated or new homes did not place children at an increased risk.¹²⁴ Even though a benefit to participants was not required in order to include control groups in the Study, there were several benefits, such as blood testing and education, to those participants.¹²⁵

118. Farfel & Chisolm, *supra* note 44; Farfel et al., *supra* note 44.

119. Farfel & Chisolm, *supra* note 44, at 199.

120. U.S. EPA, *supra* note 84, at viii.

121. U.S. DEP'T OF HUD, *supra* note 3, at 3-6, 3-32; CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 20.

122. U.S. DEP'T OF HUD, *supra* note 3, at 3-6, 3-32; CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 20.

123. BATTELLE & KENNEDY KRIEGER INST., *supra* note 52, at 66-67, §2.3.1.7.

124. See AM. ACAD. OF PEDIATRICS POL'Y STATEMENT, *GUIDELINES FOR ETHICAL CONDUCT OF STUDIES TO EVALUATE DRUGS IN PEDIATRIC POPULATIONS* (RE 9503) (Vol. 95, No. 2 at 286-94) (1995); NIH, OFFICE OF EXTRAMURAL RES., QUESTIONS AND ANSWERS ABOUT THE NIH POL'Y AND GUIDELINES ON THE INCLUSION OF CHILDREN AS PARTICIPANTS IN RES. INVOLVING HUM. SUBJECTS, §21 (1999), available at http://grants2.nih.gov/grants/funding/children/pol_children_qa.htm (last visited Oct. 15, 2002).

125. Research Project Notification, *supra* note 58, at 4. The court in *Grimes* criticized the Institutional Review Board (IRB) for trying to characterize the R&M Study as of benefit to the members of the control group in order to make inclusion of a control group acceptable under the federal regulations. See *Grimes*, 782 A.2d at 817. The IRB may have wanted to emphasize the prospect of benefits to normal individuals through enrollment in the study. However, because the study did not

As mentioned above, the protocol eligibility requirements included families with children under four years of age.¹²⁶ Because lead poisoning was a problem in very young children, the Study was targeted at high-risk housing that would be occupied by families with children.¹²⁷ Previous research showed that interventions, such as those employed in the R&M study homes, as well as in previously abated homes, would offer the expectation of reduced lead situations from those available in non-improved homes;¹²⁸ therefore it was appropriate to target these homes and the families that lived or moved into these homes for inclusion in the Study. Although the court in *Grimes* inferred that a study of the relative effectiveness of these lead hazard reductions methods was unethical,¹²⁹ the court was not presented with the context of the lead problem or the complete design of the study. Based on a full understanding of the daunting problem of lead in the overwhelming majority of housing stock in these high-risk neighborhoods, the prior studies which supported an expectation of lead dust reduction in all of the R&M homes, the disclosures made to the families in the study, and the protections built into the study for ongoing education and blood and dust monitoring, the Study design was both appropriate and ethical.¹³⁰

increase the risk to participants, it was not necessary for there to be any direct benefit to members of the control group in order to include the control group in the R&M Study. See NIH, *supra* note 124.

126. Research Project Notification, *supra* note 58, at 1.

127. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52, at 47-48, §2.3.1.4.

128. See generally Farfel & Chisolm, *supra* note 44; Farfel et al., *supra* note 44.

129. See *Grimes*, 782 A.2d at 848; see *supra* text accompanying note 10.

130. See NAT'L COMM'N FOR THE PROTECTION OF HUM. SUBJECTS OF BIOMEDICAL & BEHAVIORAL RES., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUM. SUBJECTS OF RES. (GPO PUB. No. 887-809) (1979) [hereinafter BELMONT REPORT]. The Belmont Report established three fundamental ethical principles relevant to research involving human subjects—respect for persons, beneficence, and justice. *Id.* at 5-8. The R&M Study design demonstrates a respect for persons in that there was an extensive consent process which informed families about the continuing problem of lead poisoning, the purpose of the study, the interventions that would occur and the process for ongoing monitoring. See Consent Forms for R&M Study, in Research Project Notification, *supra* note 58. The enrollees were given notice of the continuing risk of lead paint exposure. See Research Project Notification, *supra* note 58. The R&M Study design demonstrates beneficence in that every intervention had an expectation of reducing lead dust risk. See generally BATTELLE & KENNEDY KRIEGER INST., *supra* note 52. Any risks of the study were minimized and the benefits were maximized. See BATTELLE & KENNEDY KRIEGER INST., *supra* notes 52, 58. Kennedy Krieger focused the research in the highest risk areas where lead poisoning was a known risk for families. U.S. DEP'T OF HUD, *supra* note 3, at 2-19. These high risk homes contained lead paint and had lead levels exceeding Maryland's post-abatement clearance levels. BATTELLE & KENNEDY KRIEGER INST., *supra* note 52, at 45, §2.3.1.3; 47-48, §2.3.1.4. This philosophy was reinforced by the State loan program requirements that loans be made only to those owners of units that serve families at or below 50% of the statewide median income. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52, at App. A. The R&M Study design demonstrates justice in that there was fair selection and treatment of participants. See discussion *supra* under the textual heading: R&M Study Did Not Discriminate, text accompanying notes 116-30. In addition, the R&M Study was designed to address a serious health problem affecting the high-risk community from which the study population was drawn. See COUNCIL FOR INTERN'L ORGANIZATIONS OF MEDICAL SCIS. (CIOMS), ETHICS AND

C. *The R&M Study Did Not Discriminate*

All of the participants in the study were African-American.¹³¹ The demographic composition of the participants in the R&M Study was not by design but rather a function of the Study's effort to target the highest-risk neighborhoods for improvement.¹³² Various federal agencies had determined that families in older, poorer neighborhoods where housing was more likely to be in deteriorating condition were at highest risk for lead poisoning.¹³³ City Homes, a non-profit organization which owned low-income rental units in Baltimore, and which had already adopted a lead poisoning prevention policy for its homes in 1991, was the primary source of the R&M dwellings.¹³⁴ City Homes and the other landlords who referred houses to Kennedy Krieger owned many homes in the higher risk, low-income areas of the City, which had a predominantly African-American population.¹³⁵ Because the study used methods which were expected to reduce the risk of lead poisoning by reducing exposure to residential lead, it was appropriate to conduct the study in high-risk neighborhoods where the homes had not been improved.

D. *The Results of the R&M Study*

The R&M lead reduction measures resulted in significant and sustained reductions in the overall lead dust levels for all the R&M combinations of property treatments.¹³⁶ Although in some individual cases blood lead levels did increase, overall, children in each of the three R&M groups and the previously abated group who had a baseline lead concentration of over 15 µg/dL (above the 10 µg/dL CDC level of concern) had a statistically significant reduction in blood lead concentration during follow-up, after controlling for age, gender, and season.¹³⁷ Overall, children who were in the three R&M groups who had baseline blood concentrations of under 15 µg/dL had a statistically significant reduction in blood lead concentration over time, when controlling for age, gender and season.¹³⁸

RES. ON HUM. SUBJECTS, INTERN'L GUIDELINES (Proceedings of the XXVIth CIOMS Conference, Guideline 10: Equitable Distribution of Burdens and Benefits) (1992).

131. U.S. EPA, *supra* note 84, at viii.

132. BATTELLE & KENNEDY KRIEGER INST., *supra* note 52, at 45, §2.3.1.3; 47-48, §2.3.1.4.

133. U.S. DEP'T OF HUD, *supra* note 3, at 2-16, 2-19 to 2-20.

134. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52, at 2.

135. See BATTELLE & KENNEDY KRIEGER INST., *supra* note 52, at 48-49, app. G, § 3.

136. U.S. EPA, *supra* note 84, at xiii-xv.

137. U.S. EPA, *supra* note 84, at xiii-xv.

138. U.S. EPA, *supra* note 84, at xiii-xv.

E. Other Federal Studies:

In 1993 and 1994, in keeping with the national call for additional research into the effectiveness of lead reduction strategies,¹³⁹ the Department of Housing and Urban Development (HUD) awarded funds under its Lead-Based Paint Hazard Control Grant Program to 30 grant recipients in 14 cities, states, and counties, including Baltimore.¹⁴⁰

The design of the HUD study was, in many ways, similar to that of the R&M study.¹⁴¹ HUD encouraged grantees to implement lead hazard control measures of their choice in the study properties, and different classes of interventions were used within each grantee's study.¹⁴² These included various interior interventions, such as spot painting/cleaning; complete painting; window treatments; window abatement; and full abatement.¹⁴³ Some exterior and soil treatments were also included.¹⁴⁴ The grantees were to measure the dust lead levels in the homes and blood lead levels of children in the homes before and after the interventions, and were to compare these for the different levels of interventions.¹⁴⁵ Thus, HUD fully supported and encouraged research using designs similar to the R&M Study.

F. Actions of Government Based on the Results of the R&M Study

The R&M Study was influential in bringing national recognition to the value of safe and effective lead reduction measures as tools necessary to prevent lead poisoning. Many of these measures have been incorporated in state and local laws, including Maryland's 1994 law requiring lessors of residential property to (i) register each rental unit built before 1950 with a statewide rental registry; (ii) notify tenants of the risks of exposure to lead and their rights under the law; and (iii) certify that the risk reduction standard was met at the time of unit turnover either by repair and cleaning of the rental property or by passing a dust lead test.¹⁴⁶ The State's mandatory requirements for lead risk reduction were similar to the

139. U.S. DEP'T OF HUD, *supra* note 3, at xv, xvi, xxii; U.S. DEP'T OF HUD, *supra* note 4, at xv-7.

140. Warren Galke et al., *Evaluation of the HUD Lead Hazard Control Grant Program: Early Overall Findings*, 2001 SCI. RES. & PROGRAM EVALUATIONS 150 (2001),

http://www.centerforhealthyhousing.org/early_overall_findings.pdf (last visited Oct. 15, 2002). Over 2,600 treated dwellings were involved in the study. *Id.* at 150. Although the program results showed a significant reduction in the dust and blood lead levels overall, the 2001 report on the study does not yet reflect the effects of the different intensities of treatments, and the authors of the report expect there to be some variation. *Id.* at 155. All thirty grantees' IRBs reviewed and approved participation in the study. *Id.* at 150.

141. *Id.* at 155.

142. *Id.* at 151.

143. *Id.* at 152.

144. *Id.*

145. *Id.*

146. The Lead Poisoning Prevention Program Act, MD. CODE ANN., [ENVIR.], §§6-801-852 (2001); MD. REGS. CODE tit. 26 §16.02.03 (1996).

Level I and II R&M interventions.¹⁴⁷ Many of these measures also have been incorporated in HUD's lead-safety regulation for federally owned and federally assisted housing¹⁴⁸ and in its national guidelines for residential lead hazard reduction.¹⁴⁹

VI. CONCLUSION

Whether proactive preventive lead reduction procedures should be performed in existing homes is a public policy debate. The Maryland Court of Appeals in *Grimes* did not discuss or recognize this situation, nor did it have before it evidence of the prior research which formed the framework for the study. The study, when fully understood, was both appropriate and ethical for those participating in the study, and made significant contributions to the science of lead reduction standards. As the public debate regarding lead reduction continues, it is important that the facts regarding the study be known and the context of prevention research in this important area be understood.

147. See MD. REGS. CODE tit. 26, §§16.02.01 - 16.02.07 (1996); See also BATTELLE & KENNEDY KRIEGER INST., *supra* note 52, at 58-59, tbl. 2.11.

148. See 24 C.F.R. § 35 (1999).

149. See U.S. DEP'T OF HUD, GUIDELINES FOR THE EVALUATION AND CONTROL OF LEAD-BASED PAINT HAZARDS IN HOUSING (June 1995).