DO NO HARM?:

ABPsi's COMMENTARY ON KENNEDY KRIEGER'S

R & M RESEARCH STUDY

As stated in the Mission Purpose and Goals Statement of the Association of Black Psychologists (ABPsi), it is a key objective of the Organization to influence and furthermore, effect social change in conjunction with assisting in solving problems of Black communities such as this very issue that involved many African American families of Baltimore in the 1990's. It is recognized that "The Lead Based Abatement & Repair Maintenance Study in Baltimore" (The R&M Study) was conducted with the intention of providing direct access to resources to low income communities in order to possibly prevent and eventually reduce the incidence of exposure to lead while maintaining available and potential housing. The Maryland Department of the Environment (2000) provides that it is evident that even though lead exposure is still an issue in Baltimore, due to the coordinated efforts to prevent exposure, abate lead hazards, test children in high risk areas and finally provide education, the number of children with dangerous levels of lead in their blood has dropped drastically since the 1990's. Regardless of these facts however, is the obvious disregard for the health, physical and mental (psychological) well-being of participants of the R&M Study.

Families of the subjects of this study, very young children aged 25 to 34 months, were recruited to participate in a non-therapeutic study based on the assumption of potential risk that the children were already or eventually going to be exposed to lead mentioned in several studies involving lead researchers, Dr. Mark Farfel and J. Julian Chisolm (see A study of Urban Housing Demolitions as Sources of Lead in Ambient Dust: Demolition Practices in Exterior Dust Fall p 1233-1234, Assessment of Cleaning to Control Lead Dust in Homes of Children with Moderate Lead Poisoning: Treatment of Lead Exposed Children Trial p778 and Lead Based Paint Abatement and Repair & Maintenance Study in Baltimore: Findings Based on Two Years Follow-Up p viii).

The experiment was designed to document the short and long term effectiveness of a range of housing interventions to reduce children's exposure to lead in residential paint and settled house dust (Farfel & Chisolm, 4). This required however, that the participants and their families maintain or obtain housing with lead based paint in the home with the assumption as stated, that the children would be exposed to lead during the study. The Center for Disease

Control and Prevention's most recent update on Lead poisoning shows that exposure to lead can cause learning disabilities, behavioral problems, and, at very high levels, seizures, coma, and even death (www.cdc.gov) . Due to the fact that the experiment was non-therapeutic which means that it would not produce a diagnostic, preventive, or therapeutic benefit to the participants, the study itself by design purposely recruited or allowed the participants to continue to be exposed to toxins without providing a means for them to seek care to reverse the damages. Whether this was done with the best intention or not, at no time or instance should the clinical researchers have abandoned their basic responsibilities and/ or standard of care while conducting this study.

Due to the details outlined in each participant's case, it appears that following the protocols necessary to complete the study were more important to the researchers than the short term and long term health of those who participated in the "The Lead Based Abatement & Repair Maintenance Study in Baltimore" (The R&M Study). It is regrettable that the Johns Hopkins researchers failed to honor the clinical relationship they entered into with the participants particularly with their intentionally limited Informed Consent and by their ignoring the basic standards of research, including but not limited to, the "duty to warn" standard all reputable researchers adhere to. ABPsi does not condone this lack of regard for human beings and as an Organization wants to make it clear that the actions were unacceptable and have not gone unnoticed.

In conclusion, ABPsi agrees with Judge Cathell of the Court of Appeals of Maryland, that this was an atrocious act against the African American participants of the R&M study. The very right to preserve and protect one's own life and health was compromised against the will and knowledge of the participants of this experiment, which is not just a crime against American citizens, but in a much greater sense according to the Nuremberg Code, a crime against Humanity. Judge Cathell compared what happened to these people to other infamous cases of human experimentation such as the Tuskegee Experiments, The Jewish Hospital Study, the Plague Bomb Experiments in Japan and the Mengele/Nazi Experiments like those in Buchenwald. Acts of that sort should have never happened again therefore, ABPsi will not allow History to selectively ignore this issue particularly against the families and participants of the R&M study who were vulnerable due to age and lack of education of the parents, but also due to their lower socio economic status.

To all those directly affected by the Kennedy Krieger R&M Experiment in Baltimore Maryland, know that The Association of Black Psychologist recognizes your case and supports

your pursuit of justice in this matter. As the Akan of Ghana, Africa would say, "obi nnye yiye nnya bone" which means: the pursuit of beneficence brings no evil upon him who pursues it".

Background

On September 2, 1977 the Consumer Product Safety Commission announced a final ban on lead based paint sold in the United States. This act, originally set forth by the Department of Housing and Urban Development, prohibited the application of lead-based paint to housing constructed or rehabilitated with Federal assistance. Among other reasons, this legislation was enacted was to reduce the risk of children becoming exposed to lead due to the ingestion paint chips or peelings from structures and products coated by lead based paint.

Like many other American inner city neighborhoods in the 1990's, Baltimore, Maryland had lower income communities that were predominately African American with homes that were literally adjoined in rows called "row-houses" or "housing clusters". More specifically, According to Joanna Pollack, author of "*The Lead Based Paint Abatement in Baltimore: Historic Framework and Study Design",* many of those homes were constructed before the 1978 ban on lead based paint. Unfortunately, many of those that had been painted using lead based paint were in poor condition directly putting children at risk of lead contamination due flaking and chipped paint and the resultant lead dust (93). Quite literally, The 2000 Annual Maryland Department of the Environment (MDE) specifically lists that as of the 1990 census, of the 529,000 residential houses built before 1950, 95% had were likely to contain lead based paint and of the 976,000 houses built between 1950 and 1978 75% were likely to contain lead based paint.

Even though hundreds of thousands of homes were affected, Pollack reports that the MDE data indicates that less than half of the children in Baltimore had the level of lead in their blood tested by the time of the report. Most alarmingly, 60% of the children in identified high risk areas had blood levels above 10 µg/dL (micrograms of lead per deciliter of blood). Even worse, up to 22% of that sample were twice that. To put this into perspective, according to the Center of Disease Control and Prevention's website, 10-14 µg/dL is a cause for concern but in the case of a child with 20 µg/dL a complete medical, nutritional and physical exam has to be done, a developmental/psychological examination has to take place, and chelation, the conversion of toxic metals like lead to an inert form that is excreted from the body, is considered. In addition to those measures, consultations with an Environmental Lead Sanitarian, the child's health care providers and other Social Service Agents would have to be completed to ensure the safety of the child (Pollack, 94).

The MDE Annual report lists that the most effective way to prevent childhood lead poisoning is to reduce or eliminate exposure and in fact, requirements to do so for rental properties built before 1950's were already being enforced at that time . Despite those measures however, according to Pollack at that time there were several realities undermining the fast and effective process of reducing or eliminating the risk of lead exposure (95). These realities were:

- An acute shortage of lead paint free housing, particularly for low income/ high risk populations
- Society had not committed the resources to abating lead paint hazards in these private older homes
- Efforts to identify and reduce these environmental sources of lead in the home were made only after children were found to be lead poisoned
- There were no laws or regulations requiring landlord initiated preventative maintenance to reduce lead hazards in rental units
- That full abatement programs were extremely expensive in some cases more expensive than the worth of the home being treated
- Landlords who could not afford to have their rental properties abated were simply abandoning the homes creating a shortage in available housing for families with a low income (95)

In 1990 the Environmental Protection Agency contracted Battelle Memorial Institute who then subcontracted with Kennedy Krieger Institute (KKI) in Baltimore Maryland to direct the design of a study entitled, "Lead Based Paint Abatement and Repair and Maintenance Study in Baltimore". This was the result of Dr. J Julian Chisolm, (Associate Professor, John Hopkins School of Medicine) Director of Kennedy Krieger's Lead Prevention and Treatment Program as well as Dr. Mark Farfel, (Associate Professor of John Hopkins School of Hygiene and Public Health) Director of the Lead Poisoning Prevention Program, proposing to conduct research regarding lead reduction methods that could have reduced lead dust in homes on a large scale basis and quite possibly preventing or at least reducing the risk of lead exposure to young children (Pollack, 97). They were assisted by Co-Investigators from John Hopkins with others named in the study that represented the "Staff". The U.S. Environmental Protection Agency was responsible for managing, guiding and directing the study.

The Lead Based Abatement & Repair Maintenance Study in Baltimore

Purpose

According to the authors, "The Lead Based Abatement & Repair Maintenance Study in Baltimore" (The R&M Study) was designed to document the short and long term effectiveness of a range of housing interventions to reduce children's exposure to lead in residential paint and settled house dust. The authors go on to state, "Given the extent of the problem and its adverse health and social consequences, the acute shortage of affordable housing free of lead based paint in many urban areas and the high cost of complete lead based paint abatement, the preventative R&M approach may provide a means of reducing the exposure for future generations of US children who will continue to occupy housing that contains lead based paint"

(Farfel & Chisolm, 4).

Aims of the Research

- Assess the effectiveness and longevity of the three levels of R&M interventions by investigating the short and longer term changes in lead concentration and lead loading of settled house dust
- Investigate lead loadings and concentrations in settled dust between baseline and 24 month campaign for a control group of modern urban houses built after 1979 and a group of houses that received comprehensive abatement treatment between May 1989 and February 1991
- Asses children's blood lead concentrations associated with the three levels of R&M interventions and two control groups
- Asses the relationship between blood lead and dust lead. For this, statistical models for longitudinal data analysis were fit to the blood lead and dust lead data from all five study groups
- Report on compliance with laboratory and data quality objectives
- Evaluate and compare methodologies for the collection and analysis in lead in residential dust including wipe and cyclone methods.
  (adapted from Farfel & Chisolm, 1997)

The study population was sampled from households in Baltimore, Maryland. All of the participants were African American which was, as the researchers state, a reflection of the demographic of the community. The mean ages of the children in the study were 25 to 34 months

across all groups (viii). The participants were randomly assigned to groups and then studied using the measurements listed below. There were 108 families/houses studied. Of those, 96.5 % of the planned home visits were accomplished. 38 out of the original 108 families in the study moved however of the 42 total moves in the study 35 of the homes were subsequently reoccupied by another family (Farfel & Chisolm, 37).

Section 1:

Group 1—Repair & Maintenance Level I—Properties receiving a minimal level of repair and maintenance ($1,650.00).

Group 2—Repair & Maintenance Level II—Properties receiving a greater level of repair and maintenance ($3,500.00).

Group 3—Repair & Maintenance Level III—Properties receiving an even greater level of repair and maintenance ($6,000.00-$7,000.00)

Section 2: (Controls)

Group 4—Properties identified as having previously been completely abated of lead paint which were to receive no additional repair and maintenance.

Group 5—Modern Urban Dwellings— Properties constructed after 1980 and presumed not to have lead-based paint which were to receive no repair and maintenance (12, *Armstrong vs Kennedy Krieger Institute, INC.* (2011))

Measurements

The measurements were as follows:

- Parents were to fill out questionnaires every 6 months.
- Measurements of lead in drinking water were to be obtained at pre-intervention, and twelve and twenty-four months post intervention
- Measurements of lead in the exterior soil were to be obtained at pre-intervention, immediately post intervention, and twelve and twenty-four months post intervention

- Measurements of vacuum dust samples from the houses were to be obtained at the following times: pre-intervention, immediately post intervention, and one, three, six, twelve, eighteen, and twenty-four months post intervention

- Measurements of lead in the blood of the Children were to be obtained at the following times: pre-intervention, immediately post intervention, and one, three, six, twelve, eighteen, and twenty-four months post intervention

(Grimes v Kennedy Krieger Institute, INC. & Higgins v Kennedy Krieger Institute (2001))

Benefits

Parents

As an incentive to complete the protocols of the study the Parents of the children being studied were to receive the following benefits:

- $5.00 for the first questionnaire and sketch of their home

- $15.00 for completing each subsequent questionnaire

- The dust, soil, water, and blood samples would be tested for lead at the Kennedy Krieger Institute at no charge

- The results from the blood-lead tests with a summary of house test results and further information on how they could reduce further exposure to lead in their homes.

In addition to:

- Coupons for things ranging from skating trips to groceries, gifts like t shirts in the summers and hats and gloves during the winter, trinkets, and food coupons provided as an incentive to come to the clinic for blood collection
  (Grimes v Kennedy Krieger Institute, INC. & Higgins v Kennedy Krieger Institute (2001))

Eligible Landlords/Properties

KKI, acting as a subcontractor was held responsible to:

- Identify eligible landlords or properties
- Perform a structural assessment
- Determine what improvements were needed
- Hire a loan officer to process loans with aforementioned landlords
- Facilitate grants to Landlords through the Federal Lead Hazard Reduction Program Funds
- Hire and Authorize Payment to contractors to complete the work assigned to the specific property
  (Armstrong vs Kennedy Krieger Institute, INC. (2011))

The Results/Findings

All three levels of R&M under investigation were associated with statistically significant reductions in dust lead.

Dust lead concentration were found to be statistically significantly reduced in R&M 2 and 3 Homes

Dust lead loadings, lead concentration was related to the intensity of the intervention

No change was found in the amount of lead in the soil and low levels of lead were found in the water.

In regards to the level and concentration of lead found in the blood:

For children who had less than 15 µg/dL (micrograms of lead per deciliter of blood):

These children tended to have lower lead concentration at each campaign. Based on the longitudinal analysis the children showed that initial blood lead concentrations were reduced over time

For children who had more than 15 µg/dL (micrograms of lead per deciliter of blood):

Based on the longitudinal analysis the children showed that initial blood lead concentrations were significantly reduced over time (viii, Farfel & Chisolm).

As a result of this study and many others done during the 1993-2000 time period there has in fact been a major reduction in the levels of lead in the blood of children in Maryland. The MDE credits this phenomenon as the result of several years of lead poisoning prevention efforts, increased awareness of parents and property owners of the hazards of lead poisoning, outreach and redevelopment. Lastly, there is also mandatory testing of children who reside in Baltimore City as well as in high risk areas and lastly, mandatory statewide testing for children that are on Medicaid. (MDE, 2000)

Legal Action Against the KKI

Grimes v Kennedy Krieger Institute (KKI) and Myron Higgins v. Kennedy Krieger Institute (8/16/2001)

Despite the success of the study, parents of the children that were a part of the study started bringing suits against the KKI. While some those cases were dismissed and others settled out of court, it was Grimes v Kennedy Krieger Institute that received national attention. The parents brought suit against the KKI for these reasons

The Sufficiency of the Parental Consent

"The consent form did not directly inform the parents of the fact that it was contemplated that some of the children might ingest lead dust particles, and that one of the reasons the blood of the children was to be tested was to evaluate how effective the various abatement measures were" (36).

The Court found that:

•A reasonable parent would expect to be told that it was expected for the child to ingest lead containing dust and how

•A reasonable parent would expect to be told that the measure of the increase/decrease of lead in their child's blood be a way in which the researcher's determined success of the experiment

•Despite the fact that the information might cause some not to want to participate in the experiment that does not negate the need to act ethically and disclose all necessary information to the participants of the study

•Human subjects have to right to receive all material information in regards to the study they are participating in

•Whether assessed by a subjective or an objective standard, the children, or their surrogates, should have been told 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 subjects

•Due to the fact that all the information was not provided the "informed" consent is not valid

•The court also ruled that Parents nor Researchers have no right to intentionally and unnecessarily place children in potentially hazardous nontherapeutic research surroundings whether or not benefits are offered. In these cases, Parental consent is insufficient (36).

Special Relationship and KKI's Duty to Warn

In the case of E. Grimes (Case 128), the Parent was not made aware of places in the home where there was a higher potential for the child to ingest lead until 9 months after the initial blood samples were taken. The first sample of her lead in her blood was less than 9 µg /dL (normal) after being tested on April, 9, 1993 and rose to 32 g/dL (highly elevated)on then September 15, 1993 and then to 22 g µg /dL (highly elevated) on March 25, 1994 by her third and final test (16).

In the case of M. Higgins (Case 129), Mr. L. Polakoff, president of Chase Management INC the company that was a general partner to CFOD Limited Partnership. The Parent of M. Higgins rented a property through CFOD Limited Partnership in which Mr. Polakoff admitted to voluntarily submitted to the study. Mr. Polakoff was aware that the property was only partially abated as well as was in full knowledge that the researchers from KKI would refer parents with young children to live on these types of properties (18-19).

The parent of M. Higgins contended that the researchers from KKI failed to inform her about places with high levels of lead in her home that were known in by KKI as early as December of 1993 until September 14, 1994. Her child, M. Higgins tested with blood levels of 17.5 µg/dL(moderately elevated) on June 8, 1994, 21 µg /dL (highly elevated) on July 29, 1994, and 11 µg /dL (moderately elevated) on November 9, 1994. She also argued that KKI and Environmental were negligent in their undertaking to abate the home during their time living there (20).

The Court decided that even though in previous cases regarding this issue the trial courts held that there was no duty that arose from the existing relationship between the researchers and the subjects, that those judgments instead, were incorrect. It was decided that researchers may not recruit people, especially children whose consent was provided indirectly, to participate in nontherapeutic procedures that are potentially hazardous, dangerous, or deleterious to their health.

(Grimes v Kennedy Krieger Institute, INC. & Higgins v Kennedy Krieger Institute (2001), 3)

The Role of the Johns Hopkins Committee on Clinical Investigation

The court identified the Johns Hopkins University Committee on Clinical Investigation as the Institutional Review Board (IRB) at the time of the study. The role of the IRB as an oversight entity was defined as:

- To examine the protocols of the experiment and determine its appropriateness
- Whether or not the consent procedures are appropriate and adequate
- Whether or not the methods to be used meet proper standards
- Whether or not the reporting requirements are satisfactory
- A general assessment of all other procedures regarding the experiment

The court also states that its most important function is the review of the potential safety and the health/hazard impact of a research project on the human subjects of the experiment. The court found that the IRB potentially had not considered of the difference between therapeutic and nontherapeutic research and theirown role in the process. Secondly, the Court identified that that the IRB was willing to assist the researchers in getting around Federal rules and regulations designed to protect the subject in the research. This judgment came as a result of the inclusion of a letter dated May 11, 1992 from the IRB to Dr. Mark Farfel provided below:

> The next issue has to do with drawing blood from the control population, namely children growing up in modern urban housing. Federal guidelines are really quite specific regarding using children as controls in projects in which there is no potential benefit [to the particular children]. To call a subject a normal control is to indicate that there is no real benefit to be received [by the particular children].... So we think it would be much more acceptable to indicate that the 'control group' is being studied to determine what exposure outside the home may play in a total lead exposure; thereby, indicating that these control individuals are gaining some benefit, namely learning whether safe housing alone is sufficient to keep the blood-lead levels in acceptable bounds. We suggest that you modify ... consent form[s] ... accordingly."

(Grimes v Kennedy Krieger Institute, INC. & Higgins v Kennedy Krieger Institute (2001), 4)

The Court compared this case to prior instances that subjects were exposed to harmful agents quoting the 14th Amendment that protects the "freedom to care for one's health and person" especially in the case of the children who were considered in this case to be vulnerable.

Specifically, the other experiments mentioned were the Tuskegee Syphilis Study, The Jewish Hospital study, The Japanese Plague Bombs in WWII and the Typhus Studies in Buchenwald, a Nazi run Concentration Camp. In the Court's General Discussion, the Judge discussed the Nuremberg Code the result of legal thought and principles that assess the legality of scientific research on human subjects. Some points in the text are:

- "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."
- "The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury."
- During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject."

Adapted from George J. A. (1991). Mengele's Birthmark: The Nuremberg Code in United States Courts, Journal of Contemporary Health Law & Policy 17, 19-21.

The Court's Conclusion

This suit, an appeal taken to the Court of Appeals of Maryland was tried at bar and was noted to be one of few that addressed consent to research. The Court concluded that:

- The Court held that in Maryland a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject.
- The Court held that informed consent agreements in nontherapeutic research projects, under certain circumstances can constitute contracts; and that, under certain circumstances, such research agreements can, as a matter of law, constitute "special relationships" giving rise to duties, out of the breach of which negligence actions may arise.

- The Court held that there was ample evidence in the cases at bar to support a fact finder's determination of the existence of duties arising out of contract, or out of a special relationship, or out of regulations and codes, or out of all of them, in each of the cases.

David Armstrong Jr. and CLASS v. Kennedy Krieger Institute

Filed in September of 2011, Plaintiff David Armstrong Jr. and Class will bring a Class Action Complaint against Kennedy Krieger Institute Inc. The Plaintiffs David Armstrong Jr. in addition to all the children enrolled in the R&M Study, their siblings, and all other persons who suffered elevated blood levels as a result of the study seek compensatory, punitive, and declaratory relief on 9 different counts 4 of which are listed below:

Count 1

Declaratory Relief Equitable Tolling of Limitations Period

The Plaintiffs contend that at the time of the study the children were of ages 12 mo. to 5 yrs. thus negating the possibility of them even knowing about KKI's actions and therefore any potential causes of action without some form of notice. Furthermore they claim that the KKI failed to advise the parents of the risks of entering the clinical trials. In addition to that KKI failed to abide by the bare minimum legal standards for safe housing by virtue of their controlling and operating the residences in which the families resided.

Count 2

Violation of Consumer Protection Act

The Plaintiffs claim that KKI exercised charge care and or control over the R&M properties before during and after the tenancy of the minor plaintiffs. For these and other reasons listed in the original complaint the plaintiffs are evoking many of Baltimore's City Building Codes and Public Law

The Plaintiffs claim that KKI:

•KKI determined which abatement during, and after the tenancy of the minor Plaintiffs.

•KKI determined what interventions needed to be performed to make lead risk reductions.

•KKI advertised the property to the plaintiffs by way of a typed list entitled "lead safe properties."

•KKI even maintained keys to many units to show the properties to the prospective tenants.

•KKI negotiated the lease between the plaintiffs and the landlord.

•KKI entered into a separate written agreement with the land lord that the property must be leased only to KKI R&M participants for a period of up to 5 years and at a reduced rental rate

•KKI later oversaw the lead risk modifications by hiring contactors for specific work and inspected it when completed.

•KKI intentionally permitted areas throughout the buildings to have flaking, peeling and chipping paint in areas such as the walls, windows and window structures, porch and basement

Count 3

Intentional Misrepresentation-Fraud /Deceit

The Plaintiffs claim that KKI intentionally misrepresented the properties included in the R&M study in these ways and more listed in the complaint:

•that the premises were lead safe

•that the premises were in a habitable condition

•that the premises would be maintained in a habitable condition throughout the tenancy and/or time spent there

•that the premises were in compliance with all applicable statutes, code, and regulations pertaining to rental properties at the inception of Plaintiffs' tenancy

•that the premises were safe for the Plaintiffs to reside

Count 4

Intentional Misrepresentation and Concealment of Facts by a Fiduciary

The plaintiffs assert that KKI did not reveal the material facts as to the true nature of the lead risks within the R&M properties. As a direct result of KKI's concealment, the Plaintiffs were exposed to dangerous lead hazards, ingest lead, and suffer increased elevation of their blood lead levels. The Plaintiffs claim that their injuries, damages and severe permanent disabilities were caused by KKI's decision to not to act and furthermore it’s intentional concealment of the facts as they pertained to the true nature of the study.

Adapted from (Armstrong vs. Krieger, p 17-25, 2011)

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