UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Baltimore Division)

SHAYONNA FEATHERSTONE, et al.,	*	
Plaintiffs	*	
v.	*	Case No.: 1:07-CV-1120
KENNEDY KRIEGER INSTITUTE, INC., et al.	*	
Defendants	*	

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR JOINDER OR TO DISMISS

I. Introduction

The Defendants Motion is a blatant attempt at forum shopping. The Defendants have not responded to Plaintiffs' discovery propounded in the Circuit Court for Baltimore City; however, these same Defendants produced discovery in prior cases in that court regarding this exact study. The self-serving documents and affidavits which they have selectively chosen to submit to this Court in the instant case should be viewed with skepticism. The Defendants choose to characterize their actions as those of obedient servants of the National Institute of Environmental Health Services ("NIEHS"), despite, as set forth more fully herein, the explicit statement within their Award/Contract that KKI was conducting the Treatment of Lead Exposed Children, (TLC), study "**Independently and not as an agent of the Government**." *See* Page 6, *Supra.* Further, the Defendants' arguments find no support in the opinion of the Maryland Court of Appeals in *Grimes et. al., v. Kennedy Krieger Institute, Inc., et al.*, 366 Md. 29, 50 (2001)(Exhibit 1), regarding a strikingly similar non-therapeutic study. Additionally, the depositions of witnesses in

other cases involving the TLC study and documents produced by the Defendants in this and other cases reveal that the Defendants' assertion is baseless inasmuch as the Kennedy Krieger Institute, (KKI) and principal investigator Cecilia Davoli, (Davoli), the Johns Hopkins University, (Hopkins), and the members of the Hopkins' institutional review board (IRB) had a non-delegable duty to ensure the safety of the children used as research subjects in the study for which KKI designed the architecture and instrumentalities.

A. The duties of KKI and the Principal Investigators to children used as human research subjects as recognized by the Maryland Court of Appeals in *Grimes*.

The contours of the Lead-based Paint Abatement Repair and Maintenance study, (R&M study), the subject of the *Grimes* opinion, closely track those of the TLC study. As set forth *Supra*, one of the contractors used by KKI in both the R&M study and the TLC study gave sworn testimony that the levels of environmental intervention and the manner by which the homes of children in the two studies were assigned the interventions specified by KKI were virtually identical. As Mr. McNutt sworn testimony reveals, "[t]he repair and maintenance and the TLC were the same thing, but there was a few hundred dollars difference between each one." *See* Exhibit 24, *Supra.* Thus, it is useful to examine the opinion of the Maryland Court of Appeals regarding the cases of two children used as human research subjects in the R&M study as a threshold to understanding the TLC study, which was undertaken by KKI immediately after the conclusion of the R&M study.

Non-therapeutic research programs create a special relationship between the researchers and their human subjects and concomitant duties of those researchers to protect their human subjects. The breaches of such duties may ultimately result in viable negligence actions. *Grimes,*

Id. 366 Md. at 48.

In the case of *Myron Higgins, et al., v. Lawrence Polakoff, et al.,* Baltimore City Circuit Court Case No. 950660671; *Sub nom. Grimes et. al., v. Kennedy Krieger Institute, Inc., et al.,* 366 Md. 29 (2001), the Plaintiffs were lead-poisoned as a result of participating in the R&M study.

> [T]he purpose of the [R&M] experiment was to determine whether there was a less expensive way than full abatement that would be cost-effective in reducing lead poisoning in children from a lower economic background. The study, by its design, placed and/or retained children in areas where they might come into contact with elevated levels of lead dust. Clearly, KKI contemplated that at least some of the children would develop elevated blood lead levels while participating in the study.

Grimes, Id. 366 Md. at 103.

> [T]he risks associated with exposing children to lead-based paint [in the R&M study] were not only foreseeable, but were well known by KKI, and, in fact, it had to have been reasonably foreseeable by KKI that the children's blood might be contaminated by lead because the extent of contamination of the blood of the children would, in significant part, be used to measure the effectiveness of the various abatement methods. Moreover, in the present cases, the consent forms did not directly inform the parents that it was possible, even contemplated, that some level of lead, a harmful substance depending upon accumulation, might contaminate the blood of the children.

Grimes, Id. 366 Md. at 98. As will be set forth more fully herein, the Court's opinion is equally applicable to the TLC study. The similarities between the most offensive parts of the R&M study, and the TLC study are clear. For example, as KKI stated to the NIEHS, "[i]t is expected that some patients [in the TLC study] will experience increasing blood lead levels during the course of the trial." (November 23, 1992, Technical Plan Prepared by KKI, et al. Exhibit 2).

> One simply does not expose otherwise healthy children, incapable of personal assent (consent), to a nontherapeutic research environment that is known at the inception of the research, might cause the children to ingest lead dust. It is especially troublesome, when a measurement of the success of the research experiment is, in

> significant respect, to be determined by the extent to which the blood of the children absorbs, and is contaminated by, a substance that the researcher knows can, in sufficient amounts, whether solely from the research environment or cumulative from all sources, cause serious and long term adverse health effects. Such a practice is not legally acceptable.

Grimes, Id. 366 Md. at 105.

In the *Higgins* case, KKI sought summary judgment by asserting that it had no duty to warn or protect the child research subjects used in the R&M study. (*Myron Higgins, et al., v. Lawrence Polakoff, et al.,* Baltimore City Circuit Court Case No. 950660671; Kennedy Krieger Institute's Memorandum of Points and Authorities in Support of Motion to Dismiss, Exhibit 3). Not surprisingly, the Maryland Court of Appeals rejected this assertion and issued a scathing opinion castigating KKI and the IRB for their complacency, careless behavior, and wanton disregard for the safety of children for whom they had a special duty to protect. After noting that "it is, first and foremost, the responsibility of the researcher and the research entity to see to the harmlessness of such nontherapeutic research," *Grimes, Id.* 366 Md. at 100, the Court of Appeals observed that the vulnerability of the children used in the R&M study by the Defendants as research subjects was similar to that of the subjects experimented upon in other notorious examples of nontherapeutic research such as the Tuskegee study, the post-war Jewish hospital studies, the "plague bomb" experiments carried out by the Japanese, and the experimentation of the Nazis at Buchenwald. *Grimes, Id.* 366 Md. at 44-45. As explicated more fully below, the TLC study also employed the use of children as research subjects many of whom were from the same geographical area, also referred to as a catchment area, as those used in the R&M study.[1]

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[1]Assumedly for the sake of convenience to the researchers, the R&M catchment area consisted almost exclusively of homes adjacent to KKI in eastern Baltimore City. The families who lived in the areas mined by KKI for research subjects for both the TLC and R&M studies

Further, one of the selling points used by KKI to secure funding for the TLC study was that, the Pediatric Lead Clinic at KKI provided a ready source of lead-poisoned children to use as study subjects.[2] As the Maryland Court of Appeals stated, "[n]othing about the research was designed for treatment of the subject children. They were presumed to be healthy at the commencement of the project. As to them, the research was clearly nontherapeutic in nature." *Grimes, Id.*, 366 Md. at 42-43. Likewise, the TLC researchers conceded in their published report that the TLC study therapeutic in nature. "[T]he very nature of nontherapeutic scientific research on human subjects can, and normally will, create special relationships out of which duties arise." *Grimes, Id.* 366 Md. at 74.

The IRB was charged with the duty to implement additional safeguards to protect the child research subjects, was required to independently monitor the study, and was empowered to suspend the research activities of KKI and or Davoli during the TLC study, if necessary, to protect the safety of the children being used as research subjects. *Id.* at §46.111(b), §46.112, and §46.113, respectively. "Some analysts contend that IRB review tends to focus exclusively on consent requirements, rather than fully evaluating the merits of the research. Yet, it is important to recognize *that, even before consent becomes an issue, the scientific merits and the acceptability of risks need to be appraised." Grimes, Id.* 366 Md. at 79 (Internal citations and quotations omitted)(Emphasis supplied). In any event, "[a] researcher's duty is not created by, or

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were characteristically poor and African American. Not surprisingly, and likely for the same reasons, many of the children used by KKI in the TLC study, including the Plaintiffs, resided within close geographical proximity to KKI.

[2](November 23, 1992, Technical Plan Prepared by KKI, et al., page 5, Exhibit 4)(Stating, "[o]ver the years a number of clinical research studies have been carried out in this clinic population, including studies on succimer and household lead remediation...").

extinguished by, the consent of a research subject **or by IRB approval**. ... All of this is especially so when the subjects of research are children. Such legal duties, and legal protections, might additionally be warranted because of the likely conflict of interest between the goal of the research experimenter and the health of the human subject, especially, but not exclusively, when such research is commercialized." *Grimes, Id.* 366 Md. at 100 (Emphasis added).

Hence, the level of involvement of the NIEHS *vel non*, in the activities of KKI and Davoli pertaining to the TLC study has no bearing upon the Plaintiffs' claims against Hopkins and the IRB because the duties of Hopkins and the IRB to the Plaintiffs were non-delegable and distinct from those of KKI and Davoli. 45 CFR §46.114 (Stating that where, as here, cooperative research involves more than one institution, and absent conditions precedent which are inapplicable to the instant matter, "[i]n the conduct of cooperative research projects, **each institution is responsible for safeguarding the rights and welfare of human subjects** and for complying with this policy." (Emphasis added).[3] The duties of Hopkins and the IRB to the Plaintiffs could not be ceded to the control of the NIEHS nor the United States Government.

Exhibit C to the Defendants' Motion undercuts nearly all of their assertions that they were not primarily responsible for the safety of the minor plaintiffs during the TLC study. More precisely the duties of KKI under the TLC contract were as follows:

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[3] "[45 C.F.R. 46.116(e)] specifically provides: 'The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.' Those various federal or state conditions, recommendations, etc., may well be relevant at a trial on the merits as to whether any breach of a contractual or other duty occurred, or whether negligence did, in fact, occur; **but have no limiting effect** on the issue of whether, at law, legal duties, via contract or 'special relationships' are created **in Maryland** in experimental nontherapeutic **research involving Maryland children**." *Grimes, Id.* 366 Md. at 50 (Emphasis added)..

ARTICLE C.2. STATEMENT OF WORK

a. **Independently and not as an agent of the Government, [KKI]** shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the government, as need to perform the work below...

. . .

The criteria by which homes will be evaluated and the clean-up protocol shall be decided during the planning phase, but clean-up will not be identical at each site, and will consist of means suited to the catchment area of each Clinical Center.

(June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, pages 9-10)(Exhibit 5).

In **cooperation with** the Coordinating Center, the other Clinical Centers, and NIEHS staff, [KKI] shall participate in the design of the trial protocol, and then recruit, evaluate, **treat**, and follow-up patients according to trial protocol.

(June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, page 11)(Exhibit 6)

[KKI] shall identify the potential lead sources in the child's environment and decrease the exposure in those who need it.

. . .

[KKI] shall provide short term housing as it considers necessary.

(June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, pages 11-12)(Exhibit 7).

Nutritional management: [KKI] shall evaluate the children for iron deficiency and treat it...

. . .

[KKI] shall perform clinical monitoring of children, and including any laboratory procedures necessary for safety monitoring because the children are being treated under an IND.

. . .

Safety and efficacy monitoring: [KKI] has the **primary responsibility for the monitoring of the safety of the children and monitoring the efficacy of the drug.**...

(June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, page 12)(Exhibit 8).[4]

The instant Motion is yet another demonstration of the Defendants abject refusal to accept responsibility for their actions.

B. The stark similarities between the R&M study and the TLC study

The R&M study was designed to study the effects, if any, of various degrees of partial lead-based paint abatements. *Grimes, Id.* 366 Md. at 56. The TLC study was designed to study the effects, if any, of the off-label use of succimer, a chelating agent used to expedite the removal of lead from a child's body, on children with significantly elevated levels of lead in their blood while the children resided in homes which received virtually identical levels of partial lead-based paint abatements as those used in the R&M study. While the use of succimer was a part of the standard of care for children with blood lead levels higher than those of the children used in the TLC study, it was not indicated for use on children with blood lead levels within the range of the study participants.

The R&M study was funded partially by the EPA and partially by the Maryland Department of Housing and Community Development. (Transcript of May 5, 1997, deposition of Mark Farfel, *Higgins, et al., v. Polakoff, et al.,* Baltimore City Circuit Court Case No. 95066067,

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[4]It is important to note that the Plaintiffs have contended that KKI, in furtherance of the TLC study failed to adhere to the standard of care for lead-poisoned children. Specifically, iron anemia facilitates the absorption of lead into a child's body; as such, the standard of care for lead-exposed children who are anemic dictates the administration of an iron supplement, such as Fer-in-sol. On or about September 20, 1995, Keona Featherstone, one of the minor Plaintiffs, was determined to be anemic by her treating physician. The physician, in accordance with the standard of care, prescribed an iron supplement. However, rather than protect Keona's safety, the TLC researchers "advise[d] mom to stop giving the iron" during the next course of study drug administration. (September 20, 1995, Correspondence from Janet Serwint to Jeanne Butta, Exhibit 9).

page 6 @ line 17-21, Exhibit 10). The TLC study was partially funded by the NIEHS and by the Baltimore City Department of Housing and Community Development. KKI was paid at least $200,000.00 for authoring and conducting the R&M study. KKI was compensated in excess of $ 5,000,000.00 for the TLC study, a figure which included payment for the salaries of KKI employees J. Julian Chisolm, Gary W. Goldstein, and Martha B. Denckla. *See* Exhibit C to Defendants' Motion for Joinder at page 5. "The 'for profit' nature of some research may well increase the duties of researchers to insure the safety of research subjects, and may well increase researchers' or an institution's susceptibility for damages in respect to any injuries incurred by research subjects." *Grimes, Id.* 366 Md. at 94, Fn. 12.

Both the R&M study and the TLC study required KKI to obtain initial approval for, and continuing oversight of the research activities by an IRB. *See* 45 C.F.R. § 46.101, *et seq.* The IRB for the TLC study was the same IRB that grossly mishandled the R&M study, to wit the Joint Committee on Clinical Investigations (JCCI) which was constituted and staffed by Hopkins. The JCCI's stamp of approval appears on the consent form signed by Shayonna Featherstone's mother. (June 21, 1995, Clinical Investigation Consent Form for Keona Featherstone, Exhibit 11) and (February 10, 1993, Correspondence of Thomas R. Hendrix, Chairman-JCCI to J. Julian Chisolm approving Research Proposal Number 92-11-19-01, Exhibit 12). As evinced by the JCCI-IRB letter to Dr. Chisolm, the Treatment of Lead Exposed Children study was originally called the "Toxicity of Lead in Children" study. Apparently, truth in advertising was not a chief aim of the researchers or the IRB.

The following chart illustrates some of the key similarities between the studies:

The R&M study	The TLC study
Partially funded by the EPA and the Maryland Department of Housing and Community Development [5]	**Partially funded by the NIEHS and the Baltimore City Department of Housing and Community Development** [6]
KKI conducted research on Maryland children in economically depressed areas of Baltimore City	**KKI conducted research on Maryland children in economically depressed areas of Baltimore City**
Research was non-therapeutic [7]	**Research was non-therapeutic**
KKI arranged for contractors to perform less than full lead-based paint abatements on the homes of study participants [8]	**KKI arranged for contractors to perform less than full lead-based paint abatements on the homes of study participants** [9]
Interventions were virtually identical to those in the TLC study [10]	**Interventions were virtually identical to those in the R&M study** [11]

[5] *Grimes, Id.,* 366 Md. at 50.

[6] December 26, 2001, Motion of KKI for Protective Order, *Quyaisha Coles, et al., v. KKI, et al.,* Baltimore City Circuit Court Case No. 24-C-01-004337, at 4. (Exhibit 13).

[7] *Grimes, Id.,* 366 Md. 42-43.

[8] *Grimes, Id.,* 366 Md. At 36.

[9] December 26, 2001, Motion of KKI for Protective Order, *Id.*

[10] Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 49, Exhibit 14.

[11] Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.*, page 38, lines 15-21, Exhibit 15.

Research subjects were vulnerable children [12]	**Research subjects were vulnerable children** [13]
Study required continued exposure of small children to lead-based paint and lead-based paint dust to determine if partial interventions were effective [14]	**Study required continued presence of of children in homes containing lead-based paint and lead-based paint dust to control for the evaluation of the effectiveness of off-label use of drug upon the long-term psychological outcome of the research subjects** [15]
Level of interventions a home received were randomly assigned [16]	**The child research subjects were randomly assigned, through a double-blinded administration, either Succimer or a placebo** [17]
Parents were not adequately informed that the research activity increased the risk that the amount of lead in the child research subject's bodies could increase suffer lead-poisoning[18]	**Parents were not adequately informed that the research activity increased the risk that the amount of lead in the child research subject's bodies could increase suffer lead-poisoning** [19]

[12] *Grimes, Id.,* 366 Md. 42-43

[13] December 7, 1994, IRB submission from subcontractor to KKI, Exhibit 16.

[14] *Grimes, Id.,* 366 Md. at 103.

[15] January 2, 1996, Correspondence from KKI subcontractor Judith Rubin, to Merrill Brophy regarding IRB concerns over continued use of an untreated group of lead-exposed children as controls. Exhibit 17.

[16] *Grimes, Id.,* 366 Md. at 55.

[17] *Rogan, et al., The Effect of Chelation Therapy With Succimer on Neuropsychological Development in Children Exposed to Lead*, May 10, 2001, N. Engl. J. Med., Vol 344, No. 19, page 1421.

[18] *Grimes, Id.,* 366 Md. at 90.

[19] June 21, 1995, Clinical Investigation Consent Form for Keona Featherstone. *See*, Exhibit 11.

Research activity and consent protocols required approval and supervision by local IRB [20]	Research activity and consent protocols required approval and supervision by local IRB [21]

However, there was at least one difference between the two studies. Rather than entice children and their families into living in lead-infested housing only to study how much lead accumulated in their bodies, the TLC researchers took the premise one step further. In the TLC study, the human research subjects were experimented upon by KKI personnel to determine both the amount of lead they would accumulate in their bodies and the long-term health effects. Unfortunately, this distinction offers no succor to the Defendants. As stated by the Maryland Court of Appeals:

> Otherwise healthy children, in our view, should not be enticed into living in, or remaining in, potentially lead-tainted housing and intentionally subjected to a research program, which contemplates the probability, or even the possibility, of lead poisoning or even the accumulation of lower levels of lead in blood, in order for the extent of the contamination of the children's blood to be used by scientific researchers to assess the success of lead paint or lead dust abatement measures.

Grimes, Id. 366 Md. at 41.

II. Factual Summary

The Plaintiffs are Shayonna Featherstone, born October 22, 1992, and Keona Featherstone, born September 11, 1993. The Featherstone family resided in 2418 Jefferson Street in Baltimore, Maryland from approximately 1994 through 1996. During the above period, both children were enrolled in the Kennedy Krieger Institute (KKI) Treatment of Lead Exposed

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[20] *Grimes, Id.,* 366 Md. At 79; 45 C.F.R. § 46.101, *et seq.*

[21] July 1, 1994, Correspondence from Walter Rogan to J. Julian Chisolm, (Exhibit xx); *Grimes, Id.,* 366 Md. At 79; 45 C.F.R. § 46.101, *et seq.*

Children (TLC) study and their home received interventions from agents of the TLC program. Shayonna was referred to KKI by her treating physician Dr. J. Julian Chisolm in 1994 and both she and her sister were followed by KKI until as late as March of 1999.

Consistent with the Maryland Court of Appeals assessment that children in the R&M study were used as canaries in the coal mines, correspondence of Merrill Brophy to the research subject's treating physicians bore the following admonition:

> Because of the double blind nature of this clinical trial we ask that you refrain from monitoring lead levels **during the treatment phase of the study**, for each participant. If you feel you must check levels, **please do not inform the families** or us of any results.

(September 28, 1995, correspondence from Merrill Brophy to Naline Bhargava, M.D., Exhibit 18).

However, Shayonna's referring doctor, J. Julian Chislom, Jr. of KKI, needed no such admonition inasmuch as he was intimately familiar with the TLC study. Dr. Chisolm, recruited the Plaintiffs to enroll in the TLC study. Despite Shayonna's history of chronic lead-exposure, KKI placed emphasis upon the success of the study instead of her care. Dr. Chisolm, indicated that "[i]f [Shayonna] joins [the TLC study], that takes precedence over return to this **regular** Kennedy Lead Clinic." (Medical records of Shayonna Featherstone, Exhibit 19) (Emphasis supplied). Dr. Chisolm clearly possessed unique knowledge of the parameters of the TLC study and the concomitant environmental treatments to the family home. He knew from prior research conducted by KKI that the environmental treatments were not sufficient to remove the lead hazards from the home. Thus, his referral of the Shayonna to the TLC study is at odds with his prior observation:

Review of serial laboratory data show that during the past five months there has

> been no essential change in this child's blood lead concentration. Measurements have fluctuated between 18 and 21 µg Pb/dL whole blood. **One wonders whether there is a whole lot of lead paint in this dwelling although when given the address one would certainly expect that.**

(Medical records of Shayonna Featherstone, Exhibit 20)(Emphasis added).

During the children's participation in the study, their mother signed several consent forms wherein **KKI** explicitly promised that:

> All children in the TLC study will have their homes repaired and/or cleaned to get rid of lead dust and chipped paint. We will take a careful look at your home to see if it can be repaired and/or cleaned to reduce lead paint and dust hazards.
> . . .
> The benefits to your child of letting us find out if they are eligible for the TLC study are that:
> * **We** will look **carefully** at your home to **identify lead hazards** and tell you about it.
> * If your house doesn't qualify, **we** will offer you any information we have about ways to relocate your family to housing that is known to be lead safe[.][22]
> * **We** will **clean-up the lead** if it looks like your child and house are eligible.

See Clinical Investigation Consent Form, Exhibit 11.

In approximately December of 1994, agents of KKI performed an inspection of 2418 Jefferson Street. In January of 1995, the Baltimore City Health Department noted "flaking paint around windows, hole in wall [,] steps and peeling surfaces on wall between front windows." (Baltimore City Health Department, Lead Paint Poisoning Prevention Program, records for Keona Featherstone, Exhibit 21). Sometime prior to December of 1995, KKI and/or its agents conducted interventions within 2418 Jefferson Street. The work undertaken was limited to

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[22]The obvious implication of this statement was that if the family home did "qualify" to participate in the study the home must be "lead safe." The language is unambiguous by design, inasmuch as it was "geared to a 6th grade school education level." TLC Trial Protocol v.9.

replacing some windows and covering the kitchen floor in linoleum tiles. The efficacy, *vel non*, of those steps should have been readily apparent to the researchers at KKI, given the following blood-lead levels of the children:[23]

Keona Featherstone

Date	**Blood-lead Level (µg/dL)**	**Date**	**Blood-lead Level (µg/dL)**
3/16/94	5	8/21/95	*Blinded*
9/4/94	20	9/18/95	26
9/14/94	20	10/17/95	*Blinded*
12/12/94	23	11/7/95	27
12/14/94	22	11/15/95	*Blinded*
4/14/95	20	11/28/95	*Blinded*
6/12/95	28	1/16/96	23
6/21/95	28	2/96	20
7/11/95	*Blinded*		

Shayonna Featherstone

Date	**Blood-lead Level (µg/dL)**
7/22/94	32
9/7/94	21

[23]Levels of blood-lead concentrations are measured in micrograms of lead per deciliter of blood (*ug*/dl). There is no safe level of lead in a child's body and the Centers for Disease Control and Prevention have continually lowered to level of concern to where it currently stands at 10 µg/dL. *See USAA v. Riley*, 393 Md. 55, 62 Fn.4 (2006).

> Nearly 2.5 Million U.S. pre-school children are estimated to have [had] blood-lead concentrations [of 15 µg/dL or higher in 1992] that place[d] them at risk for lead's adverse health effects. Of greatest concern is the contribution of lead to neuro-behavioral and learning deficits in young children which are long lasting, if not indeed permanent.

Quality Assurance Project Plan for the Kennedy Krieger Institute Lead-Based Paint Abatement and Repair and Maintenance Study, July 22, 1992, pages 1 and 2.

12/7/94	22
2/8/95	19
7/31/95	19
11/7/95	27

Simply put, after enrolling into the TLC study, Keona's lead levels **increased**. But this likely came as no surprise to KKI inasmuch as the Technical Statement for the TLC study, prepared by KKI contained the following caveat:

> For a number of reasons, our protocol is predicated upon assurance of "lead-safe" housing...for participating families. First we have evidence that where there is an ongoing residential lead exposure, children's [blood-lead levels] may actually increase while on succimer. Secondly, the **standard of care in Baltimore is to give succimer to children on an outpatient basis only if they are residing in "lead safe" housing. Furthermore, the local standard of care includes intensive assistance to families in moving to "lead-safe" housing since they must be out of the house during abatements ordered by the Baltimore City Health Department. Lastly, we belive that the less intensive forms of dust-control alluded to in the NIEHS request for proposal are more likely to be successful in the better maintained types of housing defined herein as "lead safe".**

(November 23, 1992, Technical Plan Prepared by KKI, et al., Exhibit 22).

Similarly, KKI recognized that it alone bore responsibility for monitoring the safety of the child participants:

> **Safety Monitoring:**
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> We expect that safety monitoring will be a joint effort between the clinical center [KKI] and the Coordinating Center. **At the clinical sites the focus of the clinical monitoring will be on side effect of drug therapy and of evidence of continued exposure to lead.**

(November 23, 1992, Technical Plan Prepared by KKI, et al., page 30, Exhibit 23).

Contrary to the assurances of KKI that it would tell the Featherstone family about any lead hazards identified at 2418 Jefferson Street, KKI failed to fulfill its responsibility to this

family. Further, despite KKI's assurances from 1995 through 1999, via the consent forms, that the above actions would be undertaken in exchange for the participation of the Featherstone family in the TLC study, no additional "interventions" were ever taken within their home(s) after 1995. Arguably, the interventions performed, which were known by KKI at the time to be insufficient to abate existing lead-hazards, amounted to little more than arranging deck chairs on the Titanic.

Dust samples and XRF readings were taken by KKI from 2418 Jefferson Street prior to cleaning and during the study. It is apparent that despite its explicit promise, KKI completely failed to inform the Featherstone family about the levels of lead which existed in the dust in their home prior to or after the interventions; a clear breach of the special duty between investigator and research subject recognized by the Maryland Court of Appeals. More importantly, despite the continued rise of the Plaintiffs' lead levels, the fact that KKI was acutely aware of the dangers of lead-based paint dust to children, and Dr. Chisolm's awareness that the home likely contained "a whole lot of lead paint" the protocols focused upon using only the least-expensive testing methods and provided that the Housing and Urban Development (HUD) lead-dust loading clearance levels were to be ignored. As Fred McNutt, the principal of one of KKI's contractors, testified, the "treatment" which 2418 Jefferson Street received during the TLC study, "...was designed to lower the dust levels, but we weren't and we couldn't be held to a clearance standard because we **weren't treating the hazards**. All we were doing was cleaning existing lead dust." (Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.*, page 66, Exhibit 24). KKI was made aware by contractors such as Mr. McNutt that the interventions outlined in the KKI study protocols were insufficient, would not abate any of the existing lead-hazards in the

dwelling and presented an ongoing dangerous lead hazard to the residents.

The cavalier attitude of the TLC researchers towards the environmental hazards to which their child research subjects were exposed stands in stark contrast to the following statement authored by two KKI doctors years prior to the TLC study: "Exposure to lead-bearing dust is particularly hazardous for children because hand-to-mouth activity is recognized as a major route of entry of lead into the body and because absorption of lead is inversely related to particle size." Mark R. Farfel & J. Julian Chisolm, *Health and Environmental Outcomes of Traditional and Modified Practices for Abatement of Residential Lead-Based Paint*, 80 American Journal of Public Health 1240, 1243 (1990).

The families who "qualified" for the TLC study received "three different levels of intervention on properties. It was level one . . .a level two, and then a level three. Each level of intervention had a price cap. I believe the level one was $1,750; the level two was $3,500; and the level three was $ 7,000 or $ 7,500. . . The repair and maintenance and the TLC were the same thing, but there was a few hundred dollars difference between each one." (Transcript of the October 8, 2003, Deposition testimony of Mr. Fred McNutt, *Id.*, pages 49-50, Exhibit 25). KKI was certainly aware that the only effective means of "clean[ing] up the lead," as they had promised, was to remove the lead-based paint from the home.

On August 22, 2005, 2418 Jefferson Street was tested for the presence of lead-based paint by Arc Environmental. (August 29, 2005, Arc Environmental Report, Exhibit 26). Lead-based paint was detected at levels much higher than allowed by Maryland Department of the Environment (MDE) and HUD guidelines. KKI showed little concern for the continued exposure of their young experiment subjects to lead-based paint and lead-based paint dust.

Prevention and Toxics, July 22, 1992, pages 1-2.

III. KKI designed the TLC study and the environmental interventions employed in 2418 E. Jefferson Street.

It is important to note that despite the convenient arguments of KKI that the NIEHS exercised total control over the TLC study, the sworn testimony of KKI's contractor tells a different tale:

> Q: Did ERI exercise its own discretion as to what should be done to each property?
> A: No.
> Q: So the discretion was Kennedy Krieger's as to what should be done?
> [Counsel for KKI]: Objection, form, foundation.
> A: Well, we didn't identify the areas or the components. We were given these field sheets to put together a proposal on our own letterhead. They were Kennedy Krieger's specifications, Kennedy Krieger's field notes, so...I think a lot of times we wouldn't even go out and see the properties, because all the dimensions and everything else were in these field notes, so...

(Transcript of the October 8, 2003, Deposition testimony of Mr. Fred McNutt, *Id.*, pages 44-45, Exhibit 27).

KKI personnel designed the TLC study. The semantics employed by Davoli and Ms. Brophy in their respective affidavits are an insult to this Court. The Defendants hope to mislead the Court into believing that, "The genesis of the TLC study was an RFP issued by NIEHS without any input from Kennedy Krieger." Defendants' Motion at 3. More accurately, KKI submitted an application to the NIEHS in response to a Request for Application from the NIEHS. An RFA, "[i]dentifies a more narrowly defined area for which one or more NIH institutes have set aside funds for awarding grants, usually has a single receipt (received on or before) date specified in the RFA announcement, and is usually reviewed by a Scientific Review Group convened by the issuing awarding component." *See* web-site of the NIH:

http://grants1.nih.gov/grants/guide/description.htm, Accessed June 1, 2007. Regarding the TLC study, the NIEHS RFA "invited proposals **designed along the general outlines** provided by them, with the understanding that the three proposals which they considered best would be funded and that the principal investigators [such as Davoli] for these three proposals would get together and agree to a single, common protocol." (January 25, 1993, Correspondence from J. Julian Chisolm to Thomas R. Hendrix, Exhibit 28). 00620. Put simply, KKI submitted **their version** of the TLC study to the NIEHS in response to the RFA for study designs centered around a general hypothesis, KKI's version was selected for funding.

Clark H. McNutt was a contractor hired by KKI to perform the R&M study interventions, the specifications of which were later used *in pari materia* in the TLC study. Mr. McNutt's sworn testimony was that personnel from KKI, a landlord, and Mr. McNutt developed the contract specifications for the interventions used in the R&M study. His testimony is illuminating about who was, and was not present, at meetings crucial to the execution of the R&M study; "**We** developed specifications for that contract, and then we did different levels of intervention. Levels ones, twos, and threes on, I think it was 225 or 250 homes." (Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 37, lines 5-21, Exhibit 29) (Emphasis added). Thus, the Defendants contentions that the NIEHS designed the TLC study and the specifications for the interventions to the research subjects' home is nonsense inasmuch as KKI created the specifications years prior to the TLC study.

"In return for permitting the properties to be used in the study, and in return for renting the study homes to families with young children, KKI assisted the landlords in applying for and

receiving grants or loans of money to be used to perform the levels of abatement required by KKI for each class of home." Grimes, *Id.* 366 Md. at 52; *See* June 12, 1995, loan agreement for 2418 Jefferson Street between the NACI Corporation and the Maryland Department of Housing and Community Development, note the upper right hand corner: "**Loan Program: RELAP KENNEDY KRIEGER INSTITUTE ONLY**", Exhibit 30). However, at least one landlord recognized, albeit in hindsight, that the study was flawed.

> **A: ...It turned out to be a major fiasco. They wanted us to put children at risk in the properties so that they could study them.**
> **Q: Kennedy Krieger did?**
> **A: Yes....**

(Transcript of August 26, 2003, Deposition of Lawrence Polakoff, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 91, line 1-7, Exhibit 31)(Emphasis added).

KKI and Davoli were personally made aware by contractors such as Mr. McNutt, who, at the direction of KKI personnel performed TLC study interventions, that the interventions, as specified by KKI, would require ongoing monitoring and maintenance and were insufficient to ensure the safety of children living in the home. (Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.*, pages 62-69, Exhibit 32).[24]

As recognized by KKI researchers Mark Farfel and J. Julian Chisolm, "[e]xposure to lead-bearing dust is particularly hazardous for children because hand-to-mouth activity is

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[24]Mr. McNutt's deposition was taken in the matter of Quyaisha Coles v. KKI, et al. The Coles case involved the exact study involved in this case, to wit the TLC study. Mr McNutt testified that the specifications for the interventions he performed at the direction of Farfel and KKI pursuant to the R&M study and the manner in which the homes of research subjects were assigned the various levels of intervention were virtually identical to those he subsequently performed at the direction of KKI pursuant to the TLC study. (Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.,* pages 34-37, Exhibit 33).

recognized as a major route of entry of lead into the body and because absorption of lead is inversely related to particule size." [25] Lead poisoning poses a distinct danger to young children. It adversely effects cognitive development, growth, and behavior.[26] Of greatest concern is the contribution of lead to neuro-behavioral and learning deficits in young children which are long lasting, if not indeed permanent. Prevention is the only rational way to approach the problem. Once poisoning occurs it is doubtful that any of the current methods of treatment can fully reverse the damage.[27]

Both Shayonna and Keona have suffered from marked academic failures which have consistently rendered them unable to progress academically with their peers. Neuropsychological testing of Shayonna reveals that she is borderline mentally retarded and has a full scale IQ of 79. Tragically, Keona's level of intellectual functioning is virtually identical to that of her sister inasmuch as she has a full scale IQ of 78.

IV. Procedural Posture

The Defendants have removed the instant action from the Circuit Court for Baltimore City on the untested assertion that KKI and Davoli are entitled to removal based upon 28 U.S.C. 1442(a)(2). The Defendants conveniently fail to mention in their Motion that claims virtually

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[25]Mark R. Farfel & J. Julian Chisolm, *Health and Environmental Outcomes of Traditional and Modified Practices for Abatement of Residential Lead-Based Paint*, 80 American Journal of Public Health 1240, 1243 (1990).

[26]Centers for Disease Control and Prevention. *Recommendations for Blood Lead Screening of Young Children Enrolled in Medicaid: Targeting a Group at High Risk*, 49 Morbidity and Mortality Weekly Report 1 (Dec. 8, 2000).

[27]*Final Report: Quality Assurance Project Plan for the Kennedy-Krieger Institute Lead-Based Paint Abatement Repair and Maintenance Study. To: U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics*, July 22, 1992, pages 1-2.

identical to those in the case at bar were previously litigated. The Defendants' desire to litigate this matter in Federal Court is a transparent attempt at forum shopping and a continued effort to unnecessarily delay the resolution of this matter. Further, while the Defendants have filed virtually identical motions in this case and in the case of *Wallace, et al., v. KKI, et al.,* 1:07-CV-1140, wherein they claim that various agencies and sub-agencies of the United States Government are responsible for the Defendants' negligence, the Defendants' newly adopted position stands in stark contrast to the following observation of the Maryland Court of Appeals:

> We, however, are unaware of, and have not been directed to, any federal or state statute or regulation that imposes limits on this Court's powers to conduct its review of the issues presented. **None of the parties have questioned this Court's jurisdiction in these cases**. Moreover, 45 Code Federal Regulations (C.F.R.) 46.116(e) specifically provides: "The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective." Those various federal or state conditions, recommendations, etc., may well be relevant at a trial on the merits as to whether any breach of a contractual or other duty occurred, or whether negligence did, in fact, occur; but have no limiting effect on the issue of whether, at law, legal duties, via contract or "special relationships" are created in Maryland in experimental nontherapeutic research involving Maryland children.

Grimes, Id. 366 Md. at 50.

However, the inconsistencies between the positions of the Defendants in the instant case with those taken in the *Grimes* case do not end there. In support of the Notice of Removal in the instant case, Dr. Davoli swore to the following:

> 6. The NIEHS, directly controlled and approved the information provided to the Study participants and their families as well as the information contained in the Informed Consent forms.

(April 19, 2007, Affidavit of Cecilia Davoli, Exhibit 34). Davoli's affidavit is clearly intend to leave this Court with the impression that the NIEHS controlled every aspects of the TLC study.

However, Davoli's recent affidavit is at odds with her prior sworn testimony:

> This consent form, I agree with that. This consent form has several parts. The first part of the consent form is a general summary of information about lead, and to the best of my recollection, that all of the consent – this is for the TLC study – and all of the consent forms in all four centers contain essentially the same language, and were written by a group of investigators from all four centers. And the language was reviewed by **the IRB at Johns Hopkins for our particular center**. And also by the NIEHS IRB.

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 167, Exhibit 35)(Emphasis added).

Further, when examined about the contents of the consent form used in the TLC study, the same one approved by the Hopkins IRB and signed by the Plaintiffs' mother, Davoli painted a markedly different picture of the scope of KKI's involvement than she seeks to do now:

> Q: I didn't ask you about the other centers. In your meeting with [the mother of Quyaisha Coles] when you are reading this to [her] and it says, 'We will look carefully at your home to identify lead hazards and tell you about it,' in this context the 'we' is Kennedy Krieger?
> A: In this particular form it would have been someone in the environmental arm of the TLC study, yes, who was **employed by Kenned Krieger**.

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Id.*, page 177, Exhibit 36)(Emphasis added).

> Q: ... Doctor, let's go to the next one. It says, 'If your house doesn't qualify, we will offer you any information we have about ways to relocate your family to housing that is known to be lead safe.' 'We,' again in that context, is Kennedy Krieger, isn't it?
> A: It would have been, yes, people working within the TLC study that **worked at Kennedy Krieger.**

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Id.*, page 178-179, Exhibit 37)(Emphasis added). Further, Davoli's sworn testimony reveals that KKI was responsible, not

the NIEHS, for the treatment of the children being experimented upon in the TLC study:

Q: When you read this [part of the consent form to the mother of Quyaisha Coles] and you said 'We will have a doctor examine your child,' you didn't mean that a doctor would come from Philadelphia to examine the child?
A: No.
Q: She would reasonably assumed someone from Kennedy Krieger would examine her child?
A: **Yes, the doctor would be from Kennedy Krieger, I agree with that.**

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Id.*, page 198, Exhibit 38)(Emphasis added).

Q: Doctor, the last [promise in the consent form to parents of the study subjects], 'We will check the amount of lead in your child's body carefully.' In this context as read by [Quyaisha Coles' mother], the 'we' is Kennedy Krieger?
A: Well, we would draw the blood, that is correct. **We Kennedy Krieger draw the blood.**
Q: It says, 'We will check the amount of lead in your child's body.' Was there any other doctor in the room when you were reading this to [Quyaisha Cole's mother]?
A: Not to my recollection.

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Id.*, pages 198-199, Exhibit 39)(Emphasis added). Patently lacking from the sworn testimony of Davoli is the day to day oversight she now alleges was exercised by the NIEHS.

The Defendants through their pleadings and affidavits again attempt to mislead this Court into believing that the "Steering Committee" was controlled by NIEHS and that the same committee controlled their actions in the TLC study. This is simply untrue.

> Central policy for the [TLC study] will be set by a Steering Committee composed of **one member from each of the above-mentioned organizations [including KKI] and the Project Officer (from NIEHS) who will serve *ex officio,* making a total of seven members.** The Project Officer will **vote to resolve ties.** The Committee will elect its own Chair.

(September 21, 1994, Protocol for the TLC Trial, page 3, Exhibit 40)(Emphasis added). Hence, only 1 of the 7 members of the Committee was from the NIEHS and, absent a tie, he was a non-voting member. Further, the lone member of the Committee from NIEHS was not even the Chairman of the Committee.

To be sure, the Defendants do not seek joinder of the "NIEHS" in order to prevent disparate results; rather, they cling to this thin reed in the hopes of obtaining a different result than that which they obtained in the Maryland Courts regarding the R&M study.

V. The "NIEHS" is not a person capable of joinder in this action.

In order to sue a federal agency in its own name, Congressional consent must clearly be found. "When Congress authorizes one of its agencies to be sued *eo nomine*, it does so in explicit language, or impliedly because the agency is the offspring of such a suable entity." *Blackmar v. Guerre*, 342 U.S. 512, 515 (1952). Congress has not established that the NIEHS may be sued in that manner. *See e.g. Lloyd Ammons, et al., v. Great Lakes Chemical Corp., et al.,* 1986 WL 10743, 4 (W.D. Wash. 1986).

A motion to dismiss for failure to join alleged indispensable parties fails when the movant does not identify the individuals who should be joined. *In re Stat-tech Secs. Litigation,* 905 F. Supp. 1416 (D.C. Colo. 1995), *Charles Alan Wright and Arthur F. Miller, Federal Practice and Procedure*, 5C Fed. Prac. & Proc. Civ.3d § 1359 (2007 Supp.). The defendants have failed to establish that Congress has authorized the NIEHS to be sued *eo nomine*. Thus, The Defendants' Motion should be denied for this reason alone.

VI. Neither the NIEHS, nor the United States, are necessary parties to the instant litigation.

"A party is not necessary simply because joinder would be convenient, or because two

claims share common facts, for that would render the distinction between permissive joinder under Rule 20, Fed.R.Civ.P., and joinder under Rule 19 'practically meaningless.'" *Southern Co. Energy Marketing, L.P. v. Va. Elec. & Power Co.,* 190 F.R.D. 182, 185 (E.D. Va. 1999), (Citing to *Field v. Volkswagenwerk AG,* 626 F.2d 293, 301 (3d Cir.1980)).

Fed.R.Civ.P. 19 provides for the joinder of persons needed for just adjudication and sets out a two-part inquiry. First, under Rule 19(a), the Court must determine whether a person is necessary to the proceedings because of his relationship to the matters under consideration. *Owens-Illinois, Inc. v. Meade*, 186 F.3d 435, 440 (4th Cir. 1999). A person is necessary to the action if: (1) in the person's absence complete relief cannot be accorded among those already parties, or (2) the person claims an interest relating to the subject matter of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest.

A. Joinder is not necessary to afford complete relief to the Plaintiffs for the injuries caused by the Defendants.

"[I]t must be noted that complete relief refers to relief as between the parties already parties, and not as between a party and the absent person whose joinder is sought." 3A *Moore's Federal Practice* ¶ 19.07-1[1], at 19-93-96 (2d ed.1991). The Plaintiffs have asserted claims for money damages against the Defendants. Those claims sound in Maryland common-law tort, civil conspiracy, and fiduciary duty. No part of the relief requested by the Plaintiffs requires the joinder of the NIEHS or the United States.

Arguendo, any implication by the Defendants that joinder is required because they

themselves may bring a claim against the NIEHS, or the United States, for contribution or indemnification, is both circular and counter-intuitive and distorts the plain meaning of complete relief. The Rule 19 analysis refers only to relief between the persons already parties. No part of the analysis is contingent upon claims which the Defendants may bring against each other or another party. *Heinrich v. Goodyear Tire & Rubber Co.*, 532 F.Supp. 1348, 1359 (D.Md. 1982). Thus, any claims of the instant Defendants against the NIEHS, the United States, or anyone else are irrelevant to the joinder analysis.

The Defendants the Court to an opinion from the United States District Court for the Southern District of West Virginia. *See*, Defendants' Motion @ 13, (Citing to *Palmer v*[.] *Kokosing*, No. 2:05-0091, 2005 WL 1389177 (S.D.W.Va. June 9, 2005).

The Defendants assert as a threshold matter that the *Palmer* case and the instant case "involv[e] similar legal issues." The Defendants are wrong. The Plaintiffs in *Palmer* sought injunctive relief against a contractor hired by the Corps of Engineers. The Corps had hired the contractor to raze a housing development for a then-ongoing project of the United States. The *Palmer* Plaintiffs sought an injunction ordering the contractor to cease and desist the demolition which would have had the effect of halting the Corps' project. The Court in that matter did indeed order that the Corps be joined into the case, for obvious reasons. However, the claims in the instant case seek, *inter alia*, to hold the Defendants liable for their negligent experimentation upon children from nearly ten years ago in connection with a human research regime that has been over for several years. The Defendants argument that NIEHS must be joined because they were a party to the contract between NIEHS and KKI to fund the TLC study is superficial and ignores the clear nature of the Plaintiffs claims against them. The instant Plaintiffs seek

compensatory damages for injuries they sustained as a result of lead-poisoning, not the reformation or recision of any contract and certainly not injunctive relief, where such relief even possible. The Plaintiffs have asserted claims against the Defendants for breaches of duties, as recognized by the Court of Appeals in the *Grimes* case, none of which involve the NIEHS.

The Defendants relegate to a footnote that less than one year later, the *Palmer* Court revisited it's Order joining the United States. In dismissing the claims against the United States, the Court found that, "the United States is **not** an indispensable party under Rule 19(b) and, therefore, the claims against [the Defendant] will not be dismissed by virtue of the fact that the United States has been dismissed." *Palmer, et al., v. Kokosing West Virginia, LLC, et al.*, 2006 WL 890009, 2 (S.D.W.Va. March 29,2006, emphasis added).

Lacking any legal basis to claim that without joinder of the NIEHS, or the United States, that complete relief cannot be accorded amongst the parties to this action, the Defendants seek to muddy the waters by implying that the study was engineered by the NIEHS. Again, the Defendants are wrong. As set forth herein, KKI designed the TLC study. And as set-forth in the *Grimes* opinion, a special relationship existed between KKI and the subjects, not the NIEHS.

B. Neither the NIEHS nor the United States have sought to be joined as a party in this matter nor do either have any interests in the decade-old negligent conduct of the Defendants. Joinder is not necessary to protect the interests of the NIEHS, or the United States.

As a threshold matter, neither the NIEHS nor the United States have asserted any interest relating to the instant action between private parties which they assert requires protection. Therefore, the burden rests squarely upon the Defendants to show the nature of the unprotected interests of the unprotected party. *Cornhill Ins. PLC, v. Valsamis, Inc.*, 106 F.3d 80, 84. The Defendants baldly assert, "Without being a party to this litigation, NIEHS will be unable to

defend itself regarding its actions pursuant to the TLC Study. In addition, there will be certain findings of fact that will impair or impede the NIEHS's ability to protect its interests in this litigation and subsequent litigation." (Defendant's Motion at 12). The Defendants seek to either ignore or to altogether re-write history. The Maryland Court of Appeals clearly, unmistakably, and unequivocally condemned KKI for the manner in which the prior study was conducted. It defies reason to believe that the NIEHS was not aware of the *Grimes* opinion. However, there was no outcry from the NIEHS nor from the United States government in 2001; *a fortiori* because no interests of the agency or the United State were impinged by requiring research institutions to comply with then existing law. Were the NIEHS so inclined to protect the interests to which the Defendants cite, Fed.R.Civ.P. 24 already provides a method for the agency to voluntarily seek joinder in the instant case. *See e.g. Dyke, et al., v. Gulf Oil Corp., et al.*, 601 F.2d 557, 568, Fn. 29 (Em. App. 1979). Further still, if the NIEHS or the United States had such compelling interests on the line in the instant litigation as the Defendants contend, it defies reason why the Defendants would not have notified the agency of the instant Motion so as to afford it the opportunity to join this case of its own volition.

Neither the NIEHS nor the United States has any continuing interest in the subject matter of this case. The study has long since been concluded and the results were long since published. The Defendants' assertion that a Court, and/or a jury, is entitled to hear the interests of the NIEHS that are at stake in this case, is nonsensical and circuitous. The Defendants refer to vague interests such as a potential "chilling effect" upon current and future federally-sponsored research involving lead exposure in children. This is exactly the same "the sky is falling" argument made by KKI and Hopkins after the 2001 opinion of the Court of Appeals. ("If allowed to stand, the

court's August 16 [2001] ruling would cripple pursuit of critical medical and public health research..." (September 17, 2001, Press Release of Hopkins, Exhibit 22). However, the Defendants continue to conduct research upon human subjects.

Further, the Defendants misunderstand Rule 19 to read that the potential that the NIEHS may "face the risk of multiple and inconsistent results" warrants joinder. To the contrary, the rule clearly states, "...(ii) leave any of the persons **already parties** subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of his claimed interest. " Fed. R.Civ.Pro. 19 (a)(2)(ii), (Emphasis added).

C. The "risks" alleged by the Defendants for failing to join the NIEHS, or the United States, are neither substantial nor sufficient to require joinder.

It is not enough to merely allege that an unprotected party may have unprotected interests. Assuming, without conceding, that the NIEHS or the United States actually have any interests in the instant case, those interests must be substantial to merit a conclusion that they are necessary parties.

The instant suit is one for money damages. The "risk" to which the Defendants speak, to wit, inconsistent findings by a trier of fact in other cases involving the TLC study, is not a cognizable risk under Rule 19.

> Inconsistent obligations arise only when a party to the case risks facing conflicting judgments, so that compliance with one would conflict with the other. Inconsistent adjudications, on the other hand, are those in which a party might prevail on one theory of liability in one case, and then fail on that same theory, and even on the same or similar facts, in another case against another party; **while inconsistent as a matter of logic, these judgments would not necessarily subject the party to inconsistent legal obligations.**

Southern Co. Energy Marketing, L.P. v. Va. Elec. & Power Co., 190 F.R.D. 182, 186 (E.D. Va. 1999)(Emphasis added); *Delgado v. Plaza Las Americas, Inc.,* 139 F.3d 1, 3 (1st Cir. 1998)

(Holding that inconsistent obligations occur when a party is unable to comply with one court's order without breaching another court's order concerning the same incident); *Field v. Volkswagenwerk, AG,* 626 F.3d. 293, 301-302 (3d Cir. 1980) (Holding that potentially inconsistent tort judgments in two separate suits arising from the same set of facts did not render a plaintiff in one case party to the other case).

The only possible outcome of the instant case is an Order of Judgment against the Defendants for a sum certain or an Order of Judgment for the Defendants. Neither has the effect of collateral estoppel or res judicata on any other case between other parties, even as it relates to the TLC study.

VII. Neither the NIEHS, nor the United States, are indispensable parties to the instant litigation.

Assuming, without conceding that the NIEHS or the United States are found to be necessary parties to this matter, they are not indispensable parties. Where it is determined that a necessary party cannot be joined, the Court must determine whether the action can continue in his absence, or whether the person is indispensable pursuant to Rule 19(b) and the action must be dismissed. *Owens-Illinois*, 186 F3d. At 440. Rule 19(b) directs the Court to determine whether in equity and good conscience the action should proceed among the parties before it. The factors which the Court must consider to make this determination are: (1) to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; (2) the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; (3) whether a judgment rendered in the person's absence will be adequate; and (4) whether the plaintiff will have an adequate remedy if the action is dismissed for non-joinder. *Fed.R.Civ.P. 19(b)*. Rule 19(b) provides the Court the

ability to ascribe weight to each of the factors based upon the facts of the particular case and in light of equity and good conscience. *Assoc. Dry Goods Corp., v. Towers Fin. Corp.,* 920 F.2d 1121, 1124 (2d Cir. 1990); *See also 7 Charles Alan Wright, et al., Federal Practice and Procedure § 1608 (3d ed. 2001).*

While the trial Court is afforded discretion in the practical application of the Rule 19 inquiry, dismissal of a case for nonjoinder is a drastic remedy and should be employed sparingly. *Heinrich v. Goodyear Tire & Rubber Co.*, 532 F.Supp. 1348, 1359 (D.Md. 1982); *Nat'l Union Fire Ins. Co. of Pittsburgh, Pa., v. Rite Aid of South Carolina, Inc.*, 210 F.3d 246, 250 (4th Cir. 2000). Generally, dismissal is only ordered when the resulting defect cannot be remedied and prejudice or inefficiency will certainly result from continuing with the action without the absent person. *Owens-Illinois,* 186 F.3d at 441. This is not such a case.

A. Neither the NIEHS nor the United States can be joined in this matter.

As set forth herein above, the NIEHS cannot be sued *eo nomine* in tort. In *Blackmar v. Guerre, supra*, the Supreme Court held that the United States Civil Service Commission was not a suable entity, stating: "Congress has not constituted the Commission a body corporate or authorized it to be sued *eo nomine*." 342 U.S. at 514. In order to sue a federal agency in its own name, Congressional consent must clearly be found, "[w]hen Congress authorizes one of its agencies to be sued *eo nomine*, it does so in explicit language, or impliedly because the agency is the offspring of such a suable entity." *Id.* at 512.

Moreover, a suit against a federal agency is a suit against the federal government. *Blackmar v. Guerre*, 342 U.S. 512 (1952); *Chacon v. Granata*, 515 F.2d 922, 924 n.2 (5 Cir. 1975); *Fort Worth Nat. Corp. v. Federal Savings and Loan Ins. Corp.*, 469 F.2d 47 (5 Cir.

1972); *Krouse v. United States Gov't Treas. Dept. Int. Rev. Service*, 380 F.Supp. 219 (C.D.Cal.1974); *Hartke v. Federal Aviation Administration*, 369 F.Supp. 741 (E.D.N.Y.1973). It is well established law that the United States cannot be sued without its consent, and that a court has no jurisdiction over such a suit. *United States v. Sherwood*, 312 U.S. 584, 586-588, (1941); *Nickerson v. United States*, 513 F.2d 31 (1 Cir. 1975).

Thus, the United States would be the proper party were joinder required. However, the Federal Tort Claims Act requires that a claimant exhaust administrative remedies as a prerequisite to filing suit. Federal Tort Claims Act (FTCA), 28 U.S.C. §§ 1346(b) and 2671-79. The Plaintiffs have not filed a claim with the NIEHS because it was not indicated. The Plaintiffs have asserted state-law claims against the Defendants for violations of Maryland law in connection with experimentation upon Maryland children in Maryland. Consonant with the holding of the Maryland Court of Appeals in *Grimes*, nothing inherent in the claims advanced herein requires the joinder of the NIEHS. The Grimes Court held that the was no question that Maryland Courts had jurisdiction over claims identical to those raised herein by other children used as research subjects against these same Defendants. A *fortiori*, the Plaintiffs have not lodged an agency claim with the NIEHS for the negligence of KKI, Davoli, Hopkins, and the IRB.

B. Equity and good conscience clearly weigh in favor of the Plaintiffs being permitted to continue the instant action without the joinder of the NIEHS or the United States.

The Defendants next contend, not surprisingly, that if the NIEHS cannot be made a party that the Plaintiffs' complaint should be dismissed. The Defendants again avail themselves of the use of circular reasoning in making their argument that if the "if the NIEHS had not requested

such a Study be performed, the Kennedy Krieger Defendants would never have been sued in the first instance." (Defendants Motion at 11).

KKI, Hopkins, Davoli, and the IRB are being sued because they, not the NIEHS nor the United States, had a non-delegable duty to protect the children they used in the TLC study. KKI, Hopkins, Davoli, and the IRB are being sued because they, not the NIEHS nor the United States, breached that duty; the same duties addressed by the Maryland Court of Appeals in the *Grimes* case which dealt with virtually identical circumstances.

The Defendants cries of "prejudice" sound in the fact that they will be held liable for doing that which they contend was the work of another, the NIEHS. This stands in stark contrast to the Defendants paternalistic assertions that the interests of the NIEHS must be protected, and serves only to underscore the untenable nature of their arguments.

If the Defendants wish to cross-claim the NIEHS, the United States, or anyone else, those provisions already exist within the Federal Rules and joinder is not required. It is utterly disingenuous for the Defendants to assert that the Plaintiffs could pursue an action against others for lead poisoning which occurred prior to the TLC study, were this action dismissed, because such a result gives the Defendants a free pass for their own negligence and leaves the Plaintiffs without a remedy for the injuries caused by their participation in the TLC study. If the instant action is dismissed the Plaintiffs will have no forum in which to assert their claims against KKI, Hopkins, Davoli, or the IRB. Dismissal of a case for nonjoinder is a drastic remedy and should be employed sparingly. *Heinrich*, 532 F.Supp. 1359.

Equity and good conscience dictate that the Defendants' Motion should be denied.

Respectfully submitted,

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