IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al. *

Plaintiffs *

v. *

Case No. 1:07-cv-01120

KENNEDY KRIEGER INSTITUTE, INC., et al. *

Defendants *

* * * * * * * * * * *

DEFENDANTS' REPLY TO PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FOR FAILURE TO JOIN A RULE 19 PARTY, OR IN THE ALTERNATIVE, MOTION TO JOIN THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES AS A PARTY

Defendants, Kennedy Krieger Institute ("Kennedy Krieger") and Cecilia Davoli, M.D. (collectively referred to as "Kennedy Krieger Defendants"), by their undersigned counsel, hereby submit their Reply to Plaintiffs' Opposition to Defendants' Motion to Dismiss for Plaintiffs' Failure to Join a Rule 19 Party or, in the Alternative, Motion to Join the National Institute of Environmental Health Sciences as a Party ("NIEHS"), and state as follows:

I. INTRODUCTION

Without the NIEHS, there would have been no Treatment of Lead Exposed Children Study ("TLC Study"). The NIEHS was intimately involved in every aspect of the TLC Study from its conception, design, implementation and funding. Indeed, after the TLC Study was concluded, the NIEHS was the entity that took credit for the TLC Study and submitted articles for peer reviewed publication regarding the results of the TLC Study. In their Opposition to Defendants' Motion to Dismiss for Failure to Join a Rule 19

Party, or in the Alternative, Motion to Join the National Institute of Environmental Health Sciences as a Party ("Opposition"), Plaintiffs turn a blind eye to these obvious facts and, by implication, request that this Court do the same.

The NIEHS is an essential and, therefore, necessary party to this litigation. Without the NIEHS as a party to this suit, incomplete justice can be the only result, variant obligations may be imposed upon the parties, and the NIEHS may be irrevocably damaged in its ability to protect its interests. To ensure justice, this Court should grant Defendants' Motion to Dismiss or, in the Alternative, require Plaintiffs to Join the NIEHS as a party to this action.[1]

II. FACTUAL BACKGROUND

In an attempt to color this Court's view of the TLC study, Plaintiffs' Opposition is replete with mischaracterizations and misleading statements regarding the TLC Study and the parties and researchers involved. These statements are irrelevant to the issue before the Court at this time – namely, whether the NIEHS is a necessary party to this litigation. Therefore, the Defendants do not believe it necessary to address every misstatement at this time. Nonetheless, the Defendants are compelled to address some of these mischaracterizations to ensure that this Court does not assume these allegations are true.

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[1] Plaintiffs allege that the Defendants are required to identify the United States Government as a Defendant in this case. At most, the Defendants' alleged failure to name the United States rather than the NIEHS is nothing more than a simple misnomer. Because the Defendants are not attempting to sue the NIEHS, and because it is abundantly clear that the Defendants are seeking to join the NIEHS, this simple misnomer does not mandate that Defendants' Motion be denied. *See e.g., Idaho AIDS Found., Inc. v. Idaho Hous. & Fin. Ass'n*, 422 F. Supp. 2d 1193 (9th Cir. 2006) (party defendant asserted that the United States Department of Housing and Urban Development should be joined pursuant to Rule 19 (a) (2), the Court did not consider whether HUD could be sued). The Defendants discuss the procedure for bringing suit against the NIEHS in Section III of their Reply.

A. Pursuant to federal statutes, the NIEHS sponsored, funded, and managed the TLC Study.

It is undisputed that the NIEHS contracted with Kennedy Krieger and other clinical centers in Philadelphia, Newark, Cincinnati and Columbus to implement the TLC Study. Indeed, the NIEHS did so pursuant to federal statute. Federal law makes clear that the general purpose of the NIEHS is to conduct and support research regarding factors in the environment that affect human health:

> The general purpose of the National Institute of Environmental Health Sciences (in this sub-part referred to as "the Institute") is the conduct and support of research, training, health information dissemination and other programs with respect to factors in the environment that affect human health, directly or indirectly.

42 U.S.C.A. § 2851.

In an effort to further this general purpose, Congress required the NIEHS to "conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection, and abatement of lead-based paint and other lead exposure hazards." 15 U.S.C.A. § 2685 (a). Consequently, the NIEHS is required to conduct studies of lead exposure in children who have elevated blood lead levels:

> The Secretary of Health & Human Services (hereinafter in this sub-section referred to as "the Secretary"), acting through the Director of the Centers for Disease Control, ("CDC") and the Director of the National Institute of Environmental Health Sciences, shall jointly conduct the study of the sources of lead exposure in children who have elevated blood lead levels (or other indicators of elevated lead body burden), as defined by the Director of the Centers for Disease Control.

15 U.S.C.A. § 2685 (c) (emphasis added).

Given these directives, the NIEHS issued a Request for Proposal ("RFP") for development of the TLC Study, and the NIEHS accepted Kennedy Krieger's "proposal." The NIEHS drafted a contract and forwarded it to Kennedy Krieger for signature.[2] The NIEHS prepared the contract without any participation from Kennedy Krieger. *See* Exhibit 1 - Contract drafted by the NIEHS. This government contract served as the basis for the relationship between the NIEHS and Kennedy Krieger in conducting the TLC study. In the contract, the NIEHS identified, with great specificity, the tasks it required Kennedy Krieger to perform and Kennedy Krieger was expressly prohibited from acting outside the express scope of authority outlined in the contract. *Id.*

The goal of the TLC Study was to determine if treating children with blood lead levels in the range of 20 *ug*/dl - 45 *ug*/dl with succimer, a chelation agent, would reduce the amount of lead in their blood. The NIEHS **directed and sponsored** the TLC Study and authored its own publications about the TLC Study. *See* Exhibit 2 - *The Treatment of Lead-Exposed Children TLC Trial: Design and Recruitment For the Study and Effect of Oral Chelation on Growth and Development in Toddlers, Paediatric & Perinatal Epidemiology* 12, 313-33 (1998). The data coordinating center was at the Harvard School of Public Health, the central laboratory was at the CDC in Atlanta, and the central pharmacy was the Program Support Center of the United States Department of Health and Human Services in Perry Point, Maryland. *Id.* at p. 315. Moreover, in a press release located on the NIEHS website, the NIEHS acknowledged that it **managed** the TLC Study with the Harvard School of Public Health. *See* Exhibit 3 - Press Release by the NIEHS.

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[2] This was a multi-center study and, accordingly, the NIEHS contracted with three other Clinical Centers to conduct the TLC study in addition to Kennedy Krieger. Those other sites were Cincinnati, Columbus, Philadelphia and New Jersey.

The NIEHS conceived, developed, funded, and oversaw the TLC Study. Walter J. Rogan, M.D. of the NIEHS, was the Project Officer and principal investigator for the TLC Study. As Project Officer, Dr. Rogan's role was to effectuate research pursuant to state and federal statute. Dr. Rogan's leadership in the TLC Study was so prominent that it is still highlighted on the NIEHS web site, and is described as follows: "Dr. Rogan was project officer and one of the principal investigators for the four-site, randomized, controlled clinical trial of oral chelation therapy to prevent lead-induced disorders of growth, behavior and cognitive development in toddlers." *See* the NIEHS web site at http://dir.niehs.nih.gov/direb/staff/rogan/hom.htm (emphasis added).

Other than Dr. Rogan, many others at the NIEHS were intimately involved with the TLC Study. In fact, the NIEHS Institutional Review Board approved the TLC Study. Moreover, other Institutional Review Boards, including the Harvard School of Public Health and the Centers for Disease Control and Prevention, approved the TLC Study. *See* Exhibit 4 - *The Effect of Chelation Therapy with Succimer on Neuropsychological Development in Children Exposed to Lead, N. Engl. J. Med. Vol. 344, No. 19, p. 1422 (May 10, 2001)*. Given that the NIEHS funded, controlled and directed the TLC Study, it is improper for Plaintiffs to file suit against Kennedy Krieger, and not the NIEHS, which by its own admission, implemented the TLC Study.

B. The *Grimes* Decision is irrelevant to the TLC Study.

Plaintiffs place great reliance on *Grimes v. Kennedy Krieger Institute, Inc.*, 366 Md. 29, 782 A.2d 807 (2001). Plaintiffs' reliance upon *Grimes*, however, is misplaced because *Grimes* has nothing to do with the TLC Study. In *Grimes,* the Maryland Court of Appeals reviewed the decision of the Baltimore City Circuit Court granting summary

judgment in favor of Kennedy Krieger regarding the Repair and Maintenance Study ("R&M Study"), not the TLC Study. In granting summary judgment, the trial court ruled that Kennedy Krieger owed no duty to the minor plaintiffs. The decision was appealed and the Maryland Court of Appeals ruled that there was, in fact, a duty between Kennedy Krieger and the minor plaintiffs because of a "special relationship." The Court of Appeals reversed the grant of summary judgment in favor of Kennedy Krieger, and remanded the case to the trial court. **The Maryland Court of Appeals did not comment on, or make any reference to, the TLC Study.** Nevertheless, Plaintiffs devote a significant portion of their Opposition asserting that the *Grimes* decision is relevant to the TLC Study. To assert so is a blatant mischaracterization of the *Grimes* opinion.

Moreover, the Court in *Grimes* did not make any findings of fact relative to this case or to the TLC Study. In its opinion following a Motion for Reconsideration, the *Grimes* Court expressly stated that its opinion pertained to the trial court's grant of summary judgment and that every other issue regarding liability or damages remained open for further factual development:

> Although we discussed the various issues and arguments in considerable detail, the only conclusion that we reached as a matter of law was that, on the record currently before us, summary judgment was improperly granted – that sufficient evidence was presented in both cases which, was taken in the light most favorable to the plaintiffs and believed by a jury, would suffice to justify verdicts in favor of the plaintiffs....Every issue bearing on liability or damages remains open for further factual development, and any relevant evidence not otherwise precluded under our Rules of Evidence is admissible.

Grimes, 782 A.2d at 861, 366 Md. at 119 (emphasis added).

Indeed, the Court of Appeals specifically stated that the record before it was "not extensive," *Id.* at 50 n.12, and referred to the record as "sparse," *Id.* at 46-47. It is therefore incorrect and misleading for Plaintiffs to cite the *Grimes* opinion in support of "factual" propositions that have not been subjected to the adversarial process and/or decided by a finder of fact. To the extent that the Court of Appeals discussed factual issues, it was doing so in the context of summary judgment.

The Court of Appeals decision in *Grimes* was not, and is not, relevant to the TLC Study.

C. There Have Been Other TLC Study Cases Removed to Federal Court.

In their Opposition, Plaintiffs assert that the Defendants' contention that the federal court has subject matter jurisdiction is "newly adopted." *See* Plaintiffs' Opposition at p. 23. That statement is incorrect. In *Somers v. Kennedy Krieger Institute, Inc.*, Case No. L-02-CV-419 and *DeShields v. Kennedy Krieger Institute, Inc.*, Case No. L-02-CV-222, Plaintiffs' counsel filed suit against Kennedy Krieger with regard to its implementation of the TLC Study for the NIEHS. In response, Kennedy Krieger removed these cases to federal court pursuant to 28 U.S.C. §1442 (a) (1).

D. Keona and Shayonna Featherstone had elevated blood lead levels prior to being seen at the Kennedy Krieger Lead Clinic.

Plaintiffs' Opposition characterizes Keona and Shayonna Featherstone as healthy children prior to being seen at the Kennedy Krieger Lead Clinic.[3] This is wholly inaccurate.

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[3] The Kennedy Krieger Lead Clinic evaluated and treated many children in Baltimore City who had elevated blood lead levels. Only a very small subset of all children seen at the Kennedy Krieger Lead Clinic became enrolled in the TLC Study.

Keona Featherstone was born on September 11, 1993. Prior to her initial presentation to the Kennedy Krieger Lead Clinic on May 17, 1995, Keona Featherstone already had elevated blood lead levels. On September 14, 1994, the Maryland Department of the Environment measured Keona Featherstone's blood lead level at 20 *ug/dl. See* Plaintiffs' Opposition at p. 15. On December 12, 1994, her blood lead level was 23 *ug/dl*, as measured by the Maryland Department of Health & Mental Hygiene. *Id.* On April 14, 1995, the Maryland Department of Health & Mental Hygiene measured her blood lead level at 20 *ug/dl*. *Id.* Therefore, Keona Featherstone had elevated blood lead levels for at least 8 months before she was evaluated at the Kennedy Krieger Lead Clinic and enrolled in the TLC Study.

Shayonna Featherstone was born on October 2, 1992. She resided with her family at 1504 E. Lanvale Street, Baltimore, Maryland until 1993. A Kennedy Krieger Lead Clinic note dated September 7, 1994, indicates that the property contained flaking paint on the walls and windows. *See* Exhibit 5 - Kennedy Krieger Lead Clinic Note dated September 7, 1994 at p. 2. The floors were noted to be in poor condition. *Id.* Also, flaking paint was noted on the outside windows. *Id.* From October 1993 through April 1994, the Featherstone family resided at 2406 E. Eager Street, Baltimore, Maryland. After April 1994, the Featherstone family resided at 2418 E. Jefferson Street, Baltimore, Maryland.

On July 22, 1994, the Baltimore City Health Department recorded Shayonna Featherstone's blood lead level as 32 *ug/dl*. *See* Plaintiffs' Opposition at p. 15. She was referred to the Johns Hopkins' TAC Clinic at that time, and later referred to the Kennedy

Krieger Lead Clinic. Like her sister, Keona, Shayonna Featherstone had elevated blood lead levels prior to her referral to the Kennedy Krieger Lead Clinic.

III. THE NIEHS MAY BE JOINED AS A PARTY PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 19.

Noticeably absent as a named Defendant from this lawsuit is the NIEHS.[4] Pursuant to the Federal Tort Claims Act ("FTCA"), the NIEHS, through the federal government, may be sued, and therefore may be joined to the instant action. As discussed herein, the NIEHS is a necessary and indispensable party with substantial interests in the subject matter of this litigation. For these reasons, Plaintiffs' failure to join the NIEHS as a party to this case requires that this lawsuit be dismissed, or in the alternative, that the NIEHS be joined as a party to this litigation.

A. The NIEHS, through the United States, is amenable to suit under the FTCA.

Plaintiffs argue that the Defendants' Motion should be dismissed because the NIEHS cannot be sued in its own name and Defendants have failed to properly identify the individuals to be joined. *See* Plaintiffs' Opposition at pp. 17-18, *citing In re Stat-Tech Secs. Litigation,* 905 F. Supp. 1416 (D. Colo. 1995). In *Stat-Tech*, a *pro se* defendant filed a motion to dismiss pursuant to Rule 19 but "[made] no attempt either to identify the individuals he claims should have been joined or to aver how their absence impedes his ability to protect his interests or subjects him to multiple or inconsistent liabilities." *Stat-Tech*, 905 F. Supp. at 1421. The court held that defendant failed to meet his burden under Rule 19. *Id.*

[4] The NIEHS operates a research facility in North Carolina as a subsidiary of the National Institutes of Health ("NIH"), itself a branch of the United States Department of Health and Human Services.

Stat-Tech is easily distinguishable from the instant case because the Defendants' Motion to Dismiss identifies the NIEHS, a federal agency, as a necessary party to be joined. The Motion discusses in detail the reasons why joinder should be required.

Moreover, Defendants' Motion should not be denied on the hyper technical argument that the NIEHS cannot be sued in its own name. In making this argument, Plaintiffs improperly view Defendants' Motion as a suit against the NIEHS. Defendants' Motion, however, only identifies the NIEHS as the party to be joined, setting forth the reasons why it should be joined. If this Court grants Defendants' Motion, then it will be Plaintiffs' duty to follow the proper procedures in order to pursue a claim against it and/or the United States. It is clear from Plaintiffs' Opposition that Plaintiffs are well aware that the NIEHS is a federal agency of the United States, and made arguments contending neither the NIEHS nor the United States should be sued. Consequently, Plaintiffs' "form over substance" argument has no legal effect upon Defendants' Motion.

Plaintiffs contend that federal agencies such as the NIEHS cannot be sued without suing the United States and without congressional consent. The Defendants disagree. *See Information Syst. & Networks Corp., v. The Dept. of Health and Human Services,* 970 F. Supp. 1 (D.D.C. 1997) (a contract dispute where plaintiffs named the NIEHS as a party defendant); *Idaho AIDS Foundation, Inc. v. Idaho Housing & Finance Assoc.*, 422 F. Supp. 2d 1193 (9th Cir. 2006) (where the federal Department of Housing and Urban Development (HUD) was ordered to be joined as a necessary party); *Boles v. Greeneville Housing Authority*, 468 F. 2d 476 (6th Cir. 1972) (where the court found that HUD was an indispensable party); *Bridges v. Blue Cross and Blue Shield Assoc.*, 889 F. Supp. 502

(D.D.C. 1995) (where the court ordered the federal Office of Personnel Management to be joined as a party defendant because it had substantial interest).

In a negligence case, a party seeking to proceed against the United States for negligent acts of a United States agency or of that agency's employees committed in the scope of their employment, must pursue such claims under the FTCA, 28 U.S.C. §§ 2671 *et. seq*. The FTCA provides:

> [t]he United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances . . . With respect to any action under this chapter [ ] the United States shall be entitled to assert any defense based upon judicial or legislative immunity which otherwise would have been available to the employee of the United States whose act or omission gave rise to the claims, as well as any other defenses to which the United States is entitled.

28 U.S.C. § 2674. The FTCA sets forth prerequisites to filing suit against the United States. *See e.g.*, 28 U.S.C. § 2675. Those pre-requisites include complying with the time restrictions for bringing the action. *See* 28 U.S.C. § 2401; *Martin v. United States*, 436 F. Supp. 535 (S.D. Ca. 1977). Further, this Court has exclusive jurisdiction over FTCA claims. *See* 28 U.S.C. § 1346 (b). Additionally, the FTCA is an exclusive remedy. *See* 28 U.S.C. § 2679. Here, the proper vehicle for Plaintiffs to join the NIEHS is through the FTCA. Plaintiffs' failure to join the NIEHS is the result of Plaintiffs' own actions and these Defendants should not be prejudiced by Plaintiffs' failure to do so.[5]

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[5] The FTCA exempts discretionary functions, and must satisfy a two-part test. *See United States v. Gaubert*, 499 U.S. 315 (1991) (citations omitted). Discretionary functions are ones that involve an element of judgment or choice. *Id.* at 322. Second, the discretionary function exception should protect only those administrative decisions grounded in policy. *Id.* As shown above, the NIEHS is mandated by federal statute to conduct research regarding the effects of lead exposure in children. When an agency is required to perform a function, as the NIEHS was required to do so here, then there is no element of choice involved. *See, e.g., Starrett v. United States*, 847 F.2d 539, 541-42 (9th Cir. 1988).

This case arises from allegations of tortious harm resulting from a contract between a federal agency (the NIEHS) and a federal contractor (Kennedy Krieger), acting within the scope of their contract. The involvement in the TLC Study by the NIEHS was mandated by federal statute. Therefore, the NIEHS is amenable to suit under the FTCA.

B. The NIEHS is a necessary and indispensable party pursuant to Rule 19.

The Court analyzes Rule 19 (a) and (b) in order to determine whether an absent party is necessary and indispensable for purposes of joinder. Rule 19 (a) and (b) provide:

> (a) person who is subject to service of process and whose joinder will not deprive the court of jurisdiction over the subject matter of the action shall be joined as a party in 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 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. If the person has not been so joined, the court shall order that the person be made a party.
>
> (b) If a person as described in subdivision (a)(1)-(2) hereof cannot be made a party, the court shall determine whether in equity and good conscience the action should proceed among the parties before it, or should be dismissed, the absent person being thus regarded as indispensable.

The NIEHS is subject to both the necessary joinder analysis of Federal Rule 19 (a) and the indispensable joinder analysis of Federal Rule 19 (b).[6] Not only is the NIEHS necessary and indispensable on account of its own interests, but it is also so connected with the subject matter of this lawsuit that the NIEHS must be a party to this litigation for the proper protection of the already named Defendants whom judgment will necessarily and directly affect. A defendant cannot be required to litigate questions that primarily and

[6] Rule 19 (b) identifies four factors to be considered by the Court in determining when an action can proceed or whether it should be dismissed if a party is indispensible. The Defendants assume that the NIEHS, as a federal agency, can be joined, and therefore, a detailed analysis under Rule 19 (b) is not addressed in this Reply.

directly involve issues with third persons not before the court. *See* 30A C.J.S. Equity §142, at 113.

In addition, the absence of the NIEHS as a party Defendant will severely handicap Kennedy Krieger in asserting a defense to Plaintiffs' allegations, and substantial prejudice will be incurred. Kennedy Krieger has been sued as a result of performing the TLC Study, which was directed, controlled and managed by the NIEHS pursuant to federal statute. If the NIEHS had not requested that the TLC Study be performed, Kennedy Krieger would never have been involved in the Study and subsequently sued. It is imperative that the NIEHS be entitled to present the reasons why the NIEHS wanted the TLC Study performed, and, additionally, why the City of Baltimore was chosen as the TLC Study site. The Court cannot fashion an effective remedy without the NIEHS as a party.

Plaintiffs' suit attempts to force the Defendants to defend their actions without adding the NIEHS, which contracted with them and controlled the implementation of the TLC Study. This is fundamentally unfair to the Defendants. Both parties to a contract are necessary and indispensable parties involving actions taken pursuant to the contract.[7] *See* *Yashenko v. Harrah's NC Casino Co., LLC,* 446 F.3d 541 (4th Cir. 2006) (where the court ruled that both parties to a contract were necessary parties to the cause of action.) *See* *Palmer v. Koksing,* 2005 WL 1389177 (S.D.W.Va. 2005) (where the Court held that plaintiffs failed to join a necessary party, the United States Army Corp of Engineers), *Teamsters Local Union No. 171 v. Keal Driveaway Co.*, 173 F.3d 915, 918 (4th Cir. 1999)

[7] There is no prescribed formula for determining whether a party is indispensable since that matter can be determined only in the context of particular litigation. Provident Tradesmens Bank & Trust Co. v. Patterson, 390 U.S. 102 (1968). Therefore, a Court may not know whether a particular party is "indispensable," and it would be premature to find that the NIEHS is not a necessary party, without permitting the current parties to conduct discovery in this matter.

(*citing Delta Fin. Corp. v. Paul D. Comanduras & Assocs.*, 973 F.2d 301, 305-06 (4th Cir. 1992) (parties to a contract are necessary parties to a lawsuit based on that contract.)).

The NIEHS not only had input regarding the design of the TLC Study, but it funded and controlled the TLC Study. Kennedy Krieger was directed and controlled by the NIEHS. To establish this relationship, the NIEHS drafted a contract to be signed by Kennedy Krieger, which served as the basis for the relationship between the NIEHS and Kennedy Krieger in conducting the TLC Study.

Plaintiffs' main allegation in this case is that the Defendants breached a duty to the participants in the TLC Study. These allegations are directly based on Kennedy Krieger's contract with the NIEHS to implement the TLC Study.[8] Therefore, the Court's adjudication of this case on the merits will necessarily require it to interpret the nature, design and intent of the Study, including agreements between the NIEHS and Kennedy Krieger.

As the party charged with drafting the contract and negotiating the design and implementation of the Study, the NIEHS undoubtedly has a direct interest in the Court's determination of research obligations to which it was intimately involved. Kennedy Krieger did not have authority to deviate from its contract with the NIEHS, as the NIEHS exhibited intimate and detailed control over the TLC Study.[9] *See Ricci v. Massachusetts*

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[8] The contract states that a coordinating center, clinical centers, and the NIEHS staff, will participate in the design of the trial protocol and then recruit, evaluate, treat and follow-up patients according to trial protocol.

[9] A Project Officer from the NIEHS, Dr. Walter Rogan, served as a representative on the Steering Committee, which established central policy for the Study. The NIEHS also appointed a Data and Safety Monitoring Committee, which served as an advisory committee to the Institute. Membership was determined by the NIEHS, and the NIEHS officers attended all or parts of these meetings. The Data and Safety Monitoring Committee reviewed and approved the Study protocol and monitored the accumulating data and progress of the Study. Indeed, in "Commonly Asked Questions," an educational material distributed to the general public, the NIEHS is defined as the "central agency for the study." The "Project Office" was NIEHS, and the "Project Officer" was Dr. Rogan of the NIEHS. Dr. Rogan was a member of the Steering Committee, the Drug Management Subcommittee, and the Clinical Issues Subcommittee. Beth Ragan of the

Association for Retarded Citizens, Inc., 97 F.R.D. 737 (D. Mass. 1983) (court ordered the Dept. of Health and Human Services (HHS) be made a party to the case due to its ongoing and intimate involvement with, and monitoring of, the defendants).

There is no doubt that the NIEHS is a necessary and indispensable party.

i. <u>Under Rule 19 (a)(1), complete relief in this case cannot be accorded among the existing parties without the addition of the NIEHS.</u>

Plaintiffs argue that the NIEHS is not a necessary party to the instant litigation because joinder is not necessary to afford complete relief to Plaintiffs. The Defendants disagree.

Resolution of these claims undoubtedly involves an analysis of the actions of the NIEHS, which directed and implemented the TLC Study. It is likely that the fact finder will determine that the NIEHS, not the current Defendants, was responsible for the design and implementation of the TLC Study. In that instance, without the presence of the NIEHS as a named party, Plaintiffs would be denied appropriate and complete relief. *See Ethypharm S.A. France v. Bentley Pharmaceuticals, Inc.*, 388 F. Supp. 2d 426 (D. Del. 2005) (finding a subsidiary to be a necessary and indispensable party because of the possibility that already named defendant would be found not liable, leaving plaintiff with incomplete relief).

NIEHS was a Member of the Environmental Issues Subcommittee. In addition, Dr. Rogan reviewed and commented on the protocol for determining whether abnormal laboratory values indicated an Adverse Drug Experience (ADE). Following his review of the ADE definitions and reporting requirements, Dr. Rogan trained clinical staff on how to respond to ADEs that might arise pursuant to the TLC Study.

Dr. Rogan's published article regarding the TLC Study from the Pediatric and Perinatal Epidemiology Journal explains that the NIEHS created a web page directly associated with the NIEHS in which the details of the TLC Study structure, function, associate investigators, staff, affiliation, etc, were displayed.

Defendants strongly believe that the jury will find in their favor. Nonetheless, joining the NIEHS as a necessary party may serve to avoid multiple litigation, provide all parties with complete and effective relief in a single action, while simultaneously protecting an absent party from the possible prejudicial effect of deciding the case without it.

ii. Under Federal Rule 19 (a)(2)(i), the NIEHS has substantial interests in the subject matter of this action and failure to join the NIEHS will impair its interests.

The NIEHS is a necessary party pursuant to Rule 19 (a) for two reasons. First, permitting this action to go forward without the NIEHS would impair or impede its ability to protect a "claim[ed] ... interest relating to the subject of the action." Fed. R. Civ. P. 19(a) (2) (i). The NIEHS has substantial interests in the subject matter of this action, that being the professional mission and undertakings of the institution. The NIEHS has no way to protect those interests absent its role as a party to this lawsuit.

Moreover, the NIEHS has a direct interest in the performance of such studies, as it may affect future research endeavors that it will undertake pursuant to federal statute. Plaintiffs allege that the NIEHS has no continuing interest in the subject matter of this case because the Study has concluded and the results have been published. The Defendants disagree.

In cases seeking reformation, cancellation, rescission, or otherwise **challenging the validity of a contract**, "all parties to the contract probably will have a substantial interest in the outcome of the litigation and their joinder will be required." *See* Wright & Miller, *Federal Practice and Procedure*, § 1613 at 200-03 (2004 ed.) (citations omitted) (emphasis added). Here, there is a direct contract between the NIEHS and Kennedy

Krieger. As stated above, Plaintiffs' fundamental contention is that the TLC Study should not have been done in the first place because Plaintiffs believe that the TLC Study posed an unreasonable risk to the participants; this position is no different than a challenge to the validity of the NIEHS/Kennedy Krieger contract. NIEHS certainly has a substantiated interest in this litigation. Consequently, Plaintiffs must be required to join the NIEHS to this case.

The NIEHS, as its mission and purpose mandate, engages in federally-sponsored research involving environmental factors, such as lead exposure, in children. The NIEHS conducted the TLC Study in Newark, Philadelphia, Cincinnati and Columbus. Resolution of this case will undoubtedly have ramifications for other cases involving the NIEHS contracts for the TLC Study, and the NIEHS IRB approval of research. The NIEHS undoubtedly has an interest in this litigation.

The NIEHS possesses interests separate and distinct from those of the current Defendants. The ability of the NIEHS to protect its interests regarding research on lead-based paint and its effect on children has been, and will continue to be impeded if the NIEHS is not joined in this matter. Therefore, it must be a party to this action both to defend its actions in the TLC Study and other studies that it sponsors involving minors. The interests of the NIEHS are especially vulnerable in that if they are not vigorously asserted by counsel before the Court, the true nature and extent of these interests may not be explored until after they are irreparably prejudiced.

Moreover, in deciding whether the Defendants were negligent in their performance of the TLC Study, the Court will have to evaluate research requirements, and what conduct satisfies those requirements. Joinder of the NIEHS will provide the Court with maybe

otherwise unobtainable information regarding the TLC Study. *See Johnson v. Colts, Inc.*, 306 F. Supp. 1076, 1079 (D. Conn. 1969) (Court ordered Plaintiff to amend complaint where party to be joined would assist court in interpreting collective bargaining agreement negotiated by unions).

Plaintiffs argue that neither the NIEHS nor the United States have asserted any interest relating to the instant action and that "it defies reason to believe that the NIEHS was not aware of the *Grimes* opinion." However, it is illogical to assume that the NIEHS monitors all federal and state court filings across the country to determine whether it has an interest in the litigation. Rule 19 requires a party to existing litigation to request that a non-party be joined when appropriate. Rule 19 does not require non-parties to monitor litigation and request joinder. The NIEHS should be a litigant in this matter and have the opportunity to defend its interests and influence the outcome of this case.

iii. Under Federal Rule 19 (a)(2)(ii), the absence of the NIEHS as a party could lead to inconsistent obligations.

Permitting this suit to continue without the NIEHS could subject the parties to a substantial risk of incurring conflicting legal obligations. Fed. R. Civ. P. 19(a) (2) (ii). If this action is allowed to proceed, this Court may make rulings regarding the terms of the TLC Study protocols, parental consents, or the general appropriateness of the TLC Study. Another court in another jurisdiction may make entirely different rulings regarding the same issues involving the TLC Study. For example, this Court might find that it was inappropriate for parents or guardians to consent for minors to participate in the TLC Study. This would have the effect of halting Kennedy Krieger's research involving minors. Another court, in reviewing the TLC Study, might find that consent by a parent or

guardian for a minor to participate in a study is permissible and is required pursuant to Kennedy Krieger's mission to conduct research.[10]

The effect of these conflicting rulings would obviously lead to inconsistent obligations by Kennedy Krieger – where compliance with one judgment would conflict with the other. *See Owens-Illinois, Inc. v Meade*, 186 F.3d 435 (4th Cir. 1999) (holding that possibility that one court might compel arbitration while the other court might allow alternative judicial remedies to some of the plaintiffs warranted having one court adjudicate the entire case with all of the affected parties before it); *Teamsters,* 173 F. 3d at 915 (holding that continuing without unjoined party was impermissible because that party could file suit in another forum to protect its interests and subject joined party to conflicting legal judgments); *Schlumberger Industries, Inc. v. National Sur. Corp.,* 36 F.3d 1274 (4th Cir. 1994) (holding that the potential for factual "whipsaw" from two pending cases warranted having one court adjudicate the entire matter with all the parties before it).

iv. <u>Efficient and facilitated discovery in this case cannot be accorded among the existing parties without the addition of the NIEHS.</u>

One of the purposes of Federal Rule 19 is to provide for the full and complete adjudication of a dispute with a minimum of litigation effort, so that the interests of the plaintiff, defendants, and the public will be best served. *Cable TV Fund 14-A, Ltd. v. Property Owners Ass'n Chesapeake Ranch Estates, Inc.* 706 F. Supp. 422, 430 (D. Md. 1989).

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[10] Kennedy Krieger is an internationally recognized facility located in Baltimore, Maryland, dedicated to improving the lives of children and adolescents with pediatric developmental disabilities through patient care, special education, evaluation, **research**, rehabilitation, and professional training. In addition to the Kennedy Krieger School, the Institution's services include over 40 outpatient clinics, neurobehavioral, rehabilitative, and pediatric feeding disorder inpatient units, plus several home and community programs providing services to assist families. *See* Kennedy Krieger Institute web site at www.kennedykrieger.org/kki_2nd_inside.jsp?pid =1.

Discovery in this case will undoubtedly be hindered by the absence of the NIEHS as a party Defendant. Access to important documents such as: committee meeting minutes; IRB records; documents relating to the NIEHS and the IRB approval process; documents detailing the design and implementation of the TLC Study; and documents explaining the role of Kennedy Krieger, are essential to the matters at issue in this case. As a party Defendant, the NIEHS would facilitate access to such records and other tangible evidence and assist the Court in evaluating this complicated case. *See Johnson*, 306 F. Supp. at 1079.

In addition to facilitating access to a potentially widespread collection of relevant documents, the involvement of the NIEHS in the form of depositions and live testimony is mandatory to the understanding of the design and implementation of the TLC Study, and to the defense of this case. Also, there will be extensive testimony from numerous witnesses from the NIEHS regarding the detailed involvement and control that the NIEHS had over the Study. It would also provide a mechanism for the NIEHS to address the allegations arising from situations in which it was involved. Without being a party to this litigation, the NIEHS will be unable to defend itself regarding its actions.

For the reasons previously stated in Defendants' Motion to Dismiss, the NIEHS is an indispensable party to this litigation. If this Court disagrees, then Defendants request that this Court attempt to lessen their prejudice by allowing Defendants to depose representatives of the NIEHS and propound written discovery upon the NIEHS in order to obtain information it possesses regarding the TLC Study that it initiated and managed.[11]

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[11] The Defendants strongly believe that the Court has subject matter jurisdiction over this matter. However, it is anticipated that Plaintiffs will file a Motion to Remand this case to state court. If that occurs, the Defendants respectfully request that the Court deny Plaintiffs' Motion since it would be exceedingly difficult,

IV. CONCLUSION

The NIEHS has substantial interests that merit its inclusion in this case as a necessary and indispensable party. Without the presence of the NIEHS as a party in this case, complete relief cannot be afforded among the existing parties and the NIEHS will be unable to protect its interests as they relate to the TLC Study. Because Plaintiffs have failed to name the NIEHS as a party, this matter should be dismissed. Alternatively, in the event that this Court does not grant dismissal of this matter, this Court should order Plaintiffs to amend their Complaint to join the NIEHS as a Defendant. This case cannot proceed in equity and good conscience without the presence of the NIEHS as a named party.

For all of the reasons stated, Defendants Kennedy Krieger Institute and Cecilia Davoli, M.D., respectfully request that this Court grant their Motion to Dismiss for Failure to Join a Rule 19 Party or, in the Alternative, Motion to Join the National Institute of Environmental Health Sciences as a party.

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if not impossible, to obtain documents from federal agencies and compel depositions of federal employees regarding the TLC Study while in state court.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 18th day of June 2007, a copy of the foregoing Defendants' Reply to Plaintiffs' Opposition to Defendants' Motion to Dismiss for Failure to Join a Rule 19 Party or, in the Alternative, Motion to Join the National Institute of Health Sciences as a Party, was electronically filed and mailed, first class, postage prepaid, to:

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