

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’ MEMORANDUM IN SUPPORT OF THEIR 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**

**I. INTRODUCTION**

This action is brought by Shayonna Featherstone, a minor, and Keona Featherstone, a minor, by their mother and next friend, Sharon Jackson (“Plaintiffs”), and arises out of Plaintiff Keona Featherstone’s participation in the National Institute of Environmental Health Sciences (“NIEHS”) study conducted by Kennedy Krieger Institute, Inc. and others, known as the Treatment of Lead-Exposed Children (“TLC”) Study.

Plaintiffs seek damages in the amount of Four Million Dollars (\$4,000,000). Plaintiffs’ Complaint asserts claims of negligence, negligent misrepresentation, civil conspiracy and breach of fiduciary duty against Kennedy Krieger Institute, Inc., Cecilia Davoli, M.D. (collectively referred to as the “Kennedy Krieger Defendants”) and The Johns Hopkins University, The Institutional Review Board of The Johns Hopkins University School of Medicine Joint Committee on Clinical Investigation, Thomas R.

Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine (collectively referred to as “IRB”), N.A.C.I. Corporation, Shenan Management, Inc., Marc and Nancy Medin, Pythagoras and Anne Passas, and Helen Heath, Individually and Trading As Lady “H” Enterprises.

The federal government, through NIEHS, directed and controlled all of Kennedy Krieger’s activity in the design, implementation and follow-up of the TLC Study. Furthermore, the NIEHS Institutional Review Board (“IRB”) approved the informed consent utilized to enroll Study participants.<sup>1</sup> NIEHS maintained detailed, hands-on control over all phases of this government-sponsored and funded study.

Plaintiffs have failed to name NIEHS as a party to this litigation. Absent participation in this litigation by NIEHS, complete relief cannot be afforded among those already parties, and this action will impair or impede NIEHS’ ability to protect its interests in this litigation and future litigation. In addition, absence of NIEHS will place the parties in this litigation at a substantial risk of incurring double, multiple, or inconsistent obligations. Accordingly, the Kennedy Krieger Defendants request that the Court issue an order dismissing Plaintiffs’ Complaint or, in the alternative, requiring Plaintiffs to join NIEHS as a party to this proceeding.

The following paragraphs provide a summary of the intimate and meticulous control that NIEHS maintained over the TLC Study.

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<sup>1</sup> In their Complaint, Plaintiffs allege that the Informed Consent form was inaccurate and misleading. *See* Plaintiffs’ Complaint, a copy of which is attached hereto as **Exhibit A**.

## II. STATEMENT OF FACTS

In 1992, the federal government, through the National Institute of Environmental Health Sciences (“NIEHS”)<sup>2</sup>, issued a Request for Proposal (“RFP”) seeking clinical centers for a study entitled “Treatment of Lead-Exposed Children.” The purpose of the Study was to determine whether succimer, a drug approved by the United States Food and Drug Administration (“FDA”) for use in treating individuals with blood lead levels greater than 45 micrograms per deciliter, could prevent cognitive delay in young children with blood lead levels less than 45 micrograms per deciliter.

Specifically, Plaintiffs’ negligence claims directly call into question Kennedy Krieger’s compliance with the contract it entered into with NIEHS as well as Kennedy Krieger’s compliance with the detailed and comprehensive framework of federal regulations that govern research on human subjects.

The genesis of the TLC Study was an RFP issued by NIEHS without any input from Kennedy Krieger. NIEHS unequivocally articulated in the RFP that control over the timing parameters for each and every aspect of the TLC Study would rest with NIEHS. Furthermore, NIEHS directed the criteria for enrollment into this Study, and mandated the areas of focus in analyzing the Study’s data. Kennedy Krieger drafted its “proposal” within the specific criteria set forth by NIEHS.

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<sup>2</sup> NIEHS is a subsidiary of the National Institutes of Health (“NIH”), a branch of the United States Department of Health and Human Services.

In response to Kennedy Krieger's "proposal," NIEHS drafted a contract and forwarded it to Kennedy Krieger for signature<sup>3</sup>. No one from Kennedy Krieger participated in the preparation of that contract. See Affidavit of Merrill Brophy attached hereto as **Exhibit B**, paragraph 3. This government contract served as the basis for the relationship between NIEHS and Kennedy Krieger in conducting the TLC Study. See Contract attached hereto as **Exhibit C**. The NIEHS, through one of its Project Officers, was required to:

Maintain complete surveillance of the technical performance and contact with the contractor in order to give reasonable assurance that all specified contract deliverables are delivered on time and are in accordance with the specifications/requirements of the contract terms.

See June 25, 1993 Department of Health and Human Services Memorandum attached as **Exhibit D**.

Moreover, the Principal Investigator at Kennedy Krieger (and all clinical sites) was required to seek approval from NIEHS in order to allocate funds for *any* purpose that deviated *in any way* from the contract as drafted by NIEHS. See Affidavit of Cecilia Davoli, M.D., attached hereto as **Exhibit E**, paragraph 11; *see also* June 26, 1995 letter from Kennedy Krieger to NIEHS regarding approval for funds attached hereto as **Exhibit F**.

Further, the Statement of Work section of the contract, in describing the specific criteria to be used in protocol development, adopted *verbatim* the study criteria initially set forth by NIEHS in its RFP.

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<sup>3</sup> This was a multi-center study and, accordingly, NIEHS contracted with three other Clinical Centers to conduct the TLC study in addition to Kennedy Krieger. Those other sites were Cincinnati, Philadelphia and New Jersey.

The trial shall proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up....The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20 ug/dl to 45 ug/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficiency and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

See **Exhibit C** at 10.

NIEHS directed the Steering Committee, subject to federal government approval, to further develop the protocol and strategies for the TLC trial. The NIEHS Project Officer and Alternate Project Officer participated in nearly every subcommittee created for the TLC Study. See Protocol attached hereto as **Exhibit G** at 40-42.

The Project Officer of NIEHS supervised regular meetings and conference calls with Kennedy Krieger and the other centers regarding study design to ensure that the plans developed consistent with NIEHS objectives. See Affidavit of Cecilia Davoli, M.D. attached hereto as **Exhibit E** at paragraph 4; *see also*, and **Exhibit B** at paragraph 4. Final authority over each and every aspect of this Study rested with the Project Officer of NIEHS. *Id.* at paragraph 5; *see also* **Exhibit C** at 21. Pursuant to the contract, Kennedy Krieger did not have the authority to deviate from the approved study protocol of NIEHS. Indeed, NIEHS retained the ability to terminate the contract if Kennedy Krieger deviated from the Study protocol. "Failure of the contractor to abide by the approved shared protocol may result in the termination in accordance with the termination clause." See **Exhibit C** at 19.

Pursuant to federal regulation, Kennedy Krieger was required to obtain IRB approval of the Informed Consent Form to be utilized with enrolling study participants. After the local IRB utilized by Kennedy Krieger approved a form, Kennedy Krieger was required to forward that form to the IRB of NIEHS, for further review. The IRB of NIEHS initially rejected the Kennedy Krieger Informed Consent Form because the reading level required for comprehension was too high. *See Exhibit B* at paragraph 10 and *Exhibit E* at paragraph 12. Only after Kennedy Krieger revamped its form, secured local IRB approval again, and resubmitted the form to NIEHS, was it approved such that the Study could proceed. *Id.*

NIEHS also imposed substantial reporting requirements on the Clinical Centers participating in the Study. Kennedy Krieger was required to submit to NIEHS technical reports as well as racial/ethnic enrollment reports. *Exhibit C* at 15. During the first year of the Study, Kennedy Krieger submitted semi-annual reports that described the progress in planning, recruitment, community activity and screening, with particular emphasis on the material not covered in the Steering Committee meetings. *Id.* For all subsequent years, Kennedy Krieger submitted quarterly reports outlining the numbers of families contacted and screened, all activities planned and all activities executed during the reporting periods, again with particular emphasis on the materials not covered in the Steering Committee meetings. *Id.* NIEHS also required Kennedy Krieger to submit enrollment reports providing a summary of the planned study population and a summary of the actual number of participants enrolled according to designated racial/ethnic categories. *Id.*

NIEHS also maintained oversight of the study's implementation through periodic site visits. See **Exhibit B** at paragraph 6 and **Exhibit E** at paragraph 7. These visits were conducted to ensure that Kennedy Krieger was complying with the TLC Study protocol. *Id.* During these visits, the Project Officer of NIEHS reviewed study participant charts<sup>4</sup> to ensure compliance with federal regulations, observed the study facilities, and conducted visits to houses involved in the Study. *Id.*

The TLC Study involved assessment of the drug Succimer under certain clinical conditions. Because this drug was not approved by the FDA for use under those conditions, NIEHS submitted an Investigational New Drug ("IND") application to the FDA. See **Exhibit C** at 13; see also **Exhibit B** and **Exhibit E** at paragraph 8. Because NIEHS held the IND for the use of Succimer in children with blood lead levels less than 45 micrograms per deciliter, the Project Officer of NIEHS was actively engaged in ensuring that the Clinical Centers understood Succimer's biochemical behavior. See **Exhibit B** and **Exhibit E** at paragraph 8.

The TLC Study was fully funded by NIEHS with support from the Office of Research on Minority Health of the National Institutes of Health ("ORMH, NIH"). See **Exhibit G** at paragraph 2.2.

The intimate control exercised by NIEHS over the TLC Study extended through to the Study's conclusion. Indeed, NIEHS prohibited Kennedy Krieger from summarizing the results of the Study absent NIEHS approval. See **Exhibit C** at 13.

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<sup>4</sup> The FDA imposes regulations regarding how researchers should document their use of investigational new drugs.

### III. LEGAL STANDARDS

#### A. Federal Rule 12(b)(7) – Dismissal For Failure to Join A Rule 19 Party

A motion to dismiss for failure to join an indispensable party pursuant to Federal Rule 12(b)(7) requires a two-step process. *See* Rule 19, Fed.R.Civ.P.; *Owens-Illinois, Inc. v. Meade*, 186 F.3d 435, 440 (4<sup>th</sup> Cir. 1999). First, it must be determined whether a party is “necessary” pursuant to Rule 19(a). *Id.* Second, if a necessary party is unavailable, it must be determined whether the party is “indispensable” to the case in that the party’s appearance is so necessary that the case must be dismissed. *Id.* The Court’s analysis of the necessity and indispensability of a party under Rule 19 must be judged on a case by case basis, however, and “the court must consider the particular potential for prejudice in the context of the particular factual setting presented by the case at bar.” *See Schlumberger Indus., Inc. v. Nat’l Sur. Corp.*, 36 F.3d 1274, 1286(4<sup>th</sup> Cir. 1994).

#### B. Federal Rule 19 – Joinder of Persons Needed For Just Adjudication

Federal Rule 19 governs the “Joinder of Persons Needed for Just Adjudication,” and provides, in pertinent part, as follows:

“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.”

*See* Fed. R. Civ. P. 19(a).

Pursuant to Rule 19(b), the Court should consider the following factors to determine whether the action should proceed among the existing parties or whether the action should be dismissed if a necessary party is indispensable:

The factors to be considered by the Court include: first, to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by a shaping of relief or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence would be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for non-joinder.

*See* Fed. R. Civ. P. 19(b)

The purpose 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. *See Schutten v. Shell Oil Co.*, 421 F.2<sup>nd</sup> 869, 873 (5<sup>th</sup> Cir. 1970). Federal Rule 19 forces a court to question whether the action before it will affect parties not before it. *Teamsters Local Union No. 171 v. Keal Driveaway Co.*, 173 F.3d 915, 917 (4<sup>th</sup> Cir. 1999).

**C. Federal Rule 21 – Misjoinder and Non-Joinder of Parties**

Federal Rule 21 governs the “Misjoinder and Non-Joinder of Parties,” and provides, in relevant part as follows: “Misjoinder of parties is not ground for dismissal of an action. Parties may be dropped or added by order of the court on motion of any party or of its own initiative at any stage of the action and on such terms as are just.”

This Rule grants a trial judge broad discretion to join additional parties as defendants in order to prevent a multiplicity of suits, or to grant complete relief. *See A.S.*

*Abell Co. v. Chell*, 412 F.2d 712, 717 (4<sup>th</sup> Cir. 1969); *Caperton v. Beatrice Pocahontas Coal Co.*, 585 F.2<sup>nd</sup> 683, 691-92 (4<sup>th</sup> Cir. 1978).

#### IV. LEGAL ARGUMENT

Dismissal, pursuant to Federal Rule 12(b)(7), requires the court to determine if an “absent” party is “necessary” and, if so, determine whether that party is available to participate in the litigation. NIEHS’ control over, and involvement with, the TLC Study makes NIEHS a “necessary” party, which is available to participate in this matter.

##### A. NIEHS is a necessary party pursuant to Federal Rule 19(a).

The allegations contained in Plaintiffs’ Complaint are directly based on Kennedy Krieger’s contract with NIEHS to implement the TLC Study. NIEHS funded the TLC Study. The Kennedy Krieger Defendants did not have authority to deviate from its contract with NIEHS, as NIEHS exhibited intimate and detailed control over the TLC Study. Furthermore, the actions of the IRB Defendants regarding the TLC Informed Consent Form and other matters, were approved by the IRB of NIEHS. NIEHS is an indispensable and necessary party to this action given its very detailed level of control over every aspect of the TLC Study.

NIEHS is a subsidiary of the National Institutes of Health, itself a branch of the United States Department of Health and Human Services. Therefore, the Kennedy Krieger Defendants believe that, NIEHS is available to be made a party to this case. *See* Fed. R. Civ. P. 19(b). Assuming, *arguendo*, the NIEHS is not available to be made a party, the NIEHS is nevertheless an indispensable party pursuant to the factors identified in Federal Rule 19(b). First, without the NIEHS as a party Defendant, substantial prejudice will be incurred. The Kennedy Krieger Defendants have been sued as a result

of performing and approving a Study directed, controlled and managed by the NIEHS. In other words, if the NIEHS had not requested such a Study be performed, the Kennedy Krieger Defendants would never have been sued in the first instance. The Kennedy Krieger Defendants are entitled to present the reasons why the NIEHS wanted such a Study performed, and, additionally, why the City of Baltimore was chosen as a Study site. The Court cannot fashion an effective remedy without the NIEHS' involvement as a party. Second, prejudice to the Kennedy Krieger Defendants cannot be avoided absent the presence of NIEHS as a party Defendant. Third, a judgment rendered absent the presence of NIEHS as a party Defendant will be inadequate. For example, the fact finder determines that NIEHS, not the Kennedy Krieger Defendants, was responsible for the design and implementation of the TLC Study, they may find in favor of the Kennedy Krieger Defendants. In that instance, the Plaintiffs may be denied appropriate relief. Alternatively, if the fact finder determines that the Kennedy Krieger Defendants, and NIEHS, were culpable, the Kennedy Krieger Defendants would be denied relief afforded by having another Defendant present in the litigation responsible for the judgment. Fourth, both of the minor Plaintiffs had elevated blood lead levels prior to enrolling in the TLC Study. Therefore, to the extent the Plaintiffs have any causes of action, they would have remedies against the source or sources of those blood lead levels if this matter was dismissed.

**B. Complete relief in this case cannot be accorded among the existing parties without the addition of NIEHS.**

NIEHS must be added as a party to this matter in order provide complete relief to the existing parties. First, the present Defendants may file third party claims against NIEHS given that it designed, implemented, funded and controlled the TLC Study. The

Kennedy Krieger Defendants were directed and controlled by NIEHS. If the current Defendants do not file third party claims against NIEHS, and if Plaintiffs prevail at trial, it is likely that several Defendants will file actions against NIEHS for indemnification and contribution given its detailed control over the TLC Study.

Moreover, complete relief may not be afforded Plaintiffs if NIEHS is not added as a party. Defendants strongly believe that the jury will find in their favor. Under this scenario, Plaintiffs would likely file suit against NIEHS in a subsequent action. NIEHS must be added as a party to this action in order for all existing parties to obtain complete relief.

C. **The failure to include NIEHS as a party will impede its ability to protect its interests involving the TLC Study.**

As previously discussed, NIEHS must be a party to this action to protect its interests. There will be extensive testimony from numerous witnesses regarding NIEHS' intimate involvement and control over the TLC Study. 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 NIEHS' ability to protect its interests in this litigation and subsequent litigation.

As noted above, the parties in the instant matter might file claims against NIEHS. This would expose NIEHS to the risk of incurring multiple or inconsistent obligations based on the TLC Study. For example, if this Court ruled that NIEHS designed, directed, and controlled the TLC Study, that finding would have an adverse effect on NIEHS in subsequent litigation. NIEHS must be added as a party in order to prevent potential inconsistent judgments pursuant to its role in directing the TLC Study. See *Owens-Illinois, Inc. v. Meade*, 186 F.3d 435, 441 (4<sup>th</sup> Cir. 1999)(non-diverse Plaintiffs were

necessary parties to litigation in order to avoid conflicting legal obligations.) See also *Cleland Construction Co., Inc. v. Balfour Beatty Construction, Inc.*, 229 F.R.D. 521, 525 (D.S.C. 2005)(subcontractor was necessary party with respect to sub-subcontractors' claim against prime contractor given that subcontractor's absence would create the possibility of inconsistent judgments.)

Recently, the Fourth Circuit ruled that both parties to a contract are necessary and indispensable parties involving actions taken pursuant to the contract. See *Yashenko v. Harrah's NC Casino Co., LLC*, 446 F.3d 541 (4<sup>th</sup> Cir. 2006)(Indian tribe which contracted with casino management company was necessary party to terminated employee's cause of action.) Moreover, in an unreported case involving similar legal issues, the Federal Court for the Southern District of West Virginia ordered a plaintiff, pursuant to Federal Rule 19, to join a party who contracted with a defendant to perform construction that was the subject of the litigation. See *Palmer v Kokosing*, 2005 WL 1389177 (S.D.W.Va., June 2005)(Not Reported in F.Supp 2d). Attached as **Exhibit H** is a copy of the opinion for the Court's convenience.

In *Palmer*, defendant, Kokosing-Frucon, LLC ("Kokosing"), was involved in a construction project from which plaintiffs alleged nuisance and filed suit requesting both damages and injunctive relief. Kokosing argued that plaintiffs failed to join a necessary party - the United States Army Corp of Engineers ("Corp"). Kokosing argued that the Corp was a necessary party to the action because the Corp bought the homes and contracted with Kokosing to work on the development of the housing community. The Court held that, pursuant to Federal Rule 19, plaintiffs failed to join a necessary party and that the Corp should be joined in the action. The Court explained that the project was

controlled by the Corp in that the Corp defined the project's dimensions, specifications, and type of equipment used. *Id.* at 2. Moreover, if the Corp was not joined, Kokosing could be faced with conflicting obligations from the Court, which could result in additional litigation. Also, the Court stated that if there was a finding against Kokosing, it might file a claim against the Corp in a subsequent action. *Id.* The Court reasoned that joining the Corp as a necessary party served to avoid multiple litigation, provided the parties with complete and effective relief in a single action, while simultaneously protecting absent persons from the possible prejudicial effect of deciding the case without them. *Id.* 5

Just as the *Palmer* Court joined a necessary party, NIEHS should also be joined as a party in order to avoid inconsistent results regarding potential litigation in other jurisdictions. In addition to conducting the TLC Study in Baltimore, NIEHS conducted the TLC Study in Newark, Philadelphia, and Columbus. Any rulings by this Court regarding NIEHS' degree of direction and control involving the TLC Study in Baltimore, will certainly impact NIEHS' ability to defend itself in litigation that may ensue from its direction and control of TLC Studies in Newark, Philadelphia, and Columbus.

## V. CONCLUSION

NIEHS is an indispensable party to this litigation. Without the presence of NIEHS as a party in this case, complete relief cannot be afforded the existing parties and NIEHS will be unable to protect its interests as they relate to the TLC Study. Because Plaintiffs have failed to name NIEHS as a party, this matter should be dismissed.

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5 After the plaintiffs joined the Corp, the Court later held, in that particular instance, that the Corp was not an indispensable party and therefore denied Kokosing's Motion to Dismiss. See *Id.*, 2006 W.L. 890009 (S.D.W.Va. March 29, 2006), which is attached as **Exhibit I**.

Alternatively, in the event that this Court does not grant dismissal of this matter, this Court should order Plaintiffs to amend their Complaint and add NIEHS as a Defendant in order to provide complete relief to all parties in this litigation, and to protect NIEHS' interests by preventing additional suits against it in subsequent proceedings.

WHEREFORE, Defendants Kennedy Krieger Institute and Cecilia Davoli, M.D., respectfully request that this Court grant their Motion to Dismiss or, in the alternative, require Plaintiffs to amend their Complaint and add NIEHS as an additional Defendant to this matter.

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