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

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

* * * * * * * * * * * * *

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO REMAND

Defendants Kennedy Krieger Institute, Inc., ("Kennedy Krieger" or "KKI"), and Cecilia Davoli, M.D. (collectively referred to as the "Kennedy Krieger Defendants"), The Johns Hopkins University ("JHU"), The Institutional Review Board of the Johns Hopkins University School of Medicine Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D., David R. Cornblath, M.D., Paul Lietman, M.D. and Hayden G. Braine, M.D. (collectively referred to as "IRB Defendants"), by their undersigned counsel, respectfully oppose the Plaintiffs' Motion for Remand.

Shayonna Featherstone and Keona Featherstone, minors, by their mother and next friend, Sharon Jackson ("collectively Plaintiffs") brought suit challenging the Treatment of Lead-Exposed Children Study ("TLC Study"), a clinical study that was commissioned and funded by the federal government, through the National Institute of Environmental Health Sciences ("NIEHS"). *See* Exhibit A, Notice of Removal. Contrary to Plaintiffs' contentions in their Motion to Remand, the TLC Study was a completely independent clinical study, altogether

different from any prior study involving children exposed to lead paint, e.g., R&M Study. The participants involved were already living in homes which contained lead at the time the study commenced and the study participants had preexisting elevated lead levels. Moreover, Dr. Walter J. Rogan was appointed by NIEHS as a representative of the U.S. Government, to serve as the Project Officer of the TLC Study. In this capacity, Dr. Rogan directed and controlled Kennedy Krieger's involvement with regard to the design, implementation and follow-up of the TLC Study. Through Dr. Rogan, NIEHS maintained detailed, hands-on control over all phases of this government-sponsored and funded study. Finally, all aspects of the Study were mandated by the Contract with NIEHS.[1] For these reasons, Plaintiffs' Motion to Remand should be denied.

INTRODUCTION

I. Overview of the TLC Study.

"NIEHS has supported a series of longitudinal studies of childhood lead poisoning" since 1980. (*See* Award/Contract ("Contract"), attached as Exhibit B, at p. 9). Continuing this effort, "NIEHS has also supported clinical studies leading to the licensure of the drug succimer, an orally administered chelating drug now labeled for use in children with blood lead levels above 45 µg/dL. . . ." *Id.* Recognizing the lack of data for toddlers with blood lead concentrations in the 10-20 µg/dL range, despite their correlation with subsequent cognitive delays, NIEHS set the parameters for the TLC Study and, in 1992, issued Request for Proposals ("RFP") from clinical centers interested in being selected to participate in the TLC Study. Kennedy Krieger had no input in the development of the RFP. As articulated by NIEHS in its RFP, the purpose of this clinical 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

[1] Certain "unfunded mandates" contained in the Contract were funded through independent means. However, all aspects of the Study were mandated by the Contract with the Federal Government.

than 45 micrograms per deciliter, could prevent cognitive delay in young children with blood lead levels less than 45 micrograms per deciliter. (*See* RFP, attached hereto as Exhibit C). The "basic concept, including the ethics for the study, which was reviewed and approved at NIEHS, [was] (among other things) a randomized, blind or double blind, placebo controlled study of succimer at lead levels below 45 µg/dL." (*See* Amendment of Solicitation/Modification of Contract, attached hereto as Exhibit D, at p. 3).

In accordance with the RFP, Kennedy Krieger received written notification of NIEHS's formal acceptance of their response to the RFP, which was provided by the Project Officer and endorsed by the Contracting Officer. (Exhibit C, at Article E.2, p. 19). NIEHS subsequently drafted the Contract and forwarded it to Kennedy Krieger for signature.[2] Like the development of the RFP, Kennedy Krieger did not participate in the preparation of the Contract. (*See* Affidavit of Merrill Brophy, Exhibit E, at ¶ 3). In fact, the language and substance of the Contract largely mirrored that of the RFP. For example, the Statement of Work section of the Contract, which specifically described the criteria to be used in developing study protocol, was adopted *verbatim* from the study criteria initially set forth by NIEHS in its RFP.

This Contract, commissioned by the federal government, established the relationship between NIEHS and Kennedy Krieger for the stated purpose of conducting the TLC Study. (*See* Exhibit B). As highlighted by the Plaintiffs in their Motion to Remand, the Award imposed strict contractual requirements on Kennedy Krieger from which they could not deviate. (*See* Plaintiffs' Motion to Remand, at pp. 9 and 30). For example, NIEHS mandated the following in its Contract with KKI:

> The Contractor **shall** complete all work in accordance with the Statement of Work, terms and conditions of this contract. (Exhibit B, at p. 11).

[2] This was a multi-center study and, accordingly, NIEHS contracted with three additional Clinical Centers in order to conduct the TLC Study. These sites included Cincinnati, Philadelphia and Newark.

> [T]he Contractor **shall** furnish all necessary services, qualified personnel, material, equipment and facilities not otherwise provided by the government, as needed to perform the work . . . . *Id.* at 15.
>
> 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. Each child will be followed to age 4 at a minimum. *Id.* at 16.
>
> NIEHS believes that children eligible for the trial should be about two years old and have blood lead levels between about 20 and 45 µg/dL at the time of randomization. *Id.* at 18.
>
> The Clinical Center **shall** evaluate the children prior to randomization for iron, vitamin, or other nutrient deficiency, and treat such deficiencies . . . . *Id.* at 16.
>
> Clinical Center staff **shall** evaluate their homes . . . and provide clean-up according to trial protocol. *Id.*; *Id.* at 18.
>
> [D]ust control and clean up **will** be a component of the management of all children. *Id.* at 16.
>
> [KKI] **shall** identify lead sources in the child's environment. *Id.* at 18.

Indeed, NIEHS retained plenary authority to terminate the Contract if Kennedy Krieger deviated from the study protocol. (*See* Exhibit B at Article E.2, p.19 ("Failure of the contractor to abide by the approved shared protocol may result in termination in accordance with the termination clause.")).

The Contract named Project Officer, Dr. Walter J. Rogan, and Alternate Project Officer, Ms. Beth Ragan, as **representatives of the Government** for the TLC Study. *Id.* at Article G.2, p. 21 (emphasis added). As Project Officer, Dr. Rogan was responsible for:

> (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

Id.

The Contract also outlined the authority of the Contracting Officer who was "the only person with the authority to act as **agent of the Government under this contract**." *Id.* at p. 22 (emphasis added).[3] Thomas Hardee of NIEHS was subsequently appointed as Contracting Officer for the TLC Study. (*See* Exhibit F, June 1993 Correspondence from Thomas Hardee of NIEHS to Kennedy Krieger requesting execution of the proposed Contract). As such, Mr. Hardee had the authority to:

> (1) direct or negotiate any changes in the Statement of Work: (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

Id. The Principal Investigator at Kennedy Krieger was therefore required to seek approval from Mr. Hardee 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 G at ¶ 10; June 26, 1995 correspondence from Kennedy Krieger to NIEHS regarding approval for funds, attached hereto as Exhibit H).

The NIEHS Project Officer and Alternate Project Officer participated in nearly every subcommittee created for the TLC Study, including the Steering Committee. (*See* Protocol, attached hereto as Exhibit I, at pp. 40-42). NIEHS directed the Steering Committee, subject to federal government approval, to further develop the protocol and strategies for the TLC trial. (Exhibit D, at p. 10). In turn, Dr. Rogan was the sole representative of the federal government charged with developing and implementing the TLC Study. *Id.* at p. 21. Dr. Rogan participated in and 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

[3] Plaintiffs' incorrectly assume that "contractor" and "agent" are synonymous. KKI was not the federal government's agent but was its wholly controlled contractor for purposes of the application of federal contractor immunity.

objectives. (*See* Affidavit of Cecilia Davoli, M.D., attached hereto as Exhibit G, at ¶ 4. *See also*, Exhibit E, at ¶ 4). Final authority over each and every aspect of this study rested with the NIEHS Project Officer. *Id.* (*See also*, Exhibit B, at ¶ 21). Surely, but for meeting with each particular Study participant, inspecting each residence, and being present at each blood test and evaluation, no single person could have been more involved in directing the TLC Study, than Dr. Rogan.

Pursuant to federal regulation, Kennedy Krieger was required to obtain Institutional Review Board ("IRB") approval of the final protocol and the Informed Consent Form to be utilized in enrolling study participants. (*See*, Amendment of Solicitation/Modification of Contract, at p. 4, attached hereto as Exhibit D). After Kennedy Krieger's local IRB approved the Form, it was required to forward that Form to NIEHS' own IRB for further review. *Id.* The NIEHS IRB initially rejected the Kennedy Krieger Consent Form because the reading comprehension level required in order to execute the Consent Form was, in the NIEHS' IRB's estimation, too high. (*See* Exhibits E and G at ¶ 10). Only after Kennedy Krieger revamped the Consent Form, secured local IRB approval and resubmitted the Form to NIEHS for approval, was the Study able to proceed. *Id.*

NIEHS, through its Project Officer, Dr. Rogan, imposed substantial reporting and oversight requirements on the Clinical Centers participating in the study. For example, Kennedy Krieger was required to submit technical reports as well as racial/ethnic enrollment reports to NIEHS. (Exhibit B, at p. 15). During the first year of the study, Kennedy Krieger submitted semi-annual reports that described the Study's progress in planning, recruitment, community activity and screening, with particular emphasis on the material not covered in the Steering Committee meetings. *Id.* For each subsequent year, Kennedy Krieger submitted quarterly

reports outlining the number 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.*

Dr. Rogan and his staff maintained oversight of the study's implementation through site visits. (*See* Exhibits E at ¶ 6 and G at ¶ 7). These visits were primarily conducted so that Dr. Rogan could ensure that Kennedy Krieger was complying with the TLC Study protocol. *Id.* During these visits, Dr. Rogan also reviewed study participant charts to ensure compliance with federal regulations[4], observed the study facilities and conducted visits to houses involved in the study. *Id.* Kennedy Krieger was required to modify its procedure in order to comply with any observations or conclusions made by Dr. Rogan at these site inspections. (Exhibit E, Affidavit of Brophy, at ¶ 7). For example, during one particular site visit, Dr. Rogan determined that it was too noisy in the room where psychometric testing was being administered. *Id.* As a result, Dr. Rogan required Kennedy Krieger to immediately move the psychometric testing room to a quieter area in the facility. *Id.*

The TLC Study involved the 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 B at p. 13; *See also*, Exhibit E at ¶ 8; Exhibit G, at ¶ 7). Because NIEHS held the IND for the use of succimer in children with blood lead levels less than 45 micrograms per deciliter, Dr. Rogan,

[4] The FDA imposes regulations regarding how researchers should document their use of investigational new drugs.

as Project Officer of NIEHS, was actively engaged in ensuring that the Clinical Centers understood succimer's biochemical behavior. (*See* Exhibits E and G).

Funding for the TLC study was provided by NIEHS with support from the Office of Research on Minority Health of the National Institutes of Health ("ORMH, NIH"). (*See* Exhibit I at ¶ 2.2. *See also*, Walter J. Rogan, *The Treatment of Lead-exposed Children (TLC) Trial: design and recruitment for a study of the effect of oral chelation on growth and development in toddlers*, 12 PAEDIATRIC AND PERINATAL EPIDEMIOLOGY 314 (1998), attached hereto as Exhibit J).

The TLC Study was approved by Institutional Review Boards at the clinical centers, the Center for Disease Control and the NIEHS. (*See* Exhibit K, Walter J. Rogan, et al., *The Effect of Chelation Therapy with Succimer on Neuropsychological Development in Children Exposed to Lead*, 344 N. ENGL. J. MED., 1421, 1422 (May 10, 2001).

The intimate control exercised by Dr. Rogan, NIEHS's representative of the Government, over the TLC Study extended through to the study's conclusion and beyond. (Exhibit E, Affidavit of Merrill Brophy, at ¶¶ 4-8). Indeed, NIEHS prohibited Kennedy Krieger from summarizing the results of the study absent NIEHS approval. (Exhibit B, at p. 22). Dr. Rogan, not Kennedy Krieger, reported in national journals about the TLC Study. For example, he was the lead author of an article for the New England Journal of Medicine regarding the TLC Study. (*See* Exhibit K). Dr. Rogan was so involved in the implementation of the TLC Study that, after he published about the Study, he required that any correspondence or comments be sent directly to him. (*See* Exhibit J)

II. Keona and Shayonna Featherstone.

Both Keona and Shayonna Featherstone were suffering from elevated blood lead levels as a result of living in a home that contained lead prior to being referred for enrollment in the TLC Study. Keona Featherstone enrolled in the TLC Study in June 1995. Plaintiffs acknowledge that the Baltimore City Health Department's inspection of her residence at 2418 Jefferson Street in Baltimore, Maryland, in January 1995 found peeling paint on the wall and around the windows. (*See* Plaintiffs' Motion to Remand, at p. 17). Prior to enrolling in the TLC Study, Plaintiff Keona Featherstone's blood lead level was significantly elevated as a result of living in this home. Between September 14, 1994 and May 21, 1995 (the date Plaintiff Sharon Jackson executed the Consent Form for Keona's participation in the TLC Study), Keona's blood lead levels were tested three times, measuring between 20 and 23 µg/dL respectively. (*See* State of Maryland Department of Health and Mental Hygiene records, attached hereto as Exhibit L). Plaintiff Shayonna Featherstone also had elevated blood lead levels prior to being referred for consideration of the TLC Study. By Plaintiffs' own account, Shayonna Featherstone had a "history of chronic lead-exposure" for which she was being treated at the Kennedy Krieger Lead Clinic. (*See*, Plaintiffs' Motion to Remand, at p. 15-16). Shayonna Featherstone's blood lead level was measured at 32 µg/dL on July 22, 1994. (*See* Baltimore City Health Department, Childhood Lead Poisoning Prevention Program Form, attached as Exhibit M).

ARGUMENT

I. The TLC Study was an independent study unconnected with any prior research involving children exposed to lead paint.

In their Motion to Remand, Plaintiffs discuss two research studies involving lead paint

and mischaracterize the studies' "similarities" as a basis for remanding the instant case.[5] In fact, the TLC Study was conducted independently from the Repair and Maintenance Study ("R&M Study"), as well as any other lead research study. The clear differences between the studies entitle the Defendants to a fresh evaluation of federal jurisdiction in this case. More importantly, however, prior rulings by this Court regarding the R&M Study are not relevant to the analysis of the TLC Study and should not be considered.

The genesis of the TLC Study took shape separately from the R&M Study. Kennedy Krieger responded to NIEHS' Request for Proposal to participate in "a randomized, blind or double blind, placebo controlled study of succimer at lead levels below 45 µg/dL." (*See* Amendment of Solicitation/Modification of Contract, attached hereto as Exhibit D, at p. 3). The "basic concept, including the ethics for the study, was [previously] reviewed and approved at NIEHS." *Id.* Kennedy Krieger received notification of formal acceptance of their proposal from NIEHS Project Officer, Dr. Walter Rogan and Contracting Officer, Thomas Hardee. (Exhibit B, at p. 19; Exhibit F). NIEHS subsequently drafted the Contract and forwarded it to Kennedy Krieger for signature. (*See* Exhibit F, Correspondence from Thomas Hardee requesting KKI's execution of the Contract). Kennedy Krieger did not participate in the preparation of the Contract. (*See* Affidavit of Merrill Brophy, Exhibit E, at ¶ 3). The Statement of Work section of the Contract, which specifically described the criteria to be used in developing study protocol, was adopted *verbatim* from the study criteria initially set forth by NIEHS in its RFP, while the remainder of the Contract largely mirrored the RFP. (*See* Exhibit B). The proposal for the

[5] In support of their contention, Plaintiffs rely upon testimony provided by Mr. Clark H. McNutt in a prior case. However, Mr. McNutt was not intimately involved with the design or implementation of either the TLC or the R&M Studies. Mr. McNutt was simply a contractor hired to assist with the environmental component of the TLC Study and had no involvement with the clinical component of the TLC Study. As a result, Mr. McNutt's testimony should not be considered by this Court because he is not in a position to fully appreciate the differences between the two studies.

Repair and Maintenance Study, on the other hand, was submitted to the Environmental Protection Agency ("EPA), without their guidance or input. In response, the EPA published a Notice seeking alternative proposals. Presumably receiving no acceptable alternative, the EPA awarded the contract to Kennedy Krieger and worked to draft the study procedures.

Additionally, the two studies had independent research goals that served as the driving force for the study protocol. The TLC Study was a clinical study designed to determine the effectiveness of succimer on lowering blood lead levels between 20 and 44 μg/dL. In order to test this hypothesis, participants received up to three 26-day courses of succimer or a placebo and their progress was followed for three years. The Repair and Maintenance Study did not provide study participants with medication such as succimer, but rather focused on the influence of various levels of repairs made to homes with lead paint or lead paint dust. Its primary goal was to compare the short and long-term effectiveness of three distinct levels of clean up in eligible houses. Furthermore, R&M Study participants were not required to have elevated blood lead levels as a prerequisite to enrolling in the study.

These factors provide only an overview of the differences in the planning phases of the two studies. In implementation, the differences in the two studies are even starker. The TLC Study and the R&M Study involved different participants with different blood lead levels, living in different residences containing different lead dust levels.

For purposes of the pending Motion to Remand, one of the most important differences between the TLC Study and the R&M Study is that Dr. Walter Rogan, the representative of the U.S. Government, specifically directed each and every facet of the TLC Study. Dr. Rogan, the Project Officer pursuant to Kennedy Krieger's Contract with NIEHS, exercised his duties by participating in the Steering Committee meetings to develop and approve the study Protocol,

approving all technical questions relating to the implementation of the study, performing site visits to ensure KKI's compliance with the Contract, and otherwise supervising each and every aspect of the Study. (*See* Affidavits of Merrill Brophy and Dr. Davoli, Exhibits E and G, at ¶¶ 4-8).

Another important distinction between the two studies is the fact that succimer or a placebo was provided to TLC participants in efforts to reduce preexisting elevated blood lead levels. This drug was tested and determined to be successful in treating children with blood lead levels above 45 μg/dL. Therefore, succimer was hypothesized to have a positive effect on toddlers with lower blood lead concentrations who were still at risk for suffering cognitive delays. The R&M Study did not provide medication to study participants.

A close examination of the TLC and the R&M Studies reveals that they were conducted exclusive from one another and involved separate and distinct research directives. Thus, any prior rulings on the Repair and Maintenance Study are wholly irrelevant to this Court's independent consideration of the jurisdictional issues surrounding the TLC Study.

II The *Grimes* decision has no bearing on the jurisdictional issues pending before this Court.

In their Motion, the Plaintiffs place great emphasis on the Maryland Court of Appeals' decision in *Grimes v. Kennedy Krieger Institute, Inc.*, 366 Md. 29, 782 A.2d 807 (2001), contending that all statements made by the Court, which are *dicta*, are binding on the Defendants and this Court. Plaintiffs' reliance upon *Grimes* is misplaced. The *Grimes* case involved the R&M Study, which, as detailed above, is a different study, not connected in any way to the TLC Study. (*See* section I, at pp. 9-11). Unlike *Grimes*, the instant case was brought by different

plaintiffs against additional defendants, many of whom were not parties to the *Grimes* case.[6] (*See* Exhibit A, Plaintiffs' Complaint). The instant Plaintiffs are seeking new grounds of relief. *Id.* Additionally, the TLC Study in this case took place during a different time period, in separate residences, with differing lead-dust levels than those present in the *Grimes* litigation or any other case involving the R&M Study.

The Court of Appeals in *Grimes* made it abundantly clear that the analysis it undertook was "*based on [the] record*" before it, which was limited to a summary judgment record relating to the issue of whether Kennedy Krieger had a duty to the plaintiffs in those cases. *Id.* at 36 (emphasis in opinion). The Court of Appeals commented that in those cases, the record before it was "not extensive" and correctly identified the record as "sparse." *Id.* at 50 n.12, 46-47. Moreover, the issue of whether the Defendants in *Grimes* were acting as federal contractors when they implemented the R&M Study was not before the Court and therefore not considered.

On motion for reconsideration, the Court of Appeals stated:

> 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, if taken in a light most favorable to the plaintiffs and believed by a jury, would suffice to justify verdicts in favor of the plaintiffs.

Id. at 119. The Court continued, stating "[e]very 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." *Id.* Contrary to Plaintiffs' contentions, the *Grimes* Court never held that the instant Defendants were liable to the plaintiffs in that case.

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[6] Johns Hopkins Hospital, the Johns Hopkins University School of Medicine and Thomas Hendrix, M.D. were added to the *Higgins* lawsuit involving the R&M Study only after the *Grimes* decision was issued via an Amended Complaint filed on October 24, 2002. After a Notice of Removal to federal court was filed on December 13, 2002, *see Higgins v. Kennedy Krieger Institute*, Case No. 1:02-cv-04046-BEL, U.S.D.C. (D. Md)., Plaintiffs voluntarily dismissed the federal case. The grounds for Removal were not decided at the time the case was voluntarily dismissed.

The *Grimes* court extended its far-reaching statements against the IRB, which was not a party, and stated that a parent in Maryland cannot consent to scientific research involving more than minimal risk upon his or her child. The court reached this conclusion even though the issues were not briefed, neither the federal government nor the IRB were parties to the case or otherwise invited to participate as *amici curiae,* Maryland's General Assembly had not addressed the issue, and the court's interpretation was directly contrary to federal regulations governing such research. *See* 45 C.F.R. 46.101 *et seq*. As a result, the *Grimes* court's statements had a chilling effect not only upon research institutions located within Maryland investigating diseases affecting children, but also upon other similarly situated research institutions nationwide, out of fear of potential liability.

III. Removal under 28 U.S.C. § 1442(a)(1) is liberally construed in order to effectuate its purpose.

Kennedy Krieger and Dr. Davoli removed this case pursuant to 28 U.S.C. § 1442(a)(1). This Court has original jurisdiction under 28 U.S.C. § 1442(a)(1) because: (1) Kennedy Krieger and Dr. Davoli are considered "persons" within the meaning of the statute; (2) the Kennedy Krieger Defendants were acting at the direction of Dr. Rogan, an officer of the United States; (3) a causal nexus exists between Plaintiffs' claims and the Kennedy Krieger Defendants' actions under color of federal office; and (4) the Kennedy Krieger Defendants can assert a colorable federal defense, namely the federal contractor defense. *See, e.g., Mesa v. California*, 489 U.S. 121, 125-35 (1989); *Pack v. A.C. and S., Inc.*, 838 F. Supp. 1099, 1101 (D. Md. 1993), reconsideration denied, 857 F. Supp. 26 (D. Md. 1994). That section authorized removal of state court actions to federal court when the United States or any agency thereof or any officer (or any person acting under that officer) is sued. *See* 28 U.S.C. § 1442(a)(1).

The Supreme Court has held that § 1442(a)(1) is not narrow nor limited and has rejected lower court interpretations that reduce its scope. *See Willingham v. Morgan*, 395 U.S. 402, 407, 895 S. Ct. 1813, 1816 (1969). In their Motion to Remand, Plaintiffs have elected to ignore the broad right to removal under § 1442(a)(1). In *Durham v. Lockheed Martin Corp.*, 445 F.3d 1247 (9th Cir. 2006), the Ninth Circuit observed that since 1934, "the Supreme Court has mandated a generous interpretation of the federal officer removal statute." *Id.* at 1252. The court further noted:

> [t]he Supreme Court "has held that the right of removal is absolute for conduct performed under color of federal office, and has insisted that the policy favoring removal 'should not be frustrated by a narrow grudging interpretation of § 1442(a)(1).

Id. (internal citation omitted).

Consistent with its broad purpose, federal courts have interpreted the "person acting under" provision liberally. *See Gurda Farms Inc. v. Monroe County Legal Assistance Corp.*, 358 F. Supp. 841, 844 (S.D.N.Y. 1973) ("even a cursory survey of the application of [section 1442(a)] reveals it has been construed broadly, and its "persons acting under" provision particularly so); *see also In re "Agent Orange" Product Liability Litigation v. Dow Chemical Company*, 304 F. Supp.2d 442, 447 (E.D.N.Y. 2004); and *Winters v. Diamond Shamrock Chemical Co.*, 1195 F. Supp. 1195, 1198 (E.D. Tex. 1995) (a corporation may be considered a "person" within the meaning of § 1442(a)(1) if it implements a federal policy or directive). In this regard, entities and private persons like Kennedy Krieger and Dr. Davoli are treated as persons acting under the direction of a federal officer. *See Pack v. ACandS, Inc.*, 838 F. Supp. 1099 (D. Md. 1993).

Plaintiffs seem to argue that remand is necessary because Maryland's interest to make and enforce its own laws under the Constitution must triumph over Defendants' right to litigate a

matter that involves the enforcement of federal contracts and the interpretation of federal statutes, in a federal forum. In support, Plaintiffs rely upon statements in *Younger v. Harris*, 401 U.S. 37, 43, 97 S. Ct. 746, 750 (1971) and *Matter of Marriage of Smith*, 549 F. Supp. 761, 766 (W.D. Tex. 1982). In the case at bar, the analysis this Court must conduct under § 1442(a)(1) does not balance Maryland's rights against the plain language of the § 1442(a)(1) or the case law interpreting it. *See, e.g., Pack*, 838 F. Supp. at 1101. Rather, the proper analysis determines whether a person is acting under the color of federal office. *Id.* If so, removal is proper. Neither of these cases is determinative or applicable to the Court's analysis in this matter.

In *Younger*, the Court reviewed the district court's issuance of an injunction precluding an ongoing state prosecution for violation of California's Syndicalism Act. The Supreme Court reversed, holding that federal courts will not enjoin pending state criminal prosecutions absent a showing of irreparable loss, i.e., where there is a threat to a plaintiff's federally protected rights that cannot be eliminated by his defense against a single prosecution. In this context, analyzing 28 U.S.C. § 2283, Justice Black stated that Congress, with rare exception, does not interfere with a state's ability to try a case. *Harris*, 401 U.S. at 43, 97 S. Ct. at 750. *Younger*, is not on point in this case because 28 U.S.C. § 2283 is not in any way implicated, nor is there any issue concerning a state's right to prosecute a case.

Similarly, *Smith* is also irrelevant and should not be considered by this Court. The issue in *Smith* was whether, under 28 U.S.C. §§ 1441(b) and 1442(a), an ex-husband's failure to pay a portion of his military retirement to his ex-wife was required by a divorce decree. The ex-husband sought removal, arguing that the case implicated the laws of the United States in that the retirement bonus was authorized under the military pay statutes, and that these statutes also exempted the ex-husband from paying any portion as part of the divorce. The court remanded

the matter finding that there was no showing that federal law was an essential component of the proceeding and because the proceeding was not a civil action or criminal prosecution.

The court also stated that divorce is generally an issue left to the states and, therefore, the entire matter should remain in state court. In that context, the court stated that removal should be considered with the highest regard to the "right of the states to make and enforce their own laws in fields belonging to them under the Constitution." *Smith*, 549 F. Supp. at 766. Finally, the court stated that there was no merit to the claim for remand. Unlike *Smith*, this case is a civil, non-domestic action, where the Defendants have made their basis for seeking removal abundantly clear. Unlike the defendants in *Smith*, the instant Defendants have carefully documented the intimate level of control that Dr. Rogan of NIEHS exercised over the TLC Study, the federal regulations each Defendant was required to adhere to in implementing the study, as well as a colorable federal defense. Removal is proper in this case and for the reasons set forth in more detail below, this matter should proceed in this Court.

IV. The Kennedy Krieger Defendants have satisfied the requirements for removal under section 1442(a)(1).

A. KKI and Dr. Davoli acted at the direction of Dr. Walter Rogan, a federal officer of NIEHS and a representative of the federal government.

Plaintiffs contend that Kennedy Krieger and Dr. Davoli have not demonstrated that they were acting under the control of a federal officer. (*See* Plaintiffs' Motion to Remand, at pp. 30-31.) Defendants respectfully disagree.

The words "acting under" are defined broadly and even the Supreme Court has stated that § 1442(a)(1) must be "liberally construed." *See Colorado v. Symes*, 286 U.S. 510, 517, 52 S. Ct. 635 (1932); *Arizona v. Manypenny*, 451 U.S. 232, 242, 101 S. Ct. 1657 (1981). Indeed, a contract with the federal government agency may show the degree of direction by a federal

officer necessary under § 1442(a)(1). *See Watson v. Phillip Morris Co., Inc.*, 420 F.3d 852, 863 (8th Cir. 2005) (*rev'd on other grounds*). Contrary to Plaintiffs' unsupported contentions, private entities have successfully removed cases pursuant to § 1442(a)(1) when the actions at issue were undertaken pursuant to a federal contract and under the direction of a federal officer. *See Pack*, 838 F. Supp. at 1103 (holding that a government construction contractor was entitled to federal officer removal where the government maintained "control over the construction, design, and testing of the turbines"). *See also*, *Fung v. Abex Corp.*, 816 F. Supp. 569, 572-73 (N.D. Cal. 1992) (finding that a government contractor was entitled to federal officer removal where the government "monitored the [defendant's] performance at all times, and required the defendant to construct and repair the vessels in accordance with applicable and approved specifications incorporated into the contracts").

Plaintiffs repeatedly divert the Court's attention to a single contract clause, extracted from the Statement of Work, in a misguided attempt to suggest that the federal officer removal statute requires that the defendant act as an agent of the government. (*See* Plaintiffs' Motion to Remand at pp. 3, 8 and 30). Defendants acknowledge that they were not agents of NIEHS during the course of the TLC Study. The Contract clearly states that NIEHS's Contracting Officer, Thomas Hardee, was NIEHS' only agent with respect to the TLC Study. (Exhibit B, at p. 22). Furthermore, Project Officer, Dr. Rogan, and Alternate Project Officer, Beth Ragen, were the only representatives of the U.S. government with respect to the TLC Study. *Id.* at p. 21.

However, **28 U.S.C. § 1442(a)(1) does not require that Kennedy Krieger act as an agent of a federal agency**. To the contrary, Kennedy Krieger must simply demonstrate that they acted pursuant to the direct control of a federal officer. In paragraphs 5-39 of the Notice of Removal, Defendants expressly state they were acting under the direction of a federal officer of

NIEHS. Defendants' Notice demonstrates the detailed level of control exhibited by Dr. Walter Rogan, Project Officer of the TLC Study, NIEHS employee and representative of the U.S. Government. (*See* Exhibit A, ¶¶ 5, 13, 15, 16, 19 and 30). Furthermore, the affidavits of Dr. Cecilia Davoli and Merrill Brophy, attached in support to the Notice of Removal, specifically state that Dr. Rogan directed Kennedy Krieger's involvement throughout each and every stage of the TLC Study. (Exhibits E and G, at ¶ 4).

The TLC Study was not a study in which KKI's conduct occurred under the "general auspices" of a federal officer, as Plaintiffs contend. To the contrary, KKI's contract with NIEHS was monitored and evaluated by Dr. Rogan and administered by NIEHS contract officer Thomas Hardee. (*See* Exhibit F). Pursuant to this contract, KKI was subject to mandatory requirements imposed by NIEHS and implemented by Dr. Rogan as the Project Officer. For example, Kennedy Krieger was required to submit technical reports and racial/ethnic reports to NIEHS on a regular basis. (Exhibit B at p. 15). Kennedy Krieger was also required to submit semi-annual reports during the first year of the Study, describing the Study's progress in planning, recruitment, community activity and screening, while placing particular emphasis on any material not covered in the Steering Committee Meetings facilitated by Dr. Rogan. *Id.* For each subsequent year, Kennedy Krieger submitted quarterly reports as required by the Contract, detailing the number of families contacted and screened for the Study. *Id.* Such strict requirements allowed NIEHS to maintain direct and detailed control over the TLC Study.

In their Motion for Remand, Plaintiffs rely on *Good v. Armstrong*, 914 F. Supp. 1125 (E.D. Pa. 1996), for the proposition that a defendant must demonstrate that it acted under a specific officer in order to remove a case under 28 U.S.C. § 1442(a)(1). (Plaintiffs' Motion to Remand, at pp. 31-32; *Good*, 914 F. Supp. at 1127). Defendants have easily met that test.

Furthermore, *Good* is not only easily distinguishable, but it is also non-binding upon this Court. As such, it does not preclude removal in this case.

Although the court in *Good* ultimately granted the plaintiff's motion for remand, the court placed great emphasis on the defendant's overall inability to establish a causal nexus between the allegations in the plaintiff's complaint and the defendant's basis for removal. *Id.* at 1130. The plaintiff's complaint sought relief for alleged asbestos exposure. However, none of the documentation offered to establish the U.S. Navy's involvement in the defendant's Notice of Removal mentioned asbestos. *Id.* Furthermore, the language of the Notice of Removal and supporting affidavit only mentioned U.S. Navy involvement and did not mention any federal officer by name or title. *Id.*

The instant Defendants have met their burden even under *Good's* restrictive interpretation of the requirements for removal. Unlike the defendants in *Good*, the instant Defendants have documented examples of Dr. Walter Rogan's detailed level of control over the TLC Study. Dr. Rogan, as Project Officer and representative of the federal government, was responsible for monitoring KKI's technical progress, interpreting the Statement of Work provided in the Contract and performing inspections and evaluations as required by the Contract. (Exhibit B, at Article G.2, p. 21). Kennedy Krieger was required to submit regular reports to Dr. Rogan in addition to submitting to regular site visits. *Id.* at 15, 21. Furthermore, Kennedy Krieger needed Dr. Rogan's approval to implement any facet of the TLC Study as raised in the Steering Committee Meetings. (Exhibits E and G, at ¶ 5). Similarly, KKI needed the permission and approval of Mr. Thomas Hardee, Contracting Officer of NIEHS and sole agent of NIEHS in the TLC Study, for any proposed change to Study spending. *Id.* at p. 22. (*See also*, Exhibit F). Thus, a causal connection exists in this case between the allegations contained in the Plaintiffs'

Complaint and the actions Kennedy Krieger undertook pursuant to Dr. Rogan's direction and the Contract with NIEHS. (*See*, section IV(B) at pages 22-25 *infra)*.

There are no Supreme Court or Fourth Circuit cases following *Good's* strict requirement that the defendant allege direct control by a specific "federal officer" to establish removal jurisdiction under 28 U.S.C. § 1442(a)(1). To the contrary, the majority of courts that have considered the federal officer removal statute, in cases with facts nearly identical to *Good,* interpret the language more liberally. *See Crocker v. Borden, Inc.*, 852 F. Supp. 1322, 1326 (E.D. La. 1994) (finding that the defendant constructed the marine turbines at issue under the direction of the U.S. Navy); *Pack*, 838 F. Supp. at 1103 (holding that defendant's showing of strong government intervention satisfied the direct control requirement); *Mitchell v. AC&S, Inc.*, 2004 WL 3831228, *3 (E.D.Va. 2004) (stating that "[i]t is wholly apparent that the defendant acted under the direction of the U.S. Navy and its individual [unnamed] officers in producing the turbines at issue"); and *Carter v. AC&S, Inc.*, 2002 31682352, *4-5 (E.D. Tex. 2002). *See also* Kristina L. Garcia, *Comments: The Boyle Festers: How Lax Causal Nexus Requirements and the Federal Contractor Defense are Leading to a Disruption of Comity under the Federal Officer Removal Statute*, 46 EMORY L.J. 1629, 1645 (1997) (noting that refusal to accept direction by a branch of the armed services as the direction of a "federal officer" is to "deny that the government is composed of entities as well as people"). Moreover, *Good*'s strict interpretation of the statute is at odds with the Supreme Court's interpretation that the federal officer provision is to be construed liberally in order to effectuate its purpose.

Plaintiffs' attempts to distinguish *Pack* as well as *Yeroshefsky v. Unisys Corp.*, 962 F. Supp. 710 (D. Md. 1997), are unconvincing. Plaintiffs argue that these cases are distinguishable from this case because they involve manufacturing products to government standards. However,

the federal contractor defense is not limited to contracts involving manufactured products. To the contrary, the Court in both *Pack* and *Yeroshefsky* held that removal was appropriate under § 1442(a)(1), because the defendants were acting under the direction of a federal officer. 838 F. Supp. at 1103; 962 F. Supp. at 721. Indeed, this defense is frequently asserted in cases involving service contracts with federal agencies. *See Bowers v. J&M Discount Towing, LLC*, 472 F. Supp. 1248 (D.N.M. 2006) (auto towing company that had a contract with Internal Revenue Service had a colorable federal defense); *see also Bell Helicopter/Textron*, 328 F.3d 1329-1334 (11th Cir. 2003) (maintenance company who entered into a service contract with United States Army entitled to federal contractor defense); and *Greene v. Citicorp, Inc.*, 2000 WL 647190**1-2 215 F.3d 1336 (10th Cir. 2000)(unpublished opinion) (court affirmed removal by chemical company defendant whose conduct at issue was directed by an EPA official).

Lastly, Plaintiffs contend that KKI and Dr. Davoli were compensated researchers and therefore were not acting under the control of a federal officer. (*See* Plaintiffs' Motion to Remand, at p. 11). Again, this contention is without merit and has no bearing on whether removal is appropriate in this case. As acknowledged by the Plaintiffs, Defendants' salaries were paid by NIEHS itself, who compensated KKI for the work performed pursuant to the Contract between the parties. *Id.*; (Exhibit B, at p. 5).

In sum, NIEHS's appointment of Dr. Rogan as Project Officer allowed the agency to maintain detailed control over implementation of each and every aspect of the Study. Therefore, the Defendants have satisfied the first requirement for removal under 28 U.S.C. § 1442(a)(1).

B. A causal nexus is easily established between the actions the Kennedy Krieger Defendants were required to perform pursuant to the Contract with NIEHS and the Plaintiffs' claims.

Plaintiffs next argue that there is no causal nexus between the actions the Defendants were required to perform pursuant to the Contract with NIEHS and the allegations made in their Complaint. However, this argument must fail in light of the extensive causal nexus analysis and supporting documentation previously set forth in the Defendants' Notice of Removal. (*See* Exhibit A, Notice, at ¶ 30; Exhibit G, Affidavit of Cecilia Davoli, M.D).

In order to establish the causal nexus requirement, the Defendants must merely show "that there is a causal connection between the [P]laintiffs' claims and acts [they] performed under color of federal office." *See Pack,* 838 F. Supp. at 1101 (*citing Mesa v. California*, 489 U.S. 121, 124-25, 129-31, 134-35 (1989)). A direct causal relationship exists between the Plaintiffs' claims in the instant action and the Kennedy Krieger Defendants' actions under color of federal office. Each claim challenges the Defendants' alleged acts or omissions in conducting the TLC Study when, in fact, the study was designed by NIEHS and directed by Dr. Rogan.

Plaintiffs first contend in Count One of their Complaint that KKI and Dr. Davoli violated the Baltimore City Housing Code "[b]y controlling the decisions about the scope of repairs, the manner and means of repairs and the level of interventions to be performed . . . ." (Exhibit O, Plaintiffs' Complaint, at ¶ 37). To the contrary, the Kennedy Krieger Defendants arranged for cleaning of the participants' houses in accordance with the strict requirements set forth in the Contract with NIEHS and the Trial Protocol approved by Dr. Rogan. The Contract with NIEHS required the KKI Defendants to "evaluate [participants'] homes . . . and provide clean-up according to trial protocol." (Exhibit D, at pp. 16, 18).

Plaintiffs allege that since the cleaning of participants' homes was funded by the Baltimore City Department of Housing and Community Development, it was not undertaken pursuant to federal officer direction or control. This is incorrect and misleading. Kennedy Krieger's Contract with NIEHS specifically required lead dust clean-up. Pursuant to an unfunded mandate, NIEHS required Kennedy Krieger to "evaluate and clean up the children's homes and other sites as necessary according to trial protocol." (Exhibit B, at p. 19). The Contract further required Kennedy Krieger to "identify the potential lead sources in the child's environment and decrease the exposure in those who need it." *Id.* at 18. The source of clean-up funding, however, is wholly irrelevant and does not defeat causal connection in this case.

Pursuant to the TLC Trial Protocol, NIEHS required Kennedy Krieger to "provide interim control measures aimed at reducing exposure to lead in deteriorating paint and lead dust through in-place management of sources." *Id.* at p. 17. To accomplish this task, the Trial Protocol specifically addressed the following subjects with respect to cleaning participants' homes:

1) Environmental Assessment and Monitoring, including Initial Home Assessment and Collection of Environmental Lead Monitoring Data.
2) Lead Dust Suppression Procedures.
3) Paint Stabilization.
4) Follow-up.
5) Quality Control Procedures.

(Exhibit I, at p. 18-22). Section 6.3 provided in minute detail, the precise method required to clean the participant residences. For example, the TLC Protocol required that the cleaning crew consist of two or three individuals, trained in the EPA-Approved Lead Abatement Course developed specifically for the TLC Trial. *Id.* at p. 19, 21. It further required that the carpet be vacuumed at a rate of "one minute per square yard" and that "[a]ll surfaces . . . be vacuumed to remove loose paint." *Id.* Section 6.4 of the Trial Protocol affirmatively required "[a]ll loose

chips must be vacuumed and the surrounding surfaces washed" in a continued effort to maintain stabilization. *Id.* at 20. Families of participants were to receive educational materials on lead poisoning and cleaning materials, such as a bucket, mop, sponges and detergent. *Id.* at Section 6.5.

The Manual of Operations for the TLC Study went into even greater detail, specifying the exact method for conducting home inspections and clean-up. Beginning with an instruction to "knock on door or ring doorbell and identify yourself as a representative of the study," the Manual of Operations left no aspect of the cleaning procedure open to interpretation. (*See* Exhibit N, Manual of Operations, Home Visit 1, at p. 2). Criteria for completing the home inspection and cleaning the residence were equally detailed. *Id.* at pp. 4-8. "Each family whose child was initially eligible and whose housing was cleanable to TLC standards was offered professional clean-up." (*See The Treatment of Lead-exposed Children (TLC) Trial: design and recruitment for a study of the effect of oral chelation on growth and development in toddlers*, at p. 318., attached hereto as Exhibit J) (emphasis added).

In fact, the following excerpt from Dr. Rogan's New England Journal of Medicine article acknowledges that the TLC Study required cleaning of study participants' homes:

> We vacuumed the residences of the enrolled children (using a high-efficiency particle-arrester vacuum cleaner), mopped floors and wiped walls and surfaces with a trisodium phosphate solution, made minor repairs, and performed paint stabilization (by scraping loose paint and doing minor carpentry) at or about the time of randomization.

(Exhibit K, at p. 1422).

Regardless of the source of funding for the environmental component of the TLC Study, the Contract with NIEHS required that the residences be cleaned in accordance with Trial Protocol. The funding of the interventions is irrelevant. Kennedy Krieger could not implement

the TLC Study in accordance with the Contract without arranging for lead clean-up in study participants' homes.

Plaintiffs also allege that the KKI Defendants negligently made misrepresentations to the Plaintiffs and their family regarding the condition of the premises and the risk of harm to those who elected to participate in the TLC Study, and otherwise failed to obtain adequate informed consent. (Exhibit O, Plaintiffs' Complaint at ¶¶ 37, 43 and 62). Again, each of these allegations challenge Kennedy Krieger and Dr. Davoli's actions made pursuant to the direction and control of Dr. Rogan. The Contract required that the final draft of the Consent Form comply with applicable federal regulations and be approved by NIEHS's IRB. (Amendment of Soliciation/Modication of Contract, at p. 4, attached hereto as Exhibit D). In fact, the NIEHS IRB initially rejected the TLC Consent Form because it felt that the reading comprehension level was too high. (Exhibits E and G, at ¶ 10). In response, Kennedy Krieger revised the Consent Form, secured local IRB approval, and resubmitted the Form to NIEHS for approval. *Id.* Countless drafts were presented to NIEHS and revised to incorporate the changes deemed necessary by NIEHS before the Consent Form was presented to participant families. The information conveyed to the Study participants and their families was therefore governed by the Contract with NIEHS. *Id.* Similarly, the method and extent to which Kennedy Krieger (1) assessed the presence of lead-based paint hazards; (2) reported findings to the study participants; and (3) monitored the study participants' blood lead levels were determined by the trial Protocol, approved by Dr. Rogan, and implemented pursuant to the Contract with NIEHS.

Plaintiffs further contend that the KKI Defendants breached a fiduciary duty to the Study participants. (Exhibit O, Plaintiffs' Complaint, at ¶ 85). By the Plaintiffs' own account, however, the duty allegedly owed to the Study participants was created "by virtue of the

agreements, representations, and the position of the parties . . . ." *Id.* at ¶ 84. A direct causal relationship exists between Plaintiffs' claim and Kennedy Krieger's actions under the direction of Dr. Rogan. Final authority over each and every aspect of the TLC Study rested with Dr. Rogan. (*See* Affidavits of Merrill Brophy and Dr. Davoli, Exhibits E and G, at ¶ 4). Kennedy Krieger simply did not have the authority to deviate from the Contract or trial Protocol because NIEHS retained the authority to terminate the Contracts for such deviations. (Exhibit B, at p.19).

Plaintiffs' contention that their claims are based on the Kennedy Krieger Defendants' alleged failure to comply with the TLC Protocol is simply without merit. The only count of the Complaint alleging failure to properly review and oversee the TLC study is not brought against Kennedy Krieger or Dr. Davoli but rather JHU, the Institutional Review Board and its members. (*See* Plaintiffs' Complaint, Exhibit O, at ¶¶ 50-59). Because Plaintiffs' allegations of wrongdoing stem from the Defendants' actions taken pursuant to their Contract with NIEHS, Kennedy Krieger and Dr. Davoli have established the direct causal nexus requirement for removal jurisdiction under 28 U.S.C. § 1442(a)(1).

Even if this Court were persuaded by Plaintiffs' contention that certain allegations do not stem from the contract with NIEHS, removal of the instant action is still appropriate through this Court's exercise of supplemental jurisdiction. 28 U.S.C. § 1441(c); *see Grable & Sons Metal Prods., Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 312-14, 125 S. Ct. 2363, 2366-67 (2005) (recognizing that federal courts have original jurisdiction over state law claims arising under federal law when (1) the plaintiff's claim implicates a significant and disputed federal issue, and (2) exercising jurisdiction will not upset the balance between federal and state judicial responsibilities); 28 U.S.C. § 1367(a); *see also, Rosmer v. Pfizer, Inc.*, 263 F.3d 110 (4th Cir. 2001) (finding that § 1367(a) "is broadly phrased to provide for supplemental jurisdiction

over claims appended to any civil action over which the court has original jurisdiction" (*quoting Shanaghan v. Cahill*, 58 F.3d 106, 109 (4th Cir. 1995)).

C. KKI and Dr. Davoli have asserted a colorable federal defense.

Plaintiffs contend that Kennedy Krieger and Dr. Davoli have failed to demonstrate the applicability of the federal contractor defense to the instant matter. Defendants respectfully disagree and refer the Court to their Notice of Removal. (*See* Notice, Exhibit A, at ¶¶ 33-39).

Boyle v. United Technologies Corp., 487 U.S. 500, 108 S. Ct. 2510 (1988), sets forth the elements required to satisfy the government contractor defense: (1) the United States approved reasonably precise specifications; (2) the contractor's performance conformed to those specifications; and (3) the contractor warned the United States about the dangers associated with the contract that were known to the contractor but not to the United States. *Id.* at 512, 108 S. Ct. at 2518.

Applying the elements required to satisfy the government contractor defense discussed in *Boyle*, the Kennedy Krieger Defendants clearly satisfy the elements of this defense. The first element of the *Boyle* test is satisfied because the United States, through NIEHS, approved precise specifications for developing, implementing and reporting on the TLC Study. The RFP and Contract clearly demonstrate that NIEHS provided KKI with reasonably precise specifications regarding the implementation of the TLC Study. Kennedy Krieger fully complied with the federal government's detailed specifications, in satisfaction of the second prong of the *Boyle* test. As required by the Contract, Kennedy Krieger followed the NIEHS-approved Study Protocol in its implementation of the TLC Study. (Exhibit B, at p. 19). NIEHS was able to ensure KKI's compliance with its requirements through Project Officer, Dr. Rogan. *Id.* at p. 21, 26. (*See also*, Exhibit E, at ¶ 13 and Exhibit G, at ¶ 13). Plaintiffs are unable to offer any evidence suggesting

otherwise. Finally, the third element of the *Boyle* test is satisfied because Kennedy Krieger did not withhold from NIEHS any information regarding the potential dangers associated with the TLC Study. To the contrary, NIEHS remained intimately involved in all aspects of the Study by placing their Project Officer and Alternate Project Officer on every subcommittee and requesting regular reports from KKI on the Study's progress. Through this process, NIEHS remained fully aware of all risks and benefits associated with the Study. (Exhibit B, at p. 15; Exhibit I at p. 20-22).

Having satisfied the requirements set forth in *Boyle*, the Kennedy Krieger Defendants respectfully submit that they are entitled to the federal contractor defense.

V. Johns Hopkins and the IRB Defendants are also entitled to removal.

The United States Supreme Court has held for nearly one hundred years that state law claims arising under federal law confer original jurisdiction in federal court (1) when the plaintiff's claim implicates a significant and disputed federal issue, and (2) exercising jurisdiction will not upset the balance between federal and state judicial responsibilities. *See Grable & Sons Metal Prods., Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 312-14, 125 S. Ct. 2363, 2366-67 (2005).

In *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180, 41 S. Ct. 243 (1921), the Court held:

> The general rule is that where it appears from the bill or statement of the plaintiff that the right to relief depends upon the construction or application of the Constitution or laws of the United States, and that such federal claim is not merely colorable, and rests upon a reasonable foundation, the District Court has jurisdiction . . . .

Id. at 199, 41 S. Ct. at 244-45. This doctrine "captures the commonsense notion that a federal court ought to hear claims recognized under state law that nonetheless turn on substantial

questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable*, 545 U.S. at 312, 125 S. Ct. at 2367 (citation omitted).

Justice Brennan has observed that federal courts specialize in the interpretation and application of federal laws because they are often presented with disputes involving federal laws. *See Merrell Dow Pharmaceuticals, Inc. v. Thompson, et al.*, 478 U.S. 804, 826-27, 106 S. Ct. 3229, 3241-42 (1986) (Brennan, J., dissenting). State courts, on the other hand, are not as likely to possess this expertise because they do not encounter federal questions as frequently. *Id.* Justice Brennan further explained:

> Congress passes laws in order to shape behavior; a federal law expresses Congress' determination that there is a federal interest in having individuals or other entities conform their action to a particular norm established by that law. Because all laws are imprecise to some degree, disputes inevitably arise over what specifically Congress intended to require or permit. It is the duty of court to interpret these laws and apply them in such a way that the congressional purpose is realized. As noted above, Congress granted the district courts power to hear cases "arising under" federal law in order to enhance the likelihood that federal laws would be interpreted more correctly and applied more uniformly. In other words, Congress determined that the availability of a federal forum to adjudicate cases involving federal questions would make it more likely that federal laws would shape behavior in the way that Congress intended.
>
> By making federal laws an essential element of a state-law claim, the State places the federal law into a context where it will operate to shape behavior: the threat of liability will force individuals to conform their conduct to interpretations of the federal law made by courts adjudicating the state law claim. It will not matter to an individual found liable whether the officer who arrives at his door to execute judgment is wearing a state or a federal uniform; all he cares about is the fact that a sanction is being imposed – and may be imposed again in the future – because he failed to conform to the federal law. Consequently, the possibility that the federal law will be incorrectly interpreted in the context of adjudicating the state-law claim implicates the concerns that led Congress to grant the district courts power to adjudicate cases involving federal questions in precisely the same way as if it was federal law that "created" the cause of actions.

Id. at 827-28, 106 S. Ct. at 3242.

According to a Guidebook published by the Department of Health and Human Services ("DHHS"), the regulations cited in Plaintiffs' Complaint were promulgated by sixteen federal agencies that conduct, support, or regulate human research. (*See* Ex. P, Institutional Review Guidebook, www.hhs.gov/ohrp/irb/irb_introduction.htm). The DHHS Guidebook chronicles the detailed and deliberative process the federal government employed in arriving at the regulations at issue here. *Id.* The Introduction states:

> The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. Those "basic" regulations became final on January 16, 1981, and were revised effective March 4, 1983, and June 18, 1991. The June 18, 1991, revision involved the adoption of the Federal Policy for the Protection of Human Subjects. **The Federal Policy (or "Common Rule," as it is sometimes called) was promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research**; the FDA also adopted certain of its provisions. **As is implied by its title, the Federal Policy is designed to make uniform the human subjects protection system in all relevant federal agencies and departments.** The Federal Policy is discussed in depth in Chapter 2, Section A(i).

Id. (emphasis added). Moreover, because the TLC Study involved the use of a drug, statutes and regulations administered by the Food and Drug Administration are also at issue in this case. *See, e.g.*, 21 C.F.R. § 56.101 *et seq.* (applicable to IRBs). Consequently, there are regulations from more than one federal agency that are at issue here.

A substantial federal interest exists in the uniformity of interpretation and application of federal laws governing scientific research involving children. *Grable*, 54 U.S. at 312, 125 S. Ct. 2367. The Plaintiffs' claims in this case arise under these federal laws. Indeed, in the Notice of Removal, Defendants demonstrated that the duty elements of most of the Plaintiffs' claims necessarily depend upon federal law. A defendant need only show that one of the elements of a single claim presents a substantial federal issue in order for this Court to exercise federal removal jurisdiction over the entire case. *See* 28 U.S.C. § 1441(c); *see also Franchise Tax Bd. of*

Cal. v. Laborers Vacation Trust, 463 U.S. 1, 13, 103 S. Ct. 2841, 2848 (1983). Moreover, the TLC Study was also implemented in Philadelphia, Cincinnati and Newark. Decisions regarding the TLC Study in Baltimore may therefore have an effect on the TLC Studies conducted in these other areas. If the instant case is remanded, one state's ruling may easily be at odds with that of another jurisdiction.

It is important to note that a search of all reported federal and state cases nationwide revealed only two published opinions where an institutional review board has been named as a defendant. Not surprisingly, these cases were litigated in federal court. *See Mason v. Institutional Review Bd. For Human Research*, 1992 U.S. App. LEXIS 441 (4th Cir. 1992)(unpublished); and *Halikas v. University of Minnesota*, 856 F.Supp. 1331 (S.D. Minn. 1994). Presumably these cases were tried in federal court because the actions of IRBs are interpreted by federal statutes and the federal government has a significant interest in interpreting these statutes in a uniform fashion. Regardless, all relevant precedent addressing the issues raised by the Plaintiffs in this case support the IRB Defendants' position that they are entitled to removal in this case.

CONCLUSION

For the reasons set forth herein, Kennedy Krieger Institute, Inc., Cecilia Davoli, M.D., The Johns Hopkins University, The Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D., David R. Cornblath, M.D., Paul Lietman, M.D. and Hayden G. Braine, M.D. respectfully request that this Court exercise original jurisdiction over this case and that the Plaintiffs' Motion to Remand be denied.

Respectfully submitted,

/s/
Barry C. Goldstein
(Federal Bar No. 34796)
John T. Sly
(Federal Bar No. 26608)
Nicole A. McCarus
(Federal Bar No. 27971)
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
410-821-3511

Attorneys for Defendants Kennedy Krieger Institute and Cecilia Davoli, M.D.

/s/
Natalie C. Magdeburger
(Bar No. 7722)
Raymond L. Marshall
(Bar No. 25162)
Whiteford Taylor Preston LLP
210 W. Pennsylvania Avenue
Towson, MD 21204
(410) 832-2000

Attorneys for Defendants The Johns Hopkins University, The Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D., David R. Cornblath, M.D., Paul Lietman, M.D. and Hayden G. Braine, M.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 20th day of September, 2007, a copy of the foregoing Defendants' Opposition to Plaintiffs' Motion to Remand, Memorandum of Law and Proposed Order were mailed first-class, postage prepaid, to:

Evan K. Thalenberg, Esquire
Evan K. Thalenberg, P.A.
11 E. Chase Street, Suite 7F
Baltimore, Maryland 21202

Attorney for Plaintiffs

Michael D. Vogelstein, Esquire
201 N. Charles Street
Suite 801
Baltimore, Maryland 21201

Attorney for Marc Medin, Nancy Medin and Shenan Management, Inc., and N.A.C.I. Corporation

Via U.S. Mail
Timothy P. Knepp, Esquire
P. O. Box 21221
Baltimore, Maryland 21221

Attorney for Pythagoras Passas and Anne L. Passas

James S. Aist, Esquire
Anderson, Coe & King, LLP
201 North Charles Street, Suite 2000
Baltimore, Maryland 21201

Attorney for Defendants Pythagoras Passas and Anne L. Passas

Ralph Erskine Wilson, III, Esquire
Rollins, Smalkin, Richards and Mackie, LLC
401 North Charles Street
Baltimore, Maryland 21201

Attorney for Pythagoras Passas and Anne L. Passas

Via U.S. Mail
Helen Heath, Individually and
t/a Lady "H" Enterprises
6732 Wilmont Drive
Gwynne Oak, Maryland 21207

/s/
Barry C. Goldstein

INDEX OF EXHIBITS

Exhibit A	Notice of Removal
Exhibit B	Contract between NIEHS and Kennedy Krieger Institute, Inc.
Exhibit C	NIEHS's Request for Proposals
Exhibit D	Amendment of Solicitation/Modification of Contract
Exhibit E	Affidavit of Merrill Brophy in Support of Notice of Removal
Exhibit F	June 25, 1993 letter from NIEHS to KKI regarding execution of Contract
Exhibit G	Affidavit of Cecilia Davoli, M.D. in Support of Notice of Removal
Exhibit H	June 26, 1995 letter from Kennedy Krieger Institute, Inc. to NIEHS seeking approval for funds
Exhibit I	TLC Trial Protocol
Exhibit J	Walter J. Rogan, *The Treatment of Lead-exposed Children (TLC) Trial: design and recruitment for a study of the effect of oral chelation on growth and development in toddlers*, 12 PAEDIATRIC AND PERINATAL EPIDEMIOLOGY 314 (1998)
Exhibit K	Walter J. Rogan, et al., *The Effect of Chelation Therapy with Succimer on Neuropsychological Development in Children Exposed to Lead*, 344 N. ENGL. J. 1421 (May 10, 2001).
Exhibit L	State of Maryland Department of Health and Mental Hygiene records
Exhibit M	Baltimore City Health Department, Childhood Lead Poisoning Prevention Program Form
Exhibit N	TLC Manual of Operations
Exhibit O	Plaintiffs' Complaint
Exhibit P	Department of Health and Human Services Institutional Review Guidebook