

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

SHAWNTA DESHIELDS, et al.

Plaintiffs

v.

KENNEDY KRIEGER INSTITUTE, INC.

Defendant

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CIVIL ACTION NO.: L 02 CV 3694

**PLAINTIFF'S RESPONSE TO DEFENDANT
KENNEDY KRIEGER INSTITUTE, INC.'S MOTION FOR PROTECTIVE ORDER**

Comes now the Plaintiff, Shawnta DeShields, by her mother and next friend Phyllis Mitchell, and her attorney Evan K. Thalenberg, and Evan K. Thalenberg P.A. and in response to Defendant Kennedy Krieger Institute, Inc.'s (hereinafter "Kennedy ") for a Protective Order, respectfully submits:

1. The instant matter is a lead-paint poisoning claim wherein it is alleged that the Plaintiff, Shawnta DeShields, suffered severe and permanent injuries as the result of exposure to and ingestion of lead-based paint and lead-based paint dust at 910 N. Freemont Avenue, Baltimore, Maryland.

2. The Plaintiff has filed suit against Kennedy Krieger for negligence in regard to the Plaintiff's participation in a research study misleadingly entitled 'Treatment of Lead Exposed Children' (TLC). It is alleged that, in the course of that study, otherwise healthy children with documented elevated blood lead levels (including the Plaintiff) were referred to Kennedy Krieger for treatment, were negligently enrolled into the study and enticed and lulled into living in and/or

remaining in lead infested houses for the purpose of perpetuating research for the enrichment and increased prestige of Kennedy Krieger.

3. That on April 2, 2003 this Honorable Court held a hearing during which the scope of documents to be produced and the rationale behind the production of these documents was specifically addressed. This Honorable Court explicitly contemplated the placement of the produced documents in a “document repository” for use in regard to the other cases. (Exhibit 1) Therefore, the Defendant’s blanket assertion of privilege, aside from failing to comport with Local Federal Rule 13 requiring “particular designations of confidentiality”, is in direct defiance of the intent of this Honorable Court.

4. Any argument by Kennedy Krieger that the information requested is confidential is vitiated because Kennedy Krieger has disclaimed obligations to study participants through the waiver of confidentiality in consent forms signed with the study participants, and the Defendants own admissions that the study is a non-therapeutic study.

5. The burden is on the Defendant in seeking confidentiality to justify it and the Defendant has not shown the good cause required for the grant of a protective order, and has not shown that there is any privilege attached to any of the documents this Honorable Court ordered to be produced and for that reason, Kennedy Krieger’s Motion for Protective Order should be denied.

6. In support of the Plaintiff’s response to Kennedy Krieger’s Motion for Protective Order, the Plaintiff incorporates by reference the attached Memorandum.

WHEREFORE, for the reasons stated herein and in the attached Memorandum, the Plaintiff respectfully requests that this Honorable Court enter an Order denying Kennedy Krieger’s Motion for Protective Order.

Respectfully submitted,

Evan K. Thalenberg
(Federal Bar No. 06619)
EVAN K. THALENBERG, P.A.
216 East Lexington Street
Baltimore, Maryland 21202
(410) 625-9100

Attorney for Plaintiffs

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**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF’S
RESPONSE TO DEFENDANT’S MOTION FOR PROTECTIVE ORDER**

Plaintiff, Shawnta DeShields, by her mother and next friend Phyllis Mitchell and her undersigned counsel, submits the following Memorandum of Points and Authorities in response to Defendant Kennedy Krieger Institute, Inc.’s Motion for Protective Order:

I. FACTUAL BACKGROUND

This suit arises from the minor Plaintiff, Shawnta DeShields’ participation in a research study entitled ‘Treatment of Lead Exposed Children’ (TLC). The study was conducted to research and assess the long term effects of allowing lead to remain in the bloodstream and bodies of children versus removing the lead from the child’s bloodstream using a drug called Succimer. Under this research study, children with elevated blood lead levels were recruited and given either Succimer or a placebo on a double blind basis. Kennedy Krieger has conceded that the purpose was not to render treatment to any child enrolled in the study but instead to measure the extent of permanent damage to the cognitive functioning based upon the chronically elevated blood lead

levels of children.¹ In this manner, otherwise healthy children with documented elevated blood lead levels were referred to Kennedy Krieger Institute for treatment, and were negligently enrolled into the study and enticed and lulled into living in and/or remaining in lead infested houses for the purpose of perpetuating research for the enrichment and increased prestige of Kennedy Krieger.

II. ARGUMENT

Due to these facts, this Court entered an Order in the course of a hearing conducted on April 2, 2003, directing Kennedy Krieger to produce all documents related to the TLC study for Plaintiffs' counsel to make a determination of relevancy.

The Court: Well, it seems to me, particularly with all these other cases going on in the Circuit Court of Baltimore City, all of the documents ought to be rounded up, collected, there should be a repository, and unless there is a privilege you should be able to see all of them, and

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The Court of Appeals has made its dim opinion of such studies very clear in regard to the similar Kennedy Krieger multi-level abatement study which was conducted during the same time period:

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

In our view, otherwise healthy children should not be the subjects of nontherapeutic experimentation or research that has the potential to be harmful to the child. It is, first and foremost, the responsibility of the researcher and the research entity to see to the harmlessness of such nontherapeutic research. Consent of parents can never relieve the researcher of this duty.

See Court of Appeals opinion in *Grimes v. Kennedy Krieger Institute, Inc.*, and *Higgins v. Kennedy Krieger Institute, Inc.*, September Term 2000.

make your own determination as to whether they are relevant or not.

(Exhibit 1)

Under the Order and Rulings from the bench of this Honorable Court, Kennedy Krieger was to produce all documents pertaining to the TLC study. Any documents in regard to which Kennedy Krieger wished to assert any claim of privilege were to be identified and withheld by Kennedy to be addressed at a later date. Although the Defendant reasons that these documents contain personal information about study participants, and sensitive research data that need the protection of the Court, the Defendant also concedes that those specific documents were not produced anyway. By the Defendant's own admission, specific information pertaining to other study participants has already been withheld by the Defendant (see footnote 3 of Defendants Memorandum in Support of Motion for Protective Order). In addition, the Defendant has (the Plaintiffs would argue, wrongfully) also redacted information it deemed confidential or proprietary (see footnote 4 of Defendant's Memorandum in Support of Motion for Protective Order). Now, in direct opposition to the common sense directive of this Honorable Court to establish a "document repository" of the TLC study documents for use in the remaining cases, the Defendant seeks to have to gag the Plaintiffs from access to these documents which the court has ordered produced. This would doom the parties and the courts to spending countless months and years of labor re-fighting the same discovery battles over and over and over again to obtain access to the documents which are applicable to all the TLC claims.

The Court can establish what documents should be protected, and the scope of that protection. However, courts "could not say that there was an established or well-settled practice of protecting research data in realm of civil discovery." Burka v. U.S. Dept. Of Health and Human Services 87 F.3d 508. The documents which Kennedy Krieger seeks to protect clearly

fall into the realm of research data and as such, merit no claim of absolute privilege.

Kennedy Krieger asserted at the hearing of April 2, 2003 that the documents requested were confidential in nature, reflecting data collected by the study, or transmitted to the study, and that they contained proprietary information about Kennedy Krieger that should not be disseminated outside of the present litigation. After considering these arguments the Court ordered the Defendant to produce the documents regarding the TLC program. . Additionally, by the Defendants' own admission, this study was a non-therapeutic study in which the study participants **waived** confidentiality through a proviso in the consent form drafted by Kennedy Krieger. This waiver provided a mechanism whereby study participants allowed Kennedy Krieger to reveal information to outside parties . Clearly the Defendant is trying to hide under the guise of confidentiality only when it is favorable to them to do so.

The Defendant next argues that because Kennedy Krieger was acting under the control of the federal NIEHS during the TLC study, and was working at its behest, the information produced to the Plaintiff should be protected from dissemination under Exemption 5 to the FOIA. However, the United States Court of Appeals has stated that an agency interests which would trigger protection of material in discovery was "1. Interference with ongoing scientific research, which would occur if the data was released prior to the follow-up surveys, and individuals then modified their behavior or survey answers in response to this information, and 2. Harm to the researchers' interests in having their research published in prestigious journals which would result if any study data was disclosed prior to release of the remaining articles slated for publication." Burka v. U.S. Dept. Of Health and Human Services 87 F.3d 508. There is no dispute that the TLC study was a completed study before this argument and therefore the first prong of the rationale is inapplicable. , Furthermore, there have been many articles and publications

summarizing and disseminating the mechanism and results of the study in question and therefore the second prong of the Defendant's asserted grounds are inapplicable as well. The TLC study data have been published and available for many years in the scientific arena. These multiple publications include "The Treatment of Lead-Exposed Children (TLC) Trial: design and Recruitment for a Study of the Effect of Oral Chelation on Growth and Development of Toddlers" 12 Paediatr. Perinat. Epidemiol. 313-333 (1998) (Exhibit 3) Furthermore, the TLC program itself has posted an internet site trumpeting the publications flowing from the research (Exhibit 4) It is hardly credible for Kennedy to assert that the documents they relied on for publication to promote its own prestige should not be available to the injured participants. For these reasons, Kennedy Krieger's Motion for Protective Order should be denied.

Furthermore, the Defendant has failed to satisfy the burden Local Rule 13 with regard to Proposed Confidentiality Orders. This Rule, which places the burden of justifying confidentiality on the Defendant contemplates particularity in regard to the documents for which confidentiality is sought. The Defendant has failed to meet this burden even failing to specifically identify the documents it has already withheld. The relief sought by the Defendant would send the court and all parties down an endless and unproductive road of discovery disputes.

III. CONCLUSION

Kennedy Krieger's Motion for Protective Order should be denied. Kennedy Krieger is being sued as a result of its negligent actions in conducting the TLC study and has failed to meet its burden to establish that the information produced merits protection by this Honorable Court.

Finally, the Plaintiff respectfully submits that Kennedy Krieger's motion is entirely self-serving and is intended not to protect the participants in the study, but rather to shield itself from

further embarrassment and discovery of unfavorable factual information contained in the documents produced. If Kennedy Krieger's motion for protective order is granted, Kennedy Krieger will not only have conducted a harmful, non-therapeutic study, but it will have used the same to shield itself from the consequences of it. This must not be allowed and therefore, Kennedy Krieger Institutes's motion for protective order should be denied.

Evan K. Thalenberg
(Federal Bar No. 06619)
EVAN K. THALENBERG, P.A.
216 East Lexington Street
Baltimore, Maryland 21202
(410) 625-9100

Attorney for the Plaintiff

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REQUEST FOR HEARING

The Plaintiff respectfully requests a hearing on her response to Defendant Kennedy Krieger Institute, Inc's Motion for Protective Order.

Evan K. Thalenberg
(Federal Bar No. 06619)

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ORDER

Upon consideration of Kennedy Krieger Institute, Inc.'s Motion for Protective Order and the Plaintiff's response thereto, it is this _____ day of _____, 2003;

ORDERED, that Kennedy Krieger Institute, Inc.'s Motion for Protective Order be, and the same hereby is, DENIED.

JUDGE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 29th day of August, 2003, a copy of the foregoing Plaintiff's Response to Kennedy Krieger institute, Inc.'s Motion for Protective Order, Memorandum, proposed Order and Request For Hearing, was mailed first class to:

Ira C. Cooke, Esquire
COOKE & ASSOCIATED, LIMITED
The Chesapeake Building
305 West Chesapeake Avenue

Suite 113
Towson, Maryland 21204

Donald DeVries, Jr., Esquire
GOODELL, DeVRIES, LEECH & DAN
One South Street
20th Floor
Baltimore, Maryland 21201

Evan K. Thalenberg
(Federal Bar No. 06619)