

Motion for Protective Order

DESHIELDS v. KENNEDY KRIEGER INSTIT., INC.

Case No.:02-CV-3694

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND, NORTHERN DIVISION

September 9, 2003

Reporter

2003 U.S. Dist. Ct. Motions LEXIS 6393 *

SHAWN TA DESHIELDS, et al. Plaintiff, v. KENNEDY KRIEGER INSTITUTE, INC. Defendant.

Type: Motion for Protective Order

Title

[*1]

Text

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANT'S MOTION FOR PROTECTIVE ORDER

The Defendant, Kennedy Krieger Institute, Inc. ("Kennedy Krieger") by and through its undersigned counsel, submits the following reply memorandum in support of its Motion for Protective Order and states as follows:

Non-Production vs. Confidentiality

Plaintiffs utterly misunderstand the purpose of Kennedy Krieger's Motion for Protective Order ("Motion").¹ Because Plaintiffs neither suffer prejudice by the entry of a confidentiality order nor articulate a reason why they object to use of the documents solely for the purposes of the litigation, this misunderstanding potentially explains why Plaintiffs are objecting at all. Kennedy Krieger is not asking the Court to enter an order *precluding* production of the confidential documents. It has, in fact, already produced not only the TLC documents in its possession² but also the TLC Plus³ documents in its possession (including the confidential documents subject to the proposed order).

¹ While Kennedy Krieger does not intend to parse all of the misstatements and improper allegations contained in Plaintiffs' Response to Kennedy Krieger's Motion for Protective Order, Kennedy Krieger must clarify two points. One, Kennedy Krieger has not and will not (short of a finding of fact by a jury) agree that the TLC study was "non-therapeutic." Second, the consent form utilized by the TLC study does not contain a "waiver of confidentiality" as alleged by Plaintiffs. Rather, the TLC trial enrollment consent form states: "The TLC study records are confidential and the names are taken off them and a code number put on as soon as possible. We will protect the records as much as we can under the law. Reports that we publish from this study will be about groups of children, and it will not be possible to tell that your child was in the study."

² Kennedy Krieger did not produce documents that related solely to non-party TLC study participants. If a document contained non-party participant information and other TLC information or information related to Plaintiffs, the non-party participant information was redacted but the document was produced. Counsel for Plaintiffs' sought to obtain information about non-party TLC participants in connection with Coles v. Kennedy Krieger Institute, Inc. et al., Circuit Court for Baltimore City, case number 24-C-01-004337. The Honorable Thomas E. Noel issued a Protective Order precluding the discovery of the identities of non-party TLC study participants.

Motion for Protective Order

Kennedy Krieger is simply seeking a confidentiality order (which is clearly contemplated by and appended to the Local Rules) preventing **[*2]** further dissemination of the confidential documents outside of the course of this litigation.⁴ As stated in the Motion, this request does not seek to prevent the production of documents or limit their use in this litigation and will in no way hinder or prejudice the Plaintiffs' ability to pursue their claims in this case.

[*3] [*4]

Plaintiffs accuse Kennedy Krieger of seeking to "gag" them from access to the documents because the documents were not placed in a "document repository."⁵ In lieu of placing one set of the documents in a location for Plaintiffs to review, Kennedy Krieger went to the time and expense (which was not insignificant) to bates-number and copy the TLC documents for Plaintiffs. Kennedy Krieger then hand-delivered the documents to counsel's office.⁶ It is unclear how Kennedy Krieger's direct production of the documents to Plaintiffs can be construed as anything but exceeding its responsibility to produce TLC documents.

Plaintiffs' Reliance on Burka is Misplaced

Plaintiffs also misunderstand Kennedy Krieger's argument regarding the deliberative process. In its Motion, Kennedy Krieger discussed **[*5]** the deliberative process privilege in an effort to highlight to the Court that many of the documents Kennedy Krieger produced are "pre-decisional" and "deliberative" in nature and could be withheld by the NIEHS pursuant to [5 U.S.C. 552\(b\)\(5\)](#) ("Exemption 5"). It would make little sense to allow a governmental agency to withhold completely documents that reveal the deliberative process on one hand, yet on the other hand, fail to extend at least confidential treatment to the same and similar documents simply because they were in the possession of a research facility that conducts the government's research pursuant to contract.

Their reliance on [Burka v. U.S. Dept. of Health & Human Services, 87 F.3d](#) 508 (D.D.C. 1996) is wholly misplaced. Once again, Plaintiffs confuse the non-production or withholding of documents (not at issue here) with the production of documents under a confidentiality order (at issue here). Plaintiffs refer to Burka for the proposition that there exists no "absolute privilege" with respect to "research data." See Memorandum in Support of Plaintiff's Response to Defendant Kennedy Krieger Institute, Inc.'s Motion for Protective **[*6]** Order, p. 3. It is unclear how this proposition furthers Plaintiffs' opposition to the Motion as Kennedy Krieger does not assert that an absolute privilege exists with respect to the production of research data. Plaintiffs' analysis of Burka and application to the present issue is flawed. The two-pronged test cited by Plaintiffs⁷ does not apply to documents protected by the deliberative process privilege. In Burka, the government agency, the National Cancer Institute, did not assert the deliberative process privilege against production. Instead, it withheld the documents requested under FOIA (questionnaires and data tapes relating to a 1990 survey of ninth-grade students) because the documents were "confidential research material." [Burka, 87 F.3d at 513.](#)⁸ The holding in Burka did not expressly address the

³ TLC Plus was a follow-up study that involved additional blood tests and tests of the child's thinking skills, coordination, and social behavior in school. The TLC Plus participants attended visits at 7 and 7.5 years of age. All participants signed a new consent form in connection with their participation in the TLC Plus study.

⁴ Before filing this Motion, Kennedy Krieger asked Plaintiffs to agree to a stipulated confidentiality order. Because Plaintiffs never responded to the request, Kennedy Krieger was forced to file the subject Motion.

⁵ It is unclear what Plaintiffs seek as Mr. Thalenberg's office is now a "repository" of TLC documents.

⁶ Approximately six banker's boxes of documents were hand-delivered to Mr. Thalenberg's office.

⁷ The lower court in Burka held that the agency "had identified two interests which would trigger protection of the material in discovery: 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 [COMMIT] researchers' interest in having their research published in prestigious, peer-reviewed journals." [Burka, 87 F.3d at 513.](#)

⁸ The government argued that "confidential research data is a category of information protected in civil discovery proceedings, and that the specific records sought by Burka would be eligible for such protection and may therefore be withheld in the FOIA context, as well." Id. Because the government did not assert one of the privileges enumerated in Exemption 5 (pre-decisional

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deliberative process but nevertheless recognized that documents reflecting the deliberative process are properly withheld from production under Exemption 5 of FOIA.

[*7] [*8]

Thus, in the present case, if Plaintiffs sought to obtain directly from the government much of the confidential information already produced by Kennedy Krieger, the NIEHS would be entitled to withhold the documents that reflect the pre-decisional, deliberative process that took place during the development and conduct of the TLC study.

Kennedy Krieger Met its Burden Pursuant to FRCP 26

Kennedy Krieger has met its burden to demonstrate the need for a confidentiality order precluding Plaintiffs from disseminating the confidential documents outside the scope of the litigation. Courts weigh the following factors when deciding to limit discovery by means of a Federal Rule of Civil Procedure ("FRCP") 26 order: "the requester's need for the information from this particular source, its relevance to the litigation at hand, the burden of producing the sought-after material; and the harm which disclosure would cause to the party seeking to protect the information." [Burka, 87 F.3d at 517](#) (citations omitted). These factors weigh heavily in favor of issuing a confidentiality order in the present case to limit use of the confidential documents to the scope of [*9] this litigation.

The first prong, the requester's need for the information from this particular source, to the extent that it is applicable, weighs in favor of entering a confidentiality order. Kennedy Krieger has already produced the documents at issue in the Motion. Therefore, the Plaintiffs' (Shawnta DeShields and Lamont Mitchell) need for discovery of TLC documents is met. It is noteworthy that Plaintiffs failed to provide any reason why they object to use of the documents solely for purposes of the litigation. The second prong, the relevance of the information to the litigation at hand, does not apply because Kennedy Krieger produced the subject documents. Similarly, the burden of producing the sought-after material, though significant, is at this point irrelevant because Kennedy Krieger has already produced the sought-after material. The final prong, the harm that disclosure would cause to the party seeking to protect the information, ultimately compels a confidentiality order in this case.

As set forth more fully in Kennedy Krieger's Motion, the documents designated as "confidential" should be protected from dissemination *outside of the course of this litigation* for the [*10] following reasons: (1) Kennedy Krieger is obligated by contract to maintain the confidentiality of information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution;⁹ (2) many of the documents reflect the deliberative process of the NIEHS and its contractors;¹⁰ and (3) Institutional Review Board documents must be treated as confidential based on legislative intent and sound public policy.¹¹ In sum, open communication and

deliberative memoranda; attorney-client communications, or attorney work product), the government had the burden to show that the documents sought would be protected from production during discovery in a civil proceeding. The Court stated:

Translating this two-tiered arrangement into the FOIA context means that merely identifying information as falling within a *privileged* category -- deliberative material, attorney/client communications, work product -- may be sufficient to withhold the material from a FOIA requester. When dealing with information withheld on the grounds that it may be subject to a protective order, though, something more is required: just as the target of a discovery request must show "good cause" under Rule 26(c) to escape disclosure, the agency claiming exemption from FOIA must identify an interest similar to one which courts have found sufficient to justify the "good cause" standard in discovery proceedings.

[Burka, 87 F.3d at 518](#) (emphasis in original).

⁹ See Motion, p. 4 (quoting [48 C.F.R. § 352.224-70](#)).

¹⁰ See Motion, pp. 5-10 (stating that the purpose of the deliberative process privilege was established to prevent injury to the quality of agency decisions).

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frank discussion among researchers is paramount to the success of scientific and medical research. If researchers believed that their personal notes, observations, internal communications, and critiques would be subject to *unfettered disclosure*, the chilling effect would hinder the frank and open discussions necessary to conduct valuable and scientifically sound research. See [U.S. v. Nixon, 418 U.S. 683, 705 \(1974\)](#).

[*11]

CONCLUSION

For the reasons set forth above and in its Motion for Protective Order, Kennedy Krieger respectfully requests that this Court grant its Motion and enter a confidentiality order limiting the use of all confidential documents to the scope of this litigation.

Respectfully submitted,

/s

Donald L. DeVries, Jr.

(Federal Bar No. 04889)

Kelly Hughes Iverson

(Federal Bar No. 022982)

Erica Ward Magliocca

(Federal Bar No. 26614)

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One South Street, 20th Floor

Baltimore, Maryland 21202

(410) 783-4000

Attorneys for Kennedy**Krieger Institute, Inc.****CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 9th day of September 2003, a copy of the foregoing Reply Memorandum in Support of Defendant's Motion for Protective Order was mailed first-class, [*12] postage prepaid, to:

Evan K. Thalenberg, Esquire

Evan K. Thalenberg, P.A.

216 East Lexington Street

Baltimore, Maryland 21202

Attorneys for Plaintiff

¹¹ See Motion, pp. 10-11 (explaining that to ensure that research on human subjects is conducted in the best manner possible, members of the IRB must be free to voice opinions and criticisms with candor, without fear that a comment will later be used in litigation).

Motion for Protective Order

/s

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

DESHIELDS v. KRIEGER

CIVIL ACTION NO.: L 02 CV 3694

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND, NORTHERN DIVISION

August 12, 2003

Reporter

2003 U.S. Dist. Ct. Motions LEXIS 11325 *

SHAWNTA DESHIELDS, et al., Plaintiffs v. KENNEDY KRIEGER INSTITUTE, INC., Defendant

Type: Motion for Protective Order

Counsel

[*1] 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 .

Title

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

Text

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 where in 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 [*2] 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

PLAINTIFF'S RESPONSE TO DEFENDANT KENNEDY KRIEGER INSTITUTE, INC.'S MOTION FOR
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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 [*3] 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

**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 [*4] 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

¹ 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

PLAINTIFF'S RESPONSE TO DEFENDANT KENNEDY KRIEGER INSTITUTE, INC.'S MOTION FOR
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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 [*5] purpose of perpetuating research for the enrichment and increased prestige of Kennedy Krieger.

[*6]

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 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 [*7] 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 [*8] 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**

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 non-therapeutic 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 non-therapeutic 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.

PLAINTIFF'S RESPONSE TO DEFENDANT KENNEDY KRIEGER INSTITUTE, INC.'S MOTION FOR
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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 [*9] 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 [*10] 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 [*11] 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 Institute'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

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

(410) **[*12]** 625-9100

Attorney for the Plaintiff

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Deshields, et al v. Kennedy Krieger

1:02cv3694

US District Court for the District of Maryland

November 13, 2002, Filed

Reporter

State: US-MD

Type: Response

Title

RESPONSE in Opposition re 30 MOTION for Protective Order ,Request for Hearing, Memorandum of Law in Support thereof, Rule 26(c) Certification and proposed Protective Order filed by Shawnta DeShields. Replies due by 9/12/2003. (Thalenberg, Evan) (Entered: 08/29/2003)

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REPLY to Response to Motion re 30 MOTION for Protective Order ,Request for Hearing, Memorandum of Law in Support thereof, Rule 26(c) Certification and proposed

Deshields, et al v. Kennedy Krieger

1:02cv3694

US District Court for the District of Maryland

November 13, 2002, Filed

Reporter

State: US-MD

Type: Reply

Title

REPLY to Response to Motion re 30 MOTION for Protective Order ,Request for Hearing, Memorandum of Law in Support thereof, Rule 26(c) Certification and proposed Protective Order filed by Kennedy Krieger Institute, Inc.. (Magliocca, Erica) (Entered: 09/09/2003)

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

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,

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.
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(410) 625-9100

Attorney for Plaintiffs

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

SHAWNTA DESHIELDS, et al.	*
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	*
	CIVIL ACTION NO.: L 02 CV 3694
Plaintiffs	*
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	*
KENNEDY KRIEGER INSTITUTE, INC.	*
	*
	*
Defendant	*
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* * * * *

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

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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

¹

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.

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(Federal Bar No. 06619)
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(410) 625-9100

Attorney for the Plaintiff

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

SHAWNTA DESHIELDS, et al.	*
	*
	*
Plaintiffs	CIVIL ACTION NO.: L 02 CV 3691
	*
	*
v.	*
	*
KENNEDY KRIEGER INSTITUTE, INC.	*
	*
Defendant	*

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

SHAWNTA DESHIELDS, et al.	*	
	*	
	*	CIVIL ACTION NO.: L 02 CV 3694
Plaintiffs	*	
v.	*	
	*	
KENNEDY KRIEGER INSTITUTE, INC.	*	
	*	
Defendant	*	
	*	

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,

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(Federal Bar No. 06619)
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Attorney for Plaintiffs

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

SHAWNTA DESHIELDS, et al.	*	
	*	
	*	CIVIL ACTION NO.: L 02 CV 3694
Plaintiffs	*	
v.	*	
	*	
KENNEDY KRIEGER INSTITUTE, INC.	*	
	*	
Defendant	*	
	*	

**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

¹

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)
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Attorney for the Plaintiff

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

SHAWNTA DESHIELDS, et al.	*
	*
	*
Plaintiffs	*
v.	*
	*
KENNEDY KRIEGER INSTITUTE, INC.	*
	*
Defendant	*

CIVIL ACTION NO.: L 02 CV 3694

*

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)

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

SHAWNTA DESHIELDS, et al.

*

*

* CIVIL ACTION NO.: L 02 CV 3694

Plaintiffs

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KENNEDY KRIEGER INSTITUTE, INC. *

*

Defendant

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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)

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

SHAWNTA DESHIELDS, et al.

*

Plaintiff,

*

v.

* Case No.: 02-CV-3694

KENNEDY KRIEGER INSTITUTE, INC.

*

Defendant.

*

* * * * *

**REPLY MEMORANDUM IN FURTHER SUPPORT
OF DEFENDANT'S MOTION FOR PROTECTIVE ORDER**

The Defendant, Kennedy Krieger Institute, Inc. ("Kennedy Krieger") by and through its undersigned counsel, submits the following reply memorandum in support of its Motion for Protective Order and states as follows:

Non-Production vs. Confidentiality

Plaintiffs utterly misunderstand the purpose of Kennedy Krieger's Motion for Protective Order ("Motion").¹ Because Plaintiffs neither suffer prejudice by the entry of a confidentiality order nor articulate a reason why they object to use of the documents solely for the purposes of the litigation, this misunderstanding potentially explains why Plaintiffs are objecting at all. Kennedy Krieger is not asking the Court to enter an order *precluding* production of the confidential documents. It has, in fact, already produced not only the TLC documents in its

¹ While Kennedy Krieger does not intend to parse all of the misstatements and improper allegations contained in Plaintiffs' Response to Kennedy Krieger's Motion for Protective Order, Kennedy Krieger must clarify two points. One, Kennedy Krieger has not and will not (short of a finding of fact by a jury) agree that the TLC study was "non-therapeutic." Second, the consent form utilized by the TLC study does not contain a "waiver of confidentiality" as alleged by Plaintiffs. Rather, the TLC trial enrollment consent form states: "The TLC study records are confidential and the names are taken off them and a code number put on as soon as possible. We will protect the records as much as we can under the law. Reports that we publish from this study will be about groups of children, and it will not be possible to tell that your child was in the study."

possession² but also the TLC Plus³ documents in its possession (including the confidential documents subject to the proposed order). Kennedy Krieger is simply seeking a confidentiality order (which is clearly contemplated by and appended to the Local Rules) preventing *further* dissemination of the confidential documents outside of the course of this litigation.⁴ As stated in the Motion, this request does not seek to prevent the production of documents or limit their use in this litigation and will in no way hinder or prejudice the Plaintiffs' ability to pursue their claims in this case.

Plaintiffs accuse Kennedy Krieger of seeking to "gag" them from access to the documents because the documents were not placed in a "document repository."⁵ In lieu of placing one set of the documents in a location for Plaintiffs to review, Kennedy Krieger went to the time and expense (which was not insignificant) to bates-number and copy the TLC documents for Plaintiffs. Kennedy Krieger then hand-delivered the documents to counsel's office.⁶ It is unclear how Kennedy Krieger's direct production of the documents to Plaintiffs can be construed as anything but exceeding its responsibility to produce TLC documents.

Plaintiffs' Reliance on Burka is Misplaced

Plaintiffs also misunderstand Kennedy Krieger's argument regarding the deliberative process. In its Motion, Kennedy Krieger discussed the deliberative process privilege in an effort

² Kennedy Krieger did not produce documents that related solely to non-party TLC study participants. If a document contained non-party participant information and other TLC information or information related to Plaintiffs, the non-party participant information was redacted but the document was produced. Counsel for Plaintiffs' sought to obtain information about non-party TLC participants in connection with Coles v. Kennedy Krieger Institute, Inc. et al., Circuit Court for Baltimore City, case number 24-C-01-004337. The Honorable Thomas E. Noel issued a Protective Order precluding the discovery of the identities of non-party TLC study participants.

³ TLC Plus was a follow-up study that involved additional blood tests and tests of the child's thinking skills, coordination, and social behavior in school. The TLC Plus participants attended visits at 7 and 7.5 years of age. All participants signed a new consent form in connection with their participation in the TLC Plus study.

⁴ Before filing this Motion, Kennedy Krieger asked Plaintiffs to agree to a stipulated confidentiality order. Because Plaintiffs never responded to the request, Kennedy Krieger was forced to file the subject Motion.

⁵ It is unclear what Plaintiffs seek as Mr. Thalenberg's office is now a "repository" of TLC documents.

⁶ Approximately six banker's boxes of documents were hand-delivered to Mr. Thalenberg's office.

to highlight to the Court that many of the documents Kennedy Krieger produced are “pre-decisional” and “deliberative” in nature and could be withheld by the NIEHS pursuant to 5 U.S.C. 552(b)(5) (“Exemption 5”). It would make little sense to allow a governmental agency to withhold completely documents that reveal the deliberative process on one hand, yet on the other hand, fail to extend at least confidential treatment to the same and similar documents simply because they were in the possession of a research facility that conducts the government’s research pursuant to contract.

Their reliance on Burka v. U.S. Dept. of Health & Human Services, 87 F.3rd 508 (D.D.C. 1996) is wholly misplaced. Once again, Plaintiffs confuse the non-production or withholding of documents (not at issue here) with the production of documents under a confidentiality order (at issue here). Plaintiffs refer to Burka for the proposition that there exists no “absolute privilege” with respect to “research data.” See Memorandum in Support of Plaintiff’s Response to Defendant Kennedy Krieger Institute, Inc.’s Motion for Protective Order, p. 3. It is unclear how this proposition furthers Plaintiffs’ opposition to the Motion as Kennedy Krieger does not assert that an absolute privilege exists with respect to the production of research data.

Plaintiffs’ analysis of Burka and application to the present issue is flawed. The two-pronged test cited by Plaintiffs⁷ does not apply to documents protected by the deliberative process privilege. In Burka, the government agency, the National Cancer Institute, did not assert the deliberative process privilege against production. Instead, it withheld the documents requested under FOIA (questionnaires and data tapes relating to a 1990 survey of ninth-grade students) because the

⁷ The lower court in Burka held that the agency “had identified two interests which would trigger protection of the material in discovery: 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 [COMMIT] researchers’ interest in having their research published in prestigious, peer-reviewed journals.” Burka, 87 F.3d at 513.

documents were "confidential research material." Burka, 87 F.3d at 513.⁸ The holding in Burka did not expressly address the deliberative process but nevertheless recognized that documents reflecting the deliberative process are properly withheld from production under Exemption 5 of FOIA.

Thus, in the present case, if Plaintiffs sought to obtain directly from the government much of the confidential information already produced by Kennedy Krieger, the NIEHS would be entitled to withhold the documents that reflect the pre-decisional, deliberative process that took place during the development and conduct of the TLC study.

Kennedy Krieger Met its Burden Pursuant to FRCP 26

Kennedy Krieger has met its burden to demonstrate the need for a confidentiality order precluding Plaintiffs from disseminating the confidential documents outside the scope of the litigation. Courts weigh the following factors when deciding to limit discovery by means of a Federal Rule of Civil Procedure ("FRCP") 26 order: "the requester's need for the information from this particular source, its relevance to the litigation at hand, the burden of producing the sought-after material; and the harm which disclosure would cause to the party seeking to protect

⁸ The government argued that "confidential research data is a category of information protected in civil discovery proceedings, and that the specific records sought by Burka would be eligible for such protection and may therefore be withheld in the FOIA context, as well." Id. Because the government did not assert one of the *privileges* enumerated in Exemption 5 (pre-decisional deliberative memoranda; attorney-client communications, or attorney work product), the government had the burden to show that the documents sought would be protected from production during discovery in a civil proceeding. The Court stated:

Translating this two-tiered arrangement into the FOIA context means that merely identifying information as falling within a *privileged* category—deliberative material, attorney/client communications, work product—may be sufficient to withhold the material from a FOIA requester. When dealing with information withheld on the grounds that it may be subject to a protective order, though, something more is required: just as the target of a discovery request must show "good cause" under Rule 26(c) to escape disclosure, the agency claiming exemption from FOIA must identify an interest similar to one which courts have found sufficient to justify the "good cause" standard in discovery proceedings.

Burka, 87 F.3d at 518 (emphasis in original).

the information." Burka, 87 F.3d at 517 (citations omitted). These factors weigh heavily in favor of issuing a confidentiality order in the present case to limit use of the confidential documents to the scope of this litigation.

The first prong, the requester's need for the information from this particular source, to the extent that it is applicable, weighs in favor of entering a confidentiality order. Kennedy Krieger has already produced the documents at issue in the Motion. Therefore, the Plaintiffs' (Shawnta DeShields and Lamont Mitchell) need for discovery of TLC documents is met. It is noteworthy that Plaintiffs failed to provide any reason why they object to use of the documents solely for purposes of the litigation. The second prong, the relevance of the information to the litigation at hand, does not apply because Kennedy Krieger produced the subject documents. Similarly, the burden of producing the sought-after material, though significant, is at this point irrelevant because Kennedy Krieger has already produced the sought-after material. The final prong, the harm that disclosure would cause to the party seeking to protect the information, ultimately compels a confidentiality order in this case.

As set forth more fully in Kennedy Krieger's Motion, the documents designated as "confidential" should be protected from dissemination *outside of the course of this litigation* for the following reasons: (1) Kennedy Krieger is obligated by contract to maintain the confidentiality of information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution;⁹ (2) many of the documents reflect the deliberative process of the NIEHS and its contractors;¹⁰ and (3) Institutional Review Board documents must be treated as confidential based on legislative intent and sound public

⁹ See Motion, p. 4 (quoting 48 C.F.R. § 352.224-70).

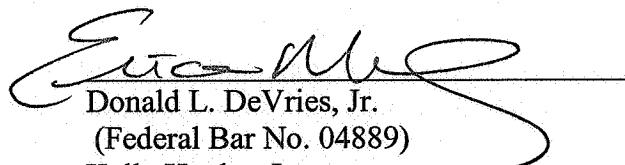
¹⁰ See Motion, pp. 5-10 (stating that the purpose of the deliberative process privilege was established to prevent injury to the quality of agency decisions).

policy.¹¹ In sum, open communication and frank discussion among researchers is paramount to the success of scientific and medical research. If researchers believed that their personal notes, observations, internal communications, and critiques would be subject to *unfettered* disclosure, the chilling effect would hinder the frank and open discussions necessary to conduct valuable and scientifically sound research. See U.S. v. Nixon, 418 U.S. 683, 705 (1974).

CONCLUSION

For the reasons set forth above and in its Motion for Protective Order, Kennedy Krieger respectfully requests that this Court grant its Motion and enter a confidentiality order limiting the use of all confidential documents to the scope of this litigation.

Respectfully submitted,



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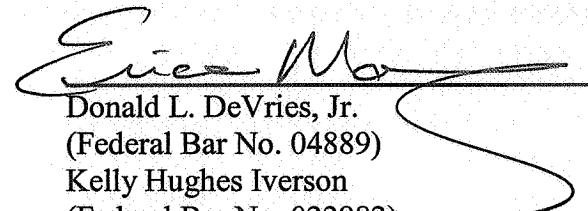
Attorneys for Kennedy
Krieger Institute, Inc.

¹¹ See Motion, pp. 10-11 (explaining that to ensure that research on human subjects is conducted in the best manner possible, members of the IRB must be free to voice opinions and criticisms with candor, without fear that a comment will later be used in litigation).

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 9th day of September 2003, a copy of the foregoing Reply Memorandum in Support of Defendant's Motion for Protective Order was mailed first-class, postage prepaid, to:

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