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.	*	

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

MOTION FOR PROTECTIVE ORDER

The Defendant, Kennedy Krieger Institute, Inc. ("Kennedy Krieger") by and through its undersigned counsel, hereby moves pursuant to Rule 26(c)(7) of the Federal Rules of Civil Procedure and Local Rule 104.13 for a Protective Order to prevent Plaintiff from reproducing and disseminating confidential documents received from Kennedy Krieger during the course of discovery and for reasons states:

1. As set forth in more detail in the accompanying Memorandum, Plaintiff's requests for production of documents have included requests for confidential research material. In the spirit of discovery, the Defendant has produced confidential research and other material to the Plaintiff, but Plaintiff has not to date agreed to maintain the confidentiality of the documents and protect them from re-disclosure. As such, this motion requests that an Order be entered to protect the confidential nature of the documents from disclosure outside the course of this litigation.

2. This Defendant incorporates the points and authorities set forth in the attached Memorandum.

3. Undersigned counsel have attempted to resolve this issue and have submitted a proposed stipulated confidentiality order to plaintiff's counsel, but to date counsel have been unable to reach agreement.

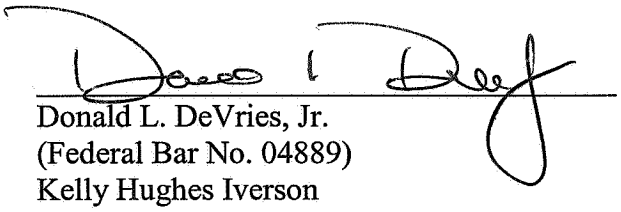
4. A proposed order is attached.

WHEREFORE, for the reasons stated in this Motion and in the accompanying Memo of Points & Authorities, Kennedy Krieger respectfully requests that the Court grant its motion and enter an Order protecting confidential documents produced in discovery, from re-disclosure.

REQUEST FOR HEARING

Kennedy Krieger respectfully requests a hearing on its Motion for Protective Order.

Respectfully submitted,



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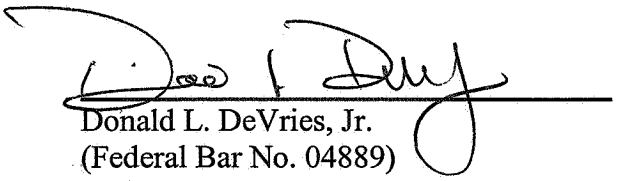
Attorneys for Kennedy Krieger Institute, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this the 8th day of August 2003, a copy of the foregoing Motion for Protective Order was mailed first-class, postage prepaid, to:

Evan K. Thalenberg, Esquire
Evan K. Thalenberg, P.A.
216 East Lexington Street
Baltimore, Maryland 21202
Attorneys for Plaintiff



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

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT'S MOTION FOR PROTECTIVE ORDER

Defendant, Kennedy Krieger Institute, Inc. ("Kennedy Krieger"), by and through its undersigned counsel, submits the following Memorandum of Points & Authorities in support of its Motion for Protective Order:

I. INTRODUCTION

This suit arises from minor Plaintiff Shawnta DeShields's participation in a federal study conducted by the National Institute of Environmental Health Sciences ("NIEHS")[1] known as the Treatment of Lead-Exposed Children ("TLC") trial. In 1992 the federal government, through the NIEHS, issued a Request for Proposal ("RFP") seeking clinical centers for this double-blind, placebo-controlled study. The purpose of which was to determine whether the drug Succimer[2] could prevent cognitive delay in young children with blood lead levels less than 45 micrograms per deciliter. The study was conducted at four clinical centers, one of which was in Baltimore.

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[1] NIEHS is a subsidiary of the National Institutes of Health ("NIH") itself a branch of the United States Department of Health and Human Services.

[2] Succimer had been approved by the United States Food and Drug Administration ("FDA") for use in treating individuals with blood lead levels greater than 45 micrograms per deciliter.

The Baltimore Clinical Consortium consisted of the Kennedy Krieger Institute, Inc., the University of Maryland, and Johns Hopkins University. Shawnta DeShields participated in the TLC study through the Baltimore Consortium. Plaintiffs assert a claim of negligence against Kennedy Krieger alleging, inter alia, that Kennedy Krieger "negligently enrolled" Shawnta DeShields into the TLC study.

On June 3, 2003, this Court entered an Order directing that Kennedy Krieger produce "all documents related to the merits of the case, save those for which Kennedy Krieger asserts a claim of privilege." Kennedy Krieger has complied in good faith with the Court's order. Yet, many of the documents that are related to the TLC trial (which is a federal research study) are confidential research documents that should not be further disseminated. Rule 26(c) (7) expressly contemplates protection of confidential research information; accordingly, Kennedy Krieger requests that this Court enter an Order preventing the further dissemination of the confidential documents it has produced to the plaintiff.

II. STANDARD FOR PROTECTIVE ORDER

Upon motion by a party, a court, for good cause, may issue a protective order "which justice requires to protect a party or person from annoyance, embarrassment, oppression or undue burden or expense . . . ." FED. R. CIV. P. 26(c). A court has broad discretion to fashion a protective order including ordering that "certain matters not be inquired to, or that the scope of the disclosure be limited to certain matters." Id. at 26(c)(4); see also Seattle Times Co. v. Rhinehart, 467 U.S. 20, 36 (1984) (finding the Federal Rules give courts "broad discretion" to decide "when a protective order is appropriate and what degree of protection is required"). The Court may also enter an Order that "confidential research . . . information need not be revealed or be revealed only in a designated way." FED. R. CIV. PRO. 26(c)(7); see also Burka v. U.S. Dept.

of Health and Human Services 87 F.3d 508 (stating "Both parties agree that in several contexts, courts have exercised their authority under Rule 26(c)(7) to shield from discovery confidential research information . . . .")

III. ARGUMENT

Kennedy Krieger has, in good faith, produced confidential material to the Plaintiff for use in this litigation, but Plaintiff has not, to date, agreed to maintain these documents confidentially and protect them from further disclosure. The documents that reflect the deliberative process of the federal government and its contractors, contain proprietary information, TLC study data, and documents that relate to institutional review board review/approvals have been designated as "Confidential." Kennedy Krieger requests the issuance of a protective order to preclude Plaintiff's counsel from reproduction and dissemination of said documents outside the course of this litigation. Importantly, this request for a protective order 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.

A. Kennedy Krieger is Obligated by Contract to Maintain the Confidentiality of Certain Documents and Data

During the course of the TLC study, Kennedy Krieger and NIEHS generated numerous documents that contain personal information about study participants[3] that reflect data collected by the study and/or transmitted to the study's Data Coordinating Center ("DCC") in Boston, and

[3] Information that relates to study participants other than Plaintiff Shawnta DeShields has not been produced. To the extent that personal information about Shawnta DeShields or plaintiff Lamont Mitchell has been produced, this Defendant does not seek to include the minor Plaintiffs' personal or medical information within the scope of this protective order.

that contain proprietary information about Kennedy Kennedy.[4] The contract between Kennedy Krieger and NIEHS, an agency within the federal Department of Health and Human Services ("HHS"), demonstrates the parties' clear intent to protect the confidentiality of these documents generated in the course of the TLC study. Contract No. NO1-ES-35362 states that documents generated during the clinical trial are to be treated as confidential. Page 29 of the contract governs the disposition of confidential information developed during the TLC study. Section H of the contract, entitled "Special Contract Requirements," and Article H.11, entitled "Confidentiality of Information," incorporates by reference 48 C.F.R. § 352.224-70. Section 352.224-70 deals with confidential material generated between "HHS" and government contractors doing work on behalf of HHS. The section states in pertinent part:

> (a) Confidential information, as used in this clause, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

48 C.F.R. § 352.224-70. The regulation sets forth the following rationale for HHS's confidentiality requirements:

> It is the policy of HHS to protect personal interests of individuals, corporate interests of non-governmental organizations, and the capacity of the Government to provide public services when information from or about individuals, organizations, or Federal agencies is provided to or obtained by contractors in performance of HHS contracts. **This protection depends on the contractor's recognition and proper handling of the information.**

48 C.F.R. § 324.7002 (emphasis added). Maintaining confidentiality serves the interests of all parties concerned (i.e., the federal government, research facilities, and study participants) by promoting the conduct of sound medical and scientific research and advancing the state of medical knowledge. Without confidentiality protection, individuals and private medical facilities

[4] Proprietary and confidential financial information about Kennedy Krieger has in some instances been redacted from otherwise discoverable documents.

would be less inclined to participate in medical research for fear of unfettered disclosure of confidential information.

In keeping with the confidentiality policy of the HHS, NIEHS and Kennedy Krieger treated numerous documents that contained data, information of a personal nature, or proprietary information as confidential during the day-to-day administration of the clinical study. Even though the study is complete, data of a personal nature, proprietary information, and data submitted by or pertaining to an institution or organization still qualifies for the protection afforded under the original contract. As such, the documents are afforded protection from disclosure outside the confines of the TLC study.

Although many confidential documents have been produced to the Plaintiff pursuant to the order of this Court, the disclosure should end there. Allowing Plaintiff the ability to ignore this provision would potentially result in reproduction and circulation of these confidential documents outside the scope of this litigation. To permit Plaintiff free reign in dissemination and reproduction of confidential documents clearly goes against the letter and spirit of the contract governing Kennedy Krieger's participation in the TLC study. Accordingly, a protective order precluding dissemination to parties outside the present litigation of documents treated confidential under § 352.224-70 is proper.

B. Documents that Reflect the Deliberative Process of the NIEHS and Its Contractors Should be Protected from Reproduction and Dissemination

Among the documents included in the Court's directive to produce "all documents related to the merits of the case" are personal notes, observations, internal communications, critiques from Kennedy Krieger and NIEHS employees, and other documents that reflect the deliberative process both of the federal agency that orchestrated the study and of its contractors. These

documents include, for example, documents that reflect the decisions to include or reject elements of the study protocol. Ordinarily, draft or pre-decisional documents of a government agency would not be available to the Plaintiffs. If Plaintiffs requested documents from the NIEHS under the federal Freedom of Information Act ("FOIA"), for example, the government agency would be able to refuse to produce documents that reflect the agency's deliberative process or draft documents that do not reflect the agency's final determination (pre-decisional documents). See 5 U.S.C. 552(b)(5).

As outlined in Kennedy's Notice of Removal, Kennedy Krieger was acting under the direction and control of the federal NIEHS during the TLC study. As a result of Kennedy Krieger's close relationship to NIEHS and the agency's control over Kennedy Krieger, Kennedy Krieger possesses documents that reflect the deliberative process both of the government and of its contractors. Kennedy Krieger has not asserted a privilege against production of these documents, as Kennedy Krieger is a government contractor/federal officer, rather than a governmental agency itself. Accordingly, the plaintiffs now have in their possession numerous deliberative and predecisional documents that reflect the inner workings of the government (here, NIEHS) as it developed this study with its contractors, who were working at its behest. In keeping with the governmental interests in confidentiality of the deliberative process, however, the plaintiffs should not be permitted to further disclose documents obtained through the proverbial "back door" that ordinarily would not be available to them through the "front door." Accordingly, Kennedy Krieger seeks a protective order from preventing the further disclosure outside the present litigation of confidential documents that reflect the deliberative process of the NIEHS and its contractors. Such an order is necessary and appropriate in view of the underlying policy goals of FOIA's Exemption 5.

FOIA's Exemption 5 excuses governmental agencies from producing documents that encompass or pertain to an agency's deliberative process. The exemption states:

> (b)(5) EXEMPTION 5 Privileged Interagency or Intra-Agency Memoranda or Letters. This exemption protects internal Federal government documents which are both predecisional and deliberative. In addition, the attorney work-product privilege and the attorney-client privilege have been incorporated into this exemption.

See 5 U.S.C. 552(b)(5).

Exemption 5 protects "inter-agency or intra-agency memorandums or letters which would not be available by law to a party . . . in litigation with the agency." Id. This exemption has been interpreted to encompass all documents normally privileged in the civil discovery context, including documents that fall within the "deliberative process privilege." NLRB v. Sears, Roebuck & Co., 421 U.S. 132 (1975). The deliberative process privilege protects from disclosure "advisory opinions, recommendations and deliberations comprising part of a process by which the governmental decisions and policies are formulated." Id. at 150 (internal quotations omitted); see also Jordan v. Dep't of Justice, 591 F.2d 753, 772 (D.C. Cir. 1978) (en banc). The deliberative process privilege, which was established to prevent injury to the quality of agency decisions, applies to all requested information that "bear[s] on the formulation or exercise of agency policy-oriented judgment." Petroleum Information Corp. v. Dep't of Interior, 976 F.2d 1429, 1435 (D.C. Cir. 1992).

To qualify for Exemption 5, information must be "predecisional" and "deliberative." See Access Reports v. Dep't of Justice, 926 F.2d 1192, 1194 (D.C. Cir. 1991). The context in which the information is used and the role the information plays in the decision-making process is evaluated in determining whether information qualifies for protection. See Formaldehyde Institute v. Department of Health and Human Services, 889 F.2d 1118, 1123-24, O.S.H. Dec.

(CCH) ¶ 28731 (D.C. Cir. 1989). The privilege protects determinations by federal agencies, for if the employees of an agency knew that their personal notes, observations, internal communications, and critiques would be subject to disclosure, frank and open communication within the agency would be hindered. See Scott v. PPG Industries, Inc., 142 F.R.D. 291 (N.D. W. Va. 1992).

Courts have upheld non-production of medical research documents several times under Exemption 5 of FOIA, as the medical research reflected the deliberative process of the agency. See Formaldehyde Inst., 889 F.2d at 1989 (finding a Department of Health and Human Services review letter evaluating an article submitted to a scientific journal by an employee of the Center for Disease Control was predecisional for purposes of Exemption 5, and therefore, protected from production); Public Citizen Health Research Group v. Auchter, 10 O.S.H. Cas. (BNA) 1647, 1982 O.S.H. Dec. (CCH) ¶ 26059, 1982 WL 45036 (D.D.C. 1982) (memorandum discussing scientific testing of a toxic gas was so fused with recommendations and agency policy considerations that segregation of the factual discussion from policy and recommendation was not feasible and was therefore exempt from disclosure under FOIA); Professional Review Organization of Florida, Inc. v. U.S. Dept. of Health and Human Services, 607 F. Supp. 423 (D. D.C. 1985) (Department of Health and Human Services panel members' evaluations fell within an exemption to FOIA because they revealed the deliberative process). Consequently, if Plaintiff requested TLC documents directly from NIEHS or another federal agency conducting medical or scientific research, the federal agency would be able to assert a privilege against the production of "deliberative process" or "predecisional" documents.

Many of the documents produced by Kennedy Krieger pursuant to the Court's order reflect the deliberative process of the NIEHS, of Kennedy Krieger, or of both the government

and its contractors working together. These documents may include, for example, minutes, notes, comments and observations from meetings of the committee (comprised of both government personnel and government contractors' personnel) that designed and approved the TLC study protocol. "Deliberative process" and "predecisional" documents might also include drafts of the protocol that were circulated before the final protocol was published, drafts of scientific papers that were eventually submitted for publication, and correspondence between the federal agencies and the government contractors relating to the design and implementation of the study.

It would be illogical 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 are in the possession of a research facility that conducts the government's research pursuant to contract. Similar to agency deliberations, open communication and frank discussion among researchers (and between researchers and agency employees) is paramount to the success of scientific and medical research. If medical 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 discussion necessary to conduct valuable and scientifically sound research. See United States v. Nixon, 418 U.S. 683, 705 (1974) ("Human experience teaches that those who expect dissemination of their remarks may well temper candor with a concern for appearances and for their own interests to the detriment of the decisionmaking process."). Accordingly, documents that reflect the deliberative process of the government agency and its contractors should be afforded the protection of confidentiality, and Plaintiffs

should not be allowed to reproduce and circulate the documents outside the course of this litigation.

C. Institutional Review Board (IRB) Documents are Confidential

Pursuant to federal regulations, Kennedy Krieger sought and obtained approval for its participation in the TLC study from the Joint Committee on Clinical Investigation ("JCCI"), which is the Institutional Review Board ("IRB") affiliated with Johns Hopkins University. Among the documents produced to the Plaintiffs are documents in Kennedy Krieger's possession relating to the JCCI approval of its participation in the NIEHS clinical trial. These documents are confidential; they not only reflect the deliberative process in the formation of the study, but they are clearly confidential under a plain reading of the recently enacted statute governing the disclosure of certain IRB documents.

Until the General Assembly enacted MD. HEALTH-GEN. CODE ANN. § 13-2003 (2002 Supp.)[5] relating to IRB minutes, there was no requirement that IRB documents be disclosed under any circumstances. IRB proceedings (such as those at issue here) that took place before the October 1, 2002 effective date of the statute, therefore, were completely confidential.

Even under the new statute, the only documents that must be made available for inspection are the final minutes of a meeting. The statute does not require disclosure of IRB submissions, correspondence, etc. Accordingly, these documents would not ordinarily be

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[5] Maryland Health Gen. Code Ann. 13-2003, which became effective October 1, 2002, provides:

13-2003. Institutional Review Board Minutes.

(a) *Availability.* – An institutional review board shall make the final minutes of a meeting available for inspection within 30 dyas of receipt of a request for the minutes of any person.

(b) *Redaction of confidential or privileged information.* – Prior to making the minutes of a meeting available for inspection under subsection (a) of this section, an institutional review board may redact confidential or privileged information.

(c) *Minutes not public records.* – The minutes of a meeting of an institutional review board are not public records under Title 10, Subtitle 6 of the State Government Article.

available for review by the Plaintiffs. Moreover, any IRB minutes that are disclosed pursuant to the statute may be expressly redacted to remove confidential or privileged information. Further, the legislature expressly determined that the minutes of an IRB are not to be deemed "public records" for purposes of the state's Public Information Act. Clearly, the legislature recognized the confidential nature of IRB documents; else, there would be no need for it to determine that after October 1, 2002, the only IRB documents that are not strictly confidential are the final minutes of a meeting, with confidential or privileged information redacted.

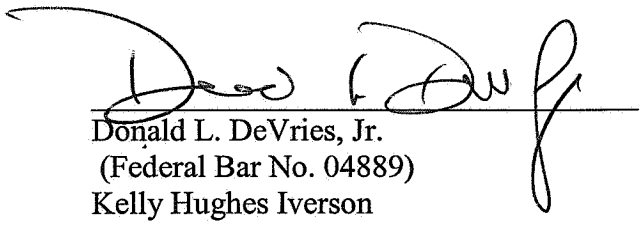
The confidentiality of IRB documents rests on sound public policy. An IRB is charged with the oversight and review of any study involving human subjects; thus, to ensure that human subject research is conducted in the best manner possible, members of the IRB must be free to voice opinions and criticisms with candor, without fear that a comment will later be used in litigation. Otherwise, the potential for subsequent disclosure and misuse would have a chilling effect on the free and fair exchange of information, an exchange that is necessary for the betterment of scientific and medical research and for the protection of study subjects.

In a good faith effort to comply with the Court's order for production of all relevant documents, Kennedy Krieger has produced to the Plaintiff the JCCI documents that are in its possession. In keeping with confidentiality concerns and the public policy underlying the free and frank exchange of scientific opinions, however, the documents produced by Kennedy Krieger should not be subject to further disclosure or dissemination beyond the bounds of this lawsuit.

IV. CONCLUSION

For the reasons set forth above, Kennedy Krieger respectfully requests that this Court grant its Motion for Protective Order and enter an Order preventing Plaintiffs from disseminating the documents designated as "Confidential."

Respectfully submitted,



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Attorneys for Kennedy Krieger Institute, Inc.

RULE 26(c) CERTIFICATION

Undersigned counsel and Plaintiffs' counsel have, in good faith, attempted to resolve this dispute without court action. On April 10, 2003, undersigned counsel circulated a proposed LR104.13 Stipulated Protective Order and requested Plaintiff's consent thereto. To date, Plaintiff's counsel has not agreed to the proposed LR104.13 Order. See April 10, 2003 correspondence to Evan K. Thalenberg from Kelly H. Iverson and proposed LR104.13 Stipulated Protective Order attached as Exhibit A.

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PROTECTIVE ORDER

The Court has considered Kennedy Krieger Institute, Inc.'s ("Kennedy") Motion for Protective Order, and oppositions from the Plaintiff, and oral argument by counsel. The Court has determined that certain discovery material produced by Kennedy should be treated confidential. Accordingly, Plaintiff is this _____ day of 2003, ORDERED:

1. The word "document" shall have the full meaning ascribed to it in the Federal Rules of Civil Procedure and shall include, without limitation, all original written, recorded, electronic, or graphic matters and all copies thereof.

2. This Order shall govern the handling of certain documents produced or testimony given in this action by plaintiffs and defendants to this action (hereinafter individually "party" or collectively "parties") and non-parties and designated "Confidential" as further set forth herein.

3. A party or non-party may obtain Confidential Treatment, as defined in this Order, for such documents that it is producing by typing or stamping "Confidential" (hereinafter "Confidential" designation) on each page of the documents for which confidential treatment is desired. Pages so designated shall hereinafter be referred to as "Confidential Documents."

Documents made available by a party or non-party for inspection by inspecting party's counsel, and the information contained therein, shall be treated by inspecting party's counsel as "Confidential Documents" under this Order. With respect to copies of those documents selected by an inspecting party's counsel and turned over to inspecting party's counsel, those documents then bearing the "Confidential" stamp (and the confidential information contained therein) shall continue to be entitled to receive Confidential Treatment pursuant to the terms of this Order.

4. Documents or transcripts or portions thereof may be designated "Confidential" pursuant to the terms of this Order:

a. If the document or portion of the document or transcript discloses personal notes, observations, internal communications, institutional review board communications, critiques, or material that would pertain to the deliberative process;

b. If the document or portion of the document or transcript discloses proprietary information or study data;

c. If the parties agree in writing to treat the said portions as Confidential; or

d. If the Court shall rule such documents to be Confidential after appropriate notice for good cause shown.

The "Confidential" designation hereunder shall be used consistently with the interests of the parties and the legitimate confidentiality interests of the parties or of other persons. The designation of any document or information as Confidential pursuant to the terms of this Order shall constitute the verification of counsel of record for the designating party that at least one of them has reviewed the document for compliance with the criteria of this Order and that the designation is in the good faith judgment of counsel consistent with the terms of this Order.

2. At depositions taken in this litigation, a party may obtain Confidential Treatment of the transcript and videotape as defined in this Order for testimony concerning Confidential Information by so advising the court reporter during the course of that testimony for which Confidential Treatment is desired or by so advising opposing counsel in writing within 21 calendar days of receipt of the transcript. Until such 21 calendar days have run, the entire transcript and videotape shall be treated as Confidential. If the transcript or videotape is filed with the Clerk of the Court, those portions so designated shall be filed under seal.

3. Except by prior Court Order or with the prior written consent of the designating party, documents and transcripts designated as "Confidential" hereunder (and the confidential information contained therein) shall receive "Confidential Treatment" as follows:

a. Confidential documents and transcripts may be disclosed only to the following persons:

i. personnel of any of the law firms or law departments representing of record any of the parties to this action and who are involved in the prosecution or defense of this action.

ii. experts and consultants employed or retained by counsel of record for the parties for the purpose of analyzing data, conducting studies, providing opinions or otherwise assisting in any way in this action, and their associates, assistants and other personnel

iii. those persons testifying as witnesses in this action. Nothing herein shall prevent a party from utilizing Confidential documents and transcripts during the testimony of a witness that

is the party (or employee of the party) that produced the Confidential document and/or designated the transcript as Confidential.

b. Any Confidential Document or transcript (or Confidential information contained therein) shall be used solely for the purpose of preparing for and conducting pretrial and trial proceedings in this action.

c. Before the disclosure of any Confidential Document or transcript (or the Confidential information contained therein) to any person covered by subparagraphs (ii) and (iii) hereof (the "Recipient"), counsel making the disclosure shall caution the Recipient against the disclosure of said information to anyone else and advise the Recipient that said information is the subject of a Court Order, and the Recipient shall acknowledge his/her agreement to abide by this Order and be subject to the jurisdiction of this Court by signing a copy of this Order, which shall be kept by disclosing counsel and, upon the conclusion of the litigation or for good cause shown and upon order of the Court, be available for inspection by counsel for the other parties. In no event shall a person covered by subparagraph (iii) hereof be allowed to retain any copies of documents or transcripts designated as Confidential pursuant to the terms of this Order. Those persons covered by subparagraph (ii) hereof must return all Confidential documents and transcripts and any copies to counsel following conclusion of this litigation.

4. Anything in this Order to the contrary notwithstanding, any party may use the services of a public court reporting service, photocopying service, printing and binding service or computer input service with regard to "Confidential" material without regard to the provisions of paragraph 7 hereof, providing such services are advised of the Confidential nature of the documents and asked to maintain their confidentiality.

5. No person receiving a document or transcript designated as "Confidential" shall disclose it or its contents to any person or use it other than as provided in paragraphs 7 and 8. Nothing in this Order is meant to limit the ability of a party producing a Confidential document or providing Confidential testimony from disclosing **its own documents or testimony of its employees** in the conduct of its own business or for purposes of this litigation. Nothing in this Order shall preclude any party to the lawsuit, their attorneys or any other person from disclosing or using, in any manner or for any purpose, any information or documents not produced by a party in this litigation, even though the same information or documents may have been produced in discovery in this lawsuit, provided the information and documents were not obtained through improper means and not subject to a separate confidentiality agreement.

6. If any counsel files with or submits to the Court (a) documents or transcripts afforded Confidential Treatment pursuant to this Order or (b) papers disclosing the confidential information contained in such documents or transcripts, such documents, transcripts or papers shall be filed in sealed envelopes on which shall be endorsed the caption of this action and a statement substantially in the following form:

"Confidential"

> "This envelope contains documents that are subject to an Order governing the use of confidential discovery material entered by the Court in this action. The envelope shall not be opened nor the contents thereof displayed or revealed except by Order of this Court."

10. Any document or transcript designated as "Confidential" or any paper disclosing the Confidential information contained in such documents or transcripts that is filed with the Court shall be maintained under seal by the Clerk and shall be made available only to the Court and to counsel for parties until further order of this Court.

11. Whenever a party objects to the treatment of a document or transcript as Confidential as defined in paragraph 4 hereof, it shall so notify in writing the party requesting such Confidential Treatment. Within 30 calendar days of receipt of said written notice, the party requesting Confidential Treatment may apply to the Court for a ruling that the document or transcript shall be treated in the manner described in this Order. If no such application is made within 30 calendar days of such notification, the document or transcript in question shall thereafter be deemed not to be subject to Confidential Treatment. If such application is made, the document or transcript shall be afforded the treatment described in this Order until the Court rules on such application. In any such application, the proponent of confidentiality must show by a preponderance of the evidence that there is good cause for the document to have such protection under the terms of the Order. Any such proceeding shall be *in camera* or under seal.

12. At the conclusion of this litigation (including any appeals), all documents or transcripts designated "Confidential", and any copies thereof, shall either be returned to the producing party, or counsel for the receiving party shall certify in writing to the destruction of said documents. This Order shall continue to be binding after the conclusion of this litigation, except that there shall be no restriction on documents or transcripts not under seal that are (a) used as exhibits and/or offered into evidence in the pretrial activities or trial of this action, and (b) not covered by any subsequent and inclusive confidentiality order.

13. Production of any material treated as Confidential under this Order by a nonproducing party in response to an apparently lawful subpoena, motion or order of or in any court or other governmental agency shall not be deemed a violation of any of the terms of this Order. However, the party receiving such subpoena, motion or order shall first promptly notify the producing party and prior to production, if it can be done without placing the nonproducing

party in violation of the subpoena, motion or order, shall give the producing party the opportunity to secure confidential treatment, whether by protective order or otherwise, for such materials upon terms comparable to those applicable to such materials under the terms of this Order and/or to seek to block the production.

14. Third parties, from whom discovery is sought in this lawsuit, may utilize this Order to protect confidential material produced by them if they notify all parties of their intent to do so and agree in writing to be bound by the terms of this Order and the jurisdiction of this Court to enforce this Order.

15. No videotapes of deposition testimony of any witness shall be disclosed to any person other than those described in Paragraph 6, subparagraphs (i)-(iii), and, if such videotapes are to be filed with or submitted to the Court, the procedures of Paragraphs 10 and 11 are to be followed.

16. All parties to this lawsuit have agreed to the terms and language of this Protective Order.

17. This Order may be modified, amended or vacated by further order of the Court upon the motion of any party for good cause shown.

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Honorable Benson Everett Legg Judge,
U.S. District Court for the District of
Maryland

cc: Counsel of Record