UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: GADOLINIUM BASED CONTRAST AGENTS PRODUCTS LIABILITY LITIGATION	Case No. 1:08 GD 50000 MDL No. 1909 Judge Dan Aaron Polster
THIS DOCUMENT APPLIES TO ALL CASES	

CASE MANAGEMENT ORDER NO. 16
PROTOCOL FOR HANDLING OF TISSUE AND RELATED PHYSICAL EVIDENCE

I. Scope of Protocol

This Protocol shall apply to all Plaintiffs and their counsel for actions relating to Gadolinium-based contrast agents ("GBCAs") that currently are pending in MDL No. 1909 or hereafter subject to transfer to these proceedings (collectively, the "MDL Proceedings"), and all Defendants and their counsel in the MDL Proceedings.

II. Protocol for Handling of Tissue and Related Evidence of Plaintiffs

1. For purposes of Sections II and III of this Protocol, "Tissue" refers to solid tissue samples or specimens taken from Plaintiffs or Plaintiffs' decedents in connection with any examination or evaluation, including any examination or evaluation related to the diagnosis or treatment of nephrogenic systemic fibrosis ("NSF") or nephrogenic fibrosing dermatopathy ("NFD"), and all wet tissue, solid tissue blocks and slides created from those samples or specimens. "Tissue" includes but is not limited to all original and recut glass slides, including all unstained slides, and all slides prepared with either standard or specialized staining.

2. Any party providing notice under Sections II or III of this Protocol shall be required to provide such notice only to counsel of record in that particular case, and not to all parties who might otherwise be subject to this Protocol.

3. Upon request, Plaintiffs shall notify Defendants of any and all Tissue in Plaintiffs' possession, custody and control, including any Tissue in the hands of any of Plaintiffs' retained experts, and cooperate to make such Tissue available for review and inspection by Defendants.

4. Defendants may proceed to obtain Tissue as long as there is a sufficient amount of tissue for the facility or healthcare provider to make an equal quantity of tissue samples (such collection of tissue samples hereinafter referred to as a "tissue set") available for each area of the body from which tissue was obtained; one tissue set for the Plaintiff and one tissue set for the defendants, collectively. Defendants shall notify Plaintiff of Defendants' intent to procure Tissue five days before the date the tissue will be requested so that the plaintiff may have the opportunity to object. Plaintiffs will not unreasonably withhold consent for Defendants to obtain tissue. Defendants do not need to obtain Plaintiffs' consent to inquire of a facility regarding the existence of Tissue, quantity of Tissue available, the need for special authorization to obtain its production, or other information regarding the Tissue. If there is no objection to the collection of tissue and the facility or healthcare provider in possession of Tissue requires Plaintiff to provide a specific release or authorization, Plaintiff shall promptly comply with any such reasonable request. Defendants shall promptly notify Plaintiffs upon receipt of Tissue.

5. For those cases where Plaintiffs do not already have Tissue in their possession pursuant to No. 3 above, they may proceed to obtain Tissue as long as there is a sufficient amount of tissue for the facility or healthcare provider to make two tissue sets available for each area of the body from which tissue was obtained; one for the Plaintiff and one for the

Defendants, collectively. If there is sufficient Tissue to make one tissue set available for Plaintiffs and one tissue set available for Defendants, collectively, Plaintiffs shall have no obligation to notify Defendants of Plaintiffs' intent to procure such Tissue; however, Plaintiffs shall promptly notify Defendants upon receipt of Tissue.

6. All parties understand that Tissue can be produced in various forms and that individual cases will vary as to what Tissue exists or the forms in which it will be made available. The parties also understand that there might not be sufficient Tissue for each party to conduct specialized staining. The procuring party shall confer with the facility or healthcare provider in possession of Tissue to determine whether there is sufficient Tissue to have recuts available for (a) the plaintiff and (b) the defendants collectively, without exhausting the tissue block. If there is insufficient Tissue for plaintiff and defendants (meaning all defendants collectively) to obtain their own samples, the parties agree to work cooperatively to reach agreement on how to proceed with whatever Tissue is available.

7. The procuring party shall notify all counsel in those instances where the producing facility has indicated that Tissue (in whole or in part) will only be made available for on-site inspection. In those instances, each party shall individually arrange for on-site inspection.

8. The parties understand that despite the exercise of reasonable care and adherence to the methods described herein, there is a risk that Tissue will be lost, damaged or destroyed in the process of transport or examination, or that the original tissue block might be exhausted. If the parties cannot reach agreement regarding the consequences of such an occurrence in a particular case, the parties may request Court intervention.

9. This Protocol is intended to establish procedures for the majority of instances in which Tissue is available. The parties recognize that there might be specific circumstances that arise in a particular case that are not addressed by the scope of this Protocol (e.g., Tissue in the possession of the NSF Registry or Tissue that is outside of Plaintiffs' custody or control). In that event, the parties agree to work cooperatively to facilitate to whatever extent might be possible the orderly receipt and review of Tissue by each side's respective experts.

III. **Confidentiality of Expert Review**

1. The parties agree that with respect to the Protocols described herein, the identities of each party's respective experts is confidential and shall not be subject to disclosure except as required by the Court or agreement of the parties.

2. Accordingly, each party shall designate a "point person" or "handler" for each expert. That individual will coordinate the expert's receipt, review and processing of Tissue. That person also will be responsible for maintaining chain of custody and for notifying counsel that Tissue is available for review by other interested parties.

IT IS SO ORDERED.

Dated: September 9, 2009

s/Dan A. Polster

Honorable Dan Aaron Polster
United States District Judge