UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: GADOLINIUM-BASED CONTRAST AGENTS PRODUCTS LIABILITY LITIGATION	Case No. 1:08GD50000 MDL No. 1909 Judge Dan Aaron Polster
This Document Applies to All Cases:	

CASE MANAGEMENT ORDER NO. 11:
DOCKET MANAGEMENT PROTOCOL FOR NON-ELIGIBLE TRIAL POOL CASES, INCLUDING PROTOCOL FOR PRODUCT IDENTIFICATION DEPOSITIONS AND LIMITED DISCOVERY ON ALLEGED NSF DIAGNOSIS AND INJURY

1. Scope and Intent of Order

A. This Order shall apply to all cases currently pending in MDL No. 1909, or that are hereafter transferred to these proceedings and/or filed directly with this Court (collectively, "the MDL proceedings"), except for the twenty cases selected by the parties as Eligible Trial Pool cases (as defined in Case Management Order ("CMO") No. 8, ¶ 1; *see also* ECF Nos. 257 & 258) or any case subsequently designated for trial either through further trial selection procedures in this MDL or remand of the case for trial in another venue.

B. This Order does not apply to the twenty cases selected as Eligible Trial Pool Cases or to any case subsequently designated for trial either through further trial selection procedures in this MDL or remand of the case for trial in another venue. For such cases, CMO Nos. 8 and 12 define the scope of and schedule for Core Case Specific Discovery.

C. Except as specifically provided, nothing in this Order shall modify the parties' fact sheet and third-party discovery obligations, the deadlines, or the limitations on case-specific discovery set forth in prior Orders of this Court, including CMO Nos. 5, 8, 9 & 10. This Order

does not govern (or permit) discovery of experts in Non-Trial Pool Cases. Furthermore, this Order does not address the timing, scope, or conduct of generic liability discovery.

2. MDL Master Case Charts

The parties are directed to continue to provide the Court with updated product identification charts at least two court days prior to each status conference. The chart shall contain product identification information on each individual case and shall now include basic diagnosis information. For each case, the chart shall include the following columns: (a) whether the plaintiff is living or whether the claim is one for wrongful death and/or survival; (b) whether the plaintiff alleges evidence of an NSF diagnosis as set forth in the PFS (see Paragraph 8(A) and 8(B) below); (c) the total number of GBCA scans identified by the plaintiff; (d) the total number of GBCA scans for which the plaintiff alleges there is evidence of product identification; and (e) on a defendant by defendant basis whether each defendant acknowledges that there is good faith substantiation that its GBCA product was administered to plaintiffs.

3. Plaintiff's Fact Sheets

Plaintiffs shall comply with the provisions of CMO 5 in providing Plaintiff's Fact Sheets (PFS) to the defendants and supplementing the PFS with information on product identification under CMO 9.

4. Manufacturer/Sponsor Defendant's Fact Sheets

The manufacturer/sponsors shall comply with the provisions of CMO 5 in providing Defendant Facts Sheets (DFS) to the Plaintiffs and supplementing the DFS in response to Supplemental PFS on product identification.

5. Defendant McKesson Disclosures

Within 30 days of the receipt of the information identified in Paragraph 3 of this Order, McKesson (a distributor defendant) if named in that action shall provide a Declaration to the parties confirming or denying any sales of a GBCA product to the facility in question during the three years preceding the procedures at issue. If the Declaration confirms that the Distributor Defendant supplied a GBCA product to the facility in question during the time period referred to above, the Declaration will include information stating, if such information is available: (i) the GBCA or GBCAs sold; (ii) the date of sale; (iii) the name and address of the facility; (iv) the customer account number; (v) the quantity of GBCA sold; and (vi) the billing document and number.

If the McKesson Defendant denies that it sold the GBCA to the facility at issue, the Declaration shall state that the Distributor Defendant has conducted a reasonable search of its customer sales and sales history databases and has confirmed that it could not locate any evidence that it supplied GBCA product to the facility in question, for the three (3) years preceding the procedure(s) at issue.

Plaintiff may take the deposition of the McKesson Declarant as appropriate, which deposition shall be held by telephone and limited only to the issues in the Declaration. Prior to noticing any depositions on the issue of product identification with respect to McKesson the parties shall meet and confer on any additional information requested by plaintiff regarding whether said information can be produced pursuant to a supplemental declaration. In the event that McKesson provides evidence (which may include the Declaration described above) that it did not distribute to any of the medical facilities where Plaintiff is alleged to have received a GBCA scan, the Plaintiff shall dismiss McKesson without prejudice within thirty (30) days.

However, the provisions of this paragraph shall not prevent McKesson from moving for summary judgment at any other time as provided by law.

6. <u>Product Identification Discovery</u>

A. *Plaintiff's Obligations*. If Plaintiff is unable to substantiate in good faith his or her allegations identifying the GBCA product(s) administered to Plaintiff, Plaintiff shall be required to conduct discovery to ascertain the identity of the manufacturers or sponsors. The method of discovery may be by any means permitted by the Federal Rules of Civil Procedure. These efforts shall commence promptly following service of Plaintiff's PFS to Defendant(s) pursuant to Section 3 of this Order. Plaintiffs shall diligently conduct discovery on product identification. Failure to do so may result in dismissal upon defendants' motion under Paragraph 7 D.

B. *Product Identification Depositions.* All parties are entitled to proper notice of depositions. The parties shall cooperate in the scheduling and taking of product identification depositions. The parties serving the deposition notice shall reasonably accommodate requests from third-party witnesses and opposing counsel to schedule the deposition at a mutually convenient time and place.

(1) Noticing and Scheduling Product Identification Depositions. The noticing of a product identification deposition shall state in the caption that "This Deposition is for the Purpose of Obtaining Information on the Issue of Product Identification." This Order does not apply to liability, causation or damage depositions.

(2) Third Party Health Care or Third Party Distributor Depositions. Plaintiff may take the product identification depositions of third party health care and third party distributor employees with knowledge of the identity of the brand of any GBCA administered to

plaintiff, as well as the custodian of records of any third party healthcare provider or distributor. Said depositions may be taken by telephone or in person and are limited in scope to the issue of brand name product identification. Depositions of McKesson employees with knowledge of the brand of any GBCA sold to the facility shall be conducted consistent with Paragraph 5.

a. Depositions Duces Tecum. Any deposition notice or subpoena accompanied by a request for production of documents or things should be taken five business days after the documents are produced, unless impracticable.

b. Deposition Canceling/Adjournments. The parties are encouraged to communicate in the canceling and moving of deposition dates. All parties should be given reasonable notice of the canceling or adjournment of a deposition. Notices of cancellation of depositions that involve air travel should be provided at least three days before the deposition takes place.

(3) Third Party Distributor Verification. In the event the DFS and discovery from the health care facility indicates that sales of the manufacturer's GBCA may have been conducted through a distributor, the plaintiff shall have the right to conduct product identification discovery with respect to the distributor identified. Prior to conducting said discovery, the plaintiff, through the PEC, shall meet and confer with the distributor's counsel to determine if there is a more efficient method of obtaining the information necessary with respect to product identification.

(4) Defendant Depositions. Any plaintiff seeking to depose an employee or former employee of a defendant for the purpose of discovering the brand of the specific GBCA administered to plaintiff must first submit in writing to that defendant the topics to be covered and the reason why plaintiff believes that employee would have information regarding product

identification. Said depositions may, but do not necessarily have to, be taken by telephone or by written examination. Said depositions are limited in scope to obtain potentially relevant evidence on the issue of product identification. The parties shall meet and confer and any unresolved issues regarding the deposition shall be raised with the Court by conference call. If representatives from Plaintiff's dispensing healthcare providers/facilities who allegedly administered the unknown brand of GBCA to Plaintiff have not been deposed for product identification purposes pursuant to this Section, Defendants may insist that such third-party depositions take place prior to depositions of Defendant witnesses for product identification purposes.

7. <u>Product Identification Related Dismissals of Manufacturer/Sponsor Defendants</u>

A. *Good Faith Substantiation of Product Identification.* Product identification may be substantiated in good faith by medical record, sworn affidavit, or testimony.

B. *Voluntary Dismissal of Manufacturer/Sponsor Defendants*. If (1) product identification is substantiated for all known GBCA scans by medical record, sworn affidavit, or testimony; and (2) the manufacturer/sponsor defendants whose products are implicated agree that the substantiation is in good faith, the plaintiff shall dismiss within seven (7) days the other manufacturer/sponsor defendants without prejudice and subject to the provisions of paragraph 7(E). However, if at any time prior to the deadline by which a voluntary dismissal is due under this Paragraph, a plaintiff provides defendants written notice that specific medical records are outstanding that may identify previously unknown scans, voluntary dismissals under this Paragraph shall not be required until 30 days following receipt of such records. In order to provide adequate notice of outstanding records under this Paragraph, plaintiff must list with specificity the institution or healthcare provider for which records are expected. For all

dismissals entered without prejudice pursuant to this CMO: (a) this Court retains jurisdiction for all purposes; and (b) to the extent that any GBCA-related claim is pursued as to a dismissed defendant, such claim must be filed in the same district court in which the case was originally filed or directly in the MDL.

C. *Evidentiary Significance*. No statement whether orally or in writing made in connection with product identification substantiation, as set forth in CMO 9 and in this Order shall be binding on any party or admissible at trial. A defendant may contest that its GBCA was used in a particular scan procedure even if it agreed there is good faith substantiation of product identification. A plaintiff may establish that another defendant's GBCA was used in a particular scan procedure even if they previously asserted that a different defendant's GBCA was used. Participation in the product identification process, as outlined in this Order, is not intended to nor does it change in any way the parties' burden of proof.

D. *Dismissal by Defendant Motion in Cases in which product identification remains unsubstantiated for any known GBCA scans.* In the event Plaintiff is not able to make good faith substantiation of product identification 120 days after receiving Part 1 of the DFS and completing the discovery as set forth in this Order, the non-identified named Defendants (including McKesson) may be dismissed with prejudice upon Defendant's motion. Defendants may also bring a motion to dismiss in cases in which the plaintiff's attorney has failed to diligently conduct product identification discovery as required under Paragraph 6 of this Order.

E. *Product Identification Amendments*. If a plaintiff seeks to add a previously dismissed defendant as a result of determining that either (1) a previously identified GBCA scan is actually the product of a dismissed defendant or (2) there is a good faith belief that a dismissed defendant is the manufacturer (sponsor) of a GBCA scan not previously identified, the defendant

may not oppose the motion within 120 days from the entry of the dismissal without prejudice for cases currently coordinated in the MDL except upon three grounds. First, the defendant may object to "shot gun" pleadings in which the plaintiff seeks to add all defendants without conducting due diligence as to which defendant is the manufacturer of the scan. Second, the defendant reserves the right to object to the naming of specific entity defendants as improper. Finally, the defendant reserves the right to object to new causes of action not previously asserted. For cases coordinated subsequent to the entry of this Order, these "bring back" procedures shall not exceed 120 days from the date of the dismissal of that defendant without prejudice. After 120 days following entry of any dismissal without prejudice, the plaintiff must bring a formal motion to add a previously dismissed defendant which motion will be granted only if plaintiff establishes that apparent injustice would result by the failure to allow the amendment.

8. NSF/NFD Diagnosis Discovery

Discovery relating to the NSF Diagnosis is stayed in the cases that are the subject of this order except as set forth in Paragraph A and B, below, or by further agreement of the parties or Order of this Court at a future date. Paragraph 3(3) of the Court's Minute Order dated April 8, 2009 (ECF No. 328) is hereby vacated by agreement of the parties. Instead, Defendants' opportunity to take diagnosis discovery is objectively based upon the allegations contained in the PFS and upon a good faith basis to question the NSF diagnosis in the individual case.

A. *Cases with No NSF Diagnosis.* In cases in which the PFS fails to allege a diagnosis of NSF/NFD (where Plaintiff does not answer "Yes" to PFS Section II Question 1), Defendant may conduct case specific discovery, including deposition discovery, to determine the nature and extent of the injuries claimed by the plaintiff to be attributed to defendants' products.

B. *Cases with an NSF Diagnosis But without a Biopsy Consistent with NSF*. In cases in which the PFS states either (a) that a plaintiff has not undergone a biopsy or (b) that a plaintiff has not had a biopsy consistent with NSF (where Plaintiff does not answer "Yes" to PFS Section II Questions 2 and/or 3), Defendant may depose the physician(s) responsible for diagnosing Plaintiff with NSF/NFD under the following conditions:

(1) Defendant's Request for Deposition. Defendant shall make the request for deposition in writing upon plaintiff's counsel and shall specifically reference this Order in the request and the good faith basis for the requested deposition. The request shall be served upon counsel for the plaintiff and upon Plaintiff's Liaison Counsel.

(2) Plaintiff's Response. Plaintiffs shall respond in writing to the request in no less than fourteen (14) days from receipt of Defendant's request for deposition. Failure to respond in a timely manner shall constitute waiver of any objection to the deposition. Plaintiff's response shall state that either (a) Plaintiff agrees to proceed with the deposition(s) under paragraph 8.B(3) below; (b) Plaintiff has scheduled a biopsy on a date certain within forty-five (45) days of receipt of Defendant's request and Plaintiff will provide the results to the defendants upon receipt; or (c) Plaintiff objects on the grounds that Plaintiff maintains there is no good faith basis to take the deposition because both (i) plaintiff's medical records that document the NSF diagnosis and (ii) a biopsy is medically unauthorized or the case is one for wrongful death. In cases in which the plaintiff objects to the deposition under subpart (c) the plaintiff must attach the specific medical records supporting the objection. Disputes regarding the good faith basis to take the deposition shall be resolved by the Court. Further, in cases in which Plaintiff has scheduled a biopsy under subpart (b), the Plaintiff shall promptly provide any biopsy results to the Defendants upon receipt thereof and amend the PFS in good faith.

(3) The NSF/NFD Diagnosis Deposition. The deposition of a treating physician under this section shall be limited in time to four (4) hours. The deposition shall relate to the clinical and pathological presentation of Plaintiff's alleged NSF diagnosis and injury and not be for any other purpose.

9. **Discovery and Trials.** All other case specific discovery not the subject of this Order is stayed. If either party seeks to set additional cases for trial or seeks to open further case-specific discovery, that request shall be subject to meet and confer efforts of the parties and further order of this Court, if necessary.

IT IS SO ORDERED.

Dated: **April 30, 2009**

s/Dan A. Polster

Honorable Dan Aaron Polster
United States District Judge