# 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. 9**

# A. <u>Introduction</u>

This Case Management Order is intended to govern certain procedures and dates for the selection of potential cases for bellwether trials. It is also intended to address the dismissal of individual Defendants from certain cases as provided herein.

# B. Cases That May Be Selected As An Eligible Trial Pool Case

To be potentially selected as an Eligible Trial Pool Case described by CMO 8, an individual case must meet four criteria: (1) The case must be on the list of cases that are included in the product identification project [Exhibit A]; (2) Counsel for the plaintiff and named Defendants all agree that based upon the currently available information there has been "good faith substantiation of product identification" of the specific GBCA product used in each procedure for which it has been identified that a GBCA was administered, each such case that meets the criteria shall be listed in the list of cases that may be selected as an Eligible Trial Pool Case described in Section G; (3) Each defendant entitled to dismissals under Section H below has been dismissed without prejudice in that

case; and (4) the Plaintiff alleges that the Plaintiff has a NSF/NFD diagnosis under Paragraph C of this Order.

#### C. <u>Cases Without A NSF/NFD Diagnosis</u>

For the purposes of this CMO and CMO 8, a Plaintiff, through notice provided to both Defendants and the PSC, can designate specific cases as being precluded from selection as an Eligible Trial Pool Case under CMO 8 on the grounds that the plaintiffs in such cases do not yet have a diagnosis of NSF/NFD. This designation must be made by December 19, 2008. In each such case the plaintiff has until January 19, 2009, to produce evidence of a diagnosis of NSF/NFD. Failure to do so shall, upon motion of the defendant, result in the dismissal of the case with prejudice, unless the plaintiff establishes either (1) that diagnostic testing itself would adversely affect his or her medical condition (e.g. the plaintiff's medical condition would make a biopsy dangerous), (2) that diagnostic testing is not medically appropriate or (3) that manifest injustice would occur. If the plaintiff established either (1) or (2) above and the case is not dismissed, then the case may be selected as an Eligible Trial Pool Case. All other cases for which there is confirmed product identification as defined in Section B(2) on Exhibit A may be selected as Eligible Trial Pool Cases.

## D. Evidentiary Significance

No statement whether orally or in writing made in connection with the Product Identification Project or this CMO shall be binding on any party or admissible for any purpose in these proceedings including trial. A defendant may contest that its GBCA was used in a particular scan procedure even if it agreed that plaintiff satisfied this Court's product identification requirement for this effort. A plaintiff may establish that another

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defendant's GBCA was used in a particular scan procedure even if they previously asserted that a different defendant's GBCA was used for the purpose of this project. Participation in the product identification process is not intended to nor does it change in any way the parties' burden of proof as to any issue including that related to identifying the specific GBCA administered to each plaintiff in each procedure in which a GBCA was used.

## E. <u>Product Identification Disputes</u>

If the parties cannot agree on whether a case has confirmed good faith substantiation of product identification for a particular procedure and whether or not that case should be included on the list of cases that may be selected as an Eligible Trial Pool Case, either party has the right to submit that dispute to the Court for resolution no later than December 15, 2008.

## F. <u>Trial Selection Date</u>

The current date of November 14, 2008 for the selection of Eligible Trial Pool Cases is vacated. The new date for the selection of Eligible Trial Pool Cases shall be January 23, 2009. All other dates set in CMO 8 are hereby extended 90 days. The parties shall prepare and submit a proposed supplemental CMO consistent with this Order within seven (7) days.

### G. List Of Cases That May Be Selected As An Eligible Trial Pool Case

By December 19, 2008, the parties shall prepare for the Court's review and approval a joint list of cases that may be selected by the parties as Eligible Trial Pool Cases that meet the criteria set forth in Sections B and C to this Order.

#### H. Dismissals without Prejudice in the Eligible Trial Pool Cases

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Each plaintiff whose case is on the list of cases that may be selected as an Eligible Trial Pool Case under Paragraph G of this Order, shall be required to dismiss, without prejudice, each sponsor or manufacturing defendant entity (and any other party whose liability is based on alleged exposure to the sponsor's GBCA), whose GBCA product was not confirmed as having been administered to plaintiff in any identified contrastenhanced scan(s).<sup>1</sup> The defendants seeking dismissal shall provide a list of said cases, including the identities of defendants to be dismissed without prejudice, to the plaintiffs counsel and the PEC by December 19, 2008. Each plaintiff shall have until January 16, 2009 to execute the dismissals without prejudice, unless that plaintiff, or the defendant discloses information under Section J.1., below, has served an amended Plaintiff Fact Sheet substantiating in good faith additional GBCA scans for which product identification is unknown or product identification as to a defendant who has sought dismissal. In the event any plaintiff fails to file an agreed dismissal of any defendant as required under this section, the trial selection date in Section F shall be stayed and continued until such time that all dismissals have been filed.

## I. <u>Rules Governing Eligible Trial Pool Cases</u>

The following rules govern the discovery of new information on product identification in the cases selected as an Eligible Trial Pool Cases under CMO 8.

1. <u>Newly Discovered GBCA Scans – Same Defendant.</u> In the event additional GBCA scans are discovered that are linked to the same manufacturer or sponsor defendant in the case, the case shall remain as an Eligible Trial Pool Case provided, however, that the additional GBCA scans are identified by March 23, 2009.

<sup>&</sup>lt;sup>1</sup> This Order does not apply to distributor defendants. Distributor defendants shall be addressed in a separate CMO.

Core Case Specific Discovery in such a case may be extended after the new scan is identified if good cause is shown by either party.

2. <u>Newly Discovered GBCA Scans-Different Defendant</u>. In the event additional GBCA scans are discovered that are linked to a different manufacturer or sponsor or the parties obtain information that a previously linked scan was, in fact, the scan of a different manufacturer or sponsor, the parties shall promptly provide notice to the Court that an additional or different manufacturer or sponsor is identified in at least one of the GBCA scans in the case. That case shall be de-designated as an Eligible Trial Pool Case unless the plaintiff specifically waives any claim that the additional/different manufacturer was responsible for the plaintiff's NSF/NFD. If the different manufacturer's or sponsor's GBCA scan is identified prior to March 31, 2009, the party who selected the case as an Eligible Trial Pool Case shall have the right to select a replacement Eligible Trial Pool Case. Core Case Specific Discovery on the replacement case will extend for five months after the replacement case is picked.

3. Amendment of Pleadings in Eligible Trial Pool Cases

The amendment of pleadings in the Eligible Trial Pool cases shall be governed by the same rules set forth in Paragraph J.3

## J. Rules Governing Cases Not Selected As Eligible Trial Pool Cases

#### 1. <u>Reciprocal Disclosure of Information Related to Product Identification</u>

If plaintiffs or defendants discover evidence demonstrating for scans listed on a plaintiffs' PFS that the brand of GBCA administered to that plaintiff for a scan listed on plaintiff's PFS is different than plaintiff has alleged in the PFS, as supplemented, that has

not been made available to the other party, that party shall disclose such evidence within 14 days.

#### 2. <u>Discovery</u>

Except as set forth in CMO 5, case-specific discovery is stayed in all cases from Exhibit A that have not been selected as Eligible Trial Pool Cases until February 8, 2009 except for *in extremis* depositions of gravely ill plaintiffs (with appropriate discovery depositions of such plaintiffs when practical). After February 8, 2009, the parties may initiate product identification discovery, except that written contention discovery, including requests for admissions, as to all parties, is stayed pending further order of this Court. All other case-specific discovery in these cases are subject to further meet and confer efforts of the parties and further order of this Court, if necessary.

#### 3. <u>Amendment of Pleadings And/Or Adding Parties</u>

#### a. Amendments prior to or on May 4, 2009

If prior to May 4, 2009 the plaintiff discovers additional GBCA scans or obtains information that a previously identified GBCA scan was improperly designated by the parties to the wrong manufacturer, then that plaintiff shall have the right to add the appropriate manufacturing or sponsor defendant under the following rules. The plaintiff must first amend the PFS with the new information and provide the amended PFS with the accompanying new information to each defendant, including the previously dismissed defendant. If the plaintiff identifies, or the remaining defendants provide information, that a specific manufacturing or sponsor defendant previously dismissed is responsible for a previously identified GBCA scan, that previously dismissed manufacturing or sponsor defendant shall be brought back into the case upon plaintiffs' motion, which manufacturing and sponsor defendants will not unreasonably oppose. If the plaintiff identifies a new GBCA scan, the plaintiff has an affirmative obligation to investigate which manufacturer is responsible for that scan and can only name those manufacturer(s) who products are in good faith linked to the scan after a meet and confer with that defendant.

#### b. Amendments after May 4, 2009

The deadline to amend pleadings and/or to add new parties, including adding defendants not previously named or defendants previously dismissed shall be May 4, 2009, as provided herein. After May 4, 2009, if the plaintiff attempts to add new defendants, including seeking to re-name a defendant previously dismissed, the plaintiff must establish that apparent injustice would result by the failure to allow the amendment.

#### 4. <u>Further Procedures Regarding Dismissals Without Prejudice</u>

With regard to all dismissals entered without prejudice in this MDL proceeding, whether already filed or to be filed herein: (a) this Court retains jurisdiction for all purposes; (b) to the extent that any GBCA related claim is pursued as to a dismissed defendant, such claim must be refiled in the same federal district court in which the case was originally filed or directly in the MDL, and (c) all dismissals of any defendant without prejudice convert to dismissals with prejudice at the time the jury receives the case for deliberation in the trial of a particular plaintiff's claims.

#### K. <u>Continuing Application of CMOs 5 and 8</u>

Each and every case, however categorized by the parties, shall be subject to all of the provisions of CMO Nos. 5 and 8 that are not inconsistent with this Order.

# IT IS SO ORDERED.

Dated: 11/26/08, 2008

/s/Dan Aaron Polster

Honorable Dan Aaron Polster United States District Judge