UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 1:13-md-2428-DPW**
This Document Relates to:	:	
All Cases	:	

FMCNA DEFENDANTS' MEMORANDUM IN SUPPORT OF REVISED PROPOSED CASE MANAGEMENT ORDER NO. [ ] (BELLWETHER CASE SELECTION)

Defendants Fresenius Medical Care Holdings, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc., (collectively "FMCNA") submit this Memorandum in Support of their Revised Proposed Procedural Order No. [ ] (Bellwether Case Selection).

INTRODUCTION

I. Factual Background

FMCNA has a two-pronged business. In one operating division, the Renal Therapies Group, it manufactures and distributes dialysis-related products such as dialysis machines, dialyzers (artificial kidneys), and dialysis solutions (dialysate). In a second, larger operating division, Fresenius Medical Services, it operates outpatient hemodialysis facilities and peritoneal dialysis home programs that provide dialysis to individuals with end-stage renal disease. This multi-district litigation concerns a component of dialysate, an acid concentrate product manufactured and distributed by the Renal Therapies Group operating division known

as GranuFlo® Dry Acid Concentrate ("GranuFlo").[1] GranuFlo is combined with a bicarbonate concentrate and water to create the dialysate used in hemodialysis treatments for end-stage renal disease patients. The Master Complaint alleges that GranuFlo is defectively designed and manufactured and that its use in hemodialysis treatments caused Plaintiffs or their decedents to suffer cardiac-related injuries and death. Plaintiffs further allege that the Fresenius Medical Services operating division of FMCNA failed to provide adequate warning to customers about GranuFlo's purported defect and alleged accompanying risks. FMCNA denies any such failure to provide adequate warning, and denies that GranuFlo is defective in any way. GranuFlo was cleared by the FDA in 2003 in its current iteration and has been on the market continuously since that time. It is currently used to provide millions of hemodialysis treatments every year.

As a practical matter, this litigation arose from a memorandum distributed by the chief medical officer of the Fresenius Medical Services operating division on November 4, 2011. See, *infra*, at 11. Although the plaintiffs' complaints encompass many individuals whose alleged injuries occurred prior to that date, the history of the litigation, the Master Amended Complaint, and the discovery sought by plaintiffs all make clear that the November 4, 2011 memorandum will be a key element of the litigation.

II. FMCNA's Revised Proposed Case Management Order

Defendant FMCNA's initial proposal, submitted to the Court on February 24, 2014, differed from the proposal submitted by the Plaintiffs' Executive Committee ("PEC") on February 21, 2014, in each of the following five areas:

[1] The Master Complaint refers to the acid concentrate product at issue in this litigation as "NaturaLyte and/or GranuFlo" but defines that term to mean "any dry acid concentrate, whether it be labeled by the Defendants as 'GranuFlo' or 'NaturaLyte' or both, yielding a concentration of acetate greater than 4 meq/L when put into solution for use in dialysis, by including sodium diacetate in the product's formulation." *See* Compl. ¶ 1 (Docket No. 471-1). While also manufactured by FMCNA, NaturaLyte is not a dry acid concentrate and does not provide more than 4 meq/L of acetate to the dialysate solution used in dialysis. Only GranuFlo is a dry acid concentrate product that contains 4 meq/L of sodium acetate and 4 meq/L of acetic acid (that together are present in the form of sodium diacetate) and, accordingly, GranuFlo is the only acid concentrate product at issue in this litigation.

1) Number of Cases to be Selected for Case-Specific Discovery and Bellwether Trials;
2) Date to Commence and Scope of Case-Specific Discovery;
3) Dismissal of Cases Selected for Case-Specific Discovery or Bellwether Trials;
4) Method of Selection of Cases for Bellwether Trials; and
5) Consent to Jurisdiction.

Based on further discussions with the PEC, FMCNA has revised its proposal in three significant ways. First, FMCNA proposes that all case-specific discovery commence on October 3, 2014, after the parties have submitted their complete list of cases selected for case-specific discovery to the Court. Second, FMCNA's revised proposal eliminates the strike-or-replace procedure contained in its initial proposal as a mechanism for maintaining a representative pool of bellwether cases in the event of a voluntary dismissal. Third, though FMCNA's revised proposal calls for the parties to select the same number of cases for case-specific discovery and bellwether trials as FMCNA's prior proposal, it incorporates a different procedure by which to select cases for bellwether trials from amongst the cases designated for case-specific discovery. Specifically, under FMCNA's revised proposal, at the conclusion of case-specific discovery, the parties will meet and confer to select ten representative cases for additional pre-trial discovery and bellwether trials. If the parties are unable to agree upon ten cases, they will each take turns striking one case at a time from the pool of twenty cases selected for case-specific discovery, until only ten cases remain.

As a result of the foregoing modifications to FMCNA's proposal, there remain only three areas of substantial disagreement between FMCNA's proposal and the PEC's proposal:

1) Scope of Case-Specific Discovery;
2) Dismissal of Cases Selected for Case-Specific Discovery or Bellwether Trials; and

3) Method of Selection of Cases for Bellwether Trials.[2]

ARGUMENT

"The purpose of adopting a bellwether approach is to assess the values of the claims at issue, develop a relevant body of law, and in doing so to provide guidance to parties pursuing settlement." In re Methyl Tertiary Butyl Ether Products Liability Litigation, No. 00-md-1898, 04-civ-3417, 2010 WL 1328249, at *4 (S.D.N.Y. April 5, 2010) (citing In re Chevron U.S.A., Inc., 109 F.3d 1016, 1019 (5th Cir. 1997); see MANUAL FOR COMPLEX LITIGATION § 22.315 (4th ed. 2004)). If bellwether trials are to reliably and effectively serve a "value ascertainment function for settlement purposes or [] answer troubling causation or liability issues common to the universe of claimants," they must "ha[ve] as a core element representativeness." Chevron, 109 F.3d at 1019. "To obtain the most representative cases from the available pool, a judge should…limit the selection to cases that the parties agree are typical of the mix of cases. The more representative the test cases, the more reliable the information about similar cases will be." MANUAL FOR COMPLEX LITIGATION § 22.315 (4th ed. 2004); see also Morgan, et al. v. Ford Motor Co., et al., Civil Action No. 06-1080 (JAP), 2007 WL 1456154, at *7 (D.N.J. May 17, 2007) ("[T]o ensure the usefulness of bellwether plaintiffs to the process and the parties' due process rights, representative plaintiffs must be chosen."). Indeed, "[i]t is critical to a successful bellwether plan that an honest representative sampling of cases be achieved," In re Yasmin and Yaz Marketing, Sales Practices and Products Liability Litigation, No. 09-md-02100, 2010 WL 4024778, at *1 (S.D.Ill. Oct. 13, 2010)), because "[l]ittle credibility will be attached to th[e bellwether] process, and it will be a waste of everyone's time and resources, if cases are selected

[2] In addition, the PEC's proposal provides that, prior to selecting cases for case-specific discovery, FMCNA shall provide certain laboratory data to the PEC for twenty-five plaintiffs/decedents of the PEC's choosing. Such laboratory data is contained in the medical records, which, pursuant to both parties' proposals, must be produced before a case becomes eligible for selection for case-specific discovery. Accordingly, it is unnecessary to address this issue in the context of the bellwether process.

which do not accurately reflect the run-of-the-mill case." Id. at *2.

FMCNA's proposal is aimed at maximizing the representativeness of the cases ultimately tried as bellwethers so as to "facilitate the resolution of all claims" in this MDL and thereby fulfill the "fundamental purpose"[3] of a bellwether approach in three ways: (1) it permits the parties to pursue fulsome case-specific discovery; (2) it provides a mechanism for addressing the asymmetrical ability of the Plaintiffs to shape the bellwether pool through voluntary dismissals; and (3) it ensures that the cases selected for bellwether trials will be representative of the broader MDL by permitting the parties to strike outlier cases from the bellwether pool and by entrusting the Court to determine the order of bellwether trials.

I. Scope of Case-Specific Discovery

FMCNA's proposal provides that each party may conduct up to seven depositions in any case selected to undergo case-specific discovery, for a maximum of fourteen depositions per case, without limitation as to the identity of the deponents. The PEC's proposal would limit the parties to seven depositions total per case and would restrict the potential deponents to five specified categories of witnesses.

Because the cases in this MDL each contain different combinations of characteristics that are relevant to the claims raised by the Master Complaint, the parties cannot ensure that the cases ultimately selected for bellwether trials will involve plaintiffs that are representative of a critical mass of the plaintiffs in this litigation without first conducting sufficiently broad discovery to instill confidence that the major variables present in the MDL will be properly represented. All of the plaintiffs in this MDL allege that they or their decedents suffered injuries, including cardiac arrest/death, as a result of receiving hemodialysis treatment using GranuFlo. Beyond this

[3] Self v. Illinois Central Railroad, et al., Nos. Civ. A. 96-4141, Civ. A. 97-0007, Civ. A. 97-0375, 2000 WL 14682, at *2 (E.D.La. Jan. 6, 2000).

baseline similarity, however, the plaintiffs/decedents in this MDL vary with respect to many characteristics, some of which will have a direct bearing on the claims set forth in the Master Complaint. For example, the plaintiffs/decedents in this MDL cover a broad age range and lived a wide variety of lifestyles. In addition, a substantial majority of the plaintiffs/decedents in this litigation suffered from at least one, and likely more than one, co-morbid medical condition. These variables may interact in a given case so as to render the case an outlier for bellwether purposes. And, importantly, many of these variables are not adequately addressed by either the Plaintiff Fact Sheets or individual medical records. Accordingly, broad discovery is necessary for the parties to determine which cases involve plaintiffs that are representative of a sufficient number of plaintiffs in the MDL to be of predictive value in resolving other cases.

By placing strict limitations on both the number of depositions and the categories of permissible deponents, the PEC's proposal will hamstring the parties' ability to explore the factual underpinnings of complex cases adequately before having to determine whether they are sufficiently representative to be tried as a bellwether. While FMCNA agrees that the categories of deponents set forth in the PEC's proposal may be highly relevant to certain cases, FMCNA also believes that there will be cases in which deponents from the PEC's limited categories will have little relevant knowledge. For such cases, it will be essential for the parties to have the ability to exercise their judgment to depose witnesses who have the most relevant knowledge, regardless of what category they might fall into. For example, many of the plaintiffs/decedents in this MDL suffered from at least one co-morbid medical condition, which was treated by a specialist and which will likely be important to understand for purposes of a causation analysis. Nonetheless, pursuant to the PEC's proposal, the parties would not be permitted to depose that specialist during case-specific discovery.

FMCNA also recognizes, however, that engaging in case-specific discovery is a costly and time-consuming endeavor. As such, FMCNA agrees that there must be some reasonable limitations imposed on the scope of discovery so as not to undermine the efficiencies gained by implementing a bellwether process in the first instance. FMCNA's proposal permits the parties each to conduct no more than seven depositions of witnesses that they believe will have pertinent knowledge based upon the preliminary exchange of Fact Sheets and medical records. This proposal, when combined with the tight timeframes proposed for case-specific discovery, appropriately balances the parties' desire to keep the discovery process cost-effective and time-efficient against the need to conduct discovery broad enough to ensure that the bellwether trial pool accounts for all of the major variables present in this MDL, while excluding outliers. Any additional artificial restrictions on the parties' ability to discover material facts are simply unnecessary.

II. Dismissal of Cases Selected for Case-Specific Discovery or Bellwether Trials

In the event that the PEC voluntarily dismisses a case selected for case-specific discovery and/or a bellwether trial, FMCNA's proposal requires the dismissal to be with prejudice. Moreover, FMCNA's proposal permits FMCNA to elect to choose not to replace the dismissed case or to select a replacement case of FMCNA's choosing. For any case selected by FMCNA as a replacement, there shall be not less than 150 days of case-specific fact discovery from the date the replacement selection was made.

This procedure for addressing voluntary dismissals is necessary to safeguard against the possibility that "advocacy [may] trump[] altruism" in the trial selection process, thereby rendering the pool of bellwether trials unrepresentative and of little predictive value. In re Yasmin and Yaz Marketing, Sales Practices and Products Liability Litigation, No. 09-md-02100,

2010 WL 4024778, at *2 (S.D.Ill. Oct. 13, 2010). More specifically, FMCNA's proposed procedure will curb the ability of the PEC to shape the bellwether trial pool unilaterally by voluntarily dismissing weak cases after discovery in three ways. First, it requires that any dismissals be made with prejudice, such that the PEC cannot dismiss cases in order to remove them from the bellwether trial pool, while leaving open the possibility of refiling them at a later date. Second, it provides a means to ensure that the bellwether pool remains representative by entrusting the choice of a replacement case to the party that does not have the ability to voluntarily dismiss and, therefore, cannot exercise the same kind of unilateral control over the bellwether trial pool. Third, it guarantees sufficient time for case-specific discovery prior to trial for any case selected as a replacement for a dismissed case, regardless of how late in the discovery period the dismissal takes place.

The PEC may assert that there is equal danger in FMCNA selectively offering to settle Plaintiffs' strongest cases so as to skew the bellwether trial pool in FMCNA's favor, but any such danger is effectively mitigated by the fact that settlement, as opposed to voluntary dismissal, is not an action that FMCNA can take unilaterally. Plaintiffs will, of course, only accept a settlement offer that attaches a fair value to a case, and a settled case can still be of predictive value for other cases in the MDL. In this way, selective settlement furthers, rather than undermines, the purposes of the bellwether process. Moreover, paragraph 7 of FMCNA's proposal adequately protects against the possibility that selective settlement could result in an unrepresentative bellwether trial pool by requiring the parties to agree, as part of any settlement, to the effect such settlement will have on the remaining pool of cases identified for case-specific discovery or bellwether trials.

III. Method of Selection of Cases for Bellwether Trials

A. Selection of Bellwether Trials

With respect to the method for selecting cases for bellwether trials, FMCNA's proposal differs from the PEC's proposal in two significant ways. First, pursuant to FMCNA's proposal, the parties will meet and confer to select ten cases for bellwether trials from amongst the twenty cases selected for case-specific discovery. If the parties are unable to agree upon ten cases, they will each take turns striking one case at a time from the pool of twenty cases until ten cases remain. Second, FMCNA's proposal places four parameters on the parties' selections of representative cases for bellwether trials. Specifically, in exercising their alternating strikes, the parties must ensure that the final trial pool includes at least one case from each of the following categories: (1) cases in which the alleged injury occurred between November 4, 2011 and March 29, 2012, (2) cases in which the alleged injury occurred prior to November 4, 2011, (3) cases in which the injured person received his or her last outpatient dialysis treatment prior to the date of the alleged injury or death at a clinic operated by FMCNA, and (4) cases in which the injured person received his or her last outpatient dialysis treatment at a clinic operated by a provider other than FMCNA.

As to the first of these differences, the procedure of alternating strikes envisioned by FMCNA's proposal will act as a necessary safety valve to ensure that no unrepresentative case remains in the pool of cases for initial trials, simply because it is particularly attractive to one side. See, e.g., In re Yasmin and Yaz Marketing, Sales Practices and Products Liability Litigation, No. 09-md-02100, 2010 WL 4024778, at *2 (S.D.Ill. Oct. 13, 2010) ("The Court finds that the process that will provide the best sampling of cases will be one that allows both sides of this litigation to have a role in selecting cases, along with a veto process in the later

stages of the litigation, in case advocacy has trumped altruism and both sides have decided to ignore my efforts at objectivity."). Indeed, a nearly identical procedure for selecting initial trials was employed recently by Massachusetts Superior Court Associate Justice Kottmyer in In re Specially Assigned Mesh Implants Cases. See MICV2011-03750, Procedural Order No. 4.

Incorporating this type of safety valve into the method for selecting initial trials is essential because,

> [n]o matter how diligently the attorneys or the transferee court fill the trial-selection pool, the possibility will always remain that…an unrepresentative case or a grossly unfavorable case will wind up in the trial-selection pool. By permitting the attorneys to strike…cases, the transferee court can minimize the chance that one of these outliers is selected as a bellwether trial, without having to disturb the preordained method of trial selection. In this way, if the abnormal case rears its head, the attorneys are equipped to deal with it on their own, without seeking court intervention.

See Eldon E. Fallon, Jeremy T. Grabill & Robert Pitard Wynne, *Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323, 2365 (2008).

As to the second distinction between the proposed methods for selecting cases for bellwether trials, placing substantive parameters on the parties' trial selections is necessary to ensure that the pool of bellwether trials accurately reflects the primary categories of cases that comprise the MDL, and presents as many common issues as possible for resolution, so as to maximize the predictive value of the bellwether process. See In re Yasmin and Yaz Marketing, Sales Practices and Products Liability Litigation, No. 09-md-02100, 2010 WL 4024778, at *2 (S.D.Ill. Oct. 13, 2010) (citing Fallon, Grabill & Wynne, *supra*, 2349-51) ("Most modern plans seem to disfavor random selection in order to have better control over the representative characteristics of the cases selected."). As indicated above, Plaintiffs make two types of claims in the Master Complaint. First, Plaintiffs assert claims based on allegations that GranuFlo is defectively designed and manufactured and that its use in hemodialysis treatments caused them

or their decedents to suffer injuries, including cardiac arrest and death. Second, Plaintiffs assert claims based on allegations that FMCNA failed to provide adequate warning to customers about GranuFlo's purported defect and alleged accompanying risks. Though most, if not all, cases involving the use of GranuFlo will raise the issues pertinent to the defective design and manufacture claims, only certain categories of cases will raise the issues pertinent to the Master Complaint's failure to warn claims.

More specifically, the Master Complaint alleges that FMCNA knew of an alleged link between the use of GranuFlo and cardiopulmonary arrest caused by alkalosis on November 4, 2011, as a result of a memo issued by its chief medical officer at the time, Dr. Raymond Hakim. See Master Compl. ¶¶ 194-96. The Master Complaint further alleges that, while this memo was circulated to FMCNA clinics upon its issuance, the information was withheld from non-FMCNA clinics until FMCNA issued a product notification on the topic on March 29, 2012. Id. at ¶¶ 198-202. In light of these allegations, a plaintiff/decedent who allegedly suffered an injury between November 4, 2011, and March 29, 2012, may be differently situated than a plaintiff/decedent who allegedly suffered an injury before that period with respect to the Master Complaint's failure to warn claims. These allegations similarly make clear that a plaintiff/decedent who was treated at a clinic owned by FMCNA may be differently situated with respect to the Master Complaint's failure to warn claims than a plaintiff/decedent who was treated at a clinic owned by an unrelated entity. Accordingly, in order to test the strength of the Master Complaint's failure to warn claims in a manner that will allow for extrapolation to the MDL as a whole, the bellwether trials should include cases from each of the four categories delineated above.

In contrast, the PEC proposal would permit each party simply to select three cases for bellwether trials from amongst the seven cases that it identified for case-specific discovery,

without any safeguards to prevent either party from picking outlier cases and without any parameters for selection to ensure that the bellwether trials resolve a sufficient number of issues common to a critical mass of the plaintiffs in this MDL. Such a procedure "is not a bellwether trial. It is simply a trial of [three] of the 'best' and [three] of the 'worst' cases contained in the universe of claims involved in this litigation. There is no pretense that the [six] cases selected are representative" of the MDL in its entirety. In re Chevron U.S.A., Inc., 109 F.3d 1016, 1019 (5th Cir. 1997).

B. Order of Bellwether Trials

Concerning the order of bellwether trials, FMCNA's proposal provides that the Court shall determine the order of trials after briefing and argument. In keeping with the underlying goals of the bellwether process, FMCNA suggests that it makes sense for the Court to determine objectively, with the benefit of briefing from the parties, which case should be tried first based upon the number of issues that the case will raise for resolution and the predictive value that the case will confer on other cases in the MDL. See, e.g., In re Yasmin and Yaz Marketing, Sales Practices and Products Liability Litigation, No. 09-md-02100, Case Management Order No. 32 ("[A]fter the exercise of any vetoes, the parties shall submit the names of the remaining PE [Pulmonary Embolism] cases to the Court without indicating which party picked which case. Also on May 2, each party shall provide to the Court and to the other party a factual summary concerning each case submitted to the Court for trial selection, so that the Court receives two submissions on each case…. Upon receiving th[is] information…, the Court will select one PE case to be the first case to be tried and the requisite number of PE cases to be backups in case the first case cannot be tried for some reason."); In re Chantix, No. 09-md-2092, Pretrial Order No. 9 (After briefing "the Court will select eight (8) individual Plaintiffs from the Discovery Pool to be

eligible for trial ("the Trial Pool")…. When the Court selects the eight Trial Pool cases, the Court will designate two (2) of those cases that are suicide/attempt cases (one of which was suggested for inclusion in the Trial Pool by Plaintiff's counsel and one by Defendant's counsel) to be the first cases set for trial.").

In contrast, the PEC's proposal provides that, because Plaintiffs bear the burden of proof, the Court will first try a case selected by the PEC, with cases alternating between the parties thereafter. It simply does not follow from the fact that Plaintiffs bear the burden of proof within the confines of a given case that the PEC should, therefore, be entitled to decide unilaterally which case should be tried first from amongst those selected for bellwether trials.

CONCLUSION

In light of the foregoing, FMCNA respectfully requests that the Court adopt and enter FMCNA's Revised Proposed Case Management Order No. [ ] (Bellwether Case Selection).

Respectfully submitted,

/s/ William H. Kettlewell_____
William H. Kettlewell (BBO # 270320)
Maria R. Durant (BBO # 558906)
Sara E. Silva (BBO #645293)
COLLORA LLP
100 High Street, 20th Floor
Boston, MA 02110
(617) 371-1000
(617) 371-1037 (fax)
wkettlewell@collorallp.com
mdurant@collorallp.com
ssilva@collorallp.com

Pending Admission Pro Hac Vice
Kevin C. Newsom
Leigh Anne Hodge
BRADLEY ARANT BOULT CUMMINGS LLP
One Federal Place
1819 Fifth Avenue North
Birmingham, AL 35203
(205) 521-8000
(205) 521-8800 (fax)
knewsom@babc.com
lhodge@babc.com

James F. Bennett
Megan S. Heinsz
DOWD BENNETT LLP
773 Forsyth Blvd., Suite 1410
St. Louis, MO 63105
(314) 889-7300
(314) 889-7302 (fax)
jbennett@dowdbennett.com
mheinsz@dowdbennett.com

Juanita Brooks
FISH & RICHARDSON
12390 El Camino Real
San Diego, CA 92130
(858) 678-5070
(858) 678-5099 (fax)
brooks@fr.com

Counsel for FMCNA

Dated: March 14, 2014

CERTIFICATION OF SERVICE

I, William H. Kettlewell, hereby certify that a true and correct copy of the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on March 14, 2014.

/s/ William H. Kettlewell

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 1:13-md-2428-DPW**
This Document Relates to:	:	
All Cases	:	

[FMCNA DEFENDANTS' REVISED PROPOSED]
CASE MANAGEMENT ORDER NO. [___]

(BELLWETHER CASE SELECTION)

The Court adopts this bellwether case selection protocol with the intent that the process of selecting and preparing individual cases for trial be both instructive and meaningful to the resolution of all cases in this MDL.

1. Selecting Cases For Case-Specific Discovery

The Plaintiffs Executive Committee ("PEC") and the Fresenius North America Defendants ("FMCNA")[1] shall each designate ten (10) cases, for a total of twenty (20) cases, to undergo "Core Case-Specific Discovery" pursuant to this Case Management Order. Core Case-Specific Discovery may only be conducted on cases that are "Eligible Cases for Selection" as defined in paragraph 2 below.

The PEC and FMCNA shall submit the complete list of twenty (20) cases selected for Core Case-Specific Discovery to the Court by October 3, 2014.

2. Eligible Cases for Selection

If bellwether trials are to produce reliable information about the other cases in this MDL,

[1] The term "FMCNA" refers to the following named defendants: Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc.

the specific plaintiffs and their claims should be representative of the range of cases pending in this MDL. The initial pool of cases that the parties shall identify for Core Case-Specific Discovery should consist of cases involving representative issues in this litigation such as:

(a) The cause or causes of the injuries incurred and alleged in the Master Complaint;

(b) Whether the last outpatient dialysis treatment received prior to the alleged injury was provided by a clinic operated by FMCNA or by a clinic operated by some other provider;

(c) The date of the injury incurred and alleged, especially whether the injury occurred or is alleged to have occurred before or after November 4, 2011;

(d) The time elapsed from the last outpatient dialysis treatment to the alleged injury; and

(e) Any other issues deemed representative of the litigation by the parties.

To be considered an Eligible Case for Selection, Plaintiff Fact Sheets, medical records required by the Plaintiff Fact Sheets, and Defendant Fact Sheets shall have been served by the parties as described in Case Management Order No. 6 and all medical records subject to Case Management Order No. 3 shall have been produced by FMCNA.

3. Consent to Personal Jurisdiction and Venue

For each case selected for Core Case-Specific Discovery, the Plaintiff and FMCNA shall be deemed to have consented to personal jurisdiction and venue in the District of Massachusetts such that the case can be tried in the District of Massachusetts in the event it is selected for bellwether trial. For those cases selected for bellwether trial(s) that name defendants in addition to FMCNA, the Plaintiffs shall dismiss the non-FMCNA defendants unless those defendants have admitted or otherwise consented to personal jurisdiction and venue in the District of Massachusetts such that the case can be tried in the District of Massachusetts.

4. Core Case-Specific Discovery

Core Case-Specific Discovery is the case-specific discovery that can be performed only for the twenty (20) cases selected under this Case Management Order, or in a replacement case selected by FMCNA as provided below in the event of a voluntary dismissal by the Plaintiff. Core Case-Specific Discovery may commence on October 3, 2014, and shall be completed on all cases selected by the PEC and FMCNA by February 27, 2015, except as described in paragraph 5 below.

The Core Case-Specific Discovery consists of the exchange of Plaintiff and Defendant Fact Sheets and medical records, and is otherwise limited to the following for each case selected:

(a) No more than seven (7) depositions each for (i) the PEC and Plaintiff together and (ii) FMCNA and any other defendant(s) together. These depositions may include but will not be limited to:

- The person alleged to have been injured; the spouse or other family member of the injured person; the Plaintiff; or a representative of the allegedly injured person's estate;
- The allegedly injured person's cardiologist or similar specialist, or primary care physician, at the time of injury;
- The allegedly injured person's treating nephrologist at the time of injury;
- The Medical Director, attending nurse, and/or staff of the outpatient dialysis clinic where the allegedly injured person last dialyzed on an outpatient basis prior to the time of the injury; and
- Any percipient witnesses to the alleged injury or end-of-life event.

(b) A total of ten (10) case-specific Interrogatories served by each party;

(c) A total of ten (10) case-specific Requests for Documents served by each party; and

(d) A total of ten (10) case-specific Requests for Admissions served by each party.

5. Selection of Cases for Further Pre-Trial Discovery and Bellwether Trials

By March 16, 2015, the PEC and FMCNA shall meet and confer to select ten (10) of the twenty (20) cases that underwent Core Case-Specific Discovery for further pre-trial discovery and bellwether trials. If the PEC and FMCNA are unable to agree upon ten (10) cases for bellwether trials, they shall each take turns striking one case at a time from the pool of twenty (20) cases until ten (10) cases remain, provided that the final pool of ten (10) cases for further pre-trial discovery and bellwether trials shall include:

(a) One case in which the alleged injury occurred between November 4, 2011 and March 29, 2012;

(b) One case in which the alleged injury occurred prior to November 4, 2011;

(c) One case in which the injured person received his or her last outpatient dialysis treatment prior to the date of alleged injury or death at a clinic operated by FMCNA; and

(d) One case in which the injured person received his or her last outpatient dialysis treatment prior to the date of alleged injury or death at a clinic operated by a provider other than FMCNA.

Once the PEC and FMCNA have identified their cases for bellwether trials, further discovery can be conducted in each of the ten (10) cases to prepare the cases for trial. The PEC and FMCNA shall work cooperatively to prepare a protocol, by way of a proposed Case Management Order, which will set forth deadlines for completion of additional fact witness discovery in the ten (10) bellwether cases, not to exceed an additional one-hundred fifty (150)

days of case-specific fact discovery. The Case Management Order shall also set forth additional deadlines for expert discovery, and dispositive and *Daubert* motions.

The Court shall determine the order of trials after briefing and argument. The PEC and FMCNA anticipate that the first bellwether case will be ready for trial in July 2015.

6. Dismissal of Cases Selected for Core Case-Specific Discovery or Bellwether Trials

The Court recognizes that the PEC may elect to dismiss a case after it is selected for Core Case-Specific Discovery and/or a bellwether trial. The Court further recognizes that no reciprocal ability to dismiss a case exists for defendants. In order to ensure a balanced pool of cases for bellwether trials, the following shall apply where a case identified for Core Case-Specific Discovery or bellwether trial is dismissed voluntarily:

(a) The dismissal shall be with prejudice; and

(b) With respect to any case dismissed by the PEC, FMCNA may elect either not to replace the dismissed case or, alternatively, to select a replacement case of FMCNA's choosing; and

(d) For any case chosen by FMCNA as a replacement, there shall be a total of not less than one-hundred fifty (150) days of case-specific fact discovery regardless of the date on which the case is selected as a replacement, and all other deadlines otherwise applicable to such cases under this Order shall be modified to permit such fact discovery period.

7. Resolution of Cases by Settlement

If the parties agree to settle a case selected by either the PEC or FMCNA for Core Case-Specific Discovery or bellwether trial, the parties shall agree, as part of the settlement, to the

effect such settlement shall have on the remaining pool of cases identified for Core Case-Specific Discovery or bellwether trial.

8. **Single-Plaintiff Trials**

Any cases that are ultimately tried shall be tried individually, with a single Plaintiff per trial.

SO ORDERED this _____day of _____, 2014.

_____

DOUGLAS P. WOODLOCK, J.