

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

In re: Fresenius GranuFlo/NaturaLyte)	
Dialysate Products Liability Litigation)	No. 1:13-MD-02428-DPW
)	
This Document Relates To:)	
)	
ALL CASES)	

**FMCNA AND PEC’S JOINT BRIEF IN SUPPORT OF PROPOSED
INITIAL BELLWETHER TRIAL CASES**

I. INTRODUCTION

The intent of the GranuFlo/NaturaLyte MDL bellwether process has been to identify individual cases that are representative of both the allegations of the Master Complaint and the docket as a whole so that the initial bellwether trials can be used to guide the resolution of the remaining claims through dispositive motions, trial, or settlement. *Manual for Complex Litigation* (Fourth) § 22.315 (2004).¹ In other words, the cases selected for trial should satisfy

¹ Federal courts have the authority to conduct a “bellwether trial” under Federal Rule of Civil Procedure 42(b), which provides in part as follows: “For convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one more separate issues, [or] claims” Fed.R.Civ.P. 42(b). Historically, the “[t]erm bellwether is derived from the ancient practice of belling a wether (male sheep) selected to lead the flock. The ultimate success of the wether selected to wear the bell was determined by whether the flock had confidence that the wether would not lead them astray, and so it is in the mass tort context.” *In Re: Methyl Tertiary Ether (MTBE) Prods. Liab. Litig.*, Case No. 00-1898, 2007 WL 1791258, at 1 (S.D.N.Y. June 15, 2007). “The notion that the trial of some members of a large group of claimants may provide a basis for enhancing prospects of settlement or for resolving common issues or claims is a sound one that has achieved general acceptance by both bench and bar.” *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir.1997). If “bellwether trials or test cases are to produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases.... Test cases should produce a sufficient number of representative verdicts and settlements to enable the parties and the court to determine the nature and strength of the claims, whether they can be fairly developed and litigated on a group basis,

two criteria: *First*, they should be instructive to the parties and to the Court in evaluating issues. *Second*, they should be representative of other cases in the MDL. This is particularly important in an MDL like this where the cases selected, and the result of any trial of a bellwether case is expected to help the parties and the Court evaluate the entirety of the MDL docket.

To that end, FMCNA and the PEC have met and conferred to identify and jointly propose to the Court two cases for the initial trials on January 11 and February 16, 2016 that present facts and issues calculated to assist the Court and the parties, to the extent possible at this stage of litigation, in final resolution of this MDL.

The foundational CMO-10, negotiated by the parties and approved by the Court prior to discovery, provided that each party's selection of ten (10) cases to undergo further pre-trial discovery and bellwether trials should include at least:

- a. One case in which the alleged injury occurred between November 4, 2011 and March 29, 2012 (corresponding to the date range of the FMCNA November 4, 2011 internal memorandum prepared by Dr. Raymond Hakim entitled "RE: Dialysate Bicarbonate, Alkalosis, and Patient Safety," (hereafter the "November 2011 Memorandum") and the FDA 'recall' date);
- b. One case in which the alleged injury occurred prior to November 4, 2011 (which would test a case based on Defendants' knowledge preceding the date of the "November 2011 Memorandum");
- c. One case in which the injured person received his or her last outpatient hemodialysis treatment prior to the date of the alleged injury or death at a clinic operated by FMCNA, as opposed to DaVita or other dialysis service provider; and

and what range of values the cases may have if resolution is attempted on a group basis. The more representative the test cases, the more reliable the information about similar cases will be." *Manual for Complex Litigation* (Fourth) § 22.315 (2004). Thus, "representativeness" is a "core element" that must be present for a bellwether trial "to achieve its value ascertainment function for settlement purposes or to answer troubling causation or liability issues common to the universe of claimants." *Chevron*, 109 F.3d at p. 1019.

- d. One case in which the injured person received his or her last outpatient hemodialysis treatment prior to the date of the alleged injury or death by a dialysis service provider other than FMCNA.

The factors identified in CMO-10, and the issues for which they stand, related to theories of general liability and focused on the “liability timeline” alleged in the Master Complaint, and particularly whether or not the last outpatient hemodialysis treatment occurred in an FMCNA clinic. The parties continue to consider these factors centrally important to bellwether trial selection.

The bellwether selection process and consequent patient-specific discovery, combined with the processing and exchange of fact sheets, have served to highlight a different set of specific causation factors and issues that, in terms of numbers of pending cases, are at least as significant for overall litigation resolution as the general liability factors that underlay CMO-10. The November 2011 Memorandum revolved around a statistical analysis of cardio pulmonary arrests occurring in the clinic and the last, monthly pre-dialysis serum bicarbonate test results of the patients arresting in the clinic versus patients who did not arrest during treatment. A number of the Phase II bellwether cases, however, involve patients who (1) did not arrest in the clinic and (2) did not have monthly pre-dialysis serum bicarbonate levels within the range for heightened risk described in the November 2011 Memorandum.

The patient-specific discovery has thus raised specific causation factors and issues, not contemplated in CMO-10 that should be accounted for in the bellwether trial selection process to make the process meaningful and to give it a likelihood of success. The additional factors include:

- a. Whether the alleged injury (arrest) occurred during, or closely following the last outpatient dialysis treatment;

- b. The patient's last monthly pre-dialysis serum bicarbonate result as compared with the ranges of concern raised by the November 2011 Memorandum; and
- c. Whether the last outpatient dialysis treatment utilized GranuFlo versus NaturaLyte.

The parties' joint recognition of these additional factors makes it impossible to identify any two of the existing ten bellwethers that could be said to encompass all of the above factors. Nonetheless, the parties have agreed, and propose that two cases be selected as the initial vehicles for the trials on January 11 and February 16 2016. These two cases (*Lastorka* and *Dial*) taken together will, in the parties' view, maximize the 'learning' that can be achieved from the first two trials.

These two cases, along with the other eight remaining Phase II bellwether cases, are further described below.

II. DESCRIPTION OF JOINTLY PROPOSED CASES: *LASTORKA* AND *DIAL*.

As the Court may predict, the parties are not in agreement as to the material facts in each of these two cases, and each sides' case specific experts have reached contrasting opinions as to the cause and nature of death in each case.² Nonetheless, to make this joint proposal, FMCNA and the PEC have used their best efforts to identify relatively objective "core" data points of each case as applied to the "representativeness" factors above, set forth below in the following charts:³

² Just as the parties remain in dispute about the general liability and causation issues as alleged in the Master Complaint.

³ The parties agree that the "core" data points set forth herein for each of the bellwether cases reflect the parties' best efforts, as of the time of this filing, to describe factors considered relevant to the Court's "representativeness" determination but agree that the "core" data points shall not be considered an admission, relied upon or otherwise used by either party in this litigation for purposes other than this joint recommendation.

Case Name: Lastorka v FMCNA	Docket No.: 13-13066
Decedent	Jackie Lastorka
Plaintiff	Edward Lastorka
Date of Decedent's Birth	9/4/43
Date Injury Alleged as Basis of Complaint	12/6/10
Date of Death	12/6/10
Age at Time of Injury Alleged	67
Approx. Date Began Chronic Hemodialysis	7/17/08
Date of Last Hemodialysis Treatment Before Injury Alleged	12/06/10
State	Mississippi
Was this a Fresenius-owned or run clinic?	Yes
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis	30 minutes into treatment
Did the injury alleged occur in the dialysis clinic?	Yes
Product Identification	GranuFlo
Last monthly pre-dialysis serum bicarbonate before injury alleged	22

Case Name: Dial v FMCNA	Docket No.: 14-11101
Decedent	Carley Dial
Plaintiff	Florella Dial
Date of Decedent's Birth	3/29/55
Date of Injury Alleged as Basis of Complaint	2/3/12
Date of Death	2/3/12
Age at Time of Injury Alleged	57
Approx. Date Began Chronic Hemodialysis	3/27/08

Date of Last Hemodialysis Treatment Before Injury Alleged	2/3/12
State	North Carolina
Was this a Fresenius-owned or run clinic?	Yes
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	10-11 hours after dialysis ended
Did the injury alleged occur in the dialysis clinic?	No
Product Identification	NaturaLyte
Last monthly pre-dialysis serum bicarbonate result before injury alleged	28

The parties propose *LaStorka* and *Dial* for the bellwether trials on January 11 and February 16, 2016 because, between the two, they raise contrasting attributes as to the factors of:

- Injury alleged before the November 4, 2011 Memorandum (*LaStorka*) versus after the November 2011 Memorandum (*Dial*);
- GranuFlo (*LaStorka*) versus NaturaLyte (*Dial*); and
- Injury during treatment (*LaStorka*) versus after successful treatment (*Dial*).⁴

III. DESCRIPTION OF REMAINING PHASE II BELLWETHER CASES

The following charts contain a brief description of the remaining eight (8) Phase II cases with regard to their “core” data for purposes of comparing same to the parties’ proposed initial trial cases (in alphabetical order)⁵:

⁴ After the parties each selected ten cases for patient specific discovery, pursuant to CMO-10, the PEC chose to dismiss 8 of the Defendants’ 10 candidates, asserting that the Defendants had chosen cases that clearly could not satisfy specific causation standards. Defendant choices were made in substantial part based on the length of time between the alleged injury and completion of the last hemodialysis treatment and corresponded to the great preponderance in the overall docket of decedents who were not injured in close temporal proximity to treatment. It is the position of the Defendants that, by virtue of the PEC’s dismissals, the remaining 10 bellwether candidates do not represent the overall docket on this key factor.

⁵ Again, there are likely factual disputes in almost every one of the Phase II cases, and the parties’ case specific experts have identified differing views of causation and the nature of death in each case but, for purposes of this joint proposal, the parties have identified and agreed upon the facts associated with the above-described topics of representativeness.

Case Name: Battle v FMCNA	Docket No.: 13-12717
Decedent	Donald Battle
Plaintiff	Leola Battle
Date of Decedent's Birth	3/11/1952
Date of Injury Alleged as Basis of Complaint	5/30/12
Date of Death	5/30/12
Age at Time of Injury Alleged	60
Approx. Date Began Chronic Hemodialysis	4/20/12
Date of Last Hemodialysis Treatment Before Injury Alleged	5/30/12
State	Virginia
Was this a Fresenius-owned or run clinic?	Yes
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	40 minutes after dialysis ended
Did the injury alleged occur in the dialysis clinic?	No
Product Identification	GranuFlo
Last Monthly Pre-Dialysis Serum Bicarbonate Before Injury Alleged	25

Case Name Conway v FMCNA	Docket No.: 14-10594
Decedent	Blondell Conway
Plaintiff	Tonya Conway
Date of Decedent's Birth	12/6/51
Date of Injury Alleged as Basis for Complaint	3/30/12
Date of Death	3/30/12
Age at Time of Injury Alleged	60
Approx. Date Began Chronic Hemodialysis	9/15/05
Date of Last Hemodialysis Treatment Before Injury Alleged	3/30/12
State	Pennsylvania

Was this a Fresenius-owned or run clinic?	Yes
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	10 hours after dialysis ended
Did the injury alleged occur in the dialysis clinic?	No
Product Identification	GranuFlo
Last Monthly Pre-Dialysis Serum Bicarbonate Before Injury Alleged	23

Case Name: Burkes v FMCNA	Docket No.: 14-10712
Decedent	Sylvester Davis
Plaintiff	Sylvester Burkes
Date of Decedent's Birth	10/10/55
Date of Injury Alleged as Basis of Complaint	8/10/12
Date of Death	8/10/12
Age at Time of Injury Alleged	56
Approx. Date Began Chronic Hemodialysis	7/24/2003
Date of Last Hemodialysis Treatment Before Injury Alleged	8/10/12
State	Michigan
Was this a Fresenius-owned or run clinic?	Yes
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	At the end of dialysis treatment
Did the injury alleged occur in the dialysis clinic?	Yes
Product Identification	GranuFlo
Last Monthly Pre-Dialysis Serum Bicarbonate Before Injury Alleged	32

Case Name: Dickson v FMCNA	Docket No.: 13-10836
Decedent	Thomas Dickson

Plaintiff	Lorraine Dickson (widow)
Date of Decedent's Birth	10/4/32
Date of Injury Alleged as Basis of Complaint	6/18/12
Date of Death	6/18/12
Age at Time of Injury Alleged	79
Approx. Date Began Chronic Hemodialysis	8/27/2010
Date of Last Hemodialysis Treatment Before Injury Alleged	6/18/12
State	California
Was this a Fresenius-owned or run clinic?	No
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	halfway through dialysis treatment OR 5 days after dialysis ended (in dispute)
Did the injury alleged occur in the dialysis clinic?	No
Product Identification	NaturaLyte
Last Monthly Pre-dialysis Serum Bicarbonate Before Injury Alleged	21 or 25 (in dispute)

Case Name: Avitia v FMCNA	Docket No.: 13-12762
Decedent	Guadalupe Gaston
Plaintiff	Sonia Avitia
Date of Decedent's Birth	5/5/47
Date of Injury Alleged as Basis of Complaint	1/8/12
Date of Death	1/8/12
Age at Time of Injury Alleged	64
Approx. Date Began Chronic Hemodialysis	March 2006
Date of Last Hemodialysis Treatment Before Injury Alleged	1/7/12

State	Arizona
Was this a Fresenius-owned or run clinic?	No
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	12+ hours after dialysis ended
Did the injury alleged occur in the dialysis clinic?	No
Product Identification	GranuFlo
Last Monthly Pre-Dialysis Serum Bicarbonate Before Injury Alleged	24

Case Name: Kyles v. FMCNA	Docket No.: 13-10831
Decedent	Nathaniel Kyles
Plaintiff	Milta Kyles
Date of Decedent's Birth	10/23/48
Date of Injury Alleged as Basis of Complaint	5/5/12
Date of Death	5/5/12
Age at Time of Injury Alleged	63
Approx. Date Began Chronic Hemodialysis	11/24/99
Date of Last Hemodialysis Treatment Before Injury Alleged	5/5/12
State	Florida
Was this a Fresenius-owned or run clinic?	Yes
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	Between 5-6 and 30+ hours after dialysis ended (in dispute)
Did the injury alleged occur in the dialysis clinic?	No
Product Identification	GranuFlo
Last Monthly Pre-Dialysis Serum Bicarbonate Before Injury Alleged	30

Case Name: Hall v FMCNA	Docket No.: 14-11302
Decedent	Georgia Martin
Plaintiff	Sheila Hall
Date of Decedent's Birth	7/24/38
Date of Injury Alleged as Basis of Complaint	11/13/10
Date of Death	11/13/10
Age at Time of Injury Alleged	72
Approx. Date Began Chronic Hemodialysis	9/30/10
Date of Last Hemodialysis Treatment Before Injury Alleged	11/13/10
State	Indiana
Was this a Fresenius-owned or run clinic?	No
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	5 hours after dialysis ended
Did the injury alleged occur in the dialysis clinic?	No
Product Identification	GranuFlo
Last Monthly Pre-Dialysis Serum Bicarbonate Before Injury Alleged	29

Case Name: Sims v. FMCNA	Docket No.: 13-10109
Decedent	Joseph Sims, Jr.
Plaintiff	Maxine Sims
Date of Decedent's Birth	5/12/45
Date of Injury Alleged as Basis of Complaint	1/18/11
Date of Death	1/19/11
Age at Time of Injury Alleged	65
Approx. Date Began Chronic Hemodialysis	7/1/08
Date of Last Hemodialysis Treatment Before Injury Alleged	1/18/11

State	California
Was this a Fresenius-owned or run clinic?	No
Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	13 hours after dialysis ended
Did the injury alleged occur in the dialysis clinic?	No
Product identification	GranuFlo
Last Monthly Pre-Dialysis Serum Bicarbonate Before Injury Alleged	27

IV. DESCRIPTION OF SCHEDULED TRIAL CASES FROM OTHER JURISDICTIONS

Currently there is one other case confirmed for trial, in the Massachusetts state consolidated proceeding, *Ogburn v. FMCNA*, with jury selection beginning on November 30, 2015. A brief description of the “core data” for the *Ogburn* case is set forth below:⁶

Case Name: <i>Ogburn-Sisneros v FMCNA</i>	Docket No.
Decedent	Billy Ogburn, Sr.
Plaintiff	Alysia Ogburn-Sisneros
Date of Decedent’s Birth	2/22/51
Date of Injury Alleged as Basis of Complaint	11/23/11
Date of Death	11/23/11
Age at Time of Injury Alleged	60
Approx. Date Began Chronic Hemodialysis	April 2010
Date of Last Hemodialysis Treatment Before Injury Alleged	11/23/11
State	Colorado
Was this a Fresenius-owned or run clinic?	No

⁶ There are additional Massachusetts state trials scheduled on April 4 and May 23 2016 but the cases have not been selected for those trials as of the date of this filing. Similarly, there are St. Louis trials tentatively scheduled for March and April/May 2016, but those trials and the selected cases are not confirmed as of the filing of this pleading.

Timing of Injury Alleged in Relation to Last Outpatient Hemodialysis?	60-90 minutes after treatment ended (in dispute)
Did the injury alleged occur in the dialysis clinic?	No
Product identification	GranuFlo
Last Monthly Pre-Dialysis Serum Bicarbonate Before Injury Alleged	22 or 34 (in dispute)

V. CONCLUSION

For all these reasons, FMCNA and the PEC respectfully propose that the Court select the *Lastorka* and *Dial* cases to proceed to trial first (in that order) on January 11 and February 16 2016, because they are representative of the MDL litigation as to the above-described factors.

Respectfully submitted,

/s _____
 Anthony Tarricone
 KREINDLER & KREINDLER LLP
 855 Boylston Street Ste 1101
 Boston, MA 02116
 (617) 424-9100
 atarricone@kreindler.com

*Plaintiffs' Liaison Counsel
 Chair, Plaintiffs' Executive Committee*

/s _____
 Leigh Anne Hodge
 Kevin C. Newsom
 BRADLEY ARANT BOULT CUMMINGS LLP
 One Federal Place
 1819 Fifth Avenue North
 Birmingham, AL 35203
 (205) 521-8000
 (205) 521-8800 (fax)
 lhodge@babbc.com
 knewsom@babbc.com

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

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