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	§	

OMNIBUS CASE MANAGEMENT ORDER

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SO ORDERED this 26th day of August, 2014.

Douglas P. Woodlock

DOUGLAS P. WOODLOCK, J.

[1] The revisions to this Case Management Order represent a joint agreement made by the parties after the date the Court entered this Order.

[2] Id.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION **This Document Relates to:** ***All Cases***	**MDL No. 1:13-md-02428-DPW**

DPW

~~[PROPOSED]~~ CASE MANAGEMENT ORDER NO. 1

APPOINTMENT OF PEC, PSC, PLAINTIFFS' LIAISON COUNSEL AND FEDERAL-STATE LIAISON COUNSEL

AND NOW, this 16th day of July 2013, the Court having carefully reviewed the applications for positions on the Plaintiffs' leadership structure, it is hereby **ORDERED** that the following attorneys are appointed to the Plaintiffs' Executive Committee ("PEC"), Liaison Counsel, Plaintiffs' Steering Committee ("PSC") and the Federal-State Liaison Counsel to carry out their respective functions:

1. **Plaintiffs' Executive Committee.** The Court hereby appoints to the Plaintiffs' Executive Committee ("PEC") the following counsel: Anthony Tarricone (Kreindler & Kreindler LLP); Chris Seeger (Seeger Weiss LLP); James C. Klick (Herman Herman & Katz LLC); Arnold Levin (Levin Fishbein Sedran & Berman); Michelle Parfitt (Ashcraft & Gerel LLP); and Steve W. Berman (Hagens Berman Sobol Shapiro LLP). Anthony Tarricone will serve as Chair and Plaintiffs' Liaison Counsel.

2. **Plaintiffs' Steering Committee.** The Court appoints to the Plaintiffs' Steering Committee ("PSC"), in addition to the PEC, the following counsel: Richard Golomb (Golomb &

Honik, PC); Bruce Steckler (The Steckler Law Firm); R. Clay Milling (Henry Spiegel Milling LLP); Randi Kassan (Sanders Viener Grossman LLP); Ellen Presby (Nemeroff Law Firm); Jim Dugan (The Dugan Law Firm, LLC); Troy Rafferty (Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.); Richard "Flip" Phillips (Smith Phillips Mitchell Scott & Nowak, LLP); Kristian Rasmussen (Cory Watson Crowder & DeGaris, P.C.); Frank Woodson (Beasley Allen Crow Methvin Portis & Miles, P.C.) and J. Burton LeBlanc (Baron & Budd, P.C.).

3. **Responsibilities of the PEC and PSC.** The Plaintiffs' Executive Committee shall serve as Lead Counsel and will be responsible for overall coordination and management of all pretrial proceedings and case preparation on behalf of the PSC and all Plaintiffs, including authority to organize, staff and direct committees to carry out various functions necessary for case preparation and prosecution. The PEC/PSC shall be responsible for:

A. Discovery

i. Initiate, coordinate, and conduct all pretrial discovery on behalf of plaintiffs in all actions that are consolidated with the instant multidistrict litigation.

ii. Develop and propose to the Court schedules for the commencement, execution, and completion of all discovery on behalf of all plaintiffs.

iii. Cause to be issued, in the name of all plaintiffs, the necessary discovery requests, motions, and subpoenas pertaining to any witnesses and documents needed to properly prepare for the pretrial discovery of relevant issues found in the pleadings of this litigation. Similar requests, notices, and subpoenas may be caused

to be issued by the PEC and PSC upon written request by an individual attorney in order to assist him/her in the preparation of the pretrial stages of his/her client's particular claims.

iv. Conduct all discovery in a coordinated and consolidated manner on behalf and for the benefit of all plaintiffs.

B. Hearings and Meetings

i. Call meetings of counsel for plaintiffs for any appropriate purpose, including coordinating responses to questions of other parties or of the Court.

ii. Initiate proposals, suggestions, schedules, or joint briefs, and any other appropriate matter(s) pertaining to pretrial proceedings.

iii. Examine witnesses and introduce evidence at hearings on behalf of plaintiffs.

iv. Act as spokesperson for all plaintiffs at pretrial proceedings and in response to any inquiries by the Court, subject, of course, to the right of any plaintiff's counsel to present non-repetitive individual or different positions.

C. Trial

i. Coordinate trial team(s)'s selection, management and presentation of any common issue, "bellwether" and/or "test" case trial(s).

D. Other

i. Submit and argue any verbal or written motions presented to the Court or Magistrate on behalf of the PEC and PSC, as well as

oppose, when necessary, any motions submitted by the defendant or other parties which involve matters within the sphere of the responsibilities of the PEC and PSC.

ii. Negotiate and enter into stipulations with defendants regarding this litigation.

iii. Explore, develop, and pursue all settlement options pertaining to any claim or portion thereof of any case filed in this litigation.

iv. Maintain adequate files of all pretrial matters and have them available, under reasonable terms and conditions, for examination by plaintiffs or their attorneys.

v. Prepare periodic status reports summarizing the PEC's and PSC's work and progress.

vi. Perform any task necessary and proper for the PEC and PSC to accomplish their responsibilities as defined by the Court's Orders.

vii. Perform such other functions as may be expressly authorized by further Orders of this Court.

viii. Serve as the recipient for all Court orders on behalf of all of the Plaintiffs.

ix. Coordinate service and filings for all Plaintiffs whether presently included or subsequently added.

x. Maintain and distribute to co-counsel and to Defendants' Counsel an up-to-date service list;

xi. Coordinate and maintain the establishment of a document depository, real or virtual, to be available to all participating Plaintiffs' counsel.

xii. Prepare agendas for court conferences and periodically report regarding the status of the case.

xiii. Explore, develop and pursue all settlement options pertaining to a claim or portion thereof of any case filed in this litigation.

E. No motion, request for discovery, or other pretrial proceeding shall be initiated or filed by any plaintiff except through the PEC without prior order of this Court.

4. Plaintiffs' Liaison Counsel

The Court appoints Anthony Tarricone as Plaintiffs' Liaison Counsel. The Plaintiffs' Liaison Counsel shall be responsible for providing communications between the court and other counsel (including receiving and distributing notices, orders, motions, and briefs on behalf of the group), convening meetings of counsel, advising parties of developments, and otherwise assisting in the coordination of activities and positions. Liaison counsel may act for the group in managing document depositories and in resolving scheduling conflicts.

5. Plaintiffs' Federal-State Liaison Counsel for Massachusetts and California Litigations.

The Court appoints Lauren Barnes (Hagens Berman Sobol Shapiro LLP) as Plaintiffs' Federal-State Liaison Counsel for Massachusetts and Gretchen M. Nelson (Kreindler & Kreindler LLP) as Plaintiffs' Federal-State Liaison Counsel for California. The Federal-State

Liaison Counsel are to provide reports to the Court on the status of the state litigation and coordination with the MDL.

6. To the extent feasible, the PEC and PSC are expected to work jointly with leadership in the pending state actions to coordinate pretrial proceedings and case management.

7. Compensation for work performed and the approved costs incurred by the PEC, PSC, Plaintiffs' Liaison Counsel, Plaintiffs' Federal-State Liaison Counsel, any subcommittee approved by the PEC and PSC or any attorney appointed by this Court, will be paid by the common benefit funds which shall be covered in a separate Case Management Order.

It is so **ORDERED.**

Dated: July 18, 2013

BY THE COURT:

Douglas P. Woodlock

Douglas P. Woodlock
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE 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	

CASE MANAGEMENT ORDER NO. 2
(Initial Scheduling Order)

THIS MATTER, having been submitted to the Court on consent of the Parties, and for good cause shown and the submissions and suggestions of counsel in connection with the Initial Status Conference held on September 27, 2013, **IT IS HEREBY ORDERED** as follows:

I. APPLICABILITY OF ORDER

1. This Order shall govern all cases (a) transferred to this Court by the Judicial Panel on Multidistrict Litigation, pursuant to its Order of March 29, 2013; (b) any tag-along actions subsequently transferred to this Court by the Judicial Panel on Multidistrict Litigation pursuant to Rule 7.4 of the Rules of Procedure of that Panel; and (c) all related cases originally filed in this Court or transferred or removed to this Court.

II. DISCOVERY

2. Generic Written Discovery:

a) The parties may serve an initial set of Generic Requests for Production and/or Interrogatories beginning on October 28, 2013.

b) Written responses shall be due and rolling document production shall begin on or before January 6, 2014.

c) Defendants shall serve Production Certification of completion on or before March 31, 2014, which may be extended for good cause shown.

3. Jurisdictional Discovery:

a) In the event that any named Defendant challenges jurisdiction by motion pursuant to Rule 12(b)(2), discovery limited to jurisdictional issues with respect to any moving Defendant shall proceed expeditiously thereafter.

b) With respect to any defendant objecting to personal jurisdiction, the discovery obligations set forth herein will be imposed in the event that personal jurisdiction is established, to commence expeditiously upon order of the Court.

4. Plaintiff and Defendant Fact Sheets:

a) The Parties will agree upon Plaintiff and Defendant Fact Sheets and will submit the agreed-upon forms to the Court no later than October 28, 2013.

b) Plaintiff Fact Sheets ("PFS"), relevant, non-privileged medical records in Plaintiffs' possession, and authorizations for additional records of a plaintiff or claimant for pending cases shall be served no later than November 27, 2013.

c) Defendant Fact Sheets ("DFS") for pending cases shall be served no later than January 31, 2014.

d) PFSs for subsequently filed cases will be served no later than 45 days after service of the defendants' answer and the DFS will be served no later than 60 days after receipt of the PFS.

5. Generic Fact (Non-Expert) Witness Depositions

a) Depositions of generic fact witnesses, including Rule 30(b)(6) depositions, and third-party discovery, may commence on or after October 28, 2013.

b) All case-specific discovery other than the exchange of Fact Sheets and relevant, non-privileged medical records and authorizations is stayed until further order of the Court.

6. Bellwether Process

a) On January 6, 2014 the Parties shall submit a proposed CMO addressing the bellwether process, which the parties agree will address case specific discovery.

III. ANTICIPATED ADDITIONAL PRE-TRIAL ORDERS

7. The parties have met and conferred in good faith to negotiate the following additional Case Management Orders: (a) treatment of confidential materials, (b) preservation of documents; (c) a protocol for product identification; and, (d) a protocol for discovery of documents and Electronically Stored Evidence (ESI). The parties are continuing discussions and will submit proposed orders in the coming weeks.

8. The parties shall meet and confer regarding the desirability and feasibility of an order facilitating the direct filing of actions into the MDL and Master Pleadings (*Master Complaint*, a *Master Answer* and a *Short Form Complaint*). A proposed Case Management Order governing the filing of Master Pleadings and direct filing of actions into the MDL shall be filed with the Court no later than November 27, 2013.

9. The parties shall meet and confer in good faith to negotiate additional Case Management Orders relating to: (a) privilege which shall include guidelines that shall govern, (1) the protocol that shall be followed regarding the preparation of privilege logs pursuant to Fed. R. Civ. P. 26(b)(5)(A)(i)-(ii), and (2) the method for resolving privilege disputes by and among Plaintiffs and Defendants and (b) service of pleadings and discovery. Such proposed Case Management Orders shall be filed with the Court no later than January 6, 2014.

10. Please refer to "Exhibit A" for a timeline of all anticipated due dates.

11. Additional Events. Additional pre-trial events not addressed in this Order, including expert discovery and dispositive motions, will be the subject of future Case Management Orders.

IV. FILING OF PLEADINGS

12. All motions, requests for discovery or other pre-trial proceedings with respect to Plaintiffs shall be initiated by and/or coordinated through the Plaintiff Steering Committee ("PSC"), to be filed by and through the Chair of the Plaintiffs' Executive Committee ("PEC"). No motion, request for discovery or other pre-trial proceedings shall be initiated or filed except by the Chair of the PEC without prior order of this Court.

V. SUPPLEMENTATION AND AMENDMENTS TO THIS ORDER

13. This Order may be modified in the interests of justice, expedience, or judicial economy on the Court's own motion or a motion by the parties for good cause shown.

IT IS SO ORDERED.

BY THE COURT:

Douglas P. Woodlock
United States District Judge

UNITED STATES DISTRICT COURT
THE 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	

EXHIBIT A
TIMELINE TO CASE MANAGEMENT ORDER NO. 2

Schedule of Events/Dates

October 28, 2013	Parties may serve Initial Written Discovery.
	Generic Fact Discovery, including Rule 30(b)(6) Depositions and Third Party Discovery, may begin.
	Parties shall file forms for Plaintiff and Defendant Fact Sheets.
November 27, 2013	Plaintiffs submit Plaintiff Fact Sheets for pending cases.
	The parties shall file any proposed orders relating to Master Pleadings.
January 6, 2014	Parties submit proposed CMO addressing bellwether process.
	Responses to Initial Written Discovery Served are due and rolling Document Production begins.
	Deadline for parties to meet and confer and, if necessary, file additional proposed Case Management Orders relating to: (a) privilege, (b) a protocol for the production of documents, (c) e-discovery, and (d) and service of pleadings and discovery.
January 31, 2014	Defendants submit Defendant Fact Sheets for pending cases.

This schedule does not address the timing of expert disclosures and discovery, evidentiary motions, or case-dispositive motions. All such issues shall be deferred pending further court conference and direction.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION,	
This Document Relates To:	
ALL CASES	MDL No. 1:13-md-02428-DPW

REVISIONS TO CASE MANAGEMENT ORDER NO. 2

Case Management Order No. 2 (dkt # 334) is hereby amended to read as follows:

2 (c): Fresenius Medical Care North America shall serve Production Certification of completion on or before June 2, 2014 which may be extended for good cause shown.

4(d): Plaintiff Fact Sheets ("PFS") for cases filed after the entry of this Order will be served no later than 45 days after service of the complaint or short-form complaint and the Defendant Fact Sheet ("DFS") will be served no later than 60 days after service of the PFS. In cases where the PFS was served before service of the complaint, plaintiff's counsel will have 45 days after service of the complaint to supplement the PFS. Defendant Fact Sheets in those instances will be due 60 days after either service of the supplemental PFS or the expiration of the 45 day period if no supplemental PFS has been received. If, however, plaintiff's counsel notifies Fresenius Medical Care North America in writing that a plaintiff does not intend to supplement the PFS, the DFS will be due 60 days from receipt of that notice.

5(b): All case-specific discovery other than the exchange of Fact Sheets, relevant, non-privileged medical records, and authorizations and requests for medical records from third parties is stayed until further order of the Court.

UNITED STATES DISTRICT COURT
FOR THE 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

REVISED CASE MANAGEMENT ORDER NO. 3
(Mechanism for Expedited Disclosure by Defendants of Plaintiffs' Medical Records and Extension of Date for Service of Plaintiff Fact Sheets)

THIS MATTER, having been submitted to the Court on agreement of the parties and for good cause shown, **IT IS HEREBY ORDERED,** that the deadlines for the completion of Plaintiff and Defendant Fact Sheets as set forth in Case Management Order No. 2 (Initial Scheduling Order) are amended as follows:

I. PRE-LITIGATION MEDICAL RECORD REQUESTS

1. In any case currently pending in this MDL where the injury/death is alleged to have been the result of treatment at a Fresenius Medical Care North America ("FMCNA") dialysis clinic, and a HIPAA compliant request (including legal proof of authority under applicable state law) for the patient's dialysis clinic medical chart was made prior to the filing of the complaint, and that request remains outstanding as of the date of this Order, counsel for Plaintiff shall by November 27, 2013, provide a designated representative of the law firm of Bradley Arant Boult Cummings with:

(a) a completed *CMO-3 Plaintiff Case Information Form* ("CIF") (Exhibit A);

(b) a copy of the pre-litigation request;

(c) a completed and executed HIPAA Authorization for the Release of Healthcare Records ("*HIPAA Authorization*") signed by the injured party or decedent's next of

kin, or the proposed representative of the decedent's estate in the form attached to this Order as Exhibit B; and

(d) any relevant, non-privileged medical records of the injured party/decedent in Plaintiff's possession or, in the absence of any such records, an executed *Affidavit of Completion and No Records Statement* in the form attached to this Order as Exhibit C.

2. No later than forty-five (45) days following receipt of the materials identified in paragraph 1(a)-(d) above, FMCNA shall either:

(a) produce to the individual Plaintiff's attorney the Plaintiff's clinic medical chart[1] in its possession, custody and control, or,

(b) provide an executed *Affidavit of Completion and No Records Statement* in the form attached to this Order as Exhibit D, provided, however, that to the extent FMCNA is unable to provide the full clinic medical chart within forty-five (45) days, the parties may extend the deadline for production by mutual agreement or upon motion by FMCNA.

3. Within forty-five (45) days following receipt of either the clinic medical chart or *Affidavit of Completion and No Records Statement* referred to in paragraph 2, the Plaintiff shall

[1]As used herein, the term "clinic medical chart" means all HIPAA protected medical information as defined in 45 C.F.R. § 164.501, whether in paper or electronic form that is maintained by the dialysis facility. The parties are still in the process of addressing Plaintiffs' request for patient data which may be in Defendants' possession, custody and control that may not be part of a traditional clinic medical chart or record related to the Plaintiff but that may be housed in Defendant's "Data Warehouse" database, or any other database containing data relating to the Plaintiff ("additional HIPAA Plaintiff Information"). The parties shall meet and confer within 20 days from the entry of this order to conduct an "over the shoulder" review of the Data Warehouse for a limted number of plaintiffs' counsel and any other agreed upon review of this type of data possessed by Defendants, in order to then either reach agreement or present to the Court competing versions of a discovery request as to this topic (including the nature, scope and timing of same), to be filed prior to the next scheduled Status Conference for consideration by the Court at that time. Plaintiffs continue to reserve the right to seek discovery of additional patient data from the defendants' databases as requested during the course of pretrial discovery.

serve a completed *Plaintiff Fact Sheet* on the designated representative of Bradley Arant Boult Cummings as set forth in paragraph 1 above.

4. Within sixty (60) days following receipt of the Plaintiff Fact Sheet, FMCNA shall serve a completed Defendant Fact Sheet on Plaintiff's counsel.

II. POST-LITIGATION MEDICAL RECORD REQUESTS

5. In any case currently pending in this MDL where the injury/death is alleged to have been the result of treatment at an FMCNA dialysis clinic and counsel for Plaintiff did not request the patient's clinic medical chart prior to the filing of the complaint, counsel for Plaintiff shall by November 27, 2013, provide the designated representative of the law firm of Bradley Arant Boult Cummings with:

(a) a completed *CMO-3 Plaintiff Case Information Form* ("CIF") (Exhibit A); and,

(b) a completed and executed HIPAA Authorization for the Release of Healthcare Records ("*HIPAA Authorization*") signed by the injured party or decedent's next of kin, or the proposed representative of the decedent's estate in the form attached to this Order as Exhibit B; and,

(c) any relevant, non-privileged medical records of the injured party/decedent in Plaintiff's possession or, in the absence of any such records, an executed *Affidavit of Completion and No Records Statement* in the form attached to this Order as Exhibit C.

6. No later than ninety (90) days following receipt of the materials identified in paragraph 5(a)-(c) above, FMCNA shall either:

(a) produce to the individual Plaintiff's attorney the Plaintiff's clinic medical chart for the facility identified in the CIF, or,

(b) provide an executed *Affidavit of Completion and No Records Statement* in the form attached to this Order as Exhibit D,

provided, however, that if the number of clinic medical chart requests received by FMCNA pursuant to paragraph 5 of this Order exceeds one hundred (100), the parties may extend the deadline for production by mutual agreement or upon motion by FMCNA.

7. Within forty-five (45) days following receipt of either the clinic medical chart or *Affidavit of Completion and No Records Statement* referred to in paragraph 5, the Plaintiff shall serve a completed *Plaintiff Fact Sheet* on the designated representative of Bradley Arant Boult Cummings as set forth in paragraph 1 above.

8. Within sixty (60) days following receipt of the Plaintiff Fact Sheet, FMCNA shall serve a completed Defendant Fact Sheet on Plaintiff's counsel.

III. NEWLY FILED, REMOVED OR TRANSFERRED CASES

9. For cases that are not currently pending in this MDL as of the date of the entry of this Order, the deadline for the completion of *Plaintiff Fact Sheets* set forth in paragraph 4(d) of *Case Management Order No. 2 (Initial Scheduling Order)* may be extended in accordance with paragraphs 5 through 8 of this CMO in a case alleging injury/death resulting from treatment at a FMCNA dialysis clinic if, prior to the existing deadline for serving the *Plaintiff Fact Sheet*, that Plaintiff provides the representative of Bradley Arant Boult Cummings identified in paragraph 1 above with the information and documents set forth in paragraphs 5 (a)-(c) above.

V. FURTHER PROCEEDINGS

10. All other provisions of *Case Management Order No. 2* remain in full force and effect.

11. This Order may be modified in the interests of justice, expedience, or judicial economy on the Court's own motion or a motion by the parties for good cause shown.

IT IS SO ORDERED.

BY THE COURT:

/s/ Douglas P. Woodlock

Douglas P. Woodlock
United States District Judge

Date: 11/7/2013

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 1:13-MD-2428-DPW**

EXHIBIT A

Case Information Form

I. CASE INFORMATION

Caption: _____ Date Filed: _____

Docket No. (Including Court):

_____

Plaintiff's Attorney and Contact Information, Including Telephone Number:

_____

_____

_____

II. PLAINTIFF'S INFORMATION

Full Name of Patient: _____

Last Address: _____

Date of Birth: _____

Patient's FMS Medical Record Number, also known as the Patient Identification Number:

_____

If unknown, please provide the following information:

a. Patient's Medicare Identification Number, if known: _____

b. Last four digits of Patient's Social Security Number: _____

Name and address of FMS dialysis facility where Patient received last dialysis treatment prior to injury / death: _____

_____

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

Patient Name:	Date of Birth:	Social Security Number:
Patient Address:		

I, or my authorized representative, request that health information regarding my care and treatment be released as set forth on this form.

In accordance with the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. 164.508, I understand that:

1. This authorization may include disclosure of information relating to **alcohol and drug abuse, mental health treatment,** except psychotherapy notes, and **confidential HIV related information,** only if I place my initials on the appropriate line in Item 11(a). In the event the health information described below include any of these types of information, and I initial the line on the box in Item 11(a), I specifically authorize release of such information to the person(s) indicated in Item 10.

2. If I am authorizing the release of HIV-related, alcohol or drug treatment, or mental health treatment information, the recipient is prohibited from redisclosing such information without my authorization unless permitted to do so under federal or state law. I understand that I have a right to request a list of people who may receive or use my HIV-related information without authorization.

3. I have the right to revoke this authorization at any time by writing to the health care provider listed below. I understand that I may revoke this authorization except to the extent that action has already been taken based on this authorization.

4. I understand that signing this authorization is voluntary. My treatment, payment, enrollment in a health plan, or eligibility for benefits will not be conditioned upon my authorization of this disclosure. **Any photostatic copy of this document shall have the same authority as the original, and may be substituted in its place.**

5. Information disclosed under this authorization might be redisclosed by the recipient, and this redisclosure may no longer be protected by federal or state law, except as noted in Item 2.

6. This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).

7. This authorization shall be valid through December 31, 2016.or the conclusion of my case, whichever occurs first; unless it is revoked as provided in Item 3, and shall remain in full force and effect until such expiration, and further authorizes the Provider to release to the Recipient any additional records created or obtained by the Provider after the date hereof. **The records requester has agreed to pay reasonable charges made by the Provider to supply copies of such records.**

8. This authorization specifically does **NOT** authorize the release of original documents and materials, including tissue slides, tissue blocks and tissue samples.

9. Name and address of health provider or entity to release this information:	
10. Name and address of entity(ies) to whom this information will be mailed or sent:	Name and address of entity as designee to whom this information will be mailed or sent:

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

11(a). Specific information to be released:

☑ Medical Records and patient data (See CMO - ___ in MDL No. 2428)

☑ Entire Medical Record, including, but not limited to, patient histories, office notes (except psychotherapy notes, biopsy/pathology specimens and/or materials, and autopsy materials), diagnoses, analyses, progress reports, laboratory reports, test results, x-rays, radiology reports, radiology films or scans (in any form), referrals, consults, billing records, correspondence, prescription records, autopsy reports, pathology reports, death certificates, consents for treatment, insurance records, and records sent to you by other health care providers.

☐ Other: _____

_____

Include: (*Indicate by initialing)*

_____**Alcohol/Drug Treatment**

_____**Mental Health Information**

_____ **HIV-Related Information**

Authorization to Discuss Health Information

11(b) ☐ By initialing here _____ I authorize _____

Name of individual health care provider

to discuss my health information with my attorney, or a governmental agency listed here:

_____

(Attorney/Firm Name or Governmental Agency Name)

*****This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).**

12. Reason for release of information:	13. Date or event on which this authorization will expire:
☐ At request of individual ☑ Other: **Litigation**	**December 31, 2016 or at the conclusion of the case, whichever occurs first.**
14. If not the patient, name of person signing form:	15. Authority to sign on behalf of patient:

All items on this form have been completed and my questions about this form have been answered. In addition, I have been provided a copy of the form.

_____ Date: _____

Signature of patient or authorized representative

ACKNOWLEDGMENT

The undersigned, as the record requester named in the above medical authorization, hereby declares under penalty of perjury, pursuant to 28 U.S.C. Section 1746, that the attorney to the patient named in the foregoing medical authorization has been given notice that the authorization will be used to request records from the person or entity to whom it is addressed, and the attorney has been given five (5) days advance notice and has been afforded an opportunity to object to the request and any objections have been resolved. The attorney for the patient named in the foregoing medical authorization has also been afforded an opportunity to order copies of the records from the undersigned requestor at a reasonable cost.

_____

2

Exhibit "C"

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	**MDL No. 1:13-md-2428-DPW**
This Document Relates to:	
[INSERT NAME AND COURT TERM AND NUMBER OF INDIVIDUAL CASE]	

AFFIDAVIT OF COMPLETION AND/OR NO RECORDS STATEMENT
(Medical Records in Plaintiff's Possession and Authorizations)

1. I, [INSERT ATTORNEY] am counsel for Plaintiff [insert Plaintiff's name and, if in representative capacity, name of injured/decedent] in the above-captioned matter

2. I am familiar with the discovery obligations set forth in CMO-2 and CMO-3 relating to the production of relevant, non-privileged medical records in Plaintiffs' possession and authorizations for additional records of a plaintiff or claimant.

3. I make this Affidavit after a reasonable inquiry of a diligent check for medical and other records of the Plaintiff in the Plaintiffs' possession and counsel's possession as of the date of this Affidavit and hereby attest that, to the best of my knowledge, information, and belief: (1) all relevant, non-privileged medical records in Plaintiffs' or Plaintiff's Counsel's possession as of the date of this Affidavit have been produced to counsel for Defendants; or (2) if no such records have been produced by the date of this Affidavit, no such records are in the possession of either the Plaintiff or counsel for the Plaintiff.

4. I hereby attest that completed authorizations for additional records of the plaintiff or claimant have been produced to counsel for the Defendants on this date.

I declare under the penalty of perjury that the forgoing is true and correct.

_____

[Insert]

2

Exhibit "D"

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	**MDL No. 1:13-md-2428-DPW**
This Document Relates to:	
[INSERT NAME AND COURT TERM AND NUMBER OF INDIVIDUAL CASE]	

AFFIDAVIT OF COMPLETION AND NO RECORDS STATEMENT

1. I, [INSERT ATTORNEY PERFORMING/SUPERVISING SEARCH], am counsel for defendants FRESENIUS USA, INC, FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA (hereinafter "North American Defendants") in the Granuflo MDL.

2. Pursuant to Case Management Order No. 3 (Mechanism for Expedited Disclosure of Plaintiffs' Medical Records), I have made a diligent check and I have sufficient knowledge of the processes conducted to comply with the discovery obligations set forth in CMO-3 entered by this Court.

3. I make this Affidavit after a reasonable inquiry of a diligent check for medical and other records of the Plaintiff in the above-referenced case as is required under Rule 26 of the Code of Civil Procedure and CMO-3, and hereby attest that to the best of my knowledge, information, and belief that no responsive documents or data were located and/or identified by Defendants' personnel and/or any third party. If responsive documents or data are identified and

/or located then the PEC will be promptly advised and a prompt production will be made to the Plaintiffs' counsel in the above-captioned case.

I declare under the penalty of perjury that the forgoing is true and correct.

_____

[Insert]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/ NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	**MDL No. 1:13-md-02428-DPW**
This Document Relates To:	
ALL CASES	

CASE MANAGEMENT ORDER NO. 4
(Preservation of Documents Order)

THIS MATTER, upon consultation with the Parties, the Court finds that an Order regarding the preservation of documents and other potential evidence is both desirable and necessary. **IT IS HEREBY ORDERED** as follows:

I. APPLICABILITY OF ORDER

1. This Order shall govern all cases (a) transferred to this Court by the Judicial Panel on Multidistrict Litigation, pursuant to its Order of March 29, 2013; (b) any tag-along actions subsequently transferred to this Court by the Judicial Panel on Multidistrict Litigation pursuant to Rule 7.4 of the Rules of Procedure of that Panel; and (c) all related cases originally filed in this Court or transferred or removed to this Court.

II. PRESERVATION OF DOCUMENTS

2. All parties and their counsel shall preserve evidence that may be relevant to this action. The duty to preserve extends to documents, data, and tangible things in the possession, custody and control of the parties to this action, including a party's employees, agents, contractors who possess or may possess materials reasonably anticipated to be subject to discovery in this action.

3. For purposes of this order, evidence that may be relevant to this action means documents, data and tangible things that relate or refer to the subject matter of this litigation, including the legal claims and theories alleged by Plaintiffs in individual Complaints pending in this multi-district litigation as of the date of this Order. This paragraph may be amended by agreement or upon motion and for good cause shown, as the litigation proceeds.

4. For purposes of this order, "documents, data, and tangible things" is to be interpreted broadly and is intended to include writings; records; files; correspondence; reports; memoranda; calendars; diaries; minutes; electronic messages; E-mail; computer and network activity logs; hard drives; backup data; removable computer storage media such as tapes, disks, and cards; printouts; document image files; Web pages; databases; spreadsheets; software; books; ledgers; journals; orders; invoices; bills; vouchers; checks; statements; worksheets; summaries; compilations; computations; charts; diagrams; graphic presentations; drawings; films; charts; digital or chemical process photographs; video, phonographic, tape, or digital recordings or transcripts thereof; drafts; jottings; and notes. Information that serves to identify, locate, or link such material such as file inventories, file folders, indices, and metadata, is also included in this definition. No party will be required to preserve any computer or network activity logs to the extent that to do so would violate relevant foreign privacy laws.

5. For purposes of this order, "Preservation" is to be interpreted broadly to accomplish the goal of maintaining the integrity of all documents, data, and tangible things reasonably anticipated to be subject to discovery under the Federal Rules of Civil Procedure 26, 45, and 56 (e). Preservation includes taking reasonable steps to prevent the partial or full destruction, alteration, testing, deletion, shredding, incineration, wiping, relocation, migration, theft, or mutation of such material, as well as negligent or intentional handling that would make material incomplete or inaccessible

6. As it concerns the preservation of documents and other potential evidence:

(a) Fresenius Medical Care North America shall comply with legal hold instructions issued August 15, 2012 and any supplemental instructions relating to the preservation of documents, data and tangible things that may be relevant to this action.

(b) Fresenius Medical Care North America shall preserve backups of the electronic data on the servers housing data described in Paragraph 3 of this Order that were made on or around November 25-27, 2011; March 12, 2012; and July 31 2013 during the pendency of this litigation.

(c) Fresenius Medical Care North America shall preserve during the pendency of this litigation the last backup made of the voice mail system prior to September 13, 2013.

(d) Fresenius Medical Care North America's obligation to preserve the specified backups shall have no bearing on their obligation, if any, to produce documents from those backups or on the cost allocations and burdens if such production is agreed or required.

(e) Fresenius Medical Care North America may continue to follow its ordinary business protocol of overwriting backups every thirty (30) days so long as it is otherwise in compliance with this order.

7. If, prior to the entry of this order, counsel for any party has become aware of the destruction and/or loss of evidence covered by this order, counsel for the party shall inform and notify opposing counsel of the destruction or loss no later than thirty (30) days after the date upon which this order is entered. If, during the pendency of this order, any party or counsel learns or becomes aware that evidence covered by this order has been destroyed or lost, counsel for the party shall inform and or notify all opposing counsel no later than fourteen (14) days after learning or becoming aware of such destruction or loss.

8. To the extent not expressly set forth herein, it is expected that the parties shall otherwise comply with their obligations concerning preservation of evidence as set forth in the applicable Federal Rules, Local Rules of this District and the law of this Circuit.

III. SUPPLEMENTATION AND AMENDMENTS TO THIS ORDER

9. This Order may be modified in the interest of justice, expedience, or judicial economy on the Court's own motion or a motion by the parties for good cause shown.

IT IS SO ORDERED

BY THE COURT:

Douglas P. Woodlock
United States District Judge

November 15, 2013

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	§	

CASE MANAGEMENT ORDER NO. 5
(Protective Order of Confidentiality)

I. SCOPE OF ORDER

1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted until the time of trial. Counsel for the parties in this Litigation expressly agree to be bound by the terms of this Order and provide an executed Confidentiality Agreement in the form attached hereto at Exhibit A.

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this Litigation, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any Party to this Litigation (the "Producing Party") to any other party or parties (the "Receiving Party"). This Protective Order is binding upon and shall inure to the benefit of all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their respective

attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

3. Third-parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.

4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential. The entry of this Protective Order does not alter, waive, modify or abridge any right, privilege or protection otherwise available to any Party with respect to the discovery of matters, including but not limited to any Party's right to assert or contest any attorney-client privilege, the attorney work product doctrine, or other privileges.

7. Nothing in this Protective Order shall prevent counsel from showing "Confidential Information" at a deposition of any witness that is a former employee of the Defendants who currently works for a company that is a competitor of the Defendants. The witness, however, must treat any such documents according to the terms of this Protective Order. Use of documents in that fashion is governed by the terms of the Protective Order below.

II. DEFINITIONS

8. Party. "Party" means any of the parties in this Litigation, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information as set forth in this Protective Order will be subject to them being bound, by agreement or court order, to this Protective Order.

9. Discovery Material. "Discovery Material" means all non-public information, documents, or tangible things, responses to discovery requests, deposition testimony or transcripts, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) ("Computerized Material") is produced by any Party in such form, the Producing Party may designate such matters as confidential by cover letter referring generally to such matter as Confidential Information. Whenever any party to whom Computerized Material designated as Confidential is produced reduces such material to hardcopy form, that party shall mark the hardcopy form with the "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER" designation. Such a designation shall subject the document and its contents to this Protective Order.

10. Confidential Information. "Confidential Information" is defined herein as information that the Producing Party believes in good-faith constitutes or contains information subject to the protections of Fed. R. Civ. P. 26(c) insofar that it is "a trade secret or other confidential research, development, or commercial information" (Fed. R. Civ. P. 26(c)(1)(G). In designating discovery materials as Confidential Information, the Producing Party shall do so in

good-faith consistent with Fed. R. Civ. P. 26(c), the provisions of this Protective Order and rulings of the Court.

a) Nothing herein shall be construed to allow for global designations of all documents as Confidential.

b) Documents not designated as "CONFIDENTIAL —SUBJECT TO PROTECTIVE ORDER" are not Confidential Information as that term is defined herein.

c) All records containing medical information of Plaintiffs obtained from Plaintiffs' healthcare providers, and any other records of the Plaintiffs that the Parties may retrieve from a third party shall be designated "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER" and treated as such under this Protective Order for a period of sixty (60) calendar days. At the expiration of the sixty day period, any records other than medical records containing HIPPA-protected material must be affirmatively designated as Confidential Information under this Protective Order or the records will lose their confidential designation, which Plaintiffs may accomplish by sending a letter to Defendants asserting that any such record is Confidential.

11. Receiving Party. "Receiving Party" means a Party to this Litigation, and all employees, agents and directors of the Party that receive Discovery Material from a Producing Party.

12. Producing Party. "Producing Party" means a Party to this Litigation, and all directors, employees and agents of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party.

13. Protected Material. "Protected Material" means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as "Confidential" in accordance with this Protective Order.

14. This Litigation. "This Litigation" means all cases currently pending in the above-captioned multidistrict litigation and all related actions that have been filed in, transferred or removed to this Court and assigned thereto.

III. DESIGNATION AND REDACTION OF CONFIDENTIAL INFORMATION

15. For each document produced by the Producing Party that contains or constitutes Confidential Information pursuant to this Protective Order, each page shall be marked "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER". Such a designation shall subject the document and its contents to this Protective Order.

16. Specific documents and discovery responses produced by the Producing Party shall, if appropriate, be designated as confidential by marking the pages of the document that contain Confidential Information in the margin or header/footer of the document in a manner that does not interfere with the document's legibility and does not obscure or cover any of the document's text or information, as follows: "CONFIDENTIAL-SUBJECT TO PROTECTIVE ORDER."

17. Material produced by any third party shall be preliminarily treated as if designated Confidential Information for fifteen (15) calendar days following receipt of the material by a Party. During this fifteen (15) day period, a Party may designate the material as Confidential Information. After fifteen (15) calendar days, if no Party made such a designation, then the material will not be treated as Confidential Information. The provisions of this paragraph do not apply to Plaintiffs' medical and other records as described in paragraph 10(c) above.

18. Information disclosed at a deposition taken in connection with this proceeding may be designated as Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of

the Producing Party's receipt of the final transcript of a deposition. At the time of deposition or within thirty (30) calendar days after receipt of the final deposition transcript, a party may designate as Confidential Information specific portions of the transcript which contain confidential matters under the standards set forth above. No objection shall be interposed at deposition that an answer would elicit confidential information. Transcripts will be treated as Confidential Information until the expiration of this time period. Any portions of a transcript designated Confidential Information shall thereafter be treated as Confidential Information in accordance with this Protective Order. If the Producing Party does not serve a designation letter within the thirty-day (30-day) period, then the entire transcript will be deemed not to contain "Confidential Information", and the confidentiality designation legend shall be removed.

19. This Protective Order shall not be construed to protect from production or to permit the "Confidential Information" designation of any document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party, generally available to the public through lawful publication or otherwise.

20. Confidential documents that are produced in this MDL pursuant to a valid Document Request, Deposition Notice or Subpoena shall be produced in their entirety with no internal redaction with the exception of information that is covered by the attorney client privilege or work product doctrine, or as necessary to comply with relevant privacy laws. The parties shall comply with the rules of this District and the First Circuit (unless otherwise ordered by the Court) with regard to the production of privilege logs and, where privacy laws are asserted, said laws are to be specifically cited.

IV. ACCESS TO CONFIDENTIAL INFORMATION

21. In the absence of written permission from the Producing Party or an order of the Court, no Confidential Information designated in accordance with this Protective Order shall be given, shown, divulged, made available, or communicated in any way to anyone except those persons designated in this Protective Order to whom it is necessary that such Confidential Information be given, shown, made available or communicated for purposes of prosecuting or defending any of the cases in this Litigation. No person authorized to receive Confidential Information under this Protective Order shall use or refer to such Confidential Information, directly or indirectly, for the preparation or prosecution of any litigation other than this Litigation absent further order of the Court.

22. The persons, other than the Court and the Court's reporter, clerk, and staff, to whom Confidential Information may be disclosed (subject to the restrictions of this Protective Order) shall be as follows:

a) All attorneys appearing in the Litigation and all employees of their respective law firms;

b) Those representatives of each Party, including attorneys employed by a Party, charged with responsibility for the prosecution or defense of this Litigation;

c) Court reporters transcribing testimony or arguments in this Litigation;

d) Outside experts, consultants or other professionals, retained or consulted by any party for the purpose of the prosecution or defense of this Litigation, who have read a copy of this Protective Order and complied with the requirements set forth in paragraph 25(a);

e) Any witness at a deposition, hearing, or trial if such person or persons execute the Acknowledgment that is attached hereto as Exhibit A or otherwise affirms on the record not to disclose such confidential material to anyone outside the deposition, hearing or trial. Confidential Information shown to any witness during a deposition shall not lose its confidential status through such use, and counsel shall exercise their best efforts and

take all steps reasonably required to protect its confidentiality during such use. If after a deposition is noticed or a hearing or trial is set, the Producing Party objects to Confidential Information being shown to that witness, the Producing Party shall attempt to confer with counsel to resolve the issue. If counsel is unable to resolve the issue themselves, counsel may seek an order from the Court prohibiting or limiting such use or for other relief. Following a deposition, the parties will comply with the provisions set forth in paragraph 18 of this Protective Order.

f) Litigation support personnel including vendor agents retained by the parties or counsel for the parties

g) Any attorney of record for claimants in cases that have been consolidated in Massachusetts Superior Court under the caption *In re: Consolidated Fresenius Cases*, case no. 2013-03400-O, and any attorney of record in any other pending state court and federal litigation in the United States in which responsive pleadings have been filed that alleges personal injury, economic loss and/or wrongful death arising from the alleged use during dialysis treatment of Defendants' dialysis products NaturaLyte GranuFlo Dry Acid Concentrate and NaturaLyte Liquid Acid Concentrate ("GranuFlo" and "NaturaLyte," respectively) for use in such other actions, provided that the proposed recipient is (a) already operating under a stipulated Protective Order in another GranuFlo action; or (b) agrees to be bound by this Protective Order and executes the Acknowledgment that is attached hereto as Exhibit A. This provision does not apply to information that is covered by the Health Information Privacy Protection Act. Plaintiff's counsel shall provide to counsel for the Defendants a list of counsel with whom it seeks to share Confidential Materials, including the style, case number, and court in which any similar claim is pending. Within ten (10) calendar days, the Defendants shall notify Plaintiff's counsel whether it objects to any person(s) on the list. Upon such notice, Plaintiffs will not share any Confidential Information in order to permit Defendants to file an appropriate protective order in a court of competent jurisdiction. Failure to file such an order within fourteen (14) calendar days shall be deemed a waiver of said objection;

h) Plaintiffs' treating physicians, nurse practitioners, or other medical professionals who treated plaintiffs (and their respective staffs);

i) Any person designated by the Court in the interest of justice, upon such terms as the Court may deem proper including Special or Discovery Masters or Mediators, if any; and

j) Mediators agreed to by the Parties or appointed by the Court.

23. Nothing contained in this Protective Order shall preclude any party from using its own Confidential Information in any manner it sees fit, without prior consent of any party or the Court. Notwithstanding any other provision herein, nothing in this Protective Order shall affect or modify the Defendant's (a) ability to utilize and review Plaintiff's information and report such information as required by law to the FDA or other regulatory agencies, or (b) its right to provide information to its insurer(s), as applicable, for purposes of evaluating Plaintiff's claims or as may be required for reporting purposes. If Defendants provide the Plaintiff's information to an insurer, this Protective Order applies the insurer.

24. It is expressly understood by and between the parties that in producing Confidential Information in the Litigation, the parties shall be relying upon the terms and conditions of this Protective Order.

V. CONFIDENTIALITY ACKNOWLEDGMENT

25. Prior to the disclosure of any Confidential Information to any person identified above, each recipient of Confidential Information shall be provided with a copy of this Protective Order, which he or she shall read and, except as provided in paragraph 22(e) above, shall sign a Confidentiality Agreement, in the form annexed hereto as Exhibit A.

a) Upon reading this Protective Order, such person shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms.

b) Outside Counsel to the Parties in this matter, the Court, and the Court's staff and official court reporter(s) are not required to sign an acknowledgement.

c) These Acknowledgments are strictly confidential. Counsel for each party shall maintain the Acknowledgments without giving copies to the other side. The parties expressly agree, and it is hereby Ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to

investigate a violation of this Protective Order, such disclosure will be pursuant to a separate court order.

d) Persons who come into contact with Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements but must comply with the terms of this Protective Order. This section shall not apply to documents shown during a deposition, which shall be governed by Paragraph 18 above.

VI. PROTECTION AND USE OF CONFIDENTIAL INFORMATION

26. Persons receiving or having knowledge of Confidential Information by virtue of their participation in this Litigation, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential Information and will limit access to such material to those persons authorized by this Protective Order.

27. Nothing herein shall restrict a person qualified to receive Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order. All persons qualified to receive Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or other work product derived from or containing Confidential Information in a manner to protect it

from disclosure not in accordance with this Protective Order. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

28. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients in the Litigation, provided that in rendering such advice, Counsel shall not disclose any other Party's Confidential Information other than in a manner provided for in this Protective Order.

29. All correspondence, pleadings, motions, exhibits, transcripts or other papers filed with the Court containing or disclosing Confidential Information shall be filed as required under Local Rule 7.2. The designating party may join in a motion to seal Confidential Information pursuant to Local Rule 7.2 by articulating its basis for withholding the documents from public access. Should the Court deny a motion to seal, the designating party shall have three (3) business days to seek relief from the Court. No Confidential Information shall be publicly disclosed until the Court rules on any requests for relief, or four (4) business days if no relief is sought.

30. Any document containing Confidential Information that the Producing Party files in any court without a confidential designation (e.g., as an exhibit to a motion or trial exhibit) loses its confidential status. The Receiving Party may thereafter use the information in the same manner as the Producing Party.

31. Any Party that is served with a subpoena or other notice compelling the production of Discovery Materials produced by another Party must immediately give written notice of such subpoena or other notice to the original Producing Party. Upon receiving such notice, the original Producing Party shall bear the burden of opposing, if it deems appropriate, the subpoena on grounds of confidentiality.

32. Should any Confidential Information be disclosed through inadvertence or otherwise to a person not authorized to receive such information under this Protective Order, then the Disclosing Party shall use its best efforts to recover any documents, pleadings, motions or transcripts containing Confidential Information and to bind such person to the terms of this Protective Order. Specifically, the Disclosing Party shall: (a) inform the person or persons to whom disclosures were made of all the terms of this Protective Order; and (b) require such person or persons execute the Confidentiality Agreement that is attached hereto as Exhibit A.

VII. CHANGES IN DESIGNATION OF INFORMATION

33. The inadvertent or unintentional failure to designate any information as Confidential in accordance with this Protective Order shall not be deemed a waiver in whole, or in part, of a Producing Party's claim of confidentiality. In the event of the disclosure of such information, the information shall be designated as Confidential Information by the Producing Party as soon as reasonably possible after the Producing Party becomes aware of the disclosure and such information shall thereafter be treated as Confidential Information subject to this Protective Order. Disclosure prior to the receipt of such notice to persons not authorized to receive Confidential Information shall not be deemed a violation of this Protective Order.

34. Any Producing Party may designate as Confidential or withdraw a Confidential designation from any material that it has produced consistent with this Protective Order, provided, however, that such re-designation shall be effective only as of the date of such re-designation. Such re-designation shall be accomplished by notifying Counsel for each Party in writing of such re-designation and providing replacement images bearing the appropriate description. Upon receipt of any re-designation and replacement image that designates material

as Confidential, the Receiving Party shall take the steps outlined in Paragraph 32 of this Protective Order.

35. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. A Receiving Party may challenge a Producing Party's confidentiality designation or re-designation by notifying the Producing Party in writing of its good-faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within fourteen (14) calendar days, the basis of the chosen designation. If a Receiving Party elects to challenge a confidentiality designation after considering the justification offered by the Producing Party, the Receiving Party may, within twenty one (21) calendar days of receiving such explanation from the Producing Party, file and serve a motion that identifies the challenged material and sets forth in detail the basis for challenging the Confidential designation. The burden of proving confidentiality rests with the party seeking confidentiality, as provided in the Federal Rules of Civil Procedure. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. If after the expiration of the twenty one (21) calendar days the Receiving Party has not filed a motion with the Court, the designation of the document subject to the dispute regarding its "CONFIDENTIAL" designation will not be changed. If a resolution is reached regarding the confidentiality designation of a challenged document, the Producing Party shall serve on all parties a notice specifying the documents and the nature of the resolution within ten (10) calendar days of reaching the resolution.

VIII. INADVERTENT OR MISTAKEN PRODUCTION OF PRIVILEGED DOCUMENTS – CLAWBACK PROCEDURES

36. Inadvertent or mistaken production of documents or electronically stored information ("ESI") (collectively "Inadvertently Produced Documents") subject to work-product or attorney-client privilege, or other legal privilege protecting information from discovery, shall not constitute a waiver of the privilege, provided that the Producing Party shall notify the Receiving Party in writing as set forth herein. In the event that a party inadvertently or mistakenly produces documents or ESI subject to a claim of privilege, the Producing Party shall, within ten (10) calendar days of the discovery of the inadvertent or mistaken disclosure, notify the other party in writing of the inadvertent or mistaken disclosure. The Producing Party may, in the notice, request a "clawback" of the inadvertently or mistakenly disclosed material. Except as set forth in paragraph 37 below, the Party receiving such clawback notice shall immediately and diligently act to retrieve the Inadvertently Produced Documents, and all copies, including any loaded to databases, and return them to the Producing Party or destroy them as agreed between the parties. All notes or other work product of the Receiving Party reflecting the contents of such materials shall be destroyed and not used except as provided under paragraph 37 below in the event of a challenge by the Receiving Party.

37. The party receiving such Inadvertently Produced Documents may, after receipt of the Producing Party's notice of inadvertent or mistaken production, move the Court to dispute the claim of privilege. If the Receiving Party elects to file such a motion, the Receiving Party, may retain possession of the Inadvertently Produced Documents as well as any notes or other work product of the Receiving Party reflecting the contents of such materials pending the resolution by the Court of the motion, but shall segregate and not use them pending resolution of the motion, except as part of the motion to the Court. The Receiving Party may, in support such a motion,

submit the Inadvertently Produced Documents to the Court in sealed envelope that shall be clearly marked:

> "THIS ENVELOPE CONTAINS DOCUMENTS MARKED AS CONFIDENTIAL THAT ARE THEREFORE COVERED BY A PROTECTIVE ORDER OF THE COURT AND IS SUBMITTED UNDER SEAL PURSUANT TO THAT PROTECTIVE ORDER AND LOCAL RULE 7.2. THE CONFIDENTIAL CONTENTS OF THIS DOCUMENT MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT"

and the Inadvertently Produce Documents shall remain sealed while in the office of the Clerk for so long as they retain their status as Confidential. If the Receiving Party's motion is denied, the Receiving Party shall promptly comply with Paragraph 36. No use shall be made of such Inadvertently Produced Documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them unless otherwise ordered by the Court.

38. Pursuant to Fed. R. Evid. 502(d), where the Parties agree in writing with regard to particular requested materials, a Producing Party may provide those requested materials for initial examination by the Receiving Party in connection with this action without waiving any privilege or protection in this action or any other federal or state proceeding. The Clawback procedures and obligations in Paragraph 36 fully apply to a claim that documents or information then in the custody of another Party for purposes of initial examination are privileged or protected.

X. MISCELLANEOUS PROVISIONS

39. Within thirty (30) calendar days of the conclusion of any attorney's last case in the Litigation, including any appeals related thereto, at the written request of the Producing Party, such attorney and any persons to whom he or she disclosed Confidential Information

under this Order shall, at the Receiving Party's option, either (a) destroy or (b) return and surrender any Confidential Information or copies thereof to the Producing Party at the Producing Party's expense. If returning materials, such persons shall return or surrender any Confidential Information produced by the Producing Party and any and all copies (electronic or otherwise), summaries, notes, compilations, and memoranda related thereto; provided, however, that counsel may retain their privileged communications, work product, Acknowledgments pursuant to this Protective Order, materials required to be retained by applicable law, and all court-filed documents even though they contain Confidential Information produced by the Producing Party, but such retained privileged communications and work product shall remain subject to the terms of this Protective Order. At the written request of the Producing Party, any person or entity having custody or control of recordings, notes, memoranda, summaries or other written materials, and all copies thereof, relating to or containing Confidential Information produced by the Producing Party shall deliver to the Producing Party a certification that reasonable efforts have been made to assure that all such Confidential Information produced by the Producing Party and any copies thereof, any and all records, notes, memoranda, summaries, or other written material regarding the discovery materials produced by the Producing Party (except for privileged communications, work product and court-filed documents as stated above) have been delivered to the Producing Party in accordance with the terms of this Protective Order. In lieu of returning the materials, the Receiving Party may destroy the materials in a manner that will protect the Confidential Information and the destroying party shall certify that it has done so.

40. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

41. It is expressly understood by and between the Parties that in producing Confidential Information in this Litigation, the Parties shall be relying upon the terms and conditions of this Protective Order.

42. The Parties reserve the right to seek additional protections for Confidential Information directly from the Court. Should any Party file a request seeking such additional protection, the Confidential Information at issue shall not be produced until the issue has been resolved by agreement of the parties or by the Court.

43. By written agreement of the parties, or upon motion and order of this Court, the terms of this Order may be modified. This Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of the Litigation.

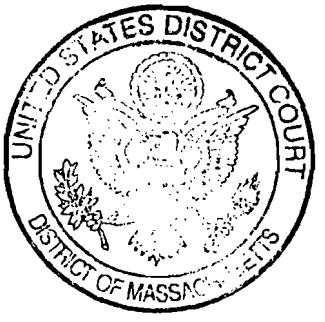
44. For good cause shown, any party may request from any other party that the times and deadlines set forth herein may be shortened or lengthened for the sake of judicial economy.

IT IS SO ORDERED.

BY THE COURT:

Douglas P. Woodlock
United States District Judge

November 15, 2013



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	§	

EXHIBIT A

CONFIDENTIALITY AGREEMENT

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order (CMO No. ___) that was issued by the United States District Court for the District of Massachusetts on _____ 2013 *in In re: Fresenius GranuFlo/NaturaLyte Dialysate Products Liability Litigation* (MDL2428).

I agree to comply with and to be bound by all the terms of this Stipulated Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Protective Order to any person or entity except in strict compliance with the provisions of this Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the District of Massachusetts for the purposes of enforcing terms of this Protective Order, even if

such enforcement proceedings occur after termination of these Proceedings.

Dated:_____ BY: _____
Signature

_____
Title

_____
Address

_____
City, State, Zip

_____
Telephone Number

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALLYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	§	**MDL NO. 1:13-MD-2428-DPW**
THIS DOCUMENT RELATES TO ALL CASES	§	

CASE MANAGEMENT ORDER NO. 6
(Regarding Plaintiff Fact Sheets and Defendant Fact Sheets)

I. PLAINTIFF FACT SHEET

1. **Service of Plaintiff Fact Sheets and HIPPA Authorizations**:

a. As set forth in Case Management Order ("CMO") No. 2, each Plaintiff in an action pending and served before the Court in MDL No. 2428 shall serve a completed Plaintiff Fact Sheet ("PFS"), the form of which has been agreed to by the parties and approved by the Court and is attached hereto as Exhibit "A."

b. Along with the PFS, each Plaintiff shall provide a *HIPAA Authorization* in the form attached at Exhibit "B." Plaintiffs may choose whether to provide one *HIPAA Authorization* that allows Defendants to fill in the information for each of Plaintiffs' Health Care Providers, or to provide a *HIPAA Authorization* for every Health Care Provider identified in the PFS. If a review of Plaintiff's medical records reveals additional Health Care Providers from whom Defendants wish to seek medical records, Plaintiff shall provide additional *HIPAA Authorizations* for those providers within ten (10) days of a request from Defendants.

2. **Deadlines for Service of the Fact Sheets:**

a. **Fresenius Clinic Cases**- In any case currently pending in this MDL where the injury/death is alleged to have been the result of treatment at a Fresenius Medical Care North America ("FMCNA") dialysis clinic and counsel for Plaintiff did not obtain the patient's clinic medical chart prior to the filing of the complaint, the deadlines for the exchange of PFS and the Defendants Fact Sheet ("DFS") is set forth in CMO No. 3. The deadlines for the exchange of Plaintiff and Defendants Fact Sheets in all other currently pending cases involving an FMCNA dialysis clinic are set forth at paragraphs 4(b) and 4(c) of CMO No. 2.

b. **Non-Fresenius Clinic Cases**- The deadline for the exchange of the PFS and DFS for cases currently pending in this MDL where the injury or death is alleged to have been the result of treatment at a non-FMCNA dialysis clinic as set forth in CMO No. 2, paragraphs 4 (b) and (c) are hereby extended thirty (30) days such that the PFS shall be served no later than December 27, 2013 and the DFS shall be served no later than February 25, 2014.

c. **Newly Filed or Transferred Cases**- The deadlines for the exchange of the PFS and DFS in cases that are newly filed or transferred into this MDL after the date of the entry of this Order are set forth in paragraph 4(d) of CMO No. 2, except that in newly filed or transferred cases where the injury/death is alleged to have been the result of treatment at an FMCNA clinic and counsel for Plaintiff did not request the patient's clinic medical chart prior to the filing of the Complaint, the deadlines for the exchange of the PFS and DFS may be extended pursuant to Paragraph 9 of CMO No. 3.

3. **Method of Service of PFS and Related Documents:**

a. **E-mail and Mail Service**- Service of the PFS and service of any documents required under CMO No. 3 shall be by mail and E-mail at:

Darrell Tucker
Bradley ArantBoult Cummings, LLP
One Federal Place
1819 Fifth Avenue North
Birmingham, AL 35203-2119

GranuFloPlaintiffCaseInformation@babc.com

b. Service of the complete PFS as set forth in paragraph 1(d) above shall be deemed good and sufficient service for all U.S. based Fresenius Defendants.

4. If a Plaintiff does not submit a PFS within the time specified in this Order, or submits a PFS that contains a material deficiency,[1] Defendants may take the following steps:

a. **Overdue PFS:** In cases where the Plaintiff does not submit a PFS within the time specified in this Order, Defendants may send a *Notice of Overdue Fact Sheet* to that Plaintiff's counsel of record within fifteen (15) days after the date the PFS was due. Said *Notice of Overdue Fact Sheet* shall permit an additional thirty (30) days to serve a completed PFS. In the event a Plaintiff does not provide the completed PFS by the expiration of the additional thirty (30) day period, Defendants may, after conducting the prerequisite meet and confer, move for relief under Fed. R. Civ. P. 37(b)(2).

b. **Materially Deficient PFS:** In cases where the Plaintiff submits a materially deficient PFS within the time specified in this Order, Defendants may send a *Notice of Materially Deficient Fact Sheet* to that Plaintiff's counsel of record within thirty (30) days after the date the PFS was due, provided however that if the number of PFS's received within five business days is 200 or more, the deadline for sending the *Notice of Materially Deficient Fact*

[1] As used herein, a materially deficient PFS or DFS means a deficiency that prejudices the opposing party through a failure to provide necessary information, thereby impeding that parties' access to material and relevant evidence.

Sheet shall be extended to sixty (60) days. Said *Notice of Materially Deficient Fact Sheet* shall permit an additional thirty (30) days to cure the material deficiency in the PFS. In the event a Plaintiff does not cure the deficiency by the expiration of the additional thirty (30) day period, Defendants may, after conducting the prerequisite meet and confer, move for relief under Fed. R. Civ. P. 37(b)(2). Plaintiff shall have fourteen (14) days to file an opposition, if any.

c. Defendants shall send a copy of all N*otices of Overdue or Materially Deficient Fact Sheets* and copies of any and all motions to dismiss under this paragraph to Plaintiffs' Liaison Counsel by E-mail at GranufloPFSDeficiency@Kreindler.com.

5. The admissibility of information in the PFS shall be governed by the Federal Rules and no objections are waived by virtue of any PFS response.

6. All information contained in the PFS is confidential and protected under the Protective Order (CMO No. 5).

II. DEFENDANT FACT SHEET

7. Defendants Fresenius USA, Inc., Fresenius Medical Care Holdings, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc. (collectively "Fresenius North America") shall serve a completed Defendant Fact Sheet ("DFS"), as set forth in CMO No. 2 and CMO No. 3, the form of which has been agreed to by the parties and approved by the Court and which is attached hereto as Exhibit "C."

8. The deadlines outlined in paragraph 1(c) above govern the timing for service of the DFS.

9. The completed DFS shall be served in an electronic form on the attorney identified on page one of the PFS. The method of service shall be by E-mail and regular mail. Additionally, a Notice of Service of the DFS shall be served by E-mail upon the attorney

identified on page one of the PFS and also on the Plaintiffs Liaison Counsel at GranufloDFS@kreindler.com.

10. If Defendants do not submit a DFS within the time specified in this Order, as set forth in paragraph 1(b) above, or submit a DFS that contains a material deficiency counsel for Plaintiff may send a *Notice of Overdue or Materially Deficient Fact Sheet* to counsel for Fresenius North America as set forth in paragraph 1(c) above, within thirty (30) days after the date that the DFS was due. Said *Notice of Overdue or Materially Deficient Fact Sheet* shall permit Fresenius North America additional thirty (30) days to cure the overdue or materially deficient DFS. In the event Fresenius North America fails to provide the completed DFS or cure the material deficiency by the expiration of the thirty (30) day period, Plaintiff's counsel shall consult with MDL Lead/Liaison Counsel, who may move for appropriate relief from the Court as set forth in paragraph 12 of CMO No. 2. Fresenius North America shall have fourteen (14) days to file an opposition, if any. Plaintiffs shall send a copy of all *Notices of Overdue or Materially Deficient Fact Sheets* to Plaintiffs' Liaison Counsel (at the E-mail address set forth in paragraph 2(c) above).

11. The admissibility of information in the DFS shall be governed by the Federal Rules and no objections are waived by virtue of any DFS response.

12. All information contained in the DFS is confidential and protected under the Protective Order (CMO No. 5).

IT IS SO ORDERED.

DOUGLAS P. WOODLOCK,
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 1:13-MD-2428-DPW**

PLAINTIFF FACT SHEET

In completing this Plaintiff Fact Sheet, you must provide information that is true and correct to the best of your knowledge. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. You must also supplement your responses in the event that you later learn or receive additional information that is responsive to any of the information requests below. In the event the Plaintiff Fact Sheet does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary. Please identify any documents that you are producing as responsive to a question or request by bates-stamp identifiers.

If you are completing this Plaintiff Fact Sheet in a representative capacity, please respond to the questions on behalf of the person you are representing whom you allege was exposed to, or treated with, GranuFlo and/or NaturaLyte. Whether you are completing this fact sheet for yourself or for someone else, please assume that "you" or "Plaintiff" means the person who was exposed to, or treated with, GranuFlo and/or NaturaLyte.

This Fact Sheet shall be completed in accordance with Case Management Orders 2 and 3. The information provided is confidential and subject to the protective order.

*[**Note:** In an effort to be forthcoming and to provide non-privileged information, the information provided in this fact sheet is, by necessity, not based solely upon the knowledge of the plaintiff and includes non-privileged information assembled and collected by the parties' attorneys which may not be known to the executing party.]*

I. CASE INFORMATION

Caption: _____ Date Filed: _____

Docket No. (Including Court):

_____

Plaintiff's Attorney and Contact Information, Including Telephone Number:

_____

_____

Name, Title and Contact Information of Each Person Providing Responses to this Fact Sheet:

_____

_____

_____

II. PLAINTIFF'S INFORMATION

Full Name of Plaintiff: _____

Last Address: _____

Date of Birth: _____

Plaintiff's FMS Medical Record Number, also known as the Patient Identification Number:

_____

If no FMS Medical Record Number, please provide the following information:

a. Plaintiff's Medicare Identification Number: _____

b. The last four digits of Plaintiff's Social Security Number: _____

Please provide the following information:

1. Date of Death/Injury: _____
2. Location of Death/Injury (Clinic, Home, Hospital, including name of clinic or hospital, if applicable, and complete address) _____

   _____
3. Cause of Death/Injury asserted by Plaintiff as of the date of this Fact Sheet:

   Non-Cardiac Event or Condition

   Cardiac Event or Condition

   Acute Coronary Syndrome

   Arrhythmia

   Bradycardia Arrhythmia

Cardiomegaly

Cardiomyopathy

Congestive Heart Failure

Coronary Artery Disease

Coronary Occlusion

Coronary Thrombosis

Myocardial Infarction

Sudden Cardiac Arrest

Cardiopulmonary Arrest

Tachycardia Arrhythmia

Atrial Fibrillation

Ventricular Fibrillation

Other (please specify)

Unknown

Do not know

☐

4. Was Autopsy Performed? _____ If So, Date_____

ATTACH DEATH CERTIFICATE AND AUTOPSY REPORT, IF APPLICABLE.

5. Please provide a list of all treating physicians or healthcare providers who provided medical care to Plaintiff within the twelve (12) months preceding the injury/death, including but not limited to all primary care physicians, cardiologists, nephrologists, and hospitals.

a. Provider Name: _____

Provider Address: _____

Type of Provider: _____

b. Provider Name: _____

Provider Address: _____

Type of Provider: _____

c. Provider Name: _____

Provider Address: _____

Type of Provider: _____

ATTACH ADDITIONAL SHEETS AS NECESSARY

III. REPRESENTATIVE/DEMOGRAPHIC INFORMATION

1. Name of Representative: _____
2. Relationship to Plaintiff (if applicable): _____
3. Address: _____
4. Appointed Position (if applicable): _____
5. Court of Appointment: _____
6. Date of Appointment: _____

IV. DIALYSIS HISTORY

1. List all dialysis clinics and/or dialysis facilities, including hospital-operated acute and chronic dialysis units, and including home hemodialysis, where the Plaintiff received dialysis treatments.

a. Dialysis Clinic Name: _____

Clinic Address: _____

b. Dialysis Clinic Name: _____

Clinic Address: _____

c. Dialysis Clinic Name: _____

Clinic Address: _____

ATTACH ADDITIONAL SHEETS AS NECESSARY

2. Please provide the date of Plaintiff's last dialysis treatment prior to or at the time of death/injury: _____

   a. Please provide the name and address of the dialysis provider: _____

_____

PLEASE PROVIDE ALL NON-PRIVILEGED, RELEVANT MEDICAL RECORDS, INCLUDING BUT NOT LIMITED TO DIALYSIS TREATMENT RECORDS, IN YOUR POSSESSION, CUSTODY OR CONTROL THAT HAVE NOT ALREADY BEEN PRODUCED PURSUANT TO CASE MANAGEMENT ORDER NO. 3

CERTIFICATION

I declare that all of the information provided in this Plaintiff Fact Sheet is true and correct to the best of my knowledge and that I have supplied all requested documents to the extent that such documents are in my possession, custody and control (including the custody and control of my lawyers).

_____	_____	_____
Signature	**Print Name**	**Date**

AUTHORIZATIONS

Provide ONE (1) SIGNED ORIGINAL copy of each of the records authorization forms attached as Ex. B to CMO No. 6. These authorization forms will authorize the records vendor selected by the parties to obtain those records from the providers identified within this Plaintiff Fact Sheet.

Date: _____

_____
Signature of Plaintiff's Counsel

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

Patient Name:	Date of Birth:	Social Security Number:
Patient Address:		

I, or my authorized representative, request that health information regarding my care and treatment be released as set forth on this form.

In accordance with the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. 164.508, I understand that:

1. This authorization may include disclosure of information relating to alcohol and drug abuse, mental health treatment, except psychotherapy notes, and confidential HIV related information, only if I place my initials on the appropriate line in Item 11(a). In the event the health information described below include any of these types of information, and I initial the line on the box in Item 11(a), I specifically authorize release of such information to the person(s) indicated in Item 10.

2. If I am authorizing the release of HIV-related, alcohol or drug treatment, or mental health treatment information, the recipient is prohibited from redisclosing such information without my authorization unless permitted to do so under federal or state law. I understand that I have a right to request a list of people who may receive or use my HIV-related information without authorization.

3. I have the right to revoke this authorization at any time by writing to the health care provider listed below. I understand that I may revoke this authorization except to the extent that action has already been taken based on this authorization.

4. I understand that signing this authorization is voluntary. My treatment, payment, enrollment in a health plan, or eligibility for benefits will not be conditioned upon my authorization of this disclosure. Any photostatic copy of this document shall have the same authority as the original, and may be substituted in its place.

5. Information disclosed under this authorization might be redisclosed by the recipient, and this redisclosure may no longer be protected by federal or state law, except as noted in Item 2.

6. This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).

7. This authorization shall be valid through December 31, 2016 or the conclusion of my case, whichever occurs first; unless it is revoked as provided in Item 3, and shall remain in full force and effect until such expiration, and further authorizes the Provider to release to the Recipient any additional records created or obtained by the Provider after the date hereof. The records requester has agreed to pay reasonable charges made by the Provider to supply copies of such records.

8. This authorization specifically does NOT authorize the release of original documents and materials, including tissue slides, tissue blocks and tissue samples.

9. Name and address of health provider or entity to release this information:	
10. Name and address of entity(ies) to whom this information will be mailed or sent:	Name and address of entity as designee to whom this information will be mailed or sent:

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

11(a). Specific information to be released:

☒ Medical Records and patient data (See CMO - ___ in MDL No. 2428)

☒ Entire Medical Record, including, but not limited to, patient histories, office notes (except psychotherapy notes), biopsy/pathology specimens and/or materials, and autopsy materials), diagnoses, analyses, progress reports, laboratory reports, test results, x-rays, radiology reports, radiology films or scans (in any form), referrals, consults, billing records, correspondence, prescription records, autopsy reports, pathology reports, death certificates, consents for treatment, insurance records, and records sent to you by other health care providers.

☐ Other: _____

_____

Include: (*Indicate by initialing*)

_____Alcohol/Drug Treatment

_____Mental Health Information

_____ HIV-Related Information

Authorization to Discuss Health Information

11(b) ☐ By initialing here _____ I authorize _____

Name of individual health care provider

to discuss my health information with my attorney, or a governmental agency listed here:

_____

(Attorney/Firm Name or Governmental Agency Name)

***This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).

12. Reason for release of information: ☐ At request of individual ☒ Other: Litigation	13. Date or event on which this authorization will expire: December 31, 2016 or at the conclusion of the case, whichever occurs first.
14. If not the patient, name of person signing form:	15. Authority to sign on behalf of patient:

All items on this form have been completed and my questions about this form have been answered. In addition, I have been provided a copy of the form.

_____ Date: _____

Signature of patient or authorized representative

ACKNOWLEDGMENT

The undersigned, as the record requester named in the above medical authorization, hereby declares under penalty of perjury, pursuant to 28 U.S.C. Section 1746, that the attorney to the patient named in the foregoing medical authorization has been given notice that the authorization will be used to request records from the person or entity to whom it is addressed, and the attorney has been given five (5) days advance notice and has been afforded an opportunity to object to the request and any objections have been resolved. The attorney for the patient named in the foregoing medical authorization has also been afforded an opportunity to order copies of the records from the undersigned requestor at a reasonable cost.

_____

2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 1:13-MD-2428-DPW**

DEFENDANT FACT SHEET

For each case, Fresenius USA, Inc., Fresenius Medical Care Holdings, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc. (collectively "Defendant") must complete this Defendant Fact Sheet ("DFS"). In completing this DFS, you must provide information that is true and correct to the best of your knowledge. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. In the event the DFS does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary. Please identify any documents that you are producing as responsive to a question or request by bates-stamp identifiers.

This DFS must be completed and served on all counsel identified as representing the plaintiff in Section I of the Plaintiff's Fact Sheet.

The terms "you," "your" or "yours" means the responding defendant.

The term "Plaintiff" refers to the injured party.

The phrase "Health Care Provider" means each of the Plaintiff's physicians or medical providers, including dialysis facilities and nephrologists.

This Fact Sheet shall be completed in accordance with Case Management Orders 2 and 3. The information provided is confidential and subject to the protective order.

[Note: In an effort to be forthcoming and to provide non-privileged information, the information provided in this fact sheet is, by necessity, not based solely upon the knowledge of the defendant and includes non-privileged information assembled and collected by the parties' attorneys which may not be known to the executing party.]

I. CASE INFORMATION

Caption: _____ **Date Filed:** _____

Docket No.: _____

Plaintiff: _____

Name, Title and Contact Information of Each Person Providing Responses to this Fact Sheet:_____

II. PRODUCT IDENTIFICATION

1. Did you distribute GranuFlo acid concentrate to the clinic, facility, or hospital where Plaintiff received the last dialysis treatment prior to injury/death as identified in Section IV of the Plaintiff's Fact Sheet (the "Named Facility") during the twelve (12) month period of time preceding the date of injury/death?

_____ Yes _____ No _____ Don't Know

2. If your answer is "yes" to Question 1 above, please provide a list of all shipments of GranuFlo acid concentrate to the Named Facility for the period of twelve (12) months prior to the alleged injury/death to Plaintiff through the date of injury or death and include the dates of shipment or distribution.

3. If your answer is "don't know" to Question 1 above and you have reason to believe that GranuFlo acid concentrate may have been shipped to the Named Facility by a distributor (i.e., contractors, subcontractors and agents) and records pertaining to that shipment reside with the distributor, please identify the distributor.

4. Please provide a complete set of product labels used for GranuFlo acid concentrate from January 2003 through October 2013 and associate each label with the code numbers to which they are applicable.

5. Does data uploaded from the Fresenius Medical Service clinic medical chart and compiled in the Data Warehouse indicate that GranuFlo acid concentrate with a composition of 8 meq/L of acetate was prescribed for this patient in the twelve (12) month period preceding the injury/death:

6. Please indicate below the model of the Fresenius dialysis machine in use by the Plaintiff's at the time of the Plaintiff's alleged injury or death at the facility identified in Section IV.2 of the Plaintiff's Fact Sheet (the "Named Facility"):

Model 2008K: ☐

Model 2008H: ☐

Model 2008K2: ☐

Model 2008T: ☐

Other: _____

Unknown: ☐

III. PLAINTIFF'S HEALTHCARE PROVIDERS

1.Dear Doctor/Dear Healthcare Provider Letters

A. Please provide a full set of "Dear Doctor" or "Dear Healthcare Provider" letters or memoranda issued by the FMS Chief Medical Office related to acid concentrate products for the years 2000 through 2012, together with a compilation of the physicians to whom the letters or memoranda were made available either through direct transmission or through access to the FMS Doctor's Corner website, and the date on which such access was given to each physician, if any.

B. For each "Dear Doctor" or "Dear Healthcare Provider" that was sent to Plaintiff's dialysis clinic(s), please identify any and all lists or databases that demonstrate that these letters were sent to our clients' treating physicians, and provide documentation that identifies that the letter was sent, if any.

C. Please provide copies of any "Reply Forms" returned in response to the "Dear Doctor" or "Dear Healthcare Provider" letters, if any.

2. Identity of Plaintiff's Dialysis Facility Director, Patient Care Technician(s) and Other Providers

For cases involving a Fresenius dialysis facility, please identify the Medical Director at the Named Facility at the time of Plaintiff's injury or death. To the extent not legible in Plaintiff's medical records produced in accordance with CMO 3, please identify to the extent possible the persons whose names are entered but not legible on the day of Plaintiff's last dialysis treatment

prior to injury/death.

IV. PLAINTIFF INFORMATION

1. Do you have in your possession any Medwatch FDA Forms 3500A filed with the FDA related to Plaintiff?

_____ Yes _____ No

2. Do you have in your possession any internal product complaints recorded by the Renal Therapies Group's pharmacovigilance department related to Plaintiff?

_____ Yes _____ No

3. Do you have in your possession any Fresenius "Reports of Clinical Variance" related to Plaintiff?

_____ Yes _____ No

If your answer to any of the above three questions is "yes," please either provide a copy of the document(s) described above or state that a privilege is being asserted with respect to such document(s).

4. Was Plaintiff one of the 941 hemodialysis patients who were the subjects of the Fresenius study described in the internal company memo dated November 4, 2011?

_____ Yes _____ No

If your answer to the above question is "yes," please provide any documents pertaining to the Plaintiff and his/her relationship to the above-referenced study.

5. Did you or any consultant perform an analysis, adjudication, or review of medical or scientific information concerning the Plaintiff, his or her use of Granuflo, and the potential for Granuflo to cause injury and or death to the Plaintiff?

_____ Yes _____ No _____ Unknown

If your answer to the above question is "yes," please identify the person(s) performing the analysis or review, their current address, and produce all documents relating to the analyses performed concerning the Plaintiff. (Note: This request does not require Defendant to reveal or

produce information or documents protected by privilege, including, but not limited to, work product of attorneys or retained consulting experts.)

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CERTIFICATION

I declare that all of the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge and that I have supplied all requested documents to the extent that such documents are in my possession, custody and control (including the custody and control of my lawyers).

Signature	Print Name	Date

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	§	

AGREED TO PROPOSED CASE MANAGEMENT ORDER NO. 7 (Revised)

(Master Complaint, Short Form Complaint, Master Responsive Pleadings, Direct Filing and Waiver of Service of Process For Direct Filed Cases)

This MDL Court recognizes that cases relating to this MDL (*In re: Fresenius GranuFlo/NaturaLyte Dialysate Products Liability Litigation*, MDL No. 2428) may originate in state court and be removed to a federal court and then transferred to this MDL Court as a "tag-along" case, may originate in another federal court and then transferred to this MDL Court as a "tag-along" case or may originate in this federal court district. This Case Management Order is entered to promote efficiency and to eliminate the delays typically associated with the "tag-along" transfer of cases to this MDL Court by the Judicial Panel on Multidistrict Litigation and to facilitate cases that originate in this federal district court being consolidated and coordinated for pretrial proceedings in this MDL. Accordingly, for all civil actions transferred to *In re: Fresenius GranuFlo/NaturaLyte Dialysate Products Liability Litigation*, MDL No. 2428 (the "MDL 2428 Proceedings") by the Judicial Panel on Multidistrict Litigation pursuant to its order of March 29, 2013, and any actions later filed in, removed to, or transferred to this MDL Court, it is **ORDERED** as follows:

I. GENERAL

1. This Order applies to Plaintiffs and the following defendants: Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., Fresenius USA Marketing, Inc., Fresenius USA Sales, Inc., and Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America (collectively referred to as "Fresenius North America"); and Fresenius Medical Care AG & CO. KGaA, Fresenius Medical Care Management AG, Fresenius SE & CO. KGaA and Fresenius Management SE (collectively referred to as to the "European Fresenius Defendants"). No defendants other than Fresenius North America and the European Fresenius Defendants are hereby bound by the provisions of this Order.

2. The previously filed attached *Master Complaint and Jury Demand* ("*Master Complaint*") naming Fresenius North America and the European Fresenius Defendants as Defendants (Exhibit "A"), and the attached revised form of *Short Form Complaint* (Exhibit "B") have been presented to the Court, and the Court **DIRECTS** that the Clerk file those documents in this MDL.

3. All factual allegations pled in the *Master Complaint* are deemed pled against Fresenius North America and the European Fresenius Defendants in any previously filed *Complaint* for any case now pending in this MDL proceeding, and as to any *Short Form Complaint* hereafter filed; provided, however, the *Master Complaint* is applicable only as against the entities from Fresenius North America and European Fresenius Defendants that are named as a defendant in the *Master Complaint* and selected as a defendant in the *Short Form Complaint*.

4. Each *Short Form Complaint* shall indicate which entities from Fresenius North America and the European Fresenius Defendants named in the *Master Complaint* are named as a defendant in the individual case, those counts in the *Master Complaint* that are being asserted in

the individual case, and the specific consumer protection statute, if any, upon which the Plaintiff relies.

5. This Order does not preclude a Plaintiff from naming other defendants in a *Short Form Complaint*. Accordingly, if a Defendant other than Fresenius North America or the European Fresenius Defendants is named as a Defendant in a *Short Form Complaint*, the specific facts supporting all allegations against that Defendant shall be pleaded in accordance with the Federal Rules of Civil Procedure on a separate sheet of paper attached to the *Short Form Complaint*. In the event that any allegations of the *Master Complaint* are incorporated in a *Short Form Complaint* against any other Defendant(s), then that Defendant may file an *Answer* to the *Short Form Complaint* containing a general denial of the allegations in the *Master Complaint*.

II. DIRECTLY FILED CASES[1]

6. Subsequent to the filing of this Order, all actions initially filed directly in the District of Massachusetts in the MDL 2428 Proceedings pursuant to the direct filing procedures stated in this Case Management Order against Fresenius North America and the European Fresenius Defendants shall occur by the filing of the *Short Form Complaint*. Plaintiffs shall file the *Short Form Complaint* attached hereto at Exhibit B (and available in Word format from Plaintiffs' Liaison Counsel's office at jferraro@kreindler.com), marking where indicated on the form that it is a "new matter".

7. To file a new civil action *via* the CM/ECF system using a *Short Form Complaint*, a Plaintiff shall follow the instructions set forth on Exhibit C. The usual court fees for a newly filed matter shall apply equally to the filing of a *Short Form Complaint* marked as a "new matter."

[1]A "Directly Filed Case" is a case filed in the District of Massachusetts for inclusion in this MDL.

8. In order to eliminate delays associated with a "tag-along" transfer to this Court of cases that might otherwise be first filed in a federal district court that is not this Court, or first filed in a state court located in a federal district that would not result in the removal of that case to this Court, but removal to a different federal district court, and to promote judicial efficiency, any Plaintiff whose case is so filed and which would then be subject to a "tag-along" transfer to the MDL 2428 Proceedings, may file his or her case directly in the MDL 2428 Proceedings in the District of Massachusetts by the filing of a *Short Form Complaint*.

9. Cases directly filed in this Court pursuant to this Order shall not name more than a single Plaintiff in the case, provided, however, that any such case may include consortium plaintiff(s) as permitted by law and, in the event of a wrongful death action, the appropriate representative(s) of the Estate.

10. Each case filed directly in the MDL Proceedings shall be filed using the *Short Form Complaint* and litigated in the MDL 2428 Proceedings for purposes of pretrial proceedings, consistent with the Judicial Panel on Multidistrict Litigation's March 29, 2013 Transfer Order. As to any Plaintiff who chooses to file the case directly in these MDL 2428 Proceedings, the Plaintiff may elect on the *Short Form Complaint*, for the Complaint to be deemed to have been originated in Massachusetts (hereafter referred to as his or her "home forum"), thereby electing for the case to be tried or otherwise resolved in the District of Massachusetts and upon such election and choice by the Plaintiff, Fresenius North America and the European Defendants shall not challenge the designation of Massachusetts as the home forum for the case, nor challenge that this MDL Court shall be the Court to try or otherwise resolve the case.

11. Regardless of whether a Plaintiff makes an election in the *Short Form Complaint* to deem this MDL Court as the home forum for the Plaintiff, solely for purposes of pretrial proceedings, Fresenius North America and the European Fresenius Defendants shall not challenge the venue of any action filed directly in the MDL Proceedings in the District of Massachusetts. The direct filing of actions in the MDL 2428 Proceedings in the District of Massachusetts is solely for purposes of consolidated discovery and related pretrial proceedings as provided by 28 U.S.C. § 1407. Upon the completion of all pretrial proceedings applicable to a case directly filed in the MDL 2428 Proceedings where the Plaintiff did not elect to choose this MDL Court as the Plaintiff's home forum in the *Short Form Complaint*, and subject to any agreement that may be reached concerning a waiver of the requirements for transfer pursuant to *Lexecon v. Milberg Weiss et al.*, 523 U.S. 26 (1998) as to cases where the election was not made, this Court, pursuant to the Rules of the Judicial Panel on Multidistrict Litigation and 28 U.S.C. §1404(a), will initiate the transfer of that case to a federal district court of proper venue as defined by 28 U.S.C. §1391, based on the district where the plaintiff or decedent resided at the time of alleged injury, where dialysis with NaturaLyte and/or GranuFlo was administered, the recommendations of the parties to that case, or on its own determination after briefing from the parties if they cannot agree. Utilization of the procedure set forth in this Order for directly filing a case in the MDL 2428 Proceedings shall not result in this Court being deemed the "transferor court" for any such directly filed case, unless the Plaintiff elects to choose Massachusetts as his or her home forum on the *Short Form Complaint*.

12. The preceding paragraphs of this Order do not preclude the parties from agreeing, at a future date, to try in this District cases filed pursuant to this Order in which the Plaintiff did NOT elect to choose Massachusetts as his or her home forum on the Short Form Complaint.

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13. The inclusion of any action in this MDL Proceeding, whether such action was or will be filed originally or directly in the District of Massachusetts, shall not constitute a determination by this Court that jurisdiction or venue is proper in this District.

14. The caption for any *Short Form Complaint* that is directly filed in MDL 2428 before this Court shall bear the following caption:

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:	§	**COMPLAINT AND DEMAND FOR JURY TRIAL**
[Names of Plaintiff]	§	
Plaintiffs,	§	
v.	§	
[Any of the following defendants]	§	
FRESENIUS USA, INC.,	§	
FRESENIUS USA MANUFACTURING, INC.,	§	
FRESENIUS USA MARKETING, INC.,	§	
FRESENIUS USA SALES, INC.,	§	
FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA,	§	
FRESENIUS MEDICAL CARE AG & CO. KGaA,	§	
FRESENIUS MEDICAL CARE MANAGEMENT AG,	§	
FRESENIUS SE & CO. KGaA	§	
FRESENIUS MANAGEMENT SE	§	
Defendants	§	

15. Any attorney admitted to practice and in good-standing in any United States District Court is admitted *pro hac vice* in this litigation and association of co-counsel for purposes of filing and/or litigation, including direct filing, is not required.

16. When electronically filing the pleadings, the signature block shall follow the below format:

RESPECTFULLY SUBMITTED,
/s/ Jane Doe
Jane Doe
NAME OF LAW FIRM
ADDRESS
TELEPHONE
FAX
EMAIL@EMAIL.com
Attorney for Plaintiff

III. USE OF SHORT FORM COMPLAINT FOR EXISTING CASES

17. Plaintiffs with cases pending in MDL 2428 at the time of entry of this revised CMO 7 shall, within 60 days of this Order, file a *Short Form Complaint*, which shall replace a Plaintiff's original "long form" Complaint, by filing the *Short Form Complaint* as an "amended complaint" via the Court's CM/ECF system, in the individual docket that was established for the case upon the filing of the original long form Complaint. Plaintiffs shall mark where indicated on the *Short Form Complaint* that the filing relates to a "pending matter" and shall not pay any additional court fees.

18. Cases transferred to these MDL proceedings after entry of this revised CMO 7 shall also have 60 days (from the date on which the case is docketed in USDC Massachusetts) in which to file their *Short Form Complaints* in the manner set forth above in Par. 17.

19. Cases which were pending at the time of entry of this revised CMO 7 may opt to choose Massachusetts as the "home forum" if the case was transferred from another jurisdiction, by checking where indicated on the *Short Form Complaint*.

20. For cases which were pending at the time of entry of this revised CMO 7, the date of filing of the original long form Complaint shall govern for purposes of calculating the period of limitations.

IV. AMENDMENTS TO SHORT FORM COMPLAINT

21. If, at any time, a Plaintiff desires to amend his or her *Short Form Complaint*, which alleges wrongful death, he or she may, as a matter of course and without the need to file a motion for leave to amend or the imposition of additional court fees, amend his/her Short Form Complaint for the purpose of substituting the duly appointed personal representative of the estate of the decedent (marking where indicated on the form that it relates to a "pending matter"). For any other amendments to a *Short Form Complaint* which has been served on any Fresenius defendant, the Plaintiff must proceed pursuant to Fed. R. Civ. P. 15.

V. SERVICE OF PROCESS ON FRESENIUS NORTH AMERICA

22. Fresenius North America agrees, without waiver of any defenses, to accept service of process of both the *Master Complaint* and any *Short Form Complaint* filed in the MDL 2428 Proceedings (or any Amendments thereto), solely on their own behalf in all cases filed directly in this MDL, in accordance with the direct filing procedures set forth in this Order, subject to the provisions of Fed. R. Civ. P. 4(d)(as modified herein).

23. For cases filed directly in the MDL 2428 Proceedings pursuant to this Order, the *Master Complaint* or *Short Form Complaint* (or any amendments thereto) and notice required

under Rule 4(d) shall be provided by mailing them with a cover letter with an E-Mail address for receipt confirmation to:

Brandt Zeigler
Bradley Arant Boult Cummings, LLP
One Federal Place
1819 Fifth Avenue North
Birmingham, AL
35203-2119

24. Fresenius North America is not required to return the waiver forms contemplated by Rule 4(d), but shall instead send a confirmation of first receipt of a *Master Complaint* or *Short Form Complaint* (or any amendments thereto) to Plaintiff's counsel by E-mail or otherwise and shall respond to the *Master Complaint* or *Short Form Complaint* (or any amendments thereto) as set forth herein at paragraphs 31 through 33. A Plaintiff who files his/her *Short Form Complaint* (or any amendments thereto) directly in the MDL 2428 Proceedings pursuant to the terms of this Order and effectuates service pursuant to paragraphs 22 and 23 is not required to file a return of service with the Court.

25. Service on Fresenius North America will be effective only if effected and confirmed as set forth above by confirmation E-mail from Brandt Zeigler of Bradley Arant Boult Cummings, LLP. This Order does not prevent any Plaintiff from effecting service on Fresenius North America pursuant to any other method authorized under the Federal Rules of Civil Procedure.

VI. SERVICE OF PROCESS ON THE EUROPEAN FRESENIUS DEFENDANTS

26. Plaintiffs shall serve a Summons, their Master Complaint and a template Short Form Complaint upon the European Fresenius Defendants in a manner consistent with Fed. R. Civ. P. 4 and applicable portions of the Hague Convention.

27. The European Fresenius Defendants agree, without waiver of any defenses, to accept service of process of any *Short Form Complaint* (or any Amendments thereto) filed in the MDL 2428 Proceedings in accordance with this Order, solely on their own behalf, subject to the provisions of Fed. R. Civ. P. 4(d)(as modified herein).

28. For cases filed directly in the MDL 2428 Proceedings pursuant to this Order, as well for cases described above in Pars. 17-18 where a *Short Form Complaint* shall be filed to replace a Plaintiff's existing long form Complaint, the *Short Form Complaint* (or any amendments thereto) and notice required under Rule 4(d) shall be provided to the European Fresenius Defendants by mailing them with a cover letter with an E-Mail address for receipt confirmation to:

Vivianne Knierim
Baker & McKenzie LLP
452 Fifth Avenue
New York, New York 10018

29. The European Fresenius Defendants are not required to return the waiver forms contemplated by Rule 4(d), but shall instead send a confirmation of first receipt of a *Short Form Complaint* (or any amendments thereto) to Plaintiff's counsel by E-mail or otherwise and shall respond to the *Master Complaint* or *Short Form Complaint* (or any amendments thereto) as set forth herein at paragraphs 31 through 33. A Plaintiff who files his/her *Short Form Complaint* (or any amendments thereto) in the MDL 2428 Proceedings pursuant to the terms of this Order and effectuates service pursuant to paragraphs 27 and 28 is not required to file a return of service with the Court.

30. Service of a Short Form Complaint on the European Fresenius Defendants will be effective only if effected and confirmed as set forth above by confirmation E-mail from the law firm Baker & McKenzie.

VII. FRESENIUS NORTH AMERICA AND EUROPEAN FRESENIUS DEFENDANTS' RESPONSIVE PLEADINGS- DIRECT FILED CASES AND CASES TRANSFERRED BY THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION (JPML)[2]

31. Neither Fresenius North America nor the European Fresenius Defendants are required to file *Short Form Answers* to any such *Short Form Complaint*. An *Entry of Appearance* following service of process (including an appearance entered prior to the filing of the *Short Form Complaint*) by an attorney representing, respectively, Fresenius North America or the European Fresenius Defendants shall constitute a denial of all allegations in the *Short Form Complaint* filed against, respectively, Fresenius North America or the European Fresenius Defendants, and an assertion of all defenses that are included in the *Master Answer* filed on behalf of, respectively, Fresenius North America and the European Fresenius Defendants.

32. If additional causes of action are alleged against Fresenius North America or the European Fresenius Defendants in a *Short Form Complaint* that were not alleged in the *Master Complaint*, the specific facts supporting these allegations shall be pleaded in accordance with the Federal Rules of Civil Procedure and the Fresenius entity or entities against whom they are alleged must be specifically identified on a separate sheet of paper attached to the *Short Form Complaint*. If additional causes of actions are added pursuant to this paragraph, Fresenius North America and the European Fresenius Defendants reserve the right to plead, or otherwise respond, specifically and separately to such additional causes of action.

[2]A "Case Transferred by the JPML" is a case filed in or removed to a federal district other than the District of Massachusetts and subsequently transferred to the District of Massachusetts by the Judicial Panel on Multidistrict Litigation.

33. Filing of a *Master Answer.*

a. A *Master Answer and Affirmative Defenses* ("*Master Answer*") shall be filed once: (a) on behalf of only Fresenius North America in MDL 2428 no later than thirty (30) days after entry of this Case Management Order; and (b) on behalf of only the European Fresenius Defendants (individually or collectively) in MDL 2428 no later than forty-five (45) after service of process. The *Master Answer* shall be deemed to respond to the allegations of all *Complaints* against, respectively, Fresenius North America and the European Fresenius Defendants in member actions filed in, removed to, or transferred to MDL 2428. The *Master Answer* is not intended to, and shall not, waive any applicable defenses available to Fresenius North America and the European Fresenius Defendants, and any Fresenius defendant may respond to any complaint by way of motion(s) permissible under the Federal Rules of Civil Procedure and Case Management Orders in MDL 2428 or otherwise. Fresenius North America and the European Fresenius Defendants (individually or collectively) may also file counterclaims, cross-claims and/or third-party complaints, pursuant to Rules 13 and 14 of the Federal Rules of Civil Procedure, in connection with any particular individual action.

b. To the extent Fresenius North America or the European Fresenius Defendants (individually or collectively) desire to respond to any particular individual *Short-Form Complaint* for the purpose of motion practice, including for the purpose of addressing any specific cause of action, or for the purpose of pleading counterclaims, cross-claims and/or third-party complaints, such motions or other responsive pleadings shall be filed within the deadlines established by applicable CMO(s), or within 45 days after service of process of the specific member action upon a Fresenius defendant, whichever is later.

c. In any member action that is remanded to a transferor court pursuant to JPML Rules 10.1-10.2, or is selected as a bellwether trial should such procedures be ordered, Fresenius North America and the European Fresenius Defendants (individually or collectively) may file an amended answer that includes, but is not limited to, state-specific affirmative defenses based on the applicable substantive state law(s) for that member action.

(i) For remanded Member actions, the amended answer shall be filed within 45 days of the remand to the transferor court.[3]

(ii) For Member Actions selected as a potential bellwether action, should that procedure be implemented by the Court, the amended answer shall be filed within 45 days of such designation.

[3] "Remand" is defined as the date on which the member case is opened, after the entry of a remand order, by the clerk of the transferor court.

34. Counsel for the Fresenius Defendants shall not further answer or respond to any original long form Complaint filed prior to the entry of CMO 7.

35. The parties may request extension of these deadlines by means of a stipulated order submitted to the Court. The foregoing provisions do not impact the parties' ability to seek leave to amend a complaint or responsive pleading in accordance with Local Rules and the Federal Rules of Civil Procedure. In no event may Plaintiffs file a request for default against any Fresenius entity or entities named in any member action without first contacting counsel for such defendant and allowing 21 days for remedy.

SO ORDERED this 3d day of February, 2014.

/s/ Douglas P. Woodlock

DOUGLAS P. WOODLOCK, J.

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:	:	**JURY TRIAL DEMANDED**
All Cases	:	

MASTER COMPLAINT
AND DEMAND FOR JURY TRIAL

The Plaintiffs' Executive Committee ("PEC") and the Plaintiffs' Steering Committee ("PSC") file this *Master Complaint and Demand for Jury Trial* ("*Master Complaint*") as an administrative device. The intent of the filing of the Master Complaint is to set forth the claims that individual Plaintiffs and/or the estates and/or heirs of deceased persons may assert against Defendants in this litigation through the adoption of this Master Complaint by such individual Plaintiffs and/or the estates and/or heirs of deceased persons as their own Complaint. The adoption of this Master Complaint will occur through the filing of a *Short Form Complaint* where the individual Plaintiffs and/or the estates and/or heirs of deceased persons will incorporate this Master Complaint into their specific case. An implementing Case Management Order will permit the filing of this Master Complaint and its adoption by the filing of a *Short Form Complaint* in each specific case.

I. SUMMARY OF THE CASE

1. This action arises from the use of NaturaLyte® and/or GranuFlo® Dry Acid Concentrates ("NaturaLyte" and/or "GranuFlo") in the dialysis treatment of persons and the resultant injuries and deaths suffered by such persons that were caused by NaturaLyte and/or

GranuFlo. The products that are the subject of the litigation are 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. These products are described hereafter collectively as "NaturaLyte and/or GranuFlo".

2. As a result of the defective nature of NaturaLyte and/or GranuFlo and Defendants' failure to properly label and warn about their products, persons who were given GranuFlo and/or NaturaLyte products as part of their dialysis treatment, including the living Plaintiffs and the deceased persons who are represented by their estates and/or heirs in this MDL, had significant health problems including but not limited to cardio pulmonary arrest, and/or sudden cardiac arrest or death.

3. Defendants concealed their knowledge of the dangers of NaturaLyte and/or GranuFlo from the living Plaintiffs and from the deceased persons who are represented by their estates and/or heirs, their health care providers, other consumers, and the medical community. Specifically, at all relevant times in this lawsuit, Defendants knew or should have known of the dangers of NaturaLyte and/or GranuFlo yet they failed to adequately inform Plaintiffs, the deceased persons who are represented by their heirs and/or estates, consumers, the prescribing medical community, and dialysis providers that NaturaLyte and/or GranuFlo presented the risk of and caused serious injuries and death.

II. PARTIES

A. PLAINTIFFS

4. This *Master Complaint* is filed for, and on behalf of all living Plaintiffs in this MDL, and if applicable, Plaintiffs' spouses, children and wards, and on behalf of decedents, and the administrators and/or executors of decedent Plaintiffs' Estates.

5. Plaintiffs are living individuals, and/or represent the Estate or interests of deceased or now incompetent individuals, who were administered NaturaLyte and/or GranuFlo for dialysis treatment and as a direct and proximate result of such administration of NaturaLyte and/or GranuFlo, suffered severe injuries and/or death, and damages therefrom.

B. DEFENDANTS

6. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. is a corporation organized under the laws of the State of New York having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

7. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing NATURALYTE and/or GRANUFLO throughout the United States.

8. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. has transacted and conducted business throughout the United States.

9. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States.

10. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. derives substantial revenue from interstate commerce throughout the United States.

11. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA is a corporation organized under the laws of the State of New York having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

12. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA is a major provider of renal care products. It provides products for chronic kidney disease and it manufactures and distributes a variety of dialysis products and equipment, including dialysis machines, dialyzers and other dialysis-related supplies.

13. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing NATURALYTE and/or GRANUFLO throughout the United States.

14. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA has transacted and conducted business throughout the United States.

15. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States.

16. Defendant FRESENIUS USA, INC. is a corporation organized under the laws of the State of Massachusetts having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451. Defendant FRESENIUS USA, Inc manufactures and distributes equipment and disposable products for the treatment of kidney failure by dialysis.

17. Defendant FRESENIUS USA, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States.

18. Defendant FRESENIUS USA, INC. has transacted and conducted business throughout the United States.

19. Defendant FRESENIUS USA, INC. has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold and/or distributed throughout the United States.

20. Defendant FRESENIUS USA MANUFACTURING, INC. is a corporation organized under the laws of the State of Delaware having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

21. Defendant FRESENIUS USA MANUFACTURING, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States.

22. Defendant FRESENIUS USA MANUFACTURING, INC. has transacted and conducted business throughout the United States.

23. Defendant FRESENIUS USA MARKETING, INC. is a corporation organized under the laws of the State of Delaware having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

24. Defendant FRESENIUS USA MARKETING, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States.

25. Defendant FRESENIUS USA MARKETING, INC. has transacted and conducted business throughout the United States.

26. Defendant FRESENIUS USA MARKETING, INC. has derived substantial revenue from goods and products used throughout the United States.

27. Defendant FRESENIUS USA MARKETING, INC. expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States.

28. Defendant FRESENIUS USA SALES, INC. is a corporation organized under the laws of the State of Massachusetts having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

29. Defendant FRESENIUS USA SALES, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States.

30. Defendant FRESENIUS USA SALES, INC. has transacted and conducted business throughout the United States.

31. Defendant FRESENIUS USA SALES, INC. has derived substantial revenue from goods and products used throughout the United States.

32. Defendant FRESENIUS USA SALES, INC. expected or should have expected its acts to have consequences within this judicial district; and, derives substantial revenue from interstate commerce transacted throughout the United States.

33. Upon information and belief, defendants FRESENIUS USA, INC, FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., and FRESENIUS USA SALES, INC. are wholly owned subsidiaries of defendants FRESENIUS MEDICAL CARE HOLDINGS, INC. and/or FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

34. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA is a partnership limited by shares organized under the laws of Germany having its headquarters and principal place of business at Else-Kröner Str. 1, 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

35. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA, a partnership limited by shares, was formerly known as FRESENIUS MEDCIAL CARE AG, a stock corporation. FRESENIUS MEDICAL CARE AG & CO. KGaA is the same legal business entity as FRESENIUS MEDICAL CARE AG.

36. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA is and was at all relevant times the parent company of defendants FRESENIUS MEDICAL CARE HOLDINGS, INC. and/or FRESENIUS MEDICAL CARE HOLDINGS, INC., d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

37. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling, and/or distributing, NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

38. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA has transacted and conducted business throughout the United States, including this judicial district.

39. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

40. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA expected or should have expected its acts to have consequences within this judicial district; and, derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

41. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG is a corporation organized under the laws of Germany having its headquarters and principal place of business at Else-Kröner Str. 1, 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

42. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG is the general partner of defendant FRESENIUS MEDICAL CARE AG & CO. KGaA, and is responsible for the management of defendant FRESENIUS MEDICAL CARE AG & CO. KGaA.

43. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG was the majority voting shareholder of FRESENIUS MEDICAL CARE AG & CO. KGaA, when it was known as FRESENIUS MEDICAL CARE AG, and was responsible for the management of

defendant FRESENIUS MEDICAL CARE AG & CO. KGaA, when it was known as FRESENIUS MEDICAL CARE AG.

44. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

45. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG has transacted and conducted business throughout the United States, including this judicial district.

46. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

47. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG is and was at all times relevant herein a wholly owned subsidiary of defendant FRESENIUS SE & CO. KGaA.

48. Defendant FRESENIUS SE & CO. KGaA is a partnership limited by shares organized under the laws of Germany having its headquarters and principal place of business at Else-Kröner Str. 1, 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

49. Defendant FRESENIUS SE & CO. KGaA was formerly known as FRESENIUS SE, which was formerly known as FRESENIUS AG. Defendant FRESENIUS SE & CO. KGaA is the same legal business entity as FRESENIUS SE and FRESENIUS AG.

50. Defendant FRESENIUS SE & CO. KGaA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting,

selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

51. Defendant FRESENIUS SE & CO. KGaA has transacted and conducted business throughout the United States, including this judicial district.

52. Defendant FRESENIUS SE & CO. KGaA has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

53. Defendant FRESENIUS SE & CO. KGaA expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

54. Defendant FRESENIUS MANAGEMENT SE is a corporation organized under the laws of Germany having its headquarters and principal place of business at Else-Kröner Str. 1, 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

55. Defendant FRESENIUS MANAGEMENT SE is the general partner of FRESENIUS SE & CO. KGaA and is responsible for the management of defendant FRESENIUS SE & CO. KGaA.

56. Defendant FRESENIUS MANAGEMENT SE was the majority voting shareholder of FRESENIUS SE & CO. KGaA when it was known as FRESENIUS SE, and was responsible for the management of defendant FRESENIUS SE & CO. KGaA, when it was known as FRESENIUS SE.

57. Defendant FRESENIUS MANAGEMENT SE was the majority voting shareholder of FRESENIUS SE & CO. KGaA when it was known as FRESENIUS AG, and was responsible for the management of defendant FRESENIUS SE & CO. KGaA, when it was known as FRESENIUS AG.

58. Defendant FRESENIUS MANAGEMENT SE at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANULFO in the stream of commerce for use by the public, including Plaintiffs.

59. Defendant FRESENIUS MANAGEMENT SE has transacted and conducted business throughout the United States, including this judicial district.

60. Defendant FRESENIUS MANAGEMENT SE has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

61. Defendant FRESENIUS MANAGEMENT SE expected or should have expected its acts to have consequences within this judicial district and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district. All defendants are hereinafter referred to collectively as "Defendants" or "Fresenius".

62. At all relevant times herein, all Defendants were in the business of promoting, manufacturing, labeling, and/or distributing NaturaLyte and/or GranuFlo. Defendants do business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and/or sold NaturaLyte and/or GranuFlo in this judicial district.

63. Defendants do not include any health care providers, any physician, hospital, health maintenance organization, dialysis centers, ambulatory surgical center, long-term care facility, registered or licensed practical nurse, pharmacist, physician-in-training, or any other person or entity that provides health care.

III. JURISDICTION AND VENUE

64. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that in each of the constituent actions there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds $150,000.

65. Defendants have significant contacts with this federal judicial district and the one identified in the *Short Form Complaint* filed by each Plaintiff, such that they are subject to the personal jurisdiction of both this Court and the Court indentified in the *Short Form Complaint.*

66. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in this federal judicial district and the one identified in the *Short Form Complaint.*

67. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district and the district identified in the *Short Form Complaint.*

IV. FACTUAL ALLEGATIONS

A. DIALYSIS GENERALLY

68. Defendants designed, manufactured, labeled, promoted, distributed, marketed, and/or sold NaturaLyte and/or GranuFlo. These concentrates are used during hemodialysis procedures.

69. The kidneys have important roles in maintaining health. When healthy, the kidneys clean the body's blood by maintaining the body's internal equilibrium of water and minerals (sodium, potassium, chloride, calcium, phosphorus, magnesium, sulfate). The acidic metabolism end-products that the body cannot get rid of via respiration are also excreted through the kidneys.

70. When kidneys fail, patients need a treatment to replace the work that the failed

kidneys did. Treatment includes either a kidney transplant or dialysis.

71. Dialysis is a method of treating acute and chronic kidney disease, especially where conservative treatment has been judged inadequate.

72. Dialysis is a procedure used to clean the blood in patients who have suffered end-stage renal disease (also known as renal failure or kidney failure).

73. There are two types of dialysis: peritoneal dialysis and hemodialysis. Hemodialysis is the most common way to treat advanced kidney failure and is often used to treat acute kidney failure.

74. Patients receive hemodialysis in a dialysis center, at home or in a hospital. Many people receive hemodialysis treatments three times per week in sessions of three to five hours each. This is known as conventional hemodialysis.

75. The procedure can help patients carry on an active life despite failing kidneys.

76. The goal of hemodialysis is to replace the functions of the patient's non-working kidneys. These functions include the removal of waste products that build up in the blood such as creatinine and urea; the appropriate adjustment of electrolyte levels (including potassium, calcium, and sodium); the correction of the acidosis (acid state) that tends to develop in these patients; and the removal of excess water that tends to accumulate in kidney failure patients.

77. Acidosis is an increased acidity in the blood as a result of the body's inability to excrete acid due to kidney failure.

78. Acidosis is a typical occurrence for patients in kidney failure.

79. Severe acidosis can lead to shock or death.

80. Dialysis attempts to correct an acidotic state, in part, by adding bicarbonate to the patient's blood.

81. The opposite of acidosis is alkalosis where a patient's blood has excess base (alkali).

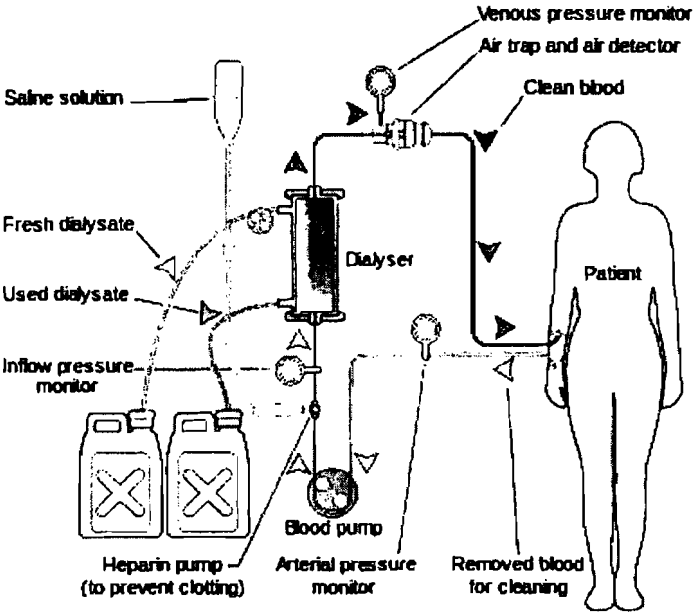
82. Alkalosis is caused by too much bicarbonate in the blood.

83. Symptoms of alkalosis include confusion, tremors, light-headedness, muscle twitching, nausea, vomiting, numbness or tingling, in the face, hands or feet.

84. Alkalosis can cause a patient to experience seizures, severe breathing difficulties, cardiac arrhythmias and/or death.

85. The keys of dialysis are 1) removal of waste products from the body; 2) the promotion of electrolyte balance in the blood; and 3) the addition of bicarbonate to the patient's blood to correct acidosis.

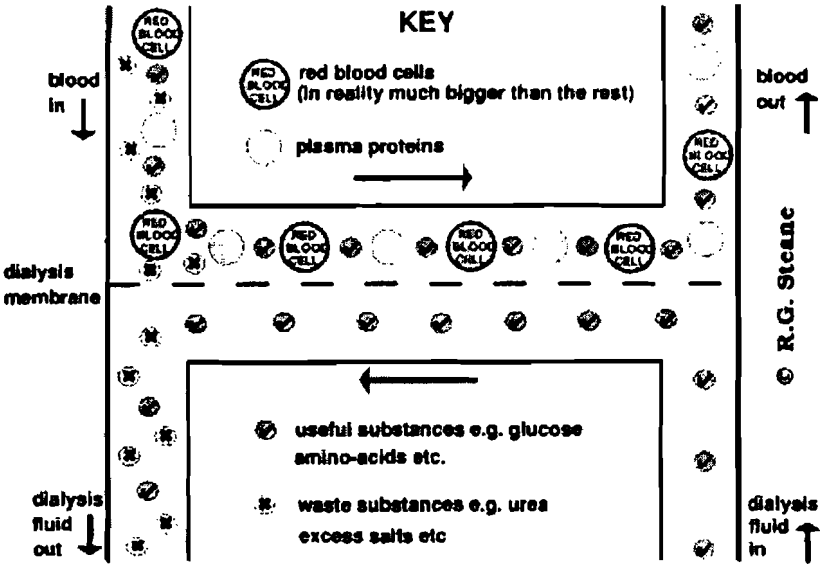
86. A person undergoing hemodialysis is connected to a hemodialysis machine (dialyzer) and then blood is removed from the body. Blood from a patient's artery circulates through the dialyzer and is returned to the body through a vein.



87. In the dialyzer, the blood passes through tiny tubes made of a semi-permeable membrane. Surrounding these tubes and flowing in the opposite direction from the blood (but not mixing with the blood itself) is a liquid solution known as dialysate. The semi-permeable membrane has tiny pores that allow small molecules to cross or diffuse through the membrane.

88. Diffusion is the process whereby random molecular motion causes a substance to go from an area of higher concentration to an area of lower concentration. Diffusion is a major physical activity, amongst other physical activities in the dialysis process.

89. During hemodialysis, the blood is pumped through the dialyzer in one direction and the dialysate is pumped in the opposite direction. Since the dialysate solution contains none of the waste products that are in the patient's blood (urea and creatinine), those waste products naturally diffuse through the membrane into the dialysate solution and are removed from the blood.



90. Depending on the electrolyte balance of the patient, the nephrologist may order a particular dialysate solution containing specific amounts of potassium, sodium, magnesium, and calcium.

91. Thus, for example, if a patient has a relatively high potassium level, the nephrologist may order a lower potassium solution to be utilized in the dialysate so that more potassium will diffuse across the membrane out the patient's blood and thus restore a proper electrolyte balance.

92. After several hours on the dialysis machine, and with this process of diffusion ongoing continuously, the patient's blood is cleaned of its excess waste products and presumably has had its electrolyte balance reestablished.

93. The dialysate used during dialysis is a mixture of 1) a bicarbonate concentrate and 2) an acid concentrate (Granuflo and/or NaturaLyte are the acid concentrate portions). The dialysate (bicarbonate and acid solutions) then flows through the dialyzer and interacts with the patient's blood.

94. Bicarbonate concentrate is used on all dialysis patients, but the amount of bicarbonate a patient receives can be adjusted.

95. Patients in renal failure tend to become acidotic, and that problem is corrected primarily by adding bicarbonate to their blood. Therefore, all dialysate solutions contain bicarbonate to correct the naturally occurring acidosis in patients in renal failure.

B. NATURALYTE AND GRANUFLO

96. NaturaLyte and/or Granuflo are acid concentrates used in the creation of dialysate.

97. GranuFlo and/or NaturaLyte have been on the market for many years and are unique in the dialysis treatment world in that they contain sodium diacetate. Through this formulation, GranuFlo and/or NaturaLyte increase the amount of acetate in dialysate (the fluid

and solutes in a dialysis process that flow through the dialyzer machine) compared to more traditional formulations made with acetic acid.

98. Defendants engaged in the design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion and/or distribution of NaturaLyte and/or GranuFlo. These concentrates are used during hemodialysis procedures.

99. Defendants manufacture, sell, and promote dialysis products in both the U.S. and the world. Their market share is the largest in both the U.S. and the world.

100. Defendants manufacture, label, promote, and sell dialysis machines and dialysis products including but not limited to dialyzers, blood lines, needles, and dialysis concentrate.

101. Fresenius facilities use Defendants' dialysis products. Defendants also sell and market their products to other dialysis facilities including to many clinics that compete with Fresenius facilities, including but not limited to DaVita Dialysis Centers, Dialysis Clinics Inc. (DCI), and Renal Ventures Management LLC, among others.

102. When introduced into the body, the acetate contained in acid concentrates is converted into bicarbonates by the liver, which increases bicarbonate levels in the blood.

103. NaturaLyte and/or GranuFlo are dry powders.

104. The purported advantage of NaturaLyte and/or GranuFlo is to allow dialysis clinics to mix their own acid concentrate (with water at the clinics) so that Defendants did not have to ship liquid acid concentrate in large 55 gallon drums around the world, which had become expensive. Thus NaturaLyte and/or GranuFlo was designed, in part, to save costs since only the dry acid concentrate was being shipped.

105. All acid concentrates (liquid or dry) contain acid. Liquid products contain acetate, whereas NaturaLyte and/or GranuFlo contain sodium diacetate.

106. During dialysis, one of the goals is to reestablish the patient's proper electrolyte balance. Patients in renal failure tend to become acidotic, and that problem is corrected primarily by adding bicarbonate to their blood. Therefore, all dialysate solutions contain bicarbonate to correct the naturally occurring acidosis in patients in renal failure.

107. NaturaLyte and/or GranuFlo contain sodium diacetate (two acetates), whereas other products contain only acetic acid with one acetate. Once in the body, acetate is converted by the patient's liver into bicarbonate. Because NaturaLyte and/or GranuFlo results in two acetate molecules, conversion by the liver results in *two molecules of bicarbonate.* Thus, the net effect of using a dialysate that contains diacetate is that the patient is exposed to an unanticipated amount of bicarbonate and consequently an unanticipated amount of total buffer that exceeds what was intended and ordered by the physician attending to the patient. The conversion of diacetate in the liver to two molecules of bicarbonate results in a higher total buffer than ordered by the physician.

108. Bicarbonate levels are described in terms of milliequivalents per liter (mEq/L). When GranuFlo and/or NaturaLyte is used, it adds 8 mEq/L to the total amount of buffer (bicarbonate) delivered to the patient in comparison to other dialysates which do not exceed 4 mEq/L. In 2005, Fresenius estimated that, "for every 4 meq/L increase in the dialysate total buffer there will be a corresponding 1 – 2 meq/L change in the pre dialysis serum bicarbonate".

109. The net effect of administering GranuFlo and/or NaturaLyte to patients is that because of the sodium diacetate formulation, a significant number of dialysis patients develop unexpectedly elevated levels of bicarbonate in their blood. Patients with elevated bicarbonate

levels in their blood suffer from metabolic alkalosis, the opposite of acidosis, and high bicarbonate levels in the blood increases a patient's risk of cardiopulmonary arrest ("CP") or sudden cardiac arrest.

110. "Total buffer" includes both bicarbonate from bicarbonate dialysate and bicarbonate resulting from the metabolism of the two acetate molecules, resulting from the dissociation of sodium diacetate, contained in the acid dialysate., i.e., GranuFlo Dry Acid Concentrate and/or NaturaLyte Dry Acid Concentrate. If for example there are 33 mEq/L from the bicarbonate concentrate, which is delivered in the dialysate in conjunction with the acetate, and 4 mEq/L of acetate from the acid concentrate, the total buffer level is 37 mEq/L. However, where NaturaLyte and/or GranuFlo (a dry acid concentrate) is used, and there are 33 mEq/L from the bicarbonate concentrate, because NaturaLyte and/or GranuFlo contains diacetate and not acetate, the contribution to the total buffer from the acid concentrate will be 8 m Eq/L. In such cases, the total buffer would be 41 mEq/L and not 37 mEq/L as with acetate instead of diacetate.

111. At all relevant times of this lawsuit, Defendants knew, or should have known, that the concentration of acetic acid or sodium diacetate (acetic acid plus acetate) contained in NaturaLyte and/or GranuFlo, respectively, was leading to a dangerous increase in serum bicarbonate levels in patients undergoing hemodialysis. Defendants knew, or should have known, that this contributes to metabolic alkalosis, which is a significant risk factor associated with many health problems including heart arrhythmia, cardiopulmonary arrest and sudden cardiac death.

112. Defendants have been aware for years that disparities between the prescribed dialysate bicarbonate levels, total buffer levels, and bicarbonate settings and readings on the dialysis machines have been a long-term problem in dialysis care.

113. Defendants have been aware for years that the warnings, training and instructions related to NaturaLyte and/or GranuFlo were inadequate and non-existent. Defendants have also been aware for years that changing the design of the products was possible and would have easily avoided the dangers relating to the disparities between the prescribed dialysate bicarbonate levels, total buffer levels, and bicarbonate settings and readings on the dialysis machines.

114. Through information and belief, the NaturaLyte and/or Granuflo product line saw steadily increased market share since its introduction, and as of 2012 was used by the majority of nearly 400,000 hemodialysis patients in the U.S.

C. INCREASED BICARBONATE LEVELS CAN ADVERSELY AFFECT THE HEART

115. The heart is a four chambered muscle that must beat rhythmically and regularly to pump blood throughout the body. The rhythmic beating is controlled by an electrical circuit within the heart.

116. The electrical conduction of the heart is affected by many of the electrolytes that are adjusted during dialysis. The most commonly recognized of these electrolytes is potassium.

117. Sudden cardiac arrest or cardiopulmonary arrest occurs when the rhythmic beating of the heart becomes irregular so that the heart can no longer pump blood effectively. The most commonly referenced irregular heart beat that leads to sudden death is v-fib (ventricular fibrillation). This occurs when the ventricles of the heart simply quiver instead of actually contract or beat. The quivering ventricles do not pump blood, and if not corrected within minutes, the patient will die.

118. The human body has an elaborate mechanism to maintain its blood pH and its bicarbonate levels within a very narrow range. Patients with renal failure become acidotic (low

blood pH) and need to have their acidosis corrected by the addition of bicarbonate, which is always done during dialysis.

119. If the patient receives too much bicarbonate, he or she can be pushed outside the normal or tolerated range and become alkalotic (high blood pH). An elevated blood bicarbonate level is not something that commonly occurs in patients who are not on dialysis because the kidneys are very efficient at controlling the amount of bicarbonate in the blood.

120. When patients receive too much bicarbonate, as can occur with the use of NaturaLyte and/or Granuflo as alleged *supra*, an electrolyte imbalance can occur. Among other physiological changes, a patient's potassium and calcium may shift on a cellular level, resulting in a significant increase in the potential for an arrhythmia or fibrillation.

121. The manufacturer of a product used in hemodialysis, such as an acid concentrate, has a duty to advise and/or warn prescribing physicians and/or healthcare facilities of any and all risks, concerns, defects and other safety information regarding said product and its use.

D. FDA APPROVAL OF GRANUFLO

122. On or about July 17, 1991, FDA cleared K911459, GranuLyte via the 510(k) process upon Defendants statements that GranuLyte was substantially equivalent to a predicate product.

123. The purpose of a 510(k) submission is to demonstrate that a device is "substantially equivalent" to a predicate device (one that has been cleared by the FDA or marketed before 1976).

124. Human studies are not required for 510(k) clearance. FDA needs only to see that the product at issue in the 510(k) submission is substantially similar to a product already on the market either through FDA approval or clearance.

125. In other words a 510(k) process allows manufacturers to piggyback off a predicate device to demonstrate safety by showing their device is substantively equivalent to those predicate devices for which safety has already been established.

126. The FDA does not "approve" 510(k) submissions. It "clears" them as substantially equivalent if they have the same intended use as predicate devices. In other words, devices that do not have the same intended use cannot be substantially equivalent.

127. The FDA does not conduct product testing relating to safety or efficacy of any product. FDA relies and mandates that manufacturers do the proper testing to assure both safety and efficacy.

128. Marketing of a cleared device cannot begin until the company receives a clearance letter from the FDA.

129. It is not legal to advertise a 510(k) cleared device as "FDA-approved."

130. The predicate product Fresenius relied upon for substantial equivalence with respect to GranuLyte was Renal Systems Renapak Concentrate Mixing System, K840182.

131. Renal Systems Renapak Concentrate Mixing System had received clearance through the 510(k) process in or about 1984. The FDA reference number is K840182.

132. Renal Systems Renapak Concentrate Mixing System, K840182 was a dry dialystate concentrate mixing system.

133. Renal Systems Renapak Concentrate Mixing System, K840182, was cleared based upon the company's assurance that its product was substantially equivalent to a liquid dialysate product.

134. Renal Systems Renapak Concentrate Mixing System, K840182 included a dry acid concentrate made up of sodium acetate.

135. The predicate product that Defendants claimed its GranuLyte powder concentrations to be similar to was Renal Systems Renapak Concentrate Mixing System, also a dry powder concentrate.

136. Defendants' GranuLyte product that was the subject of the K911459, 1991 clearance, the same applications that Defendants claimed to be substantially equivalent to the Renal Systems Renapak Concentrate Mixing System containing sodium acetate, actually contained Sodium Diacetate in its dry acid concentrate.

137. Defendants recognized that the acid component was different, but also represented in a memorandum to FDA dated February 6, 1991 that, ". . .the use of sodium diacetate or acetic acid will have no effect on the final content of the solution. One would not be able to tell, in fact, whether acetic acid or sodium diacetate had been used."

138. Upon information and belief, Defendants did not conduct any safety studies on the change from acetate to diacetate in its acid concentrate.

139. Defenants' GranuLyte K911459 cleared in 1991, contained 4.0 mEq/L of sodium diacetate in its acid concentrate. When properly mixed with the bicarbonate concentration, the final dialysate contained 10.4 Gm/L of acid.

140. Upon information and belief, this is the first time sodium diacetate was used in hemodialysis.

141. In April 1992, Defendants submitted a premarket notification of their intent to market GranuLyte Dialysate Concentrate (a granulated formula) to the FDA. The April 1992 submission was made pursuant to a 510(k) application.

142. This submission is FDA reference number K22005.

143. GranuLyte that was the subject of the April 1992 510(k), K22005, contained 14.9

Gm/L of sodium diacetate, an increase of sodium diacetate from the amount approved by FDA in 1991. The FDA eventually cleared Granulyte in a granulated (dry) formula on March 30, 1994. The FDA's decision, in part, was based on the claim by Fresenius that the product was substantially equivalent to the dialysate products already on the market, specifically K911459 containing 10.4 Gm/L of sodium diacetate. In additional support for increasing the amount of sodium diacetate in its product, Fresenius' application relied upon a list of three other manufacturers' approved products, represented by Fresenius only as being "similar" to GranuLyte, which upon information and belief, included sodium acetate, NOT sodium diacetate.

144. Later that year, on or about September 8, 1992, Fresenius changed the trade-name from GranuLyte to GranuFlo.

145. Upon information and belief, by no later than 1997, GranuFlo contained 8 mEq/L of sodium diacetate. According to the publicly available information at FDA, Fresenius did not submit a 510(k) application to allow for this increase in sodium diacetate.

146. On or about August, 2002, Defendants again submitted a 510(k) submission to alter GranuFlo.

147. Fresenius again submitted a 510(k) submission for the "Fresenius Naturalyte Granuflo Dry Acid Concentrate"[1]

148. This submission is referenced by K030497.

149. Fresenius stated in its summary that "The Fresenius Naturalyte Granuflo Dry Acid Concentrate is designed to be used as direct product replacement for the current Granuflo Concentrate (Series 1000, 2400 and 3000)."

150. Fresenius also assured the FDA that "the new Fresenius Naturalyte Granuflo Dry Acid Concentrate has the same chemical composition as the predicate devices." Those predicate

[1] *See* Fresenius 510(k) submission, K030497.

devices identified were K911459, when Fresenius first began using sodium diacetate in 1991, and K922055 when Fresenius increased the amount of sodium diacetate in its concentrates in 1994.

151. It was not until on or about January 14, 2003, that FDA eventually cleared Fresenius' 510(k) submission.

E. DEFENDANTS KNEW THERE WERE PROBLEMS WITH BICARBONATE LEVELS

152. Fresenius understood by March 23, 2001 that "total buffer" was an issue that was being confused at the clinic level. Fresenius understood that clinics seemed to be confused with the bicarbonate delivery during dialysis.

153. On or about this date, Fresenius Medical Officer Michael Lazarus, M.D. told Fresenius medical directors that "[t]here is apparently confusion regarding bicarbonate delivery and the labeling on bicarbonate and acid concentrate products."

154. In that same memo, Dr. Lazarus explained that dialysis machines must be calibrated differently depending upon the acid concentrate used and stated "When GranuFlo is used, an advantage accrues in that there is a greater amount of acetate available to be metabolically converted to bicarbonate in the body." Dr. Lazarus stressed, "[T]he total buffer is the sum of the acetate and bicarbonate."

155. Dr. Lazarus concluded the memo by telling Fresenius medical directors that they "must" observe and monitor the patient's serum bicarbonate level to determine that the prescribed dialysate bicarbonate is actually being delivered and is appropriate for the patient considering the "total buffer."

156. Defendants did not communicate this information to non-Fresenius entities.

157. In or about 2004, Defendants conducted a retrospective study of dialysis patients

who had converted from previously approved acid concentrates to GranuFlo containing diacetate between August 2002 and April 2003 ("2004 Retrospective Study").

158. Upon information and belief, the goal of Defendants' 2004 Retrospective Study was to determine the efficacy of acid concentrate containing diacetate (*i.e.*, GranuFlo) in improving pre-dialysis bicarbonate levels and/or reducing metabolic acidosis when compared with a standard acid concentrate.

159. In or about 2004, Defendants evaluated the results of their 2004 Retrospective Study, which revealed:

a. higher than normal pre-dialysis bicarbonate levels as a result of the administration of GranuFlo containing diacetate;

b. higher than normal post-dialysis bicarbonate levels as a result of the administration of GranuFlo containing diacetate; and

c. an increase in cases of metabolic alkalosis as a result of the administration of GranuFlo containing diacetate.

160. As a result of their 2004 Retrospective Study, Defendants were on notice and/or should have been on notice of the foregoing.

161. Defendants did not communicate this information to non-Fresenius entities or with the FDA.

162. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of the severe health risks associated with NaturaLyte and/or GranuFlo, Defendants intentionally and willfully concealed their knowledge of these results and/or the increased severe health risks associated with NaturaLyte and/or GranuFlo from the FDA, the medical community, the Plaintiffs, the Plaintiffs' treating physicians and/or healthcare providers and the public.

163. Upon information and belief, despite the results of their 2004 Retrospective Study

and their knowledge of these results and/or the increased severe health risks associated with NaturaLyte and/or GranuFlo, Defendants failed to advise and/or warn all doctors and/or other healthcare providers treating patients with NaturaLyte and/or GranuFlo to reduce the amount of bicarbonates being administered to and/or received by the patient during dialysis to take into account the additional bicarbonates that these individuals were receiving from NaturaLyte and/or GranuFlo.

164. In or about 2003, at or about the same time the 2004 Retrospective Study was being conducted, Defendants conducted a mortality study of hemodialysis patients ("Defendants' 2003 Mortality Study").

165. The data and/or information underlying Defendants' 2003 Mortality Study as well as the exact results remain in the custody and/or possession of Defendants.

166. Upon information and belief, Defendants evaluation of the results of their 2003 Mortality Study revealed an increase in death risk for patients whose pre-dialysis serum bicarbonate levels were at or above 24 mEq/L.

167. Upon information and belief, Defendants evaluation of the results of their 2003 Morality Study revealed a 20% increase in death risk for patients whose pre-dialysis serum bicarbonate levels were at or above 28 mEq/L.

168. As a result of Defendants' 2003 Mortality Study and 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that the administration of NaturaLyte and/or GranuFlo containing diacetate resulted in a significant increase in serum bicarbonate levels, which in turn resulted in an increase in death risk for patients receiving NaturaLyte and/or GranuFlo.

169. As a result of Defendants' 2003 Mortality Study and 2004 Retrospective Study,

Defendants were on notice and/or should have been on notice that the design of NaturaLyte and/or GranuFlo was defective.

170. Defendants were on notice and/or should have been on notice of their obligation to report the results of their 2003 Mortality Study and 2004 Retrospective Study to the medical community, the Plaintiffs, the Plaintiffs' treating physicians, the Plaintiffs' healthcare providers, the FDA and/or the public.

171. Upon information and belief, despite the results of their 2003 Mortality Study and 2004 Retrospective Study and their knowledge of the defectiveness and/or severe health risks associated with NaturaLyte and/or GranfuFlo, Defendants intentionally and willfully concealed their knowledge of these results and/or the increased severe health risks associated with NaturaLyte and/or GranuFlo from the FDA, the medical community, the Plaintiffs, the Plaintiffs' treating physicians and healthcare providers and the public.

172. Upon information and belief, despite the negative safety results of their 2003 Mortality Study and/or 2004 Retrospective Study, Defendants affirmatively misrepresented that NaturaLyte and/or GranuFlo was more effective and safer than other acid concentrates on the market.

173. Defendants advertised and/or marketed that the use of NaturaLyte and/or GranuFlo resulted in a 33% reduction in the prevalence of acidosis, without any timely and adequate disclosure of the deleterious effects of alkalosis.

174. Based upon the results of their 2004 Retrospective Study, at all relevant times, Defendants advised doctors, dialysis clinics and/or healthcare providers to use NaturaLyte and/or GranuFlo over other acid concentrate on the market to prevent and/or treat metabolic acidosis.

175. Based upon the results of their 2004 Retrospective Study, at all relevant times,

Defendants advised doctors, dialysis clinics and/or healthcare providers to use NaturaLyte and/or GranuFlo over other acid concentrate on the market to increase pre-dialysis serum levels to greater than 20 mEq/L.

176. Based upon the results of their 2004 Retrospective Study, at all relevant times, Defendants advised doctors, dialysis clinics and/or healthcare providers to use NaturaLyte and/or GranuFlo over other acid concentrate on the market and did not counsel doctors, dialysis clinics and/or healthcare providers to pay attention to the increase in serum bicarbonate levels as a result of the use of NaturaLyte and/or GranuFlo.

177. In October, 2004, The Dialysis Outcomes and Practice Patterns Study ("DOPPS") was published in the American Journal of Kidney Diseases.

178. The authors concluded that there is a significantly increased risk for mortality for patients with a very high pre-dialysis serum bicarbonate level (>27 mEq/L). The authors suggested that mild pre-dialysis acidosis may be beneficial. They stressed the need for evaluation and correction of both pre-dialysis severe acidosis and alkalosis. (<18 mEq/L or >27 mEq/L).

179. Defendants knew or should have known that high serum bicarbonate levels increases the patients' risk of mortality. Defendants knew or should have known by October, 2004 that alkalosis pre-dialysis can be just as dangerous and/or more dangerous than mild acidosis.

180. Defendants knew or should have known by July 5, 2005 that the mean bicarbonate levels in patients who were being administered NaturaLyte and/or Granuflo, were rising and that in fact some patients were actually alkalotic pre-dialysis instead of acidotic. Defendants knew or should have known that there was still confusion in the clinics about the

added bicarbonate delivered by NaturaLyte and/or GranuFlo.

181. In an internal company memorandum, dated on or about July 5, 2005, Defendants' Chief Medical Officer informed Defendants' medical directors that in just a few years of using GranuFlo in Defendants' own clinics, the mean bicarbonate for Fresenius patients had risen from 20 mmol/L to 24 mmol/L.

182. In that same July 5, 2005 memorandum, Defendants' Chief Medical Officer communicated to the Defendants' medical directors of the fact that some patients are actually now alkalotic pre-dialysis.

183. In that same July 5, 2005 memorandum, Defendants' Chief Medical Officer communicated to the Defendants' medical directors that mortality increases when the serum bicarbonate levels are >28. Defendants' Chief Medical Officer communicated to the Defendants' medical directors that GranuFlo delivers an additional 4 mEq/L of sodium acetate (total 8 mEq/L). "The acetate concentration in GranuFlo is double that of traditional liquid acid concentrates."

184. In that same July 5, 2005 memorandum, Defendants' Chief Medical Officer communicated to the Defendants' medical directors that it is important to understand and prescribe the proper bicarbonate concentration to deliver the desired total buffer.

185. Defendants did not communicate the information contained in the July 5, 2005 internal memo to non-Fresenius entities or with the FDA.

186. By April, 2009, Defendants knew or should have known that there was still a problem in the clinics with pre-dialysis bicarbonate levels of the patients and the delivery of NaturaLyte and/or GranuFlo.

187. In an internal memo, dated April 13, 2009, "Dialysate Concentrate Change and

Bicarbonate/Buffer," Drs. Lazarus and Hakim, the Medical Officers for Fresenius tell the Fresenius Medical Directors that there still seems to be confusion about bicarbonate settings and prescriptions for bicarbonate. Drs. Lazarus and Hakim explain that the bicarbonate setting on the machines represents only the bicarbonate level in the dialysate. "This number does **NOT** include the 4 mEq/L of acetate delivered by the liquid acid solution or the 8 mEq/L of acetate delivered by the GranuFlo acid powder."

188. In that same April 13, 2009 memorandum, Drs. Lazarus and Hakim recommend that patients have a dialysis prescription that maintains the patient with a pre-dialysis serum bicarbonate in the range of 20-23 mEq/L. They also reference "several in-depth discussions" of the bicarbonate delivery available for review, (Dec. 7, 2000, March 21, 2001, and July 5, 2007), and "encouraged" the directors or nursing staff to review them all.

189. Defendants did not communicate the information contained in the April 13, 2009 memo to non-Fresenius entities or with the FDA.

190. In April 2009, a conference of nephrologists and dialysis practitioners and providers was held in Boston, Massachusetts. Its title was: "ESRD: State of the Art and Charting the Challenges for the Future." It was attended by Fresenius employees, including Raymond Hakim, M.D., Ph.D., who at the time was Chief Medical Officer for Fresenius Medical Care. Dr. Hakim served on the Steering Committee for the conference.

191. During the conference, cardiopulmonary arrest was noted to be the number 1 ranking cause of death for dialysis patients, accounting for 59% of cardiovascular-related deaths among dialysis patients. It was concluded that cardiovascular-related deaths were caused by uremic cardiomyopathy, characterized by left ventricular hypertrophy (LVH), LV dysfunction, and LV dilatation, and not due to atherosclerotic heart disease.

192. Sometime in 2009 or 2010, Fresenius revised the manual used by operators for certain Fresenius-manufactured dialysis machines, including the 2008T model. The revisions instructed users, "*When entering the Acetate value for GranuFlo concentrate, only half of the listed value on the label should be entered. For example, if the label shows an Acetate value of 8, then only enter 4.*" (2008T Machine Operator's Manual P/N 490122 Rev E Copyright 2008-2010).

193. From 2008 through 2010 Fresenius failed to provide notification to all users of NaturaLyte and/or GranuFlo, of the necessity to "halve" Acetate levels when setting the parameters on dialysis machines while using these products. To the extent Fresenius provided information, it did so partially, selectively and haphazardly in a way calculated to avoid general dissemination of necessary warnings, instructions and problems associated with its products. Fresenius' failure to fully and forthrightly inform and warn the medical/dialysis community directly affected patient health and safety and led to the deaths of innumerable patients.

194. Sometime after the Boston Conference, Dr. Hakim undertook a study of patients who suffered cardiopulmonary arrest and sudden cardiac death in Fresenius clinics during 2010, which it first reported in an Internal Memorandum to Fresenius Clinic Medical Directors on November 4, 2011.

195. In an internal memorandum dated November 4, 2011, the Fresenius Medical Office reports Dr. Hakim's findings of his case-control study of 941 patient deaths in 667 Fresenius clinics. Fresenius tells the Fresenius medical directors that alkalosis is a significant risk factor associated with cardiopulmonary arrest. "The major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration." He reports:

a. Over time, there has been increasing serum bicarbonate levels pre-dialysis. "This issue needs to be addressed urgently."

b. Unadjusted OR=8.3 for cardiac event in patients pre-dialysis serum level >28 mEq/L. adjusted 6.3.

c. Again states that GranuFlo delivers more acetate and thus more bicarb than other formulas.

196. The internal November 4, 2011 memorandum went on to further state in its "summary of findings" that: "The current analysis determined that: "*borderline elevated pre-dialysis bicarbonate levels and over alkalosis are significantly associated with 6 to 8 fold greater increase of cardiopulmonary arrest and sudden cardiac death in the dialysis facility.*" (italics in original)..."In light of these troubling findings, we strongly recommend that physicians adjust dialysate bicarbonate prescriptions monthly for individual patients, with immediate attention to patients with serum pre-dialysis bicarbonate level of >24 mEq/L." The memo further urges that this dangerous issue "needs to be addressed urgently."

197. Despite Defendants' knowledge of this significant patient safety risk, Fresenius willfully and knowingly failed to notify, warn and/or instruct non-Fresenius dialysis clinics and operators to whom Fresenius sold and marketed NaturaLyte and/or GranuFlo, nor did the company inform patients or the FDA of the results of this study. Only after the November 4, 2011 Internal Memo was anonymously leaked to the FDA, which led to questioning of Fresenius in late March 2012, did Fresenius send any informational correspondence to dialysis facilities using its products. Much of the detail contained in the Internal Memo, however, was absent in the "Urgent Product Notifications" sent out by Fresenius.

F. GRANUFLO AND NATURALYTE BECOME THE SUBJECT OF A CLASS I RECALL

198. On or about March 2, 2012, FDA received an anonymous complaint raising concerns over the elevated bicarbonate levels and dialysate concentrate dose error. FDA also received the November 4, 2011 memo.

199. Shortly thereafter, in March 2012, Defendant Fresenius Medical Care North America received an inquiry from the FDA specifically about GranuFlo and NaturaLyte and alkalosis.

200. It was only on March 29, 2012, after the FDA became aware of the dangers posed by GranuFlo and the number of instances of CP in dialysis patients treated by that product, that Fresenius sent a notice to non-Fresenius clinics purchasing and using GranuFlo stating that "NaturaLyte Liquid contains 4.0 mEq/L of acetate and GranuFlo contributes 8.0 mEq/L of acetate to the final dialysate; which in addition to bicarbonate, combine to the total buffer that the patient receives from the dialysate. Since acetate is rapidly converted into bicarbonate by the liver, the bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate by ~8 mEq/L with dialysate prepared from GranuFlo (powder) or by ~4 m.Eq/L with dialysate prepared from NaturaLyte (liquid)." This correspondence did not mention any patient blood levels and failed to discuss in any manner the most at-risk population of all, "acute" dialysis patients.

201. The March 29, 2012 notice further stated that "[r]ecent analyses performed by FMCNA [Fresenius Medical Care North America] hemodialysis (HD) patient safety data confirms that alkalosis [high levels of bicarbonate] is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. A major cause of metabolic alkalosis in dialysis patients is inappropriate high dialysate total buffer concentration."

202. The March 29, 2012 notice contained an "urgent product notification involving the NaturaLyte and GranuFlo powder product lines" and recommended that "clinicians exercise their best judgment regarding bicarbonate and total buffer base prescriptions for each patient."

203. GranuFlo and/or NaturaLyte are defective and unreasonably dangerous for their intended use because they create an unreasonably dangerous level of bicarbonate in the blood stream during dialysis causing metabolic alkalosis and a corresponding substantial increase in the risk of cardiopulmonary arrest during dialysis treatment. Further, there was no warning or instructions about this risk.

204. Fresenius dialysis machines are defective and unreasonably dangerous due to inadequate instructions and warnings when used with NaturaLyte and/or GranuFlo, in that the operator must "halve" the acetate level to account for the dangers inherent in Fresenius concentrated dialysates but the requirement to "halve" the acetate levels was not described, warned about, or instructed about.

205. Fresenius failed to properly warn of the dangers associated with the use of its products up to March 29, 2012, when it manufactured and distributed it products without proper warnings and instructions, and attempted to conceal those dangers from the public and the FDA up to and including March 29, 2012. All the while being in possession of information relating to the risks posed by its products, Fresenius nevertheless continued to manufacture and distribute its products ignoring the information it possessed and failing to warn and instruct clinics, doctors, patients and others involved in the administration of dialysis using Fresenius' products.

206. On March 29, 2012, the FDA reported Fresenius's voluntary Class 1 recall of GranuFlo Acid Concentrate and NaturaLyte Liquid. This recall in effect warned users of the heightened risk for low blood pressure, hypokalemia (low potassium levels), hypoxemia (low blood oxygen), hypercapnia (high carbon dioxide levels), and cardiac arrhythmia, possibly leading to sudden death associated with the products.

207. On a teleconference between the FDA and Fresenius Medical Care North America on April 27, 2012, Fresenius was asked to provide modifications to their product labels to reflect appropriate warnings regarding total buffer.

208. The New York Times reported on June 14, 2012, that the Food and Drug Administration was investigating whether the nation's largest operator of dialysis centers violated federal regulations by failing to inform customers of a potentially lethal risk connected to one of its products.

209. The article quoted an FDA official:

> "Personally, I'm troubled by the fact that Fresenius on its own initiative didn't notify its entire customer base of this particular concern," Steven Silverman, director of compliance for the F.D.A.'s medical devices division, said in an interview this week.
>
> Mr. Silverman said the agency could issue a warning letter to Fresenius if it determined the company should have reported the safety concerns. But even if the company had no legal obligation, he said, "Candidly, I just think it's bad business and not in the interest of the public health to sit on information about risks."

210. The article also quoted:

> Dr. Thomas F. Parker III, chief medical officer at Renal Ventures, a dialysis chain that used Fresenius products, agreed. "If the data was sufficient to warn their doctors, then all users of the product should have been made aware of it."

211. On June 22, 2012, the FDA sent a letter to the Chairman/CEO of Fresenius Medical Care North America. In the letter, the FDA concluded that there is a reasonable probability that the use of, or exposure to, NaturaLyte and GranuFlo will cause serious adverse health consequences, including death. Accordingly, the FDA classified it as a Class I recall. The FDA explained that the seriousness of this recall requires 100 percent effectiveness checks and

there must be verification that every consignee has been notified of the recall and appropriate action has been taken.

212. Class I recalls are the most serious recalls. These recalls are for dangerous or defective products that predictably could cause serious health problems or death.

213. When explaining the recall of GranuFlo and NaturaLyte that was initiated March 29, 2012, the FDA explained that "the manufacturer is cautioning clinicians to be aware of the concentration of acetate or sodium diacetate (acetic acid plus acetate) contained in Fresenius' NaturaLyte Liquid and GranuFlo Dry Acid Concentrate. Inappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis. This may contribute to metabolic alkalosis, which is a significant risk factor associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia and cardiac arrhythmia, which, if not appropriately treated, may culminate in cardiopulmonary arrest. This product may cause serious adverse health consequences, including death."

G. DEFENDANTS FAILED TO DISCLOSE THAT NATURALYTE AND/OR GRANUFLO ARE DEFECTIVE – RESULTING IN INJURY AND DAMAGES TO PLAINTIFFS

214. On or about November 16, 2011, Dr. Raymond Hakim resigned from Fresenius. Through information and belief, at all relevant times to this lawsuit there was collusion involving Defendants and individuals in several of Defendants' departments and organizations to hide, mislead, and obscure information about the extreme patient safety hazard associated with the use of GranuFlo and/or NaturaLyte in order to maintain their market share as well as to minimize and diffuse the legal risks for Defendants.

215. As early as 2005 if not earlier, Defendants had knowledge of the risks associated with NaturaLyte and/or GranuFlo but Defendants failed to adequately and lawfully warn

consumers, like Plaintiffs, their physicians and healthcare providers and the medical community of the risks despite Defendants' knowledge as of about that time or earlier.

216. Plaintiffs and their health care providers relied upon the misrepresentations and actions of Defendants insofar as the hemodialysis products provided were safe and effective for use as labeled during hemodialysis.

217. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of NaturaLyte and/or GranuFlo, Plaintiffs have suffered death, serious permanent physical injury, life-changing, life-altering pain and suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital, surgical and funeral expenses and other expenses related to diagnosis and treatment thereof, for which Defendants are liable. As a direct and proximate result of Plaintiffs' use of NaturaLyte and/or GranuFlo, Plaintiffs have suffered and will continue to suffer pecuniary and other losses for which Defendants are liable.

218. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of NaturaLyte and/or GranuFlo and their resulting injuries, Plaintiffs have suffered damages and harm, including but not limited to, emotional distress for which Defendants are liable. Plaintiffs have incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort for which Defendants are liable.

219. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of NaturaLyte and/or GranuFlo, Plaintiffs have been prevented from pursuing their normal activities and employment, have experienced severe pain and suffering and mental

anguish, and have been deprived of their ordinary pursuits and enjoyments of life for which Defendants are liable.

220. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of NaturaLyte and/or GranuFlo, Plaintiffs' spouses have lost, presently and in the future, their spouse's companionship, services, society and the ability of Plaintiffs' spouses in said respect has been impaired and depreciated, and the marital association between husband and wife has been altered, and as such, the Plaintiffs' spouses have been caused mental anguish and suffering spouses in said respect has been impaired and depreciated, and the marital association between husband and wife has been altered, and as such, the Plaintiffs' spouses have been caused mental anguish and suffering for which Defendants are liable.

221. Plaintiffs' serious injuries and or death as a result of their exposure to NaturaLyte and/or GranuFlo, was caused by and was the direct and proximate result of Defendants' breaches of warranty and/or the negligence or other wrongful conduct of Defendants by and through its agents, servants, workmen and employees, in any or all of the following respects:

a. in failing to properly design, manufacture and test NaturaLyte and/or GranuFlo;

b. in selling, marketing and distributing NaturaLyte and/or GranuFlo in a dangerously defective condition;

c. in selling, marketing and distributing NaturaLyte and/or GranuFlo when it was not reasonably fit and suitable for its ordinary and intended purpose;

d. in failing to warn purchasers and users of NaturaLyte and/or GranuFlo's defective condition before, during and after sale and delivery of the product;

e. in failing to properly inspect and test NaturaLyte and/or GranuFlo;

f. in selling, marketing and distributing NaturaLyte and/or GranuFlo when it knew or should have known of its inherent design defects;

g. in failing to properly and fully investigate prior incidents involving deaths and other personal injuries related to the use of NaturaLyte and/or GranuFlo during dialysis;

h. in failing to correct known design and engineering deficiencies; and,

i. in failing to properly or adequately address defects in NaturaLyte and/or GranuFlo and implementing an inadequate Recall Campaign that defendants knew or should have known was deficient and not likely to correct the defects and dangers inherent in NaturaLyte and/or GranuFlo.

222. Defendants' failure to disclose the defective nature of NaturaLyte and/or GranuFlo, the limited reach of its recall campaign, and the failure to notify the families of patients who suffered serious injury and/or death during dialysis, of the association between NaturaLyte and/or GranuFlo and these injuries prevented Plaintiffs from knowing their injuries were potentially related to the use of the defective NaturaLyte and/or GranuFlo product.

H. DISCOVERY RULE AND TOLLING

223. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

224. Where applicable, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

225. Despite diligent investigation by Plaintiffs into the cause of their injuries the nature of Plaintiffs' injuries and damages, and their relationship to NaturaLyte and/or GranuFlo was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims.

Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

226. The running of the statute of limitations in this cause should also be tolled due to equitable tolling. Defendant(s) are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and/or Plaintiffs' physicians of the true risks associated with the Products. As a result of the Defendants' fraudulent concealment, Plaintiffs and/or Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).

I. FRESENIUS MEDICAL CARE HOLDINGS, INC. WAS UNDER A HEIGHTENED DUTY TO REPORT THE HEALTH PROBLEMS ASSOCIATED WITH GRANUFLO AND NATURALYTE

227. On or about January 19, 2000, Defendant Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America and certain of its subsidiaries agreed to pay the United States $486 million to resolve a sweeping investigation of health care fraud at National Medical Care, Inc. ("NMC"), Fresenius' kidney dialysis subsidiary. Pursuant to the agreement, three NMC subsidiaries pled guilty to three separate conspiracies and to pay a record setting $101 million in criminal fines. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America agreed to pay a record setting $385 million to resolve related civil False Claim Act claims.

228. The above settlement by Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America and its subsidiaries involved allegations that Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America's subsidiaries submitted false

claims for reimbursement through Medicare and that these same subsidiaries provided payments, discounts and other inducements to dialysis facilities to obtain their blood testing business in violation of the Medicare Anti-Kickback Act.

229. In addition to the payment of $486 million to settle the healthcare fraud claims, Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America also entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the Department of Health and Human Services on January 18, 2000. The CIA requires Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America to take actions to prevent misconduct in the future. Among other things, the CIA, which had an 8 year term, required Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America to maintain a Corporate Integrity Program which included corporate compliance officers at various levels of the organization, a confidential employee hotline for employees to report suspected misconduct, and a corporate training program on designated compliance issues. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America was also required to retain an Independent Review Organization, to conduct compliance audits, and to submit an annual report to the OIG relating to compliance efforts.

230. The CIA also imposed heightened reporting requirements upon Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America. Specifically, the CIA requires Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America to report "a violation of the obligation to provide items or services of a quality that meet professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care

program beneficiary or places the beneficiary unnecessarily in a high-risk situation. A Reportable Event may be the result of an isolated event or a series of occurrences."

231. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America violated the CIA by failing to report the health risks associated with GranuFlo and/or NaturaLyte. This failure to report the health risks associated with GranuFlo and/or NaturaLyte has resulted in injuries to the Plaintiffs in the instant litigation.

232. Additionally, on May 10, 2002, Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America entered a similar settlement agreement with respect to healthcare fraud claims for individuals who were participating in clinical trials. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America paid $1,658,923 to resolve these claims.

233. Finally, on May 26, 2011, Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America entered a similar settlement agreement to resolve healthcare fraud claims with respect to unauthorized claims for renal care. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America paid $82,642,592 to resolve these claims.

V. CLAIMS FOR RELIEF

COUNT I

STRICT LIABILITY

234. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

235. At the time of Plaintiffs' injuries, Defendants' NaturaLyte and/or GranuFlo was defective and unreasonably dangerous to foreseeable patients.

236. The NaturaLyte and/or GranuFlo used by Plaintiffs was in the same, or substantially similar, condition as it was when it left the possession of Defendants.

237. Plaintiffs did not misuse or materially alter the NaturaLyte and/or GranuFlo that they used.

238. Defendants are strictly liable for Plaintiffs' injuries in the following ways:

a. The NaturaLyte and/or GranuFlo, as designed, marketed, distributed, packaged, manufactured, sold and supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply, package and sell NaturaLyte and/or GranuFlo;

c. Defendants failed to warn and place adequate warnings and instructions on NaturaLyte and/or GranuFlo;

d. Defendants failed to adequately test NaturaLyte and/or GranuFlo;

e. Defendants failed to provide timely and adequate warnings and instructions after they knew of the risk of injury associated with the use of NaturaLyte and/or GranuFlo prior to the injuries to Plaintiffs; and,

f. Defendants failed to market a feasible alternative design for the subject NaturaLyte and/or GranuFlo that would have prevented Plaintiffs' injuries.

239. Defendants' actions and omissions were the direct and proximate cause of Plaintiffs' injuries.

240. Defendants' conduct, as described above, was extreme and outrageous.

241. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT II

NEGLIGENT FAILURE TO WARN

242. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

243. Before Plaintiffs used NaturaLyte and/or GranuFlo, and during the period in which Plaintiffs used NaturaLyte and/or GranuFlo, Defendants knew or had reason to know that NaturaLyte and/or GranuFlo was dangerous and created an unreasonable risk of bodily harm to patients.

244. Defendants had a duty to exercise reasonable care to warn patients, including Plaintiffs, of the dangerous conditions and circumstances that could lead to serious injury or death from using NaturaLyte and/or GranuFlo.

245. Despite the fact that Defendants knew or had reason to know that NaturaLyte and/or GranuFlo was dangerous, Defendants failed to exercise reasonable care in warning the medical community and patients, including Plaintiffs, of the dangerous conditions, circumstances and facts that could lead to serious injury or death from using NaturaLyte and/or GranuFlo.

246. Plaintiffs' injuries were the direct and proximate result of Defendants' failure to warn of the dangers of NaturaLyte and/or GranuFlo.

247. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the

safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT III

NEGLIGENT DESIGN

248. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

249. Defendants are the manufacturers, sellers, distributors, marketers, and suppliers of NaturaLyte and/or GranuFlo which was negligently designed.

250. Defendants failed to exercise reasonable care in designing, developing, formulating, manufacturing, inspecting, testing, packaging, selling, distributing, labeling, marketing, and promoting NaturaLyte and/or GranuFlo which is defective and presented an unreasonable risk of harm to patients, including Plaintiffs.

251. As a result, NaturaLyte and/or GranuFlo contain defects in design, which renders it dangerous to patients, including Plaintiffs, when used as intended or as reasonably foreseeable to Defendants. The design defects render NaturaLyte and/or GranuFlo more dangerous than other dialysis chemicals and cause an unreasonable increased risk of injury, including but not limited to cardio pulmonary arrest, sudden cardiac death and other adverse events.

252. Plaintiffs used NaturaLyte and/or GranuFlo in a reasonably foreseeable manner, and substantially as intended by Defendants.

253. The subject NaturaLyte and/or GranuFlo was not materially altered or modified after manufacture by Defendants and before used by Plaintiffs.

254. The design defects directly rendered the subject NaturaLyte and/or GranuFlo defective and were the direct and proximate result of Defendants' negligence and failure to use reasonable care in designing, testing, and manufacturing NaturaLyte and/or GranuFlo.

255. As a direct and proximate result of Defendants' negligent design of NaturaLyte and/or GranuFlo, Plaintiffs suffered injuries.

256. Despite the fact that Defendants knew or should have known that NaturaLyte and/or GranuFlo was defectively designed, contained design defects, and caused an unreasonable risk of harm, Defendants designed, manufactured, sold, distributed, and marketed NaturaLyte and/or GranuFlo to patients, including the medical community and Plaintiffs, and failed to warn patients, the medical community, and Plaintiffs of the increased risk of harm relative to other dialysis chemicals.

257. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT IV

NEGLIGENCE

258. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury*

Demand in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

259. Defendants had a duty to exercise reasonable care in the manufacture, labeling, marketing, sale, packaging and distribution of NaturaLyte and/or GranuFlo including a duty to assure that it did not cause unreasonable, dangerous side-effects to users.

260. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, packaging and distribution of NaturaLyte and/or GranuFlo in that Defendants knew or should have known that it created a high risk of unreasonable harm.

261. Defendants were negligent in the design, manufacture, advertising, warning, marketing, packaging and sale of NaturaLyte and/or GranuFlo in that, among other things, they:

a. Failed to use due care in designing and manufacturing NaturaLyte and/or GranuFlo so as to avoid the aforementioned risks to individuals;

b. Failed to accompany NaturaLyte and/or GranuFlo with proper and adequate warnings regarding all possible adverse side-effects associated with its use, dosing instructions and the comparative severity and duration of such adverse effects, including but not limited to serious cardio-pulmonary arrest, sudden cardiac death, and other adverse cardiac events. The warnings given did not accurately reflect the symptoms, scope or severity of the side effects;

c. Failed to provide adequate training and instruction to medical care providers for the appropriate use of NaturaLyte and/or GranuFlo;

d. Placed unsafe products into the stream of commerce; and,

e. Were otherwise careless or negligent.

262. Despite the fact that Defendants knew or should have known that NaturaLyte and/or GranuFlo caused unreasonable, dangerous side-effects which many users would be unable to remedy by any means, Defendants continued to market NaturaLyte and/or GranuFlo to patients, including the medical community and Plaintiffs.

263. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT V

NEGLIGENT MISREPRESENTATION

264. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

265. Prior to Plaintiffs' first dose of NaturaLyte and/or GranuFlo and during the period in which Plaintiffs used NaturaLyte and/or GranuFlo, Defendants misrepresented the degree to which NaturaLyte and/or GranuFlo was a safe and effective means for dialysis.

266. Defendants also failed to disclose material facts regarding the safety and efficacy of NaturaLyte and/or GranuFlo, including information regarding increased adverse events and harmful side-effects.

267. Defendants had a duty to provide Plaintiffs, physicians, and other patients with true and accurate information and warnings of any known risks and side-effects associated with the NaturaLyte and/or GranuFlo products they marketed, distributed and sold.

268. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with NaturaLyte

and/or GranuFlo that their representations regarding these drugs were false, and that they had a duty to disclose the dangers of NaturaLyte and/or GranuFlo.

269. Defendants made the representations, and otherwise failed to disclose material facts, concerning NaturaLyte and/or GranuFlo with the intent to induce patients, including Plaintiffs, to act in reliance thereon in receiving and/or using NaturaLyte and/or GranuFlo in dialysis treatment.

270. Plaintiffs justifiably relied on Defendants' representations and non-disclosures by choosing to receive and/or use NaturaLyte and/or GranuFlo in dialysis treatment.

271. Defendants' misrepresentations and omissions regarding the safety and efficacy of NaturaLyte and/or GranuFlo were the direct and proximate cause of Plaintiffs' injuries.

272. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT VI

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

273. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

274. At the time Defendants marketed, distributed and sold NaturaLyte and/or GranuFlo to Plaintiffs, Defendants warranted that the NaturaLyte and/or GranuFlo was merchantable and fit for the ordinary purposes for which it was intended.

275. Patients, including Plaintiffs, were intended direct or third party beneficiaries of the warranty.

276. NaturaLyte and/or GranuFlo was not merchantable and fit for its ordinary purpose, because it had an unacceptable propensity to lead to the serious personal injuries described in this *Master Complaint and Jury Demand.*

277. Plaintiffs reasonably relied on Defendants' representations that NaturaLyte and/or GranuFlo was safe and free of defects.

278. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiffs' injuries.

279. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT VII

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

280. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury*

Demand in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

281. Defendants manufactured, marketed, supplied and sold NaturaLyte and/or GranuFlo with an implied warranty that it was fit for the particular purpose of being a safe dialysis chemical.

282. Patients, including Plaintiffs, were the intended direct or third-party beneficiaries of the warranty.

283. NaturaLyte and/or GranuFlo was not fit for the particular purpose of being a safe dialysis chemical since it presents a serious risk of personal injury, which risk is much higher than other dialysis chemicals.

284. Plaintiffs reasonably relied on Defendants' representations that NaturaLyte and/or GranuFlo was safe and effective for dialysis.

285. Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiffs' injuries.

286. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT VIII

BREACH OF EXPRESS WARRANTY

287. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

288. Defendants expressly warranted that NaturaLyte and/or GranuFlo were safe and effective to members of the consuming public, including Plaintiffs.

289. Members of the consuming public, including patients such as Plaintiffs, were intended direct or third-party beneficiaries of the warranty.

290. Defendants marketed, promoted, distributed and sold NaturaLyte and/or GranuFlo as a safe product.

291. NaturaLyte and/or GranuFlo do not conform to these express representations because it is not safe and has serious side-effects, including serious personal injuries and death.

292. Defendants breached their express warranty in one or more of the following ways:

a. NaturaLyte and/or GranuFlo as designed, manufactured, promoted, distributed, marketed, sold and/or supplied by the Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to warn and/or place adequate warnings and instructions on NaturaLyte and/or GranuFlo;

c. Defendants failed to adequately test NaturaLyte and/or GranuFlo; and,

d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from NaturaLyte and/or GranuFlo.

293. Plaintiffs reasonably relied upon Defendants' warranty that NaturaLyte and/or GranuFlo were safe and effective when they received and/or used NaturaLyte and/or GranuFlo in dialysis treatment.

294. Plaintiffs' injuries were the direct and proximate result of Defendants' breach of their express warranty.

295. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT IX

FRAUD

296. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

297. Prior to Plaintiffs' use of NaturaLyte and/or GranuFlo and during the period in which Plaintiffs used NaturaLyte and/or GranuFlo, Defendants fraudulently suppressed material information regarding the safety and efficacy of these chemicals, including information regarding serious personal injuries and death. Furthermore, Defendants fraudulently concealed the safety information about the use of NaturaLyte and/or GranuFlo. As described above, NaturaLyte and/or GranuFlo have several well-known serious side-effects that are not seen in

other forms of dialysis chemicals. Plaintiffs believe the fraudulent misrepresentations described herein were intended to maintain and increase the sales volume of NaturaLyte and/or GranuFlo.

298. Defendants fraudulently concealed the safety issues associated with NaturaLyte and/or GranuFlo in order to induce physicians to recommend its use to Plaintiffs.

299. At the time Defendants concealed the facts that NaturaLyte and/or GranuFlo were not safe, Defendants were under a duty to communicate this information to Plaintiffs, physicians, the FDA, the medical community, and the general public in such a manner so that each group could appreciate the risks associated with using NaturaLyte and/or GranuFlo.

300. Defendants, at all times relevant hereto, withheld information from the FDA that they were required to report.

301. Plaintiffs and prescribing physicians relied upon the Defendants' outrageous untruths regarding the safety of NaturaLyte and/or GranuFlo.

302. Plaintiffs and/or their physicians were not provided with the necessary information by the Defendants.

303. NaturaLyte and/or GranuFlo were improperly marketed to Plaintiffs and/or their physicians as the Defendants did not provide proper instructions about how to use the NaturaLyte and/or GranuFlo and did not adequately warn about NaturaLyte and/or GranuFlo's risks.

304. As a direct and proximate result of Defendants' malicious and intentional concealment of material life-altering information from Plaintiffs and/or Plaintiffs' physicians, Defendants caused or contributed to Plaintiffs' injuries.

305. It is unconscionable and outrageous that Defendants would risk the lives of patients, including Plaintiffs. Nevertheless, the Defendants made conscious decisions not to

redesign, label, warn or inform the unsuspecting consuming public about the dangers associated with the use of NaturaLyte and/or GranuFlo. Defendants' outrageous conduct, which was wanton and willful, rises to the level necessary that Plaintiffs should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

306. Defendants widely advertised and promoted NaturaLyte and/or GranuFlo as safe and effective and/or as safe and effective for dialysis.

307. Defendants had a duty to disclose material information about serious side-effects to patients such as Plaintiffs.

308. Additionally, by virtue of Defendants' partial disclosures about these medications, in which Defendants touted NaturaLyte and/or GranuFlo as a safe and effective product, Defendants had a duty to disclose all facts about the risks associated with use of NaturaLyte and/or GranuFlo, including the risks described in this complaint. Defendants intentionally failed to fully disclose this information for the purpose of inducing physicians to prescribe and patients, such as Plaintiffs, to receive and/or use NaturaLyte and/or GranuFlo in dialysis treatment.

309. Had Plaintiffs been aware of the hazards associated with NaturaLyte and/or GranuFlo, Plaintiffs would not have used NaturaLyte and/or GranuFlo, which led proximately to Plaintiffs' injuries.

310. Defendants' advertisements regarding NaturaLyte and/or GranuFlo made material misrepresentations to the effect that NaturaLyte and/or GranuFlo were entirely safe, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing physicians to prescribe and patients, such as Plaintiffs, to receive and/or use NaturaLyte and/or

GranuFlo in dialysis treatment. Plaintiffs relied on these material misrepresentations when deciding to receive and/or use NaturaLyte and/or GranuFlo in dialysis treatment.

311. Upon information and belief, Plaintiffs aver that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with NaturaLyte and/or GranuFlo with the purpose of preventing physicians and patients, such as Plaintiffs, from discovering these hazards.

COUNT X

VIOLATION OF CONSUMER PROTECTION LAWS

312. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

313. Plaintiffs were administered NaturaLyte and/or GranuFlo during dialysis primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

314. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, user benefits, or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised;

c. Over-promotion of the NaturaLyte and/or GranuFlo products, including but not limited to over-promotion of its safety and efficacy; and,

d. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

315. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of NaturaLyte and/or GranuFlo.

316. Defendants uniformly communicated the purported benefits of NaturaLyte and/or GranuFlo while failing to disclose the serious and dangerous side-effects related to the use of NaturaLyte and/or GranuFlo and of the true state of NaturaLyte and/or GranuFlo's regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiffs in the marketing and advertising campaign described herein. Defendants' conduct in connection with NaturaLyte and/or GranuFlo was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of NaturaLyte and/or GranuFlo.

317. As a result of these violations of consumer protection laws, Plaintiffs have incurred serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

COUNT XI

LOSS OF CONSORTIUM

318. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

319. At all relevant times hereto, Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of the Plaintiffs' injuries from NaturaLyte and/or GranuFlo.

320. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

321. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

322. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

323. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

324. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs, and/or intimate partners of the aforesaid Plaintiffs, have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners jointly and severally for all

general, special and equitable relief to which Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners are entitled by law.

COUNT XII

WRONGFUL DEATH

325. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

326. Plaintiffs Decedents' spouse, beneficiary and/or lawful representative of Decedents' Estate brings this claim on behalf of himself or herself and as the Decedents' lawful beneficiary. The Decedents' lawful beneficiaries include the Decedents' beneficiaries

327. As a direct and proximate result of the conduct of the Defendants and the defective nature of NaturaLyte and/or GranuFlo as outlined above, Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

328. As a direct and proximate cause of the conduct of Defendants, Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths. Plaintiffs, Administrators of Decedents' estates, bring this claim on behalf of Decedents' lawful beneficiaries for these damages and for all pecuniary losses sustained by said beneficiaries pursuant to any and all relevant statutes.

COUNT XIII

SURVIVAL ACTION

329. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

330. As a direct and proximate result of the conduct of Defendants, Decedents, prior to their deaths, were obligated to spend various sums of money to treat their injuries, which debts have been assumed by their estates. As a direct and proximate cause of the aforesaid, Decedents were caused pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of their deaths; and, as a direct and proximate result of the aforesaid, Decedents suffered a loss of earnings and earning capacity. Plaintiffs' spouses, as Administrators of the Estates of Decedents, bring this claim on behalf of the estates for damages under any and all applicable statute or common law.

331. As a direct and proximate result of the conduct of Defendants, Decedents and their spouses, until the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder. This claim is brought on behalf of the Estates of the Decedents pursuant to any and all applicable statutes or common law.

332. As a direct and proximate result of the conduct of Defendants, and including the observances of the suffering of the Decedents, until the date of their deaths, Plaintiffs suffered permanent and ongoing psychological damage.

333. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Decedents until the date of their deaths, Plaintiffs have

and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Plaintiffs' spouses, as Administrators of the Estates of the Decedents, brings the claim on behalf of the Estates for damages any and all applicable statutes or common law and in their own right.

334. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of the Plaintiffs and the public.

335. As a result of the Defendants' conduct, the Plaintiffs suffered the injuries and damages specified herein.

336. Accordingly, the Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff(s) pray(s) for relief as follows:

1. Compensatory damages;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Pain and suffering, loss of life's pleasures, lost wages, lost earning capacity, and impairment of earning capacity;

4. Damages for wrongful death;

5. Damages for survival;

6. Damages for Loss of Consortium;

7. Non-economic damages for an increased risk of future complications as a direct result of Plaintiff's injuries;

8. Punitive damages;

9. Prejudgment interest at the highest lawful rate allowed by law;

10. Interest on the judgment at the highest legal rate from the date of judgment until collected;

11. Attorneys' fees, expenses, and costs of this action; and,

12. Such further relief as this Court deems necessary, just and proper.

VII. JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Respectfully submitted,

_____/S/_____
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Dated: December 20, 2013

☐ **New Matter**

☐ **Amendment Relating to a Pending Matter**

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:	§	**SHORT-FORM COMPLAINT AND DEMAND FOR JURY TRIAL**
[Insert Name of Individual Case]	§	

The Plaintiff(s) named below file this *Short-Form Complaint* against the Defendants named below and incorporate *The Master Complaint and Jury Demand* filed in MDL No. 2428 by reference. Plaintiff selects and indicates by checking-off where requested, those products, Parties and claims that are specific to his or her case. Plaintiffs (s) further allege as follows:

1. Plaintiff _____

2. Plaintiff's Spouse (*if applicable*)_____

3. Other Plaintiff and capacity, if applicable (*i.e.,* administrator, executor, guardian, conservator, etc.)_____

4. State of Residence_____

5a. ☐ By checking here, I choose Massachusetts as the "home" forum.

5b. If you did not chose Massachusetts as the "home" forum, identify the United States District Court and Division in which venue would be proper absent direct filing_____

6. Defendant(s)[*check each Defendant against whom Complaint is made*]:[1]

[1] If additional Counts and/or Counts directed to other Defendants are alleged, the specific facts supporting these allegations must be pleaded by the Plaintiff in a manner complying with the requirements of the

☐ FRESENIUS MEDICAL CARE HOLDINGS, INC.

☐ FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA

☐ FRESENIUS USA, INC.

☐ FRESENIUS USA MANUFACTURING, INC.

☐ FRESENIUS USA MARKETING, INC.

☐ FRESENIUS USA SALES, INC.

☐ FRESENIUS MEDICAL CARE AG & CO. KGaA.

☐ FRESENIUS MEDICAL CARE MANAGEMENT AG.

☐ FRESENIUS SE & CO. KGaA.

☐ FRESENIUS MANAGEMENT SE.

☐ Other _____

7. Basis of Jurisdiction

☐ Diversity of Citizenship

☐ Other: _____

Other allegations of jurisdiction and venue:

_____

_____

_____

_____

8. On or about _____, Plaintiff had the following injury:

_____

which is alleged to have been caused by Defendants NaturaLyte and/or GranuFlo administered to Plaintiff for dialysis treatment at: _____ [*insert name and address of clinic or facility where Plaintiff underwent dialysis treatment*].

_____

Federal Rules of Civil Procedure, and the Defendants against whom they are alleged must be specifically identified on a separate sheet of paper attached to the *Short Form Complaint.*

9. The following claims asserted in *The Master Complaint and Jury Demand*, and the allegations with regard thereto, are herein adopted by reference:

- ☐ Count I – STRICT LIABILITY
- ☐ Count II – NEGLIGENT FAILURE TO WARN
- ☐ Count III – NEGLIGENT DESIGN
- ☐ Count IV – NEGLIGENCE
- ☐ Count V – NEGLIGENT MISREPRESENATION
- ☐ Count VI – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
- ☐ Count VII – BREACH OF IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE
- ☐ Count VIII – BREACH OF EXPRESS WARRANTY
- ☐ Count IX – FRAUD
- ☐ Count X – VIOLATION OF CONSUMER PROTECTION LAWS
- ☐ Count XI – LOSS OF CONSORTIUM
- ☐ Count XII – WRONGFUL DEATH
- ☐ Count XIII – SURVIVAL ACTION
- ☐ Other Count(s) (*See* FN 1)

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10. Plaintiff asserts the following additional theories against the Defendants identified in Paragraph 6 above (*See* FN 1):

11. Plaintiff asserts the following additional theories against Defendants <u>other than</u> those identified in Paragraph 6 above (*See* FN 1):

WHEREFORE, Plaintiffs pray for relief as set forth in *The Master Complaint and Jury Demand* filed in MDL No. 2428.

_____

Attorney-name

Firm
Address
Phone
Fax
E-mail
Attorney for Plaintiff(s)

Instructions for Filing a *Short Form Complaint*

Before you can file a short form complaint, you must obtain an ECF login number.

To do so, go to: www.mad.uscourts.gov/ and proceed to "Attorney Admission Information". To receive a paper copy of the CM/ECF Login Request go to: http://www.mad.uscourts.gov/caseinfo/pdf/ECFRegisterFormfill.PDF. To fill out the request electronically go to: http://public.mad.uscourts.gov/ecfreg.html. Indicate where requested, that you are an attorney of record in *In Re: Fresenius Granuflo/Naturalyte Dialysate Products Liability Litigation*, MDL No: 1:13-md-2428 DPW.

After you receive an ECF login, you may file a *Short Form Complaint* at: http://www.mad.uscourts.gov/caseinfo/cmecf-general.htm as a CM/ECF Filer.

After you log in, follow these steps:

1. Open a civil case;
2. If you are not a member of the District of Massachusetts, indicate that you are an MDL Attorney;
3. Indicate that your civil case is related to MDL 1:13-md-2428;
4. Indicate the lead case number (1:13-md-2428) and check off the box for "Related Cases"; and
5. Proceed accordingly to file your *Short Form Complaint* via ECF.

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	§	

REVISIONS TO REVISED CASE MANAGEMENT ORDER NO. 7

Revised Case Management Order No. 7 (dkt # 528) is hereby amended to read as follows:

> Any plaintiff who has asserted in a Short Form Complaint ("SFC") a count for violation of the Massachusetts Consumer Protection Law M.G.L. c. 93A, shall be deemed to have fully complied with the requirements of notice pursuant to § 9(3) of c. 93A and therefore does *not* need serve a demand letter on any of the defendants prior to the filing of his/her SFC.

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	§	

PROPOSED CASE MANAGEMENT ORDER NO. 8
(PRIVILEGE PROTOCOL)

This Order is entered to set forth guidelines and protocols that shall govern (1) assertions of the attorney-client privilege and/or the work product doctrine; (2) the protocol that shall be followed regarding the preparation of privilege logs pursuant to Fed. R. Civ. P. 26(b)(5)(A)(i)-(ii); and (3) the method for resolving privilege disputes by and among Plaintiffs and Defendants.

I. GOVERNING LAW

A. Attorney-Client Privilege:

1. The parties agree that Massachusetts law will govern the existence and scope of the attorney-client privilege.

B. The Work Product Doctrine:

2. The parties agree that Federal law will govern the assertion of and claim to protection under the work product doctrine.

II. PROTOCOLS GOVERNING ATTORNEY-CLIENT PRIVILEGE AND WORK PRODUCT DOCTRINE

A. Redactions Relating to Attorney-Client Privilege and Work Product Doctrine

3. The parties shall redact only those portions of a document that fall within the scope of the work product doctrine and/or attorney-client privilege or as necessary to comply with foreign privacy and data protection laws relating to documents produced by the European Fresenius Defendants, and not the entire document or page unless the entire document or page is within such scope.

4. When a document is redacted on the basis of privilege, the producing party shall list the information pertaining to the redacted portion of the document on a privilege log as set forth in Paragraph 5 below. If a redaction is subsequently changed by order of the Court or by agreement of the parties, the party claiming privilege shall provide a replacement document with the redaction removed bearing the same bates number as the original document, with an associated load file containing the replacement image.

B. Privilege Log

5. The parties shall produce privilege logs in Excel format or a similar electronic format that allows text searching, sorting and organization of data. Consistent with Rule 26(b)(5)(A) and the Advisory Committee Comments thereto, and subject to all relevant foreign privacy and data protection laws[1], a privilege log shall contain, where available, the following:

a. The document date;

b. The source of the document;

c. The identity of the person(s) who prepared the document;

d. The identity of any person(s) to whom the document was disseminated;

e. The subject/title and document type;

f. The specific privilege or protection allegedly applicable to the document;

[1] In the event that foreign privacy or data protection laws prohibit the specific identification of a party or parties to a communication, sufficient information will be provided to identify the basis for the privilege and to enable other parties to assess the claim.

g. Information pertinent to the applicability of the privilege or protection sufficient to enable the other party to evaluate the applicability of the claimed privilege or protection; and,

h. The number of pages in any document withheld for privilege.

6. The producing party will produce an updated privilege log within 30 days of each production.

The parties shall have the right to request an expedited privilege log, but not sooner than 15 days, for certain custodians or document sources for purposes of deposition preparation. In addition, the parties shall have the right to request an extension of the privilege log deadline, not to exceed 45 days, for document productions involving a large volume of privileged documents. If the producing party objects to the expedited or extension request, the parties will meet and confer in good faith in an attempt to resolve the disagreement without court intervention. If the parties cannot reach an agreement, the requesting party may seek court relief. Privilege logs shall be supplemented under Fed. R. Civ. P. 26 (e)(1) as to any document that becomes producible thereafter.

C. Challenges to Claims of Privilege and/or Work Product Doctrine

7. A receiving party may challenge a redaction or claim of privilege at any time after the document or a privilege log identifying the document subject to such redaction or claim is produced. A receiving party does not waive its right to challenge a redaction or claim of privilege by electing not to challenge promptly after the subject document or privilege log identifying it has been produced.

8. A receiving party may challenge a producing party's redaction or designation of privilege from production by notifying the producing party, in writing (a letter to lead and liaison

counsel delivered by email shall be sufficient), of its good faith belief that the redaction or designation was not proper, including a brief explanation of the basis of the dispute with regard to each redaction or claim of privilege at issue.

9. Thereafter the producing party shall have seven (7) days to review the redacted or designated material, to consider the circumstances, and to meet and confer with the receiving party. If no resolution can be reached after those seven (7) days, the receiving party may file and serve a motion that challenges the redaction or claim of privilege. The burden of proof in connection with any claim of privilege shall be on the producing party.

III. GENERAL PROVISIONS

10. If any party produces a privileged document through mistake, inadvertence or otherwise, the producing party may have the privileged document returned and/or destroyed by the receiving party by following the procedure set out in CMO No. 5 or consistent with agreement of the parties or further order of the Court.

SO ORDERED this 28th day of January, 2014.

Douglas P. Woodlock

DOUGLAS P. WOODLOCK, J.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

REVISED CASE MANAGEMENT ORDER NO. 9
(PRODUCT IDENTIFICATION)

This Case Management Order has been revised at Paragraph 1 to reflect the correct electronic mail address to which Plaintiff's counsel should submit the requests for information described in this Order.

This Case Management Order applies only to cases in this MDL where the allegedly injured party was a patient who last dialyzed at a Fresenius Medical Care North America ("FMCNA") dialysis clinic prior to the injury or death giving rise to the lawsuit. For any such case in which the Plaintiff seeks identification of the acid concentrate product (*i.e.* GranuFlo or NaturaLyte) used in the last hemodialysis treatment prior to the alleged injury or death, the parties shall follow the procedures set forth herein.

1. Plaintiff shall, at the time of submission of his or her Plaintiff Fact Sheet ("PFS"), separately request that FMCNA provide the information described in paragraph 3 below by submitting a written request via electronic mail to GranuFloProductIDReq@collorallp.com. Along with this request, Plaintiff shall submit:

(a) A completed electronic template in the form provided by FMCNA containing the following information: Patient's First Name, Last Name, Middle Initial, Appellation if any,

FMCNA Medical Record Number ("MRN") if available, Social Security Number, Date of Birth, Date of Injury or Death, Date of Last Dialysis Treatment, the Name and Address of the Named Facility identified in Section IV.2 of the Plaintiff's Fact Sheet, Case Number, and Plaintiff's Counsel (the "Electronic Template"); and

(b) A duly executed HIPAA release limited in scope to the information described in paragraph 3 below.

2. If the information in the Electronic Template is incomplete or inaccurate, FMCNA will notify counsel for the Plaintiff of the specific deficiency/inaccuracy and will not undertake to provide the information described in paragraph 3 below until such time as the deficiency/inaccuracy is cured by the Plaintiff.

3. Within fourteen (14) days of the first Friday following receipt of the request, complete Electronic Template, and executed HIPAA form, FMCNA shall provide the following information :

(a) For a patient who received his/her last dialysis treatment prior to death/injury at an FMCNA clinic utilizing the Proton system, FMCNA will identify the last "acetate value" for that patient reflected in its "Data Warehouse" prior to injury or death[1];

(b) For a patient who received his/her last dialysis treatment prior to death/injury at an FMCNA clinic utilizing the eCube system, FMCNA will identify the last "concentrate identifier" for that patient reflected in its "Data Warehouse" prior to injury or death[2].

4. The information required by paragraph 3 above shall be provided by FMCNA electronically in the form of a letter signed by a duly authorized representative of FMCNA under

[1] An acetate value of "8" indicates GranuFlo.

[2] A concentrate identifier that begins with "G" indicates GranuFlo and a concentrate identifier that begins with "N" indicates NaturaLyte.

the penalties of perjury indicating; (a) that a query was made of FMCNA's "Data Warehouse" for the requested information; (b) the result of the query; (c) verification that, to the best of the FMCNA representative's information and belief, the query was accurately performed based on the information supplied by the Plaintiff; and (d) that the result provided accurately reflects the information contained in the "Data Warehouse."

5. Nothing in this Case Management Order shall relieve any Plaintiff from the obligation to submit a complete Plaintiff Fact Sheet per Case Management Order No. 6.

SO ORDERED this 28th day of April, 2014.

Douglas P. Woodlock

DOUGLAS P. WOODLOCK, J.

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	

[PROPOSED] CASE MANAGEMENT ORDER NO. 10

(Bellwether Case Selections and Trial Deadlines)

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.

I. Selecting Cases For Case-Specific Discovery

On September 15, 2014, 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. The cases that the PEC and FMCNA designate to undergo Core Case-Specific Discovery may only be drawn from those cases that are "Eligible Cases for Selection" as defined in Section II below.

The PEC and FMCNA shall submit the complete list of twenty (20) cases selected for Core Case-Specific Discovery to the Court by September 19, 2014.

[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. For purposes of this Case Management Order, the term "party" shall refer to, on the one hand, the Plaintiff and/or PEC and, on the other hand, FMCNA, for a total of two (2) parties.

II. Eligible Cases for Selection

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

A case may be considered an Eligible Case for Selection only where:

a. Plaintiff Fact Sheets and Defendant Fact Sheets have been served by the parties (as described in Case Management Order No. 6);

b. Product Identification has been provided pursuant to Case Management Order No. 9; and

c. All medical records subject to Case Management Order No. 3 shall have been produced by FMCNA.

III. 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 should it be selected for bellwether trial.

For those cases selected for bellwether trial(s) that name defendants in addition to FMCNA, the claims against such non-FMCA defendants shall be severed and stayed.

IV. Core Case-Specific Discovery

Core Case-Specific Discovery can be performed only in the twenty (20) cases selected under this Case Management Order (or in a replacement case as outlined in Section VI). 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.

Core Case-Specific Discovery consists solely of:

a. The exchange of Plaintiff and Defendant Fact Sheets and medical records (supplemented as necessary);

b. Product identification;

c. No more than one (1) deposition from each of the following four categories:[2]

   i. The person(s) involved in the care and life of the dialysis clinic patient at the time of his or her injury, whether the spouse or family member or other representative. (Should the parties choose to depose more than one (1) person from this category, the depositions collectively shall not exceed seven hours and shall, to the extent practicable, be conducted on the same day)

   ii. Treating nephrologist(s) (Should the parties choose to depose more than one (1) person from this category, the depositions collectively shall not exceed seven hours and shall, to the extent practicable, be conducted on the same day);

   iii. Dialysis clinic medical director;

   iv. Dialysis clinic staff person with knowledge of the patient's care, or a percipient witness if the injury which gave rise to the lawsuit occurred in the clinic, or a nutritionist (Should the parties choose to depose more than one (1) person from this category, the depositions collectively shall not exceed seven hours and shall, to the extent practicable, be conducted on the same day); and

d. Up to two (2) additional depositions selected by each party;

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

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

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

[2] For deponent categories (i)-(iv), the parties shall have an equal amount of time to question the deponent, regardless of which party noticed the deposition.

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

By March 13, 2015, the PEC and FMCNA shall narrow their initial selection of ten (10) Core Case-Specific Discovery cases down to five (5) recommended for further pre-trial discovery and bellwether trials and submit the recommendations to the Court. With the recommendations, the parties shall provide sufficient detail concerning their proposed selected cases to enable the Court to ensure the final pool of ten (10) cases are representative of the issues in this litigation. The final pool of ten (10) cases for further pre-trial discovery and bellwether trials shall include at least:

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.

After consideration of the parties' submissions, the Court shall determine the pool of Core Case-Specific Discovery cases after conferring with the parties.

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

The Court recognizes that the PEC may elect to dismiss, and that FMCNA may elect to settle and thus cause the dismissal of, a case after it is selected for Core Case-Specific Discovery and/or a bellwether trial. To ensure a balanced pool of cases for bellwether trials, the PEC and FMCNA shall meet and confer upon notice that a case from the bellwether pool is to be dismissed and attempt to reach agreement as to how the case will be replaced. If the parties cannot agree, they shall notify the Court of the existence of their dispute, and within five (5)

business days, submit competing proposals as to how the case at issue shall be replaced. The proposals shall contain sufficient information concerning the case at issue to the permit the Court to make an informed decision as to the manner in which it will be dismissed and the procedure for its replacement.

Any case chosen as a replacement to a dismissed case shall have at least one-hundred fifty (150) days of case-specific fact discovery regardless of the date on which the case is selected as a replacement, except for good cause shown to shorten this time period. All other deadlines otherwise applicable to such cases under this Order shall be modified to permit such fact discovery period.

VII. Bellwether Trial Case Deadlines

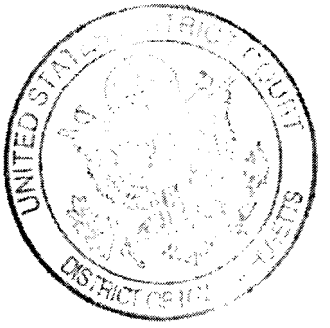
Once the Court has issued its Bellwether Order approving the PEC and FMCNA's proposed cases for bellwether trials, further discovery can be conducted in each of the ten (10) cases to prepare the cases for trial. The PEC and FMCNA shall work cooperatively to prepare a protocol, by way of a proposed Case 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.

After ruling on dispositive motions, the Court shall entertain briefing and argument and make a determination on the order of trials. With such determination, the Court shall set final deadlines for pre-trial matters including motions *in limine*, trial exhibits and deposition designations. Any cases that are ultimately tried shall be tried individually, with a single Plaintiff per trial.

SO ORDERED this 8th day of April, 2014.

/s/ Douglas P. Woodlock

DOUGLAS P. WOODLOCK, J.



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	

Case Management Order No. 11

(Bellwether Expert Discovery and Trial Deadlines)

The following deadlines shall apply to cases selected for bellwether trials pursuant to Case Management Order No. 10 (Bellwether Case Selection):

DEADLINE	EVENT
May 1, 2015	Expert reports disclosed by PEC and FMCNA simultaneously on matters of general applicability/general causation.
June 1, 2015	Rebuttal expert reports disclosed by PEC and FMCNA simultaneously on matters of general applicability/general causation.
July 14, 2015	Depositions completed of general applicability/general causation experts. To the extent practicable, the PEC's expert on a topic shall be deposed before the corresponding FMCNA expert. The parties shall otherwise agree to the scheduling of the depositions or seek the Court's intervention if they cannot agree.
July 14, 2015	Fact Discovery completed. (The parties shall agree upon the scope of any remaining discovery or seek the Court's intervention.)
August 4, 2015	Initial Disclosure of Case Specific Experts, including expert reports. by PEC and FMCNA simultaneously.
September 8, 2015	Case-specific expert rebuttal reports disclosed by PEC and

	FMCNA simultaneously.
September 29, 2015	Depositions completed of Case Specific experts.
October 27, 2015	*Daubert* and other dispositive motions filed.
November 17, 2015	Oppositions to *Daubert* and dispositive motions filed.
December 7, 2015 & December 14, 2015	*Daubert* Hearings
January 11, 2016	First MDL Bellwether Trial
February 16, 2016	Second MDL Bellwether Trial

After ruling on dispositive motions, the Court shall determine the order of trials and set final deadlines for pre-trial matters including motions *in limine*, trial exhibits, and deposition designations.

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

SO ORDERED this 6th day of June, 2014.

Douglas P. Woodlock

DOUGLAS P. WOODLOCK, J.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION,	)	
This Document Relates To:	)	
ALL CASES	)	MDL No. 1:13-md-02428-DPW

CASE MANAGEMENT ORDER No. 12
(Order Governing the Format of Generic Document Production)

With regard to the procedures and format relating to the production of documents and things by Plaintiffs and by 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. (collectively, "FMCNA"); and Fresenius Medical Care AG & Co. KGaA, Fresenius Medical Care Management AG, Fresenius SE & Co. KGaA and Fresenius Management SE (collectively, the "European Fresenius Defendants") in response to generic requests for discovery, the Court hereby Orders:

A. GENERAL

1. In the event this Order does not otherwise provide for the method of production, the parties shall meet and confer in good faith on a manner of production that balances the needs for production to be efficient, cost effective and reasonably useable.

2. Except as specifically limited herein, the Order governs the production of discoverable documents by Plaintiffs and by FMCNA and the European Fresenius Defendants during generic discovery in this Litigation as set forth at paragraph 2 of Case Management Order No. 2. A protocol for the production of discoverable documents for case-specific discovery on a going forward basis will be the subject of separate discussion and, if necessary, additional Case Management Order(s).

3. All documents that are responsive to generic discovery requests will be produced, subject to objections and responses, and subject to the parties' Protective Order and/or Confidentiality Order, in the manner provided herein.

B. PRODUCTION PROTOCOLS

4. General Format of Production. All documents produced pursuant to generic discovery requests in this litigation shall be produced as electronic TIFF images with associated text (OCR or extracted text as set forth herein), metadata, and objective coding, unless another production format is designated herein or otherwise agreed to by the parties.

5. Production of Electronic Images and Associated Data. Except as limited in this paragraph or as described herein and/or as otherwise agreed to by the parties, all documents that originally existed in electronic or hard-copy form that are produced in these proceedings shall be produced in electronic image form in the manner provided herein. To the extent exceptions to the foregoing are required, the parties will meet and confer to discuss alternative production requirements, concerns, or formats. Except for redacted documents, each document produced pursuant to this Order shall convey the same information in the electronic image(s) produced as the original document. Documents that present other imaging or formatting problems shall be promptly identified by the receiving party and the parties shall meet and confer to attempt to resolve the problems.

a. Document Image Format. All production document images, whether scanned from hard copy documents or generated from native electronic documents, shall be provided as single-page Tagged Image File Format (".tiff format"), using Group 4 compression at 300 dpi resolution, and shall reflect, to the extent practicable, without visual degradation, the full and complete information contained in the original document, unless redacted. Reasonable efforts will be used to scan the pages at or near their original size and so that the image appears straight and not skewed. Physically oversized originals, however, may appear reduced. In addition, reducing image size may be necessary to display Bates numbers without obscuring text. Unless otherwise indicated by this or other Case Management Orders or as agreed between the parties, the documents shall be produced in accordance with Rule 34 of the Federal Rules of Civil Procedure. The parties shall meet and confer to the extent reasonably necessary to facilitate the import and use of the produced materials with commercially available document management or litigation support software.

b. Load Files: Load file means an electronic file provided with a production set of document images that facilitates the loading of such information into a receiving party's document review platform, and the correlation of such data in the platform. A properly delimited ASCII text file containing Metadata and any objective coding required to be provided pursuant to this Order, an IPRO (LFP file) or OPTICON load file for tiff images, and document level ASCII OCR or Extracted text files named with the corresponding StartBates or BegBates document ID. The receiving party will provide the producing party with load file specifications 14 days in advance of the date of the first production. The producing party will have the right to request a sample load file and deliver a small first production to ensure the load file works and avoid any unnecessary costs associated with a faulty large-scale production.

c. Document Unitization. Each page of a hard copy document shall be scanned into an image and if a document is more than one page, the unitization of the document and any attachments shall be maintained as it existed in the original when creating the image file. For documents that contain fixed notes, the pages will be scanned with the notes and those pages will be treated as part of the same document. Post-it notes should be removed prior to scanning and scanned as a separate page immediately following the page it was attached to. The relationship of documents in a document collection (*e.g.*, cover letter and enclosures, email and attachments, binder containing multiple documents, or other documents where a parent-child relationship exists between the documents) shall be maintained. If more than one level of parent-child

relationship exists, documents will be kept in order, but all will be treated as children of the initial parent document. Such information shall be produced in the load file and metadata or objective coding, as set forth herein, in a manner to enable the parent-child relationship among documents in a document collection to be reconstituted by the receiving party in commercially available document management software, such as Concordance. All documents produced shall have a character that delineates page breaks in the OCR text so that the receiving party can determine where one page ends and another page begins. Parent-Child as well as other document family relationships and document unitization relationships shall be maintained even if that results in the production of documents considered to be duplicate documents as defined in paragraph B(5)(e) below.

d. Color. If an original document contains color, the producing party shall not deny reasonable requests for color copies of the original. Upon receipt of a request for a color copy of a document originally produced in black-and-white, the producing party shall provide a replacement image and load file bearing the same Bates number for that previously produced document with its next production.

e. Duplicates. Each party will take reasonable steps to de-duplicate electronic documents and other ESI in accordance with the terms of this Order. The parties will de-duplicate data within a custodian for all sources (i.e., custodial de-duplication or vertical de-duplication). Near duplicates or similar documents will be produced. Duplicated electronic files will be identified based upon calculated MD5 Hash values for binary file content using industry standard tools. For electronically stored information that is not email: contents only will be used for MD5 Hash value calculation and will not include operating system metadata (filename, file dates) values. For email, certain email metadata such as the To, From, CC, Subject, Body, and binary streams of all attachments will be used for MD5 Hash value calculation. All files bearing an identical MD5 hash value make a duplicate group.

f. Messaging Files: Duplicate messaging files will be identified based upon MD5 Hash values for the message family, including parent object and attachments. Duplicate messaging materials will be identified at a family level, including message and attachment(s).

g. Bates Numbering and Source Index. Each page of a produced document shall contain a legible, unique identification number ("Bates number") and confidentiality notice, where applicable, which will be electronically burned onto the page image in a manner that does not obliterate, conceal, obscure, or interfere with any information from the source document. No other stamp or information will be placed on a document other than Bates-number, confidentiality notice, and any redactions as may be required. This provision does not apply to databases or documents produced in native electronic format.

h. File Naming Conventions. Each page image file shall be named with the unique Bates number of the page of document, followed by the extension ".TIF." In the event the Bates number contains a symbol and/or character that cannot be included in a file name, the symbol and/or character will be omitted from the file name.

i. Production Media. Document productions will be made by electronic transfer, or on CD-ROM, DVD, external hard drive, or such other readily accessible computer or electronic media as the parties may hereafter agree upon (the "Production Media"). Each piece of Production Media shall be marked with a specific identifying number, like a Bates number, as well as the following: production number, production date, and the Bates number range(s) of the materials on the Production Media.

j. Metadata: Metadata means corresponding data about an electronic document that is generally not seen on the face of the document or when the document is printed (e.g., date created, date sent, author, recipient, etc.). For electronic documents, e-mails and hardcopy documents, the parties agree to produce objective coding and metadata as set forth in "Attachment A", to the extent such coding and/or metadata is responsive, not privileged, not subject to applicable foreign privacy and data protection laws, available and applicable. The producing party may redact, or remove from production, protected and/or privileged metadata, so long as all revisions or redactions, if made for purposes of attorney-client privilege or work product protection, are individually noted on the privilege log.

k. OCR/Extracted Text: The producing party shall produce corresponding Optical Character Recognition (OCR) text files for hard-copy documents and any electronic documents that require redaction prior to production. For electronic documents that require redaction, the process shall be that the producing party shall export the document to a TIFF image and perform the OCR process off that TIFF image. Printing electronic documents to paper for the purpose of performing the OCR scan shall not be permitted by this Order. When subjecting physical documents to an OCR process, the settings of the OCR software shall maximize text quality over process speed. Settings for "Auto-Skewing" and "Auto-Rotation" should be turned on when documents are run through the process. For documents that exist in electronic format that have not been redacted and that are produced as images, the producing party shall produce extracted text files reflecting the full text that has been electronically extracted from the original, native electronic files. The parties shall coordinate regarding the specifics for delivering OCR and extracted text as part of productions, including any load files specifications. For any document that will undergo the OCR process and contain a redaction, the producing party shall burn a Bates number onto the image or document prior to the OCR process such that the Bates number becomes part of the OCR file. In the event the Producing Party updates the OCR to include the production Bates numbers into the OCR text for its own use, the producing party shall provide an identical production to the Receiving Party.

l. Native Format Productions. Native production means electronic documents that are produced in the format in which they were created and used (also referred to in terms of "Native Format"). A receiving party may, after receipt and review of documents produced in .tiff format pursuant to this Order, request that specific Excel spreadsheets and other documents be provided by the producing party in native format. Any such reasonable request will not be denied. The parties agree that any documents produced in native format will be given the same level of confidential protection as is due the originally produced document under CMO no. 5 regardless of whether the document in its native format contains a confidentiality designation. Any native files that are produced shall be produced with a Bates-numbered TIFF image slip-sheet stating "Document [Begin Bates number] to [End Bates number] is a [document type] that has been

produced in native format." The slip-sheet shall also contain a MD5 hash generated for the produced native file. Any native files that are produced shall be produced with the source file path provided, as well as all extracted text and applicable metadata fields set forth in Attachment A. Spreadsheets that require redactions will be converted to TIFF images as follows: remove user-defined print areas; unhide and expand all columns, rows and sheets; expand/outline groupings; print to TIFF each sheet across (left to right) and then down; set for landscape orientation; and remove blank pages as possible. Any autodate macros will be indicated as "<autodate>".

m. Databases. The parties shall meet and confer concerning the scope and production format for discoverable information contained in databases and other structured data sources. Such production shall be governed by separate stipulation of the parties or Order of the Court.

n. Video, Audio, other electronic media that cannot be rendered as Tiff images. Except as subject to redaction or other protection, the producing party shall produce requested relevant video, audio and other electronic media that cannot easily be rendered as Tiff images in their original media format, i.e., CD Audio, DVD Video, etc. unless the original format is unreasonable, or unduly burdensome or costly, in which situation the parties will meet and confer on the format for producing this type of information. Audio and video files may be edited, only after consultation with the opposing party, if redactions are required, subject to appropriate identification of any such modification to the original audio or video file.

o. Original Documents. The producing parties shall retain the original hard-copy and native source documents in their original format (together with, except as may be otherwise expressly agreed among the parties, the means to access, retrieve, and view such documents) for all documents produced in this proceeding. Producing parties shall maintain the original native electronic source documents in a manner so as to preserve the "metadata" associated with these electronic materials in the event review of such metadata becomes necessary. Subject to preservation of appropriate privileges and other protections of the producing party's information from production in accordance with applicable law, upon a showing of good cause or particularized need, after reasonable request and any necessary meet and confer, where a document existed originally in only hard copy format, the producing party will make originals of any produced document available for inspection by the requesting party in the form in which such documents are kept in the ordinary course of business.

6. Replacement Images. If a document produced by a producing party has an error or the images must be replaced due to inadvertent or mistaken production, a change in confidentiality, or other reason the replacement production must be marked as a replacement, and the producing party must provide a reason for the replacement. The load file of the replacement document(s) must be separately produced in a complete replacement file, which contains the replacement document(s) only.

7. Disputes: The parties will meet and confer in good faith, and endeavor to resolve any dispute related to this Order before submitting such disputes to the Court for determination.

8. Relief and Modification: After an appropriate meet and confer in good faith, either party may apply to the Court for relief or modification of this Order.

SO ORDERED this 19th day of June, 2014.

Douglas P. Woodlock

DOUGLAS P. WOODLOCK, J.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALTE DIALYSATE PRODUCTS LIABILITY LITIGATION	§	MDL NO. 1:13-MD-2428-DPW
THIS DOCUMENT RELATES TO ALL CASES	§	

CASE MANAGEMENT ORDER NO. 13

(Protective Order Regarding Inadvertently or Mistakenly Produced Protected Health Information)

I. SCOPE OF ORDER

1. This Protective Order incorporates by reference Case Management Order No. 5 (Protective Order of Confidentiality), Document 413.

2. This Protective Order applies all to Discovery Material produced or disclosed in this Litigation, whether produced or disclosed prior or subsequent to the entry of this Protective Order.

II. DEFINITIONS

3. Protected Health Information. "Protected Health Information" is defined herein as "individually identifiable health information...that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium." 45 C.F.R. § 160.103. Individually identifiable health information ("IIHI") as used herein shall mean any information about the past, present or future physical or mental health or condition, or treatment, of an individual, the provision of health care to an individual, or the past, present or

future payment for the provision of health care to an individual. To the extent that the materials described above include IIHI of a relative or other person (other than the patient), such information also shall be considered IIHI.

4. Party. "Party" means any of the parties in this Litigation, including employees, agents, officers and directors of such parties. "Parties" means all of the parties in this Litigation.

5. Discovery Material. "Discovery Material" means all non-public information, documents, medical records, or tangible things, responses to discovery requests, deposition testimony or transcripts, including exhibits thereto, and any other similar materials, or portions thereof.

6. Receiving Party. "Receiving Party" means a Party to this Litigation, and all employees, agents and directors of the Party that receive Discovery Material from a Producing Party.

7. Producing Party. "Producing Party" means a Party to this Litigation, and all directors, employees and agents of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party.

8. This Litigation. "This Litigation" means all cases currently pending in the above-captioned multidistrict litigation and all related actions that have been filed in, transferred or removed to this Court and assigned thereto.

III. INADVERTENT OR MISTAKEN PRODUCTION OF PROTECTED HEALTH INFORMATION – CLAWBACK PROCEDURES

9. In view of the large volume of Discovery Material produced in this Litigation, the Court recognizes that Discovery Material may inadvertently include Protected Health Information that should have been withheld in whole or in part on the basis of an absolute or qualified privilege or other legal protection from disclosure, including but not limited to the

protections afforded Protected Health Information under the Health Insurance Portability and Accountability Act ("HIPAA") and various state and federal laws and regulations ("PHI Privilege").

10. Inadvertent or mistaken production of Protected Health Information shall not constitute a waiver of any objection or applicable privilege or legal protection, including without limitation any PHI Privilege, either as to the specific information disclosed or as to any other information relating thereto or of the same or related subject matter. No action taken or not taken in accordance with this CMO nor failure to object to such action shall be construed as a waiver of any claim or defense in this Litigation.

11. In the event the Producing Party discovers it has inadvertently or mistakenly produced Protected Health Information, the Producing Party shall, within thirty (30) calendar days of the discovery of the inadvertent or mistaken disclosure, notify the Receiving Party in writing of the inadvertent or mistaken disclosure. The Producing Party may, in the notice, request a "clawback" of the inadvertently or mistakenly disclosed Protected Health Information. Except as set forth in paragraph 12 below, the Party receiving such clawback notice shall immediately and diligently act to retrieve any inadvertently or mistakenly produced protected health information, and all copies, including any loaded onto any litigation support databases, and return them to the Producing Party or destroy them as agreed between the Parties. All notes or other work product of the Receiving Party reflecting the contents of such materials shall be destroyed and not used.

12. If, upon receipt of such clawback notice set forth in paragraph 11, the Receiving Party challenges the designation of Protected Health Information, the Receiving Party shall notify the Producing Party of the challenge, in writing, within 10 days following receipt of the

clawback notice. Upon receipt of a challenge to the designation of Protected Health Information, the Producing Party may, within 14 days, move the Court to resolve the challenge to the Protected Health Information. Pending the resolution of such motion, the Receiving Party may retain possession of the inadvertently or mistakenly disclosed Protected Health Information as well as any notes or other work product of the Receiving Party reflecting the contents of such materials but shall segregate and not use such information or materials pending resolution of the motion, except as part of any briefing on the motion to the Court. The parties may, in support of their positions, submit the inadvertently produced information to the Court in a sealed envelope that shall be clearly marked:

> "THIS ENVELOPE CONTAINS DOCUMENTS MARKED AS CONFIDENTIAL THAT ARE THEREFORE COVERED BY A PROTECTIVE ORDER OF THE COURT AND IS SUBMITTED UNDER SEAL PURSUANT TO THAT PROTECTIVE ORDER AND LOCAL RULE 7.2. THE CONFIDENTIAL CONTENTS OF THIS ENVELOPE MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT."

If the Producing Party's motion is allowed, the Receiving Party shall promptly comply with paragraph 11 above and no use shall be made of such inadvertently or mistakenly produced Protected Health Information during depositions or at trial, nor shall the information be disclosed to anyone who was not given access to it prior to the request to return or destroy it unless otherwise ordered by the Court.

13. In the event the Receiving Party discovers Protected Health Information in Discovery Material that identifies any individual other than a named plaintiff, the Receiving Party shall as soon as practicable within thirty (30) calendar days of the discovery of the Protected Health Information, notify the Producing Party in writing of the Protected Health Information, specifically indicating the Discovery Material in question, so that the Producing

Party can determine whether an inadvertent or mistaken disclosure has occurred. After receiving notice from the Receiving Party, the Producing Party then has thirty (30) calendar days to determine whether an inadvertent or mistaken disclosure has in fact occurred, and if so, to notify the Receiving Party in writing of the inadvertent or mistaken disclosure and invoke the procedures relating to "clawback" of such Discovery Material as set forth in paragraph 11 herein. Nothing herein obligates the Receiving Party affirmatively to review Discovery Material specifically for Protected Health Information; this paragraph is intended only to require the Receiving Party to notify the Producing Party in instances where the Receiving Party plainly identified Protected Health Information in Discovery Material.

14. Once the Receiving Party has returned or destroyed the inadvertently or mistakenly disclosed Protected Health Information, the Producing Party then has an additional thirty (30) calendar days to produce Discovery Material that has been redacted to omit the inadvertently or mistakenly disclosed Protected Health Information.

15. The Parties hereby confirm the continued applicability of any and all protective orders in this Litigation including but not limited to protective orders governing the disclosure of Protected Health Information in this Litigation.

IT IS SO ORDERED.

BY THE COURT:

Douglas P. Woodlock
United States District Judge

Dated: June 19, 2014

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	§	

[PROPOSED] QUALIFIED HIPAA PROTECTIVE ORDER
(Third Party Medical Record Production)

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure and 45 C.F.R. § 164.512(e)(1), the Court finds good cause for the issuance of a qualified protective order and ORDERS as follows:

1. The parties and their attorneys are hereby granted the right, upon receipt of a valid authorization in compliance with prior Orders entered in the above-captioned litigation, to receive from any health care provider, health plan, or other entity covered by the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA"), any and all protected health information ("PHI") to the extent and subject to the conditions outlined herein.

2. For purposes of this qualified protective order, "protected health information" or "PHI" shall have the same scope and definition as set forth in 45 C.F.R. § 160.103 and 164.501. PHI includes, but is not limited to, information relating to the past, present, or future physical or mental health condition of any individual who is a party to any case pending in this multi-district litigation (or the decedent or ward of a party who sues in a representative capacity), as well as any and all information relating to the provision of health care to such individual.

3. This order authorizes any third party that is a "covered entity" (as defined by 45 C.F.R. § 160.13) who is provided with a HIPAA-compliant authorization or subpoena for the production of documents, or a subpoena commanding attendance at deposition or trial, to disclose the PHI in response to such request or subpoena to the attorneys representing parties in the above-captioned multi-district litigation. This order is intended to authorize such disclosures under the privacy regulations issued pursuant to HIPAA. 45 C.F.R. § 164.512(e)(1)(i).

4. The parties and their attorneys shall only be permitted to use or disclose the PHI in a manner consistent with Case Management Order No. 5 (Protective Order of Confidentiality).

5. The parties are expressly prohibited from using or disclosing the protected health information obtained pursuant to this order for any purpose other than this litigation. Further, the parties are ordered to either return to the covered entity from whom or which such protected health information was obtained, or to destroy the protected health information obtained pursuant to this order (including all copies made), immediately upon conclusion of this litigation. *See* 45 C.F.R. §164.12(e)(1)(v). Counsel are not required to secure the return or destruction of PHI submitted to the Court.

6. Until further order of this Court, neither counsel for Fresenius Medical Care North America nor their staff, agents or anyone on their behalf shall discuss the PHI (or otherwise the care and treatment) of an individual alleged to have been injured in any case pending in this MDL with that individual's treating physicians.

SO ORDERED this 15th day of July, 2014.

William P. Woodlock

DOUGLAS P. WOODLOCK, J.