

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE: FRESENIUS GRANUFLO/	)	
NAUTRALYTE DIALYSATE PRODUCTS	)	
LIABILITY LITIGATION	)	MDL No. 13-02428-DPW
	)	
_____	)	

CASE MANAGEMENT ORDER NO. 17 (LONE PINE ORDER)  
January 26, 2017

In January and February 2016, shortly after the first bellwether case was tried in Massachusetts state court – where a large number of similar cases within state jurisdiction have been consolidated before Judge Kirpalani – and on the literal eve of back to back bellwether trials scheduled to begin in this court – where the United States Judicial Panel for Multidistrict Litigation had assigned to me similar cases from throughout the country – the parties reported a private global settlement that could resolve the vast majority of the thousands of products liability cases filed regarding the defendants’ GranuFlo and NaturaLyte products used during kidney dialysis treatment.

The parties sought a stay of proceedings to permit focus on effectuating the settlement. I essentially authorized such a stay subject to continuing various case management housekeeping activities and addressing matters having impact in other

jurisdictions. I have since then observed the parties pursuing the laborious settlement process in a diligent manner and have continued the stay for about a full year. A similar stay has remained in place in the Massachusetts state court. I have, however, made clear to the parties that they were held for trial of the remaining designated bellwether case in this court, *Dial v. Fresenius Medical Care Holdings, Inc., et al*, No. 14-11101-DPW, which they reported would not settle, beginning February 6, 2017.

As the December 31, 2016 deadline for opting-in to the proposed settlement approached, the defendants on November 18, 2016 moved [Dkt. No. 1797] for an order ("*Lone Pine Order*")<sup>1</sup> designed to identify the viability of cases as to which communications regarding the settlement had not yielded adequate information. After reviewing the submissions of parties opposing such an order – and in the case of the Plaintiffs' Executive Committee reserving certain rights should the settlement not be implemented – I conducted a hearing on December 14, 2016 in which interested parties could be heard.

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<sup>1</sup> A *Lone Pine Order* takes its name from a New Jersey case in which the trial court entered a pre-trial order requiring plaintiffs in mass tort litigation to provide detailed factual submissions, or face the risk of having their cases dismissed. See generally *In re Fosamax Products Liab. Litig.*, (No. 06 MD 1789(JFK), 2012 WL 5877418 (S.D.N.Y. Nov. 20, 2012).

On the basis of that hearing and related submissions, I adjusted upon joint motion [Dkt. No. 1813] of the Plaintiffs' Executive Committee and the defendants, various deadlines to balance the competing interests. Most pertinently, I set January 13, 2017 as the date by which plaintiffs could opt-in to the settlement and May 17, 2017 as the date by which the defendants must fund the settlement, if it was not voided by the defendants after an opportunity to review the dimensions of the settlement and the prospects of any remaining litigation [Dkt. No. 1817]. At the same time, I announced my adoption in principle of a "*Lone Pine* Case Management Order" requiring parties who chose not to opt-in to provide essential information by March 29, 2017, the date I told counsel at the December 14, 2016 hearing I believed sufficient [Dkt. No. 1816]. This was done to focus the attention of plaintiff's counsel on the availability of settlement and the looming opt-in deadline, to facilitate the defendants' evaluation of the settlement and to provide a foundation for further case management and pre-trial proceedings as to those cases which plaintiffs chose not to settle.

In opposing the entry of a *Lone Pine* order at the December 14, 2016 hearing, counsel for certain plaintiffs had objected to the short time period for *Lone Pine* submissions. I agreed that this foreshortened timing was problematic. But I share the views

expressed by Judge Fallon, a seasoned MDL judge, in the *Vioxx* litigation that

[a]t this advanced stage of the litigation, it is not too much to ask a Plaintiff to provide some kind of evidence to support their claim . . . . Surely if Plaintiffs' counsel believe that such claims have merit, they must have some basis for that belief; after all this time it is reasonable to require Plaintiffs to come forward and show the basis for their beliefs and show some kind of basic evidence of specific causation.

*In re Vioxx Products Liab. Litig.*, 557 F. Supp. 2d 741, 744 (E.D. La. 2008).

In considering whether to enter this Order, I found the several categorical oppositions to any *Lone Pine Order* mounted by a few plaintiff's firms to be without force and sought to alert plaintiffs that any cases not settling would move promptly to a trial footing, once the question of settlement funding *vel non* was resolved. Nevertheless, I did not wish to burden – especially during the holiday season – final evaluations by plaintiffs concerning whether to settle with a case management diversion requiring the shortened response time sought by the defendants in their initial proposed *Lone Pine Order*.

The opt-in date having passed and the process of reviewing opt-in paperwork having begun, I now – as I informed the parties at a status conference last week I would – provide this detailed order regarding the disclosure obligations of those plaintiffs

who chose not to opt-in and who wish to pursue their litigation on the merits.

This order is, as a matter of design, essentially a parallel to the Order issued Monday in the Massachusetts state court. While the prospective global settlement is a private one negotiated by the parties as to which this court's role has been limited to facilitation through an effective stay of the litigation and providing a limited mechanism for review of certain of the settlement master's determinations, the prospect that some number of non-settlement cases will require resolution on the merits and the likelihood that a number of cases in this litigation have not been carefully reviewed by plaintiffs' counsel to determine whether in fact they have merit, requires a case management order under the general rubric of Fed. R. Civ. P. 16 to assure that the larger purposes of the assignment of the Judicial Panel for Multidistrict Litigation are served.

Accordingly, for good cause shown and in order to promote the fair and efficient administration of this litigation, it is hereby ORDERED that all plaintiffs who have elected not to participate in the global settlement of this litigation, shall submit for docketing in their respective cases on or before 5:00 p.m. Eastern time, March 29, 2017, the following:

1. An affidavit – sworn under oath – or declaration – submitted in the form set out in 28 U.S.C. § 1746 – executed by

counsel for the plaintiff with an appearance entered in this MDL, attesting that counsel has reviewed documents or data supporting the contention that GranuFlo® or NaturaLyte® acid concentrate was used during the patient's last dialysis treatment prior to alleged injury. Counsel shall identify with particularity all documents and data reviewed to support that contention and append copies of all such documentation or data to his/her Affidavit.

2. An affidavit – sworn under oath – or declaration submitted in the form set out in 28 U.S.C. § 1746 – executed by a qualified physician, or other medical expert (“the expert”) setting forth the following:

- a. The name, professional address, and curriculum vitae of the expert, including – if applicable – any experience actually treating the patient;
- b. A list of the patient's medical records reviewed by the expert prior to the preparation of the expert's submission;
- c. A description of the specific injury suffered by the patient including the date, time and location where such injury occurred and the time of injury in temporal proximity to the patient's last dialysis treatment; and

d. A detailed opinion whether the expert believes to a reasonable degree of medical certainty that GranuFlo® or NaturaLyte® acid concentrate caused the patient's injury and, if so, the factual, medical and scientific bases for that opinion.

3. Plaintiffs shall separately send the affidavits or declarations to counsel for Fresenius via electronic mail at [GranuFloPlaintiffCaseinformation@bradley.com](mailto:GranuFloPlaintiffCaseinformation@bradley.com).

4. Failure to comply with the terms of this Order within the time period prescribed will be reviewed by the Court and, upon motion of Fresenius, may result in the dismissal of a delinquent Plaintiff's action with prejudice.

**/s/ Douglas P. Woodlock**  
DOUGLAS P. WOODLOCK  
UNITED STATES DISTRICT JUDGE