UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSSETTS

IN RE: FRESENIUS GRANUFLO/ NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	)	No: 1:13-MD-2428-DPQ
This Document Relates To:	)	
Angelos Zachery, Sherman George, Sorita Harris, Marysia Mike, Mohalie White and Jessie Hallums, Ind., and as Executor of Estate of Nellie Fredrick McClendon v. Fresenius USA, et al.	)	
No: 1:14-cv-13150	)	

OPPOSITION TO DEFENDANT FMCNA'S MOTION FOR ENTRY OF LONE PINE CASE MANAGEMENT ORDER

Plaintiffs Angelos Zachery, Sherman George, Sorita Harris, Marysia Mike, Mohalie White, and Jessie Hallums, Individually, and as Executor of Estate of Nellie Fredrick McClendon ("Plaintiffs") hereby oppose Defendant Fresenius's Motion for Entry of *Lone Pine* Case Management Order (Doc. #1797).

On November 18, 2016, Fresenius filed a Motion requesting that the Court require all plaintiffs who have elected not to opt in to the GranuFlo and Naturalyte global settlement to produce evidence of product identification, and to engage, at each plaintiff's expense, an expert witness to opine about specific causation in the case. According to Fresenius's proposal, if a plaintiff fails to do so, the case is to be dismissed with prejudice. Fresenius claims this "case management" scheme is supported by *Lore v. Lone Pine Corp.*, 1986 WL 637507 (N.J. Super Ct. Nov. 18, 1986) – an unreported New Jersey trial court decision. Fresenius's motion should be denied because: (1) A

Lone Pine order is a rarely-utilized and an extreme remedy that is not appropriate for this litigation; (2) *Lone Pine* orders afford defendants an unfair, prejudicial advantage in the litigation and contrary to the federal rules of civil procedure; and (3) A *Lone Pine* order would greatly and unnecessarily increase the costs in this case, in violation of Fed. R. Civ. P. 1.

ARGUMENT

I. A *Lone Pine* order is a rarely utilized and extreme remedy that is not appropriate for this litigation.

Fresenius bases its request on the decision *Lore v. Lone Pine Corp.*, 1986 WL 637507 (N.J. Super Ct. Nov. 18, 1986). *Lone Pine* is an unreported New Jersey trial court decision in an environmental toxic tort case, in which plaintiffs claimed that a landfill polluted their properties and caused various physical ailments. *Lone Pine*, 1986 WL 637507, at *1. There were over 450 named defendants and it was unclear what the causes of the plaintiffs' injuries were or which defendants caused them. *Id.* The court found that, after sixteen months of litigation, the plaintiffs had failed to "provide anything that resemble[d] a prima facie cause of action." In addition, during the course of the litigation, the Environmental Protection Agency had issued a Record of Decision ("R.O.D.") summarizing sixteen studies that had been done on the landfill. *Id.* at *1. The R.O.D. was "completely contrary" to the claims of the plaintiffs suggesting that there was no groundwater contamination, no transport of pollution by air, groundwater, or surface water, and no contamination beyond the landfill and its immediate vicinity. *Id.* at *2-3. In an effort to determine whether *any* of the claims was valid, the New Jersey trial court had to resort to extreme measures and ordered plaintiffs to produce: "[r]eports of treating physicians and medical or other experts, supporting each individual

plaintiff's claim of injury and causation." *Id.* at *2. Failure to do so led to dismissal of the claim with prejudice.

Clearly, the *Lone Pine* court issued the order because: (1) a governmental agency had issued a report in direct contravention of the plaintiffs' claims; (2) the plaintiffs had put forth *no* independent evidence in support of their claims; and (3) the plaintiffs were unable to identify which of hundreds of defendants allegedly caused an injury and how that injury was caused. This fact pattern could not be further from the present case.

In this case, however, the governmental agency reviewing the risks associated with the usage of GranuFlo and Naturalyte, the Food and Drug Agency ("FDA"), agreed with Plaintiffs' position that the product labels associated with GranuFlo and Naturalyte were inadequate and issued a Class 1 Recall of these products in June 2012.[1] Thus, unlike *Lone Pine*, Plaintiffs' claims in this litigation are not in any way *contrary* to those of regulatory authorities – they mirror their concerns and findings.

This is also not a case in which Plaintiffs have failed to identify what their injuries are, who caused those injuries, and how those injuries were caused. *See, e.g., Acuna,* 200 F.3d at 340 (observing that plaintiffs had failed to identify which facilities were alleged to have caused their injuries and neither the defendants nor the district court had been put "on notice from plaintiffs' pleadings as to how many instances of which diseases were claimed as injuries."). Here, the majority of Plaintiffs in this MDL allege a finite type of injury – cardiac arrest and death. Plaintiffs know what caused those injuries – GranuFlo and Naturalyte, products manufactured by Fresenius. Plaintiffs

[1] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm305630.htm (last visited on 12/2/2016)

further have evidence showing that FMCNA knew of the risks associated with these products and willfully concealed that information from providers of dialysis treatments.

II. *Lone Pine* Orders Afford Defendants an Unfair, Prejudicial Advantage in the Litigation and Are Contrary to the Federal Rules of Civil Procedure.

Lone Pine orders originate from procedural rules that do not *specifically* grant the authority for courts to issue such orders. It is not surprising, then, that Defendants cite not a single case from the First Circuit in support of their Motion. That is because no such case exists. Instead of resorting to amorphous concepts such as inherent case management authority to justify a *Lone Pine* order, the Court should first look to existing procedural devices to address the issues raised, and should not ignore existing procedural rules and safeguards merely because this case is a mass tort case.

The self-serving procedure Fresenius proposes serves as an improper and untimely substitute for summary judgment motions. Summary judgment motions under Federal Rule of Civil Procedure 56 are intended to impose procedural safeguards that adequately protect the interests of *all* parties, while still addressing alleged factual deficiencies that *Lone Pine* orders are supposed to remedy. In the ordinary course of pharmaceutical litigation, defendants typically move for summary judgment under Rule 56 after all discovery has been conducted. At that point, plaintiffs are required to offer evidence, expert witness testimony, and set forth specific facts that show a genuine triable issue of fact. The fact that in the single tried case, *Ogburn*, the jury found in the favor of Fresenius on the causation issue, is in and of itself no proof that all other juries would come to a similar conclusion. Fresenius's position in that regard has no merit.

III. A *Lone Pine* Order Would Greatly and Unnecessarily Increase the Costs in This Case.

The scope and purpose of the Federal Rules of Civil Procedure are "to secure the just, speedy, and inexpensive determination of every action." Fed R. Civ. P. 1. Fresenius asks the Court to require that Plaintiffs opting out of the global settlement produce Rule 26 expert reports within a time frame that is unachievable for most. A conservative estimate of the average cost of each such report would be $5,000 (10 hours of medical record review and drafting of a Rule 26 expert report). If the Court imposes such a requirement, the costs would be stifling and may bar the door to justice for many Plaintiffs. This is not to mention the inevitable challenges to these reports that Fresenius would muster and the time and costs (including additional expert fees) that would be needed to deal with those challenges. Removing the safeguards of the rules of civil procedure and requiring the expenditure of vast sums of money through the device of a *Lone Pine* order is simply unfair to those plaintiffs who have not had the benefit of rulings and bellwether trials in this Court to guide their decisions.

IV. Plaintiffs' Alternative Position

Should the Court agree with Fresenius's position regarding a *Lone Pine* order, Plaintiffs respectfully propose that such order be limited to providing proof of the usage of GranuFlo or Naturalyte at the Decedent Plaintiff's last dialysis. That information ensures that meritless cases would cease to continue being litigated, and at the same time Plaintiffs would not be unfairly burdened with the unjustified expense of having to produce a Rule 26 expert report at this juncture.

Ultimately, should the Court decide to grant Fresenius's Motion, Plaintiffs submit that the deadline proposed by Fresenius for submission of Rule 26 expert reports – January 17, 2017 – is extremely burdensome as well as unrealistic for several reasons. Experts in this field are busy professionals. They would require advance notice to clear

their schedules to make time for review of Plaintiffs' medical records and drafting of the requisite reports. Moreover, with the holiday season upon us, any such arrangement becomes even more difficult and likely more time consuming to make.

The deadline for Plaintiffs in this litigation to opt into the global settlement is set at December 31, 2016. After that, Fresenius would have a few weeks to decide whether it would participate in the settlement. Thus, to require that the Plaintiffs who have chosen to opt out of the settlement to produce Rule 26 expert reports before it is even known that the settlement will be consummated is inappropriate and premature. This is especially true because should the global settlement not materialize as planned, all other Plaintiffs will be in the same situation as those who have chosen to opt out and the disparate treatment of the latter group would be greatly prejudicial.

In the event that the court deems that a *Lone Pine* order is warranted, the "court should strive to strike a balance between efficiency and equity." *In re Vioxx Prod. Liab. Litig.,* 557 F.Supp. 2d 741, 743 (E.D.La.2008); *see also Antero Resources Corp. et al v. Strudley,* 347 P.3d (Colo.2015) ("Federal courts considering whether to issue Lone Pine orders seek to balance efficiency and equity."); *see Digitek*, 264 F.R.D. at 259 ("Given a choice between a 'Lone Pine order' created under the court's inherent case management authority and available procedural devices such as summary judgment, motions to dismiss… and similar rules, [we find] it more prudent to yield to the consistency and safeguards of the mandated rules…"). In the Plaintiffs propose the deadline for producing the Rule 26 reports be set no sooner than July 15, 2017. In the *Vioxx* litigation, the parties announced the establishment of a Vioxx Resolution Program on November 9, 2007. Also on that date, the Court entered two pre-trial orders requiring plaintiffs to provide case specific expert reports, very similar to those FMCNA has

requested in its proposed order herein, by a certain date – plaintiffs with a last name beginning with A through L by May 1, 2008, and plaintiffs with a last name beginning with L through Z by July 1, 2008. These dates were later extended by the Court to July 1, 2008 and August 1, 2008 respectively – which gave individual plaintiffs seven and eight months respectively to procure and provide expert reports. After balancing the equities, the Court in *Vioxx* recognized the importance of ensuring that all plaintiffs had a fair opportunity o comply with the pre-trial orders. In this case, FMCNA is asking the Court to allow less than six weeks form the date of this pleading for individual plaintiffs to procure and provide individual physician certifications. For most individual plaintiffs, this deadline would be very difficult, if not impossible, to meet.

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court deny Fresenius's Motion for Entry of a Lone Pine Case management Order in its entirety, or alternatively limit the scope of such order as proposed *supra.*

Respectfully submitted,

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