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

FMCNA DEFENDANTS' MEMORANDUM IN SUPPORT OF PROPOSED PHASE II DISCOVERY PROTOCOL

Defendants Fresenius Medical Care Holdings, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc., (collectively "FMCNA" or "Defendants") submit this Memorandum in Support of FMCNA's Proposed Phase II Discovery Protocol, which will govern the next phase of case-specific fact discovery ("Phase II discovery") in each of the ten cases selected for bellwether trial pursuant to Case Management Order No. 10.

The parties have reached agreement as to all but one aspect of Phase II discovery – namely, whether the parties should be permitted in Phase II to take trial depositions of treating physicians who sat for discovery depositions during Phase I. Because none of Decedents' treating physicians can be compelled to testify in-person at trial, Phase II discovery must provide the parties with a full and fair opportunity to develop trial testimony via deposition in order to ensure that what is ultimately presented to the jury provides a complete and accurate picture of the Decedent's treatment history and the treating physician's views thereon.

BACKGROUND

As required by Case Management Order No. 10, the parties have worked cooperatively to prepare a joint proposed protocol regarding the scope of the additional fact discovery that will be necessary in order to prepare adequately these cases for trial. To that end, the parties have

agreed that absent leave of the Court: (1) Phase II discovery shall consist of no more than ten depositions per side, each lasting a maximum of seven hours and (2) the Federal Rules of Civil Procedure shall govern written discovery. The parties disagree, however, as to one limited issue: whether the parties should be permitted to use one or more of their Phase II depositions to take trial depositions of a narrow category of critical witnesses – Decedents' treating physicians – who previously sat for discovery depositions. For the reasons set forth below, such trial depositions are necessary for the parties to fully prepare of these cases for trial.

ARGUMENT

The purpose of Phase I discovery was not trial preparation. Rather, Phase I discovery was intended only to allow the parties to gather sufficient information to narrow the pool of twenty cases selected for case-specific discovery to a pool of ten representative cases for bellwether trial. In keeping with this purpose, Case Management Order No. 10 strictly curtailed the number and length of depositions to be taken during Phase I. With respect to treating nephrologists in particular, Case Management Order No. 10 allowed for only one deposition lasting no more than seven hours, with such time to be split equally between the parties.[1] Given these time constraints, FMCNA necessarily limited its questioning in Phase I to those topics that were absolutely essential to a fair assessment of whether a given case was adequately representative to be included in the bellwether trial pool.

For purposes of preparing a case for trial in Phase II, however, fulsome depositions of these witnesses are critical. That is because end-stage renal disease, or dialysis, patients commonly suffer from a number of other diseases – mainly diabetes and hypertension. These other disease states independently cause severe detriment to other critical organs, including the

[1] Case Management Order No. 10 permitted the parties to depose multiple treating nephrologists, but all such deponents were treated as a single witness for purposes of complying with the seven-hour time limit.

heart, lungs, vascular system, gastrointestinal system and liver. Routinely, these other adverse conditions develop and exacerbate in parallel with progressive renal failure and dialysis. Because of these comorbid disease states and the repetition and stress of hemodialysis treatment itself, the overall probability or likelihood of death for dialysis patients is high at first blush. Notwithstanding many examples of patients living and thriving for more than 30 years on hemodialysis, the annual mortality rate for dialysis patients even today is in the 15-20% range – meaning, roughly, that one patient in five dies each year.

Moreover, cardiac arrest has long been identified as among the most common causes of death in the dialysis population. Because of the stress, length, and recurrence of the hemodialysis treatment itself, some cardiac or cardiopulmonary arrests will inevitably occur with regular frequency while patients are in dialysis facilities, including during treatment. Over the years, this frequency has been tracked by the United States government and others and has remained remarkably consistent at approximately six incidents of arrest during every 100,000 treatments administered.[2] For these reasons, the fact that a bellwether patient may have experienced a cardiac arrest temporally near or even during a hemodialysis treatment tells the jury nothing about whether the arrest was causally related to the treatment itself.

Testimony from Decedents' treating physicians will be essential to the jury's determination of specific causation in each of the bellwether trials. Importantly, however, the time allotted to each party for questioning in Phase I was not sufficient – nor was it intended to be – to elicit the full spectrum of information from Decedents' treating physicians that the jury will require to properly evaluate the specific causation issues that these cases will present.

[2] Significantly, this frequency has not changed over the years beginning in about 2002 during which time GranuFlo moved from a very small market share to the 60%+ market share it has today.

This is a critical consideration for purposes of formulating an appropriate Phase II discovery protocol because none of the injuries at issue in the bellwether cases occurred within 100 miles of the courthouse and, therefore, the deposition testimony of Decedents' treating physicians will likely become their trial testimony. Accordingly, the parties must have an opportunity to further develop the information obtained in initial discovery such that the videotaped deposition testimony put before the jury provides a fulsome picture of Decedents' complex treatment histories and the treating physicians views thereon – facts which go to the very core of Plaintiffs' claims.

Despite the fact that Decedents' treating physicians cannot be compelled to appear at trial, Plaintiffs have taken the position that the parties should not be permitted to "redo" any depositions that have previously been taken. This position, however, fundamentally misconstrues the nature of the treating physician depositions that were taken during Phase I. Because of the restrictions imposed by HIPAA, FMCNA had no opportunity to interview Decedents' treating physicians prior to taking their Phase I depositions. Thus, unlike Plaintiffs, who could speak with these physicians at their leisure prior to formally questioning them at deposition, FMCNA had no advance insight into how the testimony of Decedents' treating physicians might take shape. Rather, for FMCNA the Phase I depositions were purely information-gathering endeavors; they were quintessential discovery depositions. Viewed against this backdrop, Plaintiffs cannot credibly assert that by conducting additional depositions of Decedents' treating physicians the parties would be "redoing" what has already been done.[3] Quite to the Contrary, the trial depositions that FMCNA proposes to take are the logical – and,

[3] Moreover, Plaintiffs vastly overstate the impact of FMCNA's proposal. The parties deposed 15 doctors, eight of which were treating physicians, during Phase I. Thus, FMCNA's proposal implicates only eight of potentially two hundred depositions to be taken during Phase II.

indeed, necessary – next step in preparing cases for trial where certain crucial witnesses will not be available to provide live testimony.

Finally, the proposed trial depositions will count against the limit of ten depositions per side. Conducting these depositions will not require the expenditure of any resources beyond that which is already contemplated by the parties' agreed-upon Phase II discovery protocol.

CONCLUSION

For the foregoing reasons, FMCNA respectfully requests that this Court permit the parties to take trial depositions during Phase II discovery of treating physicians that previously sat for discovery depositions during Phase I discovery.

Respectfully submitted,

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Dated: April 28, 2015

CERTIFICATE OF SERVICE

I, William H. Kettlewell, hereby certify that a true and correct copy of the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on April 28, 2015.

/s/ William H. Kettlewell
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