IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

IN RE: SORIN 3T HEATER-COOLER SYSTEM PRODUCTS LIABILITY LITIGATION (NO. II)	:	MDL DOCKET NO. 2816 Civil Action No. 1:18-MD-2816 Hon. John E. Jones, III THIS DOCUMENT RELATES TO: ALL CASES

CASE MANAGEMENT ORDER NO. _15
(Docket Control Order For Any Ongoing Litigation)

This Case Management Order ("CMO") applies to (i) all Plaintiffs alleging personal injury (and related) claim(s) against LivaNova Holding USA, Inc., f/k/a Sorin Group USA, Inc. and related entities ("Defendant") who have cases pending against Defendant as of the date this CMO that are not dismissed under the terms of the Master Settlement Agreement entered between Plaintiffs' Lead Counsel, Anapol Weiss, and LivaNova Holding USA, Inc. on March 28, 2019 (the "MSA") and (ii) all Plaintiffs with cases alleging personal injury (and related) claim(s) against Defendant that are newly filed in, removed to, or transferred to this MDL after the entry of this CMO ("Litigating Plaintiffs") (collectively, the "Parties").

Consistent with the Court's inherent authority to manage these judicial proceedings, and in light of the MSA entered after years of litigation, the Court finds it appropriate at this time to exercise its discretion to enter this CMO in order to efficiently manage any cases against Defendant by Litigating Plaintiffs.

This CMO requires all Litigating Plaintiffs to produce certain specified information regarding their claim(s) and provides for bifurcated discovery on statute of limitations, other time-based defenses, and causation issues and related dispositive motion practice, prior to any further discovery. Litigating Plaintiffs who represent themselves *pro se*

shall be bound by the requirements of this CMO and shall fully comply with all obligations required of counsel by this CMO, unless otherwise stated.

A. Background and Status of Proceedings

1. On February 1, 2018, the United States Judicial Panel on Multidistrict Litigation ("JPML") established MDL No. 2816 to centralize cases against Defendant alleging injuries arising from the use of the Sorin 3T Heater-Cooler Device. Over 80 cases have been filed in, removed to, or transferred to the MDL.

2. District courts have inherent authority to manage their dockets. This is especially true in large litigations. *In re Asbestos Prods. Liab. Litig.*, 718 F.3d 236, 243 (3d Cir. 2013) ("'[D]istrict court judges must have authority to manage their dockets, especially during [a] massive litigation . . . .'") (quoting *In re Fannie Mae Sec. Litig.*, 552 F.3d 814, 822-23 (D.C. Cir. 2009)); *see also Ramirez v. &H Lemont, Inc.*, 845 F. 3d 772, 776 (7th Cir. 2016) ("[A] court has the inherent authority to manage judicial proceedings and to regulate the conduct of those appearing before it."). The District Court's power extends to, for example, "controlling and scheduling discovery, including orders affecting disclosures and discovery under Rule 26 and Rules 29 through 37," "adopting special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems," and "facilitating in other ways the just, speedy, and inexpensive disposition of the action." Fed. R. Civ. P. 16(c)(2)(F),(L)&(P).

3. As the Third Circuit has recognized, "[M]ultidistrict litigation 'presents a special situation, in which the district judge must be given wide latitude with regard to case management in order to effectively achieve the goals set forth by the legislation that created the Judicial Panel on Multidistrict Litigation.' This wide latitude applies, in particular, to issuing discovery orders, and to dismissing actions for non-compliance with such orders . . . ." *In re*

Avandia Marketing, Sales Practices & Prods. Liab. Litig., 687 F. App'x 210, 2017 WL 1401285, at *214 (3d Cir. Apr. 19, 2017) (citation omitted); *see also In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 496 F.3d 863, 866 (8th Cir. 2007) (affirming MDL court's dismissal of claims for failure to comply with discovery orders); *In re Phenylpropanolamine Prod. Liab. Litig.*, 460 F.3d 1217, 1229 (9th Cir. 2006) ("In re PPA") ("administering cases in multidistrict litigation is different from administering cases on a routine docket . . .") (finding no abuse of discretion in MDL Court's dismissal of claims for failure to comply with discovery and product identification case management orders); *Freeman v. Wyeth*, 764 F.3d 806, 809 (8th Cir. 2014) (affirming MDL court's dismissal of claims for failure to provide medical authorizations); *In re Asbestos Prods. Liab. Litig.*, 718 F.3d at 246 ("'[A]dministering cases in multidistrict litigation is different from administering cases on a routine docket.'") (quoting *in re PPA*, 460 F.3d at 1229). This is particularly true with respect to managing discovery and taking actions designed to move the cases "in a diligent fashion toward resolution by motion, settlement or trial." *In re PPA*, 460 F.3d at 1232.

4. During the course of these MDL proceedings, this Court has exercised its discretion and inherent authority and has established discovery procedures. Fed. R. Civ. P. 1; Fed. R. Civ. P. 16(c).

5. The Court is aware that, without admission of fault or liability, LivaNova Holding USA, Inc. has entered the MSA to establish a framework for the comprehensive resolution of all cases alleging personal injury (and related) claims related to the Sorin 3T Heater-Cooler Device.

6. Docket Control Orders "have been routinely used by courts to manage mass tort cases." *In re Vioxx Prod. Liab. Litig.*, 557 F. Supp. 2d 741, 743 (E.D. La. 2008)

(Fallon, J.). Appellate courts, including the Third Circuit, have regularly upheld their use in MDL cases. *See, e.g.*, *In re Avandia*, 687 F. App'x at 214 (affirming MDL court's dismissal for failure to comply with an order requiring future plaintiffs to provide an expert report, noting the district court must be given "wide latitude with regard to case management" in multidistrict litigation)(citation omitted); *see also Dzik v. Bayer Corp.*, 846 F.3d 211, 216 (7th Cir. 2017) (affirming MDL court's dismissal for failure to comply with discovery order; "District courts handling complex, multidistrict litigation must be given wide latitude with regard to case management in order to achieve efficiency.") (internal quotation marks omitted); *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.*, 30 F. App'x 27, 27, 30 (3d Cir. 2002) (affirming district court's dismissal of appellants' case within multi-district litigation because of their counsel's failure to comply with a discovery order concerning expert reports, noting "[i]n the context of a mass tort MDL case, the delay occasioned by counsel's conduct is particularly pernicious because of the complex problems presented on the issue of causation and the need for the efficient and uniform resolution of discovery matters"); *Acuna v. Brown & Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000) (such "orders are designed to handle the complex issues and potential burdens on Defendant and the court in mass tort litigation. In the federal courts, such orders are issued under the wide discretion afforded district judges over the management of discovery under Fed. R. Civ. P. 16").

7. Moreover, the use of so-called "Lone-Pine" orders may be appropriate when a defendant has taken steps to settle a significant portion of the claims pending against it. *See, e.g.*, *In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig.*, MDL No. 2385 (S.D. Ill. May 29, 2014), available at http://www.ilsd.uscourts.gov/documents/mdl2385/CMO78.pdf (in settlement context, requiring non-settling plaintiffs to produce causation expert reports); *see also*

In re Vioxx Prods. Liab. Litig., MDL No. 1657 (E.D. La. 2008), Pretrial Order No. 28 (available at http://www.laed.uscourts.gov/sites/default/files/vioxx/orders/vioxx.pto28.mdl.pdf) and Pretrial Order No. 29 (available at http://www.laed.uscourts.gov/sites/default/files/vioxx/orders/vioxx.pto29.mdl.pdf).

8. This Court finds it particularly appropriate to enter this Docket Control Order so the Court can efficiently manage an MDL that is proceeding on a settlement front. Other MDL courts have exercised their discretion and inherent authority to enter an order establishing certain discovery and other requirements for future cases filed against settling defendants in tort litigation. *See, e.g.*, *In re American Medical Systems, Inc. Pelvic Repair Systems Prods. Liab. Litig.*, MDL No. 2325 (S.D. Va. June 7, 2017) (the "AMS Mesh MDL"); *In re Testosterone Replacement Therapy Products Liab. Litig.*, MDL No 2545 (N.D. Ill. June 11, 2018) (the "TRT MDL"). The AMS Mesh MDL is one of seven centralized MDL proceedings pending before Judge Goodwin in the Southern District of West Virginia arising from different mesh products manufactured by different defendants. The court explained that it was establishing requirements for future claims against the AMS Defendant only due to "recent settlement developments," in particular a "dramatic[]" decline in the number of cases against AMS on the active docket "[a]s a result of AMS's efforts and those of multiple counsel for plaintiffs." *Id.* at 1-2. The Court recognized that:

> [C]ase management is of the utmost importance and the Court is vested with substantial discretion to manage discovery and set deadlines that will help secure "the just, speedy, and inexpensive determination of every action and proceeding."

Id. at 2 (citation omitted). The parties' significant progress in resolving existing claims made it appropriate to establish requirements for the speedy and just resolution of any future claims. *See*

id. These requirements included expert disclosures regarding causation, among other items, for newly filed cases. *See id.* at 3-7.

For the foregoing reasons, and other good cause appearing therefor, it is Ordered as follows:

B. Requirement for Litigating Plaintiffs to have Proof of NTM Infection

9. In order to proceed, a Litigating Plaintiff, must have positive bacterial culture results showing infection with a non-tuberculosis mycobacteria ("NTM") following surgery with a Sorin 3T.

C. Litigating Plaintiffs' Requirements to Produce Certain Specified Information Regarding their Claims

10. **Litigating Plaintiffs' Production Requirements**: Litigating Plaintiffs shall serve the following documents and/or information upon counsel for the Defendant:

a. **Obligations Under Order Regarding Plaintiffs' and Defendants' Fact Sheets and Service Protocol**: If not already completed, executed, and served, each Litigating Plaintiff must comply with all requirements of this Court's July 31, 2018, Order Regarding Plaintiffs' and Defendants' Fact Sheets and produce to Defendant the items described in Section C.10, within the timeframe provided herein.

b. **Medical Records Confirming Use of Sorin 3T Heater-Cooler Device:** All medical records that document the use in Litigating Plaintiff's surgery of a Sorin 3T Heater-Cooler Device.

c. **Medical Records Relating to Alleged Injury:** All medical records that document the Litigating Plaintiff's alleged Sorin 3T Heater-Cooler Device-related injury/injuries, including records of any bacterial culture results, bacterial speciation, and genetic analysis of Litigating Plaintiff's infection-causing pathogen.

d. **Medical Records Relating to Medical Condition:** All medical records relating to the Litigating Plaintiff from health care providers for the period from two (2) years prior to the date of the Litigating Plaintiff's surgery with the Sorin 3T Heater-Cooler Device to the present.

e. **Record Collection Production**: The Litigating Plaintiff and his/her counsel shall affirmatively collect and produce such Medical Records from all available sources in the Litigating Plaintiff's possession, custody or control, which includes but is not limited to any relevant medical records that can be collected from the Litigating Plaintiff's medical facilities, health care providers, and/or pharmacies that treated and/or dispensed drugs to, or for, the Litigating Plaintiff. A Litigating Plaintiff and his/her counsel shall not be in compliance with this CMO by producing only records in the Litigating Plaintiff or his/her counsel's current possession, or by only producing authorizations to allow the Defendant to collect such records.

f. **Affidavit**: An affidavit signed by the Litigating Plaintiff and his/her counsel (i) attesting that the Litigating Plaintiff has complied with all requirements of this Court's Order Regarding Plaintiffs' and Defendants' Fact Sheets and Service Protocol; (ii) attesting that records have been collected from all medical records described in Sections C.10.b – C.10.e have been collected; and (iii) attesting that all records collected have been produced pursuant to this CMO. If any of the documents or records described in Sections C.10.b – C.10.e do not exist, the signed affidavit by the Litigating Plaintiff and the Litigating Plaintiff's counsel shall state that fact and the reasons, if known, why such materials do not exist, and shall provide a "No Records Statement" from the medical facilities and/or other healthcare provider.

g. **Expert Reports**: Expert reports in compliance with Federal Rule of Civil Procedure 26 as follows:

(1) A Rule 26(a)(2) expert report on general causation concerning the alleged injury/injuries.

(2) A Rule 26(a)(2) case-specific expert report concerning the causation of the Litigating Plaintiff's alleged injury/injuries and alternative causation. The reports required by Sections C.10.g.1 and C.10.g.2 may be combined in a single report by a single expert.

(3) A Rule 26(a)(2) expert report on the basis for liability concerning the Defendant.

11. **Deadline to comply**:

a. For each Litigating Plaintiff with personal injury (and related) claims pending against the Defendant as of the entry of this CMO, the items required by Section C.10 shall be produced no later than September 24, 2019, or 90 days after the date such Litigating Plaintiff elects not to settle his/her claims, whichever is sooner.

b. For each Litigating Plaintiff with personal injury (and related) claims newly filed in, removed to, or transferred to this MDL against the Defendant after the entry of this CMO, the items required by Section C.10 shall be produced no later than 90 days after the case is filed in, removed to, or transferred to this MDL.

12. **Failure to comply**: The Court has established the foregoing deadlines for the purpose of ensuring that pretrial litigation against the Defendant will progress as smoothly and efficiently as possible. Accordingly, the Court expects strict adherence to these deadlines. Should any Litigating Plaintiff fail to meet the requirements of Section B.9, or fail to comply with the obligations of Sections C.10, C.11, and D.13 or should the Defendant deem the Litigating Plaintiff's compliance with this CMO deficient, counsel for the Defendant shall notify the Court of the alleged deficiency, and the Court shall issue an "Order To Show Cause Why the

Case Should Not Be Dismissed With Prejudice and/or Sanctions Ordered." Litigating Plaintiff's counsel shall have 21 days to respond to said Order To Show Cause, which includes the ability to cure the alleged discovery deficiency. There shall be no imposition of a sanction for any Litigating Plaintiff who cures a deficiency within 21 days after entry of an Order to Show Cause. If the Litigating Plaintiff fails to show cause within 21 days of entry of the Court's Order To Show Cause, the Court shall dismiss the Litigating Plaintiff's case with prejudice and may impose additional sanctions the Court deems appropriate. *See, e.g.*, *Freeman*, 764 F.3d at 810; *In re PPA*, 460 F.3d at 1232.

D. Discovery On Statute of Limitations and Other Time-Based Defenses

13. Litigating Plaintiffs must, within the time frames established by Section C.11, serve upon counsel for the Defendant, in the manner described in this Court's July 31, 2018, Order Regarding Plaintiffs' and Defendants' Fact Sheets and Service Protocol, an affidavit signed by the Litigating Plaintiff and his/her counsel providing the following information: (1) the date the Litigating Plaintiff first learned his alleged injury/injuries may be related to the use of Sorin 3T Heater-Cooler Device; (2) how the Litigating Plaintiff first learned his alleged injury/injuries may be related to the use of Sorin 3T Heater-Cooler Device; (3) the date the Litigating Plaintiff first spoke to or corresponded with an attorney about potential litigation related to the use of a Sorin 3T Heater-Cooler Device; and (4) the date the Litigating Plaintiff first retained counsel for litigation related to use of a Sorin 3T Heater-Cooler Device. The Defendant is permitted to serve written discovery on each Litigating Plaintiff related to these topics (and others), and each such Litigating Plaintiff must respond to the discovery prior to the Defendant's depositions of the Litigating Plaintiff or the his or her prescribing and treating healthcare providers, provided that the Litigating Plaintiff shall have at least 30 days to respond to such discovery.

E. Case-Specific Bifurcated Discovery On Statute of Limitations, Other Time-Based Defenses, and Causation Issues And Related Dispositive Motion Practice

14. If a Litigating Plaintiff complies with the production requirements outlined above in Sections C.10, C.11, and D.13, then the Parties, as applicable, shall submit a proposed Scheduling Order to the Court that: (a) grants the Parties 180 days from the entry of the Scheduling Order to conduct bifurcated discovery on case-specific statute of limitations, other time-based defenses, and causation issues, including as to the adequacy of the Instructions for Use or Operating Instructions and information provided to hospitals at various times ("Bifurcated Discovery"); and (b) sets a briefing schedule that gives the Parties 45 days from the close of Bifurcated Discovery for the Parties to submit summary judgment motions and Daubert motions, 28 days for responses, and 28 days for replies.

15. During such Bifurcated Discovery, the Parties are permitted to: (a) serve written discovery related to statute of limitations, other time-based defenses, and causation issues (as described above) specific to the Litigating Plaintiff; (b) take the depositions of the Litigating Plaintiff, the Litigating Plaintiff's spouse, and any other non-party fact witness specific to the Litigating Plaintiff identified in the Plaintiff Fact Sheet or through other discovery for up to seven hours each, with counsel for the Defendant questioning first at each deposition; (c) take the depositions of each of the Litigating Plaintiff's treating healthcare providers, with counsel for the Defendant questioning first at each deposition. If a Litigating Plaintiff serves any written discovery upon the Defendant pursuant to clause (a) above, the Parties shall meet and confer about an appropriate deadline for responding to such discovery, which deadline shall be at least 60 days after service of such discovery. The Court's use of the term "specific to the Litigating Plaintiff" is intended to express the Court's intention not to permit additional "generic" discovery

against the Defendant at this time. No other depositions may be taken during the expedited discovery period absent prior leave granted by the Court upon a showing of good cause.

16. If a case survives the Defendant's summary judgment motions, the Court will set a Case Management Conference to determine whether any non-duplicative discovery is necessary and to discuss other case management issues. Discovery with regard to any other defendants, including hospitals and other medical defendants, will be addressed at this time as well. The filing and briefing of summary judgment motions and Daubert motions after the Expedited Discovery discussed above shall not prejudice or otherwise foreclose the opportunity for any Party or other defendant to file later, non-duplicative summary judgment and Daubert motions after completing full fact and expert discovery. The Court's use of the term "non-duplicative" is intended to express the Court's intention not to permit later summary judgment motions concerning topics addressed in summary judgment motions filed at the conclusion of the expedited discovery period or Daubert motions concerning witnesses addressed in Daubert motions filed at the conclusion of the expedited discovery period.

17. The foregoing provisions do not preclude any Party or other defendant from filing non-duplicative dispositive motions, including motions relating to personal jurisdiction.

18. This Order does not affect the hospital discovery previously authorized under CMO 14 (Dkt # 236).

IT IS SO ORDERED:

April 16, 2019

s/ John E. Jones III
The Honorable John E Jones III
United States District Judge
Middle District of Pennsylvania