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

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

PROPOSED CASE MANAGEMENT PLAN

This Proposed Case Management Plan is jointly submitted pursuant to Paragraph 2 of Case Management Order No. 2 (ECF No. 7) ("CMO 2"). In accordance with CMO 2, the Proposed Case Management Plan addresses the following issues:

A. Consolidation or grouping of cases or issues;
B. Discovery scope, dispute resolution and proposed discovery and case schedule;
C. Proposed protective order for claims of confidentiality and privilege;
D. Proposed mediation procedures;
E. The attorneys who will be present at the initial conference; and
F. Other issues.

A. Consolidation or grouping of cases or issues.

Plaintiffs' Position:

Seventeen of the transferred actions had been previously consolidated into two Federal Courts. Ten *M. abscessus* cases filed in South Carolina were consolidated for pre-trial purposes before Judge Bruce Hendricks in the District of South Carolina. All but one Plaintiff was deposed before the Panel transferred the cases to this Court. The parties propose that *Blevins* (Civil Action No. 1:18-cv-00235), an *M. Abscessus* infection action originally filed in North Carolina, be consolidated for pretrial purposes before Judge Hendricks. After completion of generic expert discovery, all ten South Carolina cases and *Blevins* should be remanded to Judge Hendricks for further disposition.

All seven of the remaining Iowa cases were consolidated and assigned to Chief District Judge John A. Jarvey in the Southern District of Iowa before being transferred to this Court. All Iowa Plaintiffs will use the discovery completed in *Baker v. Sorin Group Deutschland GmbH, et al.* (Civil Action No. 1:16-cv-00260). As only case specific and third-party discovery pertaining to Iowa remain outstanding, Plaintiffs desire that these actions be remanded back to Judge Jarvey following Daubert rulings in the *Baker* case. Judge Jarvey previously set the following trial dates for the Iowa cases:

Prescott (Civil Action No.1:18-cv-00244):	January 7, 2019
Crawford (Civil Action No.1:18-cv-00241):	March 11, 2019
Smith (Civil Action No.1:18-cv-00248):	July 22, 2019
Adams (Civil Action No.1:18-cv-00245):	September 9, 2019
Jenkins (Civil Action No.1:18-cv-00244):	November 12, 2019
Reed (Civil Action No.1:18-cv-00242):	January 13, 2020
Thomas (Civil Action No.1:18-cv-00247):	March 9, 2020

Hopefully, Judge Jarvey will accelerate case specific discovery, maintain the established trial order and slightly push back the original trial dates.

Before consolidation, *Brackenbury* (Civil Action No.1:18-cv-00264) was scheduled for trial on November 19, 2019. *Brackenbury* will also use the *Baker* discovery and should be remanded back to Minnesota after the Daubert motions have been decided in *Baker*. *Eisenberg* (Civil Action No.1:18-cv-00244) was scheduled for trial on July 9, 2019. Case specific discovery was taken in *Eisenberg* and this case should be remanded back to South Dakota after the Daubert motions are decided in *Baker*.

Defendants' Position:

There are now more than 50 cases from multiple jurisdictions in the MDL inventory. The JPML created this MDL in recognition of the fact that it is neither desirable nor possible to simultaneously work up and bring to trial all, or even a portion, of the case inventory. Having consolidated the multiple cases for discovery and pretrial purposes, the Transfer Order requires creation of a structure to efficiently and fairly handle this multidistrict litigation through discovery, and ultimately for trial of the cases in an orderly fashion.

Defendants' Proposed Case Management Plan offers the following organized structure and a systematic procedure for this MDL:

- Divide the case inventory into three groups, for purposes of case-specific discovery and Bellwether selection, using the types of infection alleged as the natural categories;

- Divide discovery into "litigation-wide" and "case specific" to avoid duplication and take full advantage of the MDL system;

- Address litigation-wide discovery first by –
  - Conducting litigation-wide discovery needed for both Plaintiffs and Defendants;
  - Disclosing, deposing, and conducting *Daubert* motions/hearings for litigation-wide experts;
  - Filing and deciding litigation-wide dispositive motions.

- Address case-specific discovery by –
  - Selecting representative cases form the three groups to fully work up for trial;
  - Conducting case-specific discovery for the selected cases;
  - Disclosing Plaintiff and Defendant experts for the selected cases

- Utilize a "Bellwether" process, selecting one case from each group –
  - Bellwether case expert depositions;
  - Remand Bellwether cases to transferor courts for *Daubert* and dispositive motions and trial.

Plaintiffs' competing proposed plan would effectively "undo" the MDL formation for two large swaths of cases (comprising over 30% of the current MDL inventory), resulting in a haphazard progression of case-specific discovery and serial trials that are not representative of the inventory, and a truncated period for MDL litigation-wide discovery that does not afford LivaNova any opportunity for meaningful third-party discovery on litigation-wide issues. Plaintiffs' proposed plan is short-sighted, prejudicial to LivaNova, and would do little to advance the litigation toward a global resolution.

1. Defendants' proposed case grouping for case-specific discovery and trial.

Consistent with the Transfer Order and this Court's CMO 2, LivaNova proposes a grouping of the cases based on infection type, which will produce case efficiencies and will assist the Court and parties in identifying Bellwether test cases that are representative of the overall inventory.

Plaintiffs have asserted, and Defendants do not dispute, that the current inventory of MDL cases is comprised of three categories of approximately equal size: (1) *M. chimaera* cases, (2) *M. abscessus* cases, and (3) "other infection" cases, consisting of other NTM, non-NTM, or otherwise unspecified pathogens. The infection-type at issue in any given case is important because it has substantive implications—each pathogen is a different bug with different characteristics that affect growth patterns and transmission potential, and that impact the type of proof Plaintiffs must marshal to prevail on their product liability claims. For instance, Plaintiffs allege that Defendants' manufacturing facility was a potential point-source for certain *M. chimaera* cases, but there is no analog to that argument for *M. abscessus* or "other infection" cases.

Given the current spectrum of alleged infections at issue, Defendants propose that the Court categorize and group the MDL case inventory into three representative buckets of cases:

1. Cases involving *M. chimaera* infections;

2. Cases involving *M. abscessus* infections; and

3. Cases involving "other infections," including other NTM pathogens, non-NTM pathogens, or alleged infections that have not been specified or cultured.

Once the litigation-wide discovery is complete, the Court should rely upon this infection-type case-grouping to designate representative cases for: (a) a centralized case-specific discovery pool, and (b) a centralized Bellwether trial selection process.

- As for the initial case-specific discovery pool, LivaNova proposes that the Court designate three (3) cases from each category for case-specific discovery (for a total of nine (9) cases).[1]

- As for the Bellwether selection, LivaNova proposes that the Court designate one case from each category (among the three worked up in case-specific discovery) for remand and trial. This would result in an initial selection of three (3) Bellwether cases.[2]

The division of the MDL inventory, and the orderly and deliberate conduct of case-specific discovery and Bellwether selection, in the manner proposed by LivaNova here, will ensure that representative cases are designated for trial, and that the Bellwether trial process will provide useful and productive information that can be relied upon in resolving the litigation as a whole.

2. The Court should reject Plaintiffs' early-remand approach.

In arguing for early remand, Plaintiffs simply rehash the same arguments made and rejected at the MDL formation stage. Plaintiffs argued to the JPML that there was no more discovery needed from LivaNova, and therefore there was no need to form an MDL. The JPML rejected that view, finding that "coordinating the schedules and motions practice of 21 different courts would be difficult," and centralization would "promote the just and efficient conduct of this litigation." *In re Sorin 3T Heater-Cooler Sys. Prods. Liab. Litig.*, MDL No. 2816, 2018 U.S. Dist. LEXIS 17217, at *3, 5 (J.P.M.L. Feb. 1, 2018). The Manual for Complex Litigation agrees: the MDL is the best forum to conduct the litigation-wide discovery and expert work necessary to handle these cases efficiently from a pretrial standpoint and to value them accurately to facilitate resolution. *See*

[1] MDL courts routinely manage the number and type of cases that proceed to case-specific discovery and beyond, and there is nothing in the Manual for Complex Litigation, or elsewhere, that bars MDL courts from retaining jurisdiction over matters through case-specific discovery, even if those matters are ultimately remanded for trial pursuant to *Lexecon v. Milberg Weiss*, 523 U.S. 26 (1998). In fact, many MDL courts do just that, and this Court should as well.

[2] Other MDL courts have adopted a similar categorical division of the MDL inventory for purposes of Bellwether selection. *See, e.g.*, Pretrial Order No. 19, *In re Stryker Rejuvenate and ABG II Hip Implant Prods. Liab. Litig.*, MDL No. 2441 (D. Minn. May 28, 2014).

Manual for Complex Litig. § 20.132 (noting that MDLs "afford a unique opportunity" for the global resolution of litigation).

In the context of multidistrict litigation, the importance of selecting *representative* cases for trial cannot be overstated. The results of Bellwether trials provide data to the parties related to the strengths and weaknesses of their respective cases, and the value of similarly situated plaintiffs' claims. *See* Manual for Complex Litig. (Fourth) § 22.315 ("If individual trials, sometimes referred to as Bellwether trials or test cases, are to produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases."). "The more representative the test cases, the more reliable the information about similar cases will be." *Id.* In other words, the Bellwether process and the data derived from it are key to resolving litigations on a global basis. Here, the division of the MDL case inventory in the manner proposed above would ensure that a representative sample of cases would be worked up in case-specific discovery and tried.

Plaintiffs' early-remand approach to case management and trial selection is haphazard, and ignores "representativeness" entirely as a consideration—instead focusing on cases that were first-filed and furthest along. Plaintiffs propose the immediate remand of seventeen-plus cases for what they call "case-specific discovery" (it is actually much more than that) and serial trials, without regard to whether the remanded cases are representative, or whether their trials will move the overall litigation closer to resolution. Indeed, there is good reason to believe the cases proposed by Plaintiffs for remand are *not* representative, given that all seventeen of them come from two hospitals tallying seven or more NTM infections each, and consist solely of *M. chimaera* and *M. abscessus* cases in only two different geographies. While Plaintiffs' approach may result in the early resolution of seventeen *individual cases* (chosen by Plaintiffs), it provides little if any benefit to the MDL litigation as a whole.

Indeed, Plaintiffs' early-remand approach would be unnecessarily taxing on the Parties' resources, and may even impede MDL proceedings and the Parties' progress toward resolution.[3] It simply is not tenable to remand seventeen cases simultaneously now (while MDL proceedings are ongoing), with the remainder

[3] The same is true of the *Baker* litigation. Given that *Baker* involves exclusively asymptomatic patients without infection, its trial would be neither representative of the personal injury actions that make up this MDL, nor helpful in efforts to resolve the overall litigation.

remanded all at once after litigation-wide proceedings. Massive case-specific discovery efforts would be required simultaneously in numerous cases and jurisdictions across the country, and trials would be scheduled independently by courts largely without regard to party resources, and without the centralized management needed to shepherd the litigation as a whole to resolution. To ensure the orderly conduct of MDL proceedings and promote the just and efficient resolution of the litigation as a whole, the Court should manage, as outlined above, a centralized process for case-specific discovery and Bellwether selection that ensures a representative sampling of cases in the MDL are tested.

B. Discovery scope, dispute resolution and proposed discovery and case schedule

Plaintiffs' Position:

United States Chief Magistrate Judge Susan E. Schwab was appointed to resolve recent discovery disputes in *Baker*. If available, the parties recommend Judge Schwab as the discovery dispute master for this consolidated litigation.

In *Baker v. Sorin Group Deutschland, GmbH, et al*., Defendants produced 362,556 pages of documents in 16 separate ESI productions on or about November 3, 2016, December 5, 2016, January 23, 2017, March 1, 2017 March 9, 2017, March 27, 2017, April 25, 2017, August 3, 2017, September 14, 2017, September 29, 2017, November 9, 2017, November 21, 2017, February 28, 2018, March 13, 2018, April 4, 2018 and April 17, 2018. The documents reside in an electronic database maintained by Anapol Weiss and have been made available to any plaintiffs' counsel with a filed 3T case in Federal or State Court. Plaintiffs suggest the discovery platform in *Baker* be utilized in these proceedings with modified ESI and Protective Orders as set forth later in this submission.

On March 29, 2018, the *Baker* Plaintiffs sent Defendants a letter seeking clarification on whether they had produced all documents responsive to their November 2016 Request for Production of Documents. On April 21, 2018, Defendants responded, claiming in large part that the categories of documents referenced in Plaintiffs' March 29, 2018 letter exceeded the scope of the original request. Judge Schwab should determine the timing, scope and breadth of additional responsive documents in *Baker*. Similarly, on May 1, 2018, the *Baker* Plaintiffs sent a letter to Defendants identifying material deficiencies with Defendants' 157-page privilege log, including the broad array of documents withheld on the basis of various unsubstantiated privileges. Following a May 3,

2018 discovery conference, Judge Schwab issued an order requiring Defendants to inform the *Baker* Plaintiffs within 20 days when they will respond to the privilege log objections. Currently, the *Baker* Plaintiffs are preparing their objections to Defendants' redaction log. These important issues are now, or will soon be, ripe for resolution in the MDL proceedings. Judge Schwab's rulings should equally apply to all cases transferred into this MDL.

The parties shall exchange proposals for a Plaintiff Fact Sheet and a Defense Fact Sheet before May 31, 2018. Plaintiffs shall provide Defendants with topics for 30(b)(6) depositions on or before June 29, 2018. Defendants shall, after a meet-and-confer, file objections to any proposed deposition topics no later than July 13, 2018. Rule 30(b)(6) depositions shall be completed by August 30, 2018 unless either party shows good cause for extending this deadline.

The *Baker* Plaintiffs have deposed the following management-level employees:

- Sorin Group USA's Director of Quality Assurance, Carrie Wood, on October 3, 2017;
- Sorin Group Deutschland's Director of Quality Assurance, Christian Peis, on November 28, 2017;
- LivaNova's Vice President of Quality Assurance and Regulatory Affairs, Thierry Dupoux, on November 30, 2017;
- Sorin Group Canada's Microbiology Manager, Paul Talbot, on April 17, 2018;
- Sorin Group USA's Marketing/Product Manager, Shanna Schmidt, on April 24, 2018; and
- Sorin Group USA's Senior Account Manager, Patricia Monaghan, on May 2, 2018.

Additionally, plaintiffs in related state court actions pending in the Philadelphia County Court of Common Pleas (*Piechowski v. Sorin Group Deutschland, GmbH, et al*. and/or *Gerngross v. Sorin Group Deutschland GmbH, et al*.) have deposed the following management-level employees and witnesses:

- Sorin Group USA's Senior Account Manager, Patricia Monaghan, on September 27, 2017;
- Sorin Group Deutschland's Director of Quality Assurance, Christian Peis, on October 17, 2017;

- LivaNova's Vice President of Quality Assurance and Regulatory Affairs, Thierry Dupoux, on October 19, 2017;
- Sorin Group USA's Director of Quality Assurance, Carrie Wood, on Wood, on December 12, 2017;
- Sorin Group Canada's Microbiology Manager, Paul Talbot, on December 12, 2017;
- Sorin USA's Senior Field Service Engineer, Joanne Riordan, on December 13, 2017;
- Sorin USA's Quality Engineer, Ryan Coyle, on December 15, 2017;
- Sorin Group USA's Marketing/Product Manager, Shanna Schmidt, on February 8, 2018;
- Sorin Deutschland's Industrial Quality Assurance Manager, Celeste Kreul, on March 1, 2018;
- Sorin Deutschland's Global Product Manager, Christian Hofstetter, on March 20, 2018; and
- Sorin Deutschland's Director of Quality Assurance, Katja Richter, on March 21, 2018.

Finally, plaintiffs in a number of related State Court actions pending in York County, Pennsylvania are scheduled to depose the following management-level employees:

- Sorin Deutschland's Global Product Manager, Christian Hofstetter, on June 26, 2018;
- Sorin Deutschland's Director of Quality Assurance, Katja Richter, on June 26, 2018;
- Sorin Group Deutschland's Director of Quality Assurance, Christian Peis, on June 27-28, 2018; and
- LivaNova's Vice President of Quality Assurance and Regulatory Affairs, Thierry Dupoux, on July 17-18, 2018.

Previously, the York County plaintiffs deposed Sorin Group Canada's Microbiology Manager, Paul Talbot, Sorin Group USA's Marketing/Product Manager, Shanna Schmidt, and Sorin Group USA's Senior Account Manager, Patricia Monaghan.

The MDL Plaintiffs do not intend to re-depose any of these witnesses, but may address any topics covered with these witnesses during 30(b)(6) depositions. The MDL Plaintiffs seek to depose the following individuals:

- LivaNova's former Vice President of Quality Assurance & Regulatory Affairs, Erich Frese;
- Sorin Deutschland's former Director of Research and Development, Erwin Knott;
- Sorin Deutschland's Research and Development Consultant, Jens Waldmann;
- Sorin Deutschland's Water Hygiene Consultant, Martin Exner, Ph.D.; and
- Sorin Deutschland's Water Hygiene Consultant, H.P. Werner, Ph.D.

Prior to consolidation, this Court presided over *Whipkey* (Civil Action No. 1:17-cv-01233) and scheduled *Whipkey* for trial in November 2018. *Whipkey* involves WellSpan York Hospital, the same hospital where significant third-party discovery is being completed in *Baker*, including the depositions of perfusionists, infection control personnel, biomedical engineers and an infectious disease physician. As such, generic liability discovery will be completed in *Whipkey* by the close of fact discovery in *Baker*, leaving only case specific discovery of the plaintiff's treating physicians and damages experts. Should the Court wish to select a "Bellwether" or trial case, the parties recommend *Whipkey*.

Plaintiffs disagree with Defendants' suggestions for case specific discovery and a robust bellwether process stratifying the actions based on infection type given the relatively small number of actions in this MDL. The design defect and failure to warn theories of liability are the substantially the same for all actions, irrespective of the type of infection. Plaintiffs allege that the 3T mists bacteria into the sterile surgical field destroying the laminar flow systems in operating rooms and that Defendants failed to provide adequate cleaning and disinfection protocols for the 3T or warn that the devices were a potential source of patient infection. As Defendants themselves acknowledged at the JPML hearing, "it isn't going to matter if this is an *M. Abscessus* case or an *M. Chimaera case*, because the discovery to date has focused almost exclusively on the mode of transmission." See the January 25, 2018 JPML Transcript at 4-5. Case-specific discovery, including discovery into the infection control practices of dozens of hospitals and the individual medical treatment of each Plaintiff, should thus proceed following remand to the transferor courts.

For the remaining case management deadlines, Plaintiffs suggest as follows:

1. All generic liability fact discovery shall be completed by October 15, 2018.
2. Plaintiffs' Rule 26(a)(2) expert reports for MDL-wide liability shall be served on or before October 30, 2018.
3. Defendants' Rule 26(a)(2) expert reports for MDL-wide liability shall be served on or before November 30, 2018.
4. All expert depositions shall be completed by January 30, 2019.
5. *Daubert* motions shall be filed on or before January 30, 2019.
6. Oppositions to *Daubert* motions shall be filed on or before February 28, 2019.
7. Replies in support of *Daubert* motions shall be filed on or before 14 days after the opposition was filed.
8. All other dispositive motions shall be determined by the transferor court.

Defendants' Position:

1. Anticipated scope of discovery

As specified in greater detail below, discovery in the MDL should proceed in phases: (1) litigation-wide discovery addressing witnesses and issues generally applicable to all cases, and (2) case-specific discovery conducted in a representative subset of MDL cases, once litigation-wide discovery is complete. In addition, concurrent with the conduct of discovery in these two phases, preliminary case-specific discovery should be conducted in all MDL cases through a Court-approved Plaintiff Fact Sheet ("PFS") and Defendant Fact Sheet ("DFS").

a. Summary of discovery conducted to date

The majority of MDL cases had not commenced discovery prior to transfer. A minority did commence discovery, with some degree of written discovery, document production, and deposition discovery completed. No cases have completed fact discovery or exchanged expert reports. In some MDL cases, substantial company witness discovery has been completed, including numerous depositions of LivaNova witnesses and upwards of 300,000 pages of document production. Defendants agree with Plaintiffs that LivaNova witnesses already deposed should not be re-deposed, and agree in principle that an early deadline for Plaintiffs to identify 30(b)(6) topics, and for Defendants to respond, is appropriate in order to ensure that Defendants can designate, prepare and produce its

designees, many of whom will likely be foreign witnesses, in a timely manner consistent with Defendants' proposed deadlines.

b. Scope of litigation-wide discovery to be conducted

Plaintiffs are wrong in their assertion that litigation-wide discovery is nearly complete. While LivaNova agrees that substantial company discovery has taken place (including many depositions and upwards of 300,000 pages of document production in some cases), and agrees with Plaintiffs commitment not to re-depose witnesses who have already testified,[4] the scope of litigation-wide discovery goes far beyond company discovery, and litigation-wide discovery is not just a one-way street intended to benefit Plaintiffs. Moreover, Plaintiffs themselves are inconsistent in their characterizations of company discovery status—on the one hand they contend it is nearly complete, and on the other, they seek open-ended 30(b)(6) depositions, and seek additional document discovery through new key-word searches of already-collected documents (to which Defendants object).

In addition to company discovery, targeted hospital discovery will be a critical component of the litigation-wide discovery phase. Plaintiffs contend that all alleged infections were caused by a common source and common pathway, and LivaNova is entitled to discovery to rebut these assertions. As part of the litigation-wide discovery period, LivaNova seeks to take discovery from key hospitals producing multiple plaintiffs, as well as a representative number of other hospitals to test the maintenance and cleaning practices of hospitals around the country, to evaluate their respective compliance with LivaNova's instructions for use ("IFUs"), and to learn about other issues such as water quality that could be causing or contributing to NTM infections.

LivaNova is likewise entitled to discovery on certain centralized testing facilities that have conducted genetic testing of patient infection. This discovery is

[4] While Plaintiffs purport to commit that they will not re-depose witnesses *in their individual capacities* who have already testified, they notably reserve the right to "address any topics covered with these witnesses during 30(b)(6) depositions," leaving the company discovery door virtually wide open. Plaintiffs additionally identify certain individual company witnesses and consultants they intend to depose. Accordingly, Defendants view with skepticism Plaintiffs' assertion that all company discovery is complete, and the Court should too. To the extent additional depositions are taken, at least some of them will be foreign witnesses, which take substantial time to arrange even for witnesses willing to be deposed.

necessary to test Plaintiffs' assertion that every 3T was packaged and sold already-contaminated with the infection-causing *M. chimaera* pathogens (an untenable assertion given the variation in infection types alleged). At minimum, the Court should permit litigation-wide discovery on the following groups of institutions:

- Centralized testing facilities including National Jewish Health and the University of Texas Health System;

- Hospitals with the highest number of associated cases (MDL and state combined), including the University of Iowa Hospitals and Clinics (5 cases), WellSpan York (16 cases), Penn Presbyterian Medical Center (6 cases), and Greenville Hospital (10 cases); and

- A representative sampling of other hospitals treating MDL Plaintiffs, including hospitals in different geographies and associated with infections from each of the three proposed Bellwether categories.

In addition, LivaNova may also require discovery of water utilities, to explore the degree and nature of contamination of different hospitals' water supplies, and of certain study authors involved in the publications Plaintiffs purport to rely upon in support of some of their common theories. LivaNova is evaluating but needs more time to determine whether this discovery will ultimately be necessary. Regardless, it should not be foreclosed at the outset of the MDL by an unreasonably short discovery period.

Plaintiffs suggest that the proposed hospital discovery is case-specific only, but it is actually much more than that.[5] Over 40% of the MDL and state court cases combined (37 out of 92) are related to clusters of infections from only four (5) different hospitals, while the vast majority of remaining hospitals are associated with only one or two cases. If every 3T was contaminated by *M. chimaera* at production as Plaintiffs allege, and if every 3T disseminates NTM in the operating room every time it is turned on, then why are there so few "outbreak" hospitals,

[5] Just because hospital discovery may have case-specific implications for some cases does not mean that it lacks litigation-wide value. Here, the MDL Plaintiffs represent a significant percentage of global NTM infection complaints, and there may be important learnings from the cumulative collection of data on their infections, and their treating-hospitals' varying practices. This collection of data may reveal potential alternative causes of NTM infections, and provide relevant data as to the effectiveness of Defendants' IFUs.

and so many with only one infection? And why the variation in pathogen type between geographies? These questions touch on litigation-wide issues of risk quantification, IFU effectiveness, and alternative causation that are critical to LivaNova's defenses, and LivaNova should be afforded sufficient discovery time to explore these questions and their answers.

Finally, the *Baker* case cannot serve as a proxy for MDL proceedings, as Plaintiffs suggest. For one, the *Baker* case is not a part of this MDL, and for good reason: it is a medical monitoring case filed exclusively by asymptomatic plaintiffs. The *Baker* plaintiffs cannot inform the Plaintiffs' contention here that there is a unique outbreak strain of *M. chimaera*—they are by definition asymptomatic and therefore will not have any testing to support this theory. Nor do the *Baker* plaintiffs have other NTM infections of the sort alleged by the MDL plaintiffs.[6] Moreover, in contrast to the MDL, the *Baker* case involves only two hospitals—providing far too limited a sampling to address the role of the hospitals, in terms of compliance with IFUs, effectiveness of IFUs, and alternative sources of NTM. For similar reasons, the discovery adduced in the state court cases also will not produce sufficient sampling of discovery or expert work to address the litigation-wide liability issues presented in the MDL.

c. Scope of case-specific discovery to be conducted

Only a minority of cases had commenced discovery prior to MDL formation. Accordingly, to the extent cases are selected to proceed to the case-specific discovery pool or trial, most of the cases presently in the MDL would require case-specific discovery.

The plaintiffs in the MDL cases, by and large, are sick patients with long and complicated medical histories. In each case, discovery will be required into the plaintiff's underlying cardiovascular condition, the reasons for the underlying surgery, the conduct of and recovery from the surgery and the alleged infection, alternative causal factors and co-morbidities for the infection, and related damages—implicating a wide range of medical specialties including cardiology, cardiothoracic surgery, primary care/family practice, infectious disease, and

[6] Because of these significant differences, *Baker* also cannot be considered an appropriate Bellwether for the MDL cases. *See* Manual for Complex Litig. (Fourth) § 22.315 ("If individual trials, sometimes referred to as Bellwether trials or test cases, are to produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases.").

neurology, among many others. Medical records for single plaintiffs have exceeded 50,000 pages in some cases. Time will be required to collect and digest these records, identify the relevant providers for deposition, and then schedule and conduct the depositions themselves.

Case-specific hospital discovery will also be required into the specific anesthetic and perfusion practices employed at the operating institution, separate and apart from the broader sampling of nationwide hospital discovery conducted at the litigation-wide discovery stage, discussed above. This will include the historic cleaning and maintenance practices with respect to the 3T at issue, and, if the hospital performed an investigation into the alleged infection or infections, the details of that investigation.[7]

As noted above, the high anticipated volume of case-specific discovery makes it infeasible to work up every MDL case simultaneously. These practical realities should inform the Court's discovery structure, schedule, and Bellwether process.

Thus, as discussed in greater detail above, once litigation-wide discovery is complete, case-specific discovery should proceed only on a subset of the MDL inventory (LivaNova proposes three cases from each infection-type category for a total of nine cases). The remaining cases can proceed immediately with Plaintiff Fact Sheet discovery (discussed below), but otherwise remain on hold pending the identification of a Wave II class, should one become necessary.

2. Defendants' proposed discovery plan and case schedule

To fully utilize the benefits of the MDL process and effectively handle the numerous cases, the proposed Discovery Plan and Schedule addresses:

- Litigation-wide fact discovery (*e.g.*, company discovery and discovery of certain key third parties).
- Litigation-wide expert discovery (*e.g.*, experts on general causation and product defect).
- Litigation-wide dispositive motion practice (*e.g.*, motions to exclude litigation-wide expert opinions).

[7] To avoid inconsistent rulings on the permissible scope of hospital discovery at the case-specific level, it is doubly important for the MDL Court to manage this aspect of discovery.

- Case-specific discovery pool selection.
- Bellwether case trial selection.

Defendants propose the following schedule for this framework, along with additional deadlines for effective case management (an additional column has been added containing Plaintiffs' proposed litigation-wide discovery deadlines for the Court's convenience):

Event Description	Defendants' Proposal	Plaintiffs' Proposal
Administrate Deadlines		
In-Person Status Conferences	Monthly	Monthly
Parties Exchange Proposed PFS/DFS	June 15, 2018	May 31, 2018
Science Day	October, 2018[8]	
Parties and Pleadings		
Joinder of Parties	August 1, 2018	August 1, 2018
Amendment of Pleadings	December 3, 2018	December 3, 2018
Litigation-Wide Discovery		
Litigation-Wide Discovery Commences	June 1, 2018	June 1, 2018
Plaintiffs to Identify Topics for 30(b)(6) Depositions	July 1, 2018	June 29, 2018
Defendants to Respond to Plaintiffs' Proposed Topics	August 1, 2018	July 13, 2018
Litigation-Wide Fact Discovery Deadline	May 1, 2019	October 15, 2018
Plaintiffs' Expert Reports	May 1, 2019	October 30, 2018
Defendants' Expert Reports	July 1, 2019	November 30, 2018
Expert Depositions Completed	August 15, 2019	January 30, 2019
Litigation-Wide Daubert/Dispositive Motions Filed	September 15, 2019	January 30, 2019
Case-Specific Discovery		
Parties to Submit Proposals for Selection of Cases for Case-Specific Discovery Pool	December 1, 2018	n/a
Court Defines Process for Selection of Cases for Case-Specific Discovery Pool	January 1, 2019	n/a
Wave I Cases for Case-Specific Discovery Selected	February 1, 2019	n/a

[8] On an available date to be subsequently determined by the Court and parties.

Case-Specific Discovery Commences	March 1, 2019	n/a
Case-Specific Fact Discovery Deadline	November 1, 2019	n/a
Plaintiffs' Expert Reports	November 1, 2019	n/a
Defendants' Expert Reports	December 15, 2019	n/a
Bellwether Procedure		
Parties to Submit Proposals for Selection of Bellwether Cases	October 15, 2019	n/a
Court Defines Process for Selection of Bellwether Cases	November 15, 2019	n/a
Three Bellwether Cases Selected (Wave I Cases, 1 Case Per Category)	December 15, 2019	n/a
Case-Specific Expert Depositions Complete (3 Selected Bellwethers Only)	February 1, 2020	n/a
Bellwether Cases Remanded for Case-Specific Daubert/Dispositive Motions and Trial	February 8, 2020	n/a

3. Discovery tools

Initial Disclosures

Defendants propose that Rule 26(a)(1) initial disclosures should not be required in this MDL. Substantial company discovery was completed in some cases prior to MDL formation, and Plaintiffs are in possession of that discovery. In lieu of case-specific initial disclosures, Defendants suggest the use of Plaintiff and Defendant Fact Sheets.

Written Discovery

In lieu of traditional written discovery tools (interrogatories, requests for production, requests for admission), Defendants propose that written discovery should proceed pursuant to a Court-ordered protocol governing the completion of Plaintiff Fact Sheets and Defendant Fact Sheets. The Parties will exchange proposed Fact Sheets by June 15, 2018. Defendants believe that the Plaintiff Fact Sheet should require proof or certification of infection, including all underlying evidence. Once the Fact Sheets are finalized and approved by the Court, Defendants propose that Fact Sheet discovery proceed according to the following procedure:

- For cases in the MDL at the time of the Court order approving the form of Fact Sheets, all MDL Plaintiffs complete and serve Plaintiff Fact Sheets within 60 days of the Court order approving the form. Defendants complete and serve Defendant Fact Sheets within 60 days of receipt of a corresponding PFS.

- For cases transferred to the MDL after the date of the Court order approving the form of Fact Sheets, Plaintiffs shall complete and serve Plaintiff Fact Sheets within 30 days of the date of case transfer (if transferred to MDL) or filing (if filed directly in the MDL). Defendants complete and serve Defendant Fact Sheets within 30 days of receipt of a corresponding PFS.

- Within five (5) weeks of receipt of a completed PFS or DFS, the receiving party shall notify the serving party's counsel in writing of any observed deficiencies in the PFS or DFS received.

- Within three (3) weeks of receipt of a deficiency letter, counsel for the party originally completing and serving the PFS or DFS shall respond to the deficiency letter by either (1) curing the alleged deficiencies; (2) disputing the alleged deficiencies and setting forth reasons the PFS is not deficient; or (3) explaining why the alleged deficiencies cannot be timely cured.

- If the dispute cannot be resolved through the meet and confer process, the party claiming continued deficiencies may initiate discovery motion practice with Chief United States Magistrate Judge Susan E. Schwab. If Magistrate Judge Schwab determines that a PFS or DFS is "deficient" in any respect, the party originally completing and serving the PFS or DFS will have two (2) weeks from the date of such finding to correct the identified deficiencies.

- Defendants may make a motion for dismissal related to PFS deficiencies in the following scenarios: (1) a Plaintiff fails to produce a completed PFS by the designated deadline, after Defendants provide two weeks' notice of their intention to make a motion for dismissal; or (2) a Plaintiff fails to correct a PFS deficiency finding made by Magistrate Judge Schwab, within two weeks of such finding. Defendants shall file a motion for dismissal 14 days in advance of a scheduled Court

conference; Plaintiff shall respond 7 days in advance; and the matter shall be heard at the Court conference.

- Defendants may also make an early motion for summary judgment based upon discovery obtained through the PFS, to the extent such discovery demonstrates any of the following: (1) a 3T was not used during a Plaintiff's surgery; (2) a Plaintiff fails to provide proof of an infection; (3) undisputed evidence of an untimely claim; or (4) other undisputed evidence showing a Plaintiff cannot prove a required element of any claim.

4. Procedures for Resolving Discovery Disputes.

The Parties agree that, if available, Chief United States Magistrate Judge Susan E. Schwab should be designated pursuant to 28 U.S.C. §636, to handle any discovery disputes. The parties should utilize the meet and confer requirements set forth in Local Rule 26.3, and discovery disputes should be handled consistent with this Court's procedure of first submitting letter to the Court via the ECF system, followed by a telephone conference. Motions raising discovery disputes should only be allowed as authorized by the Court following completion of the other dispute resolution procedures.

C. Procedures or Protective Orders for the Handling of Claims of Confidentiality and Privilege.

Plaintiffs' Position

As set forth above, the parties recommend that Judge Schwab address any disputes concerning claims of confidentiality or privilege. On December 1, 2016, this Court approved the entry of a protective order in *Baker, et al. v. Sorin Group Deutschland GmbH, et al*., Civil Action No. 1:16-cv-00260, later amended by agreement of the parties on August 15, 2017. On January 5, 2017, Defendants entered into an ESI agreement in *Baker*. Plaintiffs have submitted modified protective and ESI orders to defense counsel addressing issues that arose in *Baker* and in State Court actions. To the extent the parties do not fully agree on either the protective order or the ESI order, Plaintiffs propose Judge Schwab resolve any difference, including the overuse of the "confidential" designation for documents which renders the filing of briefs and motions cumbersome.

Defendants' Position

To date, the Parties have litigated the MDL and state court cases pursuant to an ESI Protocol, and a Protective Order governing the production of confidential documents, which this Court previously reviewed and approved in the context of the *Baker* case. Defendants propose that both apply in this MDL as well.

Plaintiffs, however, wish to modify both the Protective Order and ESI Protocol, and even propose a process to identify, test and evaluate search terms from scratch (essentially requiring entirely new productions by Defendants at great cost). Defendants stand by their productions in *Baker* and in the state courts cases, in response to differing and inconsistent requests from many different plaintiffs. Defendants are willing to stand by them in this MDL as well. If allowed, Plaintiffs' proposed modifications appear to Defendants to likely lead to significant additional efforts to retrace earlier steps and make new productions in the MDL—a process Plaintiffs' proposed discovery schedule does not currently contemplate.

D. Proposed Mediation Procedures

The parties agree that this topic is premature at this stage of the MDL proceedings.

E. A List of Attorneys Attending the Initial Case Management Conference.

As of the time of this filing, the parties understand that the following counsel will attend the May 31, 2018 conference:

For Plaintiffs: Sol H. Weiss, Paola Pearson, Michael K. Johnson, Roopal P. Luhana, Matt Schultz, Wesley Bowden, Karen A. Lorenzen, Steven W. Sanford, J. Stephen Welch, Jay Ward, Ashlee E. Winkler, David L. Rosenband, Justin Hakala, Kelsey W. Shannon and Nicole T. Matteo.

For Defendants: Linda Svitak, Del Ehrich, Jared Briant, Mark Gebauer, and Magda Patitsas.

F. Other Issues

1. Unresolved issues as to service of process, personal jurisdiction, subject matter jurisdiction, or venue:

Plaintiffs' Position:

The Court should make an MDL-wide determination as to whether personal jurisdiction exists over LivaNova PLC, taking into account all evidence that postdates the Court's September 29, 2016 decision in *Baker*.

Defendants' Position:

LivaNova PLC is named as a Defendant in several MDL cases, though it has not been served with process. This Court previously granted LivaNova PLC's motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(2), *see Baker v. LivaNova PLC*, 210 F. Supp. 3d 642, 651 (M.D. Pa. 2016), and courts in 9 other cases have followed suit, including after full jurisdictional discovery in *Prescott v. LivaNova PLC*, 2017 WL 2591270 (S.D. Iowa). One court has denied LivaNova PLC's Rule 12(b)(2) motion to dismiss, permitting jurisdictional discovery to proceed. *See Kuhnmuench v. LivaNova PLC*, No. 2:17-cv-11719, ECF No. 38 (E.D. Mich. Nov. 15, 2017). Defendants contend that LivaNova PLC should be dismissed from the remaining actions consistent with this Court's prior reasoning. Defendants anticipate motion practice on this issue to the extent service is made on LivaNova PLC.

Counsel for some plaintiffs in the MDL have asked LivaNova Deutschland GmbH to waive formal service through the Hague Convention, or to permit Defendants' counsel to accept service on its behalf. In several MDL cases thus far, LivaNova Deutschland has agreed to waive formal service requirements in exchange for the plaintiffs' dismissal of LivaNova PLC *with prejudice*.

Dated: May 16, 2018

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