

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

IN RE: COOK MEDICAL, INC., IVC
FILTERS MARKETING, SALES PRACTICES
AND PRODUCT LIABILITY LITIGATION

Case No. 1:14-ml-2570-RLY-TAB
MDL No. 2570

This Document Relates to All Actions

CASE MANAGEMENT ORDER # 12
(FOURTH AMENDED CASE MANAGEMENT PLAN)

I. Parties and Representatives

A. Plaintiffs and Plaintiffs' Leadership Structure:

As of September 11, 2015, there are 121 cases in MDL 2570.

Plaintiffs' Leadership Structure, as previously approved by the Court, is as follows:

Plaintiffs' Co-Lead Counsel	
Ben C. Martin	Law Offices of Ben C. Martin
David P. Matthews	Matthews & Associates
Michael W. Heavside	Heavside Reed Zaic

Plaintiffs' Liaison Counsel & State/Federal Liaison Counsel	
Joseph N. Williams	Riley Williams & Piatt

Plaintiffs' Executive Committee (PEC)	
Troy Brenes	Lopez McHugh, LLP

Ramon Lopez	Lopez McHugh, LLP
John Dalimonte	Karon and Dalimonte
Joseph R. Johnson	Babbitt, Johnson, Osborne & LaClainche
Teresa Toriseva	Toriseva Law
Julia Reed Zaic	Heaviside Reed Zaic
Thomas Wm. Arbon	Law Offices of Ben C. Martin
Tim K. Goss	Freese & Goss, PLLC
Matthew R. McCarley	Fears Nachawati, PLLC

Plaintiffs' Steering Committee (PSC)

Turner W. Branch	Branch Law Firm
Russell W. Budd	Baron & Budd, P.C.
William B. Curtis	Curtis Law Group
Brian Keith Jackson	Riley & Jackson, P.C.
Christopher T. Kirchmer	Provost Umphrey Law Firm, L.L.P.
John "Scotty" MacLean	MacLean Law Firm, P.C.
Howard L. Nations	The Nations Law Firm
Gregory D. Rueb	Rueb & Motta, PLC
Laura E. Smith	Heaviside Reed Zaic
Paul L. Stoller	Gallagher & Kennedy, P.A.

B. Defendants and Defendants' Counsel:

Cook Incorporated
Cook Medical LLC (*formerly known as* Cook Medical Incorporated)
William Cook Europe ApS

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Counsel shall promptly file a notice with the Clerk if there is any change in this information.

II. Jurisdiction and Statement of Claims

On October 15, 2014, the United States Judicial Panel on Multidistrict Litigation transferred 13 civil actions the United States District Court for the Southern District of Indiana for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. §1407. Since that time the Panel has filed three Conditional Transfer Orders. The Parties do not dispute that this court has Jurisdiction over these matters pursuant to 28 U.S.C. §1407.

A. Plaintiffs' claims arise from bodily injury and death caused by defective inferior vena cava filters, which are medical devices placed in the inferior vena cava of the human body and which are intended to prevent pulmonary emboli. The filters are unreasonably dangerous and tend to tilt, perforate, migrate and fracture after being placed in the human body. Plaintiffs' claims are generally brought in terms of negligence, strict liability, implied warranty, and failure to warn and may also include claims of fraud and misrepresentation.

B. William Cook Europe ApS ("WCE"), which is located only in Bjaeverskov, Denmark, manufactures the Günther Tulip™ Inferior Vena Cava Filter ("Günther Tulip") and the Celect® Inferior Vena Cava Filter ("Celect"). Cook Incorporated ("CI") assisted

WCE in the design and development of the devices. Cook Medical LLC (“CML”) is involved in the marketing and selling of the devices.

The Günther Tulip and Celect are intended to prevent recurrent pulmonary embolism or PE in certain situations spelled out in the Instructions For Use for each prescription medical device. Pulmonary embolism is a dangerous condition in which the vessels of the lungs become blocked by large blood clots. An estimated 600,000 people suffer from PE every year, and about one-third of them, can die if they are not treated. Many of these individuals who suffer from recurrent PE, which occurs in a variety of circumstances, benefit from products like Cook’s vena cava filters.

The Günther Tulip vena cava filter was first released for sale in Europe in 1992 and in the U.S. in 2000. The Celect filter was first released for sale in Europe in 2006 and in the U.S. in 2007. Both filters have long worldwide track records of safety and efficacy. While Plaintiffs contend that the filters are defective because they tilt, perforate, migrate and fracture, the incidence of such failures is well below one percent (1%) for both devices. For example, from October 1, 2008, through October 24, 2014, 202,296 Celects were sold worldwide, and the incidence of fractures was 0.0425%, the incidence of perforation was 0.07917%, and the incidence of migration was 0.0069%. In that same time period, Cook sold 180,095 Günther Tulips, and the incidence of fractures was 0.0056%, the incidence of perforation was 0.0583% and the incidence of migration was 0.0050%.

The Günther Tulip and Celect were not negligently designed or manufactured. For example, all of Cook’s design, testing and development, manufacturing, marketing and post-market surveillance of the Günther Tulip and Celect complied with ISO 13485:2003; the Medical Device Amendments to the Federal Food Drug & Cosmetic Act and regulations enacted by the Food and Drug Administration pursuant to those statutes; Council Directive 93/32/EEC of the European Communities, The Medical Device Directive and regulations of the Medicine and Healthcare Products Regulatory Agency in the United Kingdom; BEK no. 1263 of 15.12.2008, Ministry of Health and Prevention, Denmark; The Canadian Medical Device Regulations SOR/98-282 May 1998; The Australian Therapeutic Goods (Medical Devices) Regulations 2002, and the Australian Regulations Guidelines for Medical Devices (ARGMD); Applicable articles of the Japanese Pharmaceutical Affairs Law (MHLW Ministerial Ordinance no. 169, 2004); MEDDEV 2.7.1 – Guidelines on Medical Devices – Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies – December 2009; Global Harmonization Task Force “Clinical Evaluation” SG5/N2R8:2007; Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice ISO 14155:2011; and NB-MED/2.12/REC1 plus, as appropriate, MEDDEV 2.12.2/REV6.

As to Plaintiffs’ failure to warn claims, they cannot prevail because of the learned intermediary doctrine. *See, e.g., Felix v. Hoffman-LaRoche, Inc.*, 540 So.2d 102, 104 (Fla. 1989); *Phelps v. Sherwood Medical Industries, Inc.*, 836 F.2d 296, 300 (7th Cir. 1987); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548-549, 180 Ind. App. 3 (1979), *reh’g denied*, and cases there cited.

III. Pretrial Pleadings and Disclosures

The following deadlines are established to create a Discovery Pool from which the Court will select three cases to serve as Bellwether trials beginning no earlier than February 2017, as recommended by Magistrate Judge Baker in Case Management Order #5.

- A. The parties shall each serve a master set of Fed. R. Civ. P. 26 initial disclosures on or before January 19, 2015.
- B. Only cases filed on or before February 16, 2015, may be considered for inclusion in the Discovery Pool.
- C. Each plaintiff must serve a substantively complete Plaintiff Profile Form (PPF), including medical authorizations, and a Plaintiff Fact Sheet (PFS) on or before April 15, 2015. Each defendant must serve a substantively complete Defendant Fact Sheet (DFS) as to each individual plaintiff on or before May 15, 2015, disclosing each associated complaint file(s), name(s) of sales representatives, and all available information identifying the specific device. In cases filed or transferred into the MDL after the date of entry of the Party Profile Forms & Fact Sheet Protocol, each plaintiff shall submit a substantially complete PPF and PFS to defendants within forty-five (45) days of filing their complaint, and defendants shall submit a substantially complete DFS within ninety (90) days of the filing of the complaint.
- D. The parties shall serve Master Discovery (Request for Production of Documents and Interrogatories), if any, on or before April 15, 2015.
- E. The parties have filed a list of a total of ten (10) cases, five (5) for each side, to be included in the Discovery Pool.
- F. **Case Specific Discovery for Discovery Pool Cases:** Case-Specific Discovery for Discovery Pool cases shall commence immediately after the completion of the following: 1) ESI production is served by the defendant(s) for the initial twenty (20) custodians requested by plaintiffs; 2) ESI production is served by the 10 Discovery Pool plaintiffs; and 3) substantively complete Plaintiff/Defendant Profile Forms and Fact Sheets are served in each Discovery Pool Case. The Defendant Fact Sheets shall disclose each associated complaint file(s) and names of sales representatives.
- G. Case-Specific Depositions shall be limited to (1) Plaintiff(s); (2) one additional fact witness which may include an additional physician; (3) implanting physician; (4) any retrieval physicians; (5) sales representatives directly associated with the sale of the product to the implanting physician. The parties will communicate regarding the appropriate sequencing of Case-Specific Depositions for each Discovery Pool Case. The parties agree that the sales representative depositions will generally occur prior to implanting/retrieval physician depositions. If the parties disagree regarding

the proper sequencing of depositions in a specific Discovery Pool case, they will meet and confer prior to contacting the Court for assistance in resolving the issue. Additional Case-Specific depositions may be taken by agreement or by leave of Court upon good cause shown. Any written Case-Specific Discovery shall not be duplicative of Master Discovery.

- I. All motions for leave to amend the pleadings and/or to join additional parties in Discovery Pool cases shall be filed on or before March 30, 2016.
- J. Plaintiff(s) shall serve Defendant(s) (but not file with the Court) a statement of special damages, if any, and make a settlement demand in all Discovery Pool cases, on or before November 2, 2015. Defendant(s) shall serve on the Plaintiff(s) (but not file with the Court) a response thereto within 60 days after receipt of the demand.
- K. The Parties shall serve upon each other any and all final, non-duplicative written discovery in Discovery Pools cases no later than January 13, 2016. All discovery responses including written discovery responses shall be served no later than February 15, 2016. All depositions shall be completed by April 1, 2016.
- L. The Parties shall make presentations to the Court in mid-April 2016, on a date to be established by the Court, as to which Discovery Pool cases they propose be Bellwether cases for trial. The plaintiffs shall select a total of two (2) cases to be Bellwether cases and the defendant(s) shall select a total of two (2) cases to be Bellwether cases. The parties will make proposals as to how the Bellwether selections will be handled prior to the presentations. The Court shall inform the parties as to which cases and the order of the trials will be tried within twenty-one (21) days of the presentations.
- M. Plaintiff(s) shall disclose the name, address, and vita of any expert witness, and shall serve the report required by Fed. R. Civ. P. 26(a)(2) in the Bellwether trial cases on or before May 4, 2016. Defendant(s) shall disclose the name, address, and vita of any expert witness, and shall serve the report required by Fed. R. Civ. P. 26(a)(2) on or before June 6, 2016. The plaintiff(s) shall serve any rebuttal expert disclosures including supplemental reports required by Fed. R. Civ. P. 26(a)(2) on or before July 6, 2016.
- N. Independent Medical Examinations, if any, shall not occur until after the selection of the discovery pool cases. The parties shall meet and confer regarding a protocol for IMEs and propose the same to the Court no later than October 5, 2015.
- O. If a party intends to use expert testimony in connection with a motion for summary judgment to be filed by that party, such expert disclosures must be served on opposing counsel no later than 90 days prior to the dispositive motion deadline. If such expert disclosures are served the parties shall

confer within 7 days to stipulate to a date for responsive disclosures (if any) and completion of expert discovery necessary for efficient resolution of the anticipated motion for summary judgment. The parties shall make good faith efforts to avoid requesting enlargements of the dispositive motions deadline and related briefing deadlines. Any proposed modifications of the CMP deadlines or briefing schedule must be approved by the court.

- P. Any party who wishes to limit or preclude expert testimony at trial shall file any such objections no later than sixty days before each Bellwether trial. Any party who wishes to preclude expert witness testimony at the summary judgment stage shall file any such objections with their responsive brief within the briefing schedule established by Local Rule 56-1.
- Q. All parties shall file and serve their final witness and exhibit lists for each of the Bellwether trials on or before August 15, 2016. The lists should reflect the specific potential witnesses the party may call at each bellwether trial. It is not sufficient for a party to simply incorporate by reference “any witness listed in discovery” or such general statements. The list of final witnesses shall include a brief synopsis of the expected testimony.
- R. Any party who believes that bifurcation of discovery and/or trial is appropriate with respect to any issue or claim shall notify the Court as soon as practicable.
- S. Discovery of electronically stored information (“ESI”).

The parties anticipate a substantial volume of ESI will be produced in these matters. The majority of the relevant ESI will come from the Defendant manufacturer, William Cook Europe ApS, which is located in Bjaeverskov, Denmark. The parties have agreed upon an ESI and Document Production Protocol, which was entered by the Court as Case Management Order No. 11. The Court has also entered an order dated September 14, 2015 [Docket No. 649] addressing Denmark ESI.

IV. Discovery¹ and Dispositive Motions

Due to the time and expense involved in conducting expert witness depositions and other discovery, as well as preparing and resolving dispositive motions, the Court requires counsel to use the CMP as an opportunity to seriously explore whether this case is appropriate for such motions (including specifically motions for summary judgment), whether expert witnesses will be needed, and how long discovery should continue. To this end, counsel must select the track set forth below that they believe best suits this case. If the parties are unable to

¹ The term “completed,” as used in Section IV.B, means that counsel must serve their discovery requests in sufficient time to receive responses before this deadline. Counsel may not serve discovery requests within the 30-day period before this deadline unless they seek leave of Court to serve a belated request and show good cause for the same. In such event, the proposed belated discovery request shall be filed with the motion, and the opposing party will receive it with service of the motion but need not respond to the same until such time as the Court grants the motion.

agree on a track, the parties must: (1) state this fact in the CMP where indicated below; (2) indicate which track each counsel believes is most appropriate; and (3) provide a brief statement supporting the reasons for the track each counsel believes is most appropriate. If the parties are unable to agree on a track, the Court will pick the track it finds most appropriate, based upon the contents of the CMP or, if necessary, after receiving additional input at an initial pretrial conference.

- A. Does any party believe that this case may be appropriate for summary judgment or other dispositive motion?

Counsel for the parties have discussed the possibility of summary judgment in great detail. Unfortunately, until the Discovery Pool is established it will be too early to determine whether a motion for summary judgment is a possibility in a particular case.

- B. Select the track that best suits this case:

X Track 4: Dispositive motions in Bellwether trial cases shall be filed by July 1, 2016. Non-expert discovery in Discovery Pool cases shall be completed by June 1, 2016; expert witness discovery in Bellwether trial cases shall be completed by August 15, 2016. The MDL consists of complex products liability cases that will require a great deal of discovery. Counsel for both parties believes that the complexity of these cases and the size of the MDL is such that a departure from track 1-3 is appropriate.

Absent leave of court, and for good cause shown, all issues raised on summary judgment under Fed. R. Civ. P. 56 must be raised by a party in a single motion.

VI. Trial Date

The parties request that the first Bellwether trial be scheduled no earlier than February 2017, as recommended by Magistrate Judge Baker in Case Management Order #5. The trials are to be by jury and each trial is anticipated to take 15-20 days.

- A. **Case.** At this time, all parties do not consent to refer this matter to the currently assigned Magistrate Judge pursuant to 28 U.S.C. 636(b) and Federal Rules of Civil Procedure 73 for all further proceedings including trial. [This section should be marked in the affirmative only if all parties consent. Do not indicate if some parties consent and some do not. Indicating the parties' consent in this paragraph may result in this matter being referred to the currently assigned Magistrate Judge for all further proceedings, including trial. It is not necessary to file a separate consent. Should this case be reassigned to another Magistrate Judge, any attorney or party of record may object within 30 days of such reassignment. If no objection is filed, the consent will remain in effect.]

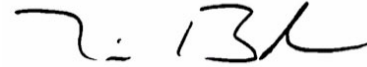
- B. **Motions.** The parties may also consent to having the assigned Magistrate Judge rule on motions ordinarily handled by the District Judge, such as motions to dismiss, for summary judgment, or for remand. If all parties consent, they should file a joint stipulation to that effect. Partial consents are subject to the approval of the presiding district judge.
- C. **Waiver of Lexecon is confirmed by Plaintiffs for the Discovery Pool cases only. Nothing in this Case Management Order or otherwise shall indicate a waiver of Lexecon as to the remaining cases.**

VIII. Required Pre-Trial Preparation

- A. **TWO WEEKS BEFORE ANY BELLWETHER FINAL PRETRIAL CONFERENCE, the parties shall:**
 - 1. File a list of trial witnesses, by name, who are actually expected to be called to testify at trial. This list may not include any witnesses not on a party's final witness list filed pursuant to section III.Q.
 - 2. Number in sequential order all exhibits, including graphs, charts and the like, that will be used during the trial. Provide the Court with a list of these exhibits, including a description of each exhibit and the identifying designation. Make the original exhibits available for inspection by opposing counsel. Stipulations as to the authenticity and admissibility of exhibits are encouraged to the greatest extent possible.
 - 3. Submit all stipulations of facts in writing to the Court. Stipulations are always encouraged so that at trial, counsel can concentrate on relevant contested facts.
 - 4. A party who intends to offer any depositions into evidence during the party's case in chief shall prepare and file with the Court and copy to all opposing parties either:
 - a. brief written summaries of the relevant facts in the depositions that will be offered. (Because such a summary will be used in lieu of the actual deposition testimony to eliminate time reading depositions in a question and answer format, this is strongly encouraged.); or
 - b. if a summary is inappropriate, a document which lists the portions of the deposition(s), including the specific page and line numbers, that will be read, or, in the event of a video-taped deposition, the portions of the deposition that will be played, designated specifically by counter-numbers.

5. Provide all other parties and the Court with any trial briefs and motions in limine, along with all proposed jury instructions, voir dire questions, and areas of inquiry for voir dire (or, if the trial is to the Court, with proposed findings of fact and conclusions of law).
6. Notify the Court and opposing counsel of the anticipated use of any evidence presentation equipment.

SO ORDERED: 12/3/2015



Tim A. Baker
United States Magistrate Judge
Southern District of Indiana

AGREED TO BY:

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