

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

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This Document Relates to All Actions  
\_\_\_\_\_

**CASE MANAGEMENT PLAN**

**I. Parties and Representatives**

A. Plaintiffs and Plaintiffs' Leadership Structure;

As of November 12, 2014, there are 33 cases in MDL 2570.

The undersigned plaintiffs' counsel (hereinafter "Plaintiffs' Counsel"), hereby submit this Joint Case Management Plan. Plaintiffs' Counsel have met and conferred with those attorneys that have expressed an interest in a leadership role in this matter. Having conferred and come to a majority agreement with the before-mentioned attorneys, Plaintiffs' Counsel present a preliminary Leadership Structure for the litigation. However, there are several law firms who have yet to provide input into this selection. Plaintiffs request an additional two weeks so that all attorneys representing plaintiffs in this matter may have the opportunity to consider and comment on the proposed leadership structure.

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Ben C. Martin	Law Offices of Ben C. Martin

<b>Plaintiffs' Liaison Counsel</b>	
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Ramon Lopez	Lopez McHugh, LLP
Joseph R. Johnson	Babbitt, Johnson, Osborne & LaClainche
Teresa Toriseva	Toriseva Law

<b>Plaintiffs' Steering Committee (PSC)</b>	
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David P. Matthews	Matthews and Associates
Julia Reed Zaic	Heaviside Reed Zaic

<b>State/Federal Liaison Counsel</b>	
Fredrick R. Hovde	Hovde, Dassow + Deets, LLC

B. Defendants and Defendants' Counsel:

Cook Group Incorporated  
Cook Incorporated  
Cook Medical Incorporated (converted to Cook Medical LLC on January 1, 2014)  
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 to 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 assisted WCE in the design and development of the devices. Cook Medical Incorporated is involved in the marketing and selling of the devices. Cook Group Incorporated is simply a holding

company and conducts no operations or manufacturing and should be dismissed from these cases.

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 (7<sup>th</sup> 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 in August 2016.

- 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, on or before March 1, 2015, for their case to be considered for the Discovery Pool. Each defendant must serve a substantively complete Defendant Profile Form (DPF) as to each individual plaintiff on or before April 1, 2015, disclosing each associated complaint file(s), name(s) of sales representatives, and all available information identifying the specific device. PPFs and DPFs are due within sixty (60) days for Plaintiff and ninety (90) days for Defendant for any cases filed after February 16, 2015.
- D. The parties shall serve Master Discovery (Request for Production of Documents and Interrogatories), if any, on or before January 30, 2015.
- E. The parties shall file a list of a total of ten (10) cases, five (5) for each side, to be included in the Discovery Pool by May 1, 2015.
- F. Case-Specific Discovery for Discovery Pool cases, except for the depositions of plaintiffs (which can begin any time), shall commence four (4) months after ESI production is served in substantively complete form by the defendant(s), though non case specific discovery by either party shall be allowed to commence immediately. 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. 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.
- G. The Plaintiffs shall serve a substantively completed Plaintiff Fact Sheet (PFS) for each Plaintiff in a Discovery Pool case by April 1, 2015.
- H. The Defendants shall serve a substantively completed Defendant Fact Sheet (DFS) for each of the Discovery Pool cases (10 cases) by April 1, 2015. The defendants will disclose the identity and locations of all sales representatives for each case in the Discovery Pool to the extent that information can be determined.

No proposal for case selection on plaintiffs' behalf must be made until after the Defendant Fact Sheets have been served.

- 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 December 18, 2015.
- 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 May 1, 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 any and all final, non-duplicative written discovery in Discovery Pools cases no later than November 13, 2015. All discovery responses including written discovery responses shall be served no later than December 18, 2015. All depositions shall be completed by December 18, 2015.
- L. The Parties shall make presentations to the Court in early August 2015, 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 September 18, 2015. 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 October 19, 2015. The plaintiff(s) shall serve any rebuttal expert disclosures including supplemental reports required by Fed. R. Civ. P. 26(a)(2) on or before November 18, 2015.
- N. Independent Medical Examinations, if any, shall not occur until after the selection of the Bellwether trial cases. The parties shall meet and confer regarding a protocol for IMEs and propose the same to the Court no later than December 1, 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 April 1, 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. Some of the parties in cases that are now a part of MDL 2570 have previously agreed to an ESI Order and a Stipulated Protective Order. The parties anticipate utilizing substantially similar or nearly identical orders in this MDL. The parties propose that with the implementation of Plaintiffs’ Leadership Structure they will be able to complete their ESI negotiations and submit to the Court both an Agreed ESI Order, which will address the topics in the Court’s form: ESI Supplement to Case Management Plan, and the related Stipulated Protective Order, or submit their respective positions on any disagreements, on or before January 16, 2015. Case specific discovery, except for the depositions of the plaintiffs (which can begin any time), shall commence four (4) months after ESI production is served in substantively complete form by the defendant(s), though non case specific discovery by either party shall be allowed to commence immediately.

#### **IV. Discovery<sup>1</sup> and Dispositive Motions**

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<sup>1</sup>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.

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 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 Discovery Pool or Bellwether trial cases shall be filed by January 20, 2016. Non-expert discovery in Discovery Pool cases shall be completed by January 20, 2016; expert witness discovery shall be completed by April 1, 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.

## V. **Pre-Trial/Settlement Conferences**

The parties do not anticipate an early settlement of these matters at this time; however, the scheduling of any settlement conferences is up to the Court's discretion. The parties are open to the scheduling of regular Status Conferences and the procedures as outlined in the Court's Order entered on October 31, 2014, Document [4].

## VI. **Trial Date**

The parties request that the first Bellwether trial be scheduled in August 2016. The trials are to be by jury and each trial is anticipated to take 15-20 days.



## **VII. Referral to Magistrate Judge**

- 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.

## **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.I.
  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.

**B. ONE WEEK BEFORE ANY BELLWETHER FINAL PRETRIAL CONFERENCE, the parties shall:**

1. Notify opposing counsel in writing of any objections to the proposed exhibits. If the parties desire a ruling on the objection prior to trial, a motion should be filed noting the objection and a description and designation of the exhibit, the basis of the objection, and the legal authorities supporting the objection.
2. If a party has an objection to the deposition summary or to a designated portion of a deposition that will be offered at trial, or if a party intends to offer additional portions at trial in response to the opponent's designation, and the parties desire a ruling on the objection prior to trial, the party shall submit the objections and counter summaries or designations to the Court in writing. Any objections shall be made in the same manner as for proposed exhibits. However, in the case of objections to video-taped depositions, the objections shall be brought to the Court's immediate attention to allow adequate time for editing of the deposition prior to trial.
3. File objections to any motions in limine, proposed instructions, and voir dire questions submitted by the opposing parties.
4. Notify the Court and opposing counsel of requests for separation of witnesses at trial.

**IX. Other Matters**

The parties propose that they have additional time to meet and confer, once the Plaintiff's leadership structure has been approved by the Court, regarding the creation of: (1) Plaintiff & Defendant Profile Forms, including the appropriate medical authorizations; (2) Plaintiff & Defendant Fact Sheets; (3) a Pathology Protocol; (4) a Deposition Protocol; (5) a protocol regarding the appropriate means of assertions of privilege claims; and (6) a Screening Order that will address how deficiencies in the PPF, DPF, PFS or DFS are handled and provide a procedure for expedited dismissals of cases that fail to comply with various requirements of this CMP. In the event the parties are unable to reach an agreement on these matters they will seek the assistance of Magistrate Judge Tim A. Baker no later than January 15, 2015.

The parties propose that the creation of a Master Complaint, a Short Form Complaint (for direct filing into MDL 2570), a Master Answer and updating the Service List for MDL 2570 be discussed at the upcoming Initial Pretrial Conference.

Respectfully submitted,

/s/ Ben C. Martin

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\*\*\*\*\*

X	PARTIES APPEARED BY COUNSEL ON NOVEMBER <u>17</u> , 2014, FOR AN INITIAL PRETRIAL CONFERENCE.
	APPROVED AS SUBMITTED.
X	APPROVED AS AMENDED.
	APPROVED AS AMENDED PER SEPARATE ORDER.
	APPROVED, BUT ALL OF THE FOREGOING DEADLINES ARE SHORTENED/LENGTHENED BY _____ MONTHS.
	APPROVED, BUT THE DEADLINES SET IN SECTION(S) _____ OF THE PLAN IS/ARE SHORTENED/LENGTHENED BY _____ MONTHS.
	THIS MATTER IS SET FOR TRIAL BY _____ ON _____ . FINAL PRETRIAL CONFERENCE IS SCHEDULED FOR _____ AT _____.M., ROOM _____.
	<p style="text-align: center;">A SETTLEMENT/STATUSCONFERENCE IS SET IN THIS CASE FOR _____ AT _____ .M. COUNSEL SHALL APPEAR:</p> <p style="text-align: center;">_____ IN PERSON IN ROOM _____; OR</p> <p style="text-align: center;">_____ BY TELEPHONE, WITH COUNSEL FOR INITIATING THE CALL TO ALL OTHER PARTIES AND ADDING THE COURT JUDGE AT (____) _____; OR</p> <p style="text-align: center;">_____ BY TELEPHONE, WITH COUNSEL CALLING THE JUDGE'S STAFF AT (____) _____;</p>
	DISPOSITIVE MOTIONS SHALL BE FILED NO LATER THAN _____

Upon approval, this Plan constitutes an Order of the Court. Failure to comply with an Order of the Court may result in sanctions for contempt, or as provided under Rule 16(f), to and including dismissal or default.

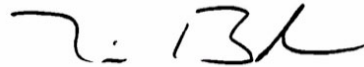
This Case Management Plan supersedes any CMP that may have been previously approved in any of the member cases.

Approval of this CMP does not approve the above Leadership Structure.

**Approved and So Ordered.**

11/25/2014

Date



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

Distribution via CM/ECF

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