

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION

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

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

This Document Relates to All Actions

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**COOK DEFENDANTS' MEMORANDUM REGARDING THE NEW DISCOVERY  
POOL AND COOK'S PROPOSED BELLWETHER TRIALS**

**I. INTRODUCTION**

The bellwether trial system is designed to select for trial cases whose resolution will provide information the parties can use in resolving other cases in the MDL. The Court and the Parties will make the most efficient and effective use of the time and resources they invest in bringing multiple cases to Bellwether trials by selecting cases that are the most representative of the MDL as a whole. The Court already ruled as such in its April 15, 2016 Order On Fifth Amended Case Management Plan (hereinafter "Bellwether Order"), in which the Court determined the representative Bellwether selection criteria for MDL 2570. [Docket No. 1341].

The Court's Bellwether Order outlines the representative cases for trial:

The new discovery pool may include any of the seventy-four "Discovery Pool Eligible Cases," **keeping in mind that they should be as representative of the whole MDL as possible**, primarily alleging injuries from the Celest IVC filter due to migration, IVC perforation, and an inability to be removed.<sup>1</sup>

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<sup>1</sup> The Court's April 15, 2016 Order uses "inability to be removed," to which Cook Defendants refer to as "Inability to be Retrieved," mirroring the language used on the Plaintiff Profile Forms and Fact Sheets.

[Bellwether Order at p. 3] [emphasis added]. If the cases chosen for Bellwether trials are not representative of the whole MDL, they are unlikely to serve as any use to the Parties in resolving other cases in the MDL and their value as bellwethers will be lost.

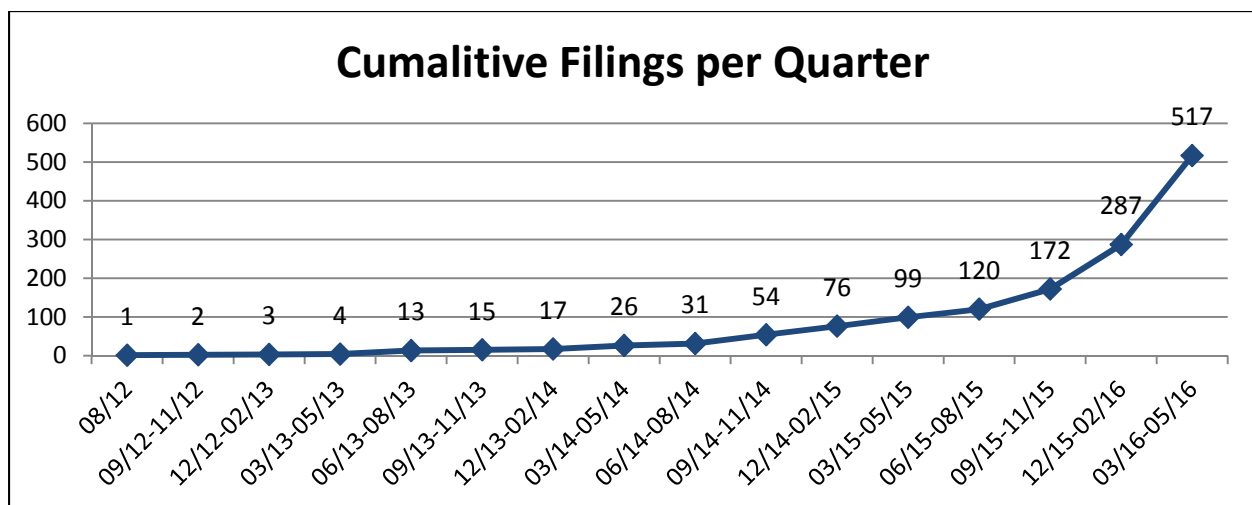
**II. IN ORDER TO PRODUCE RELIABLE AND MEANINGFUL INFORMATION, THE CASES SELECTED FOR BELLWETHER TRIALS MUST BE REPRESENTATIVE OF THE MDL.**

As the Court recognized in its Bellwether Order, Bellwether trials are intended “to provide meaningful information and experience to everyone involved in the litigation.” Fallon, E.E., Grabill, J.T., and Wynne, R.P., Proceedings of the Tulane Law Review Symposium: The Problem of Multidistrict Litigation: Bellwether Trials in Multidistrict Litigation, 82 Tul. L. Rev. 2323, 2332 (June 2008) (hereinafter “Bellwether Trials”). Ultimately, the goal of the Bellwether trial process is test the strengths and weaknesses of the theories that permeate the majority of cases in this MDL, and to establish representative settlement values for categories of cases found within the MDL. Bellwether Trials, at 2325. “[A] case may take on ‘bellwether’ qualities . . . when it is selected for trial because it involves facts, claims, or defenses that are similar to the facts, claims, and defenses presented in a wider group of related cases.” Bellwether Trials, at 2332.

This Court previously modified the Bellwether selection process for this MDL to ensure that the selected Bellwether trial cases are representative of MDL 2570 as a whole, and to avoid trials of “outlier” cases. In so doing, this Court specifically noted in its Order that “[t]he more representative the Bellwether cases, the more reliable the information obtained at trial will be.” Bellwether Order at p. 1; *see also* Order on April 19, 2016, Status Conference [Docket No. 1397].

Since the Parties' briefing on the Bellwether selection process and the Court's Order on the same, the MDL has continued to grow exponentially. Indeed, as of May 6, 2016, the MDL contained 517 cases, compared to 33 when the original Case Management Plan was entered by the Court in November of 2014 and nearly 350 at the time of the Parties' Bellwether briefing in March 2016. A chart showing MDL filings by quarter is at Figure 1.

**Figure 1.**



As of May 6, 2016, 267 of the 517 MDL Plaintiffs have served Plaintiff Profile Forms and Fact Sheets ("PPFs/PFSs") on Cook. The statistics Cook provided to the Court – which make clear the alleged injuries common to the entire MDL – are updated at Table 1.<sup>2</sup>

<sup>2</sup> It is important to note that the information available to judge common injuries and theories within this MDL is based on self-reporting by the Plaintiffs in the PPF/PFS. There are 267 cases in which a PPFs/PFSs has been served. Based on the medical records that the Cook Defendants have reviewed to date, the Cook Defendants believe that the incidence of the various alleged device failure modes at issue in this MDL are overstated. Nonetheless, the Plaintiffs' self-reporting is the best information currently available on the makeup of the MDL.

**Table 1. MDL 2570 Statistics**

MDL cases w/ PPF	Totals	Death	Bleeding	Migration	IVC Perforation	Unable to be Retrieved	Open Removal	Organ Perforation	Other	Fracture	Tilt
Totals - <sup>3</sup> Cases/ Devices	267/ 271	9 5%	43 17%	<b>117</b> <b>46%</b>	<b>134</b> <b>53%</b>	<b>133</b> <b>51%</b>	47 18%	81 31%	106 41%	66 25%	113 43%
Günther Tulip™	82 30%	1 6%	13 16%	<b>25</b> <b>30%</b>	<b>41</b> <b>50%</b>	<b>42</b> <b>51%</b>	7 9%	20 24%	30 37%	10 12%	33 40%
Celect®	186 69%	8 4%	31 17%	<b>96</b> <b>52%</b>	<b>99</b> <b>53%</b>	<b>91</b> <b>49%</b>	39 21%	63 34%	77 41%	58 31%	80 43%

As demonstrated by Table 1, Migration, IVC Perforation and Unable to be Retrieved are the most frequently alleged injuries in this MDL. In addition, based on the 517 cases filed as of May 6, 2016, roughly 40% of Plaintiffs were implanted with a Günther Tulip filter, and 60% of Plaintiffs were implanted with a Celect filter. For both the Günther Tulip and the Celect, Migration, IVC Perforation, and Unable to be Retrieved, remain the primary injuries alleged in the MDL and continue to be the most representative of the MDL as a whole. Accordingly, the selection criteria previous outlined by this Court in the Bellwether Order should remain the primary criteria for the Court's selection of Bellwether trials.

### **III. THE PARTIES' DISCOVERY POOL SELECTIONS**

There are fourteen cases in the New Discovery Pool from which the Court presumably will select three Bellwether trials.<sup>4</sup> As Cook explains below, when two categories of unrepresentative injuries are removed from the Case Pool – outlier cases alleging a fractured filter or an “open procedure” to remove a filter – there are six cases that fall within this Court's defined criteria for representativeness.

<sup>3</sup> This table does not include Celect Platinum cases, of which there are two, or cases where insufficient information was provided to identify the product at issue, of which there are five.

<sup>4</sup> On May 12, 2016, the Parties filed a Joint Status Report, pursuant to the Court's Order On Fifth Amended Case Management Plan [Docket No. 1341] and the Court's Minute Entry of May 5, 2016 [Docket No. 1408], reporting on the fourteen (14) New Discovery Pool selections, with the Parties each having already exercised their three strikes.

**a. Plaintiffs' Discovery Pool Selections Are Not Representative of the MDL.**

Plaintiffs selected the following seven cases as their New Discovery Pool: *Allen*, *Blithe*, *Brady*, *Brand*, *Newsome*, *Sumner* and *True*. Even a cursory comparison of the Plaintiffs' Discovery Pool selections with the current make-up of the MDL reveals their case selections are, as with their original discovery pool selections, not representative of the MDL.

As demonstrated by the Table 2, Plaintiffs' selections are not representative of the MDL as a whole because the alleged device failures or injuries of Fracture and Open Removal are over-emphasized. Indeed, 4 of the Plaintiff's proposed Bellwether cases (or **57%**) allege Fracture and 5 (or **71%**) allege Open Removal, while only **25%** of the cases in the MDL allege Fracture and only **18%** allege Open Removal. As a result, the Plaintiffs' New Discovery Pool cases are unrepresentative and intentionally skewed to outlier failure modes and injuries that do not represent the MDL as a whole, and which would not provide helpful information to the Court or Parties regarding the MDL as a whole.

**Table 2. Comparison of MDL 2570 to Plaintiffs' Selections**

MDL cases w/ PPF	<i>Fracture</i>	<i>Open Removal</i>
MDL	25%	18%
All Celect®	31%	21%
Plaintiffs' Selections (all Celect)	57%	71%

Further, Plaintiffs have failed to pick a single Günther Tulip case. Günther Tulip cases make up close to 40% of the MDL, but Plaintiffs failed to make even one of their ten discovery pool picks a Tulip case.

**b. Cook Defendants' Discovery Pool Selections Are Representative of the MDL.**

In comparison, Cook Defendants' seven New Discovery Pool selections more closely track the current make-up of the MDL and, therefore, are more representative of the MDL. For instance, Cook Defendants' selection of two (2) Günther Tulip (or 29%) and five (5) Celect (or 71%) cases is nearly identical to the make-up of the MDL. Cook Defendants' selections also more closely track the make-up of the alleged device failures and injuries in the MDL. Specifically, Cook Defendants' New Discovery Pool Selections not only adhere to the Court's Bellwether Order (i.e. consist of cases with allegations of Migration, Perforation and an Inability to Remove), they remain more closely aligned with the MDL device failures and alleged injuries of Fracture and Open Removal. *See* Table 3, below. In contrast, Plaintiffs' selections ignored the Court's Bellwether Order and over-emphasize the device failures and alleged injuries of Fracture and Open Removal.

**Table 3. Cook Defendants' Selections**

Cook Defendants' Selections	Totals	Migration	IVC Perforation	Unable to be Retrieved	Open Removal	Fracture
<b>Totals</b>		5 71%	6 86%	2 29%	0 0%	2 29%
<b>Günther Tulip™</b>	2 29%	1 50%	2 100%	1 50%	0 0%	0 0%
<b>Celect®</b>	5 71%	4 80%	4 80%	1 20%	0 0%	2 40%

Cook Defendants believe that an additional selection criterion of the Plaintiffs' age should be considered in order to ensure the Bellwether cases are representative of the average MDL 2570 plaintiff. Exhibit A illustrates the Plaintiff age ranges at the time of implant based on

the 267 PPFs/PFSs served as of May 6, 2016. As the Honorable Joseph R. Goodwin, U.S. District Court Judge, held in his Pretrial Order # 51 (Order re: Bellwether Case Selection), entered August 7, 2013, in the *In re: Boston Scientific Corp., Pelvic Repair System Product Liability Litigation*, the “[a]ge range of the plaintiff: 40-60 years old at time of implant” should be considered in the selection of Bellwether trial cases. *See* Exhibit B, attached hereto. While the Boston Scientific Corporation-made synthetic transvaginal mesh, the medical device at issue in MDL 2326, is for the treatment of pelvic organ prolapse and stress urinary incontinence and is not the same medical device as the IVC filters at issue here, consideration of the Plaintiffs’ age is as appropriate here as in MDL 2326 because the goal in both MDLs is to identify typical or representative cases for Bellwether trials.

### **c. Identifying Representative Bellwethers**

Following the Court’s Bellwether Order directive, upon receipt of Plaintiffs’ New Discovery Pool Cases, Cook Defendants organized the fourteen New Discovery Pool Cases into the categories identified by the Court: Perforation, Migration and Inability to be Removed.<sup>5</sup> See Table 4, below. The fact that the same case may be listed in multiple categories reflects the fact that, for many cases, more than one of the injury categories is alleged.

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<sup>5</sup> Donna Newsome does not fall into the 3 categories suggested by the Court. She alleges: Tilt, Organ Perforation, and Other (post-implant saddle embolus). She also had an open removal of her filter.

**Table 4. Cases by Category**

<b>Migration</b>	<b>IVC Perforation</b>	<b>Unable to be Retrieved</b>
Allen, S. Avery-Montgomery, D. (GT) Blithe, K. Brand, T. Hill, E. Johns, L. Perry-O’Farrow, L. Shafer, D. Sumner, G. True, T.	Alford, J. Avery-Montgomery, D. (GT) Blithe, K. Brady, R. Gage, A. (GT) Hill, E. Perry-O’Farrow, L. Shafer, D. Sumner, G. True, T.	Alford, J. Avery-Montgomery, D. (GT) Blithe, K. Brand, T. Gage, A. (GT) <sup>6</sup>

(GT) = Günther Tulip™

**d. It is Necessary to Eliminate the Non-Representative Cases from the Parties’ Discovery Pool Selections**

To fulfill the goal of identifying three representative cases for trial, Cook Defendants’ first note that this Court’s specific guidance eliminates cases where “fracture” is the alleged failure mode/injury. The Court correctly stated that “migration, IVC perforation, and an inability to be removed” are more representative of the MDL cases as a whole, and thus would better serve the Bellwether purpose. As noted in Table 1, only 25% of the cases in this MDL in which PPF’s have been supplied are fracture cases. In fact, the percentage of cases in the MDL where fracture is alleged has decreased since Cook Defendants last presented statistics to the Court on March 17, 2016. [Docket No. 1245] Accordingly, to eliminate the outlier fracture cases, the following cases should be removed from consideration as a Bellwether trial case: *Susie Allen*, *Tonya Brand*, *Leticia Perry O’Farrow*, *Daniel Shafer*, *Ginger Sumner*, and *Tammy True*.

To further eliminate outliers from the Parties’ Discovery Pool selections and to limit the selections to the alleged device failures/injury categories identified by the Court and those categories supported by the updated MDL statistics provided herein, the Court should not

<sup>6</sup> Arthur Gage testified in that physicians have told him that his filter cannot be removed because it would damage his vena cava and kill him. (Deposition of Arthur L. Gage, Sr., taken August 13, 2015, p. 53, lines 19-25; p. 60., lines 21-25; p. 61, lines 1-18; p. 62, lines 1-6, 18-24; p. 63, lines 24-25; p. 64, lines 1-8).



consider cases that involve an open surgical procedure to remove the device. These cases are outliers as is evidenced by a review of the MDL statistics (which are based on Plaintiffs' own allegations in the PPFs). Only 18% of cases include an invasive open removal procedure. Thus, not only is having this more invasive type of filter retrieval not representative of the cases as a whole, it represents one of the top (if not the very top) indicator of a case that Plaintiffs would consider their "best case." As this Court is well aware, trying one of the Party's "best" cases is not a true "Bellwether." *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997). Such cases with an unusual, and enhanced injury, will not further the goals of the Bellwether process. As Judge Pallmeyer noted in MDL 2272 when entering a recent Case Management Order discussing Bellwether select, "[n]ext steps will include additional bellwether trials of balanced and representative cases whose disposition will provide guidance [...]." Case Management Order No. 10, MDL 2275, Master Docket Case No. 1:11-cv-05468, United States District Court, Northern District of Illinois, Eastern Division, Docket No. 1652, Exhibit C hereto.

Accordingly, to eliminate the "outlier" "open removal cases" from the pool of fourteen cases being considered, the *Kylie Blithe* case should be removed from consideration. *Tammy True*, *Ginger Sumner*, and *Susie Allen* were already identified as "outlier" fracture cases, but are also open removals and if not removed from consideration as fracture cases, they should be removed as open removal cases. Cases with multiple "outlier" factors, such as these, compound the complexity of the case making these cases further from being representative as the Court has already defined and the MDL 2570 statistics provided herein support. Table 5, below, indicates the "outlier" cases eliminated due to allegations of fracture and/or having an open removal.

**Table 5. Cases Eliminated Because Fracture or Open Removal**

<b>Migration</b>	<b>IVC Perforation</b>	<b>Unable to be Retrieved</b>
<del>Allen, S.</del> (open/fracture) Avery-Montgomery, D. (GT) <del>Blithe, K.</del> (open) <del>Brand, T.</del> (fracture) Hill, E. Johns, L. <del>Perry O'Farrow, L.</del> (fracture) <del>Shafer, D.</del> (fracture) <del>Sumner, G.</del> (open/fracture) <del>True, T.</del> (open/fracture)	Alford, J. Avery-Montgomery, D. (GT) <del>Blithe, K.</del> (open) Brady, R. Gage, A. (GT) Hill, E. <del>Perry O'Farrow, L.</del> (fracture) <del>Shafer, D.</del> (fracture) <del>Sumner, G.</del> (open/fracture) <del>True, T.</del> (open/fracture)	Alford, J. Avery-Montgomery, D. (GT) <del>Blithe, K.</del> (open) <del>Brand, T.</del> (fracture) Gage, A. (GT)

This leaves the following cases as potential representative Bellwether selections that meet the Court's Bellwether Order and thus have not been identified as "outlier" cases:

**Table 6. Cases Remaining After Fracture and Open Removal Cases Are Eliminated**

<b>Migration</b>	<b>IVC Perforation</b>	<b>Unable to be Retrieved</b>
Hill, E. Johns, L. Avery-Montgomery, D. (GT)	Alford, J. Avery-Montgomery, D. (GT) Brady, R. Gage, A. (GT) Hill, E.	Alford, J. Avery-Montgomery, D. (GT) Gage, A. (GT)

#### **IV. THE REMAINING REPRESENTATIVE DISCOVERY POOL CASES & COOK'S PROPOSED BELLWETHER SELECTIONS**

Of the representative cases remaining, as shown in Table 3, Cook Defendants believe that the *Alford*, *Gage* and *Hill* cases would be the three most appropriate selections for Bellwether trials starting in the spring of 2017. These cases involve "facts, claims, or defenses that are similar to the facts, claims, and defenses presented in a wider group of related cases" and would "assist in the maturation of disputes by providing an opportunity for coordinating counsel to organize the products of pretrial common discovery, evaluate the strengths and weaknesses of their arguments and evidence, and understand the risks and costs associated with the litigation"

in addition to following this Court' guidance regarding representative cases. *Bellwether Trials*, at 2324.

In the MDL, as of May 6, 2016, the split between Celect and Günther Tulip filed cases is approximately 60%/40%, based on the device identified in each Plaintiffs' Short Form Complaint.<sup>7</sup> Therefore, Cook proposes the selection of two Celect cases and one Günther Tulip case for the three Bellwether trials.

After eliminating the "outlier" cases, as outlined herein, there are only six cases remaining for which Cook Defendants believe the Court should even consider as potential Bellwether trials: *Alford*, *Avery-Montgomery*, *Brady*, *Gage*, *Hill* and *Johns*.

**a. Cook's Proposed Bellwether Selections**

**i. Arthur Gage – Günther Tulip - Perforation & Unable to be retrieved**

Mr. Arthur Gage is a representative case that would further the goals of the Bellwether process. *Gage* represents a large percentage of the MDL 2570 Günther Tulip cases, and lacks any unusual circumstances or comorbidities that make this case non-representative and therefore inappropriate as a Bellwether trial selection. Mr. Gage was implanted with a Günther Tulip IVC filter after experiencing a gross hematuria while on anti-coagulation medicine. Mr. Gage was 61 at the time of implant, making him representative of the majority of plaintiffs in the MDL (*see* Exhibit A), and has a history of pulmonary embolism and deep vein thrombosis. Mr. Gage alleges that his IVC filter has perforated his vena cava and he testified in his deposition that the filter cannot be removed. (Deposition of Arthur L. Gage, Sr., taken August 13, 2015, p. 53, lines 19-25; p. 60., lines 21-25; p. 61, lines 1-18; p. 62, lines 1-6, 18-24; p. 63, lines 24-25; p. 64, lines 1-8).

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<sup>7</sup> There were 517 filed cases as of May, 6, 2016, but 8 are multi-product implant cases making the total number of devices at issue in MDL 2570, 525. Also, as of May 6, 2016, less than 1% of cases allegedly involve Celect Platinum (2), or the device was unknown (5).

Based on the factors of his age, reason for implant, and alleged failure mode of perforation, Mr. Gage's case is representative of others in the MDL and would be an appropriate Bellwether selection. Mr. Gage's case is representative of the 30% of MDL cases that involve Günther Tulip; the 50% of Günther Tulip cases that allege IVC perforation, and the 51% of Günther Tulip cases that allege inability to retrieve.

**ii. Elizabeth Hill – *Celect - Perforation & Migration***

Ms. Elizabeth Hill is a representative case that would further the goals of the Bellwether process because it would be a trial that represents a large percentage of the MDL 2570 case pool, and lacks any unusual circumstances or comorbidities that make this case non-representative and therefore inappropriate as a Bellwether trial selection. Ms. Hill was 57 years of age at the time she was implanted with a Celect IVC filter, making her representative of the majority of plaintiffs in the MDL (*see* Exhibit A) Ms. Hill's IVC filter was placed in preparation for back surgery. Ms. Hill claims her IVC filter migrated and perforated the vena cava, as well as a surrounding organ and has caused bleeding. Ms. Hill's medical records indicate at least one failed retrieval attempt some four months after placement and that a GI endoscopy procedure may have revealed that a strut of her IVC filter had perforated her duodenum. Ms. Hill's IVC filter was successfully removed percutaneously nearly two years after implant using advanced retrieval techniques.

Ms. Hill's case is representative of an alleged Celect migration and perforation wherein advanced retrieval techniques were required to successfully remove her device. Ms. Hill's age at implant, her device's in vivo time and near two year post-implant retrieval using advanced techniques are representative of the MDL and would provide the parties valuable guidance moving forward as a Bellwether trial. Ms. Hill's case accounts for 69% of the MDL that involve

Celect, and her allegations of IVC perforation and migration account for 53% and 52% of the MDL Celect cases, respectfully.

**iii. John Alford – Celect - Perforation & Unable to be Retrieved**

Mr. John Alford is a representative case which would further the goals of the Bellwether process because it would be a trial that represents a large percentage of the MDL 2570 case pool, and lacks any unusual circumstances or comorbidities that make this case non-representative and therefore inappropriate as a Bellwether trial selection. Mr. Alford, 56 at the time of implant, making him representative of the majority of plaintiffs in the MDL (*see* Exhibit A), was implanted with a Celect IVC filter on November 30, 2011 due to history of deep vein thrombosis and a desire to not take anti-coagulation medicine. Mr. Alford claims perforation of the vena cava and the inability to retrieve, allegedly having had one failed retrieval attempt. Mr. Alford's case is representative of the MDL in that it is a common claim of perforation and a resulting inability to retrieve. Mr. Alford's age, implant indication, a failed retrieval attempt and the lack of any comorbidity, make his case a representative MDL case and an appropriate Bellwether selection. Mr. Alford's case accounts for 69% of the MDL as a case which involves a Celect, 53% of which alleged IVC perforation and 52% alleging migration.

**b. Case Specific Facts Render The Remaining Cases Less Likely to Further the MDL Process If Chosen As Bellwether Cases**

The Honorable Joseph R. Goodwin, U.S. District Court Judge,<sup>8</sup> noted in his Pretrial Order # 51 (Order re: Bellwether Case Selection), entered August 7, 2013, in the *In re: Boston Scientific Corp., Pelvic Repair System Product Liability Litigation* (attached hereto as Exhibit B), a case where “comorbidities or other circumstances . . . make the plaintiff an outlier or otherwise not representative of the majority of plaintiffs . . . is not a true [B]ellwether case.” The

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<sup>8</sup> The Cook Defendants understand that the Court knows Judge Goodwin from recent conferences of all MDL Judges.

remaining representative cases based on the Court's Bellwether Order are less likely to further the MDL process and assist the Parties and this Court due to comorbidities and other circumstance surrounding each case. Cook Defendants' are therefore recommending that these matters not be selected as Bellwethers cases.

**i. Brady – Celect – Perforation & Damage to Vena Cava**

Mr. Brady, 56 at the time of placement, was implanted with a Celect filter on February 2, 2012, following an acute onset of deep vein thrombosis and pulmonary embolus. Mr. Brady required venous thrombectomy and consented to the placement of an IVC filter. Mr. Brady alleges that his Celect filter subsequently perforated his IVC in three places. Mr. Brady underwent a percutaneous retrieval attempt in early October of 2012 and a second, and successful, retrieval in late October of 2012. Mr. Brady also alleges that his IVC filter required him to undergo groin surgery to remove nerves that were causing him pain. Mr. Brady's successful percutaneous retrieval within one year and his unique allegations regarding his nerve surgery make him less representative than the other Celect perforation cases. In addition, the placement of Mr. Brady's IVC filter in connection with a thrombectomy, the surgical removal of a clot, is common, but the failure to attempt the removal of his IVC filter following the procedure further makes this a non-representative case. Mr. Brady himself has stated that there is no good reason why his physician placed his IVC filter. Therefore, due to at least in part the failure to remove his IVC filter following the conclusion of his thrombectomy procedure, Mr. Brady's case is not an appropriate Bellwether case selection.

**ii. Donna Avery-Montgomery – Günther Tulip – Perforation, Migration, Tilt & Unable to be retrieved**

Ms. Avery-Montgomery, 42 at the time of placement, was implanted with a Günther Tulip IVC filter on April 5, 2007, due to a severe motor vehicle accident involving significant

trauma therein the device was placed as a precautionary matter, an off-label, or non-FDA cleared reason for placement. Ms. Avery-Montgomery claims her device has migrated, tilted, perforated her vena cava, is unable to be retrieved, and is causing her bleeding, other issues (PTSD, heart/chest palpitations, blood pressure issues, anxiety/chest pain, femoral perforation, and abdominal bleeding). Ms. Avery-Montgomery is now 51 years of age and her medical records indicate she suffers from various comorbidities and other ailments unrelated to her IVC filter. Ms. Avery-Montgomery's comorbidities, including ongoing heart issues, make her case less likely to further the MDL process if selected as a Bellwether case.

**iii. Linda Johns – Celect – Migration & “Other”**

Ms. Linda Johns, 48 at the time of placement, was implanted with a Celect IVC filter due to a pulmonary embolism while on anti-coagulants, an approved Indication For Use of the devices at issue in this MDL. In addition, Ms. John's has been diagnosed with coagulation related health problems, specifically Crohn's Disease, Factor V Leiden, and a Protein Deficiency. Ms. John claims her IVC filter migrated, is causing her bleeding and “Other” issues (severe or persistent chest pain and shortness of breath). Ms. John's medical records, however, do not appear to indicate that there is indeed a true migration of the IVC filter. That, compiled with her various diagnosed health problems, which may all also be the source of her current conditions, make this matter a less than desirable Bellwether case.

**V. PROPOSED ORDER OF THE BELLWETHER TRIALS**

Once the Bellwether cases have been selected, Cook Defendants respectfully request that the Court then set the order in which they are to be tried, with input from the Parties, following the Settlement Conference scheduled to take place on June 27-28, 2016. Thus, the Court could prioritize cases that highlight issues where the Parties disagree and need the input of a jury (e.g.,

the value to place on a particular type of alleged device failure and the clinical consequences of that alleged failure mode or the strength of a particular claim or defense). If a Bellwether case is dismissed or resolved prior to trial, or if it becomes clear that the case highlights issues where the Parties are *not* in disagreement, the Cook Defendants would also urge the Court to adopt a process by which such case can be replaced as a Bellwether by another Discovery Pool Eligible Case.

#### IV. CONCLUSION

Based on the foregoing, Cook proposes that the Court select the two Celect cases, as summarized above, *Alford* and *Hill*, and one Günther Tulip case, as summarized above, *Gage*, as the Bellwether trials, and grant it all other proper relief.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 20, 2016, a copy of the foregoing was served by electronic mail to Plaintiffs' Co-Lead Counsel with distribution to all other plaintiff counsel of record to be made by Plaintiffs' Co-Lead Counsel:

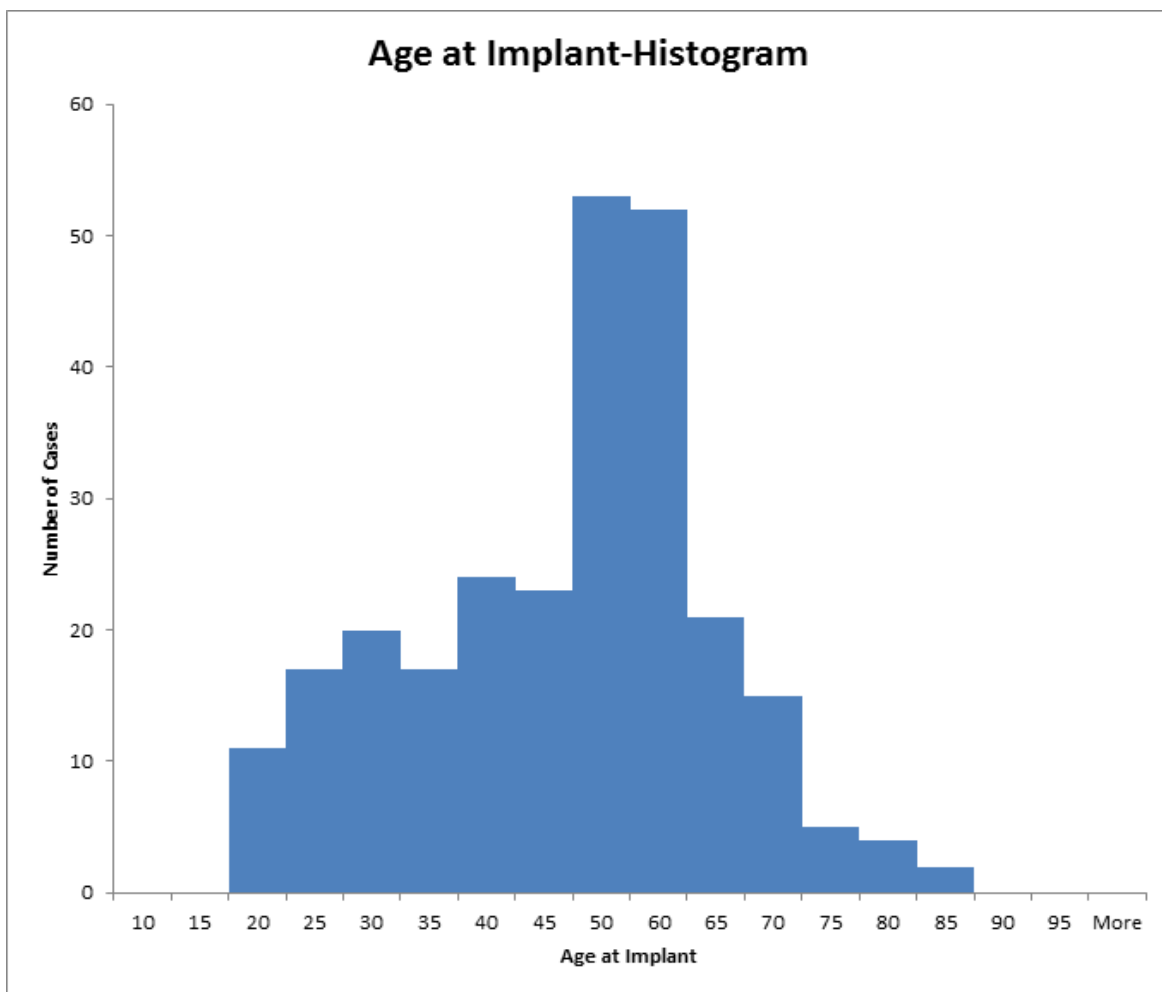
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**Exhibit A**



**Exhibit B**

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.,  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

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THIS DOCUMENT RELATES TO ALL CASES

**PRETRIAL ORDER # 51**  
(Order re: Bellwether Case Selection)

On August 1, 2013, I heard bellwether presentations from the parties in this MDL. I am not satisfied with most of the proposed selections I received from the parties. From the plaintiffs there were multi-product picks, while defendants offered several picks with potential statute of limitations issues (plaintiffs offered one pick that defendants assert may be subject to a statute of limitations issue). Both parties offered selections that were not representative based on age and other factors or because they had conditions that made the cases outliers (Alzheimer's disease, vaginal obliteration, participation in drug studies, active runner with infertility issues, etc.). I find it necessary for the parties to resubmit their bellwether selections with more representative cases. Because the parties seem unwilling or unable to do this on their own, I find it necessary to set the following parameters for what is representative:

- (1) No more than eight (8) nominations per side, including only the Obtryx, Advantage/Fit, Pinnacle and Uphold products;
- (2) Single product cases only;
- (3) Age range of plaintiff: 40-60 years old at implant;
- (4) Number of revision surgeries; i.e., surgery under general anesthesia: 0-3;

(5) No statute of limitations issues; and

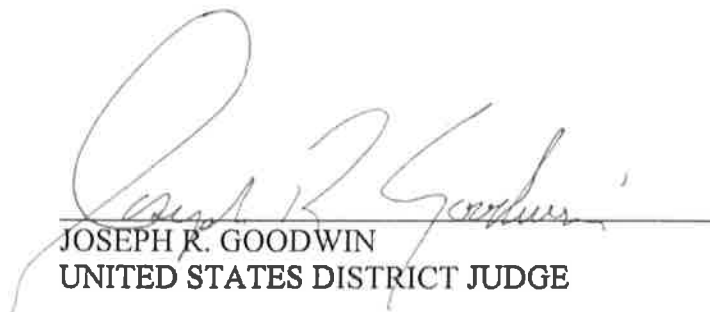
(6) No comorbidities or other circumstances that make the plaintiff an outlier or otherwise not representative of the majority of plaintiffs such that the case is not a true bellwether case.

It is **ORDERED** that the parties file their amended bellwether selections simultaneously on **Monday, August 12, 2013, at noon**. **The parties may agree to an earlier time if they wish.** The submissions may be accompanied by a three-page brief in support of the selections. Each side may file a two-page response to the opposing parties' selections on or before **Wednesday, August 14, 2013, at noon**. Thereafter, I will choose six (6) bellwether cases (rather than five (5)) for the three rounds of trials scheduled for February 11, June 17, and September 9, 2014.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2326 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:13-cv-18645. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial

orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at [www.wvsc.uscourts.gov](http://www.wvsc.uscourts.gov).

ENTER: August 7, 2013



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

<b>IN RE: ZIMMER NEXGEN KNEE</b>	)	
<b>IMPLANT PRODUCTS LIABILITY</b>	)	<b>MDL NO. 2272</b>
<b>LITIGATION</b>	)	
	)	
<b>This Document Relates to All Cases</b>	)	<b>Master Docket Case No. 1:11-cv-05468</b>
	)	
	)	<b>Honorable Rebecca Pallmeyer</b>

**CASE MANAGEMENT ORDER NO. 10**

The court is committed to completing its work on this MDL and to advancing the progress of the litigation, with the goal of full resolution so consolidated proceedings in 2017. Next steps will include additional bellwether trials of balanced and representative cases whose disposition will provide guidance; mediation efforts; and, in some instances, suggestions of remand, with the aim of full resolution of the consolidated proceedings in 2017. To that end, this Case Management Order No. 10 directs the parties as to further case management and will govern the bellwether selection, trial, and global mediation process.

1. Withdrawals and Dismissals. All motions for leave to withdraw or to voluntarily dismiss not filed on or before February 12, 2016, will be denied, absent good cause shown. Any case not dismissed by February 12, 2016 that, without good cause, later becomes the subject of a motion for voluntary dismissal or a motion to withdraw may be the subject of sanctions.

2. Bellwether Trial Eligibility. All cases that have complied with CMO 8 and that meet the criteria for Track One cases as identified in CMO 9 are eligible for bellwether trial selection. CMO 9 requires Track One designations by February 12, 2016.

3. Zimmer's Defense Bellwether Pick. Zimmer will be permitted to pick one case which will be scheduled as the next trial before additional bellwether cases selected by the Court

4. Bellwether Pool. The bellwether case pool ("Bellwether Pool") will consist of 24 cases selected randomly from all cases in the MDL that have complied with CMO 8 and are Track One cases under CMO 9. The cases selected will fall into two categories: 17 cases involving a Flex femoral component without a 5950 MIS Tibial component, and 7 cases involving a 5950 MIS Tibial component. The parties will prepare a list of all cases transferred into the MDL before October 15, 2015, and place each case in its appropriate category. The court will then randomly select the designated number of cases from each category on or before February 19, 2016. By February 26, 2016, the parties will exchange all medical records and x-rays in their respective possessions for the plaintiffs in the Bellwether Pool. On March 3, 2016, each party will strike 6 cases from the pool of 24, but neither party will use all of its strikes to eliminate the 5950 MIS Tibial Component category. Also on March 3, 2016, each party will notify the court if a party in any of the cases refuses to waive the venue rights recognized in *Lexecon*. Should any party refuse to waive *Lexecon*, such a refusal will constitute one of the six strikes for the side; or, in the alternative, the opposing side will be entitled to take another strike, which must be exercised by March 8, 2016. The party refusing to waive *Lexecon* must notify the court and parties of which option it chooses on March 4, 2016. On March 10, 2016, the parties will then each submit one-page briefs (no more than 10 pages total) containing a summary of facts and statement of appropriateness for bellwether trial for each of the remaining cases. The Court will then select 4 cases from the remaining cases for trial. It will also declare the order of the trials. Discovery will begin in all cases upon the court's selection of a case, and it will conclude 30 days before the date trial in the case is slated to begin.



5. Intended Trial Dates in 2016. The court intends to conduct trials in 2 cases in 2016. The parties and the court will work to schedule consecutive trials, the first of which will begin no earlier than October 1, 2016, and the second of which will conclude no later than November 23, 2016.

6. Expert Reports and Expert Discovery for 2016 Bellwether Trials.

- a. On or before June 1, 2016, Plaintiffs will disclose in writing the identities of experts as required by Fed.R.Civ.P. 26(a)(2)(A) and will serve the reports and other materials required by Fed.R.Civ.P. 26(a)(2)(B), for the bellwether cases scheduled for trial in 2016.
- b. On or before July 1, 2016, Zimmer will disclose in writing the identities of experts as required by Fed.R.Civ.P. 26(a)(2)(A) and will serve the reports and other materials required by Fed.R.Civ.P. 26(a)(2)(B), for the bellwether cases scheduled for trial in 2016.
- c. Plaintiffs and Zimmer will make their designated experts available for deposition between July 1, 2016, and August 1, 2016. If an expert is a general expert who has been previously deposed in this MDL, the court expects that questioning will not be redundant of prior depositions.

7. Motion Practice – 2016 Trials. As the court is now well-versed on the issues in this consolidated litigation, it will not entertain voluminous briefs of the nature that generated earlier *Daubert* rulings. The court will address *Daubert* challenges to expert testimony on general causation issues, but will not permit re-litigation of issues within the scope of its prior *Daubert* or motion *in limine* rulings. Following expert disclosures, the court will impose page

limitations on any further *Daubert* motions.<sup>1</sup> All motions in limine, motions to exclude or limit expert testimony, and all dispositive motions shall be filed no later than August 15, 2016. All responses to those motions shall be filed no later than August 30, 2016, and all replies shall be filed no later than September 9, 2016. The court will hold a hearing to consider these motions on a date convenient for the court.

8. Mediation. Following the first two trials, the parties will engage in a mediation process targeted to occur from December 2016 to January 2017.

9. Non-Damages Expert Reports and Expert Discovery for 2017 Bellwether Trials.

a. On or before November 1, 2016, Plaintiffs will disclose in writing the identities of experts as required by Fed.R.Civ.P. 26(a)(2)(A) and will serve the reports and other materials required by Fed.R.Civ.P. 26(a)(2)(B), for the three bellwether trials scheduled to occur in 2017.

b. On or before December 1, 2016, Zimmer will disclose in writing the identities of experts as required by Fed.R.Civ.P. 26(a)(2)(A) and will serve the reports and other materials required by Fed.R.Civ.P. 26(a)(2)(B), for the bellwether trials scheduled to occur in 2017.

c. Plaintiffs and Zimmer will make their designated experts available for deposition between December 5, 2016, and January 25, 2017.

10. Post-Mediation Activity in 2017. Should the mediation process fail to result in substantial disposition of the MDL, the parties reserve the right to move the court for a suggestion of remand, or for resumption of bellwether trials. The court will set a schedule for

<sup>1</sup> General causation *Daubert* briefing that was not previously ruled upon will be addressed in a separate order.

the filing of motions in limine, motions to exclude or limit expert testimony, and dispositive motions in a future order.

ENTER:

January 22, 2016

Robert R. Ragsdale

REBECCA R. PALLMEYER  
United States District Judge