

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION**

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

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

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This Document Relates to All Actions

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**PLAINTIFFS' SUBMISSION ON BELLWETHER TRIAL SELECTIONS**

In accordance with this Court's order of April 15, 2016 [Doc. 1341], Plaintiffs submit this memorandum regarding their suggestions for bellwether trial selections.

**I. Bellwether Selection Criteria**

In the mass tort context, the term "bellwether" refers to the trial of a representative group of cases in order to "provide a basis for enhancing prospects of settlement or for resolving common issues or claims." *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997). The rationale for doing so is fairly obvious: "[i]f a representative group of claimants are tried to verdict, the results of such trials can be beneficial for litigants who desire to settle such claims by providing information on the value of the cases as reflected by the jury verdicts." *Id.*; *see also Briggs v. Merck Sharp & Dohme*, 796 F.3d 1038, 1051 (9th Cir. 2015) ("typically used to facilitate settlement in similar cases by demonstrating the likely value of a claim or by aiding in predicting the outcome of tricky questions of causation or liability."); *Grant Heilman Photography, Inc. v. McGraw-Hill Companies*,

115 F. Supp. 3d 518, 522-23 (E.D. Pa. 2015) (“Bellwether trials ... are recognized as an effective means for a trial judge to enhance settlement prospects or resolve common issues or claims in complex litigations.”); *In re Medtronic, Inc.*, No. 05-MDL-1726 JMR/AJB, 2008 WL 3895933, at \*2 fn. 1 (D. Minn. Aug. 15, 2008) (“It is anticipated that a bellwether trial will yield results which will assist the parties in subsequent efforts to resolve other cases of a similar nature without the necessity of a trial.”).

As noted by courts across the country, “[i]t is critical to a successful bellwether plan that an honest representative sampling of cases be achieved.” *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, No. 3:09-MD-02100-DRH, 2010 WL 4024778, at \*1 (S.D. Ill. Oct. 13, 2010); *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019-20 (5th Cir. 1997) (to be effective, a bellwether trial “has as a core element representativeness”); *see also* Manual for Complex Litigation (4th) (“Manual”) § 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.”). “[B]ecause the primary purpose of bellwether trials is to provide data points for settlement discussions with respect to the universe of cases, the goal is to select the ‘best’ representatives of the universe of cases, not outliers likely to result in victory for one side or the other.” *In re: Gen. Motors LLC Ignition Switch Litig.*, No. 14-MC-2543 (JMF), 2016 WL 1441804, at \*9 (S.D.N.Y. Apr. 12, 2016). “The more representative the test plaintiffs, the more reliable the information about similar plaintiffs remaining in the case.” *Morgan v. Ford Motor Co.*, No. 06-

1080JAP, 2007 WL 1456154, at \*6-7 (D.N.J. May 17, 2007) (“to ensure the usefulness of bellwether plaintiffs to the process. . . representative plaintiffs must be chosen”).

This means ensuring that there is appropriate representation with respect to the type of:

- product, *In re: Gen. Motors LLC Ignition Switch Litig.*, 2016 WL 1441804, at \*3 (S.D.N.Y. Apr. 12, 2016) (ignition-switch litigation, court specified vehicles eligible for inclusion); *In re Hydroxycut Mktg. & Sales Practices Litig.*, 2012 WL 3637278, at \*1 (S.D. Cal. Aug. 21, 2012) (approving bellwether plan requiring each side to pick at least one case from two categories of products);
- injuries, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, 2010 WL 4024778, at \*2 (S.D. Ill. Oct. 13, 2010) (bellwether pool with equal numbers of venous and gallbladder cases); and
- legal issues, *In re Welding Fume Products, No.*, 2007 WL 1702953, at \*1 (N.D. Ohio June 6, 2007) (finding that one case was a “good choice for a bellwether trial” because it raised issues concerning Mississippi law shared by many other MDL plaintiffs).

Plaintiffs address these factors as they relate to the pool of 14 potential bellwether trial cases in this MDL.

## **II. Plaintiffs’ Analysis of Potential Bellwether Trial Cases**

### **A. Plaintiffs’ Selections (in alphabetical order)**

#### **1. Susie Allen (Case #1:14-cv-01252-RLY-TAB)**

Susie Allen, now 56 years old, was implanted with a Cook Celect filter at age 49 on March 27, 2008, due to recurrent deep vein thrombosis.

On January 30, 2012, it was noted that the inferior vena cava filter had fractured at the L3 limbs level. On July 9, 2013, a strut of the IVC filter was identified within the aortic

wall (perforation), and on that same date Ms. Allen underwent an attempted percutaneous removal procedure through the jugular vein. That attempt failed.

On July 13, 2013, Ms. Allen had another attempted removal procedure of the filter through abdominal entry and endovascular aortic repair. The struts of the filter had perforated the vena cava and had progressed to penetrate the aorta and into a vertebral body. All 4 struts were clipped and removed but the filter remains in place. The filter retrieval hook remains embedded in the IVC wall.

2. Kyle Blithe (Case 1:14-cv-06010-RLY-TAB)

Kyle Blithe is a 55-year-old woman who was implanted with a Cook Celect at age 49 on August 15, 2009 after she suffered a pulmonary embolism. At the time of implantation, the filter demonstrated a 12 degree tilt with the apex directed to the left.

A retrieval of the filter was attempted on November 3, 2009. During the attempted retrieval, it was noted that the filter was tilted, with the apex directed to the left with an angle of 32.3 degrees. In addition, the hook of the filter was embedded in the inferior vena cava. Several attempts were made to snare the top of the filter without success and the retrieval was abandoned. After the procedure, the orientation of the filter was more vertical, with the apex angled to the left at 11.3 degrees.

Retrieval of the filter was again attempted on November 12, 2009. The retrieval attempt was abandoned after several unsuccessful attempts to snare the filter. The filter was tilted completely to one side, a tip was embedded in the inferior vena cava and one

limb distally seemed to be eroded all the way through the cava. Only a wire from the filter was removed.

A CT scan performed on November 26, 2009 revealed that the struts of the filter had penetrated the wall of the inferior vena cava and that the retrieval hook was in the left lateral wall.

3. Robert Brady (Case 1:14-cv-06000-RLY-TAB)

Robert Brady, age 60, was 55 years of age when he was hospitalized and found to have bilateral PE and left lower extremity DVT on February 4, 2012. Two days later, Mr. Brady had percutaneous thrombectomy performed and was implanted with a Cook Celect filter. He was started on Lovenox and Coumadin, and was discharged on February 8, 2012.

On July 13, 2012, Mr. Brady was found to have bilateral PE and a massive blood clot in his right groin. Mr. Brady underwent thrombectomy of several large clots just below the filter, with near complete resolution.

On September 26, 2012 to evaluate whether the clots had resolved and the filter could be removed, the filter was visualized on a CT scan with the filter legs protruding outside the IVC, with one strut abutting the anterior vertebral body, another abutting the duodenum, and one within the right psoas muscle. These findings were confirmed on CT scans performed on May 27, 2012.

Retrieval of the filter was attempted on October 17, 2012, but was unsuccessful, secondary to the filter being embedded in the wall of the IVC. A second attempt at retrieval was successful on October 29, 2012.

Mr. Brady suffered trauma to his IVC as a result of the need for a complex removal. On November 2, 2012, he was found to have an intramural hematoma and focal dissection flap of his IVC at and below the level of the renal veins, with caval narrowing and a small pulmonary embolus.

Mr. Brady underwent dissection of his IVC and angioplasty to smooth out the IVC on November 8, 2012. An MRA of Mr. Brady's abdomen was performed on November 27, 2012, demonstrating continued stenosis of the infrarenal IVC, which was noted to be secondary to the filter removal procedure. He underwent another IVC venoplasty on November 8, 2012.

Mr. Brady underwent a venoplasty and angioplasty again on December 10, 2012. MRI's have demonstrated the stenosis of his IVC and thickening of the caval wall to be gradually improving.

4. Tonya Brand and Allen Brand (Case 1:14-cv-06018-RLY-TAB)

Tonya Brand is a 51-year-old woman who was implanted with a Cook Gunther Tulip filter at age 44 on March 19, 2009. The filter was placed "prophylactically" as Mrs. Brand was scheduled to undergo back surgery, however Mrs. Brand had experienced a DVT in 2007.

On June 16, 2011 a venous Doppler study detected a foreign body in Mrs. Brand's medial right thigh. Four days later Mrs. Brand noticed a foreign object protruding from the skin on her thigh and pulled out a piece of metal. This was later determined to be a fractured piece of the IVC filter. On June 23, 2011, diagnostic imaging determined that

her IVC filter had two fragmented legs. One of fragments was seen along the posteromedial aspect of the filter overlying the L2-L# level. The second fragment's location was not identified. On June 23, 2011 a CT scan was performed that confirmed the filter had fractured.

On July 14, 2011, an attempt was made to remove the filter percutaneously through a jugular approach. The hook at the apex of the filter had become embedded in the caval wall, and the retrieval attempt was abandoned after several unsuccessful attempts to snare the hook.

An open surgery was performed on October 22, 2015. At that time, three struts were penetrating the wall of the vena cava and there was perforation of at least one strut into the aorta. The filter was removed but the fractured pieces from the filter could not be recovered and remain in her body. One piece remains in the psoas muscle at the L3 level. A second fragment is lodged at the T12-L1 level.

5. Donna Newsome (Case 1:14-cv-06015-RLY-TAB)

Donna Newsome was 48 years old at the time her Cook Celect IVC filter was implanted on October 5, 2012, for short-term use associated with back surgery.

On November 10, 2012, a pulmonary embolism was identified within the right lower lobe of the pulmonary artery and retrieval of the filter was scheduled for December 18, 2012. At that time, the cranial hook and apex of the filter were found to be embedded in the posterior inferior vena cava wall and the filter could not be removed. Post procedure vena cavagram showed no change in the position of the filter.

A January 22, 2014 inferior venacavagram at Houston Methodist Willowbrook Hospital demonstrated that two posterior wires were protruding (perforating) extensively through the vena cava walls.

Ms. Newsome had open removal of the device on August 26, 2014, at which time it was noted that the struts of the filter were exiting through the wall of the vena cava with several of the struts of the filter perforating the serosa of the duodenum. After freeing the proximal portion of the filter, the twisted struts were cut with wire cutters and the remainder of the filter was removed.

6. Ginger Sumner (Case 1:13-cv-01845-RLY-TAB)

Ginger Sumner age 52, was implanted with a Cook Celest filter on July 2, 2010 after anticoagulation therapy proved unsuccessful in treating her deep vein thrombosis. She has protein S deficiency. A CT scan in June 2011 revealed that one strut may have perforated.

On November 21, 2011, a CT scan confirmed that the strut had penetrated her vena cava.

On July 15, 2014, Ms. Sumner experienced sharp pain and was taken to the hospital by ambulance. She was discharged a few days later while the hospital assembled the surgical team needed to remove the filter. On July 20, 2014, the filter was found to have perforated the right side of her periureteral area, spine, aorta, and duodenum, and a strut had fractured and embolized to her lung.

Ms. Sumner underwent open surgery to remove the filter on July 25, 2014. Although the filter itself was successfully removed on July 25, the surgical team was unable to remove the strut in her lung and the one that had lodged in her spine.

7. Tammy True (Case 1:14-cv-06004-RLY-TAB)

Tammy True is a 46-year-old woman who was implanted with a Cook Celect filter on March 28, 2010 after developing a pulmonary embolism. A CT scan on March 11, 2011 revealed that struts from Ms. True's device had perforated the vena cava in three different places – one prong into her aorta, another into her duodenum, and another into an adjacent vertebral body.

Ms. True underwent an attempted percutaneous removal on March 18, 2011. During the procedure, several of the perforating struts were withdrawn back within the lumen but the struts were then seen facing her heart. The strut perforating her spine was fractured and could not be removed. Ms. True underwent open removal surgery on March 29, 2011. The surgery was successful as to removal of the filter, which required a dissection of part of Ms. True's vena cava. However, the fractured strut perforating Ms. True's L3 vertebra could not be removed. Ms. True had another filter implanted on April 6, 2011 and it remains.

B. Cook Defendants' Selections

1. John Alford (Case #1:14-cv-01870-RLY-TAB)

John Alford, age 60, was implanted with a Cook Celect filter on November 30, 2011, due to deep vein thrombosis with factor V Leyden deficiency. The procedure was a percutaneous implant through the jugular vein.

In 2012, it was noted that the filter had perforated the vena cava. Doctors noted the filter was unable to be removed because it is tilted and embedded in the wall of the vena cava.

2. Donna Avery-Montgomery (Case #1:14-cv-01871-RLY-TAB)

Donna Avery-Montgomery, age 51, was implanted with a Cook Gunther Tulip filter at age 42 on April 5, 2007, prophylactically after a car accident.

On March 22, 2012, Ms. Avery-Montgomery was diagnosed with erosion (perforation) of the IVC wall by the IVC filter. That same day, doctors noted that the device was unable to be retrieved due to the perforation of four struts through the IVC wall.

3. Elizabeth Hill (Case 1:14-cv-06016-RLY-TAB)

Mrs. Hill is 62 years old, and was implanted with a Cook Celect filter on 11/17/10. She was considered a risk for DVT and pulmonary embolus in conjunction with spinal surgical intervention. She was instructed by her orthopedic surgeon to have the filter removed and an unsuccessful attempt to do so was attempted on February 23, 2011 in Florida.

Subsequently, Mrs. Hill experienced abdominal pain and vomiting and in the context of an endoscopy on or about August 15, 2013 it was discovered that the filter had

migrated and was perforating the vena cava and duodenum. The filter was removed on August 21, 2013.

4. Arthur Gage (Case #1:14-cv-01875-RLY-TAB)

Arthur Gage is a 66 year old man who was implanted with a Cook Gunther Tulip filter at age 61 on April 28, 2009.

On December 3, 2013, Mr. Gage was diagnosed with an IVC filter perforation of the IVC wall. Doctors noted that the filter was not retrievable due to the tilt of the filter. Mr. Gage has had multiple episodes of DVT since the filter implant.

5. Linda Johns (Case #1:14-cv-01877-RLY-TAB)

Linda Johns is a 54 year old woman who was implanted with a Cook Celest Inferior Vena Cava Filter at age 47 on April 28, 2009.

In 2012, Ms. Johns was diagnosed with recurrence of deep vein thrombosis post implant.

6. Letitia Perry-O’Farrow (Case 1:14-cv-01875-RLY-TAB)

Letitia Perry-O’Farrow is a 49-year-old woman who was implanted with a Cook Celest at age 43 on July 15, 2010. The filter was placed prophylactically as Ms. Perry-O’Farrow was scheduled to undergo bariatric surgery.

On August 20, 2010 Ms. Perry-O’Farrow presented for the scheduled removal of her IVC filter. An attempt was made to retrieve the filter using a percutaneous jugular approach. The filter was found to be tilted posteriorly and laterally to the left. Several

attempts were made to snare and remove the filter, but the filter was embedded and could not be retrieved. Some damage to the filter legs was noted after the retrieval attempt. On July 01, 2013, a CT scan revealed limbs extending into the right renal vein and a fragment of the filter outside the IVC.

The filter and the fractured strut remain in Mrs. Perry-O'Farrow's body.

7. Daniel Shafer (Case 1:13-cv-01946-RLY-TAB)

Daniel Shafer, age 61, was implanted with a Cook Celest filter at age 54 on October 19, 2011. The filter was placed prophylactically as Mr. Shafer was scheduled for a back surgery; however, Mr. Shafer had a history of DVT in March of 2011 and had difficulty regulating his Coumadin to stay within therapeutic levels. The back surgery was never performed.

On October 28, 2011, Mr. Shafer had swelling in his legs and pain in his right leg. Radiologic imaging demonstrated no evidence of DVT within the left lower extremity. A CT scan on October 29, 2011 indicated his iliac veins and IVC were distended up to the level of the IVC filter. There was also mild inflammation surrounding the IVC with multiple small para-aortic and juxta caval lymph node present. Possibility of IVC acute thrombophlebitis raised. The discharge summary from the October 2011 hospital stay is dated November 04, 2011 and includes a diagnosis of IVC thrombosis with IVC filter in place and right lower extremity DVT. A CT scan from September 18, 2012, notes chronic appearing occlusion from right groin to the IVC of note. The CT report from the September hospital stay states the acute vein thrombosis involving the IVC and bilateral iliac veins

were seen on CT from October 29, 2011. This case involves post-thrombotic syndrome emanating from an IVC filter.

### **III. Discussion and Identification of Representative Trial Cases**

A. “The defense picks” are not representative of the Cook IVC filter cases filed in the MDL.

In exploring the cases chosen by Cook as discovery pool cases (“defense picks”), several observations should be made.

Two of the defense picks, Avery-Montgomery and Gage, involve Gunther Tulip filters. Given the Court’s directive that the trial selections should represent the whole of the MDL (which are a majority Celect filter cases), with primary focus on the Celect filter, we respectfully submit that if a Tulip case is required the case most representative of the of complexities in this MDL is the Tonya Brand case, which will be discussed in the next section of this brief.

Avery-Montgomery is a Gunther Tulip case and involves issues apart from those presented by filter failure and challenge the plaintiff rather than the product. This issue involves the Plaintiffs’ capability to successfully participate in trial in any meaningful way. Avery-Montgomery suffers from severe emotional and anxiety related medical problems that will make it difficult, if not impossible, for her to attend and participate a trial of her case.

Gage is a Gunther Tulip case involving recurrent DVT. Though this injury may certainly be related to the presence of the filter, this problem alone is not representative of

a complication present in any significant number of cases – especially given that Gage suffered from venous thrombotic issues prior to implantation of the filter. This is not a “failure mode” identified by the Court as appropriate for treatment in this process.

Johns is another case that involves post implant DVT’s, and Johns has no other true failure mode associated with her filter. While the post implant thrombotic events are likely caused by the presence of an unretrieved filter, this class of cases was not identified by the Court for Bellwether treatment at this time.

Alford is another case that is not representative of the MDL filings as he suffers from the Factor V clotting disorder. A Factor V case might otherwise be a triable and more representative case if the victim had a known injury other than an embedded filter. In Alford’s case it is believed that the genetic clotting issues that can affect the hemodynamics of the blood stream. It is the hemodynamics of the blood stream that is affected by the presence of a retained IVC filter. A defense verdict would not tell the Court or the parties anything about the likelihood of recovery in an embedded filter case that involves a Plaintiff without a genetic clotting disorder.

Daniel Shafer’s case involves a significant injury – a post implant thrombus and collection of clot below the IVC filter and could be related to the embedded filter, but Shafer has preexisting clotting problems including a pre-implant deep vein thrombosis.

Hill and Perry-O’Farrow are the other two “defense picks”. Hill had a filter that was perforating the vena cava into the duodenum, but the filter was successfully removed. Because of Hill’s recovery it does not appear that she has any signature injury with any

major sequellae from signature injury. Perry-O’Farrow’s filter was damaged in the attempt by her physician to retrieve it, and now she has a fractured strut in her body after that failed retrieval attempt. The filter also remains in her body. This retrieval injury/condition of filter will create issues that are not representative.

It appears from the list of defense picks that the likely reason those cases were chosen by Cook is that, as a whole and individually as well, the respective “defense pick” plaintiffs either do not suffer from significant sequellae or that they have a preexisting condition or filter damage during retrieval that will be argued is iatrogenic and unrelated to any filter failure.

#### **IV. Plaintiffs’ Bellwether Trial Recommendations**

This Court directed the parties to select cases for the process that are “as representative of the whole MDL as possible, primarily alleging injuries from the Celect IVC filter due to migration, IVC perforation, and an inability to be removed.” April 15, 2016 Order at 3. Based on that direction, Plaintiffs recommend the following cases:

1. Ginger Sumner
2. Robert Brady
3. Tonya Brand

In accordance with this Court’s Order, these are cases that involve Celect filters (Sumner and Brady) and a representative Gunther Tulip case (Tonya Brand) and involve injuries due to migration, perforation, and the inability to remove the filters. Out of an abundance of caution given the comment of the court regarding the “Celect” cases as being the majority of the filed cases, plaintiffs submit the Donna Newsome case as the third pick

in the place of Brand should the court desire that the Celect filter cases are the only ones to be considered as it is a Celect filter case. Plaintiffs continue to believe that all of the seven “plaintiff picks” as outlined above are representative as all involve the signature failures the court suggested as being proper for selection.

Plaintiffs would also state that any suggestion by Cook that a fracture case or an open removal case is not representative for purposes of trial is misplaced and erroneous. It is open retrieval that many times becomes the necessary result of the signature failure modes the court has outlined. In other words there is no “open retrieval” in the absence of a migration, penetration, or embedded filter. That the plaintiff who suffers from a perforated vena cava from a strut that has penetrated it or suffers from a fracture of a filter (which is now well known to bring forth tilt, embedded filter and the unretrievable filter) does not make it an outlier. It makes it a more representative case of what can (and we now know will) happen if the filter stays in long enough.

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 20<sup>th</sup> day of May, 2016, a copy of the foregoing was served electronically and notice of the service of this document will be sent to all parties by operation of the Court's electronic filing system to CM/ECF participants registered to receive service in this matter.

*/s/ Ben C. Martin*

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