**BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION**

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| **IN RE: COOK IVC FILTERS PRODUCT LIABILITY LITIGATION** | : | **MDL DOCKET NO. _____** |

# PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. §1407

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*v. Cook Medical Incorporated, et al., 1:13-cv-00013 (D.S.IN 2013)*

## I. INTRODUCTION

The Scheduled of Actions (hereinafter referred to as "Related Actions" (Exhibit A)) are product liability cases being asserted against Cook Medical, Incorporated alleging defect in its IVC filter, a medical device placed in the inferior vena cava to catch blood clots and stop them from travelling to the heart or lungs. The cases generally allege defective design, misrepresentation in marketing, and failure to warn doctors and patients. There are twenty-seven (27) cases in eleven (11) different jurisdictions from all over the United States as follows:

1. Southern District of Indiana (14 cases)
2. Middle District of Pennsylvania (2 cases)
3. District of Nevada (2 cases)
4. Middle District of Tennessee (2 cases)
5. Central District of California (1 case)
6. District of Montana (1 case)
7. Eastern District of North Carolina (1 case)

8. Northern District of Ohio (1 case)
9. Eastern District of Washington (1 case)
10. Northern District of West Virginia (1 case)
11. Western District of Kentucky (1 case)

## II. SUMMARY OF THE CASE AND THE ALLEGATIONS OF PRODUCT DEFECT

1. Defendant Cook Medical is a family owned company with its world headquarters housing nearly 2500 employees in Bloomington, Indiana.

2. The products at issue in the "Related Actions", as attached hereto as Exhibit A were manufactured and made in Bloomington, Indiana.

3. Defendants design, market, and sell IVC filters, which are medical device products that are designed to prevent recurrent pulmonary embolism via placement of the filter in the vena cava. One such Defendant's product, the Cook Celect Vena Cava Filter, is introduced via an 8.5 French coaxial introducer sheath system. The Cook Celect Filter Set is collectively referred to herein as the Cook Filter. Another such Defendants' products, the Gunther Tulip Vena Cava Filter, is introduced into the vena cava via a 7 or 8.5 French coaxial introducer sheath system, depending on the insertion location: femoral or jugular.

4. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filter device and/or its components under Section 510(k) of the Medical Device Amendment.

5. On or about November 10, 2003, Defendants obtained Food and Drug Administration ("FDA") approval to market the Gunther Tulip Cook Filter device and/or its components under section 510(k) of the Medical Device Amendment.

6. On March 19, 2008, Defendants obtained Food and Drug Administration ("FDA") approval to market the Cook Filter device and/or its components under section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device.

7. An IVC filter, like the Cook Filter, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered "pulmonary emboli" or PE. PE presents grave risk to human life and often results in death.

8. The Cook Celect Filter is a retrievable filter, and is based on the Gunther Tulip filter. The Cook Celect Filter and Gunther Tulip filter have four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

9. Plaintiffs all allege that the Cook filter was widely advertised and promoted by the Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava when in fact, Defendants knew its Cook Filter was defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

10. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology electronically on March 30, 2011 and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

11. This same study reported that tilt was seen in forty percent of the implanted Gunther Tulip and Celect IVC filters. Defendants knew or should have known that their IVC filters were more likely than not to tilt.

12. The Defendants failed to disclose to physicians, patients or Plaintiffs that its Cook Filter was subject to breakage and migration. Further, the Defendants continued to promote the Cook Filter as safe and effective even when inadequate clinical trials had been performed to support long or short to efficacy.

13. Plaintiffs all allege that the Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filter, as aforesaid.

14. The Cook Filter is constructed of conichrome. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

15. The failure of the Cook Filter is attributable, in part, to the fact that the Cook Filter suffers from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo. Plaintiffs allege that Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filter, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

16. Plaintiffs in the "Related Actions" further allege that the Cook Filter was designed, manufactured, distributed, sold and/or supplied by the Defendant, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendant's knowledge of the products failure and serious adverse events being caused by the product.

## III. PENDING ACTIONS

Movants' counsel is aware of twenty-seven (27) filed cases in eleven (11) different jurisdictions (Exhibit A). There may be other pending federal actions of which Movants are unaware. Pursuant to Panel Rule 7.5(e) regarding notice of "tag-along" actions, these actions should also be transferred. It is anticipated that other Plaintiffs will file additional federal actions against the Defendants based on the same or similar legal theories. Counsel for the Plaintiffs listed herein collectively have another hundred or so similar cases to prosecute.

## IV. ARGUMENT

### A. The Panel Should Consolidate the Related Actions against Cook in one Court

With more filings to come, consolidating these 27 actions pending in 11 different districts for pretrial proceedings will promote Section 1407's goals of insuring the just and efficient conduct of the actions and avoiding inconsistent or conflicting substantive and procedural determinations.

It is expected that the depositions of corporate witnesses will be the same in each of the Related Actions and consolidation will avoid them being repeated. Additionally, the general causation expert discovery and depositions will be the same for all or nearly all of the claims.

The general liability (product defect) written discovery will be the same in each of the Related Actions. In other words, the design, safety, marketing, and performance of the allegedly defective product will be at issue in each of the Related Actions and discovery on those issues will be virtually identical for all the cases.

The electronically stored information (ESI) issues will be the same in each of the Related Actions.

While fact specific information relative to the plaintiff will vary, an MDL court could easily establish Plaintiff Fact Sheet categories that are identical for all plaintiffs. In other words, the general categories of plaintiff specific information will be the same for each case, even as some of the plaintiff specific information will certainly vary. In sum, much common case needs will be the same in every case and consolidation would reduce waste and duplication.

B. The Panel Should Assign this consolidated proceeding to the Southern District of Indiana where Cook Medical is headquartered.

The United States District Court for the Southern District of Indiana is an appropriate transferee forum to hear this complex litigation for a series of reasons:

It is the home of the Cook Medical defendants. Cook was founded in 1963 in Bloomington, Indiana. (See www.cookmedical.com/about). Cook Medical's world headquarters in Bloomington, Indiana is home to 2,478 employees. That's more than the total population of the nearby town of Spencer, Indiana. (See www.cookmedical.com/about).

The evidence necessary in these matters will be found in the district as the products alleged to be defective were all made there and importantly, over half of all of the currently filed "Related Actions" are filed in the Southern District of Indiana. Specifically, fourteen (14) of the twenty-seven (27) Related Actions are already filed in the district.

Many and perhaps most of the corporate witnesses and documents will be located in the district and the products at issue were made in the transferee forum district.

In conclusion it is hard to imagine a more appropriate forum than that of where the Defendants made, marketed and sold the product and where the Defendant is headquartered

C. The Panel has been down this road many times, and has consistently ruled in favor of consolidation where so many product liability personal injury actions were pending in so many different districts, and has repeatedly found that the home of the manufacturer of the product at issue is an appropriate transferee forum insofar as witnesses and documents will be found there, especially when over half of the Related Action are already pending in the home forum for the defendant as they are here.

Petitioner offers the following few examples of similar litigations that were consolidated for the same reasons this medical device litigation should be consolidated:

1. Twenty (20) pending product liability cases were transferred by this panel to the Northern District of Georgia because centralization was necessary for just and efficient disposition of pretrial proceedings, where an allegedly defective product had been

manufactured and packaged in defendant's factory in Georgia and relevant documents and witnesses were likely located in Georgia. In re Conara Peanut Butter Prods. Liab. Litig. 528 F.Supp 2d 1343 (2007, Jud Pan Mult Lit).

Here, the same logic holds true. There are twenty-six (26) product liability actions that should be consolidated in the home district of the defendant where the product at issue was made.

2. Although "swine flu" actions differed in certain respects, Panel was persuaded that twenty-six (26) actions pending in seventeen (17) federal districts involved substantial common questions of fact concerning development, production, testing and administration of "swine flu" vaccine and transfer was necessary in order to prevent duplicative discovery concerning same documents and witnesses and to eliminate possibility of conflicting pretrial rulings. In re Swine Flu Immunization Prod. Liab. Litig., 446 F. Supp 244 (1978, Jud Pan Mult Lit).

Here, there are a large number of Related Actions and also a large number of different venues spread around the country and because there are substantial common questions of fact concerning the product (IVC filter), transfer is necessary to prevent duplication and to eliminate risk of inconsistent rulings.

3. Product liability actions involving causal relationship between ingestion of defendants' product and contraction of severe side effects , and defendant's foreknowledge of these side effects, merited centralization pursuant to 28 USC 1407 in order to prevent duplication of discovery and eliminate possibility of conflicting pretrial rulings. In re Upjohn Co. Antibiotic "Cleocin" Prod. Liab. Litig., 450 F. Supp 1168 (1978 Jud Pan Mult Lit).

Here, injuries are alleged to have occurred from product failure (filter migration, tilt, perforation, and fracture) and plaintiffs all allege that defendant knew or should have known that the product would fracture, for example. Such questions merit centralization for purposes of consolidating discovery to reduce judicial waste.

4. Thirty-One (31) actions arising out of allegations involving drug manufacturer's marketing and manufacturing of two anti-inflammatory prescription medications were centralized in Northern District of California because all actions focused on alleged increased health risks from taking prescription medications and whether manufacturer knew of increased risks and failed to disclose them to medical community and consumers and/or improperly marketed medications to both of those groups. In re Bextra and Celebrex Prod. Liab. Litig., 391 F.Supp 1377 (2005 Jud Pan Mult Lit).

Here, twenty-seven (27) actions arise out of allegations that Cooks IVC filter is defective and that its marketing and manufacture was negligent. All cases focus on health hazards resulting from failure of the IVC filter and allegations of failure to warn doctors and consumers.

5. Transfer and consolidation of pretrial proceedings was appropriate under 28 USC §1407 because plaintiffs' thirteen (13) products liability actions involved common fact questions as to design, safety, testing, marketing, and performance of hernia patches manufactured by defendants and one defendant's headquarters was located in transferee forum. In re Kugel Mesh Hernia Patch Prods. ,Liab. Litig. 493 F.Supp 1371 (2007 Jud Pan Mult Litig)

This is perfectly analogous. Kugel Mesh Hernia Patch Product litigation was centralized based on common questions of fact that all personal injury product liability

cases contained and it was assigned to the district where one of the defendants was located. Here, Cook Medical's world headquarters are located in the proposed transferee district *and* over half of the Related Actions are already filed in the Southern District of Indiana.

6. Pending actions, concerning class litigation against manufacturer of Avandia ad its sister drugs, were transferred to forum where manufacturer's principal place of business was located, witnesses and documents were likely to be found, and where tag-along cases were filed. Dabon v. GlaxoSmithKline, Inc., (In re Avandia Mktg.), 528 F.Supp 1339 (2007 Jud Pan Mult Lit).

Once again, similar claims against a medical device (or drug) manufacturer should be consolidated in a district where the manufacturer's principal place of business is fund, and where witnesses, documents and tag-along cases are also found.

**WHEREFORE**, plaintiffs seek that this Panel order that the "Related Actions" and all tag-alongs be consolidated and coordinated for pretrial proceedings before the United States District Court for the Southern District of Indiana.

Date: July 21, 2014

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that I served a true and correct copy of the foregoing PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. §1407 this 21st day of July, 2014 upon the following persons, by JPML CM/ECF filing:

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