

**BEFORE THE UNITED STATES JUDICIAL PANEL
ON
MULTIDISTRICT LITIGATION**

In re: Cook Medical, Inc. IVC Filters)	
Marketing, Sales Practices and Products)	MDL No. 2570
<u>Liability Litigation</u>)	

**COOK DEFENDANTS' RESPONSE TO MOTION FOR TRANSFER AND
COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. 28 U.S.C. § 1407**

Defendants Cook Medical Incorporated (“CMI”) (which is alleged in some cases to be also known as Cook Medical, Inc.), Cook Incorporated d/b/a Cook Medical (“Cook”), Cook Group Incorporated (“Cook Group”) (sued in some cases as “Cook Group, Inc.”) and William Cook Europe ApS (“WCE”) (collectively “Cook” or “Cook Defendants”), by counsel, respectfully submit this Response to the Motion for Transfer and Coordination or Consolidation to the Southern District of Indiana pursuant to 28 U.S.C. § 1407 (Dkt. No. 1) (“Motion for Transfer”) and Plaintiff’s [sic] Memorandum of Law in Support of Motion for Transfer and Coordination or Consolidation under U.S.C. § 1407 (Dkt. 1-1) (the “Memorandum”).

I. Introduction

While the twenty-seven (27) product liability cases in eleven (11) jurisdictions listed in Plaintiffs’ Schedule of Actions exist, Plaintiffs’ characterization of the commonalities among them and the efficiencies that would result from granting the Motion for Transfer is overstated. The pending cases allege a number of different device “failures” involving Cook Defendants’ vena cava filter products. The alleged “failure” for the devices at issue varies in each case from perforation, fracture, migration, and tilt, to those in which the allegations are that the device is simply unable to be retrieved or removed, something that is hardly guaranteed. These distinctly

different “failures”, if any at all, have been investigated by Cook Defendants in the pending matters, where sufficient medical records and imaging have been provided or obtained, in previous litigation of these claims and as part of Cook’s normal complaint investigations. Cook’s investigation has revealed that, based on the limited information available to it, each case is the result of a uniquely different series of events. For example, a patient’s pre-existing conditions and a patient’s hospital and medical care, including the experience of his or her physician, can be critical to performance of the device. There is not sufficient commonality among these cases to warrant granting the Motion for Transfer.

In addition, the Günther Tulip™ and Celect® vena cava filters are two different products, with their own subset product lines, for which nine (9) separate clearances to market have been granted by the United States Food and Drug Administration (“FDA”) pursuant to Section 510(k) of the Medical Device Amendments to the Food, Drug & Cosmetic Act (the “MDA”). There are now fourteen (14) different variations of those products for sale in the United States. Based on the information available to date on the cases identified in the Motion for Transfer, at least seven different vena cava filters are at issue in these 27 cases.¹

To the extent that discovery or other pretrial matters may be duplicative, there are alternative methods of dealing with such issues that do not involve transfer and coordination or consolidation pursuant to Section 1407. Cook is entitled to have Plaintiff’s Motion for Transfer denied.

¹ Plaintiffs, in fact, often cannot identify or confirm (*via* a Lot #), which device is at issue other than to state it was a “Cook Celect” or “Cook Tulip.”

II. Factual Background

A. Cook's Vena Cava Filter Products

Pulmonary embolism ("PE") is a dangerous condition in which the vessels of the lungs become blocked by a large blood clot. Blood clots typically form in the legs and travel to the lungs, where they become trapped in the small blood vessels. It is normal for some small blood clots to form in the bloodstream. These harmless clots break down naturally due to the flow of blood through the vessels. But, large clots that do not break down on their own may become PE.

One of the most common causes of PE is a condition called deep vein thrombosis ("DVT"). DVT occurs when a blood clot forms inside a major vein, commonly in the legs. These blood clots can form for many reasons, including a period of travel, such as long plane rides, ordered bed rest during pregnancy, serious injury, recent surgery, a genetic blood-clotting disorder, cancer, birth control pills or hormone replacement therapy. Experts estimate that up to 600,000 people suffer from PE every year. Most are caused by DVT. About one in three of these people can die if they are not treated.²

WCE, which is located only in Bjaeverskov, Denmark, manufactures and sells a variety of medical devices, including the inferior vena cava filters at issue which are used to address recurrent PE in a variety of circumstances. WCE manufactures the Günther Tulip™ Inferior Vena Cava Filter ("Günther Tulip") and the Celect® Inferior Vena Cava Filter ("Celect"). Attached for your convenience as **Exhibit A** are diagrams of a vena cava, a Celect filter catching a blood clot and illustrations of both devices.

² National Heart Lung and Blood Institute. PE. National Heart Lung and Blood Institute Web site. <https://www.nhlbi.nih.gov/health/health-topics/topics/pe>. Accessed on August 13, 2014.

The Günther Tulip and the Celect are Class II medical devices sold by CMI in the U.S. Cook first received clearance to market the Celect in the U.S. from the FDA pursuant to Section 510(k) of the MDA in April 2007, and subsequent clearance was granted in March 2008, April 2009, March 2012, May 2012, and July 2012 following additional 510(k) submissions. While Cook expects plaintiffs to note that Cook's application for 510(k) clearance to market the Celect stated that it was "substantially equivalent" to the Günther Tulip as a "predicate device," "[a] claim of substantial equivalence does not mean that the new and predicate devices must be identical." See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (a copy of which is attached hereto as **Exhibit B**). For example, the Celect was designed differently than the Günther Tulip in order to be more easily retrievable. See **Exhibit A** for comparison illustrations.

The Günther Tulip was first released for sale in Europe in 1992 and in the U.S. in 2000. Cook was granted 510(k) clearance to market the Günther Tulip in October 2000, and subsequent iterations were granted clearance in October 2003, May 2005, and November 2007. In the approximately five-and-a-half-year period beginning October 1, 2008 and ending March 14, 2014, over 181,325 Celect filters were sold worldwide and over 167,759 Tulip filters, so over 349,000 filters total. The incidence of the failures alleged by Plaintiffs is well below one percent (1%) for both devices.

The Intended Use of the Celect and the Günther Tulip filters are outlined in the Instructions For Use ("IFU") which accompany each device. An example Celect IFU is attached

hereto as **Exhibit C**. The Celect and Günther Tulip Filters are intended for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anti-coagulant therapy is contraindicated;
- Failure of anti-coagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anti-coagulant therapy has failed or is contraindicated. The product can be permanent or retrievable.

FDA cleared the filters to be placed in the vena cava by accessing it through the femoral or jugular vein. A diagram of a Celect jugular and femoral placement is attached hereto as **Exhibit D**. Physicians are to use diagnostic imaging during placement with the target area for placement being just below the renal veins in the straight portion of the vena cava. Accurate and adequate placement of the devices is critical to the devices performance. Subsequent medical care, follow-up and monitoring is also critical.

WCE also manufactures a retrieval set that has been cleared by FDA for use with both the Günther Tulip and Celect. There are specific procedures for proper retrieval of the Günther Tulip or Celect filter which are outlined in the IFU which accompany the retrieval sets. An example retrieval illustration is attached hereto as **Exhibit E**. Generally, filters are retrieved when the patient has achieved a significantly reduced risk of pulmonary embolism through anti-coagulation and other therapies. How long a filter is retrievable depends on the filter, each patient and his or her physician. No guarantee for retrieval is provided.

B. Plaintiffs' Motion for Transfer Misrepresents Cook's Products

In the twenty-seven cases listed in Plaintiffs' Schedule of Actions, Plaintiffs have generally alleged that a defect in the design of the filters make them more likely to fracture, migrate, tilt or perforate the inferior vena cava, sometimes causing damage to surrounding

organs. In many instances, plaintiffs do not recognize or acknowledge the warnings provided by Cook in the IFU to the physicians that place the device, the “learned intermediary” between the Plaintiffs as patients of those physicians and Cook. Cook’s IFUs accompany every filter into the hands of the Plaintiff’s physician. Nor do Plaintiffs seem to recognize that how the filter is retrieved or sought to be retrieved, as well as how other conduct of a physician and other healthcare providers may have played a significant role in causing or contributing to the alleged injuries. The scope and significance of the alleged injury arising from the filter is disputed in all cases (Cook has not yet been able to obtain all of the hospital and medical records, including imaging, necessary to fully investigate each case). In some cases, the plaintiffs challenge the adequacy of Cook’s IFU warnings and the adequacy Cook’s testing and analysis of what they describe as the design changes made from the Günther Tulip to the Celect. Cook Defendants have denied these allegations and will continue to vigorously defend their products.

The filters at issue have a long proven track record. In fact, the Günther Tulip and the Celect are among the top-selling inferior vena cava filters in the world. They are supported by a significant amount of clinical research data. Their proven track records are as long as those of any filter products available today.

Cook does not dispute the existence of the study cited by plaintiffs in paragraph 10 on p. 5 of their Memorandum: Durack JC, Westphalen AC, Kekulawela S, et al. Perforation of the IVC: Rule Rather Than Exception After Longer Indwelling Times for the Günther Tulip and Celect Retrieval Filters. *Cardiovasc Intervent Radiol* 2012; 35:299-308. E pub 30 March 2011. However, while plaintiffs are not incorrect in noting that the Durack study reported perforation rates to be higher than expected, the authors also noted that, “[t]he larger series

suggest that the overall perforation-related **complication rate remains very low**,” *id.*, at 305 (emphasis added), and that, in their study of 272 filters inserted over a two-year time period, “there were **no** documented cases of **symptomatic** IVC filter perforations. . . .” *Id.*, at 303 (emphasis added).

Moreover, later studies have confirmed that, “the reported incidence of **symptomatic** IVC [inferior vena cava filter] perforation is **low** compared with the number of patients in whom IVC perforation is observed.*” McLoney ED, Krishnasamy VP, Castle JC, et al. Complication of Celect, Günther Tulip and Greenfield Inferior Vena Cava Filters on CT Follow-up: A Single-Institution Experience. *J Vasc Inter v. Radiol* 2013; <http://dx.dor.org/10.1016/j.jvir.2013.07.023> (footnotes omitted).

Cook Defendants’ evidence will show that the Celect was not negligently designed or manufactured. Specifically, all of Cook’s design, testing and development, manufacturing, marketing and post-market surveillance of the Celect and Günther Tulip complied with ISO 13485:2003; the Federal Food Drug & Cosmetic Act, Medical Device Amendments, and regulations enacted by the FDA pursuant to those statutes, including 21 CFR Parts 801, 803, 806 and 820; Council Directive 93/32/EEC of the European Communities, The Medical Device Directive; BEK no. 1263 of 15.12.2008, Ministry of Health and Prevention, Denmark; The Canadian Medical Device Regulations SOR/98-282 May 1998; The Australian Therapeutic Goods (Medical Devices) Regulations 2002, and the Australian Regulations Guidelines for Medical Devices (ARGMD); Applicable articles of the Japanese Pharmaceutical Affairs Law (MHLW Ministerial Ordinance no. 169, 2004); MEDDEV 2.7.1 – Guidelines on Medical Devices – Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies –

December 2009; Global Harmonization Task Force “Clinical Evaluation” SG5/N2R8:2007; Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice ISO 14155:2011; and NB-MED/2.12/REC1 plus, as appropriate, MEDDEV 2.12.2/REV6.

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

“The learned intermediary rule provides that the failure of a manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of patient’s injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated.” *Christopher v. Cutter Laboratories*, 53 F.3d at 1192 (citing *Felix*, 540 So.2d at 105 and *Zanzuri v. G.D. Searle & Co.*, 748 F.Supp. 1511, 1517 (S.D. Fla. 1989)). *See also Phelps v. Sherwood Medical Industries*, *supra*, F.2d at 300 (in which the Court approved an Instruction that, if the jurors found that the physician using the defendant’s catheter was already aware of the risk of the catheter breaking if he used it a certain way, ““then you are instructed that the Defendant had no duty to with respect to such potential properties since they were already known *to the user, the operating surgeon.*” (Court’s emphasis)); *Mulder v. Parke, Davis & Co.*, 288 Minn. 332, 181 N.W.2d 882, 885 (“The manufacturer is not liable if the doctor is fully aware of the facts which were the subject of the warning. . . .”).

Thus, while many of the Complaints allege perforation or damage to the vena cava, Cook warned the physicians who implanted the filters of those risks in its IFU for each device, as each IFU specifically lists the following as Potential Adverse Events, among others: “Damage to the vena cava,” “Vena cava perforation,” and “Death.”

The evidence will show that Cook acted with reasonable care in the design of its products. Cook conducted extensive pre-market testing on both the Celect and Günther Tulip, including conducting clinical studies which were not required by FDA. The Celect is more than simply a design modification of the Günther Tulip. The Celect was designed separately and most importantly, independently cleared for market by FDA and the numerous foreign regulatory bodies. Extensive bench tests, animal tests and clinical studies have been conducted for both filters. These test results were then made a part of the 510(k) applications submitted to the FDA. These documents, along with complete copies of the Design History Files, WCE’s Quality Policies have been produced to Plaintiffs’ counsel in most of the cases listed on the Schedule of Actions.

Cook’s evidence will show that perforation of the vena cava by a Celect filter and fracture of a Celect or Günther Tulip filter are extremely rare. For example, between October 1, 2008 and March 14, 2014, Cook sold 181,325 Celect filters worldwide, but only 53 fractures were reported, for an occurrence rate or incidence of just .0292%. During the same time period only 13 migrations 144 perforations were reported, for an occurrence or incidence of just .0072% and .0794%. Cook sold 167,759 Günther Tulip filters worldwide during the same time period, but only 4 fractures were reported, for an occurrence rate or incidence of just .0024%. During the same time period only 7 migrations and 88 perforations were reported, for occurrence or

incidence of just .0042% and .0525%. Moreover, most of these fractures, perforations and migrations did not cause clinically significant complications, which is consistent with the great weight of the medical and scientific literature.

III. Argument

A. Transfer under 28 U.S.C. § 1407(a)

28 U.S.C. § 1407(a) permits transfer of civil actions “involving one or more common questions of fact . . . to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made . . . for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.” However, transfer is not appropriate in all cases, and alternative to transfer exist:

[S]uitable alternatives to Section 1407 transfer are available in order to minimize the possibility of duplicative discovery. For example, notices for a particular deposition could be filed in all actions, thereby making the deposition applicable in each action; the parties could seek to agree upon a stipulation that any discovery relevant to more than one action may be used in all those actions; and any party could seek orders from the three [district] courts directing the parties to coordinate their pretrial efforts.

In re Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litig., 446 F. Supp. 242, 244 (J.P.M.L. 1978). For example, in *In re DuPont Benlate Settlement Agreements Litig.*, Docket No. 1340, 2000 U.S. Dist. LEXIS 7378 (J.P.M.L. May 25, 2000), the Panel denied transfer of 26 actions, finding

that Section 1407 centralization would neither serve the convenience of the parties and witnesses nor further the just and efficient conduct of this litigation. Movant has failed to persuade us that any common questions of fact (as opposed to questions of law) are sufficiently complex, unresolved and/or numerous to justify Section 1407 transfer in this docket in which some constituent actions have already been pending for several years. We point out that alternatives to transfer

exist that can minimize whatever possibilities there might otherwise be of duplicative discovery and/or inconsistent pretrial rulings.

Id. at *2 (citing *In re Eli Lilly & Co.*, 446 F. Supp. at 244 and Manual for Complex Litigation, Third, § 31.14 (1995)).

The Panel has also found that,

[t]he convenience of counsel, however, is not by itself a factor to be considered under Section 1407 in the Panel's decision whether to order transfer or in the selection of a transferee forum for a group of actions. Only if the inconvenience of counsel would impinge on the convenience of the parties or witnesses would the convenience of counsel become a factor to be considered by the Panel.

In re Anthracite Coal Antitrust Litig., 436 F. Supp. 402, 403 (J.P.M.L. 1977); *see also In re Directbuy, Inc., Mktg. & Sales Practices Litig.*, 682 F. Supp. 2d 1349, 1350-51 (J.P.M.L. 2010) (citing *In re Anthracite Coal*).

B. Cases Against the Cook Defendants Relating to Cook's Vena Cava Filter Products Should Not Be Transferred to an MDL.

The factors of § 1407 do not support Plaintiffs' Motion for Transfer. First, the facts of each plaintiff's case are as unique as the plaintiffs themselves. For example, whether each plaintiff was an appropriate candidate for the placement of a vena cava filter is as different a question for each plaintiff as are his or her unique physical and mental characteristics. Similarly, whether Cook's vena cava filters were appropriately used in a given plaintiff depends on that plaintiff's unique medical situation, and the care and skill of that plaintiff's physician who used the Cook vena cava product, including in some cases, the physician who performed or attempted to perform a retrieval of the device. The various plaintiffs' claims do not overlap. Individual discovery on each plaintiff's claim will be required, regardless of whether an MDL is created.

Among the twenty-seven cases listed on Plaintiffs' Schedule of Actions the uniqueness of each case outweighs the commonalities. Thus far, Cook has only been able to confirm the exact device at issue in thirteen of the twenty-seven cases listed on the Schedule of Actions. Among these thirteen there are eleven cases involving some model of the Celec and two involving some model of the Günther Tulip. In total, thus far, there are at a minimum seven different models of the Celec and Günther Tulip products at issue. The FDA clearance dates, the underlying FDA submission and approval, product numbers, IFUs and packaging are all different for these models. These differences weigh against granting the Motion for Transfer. The efficiencies that are obtainable in the context of multiple products at issue in an MDL are already possible and being obtained through the coordination among counsel in the filed cases. There is no reason why this level of cooperation and coordination cannot continue.

The allegations asserted by plaintiffs also vary greatly. Cook's analysis of the twenty-seven claims of which Cook has some knowledge, though generally not all of the hospital and medical records, including imaging, necessary to complete its investigation, is as follows: the *Eslick*, *Huffman*, *Moore*, *Perry-O'Farrow*, *Sumner*, *Wells* and *West* cases involve claims of perforation. The *Carter*, *Cash*, *Shafer* and *Walck* cases involve claims of perforation and fracture. The *Adams*, *Allen*, *Chapman*, *True* and *Wonder* plaintiffs claim perforation, fracture and difficulty with retrieval. The *Angus*, *Bobo*, *Brady*, *Cadena*, *Cadle*, *Elder*, *Jung*, *Metro* and *Padget* cases involve claims of perforation and difficulty with retrieval. *Harris*, *Naly* and *Tasker* involve difficulty with removal. There are no Complaints that allege only fracture.

Although there are some similarities among these cases, the similarities consist primarily of the unverified allegations contained in the Plaintiffs' complaints. For instance, perforation of

the vena cava wall is a matter of definition among physicians. In some cases, a physician may be relying only on an x-ray, and what may appear to be a perforation may be merely “tenting.” A CT scan is the best method for diagnosing a perforation, and it is the method recommended by the Society of Interventional Radiologists. X-rays and CTs are not readily comparable. What may appear to be a perforation on an x-ray may not really be perforation when a CT is done.

Difficult retrievals include at least two scenarios: 1) filter leg embedment due to the natural ingrowth of the filter over time; or 2) filter tilting with the hook of the filter subsequently becoming embedded in the vena cava wall. Retrieval of the devices is possible in either scenario, but doing so may well require a physician who is current with the medical and scientific literature on advanced retrieval techniques and who has the skill and resources necessary to effectively utilize those techniques.

Filter leg fracture can arise in at least two scenarios: 1) a filter leg may be caught in a smaller vein (e.g. a renal vein); or 2) a filter may be manipulated by external forces (e.g. surgery). Secondary legs will typically only fracture if caught by a structure. These scenarios typically involve unusual stress on the device beyond the normal anatomical and physiological loading cycles exerted on filters, and do not imply much less prove a design defect.

Cook Defendants urge the Panel to consider that the number of products at issues; the variations in the types and degrees of injuries; that causation varies significantly with individual factors such as age, medical history, and the amount of time that elapsed from implant of the device until the onset of injuries; and that the substantive law applicable in each action will be that of the State wherein each action was filed, in considering whether consolidation is warranted.

The power of the Internet and television advertising by lawyers in today's world mean that when the Cook Defendants are drawn into highly publicized MDLs, there is a very real threat that they will be drawn into even more cases. That appears to be exactly what is happening, as more and more cases—cases that the Cook Defendants believe to be baseless—are being filed against the Cook Defendants.

The problem with an MDL from the Cook Defendants' perspective is that an MDL makes it easy for plaintiffs to file cases, and for plaintiffs' lawyers who have just a few cases, or who are filing cases later than others did, to live off the work-product of those plaintiffs' lawyers who have been in the MDL longer or who have more cases or resources. To paraphrase a movie line, if you build it, they will come. If an MDL is created, plaintiffs will flock to it, leading to a dramatic growth in the number of lawsuits filed against the defendants in that MDL. Indeed, that has been exactly what has happened in many MDLs around the country.

Plaintiffs assert in their Brief that the “depositions of corporate witnesses will be the same in each of the Related Actions and consolidation will avoid them being repeated,” that the “written discovery will be the same in each of the Related Actions,” and that “the electronically stored information (ESI) issues will be the same in each of the Related Actions” and that an “MDL court could easily establish Plaintiff Fact Sheet categories that are identical for all plaintiffs.” Brief at 7. These are arguments of convenience for Plaintiffs' counsel. The convenience of counsel is not, by itself, a factor to be considered in determining whether transfer is proper under Section 1407. *See In re Anthracite Coal Antitrust Litig.*, 436 F. Supp. 402, 403 (J.P.M.L. 1977); *In re Directbuy, Inc., Mktg. & Sales Practices Litig.*, 682 F. Supp. 2d 1349, 1350-1351 (J.P.M.L. 2010). The individual plaintiffs in the matters listed in the Schedule of

Actions are located all over the country. They should be required to litigate these cases in the District Courts in which they chose to file their cases.

Here, the alternatives to transfer are sufficient to address any potential issues with duplicative fact and expert discovery. *See, e.g., In re DuPont Benlate Settlement Agreements Litig.*, 2000 U.S. Dist. LEXIS 7378 (J.P.M.L. May 25, 2000); *In re Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litigation*, 446 F. Supp. 242, 244 (J.P.M.L. 1978). In fact, to date, the Parties have been coordinating the discovery in all matters, including coordinating the deadlines being established in the various case management plans around the country. Cook Defendants have agreed with Plaintiffs' on an ESI production format to be utilized in all pending matters. The Parties have agreed that written discovery can be used across all cases so long as appropriate protective orders are in place to protect Cook Defendants confidential information and trade secrets. Thus, the Cook Defendants are not opposed to consolidating or coordinating discovery and other pretrial matters in the twenty-seven pending cases listed in the Schedule of Actions and any others, should more be filed, including within federal districts or between different federal districts. As there are only a small number of cases and courts involved, such coordination should not be difficult to achieve. An MDL is not required for such coordination.³

C. This is Not the Same Road as this Panel has Been on Before

Plaintiffs' assert in the final section of their brief that "The Panel has been down this road many times, and has consistently ruled in favor of consolidation where so many product liability

³ Cook Defendants note that if the Panel should grant Plaintiffs' Motion for Transfer, they would agree to the transferee district being the Southern District of Indiana before Chief Judge Richard L. Young and Magistrate Judge Tim A. Baker as they already have an understanding of the issues in cases involving Cook's vena cava filter products and the unique circumstances involved present in each case.

personal injury actions were pending . . .” Brief at 8. The cases cited by Plaintiffs for the proposition that a number of cases warrant granting the Motion for Transfer are distinguishable from the decision before the Panel here on the twenty-seven cases listed in Plaintiffs’ Schedule of Actions.

The twenty (20) product liability cases in *In re ConAgra Peanut Butter Prod. Liab. Litig.*, 495 F.Supp. 2d 1381 (J.P.M.L. July 17, 2007), that were centralized to the Northern District of Georgia because they were manufactured and packaged in defendants factory in Georgia and the relevant documents and witnesses were likely located in Georgia all involved one event of the contamination of peanut butter and the Motion for Transfer was unopposed. *Id.*, at 1382. Here, Plaintiffs allege various injuries and have vastly different medical history which makes their own individual experiences with the devices at issue unique and weighs in disfavor of granting the Motion for Transfer.

Plaintiffs also cite *In re Swine flu Immunization Prod. Liab. Litig.*, 446 F. Supp 244 (J.P.M.L. 1978) for the proposition that common questions of fact concerning the development, production and testing of a product warrants transfer. The “swine flu” vaccine at issue, however, was the same vaccine in each case whereas here, we have at least seven different products at issue.

A third case cited by plaintiffs, *In re Upjohn co. Antibiotic “Cleocin” Prod. Liab. Litig.*, 450 F. Supp. 1168 (J.P.M.L. 1978), is likewise distinguishable. There, the plaintiffs alleged the same severe side effects as a result of taking Cleocin. Again, here, the same product and the same “side effects” or injuries are not present in each case, much less than same product.

Plaintiffs have failed to consider that there are numerous different devices at issue here, and that the particular circumstances of use for each Plaintiff are as unique as is each Plaintiff. These facts warrant proceeding with these matters individually as the Cook Defendants and Plaintiffs have been doing and coordinating discovery amongst cases to the extent possible and necessary.

III. Conclusion

The twenty-seven pending cases against Cook listed in Plaintiffs' Schedule of Actions should not be forced into an MDL because the differences in the products at issue in each case and the individual facts and circumstances of each case outweigh the commonalities. To the extent that there are overlapping discovery and pretrial issues among the pending cases, these can be resolved through coordination between the district courts involved. Transfer under Section 1407 is not required.

The Cook Defendants should be permitted to defend the claims against without being involved in a highly publicized MDL. Creation of an MDL will only lead to more meritless claims being filed against the Cook Defendants, as the existence of an MDL will be one more line in the advertisements of the plaintiffs' lawyers, and one more line in their websites soliciting lawsuits. MDLs foster litigation by making it too easy for plaintiffs and plaintiffs' lawyers to file and pursue lawsuits.

The Cook Defendants respectfully request that Plaintiffs' Motion for Transfer be denied, and for all other proper relief. In the alternative, should the Panel grant Plaintiffs' Motion for Transfer, Cook Defendants consent to the transferee district being the Southern District of Indiana.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2014, I electronically filed the foregoing document with the Clerk of the Panel using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this matter.

/s/ Douglas B. King

Douglas B. King, Esq.