BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

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

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS FOR COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. §1407

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ATTORNEYS FOR PLAINTIFFS ON BEHALF OF THEMSELVES AND OTHERS SIMILARLY SITUATED

Melissa Ebert, and on behalf of all others similarly situated v. C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.; 5:12-cv-12-01253; In the USDC Eastern District of Pennsylvania

I. INTRODUCTION

1. The Schedule of Actions (hereinafter referred to as "Related Actions" (Exhibit "A")) lists the product liability cases being asserted against C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively the "Bard Defendants" or "Defendants"), alleging defective inferior vena cava filters (hereinafter "IVC filters" or "filters"). IVC filters are medical devices placed in the inferior vena cava, ostensibly to catch blood clots and stop them from traveling to the heart or lungs. Recent studies, however, have shown that the filters have no efficacy. In fact, the filters have been shown to double the risk of pulmonary embolism, the very condition which they are intended to prevent. The filed cases generally allege defective design, misrepresentation in marketing, and failure to warn doctors and patients adequately about the risks of the devices and for refusing to warn that the filters were not effective—in other words that they did not work—and that they increased the risk that the patients

receiving their filters would be more likely to develop a pulmonary embolus than if there was no filter implanted at all. There have been at least twenty-five (25) cases filed in twenty-three (22) different federal jurisdictions all over the United States—to wit:

1. Eastern District of Pennsylvania *(3 cases)*
2. Eastern District of Wisconsin *(2 cases)*
3. Southern District of Texas, Houston division
4. Southern District of Texas, Corpus Christi division
5. District of Nebraska
6. Eastern District of Michigan, Southern division
7. Middle District of Georgia, Macon division
8. Northern District of Mississippi, Oxford division
9. Middle District of Florida, Jacksonville division
10. Middle District of Florida, Tampa division
11. Middle District of Florida, Orlando division
12. Middle District of Louisiana
13. Middle District of Tennessee
14. District of New Mexico, Albuquerque
15. Central District of California, Western Division, Los Angeles
16. Northern District of Illinois, Chicago division
17. Northern District of Texas, Dallas division
18. Western District of Texas, San Antonio, division
29. Western District of Virginia, Roanoke division
20. Western District of Missouri, Western division
21. Western District of New York
22. Northern District of Ohio, Western division

II. SUMMARY OF THE CASES AND THE ALLEGATIONS OF PRODUCT DEFECT

2. Defendant C.R. Bard, Inc. is a multi-national corporation which is incorporated and maintains it home office in in New Jersey, but which has a corporate presence throughout the United States.

3. Defendant Bard Peripheral Vascular, Inc. is a division of C.R. Bard, Inc. that maintains its home office in Tempe, Arizona, but sells its products throughout the United States and the world.

4. Defendant C.R. Bard, Inc. manufactures the IVC filters at issue in the "Related Actions". Defendant Bard Peripheral Vascular, Inc. is the division of C.R. Bard, Inc. that designs, markets and sells the IVC filters at issue in the "Related Actions".

5. IVC filters are implanted medical devices marketed as stopping blood clots (called "thrombi") from traveling from the lower portions of the body to the heart and lungs. IVC filters are 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 thromboses" or DVT. Once a thrombi reaches the lungs it is considered a "pulmonary embolus" or PE.

6. The Defendants have designed, manufactured, marketed and sold seven (7) versions of its IVC filter. The first Bard filter was its Simon Nitinol filter, which was and remains a permanent filter, meaning it was intended to be implanted into the body for the life of the patient. Bard then created its second IVC filter-- the "Recovery" filter, which was initially cleared by the FDA only as a permanent device but later received clearance for use as an optional or retrievable filter. Defendants' optional/retrievable filters are represented to be capable of being left in the body permanently but can be removed from the patient after placement. The Recovery filter was replaced on the market by the G2 and G2 Express filters (collectively "G2 filter systems"). The G2 filter systems demonstrated a propensity to

fracture, tilt, perforate and migrate as did its predicate device, the Recovery filter.[1] The G2 filter system evolved into the Eclipse filter system[2], which led to the Meridian filter system[3], and then the current Denali filter system.[4] All of the optional/retrievable IVC filters designed, manufactured, marketed and sold by the Defendants trace their basic conical, multi-leg, nitinol wire construction design to one common predecessor, the Recovery filter, and all continue to share several of the same design defects and complications associated with the Recovery filter and G2 filter systems.

7. Defendants sought Food and Drug Administration ("FDA") clearance to market each of its optional/retrievable IVC filters under the notification provisions of Section 510(k) of the Medical Device Amendments of 1976 to the federal Food, Drug and Cosmetic Act ("Act"). Under Section 510(k) of the Act (21 U.S.C. 321 *et seq.*), an entity engaged in the design, manufacture, distribution or marketing of a device intended for human use may notify the FDA ninety (90) days before it intends to market the device, and may sell the new device based upon a showing that the device is substantially equivalent to a legally marketed predicate device. *See* 21 C.F.R. §§ 807.81, 807.92(a)(3). "Substantial equivalence" means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process.

8. On or about November 27, 2002, Defendants obtained Food and Drug Administration ("FDA") clearance to market the Recovery filter device and/or its components as a permanent IVC filter

[1] On August 29, 2005, the FDA cleared the G2 Filter for use as permanent filter under Section 510k based upon the Defendants' assertion that the device was substantially equivalent to the Recovery filter system. The G2 Filter was later cleared for retrievable use. The G2 Express is the same filter as the G2; it simply incorporated a hook on the cap of the device to aid with its retrieval.

[2] On January 14, 2010, the FDA cleared the Eclipse filter for permanent and retrievable use based upon the Defendants' assertion that the device was substantially equivalent to the G2 filter system.

[3] On August 24, 2011, the FDA cleared the Meridian filter for permanent and retrievable use based upon the Defendants' assertion that the device was substantially equivalent to the Eclipse filter system.

[4] On May 15, 2013, the FDA cleared the Denali filter for permanent and retrievable use based upon the Defendants' assertion that the device was substantially equivalent to the Eclipse filter system.

under Section 510(k) of the Medical Device Amendments. Defendants' notification of intent to market asserted that the Recovery filter was substantially equivalent to the Simon Nitinol Filter ("SNF"), their "predicate device". On July 25, 2003, The FDA cleared the Recovery filter for the additional intended use of *optional retrieval.*

9. The Recovery filter quickly proved to be problematic for the Defendants in that it presented an increased risk of fracturing, titling within the inferior vena cava, perforating the wall of the inferior vena cava (frequently penetrating into other organs and tissues such as the aorta and duodenum), and migrating through the body. *See e.g.*, Hull JE, Robertson SW. Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration. *J. Vasc. Interv. Radiol.*. 2009;20(1):52-60; Nicholson W, *et al*. and Prevalence of Fracture and Fragment Embolization of the Bard Recovery and Bard G2 Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade. *Arch. Int. Med.* 2010 Nov.; 170:1827-31. All six (6) of the "optional" filters (in other words, all of the Defendants' filters except the SNF) employ the same basic design and are constructed of the same materials as the Recovery and G2 filters. All of the Defendants' optional filters have demonstrated the same problems—namely, they migrate, fracture, perforate, and tilt, and, in addition, as referenced above, studies show that they lack efficacy and, indeed, actually increase the risk of PE.

10. Plaintiffs all allege that Defendants' IVC filters were widely advertised and promoted by them as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava when, in fact, Defendants knew or should have known their IVC filters were defective due to, *inter alia*, the filters' inability to withstand normal and expected anatomical and physiological loading cycles exerted *in vivo*.

11. Defendants knew or should have known that their IVC filters were likely to fracture, tilt, perforate the vena cava wall and/or migrate, and thus cause injury.

12. Despite their knowledge, Defendants failed to disclose to physicians, patients or to the Plaintiffs that their IVC filters were subject to fracture, tilt, perforation and migration. Defendants then continued to promote their IVC filters as safe and effective, despite the absence of adequate clinical trials to support long or short term efficacy and even after studies have shown them to lack such 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 their IVC filters, as aforesaid.

14. The failure of the Defendants' IVC filters is attributable, in part, to the fact that they all suffer from a design defect causing them 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 Plaintiffs, their physicians, and the general public on notice of the dangers and adverse consequences caused by implantation of Defendants' IVC filters, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

15. Plaintiffs in the "Related Actions" further allege that Defendants' IVC filters were designed, manufactured, distributed, sold and/or supplied by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of their filters' defects and the serious adverse events resulting therefrom.

III. PENDING ACTIONS

16. Movants' counsel is aware of at least twenty-five (25) filed cases in twenty-two (22) different federal jurisdictions. *See* 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 upwards of two hundred or more similar cases to prosecute.

IV. ARGUMENT

A. The Panel Should Consolidate the Related Actions against the Bard Defendants in One Court

17. With more filings to come, consolidating these twenty-five (25) actions pending in twenty-two (22) different districts for pretrial proceedings will further Section 1407's goals of promoting and ensuring the just and efficient conduct of the actions and avoiding inconsistent or conflicting substantive and procedural determinations.

18. 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.

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

20. While fact-specific information relative to each 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 of the common case needs will be the same in every case and consolidation would reduce waste and duplication.

21. Litigation regarding the Bard Defendants' IVC filters that has occurred to date offers this Panel a unique opportunity—namely, to evaluate the evident waste of judicial resources which has occurred in a mass tort without the guidance and control of a single judge, and then determine whether that waste should be halted by the transfer and consolidation of the proceeding.

22. To date, there have been several experts retained by plaintiffs' counsel to testify as to general liability and causation. Hours upon hours of depositions have been taken of these same experts over and

over about the same subject matter. Literally dozens of hours have been dedicated to the same experts writing report after report because they are required to do so under various scheduling orders. These experts' qualifications have then been attacked time and again by motions to strike their testimony on the very same bases every time. The following chart is demonstrative:

Expert	**Expertise**	**Number of depositions taken (noticed to be taken)**	**Motions to exclude**
William Hyman, Ph.D.	FDA/Marketing	5	10
Robert McMeeking	Testing/Failure modes	2	4
Matthew Begley	Testing/Failure modes	2	4
Robert Ritchie	Metallurgy	4	3
Michael Freeman	Epidemiology	3	6
Suzanne Parisian	FDA/Marketing	5	7

23. Notably, all twenty-one (21) depositions referenced above were taken or noticed in the year 2014 or in the first few months of 2015. There is no indication that the massive discovery efforts undertaken by the Defendants to re-depose and challenge those same experts will ever cease without the efforts of a centralized court with authority to monitor and guide the process. Indeed, the necessity of both parties to move in limine for rulings in so many different courts has brought forth hundreds of individual motions in limine and thousands of interrogatories and requests for production relating to the same information. Indeed, twelve (12) motions for summary judgment have been filed, some even in the same jurisdiction, resulting in different and sometimes conflicting rulings on the same issues.

24. One of the goals of an MDL is to create the opportunity for settlement of cases. Though the terms of the various settlements that have occurred over the past three (3) years are all confidential, it is known that very few cases have resolved over that same time period. There is little reason to believe that the strategy of picking off the cases one by one on the eve of trial will ever change given that the Bard Defendants have refused to enter into any meaningful global settlement discussions. Though bellwether trials may not be the answer to resolution of the IVC filter litigation, less than five percent of cases, filed and unfiled together, have been resolved over the several years of this current litigation. Plaintiffs' counsel is aware of well over two hundred (200) unfiled cases that will be filed in the near future, and it is likely there will be hundreds or thousands more to come.

25. The Bard Defendants are likely to assert that the current IVC filter litigation has advanced too far for MDL consolidation at this juncture. To the contrary, it is well known that "more recently filed actions could benefit from coordination with those that are further advanced, as could the parties in all actions taken as a whole." *A View From The Panel, A Part Of The Solution*", Hon. John G. Heyborn II, 82 Tul.L.Rev. 2225 (2007-2008).

26. In truth, the IVC filter litigation is still evolving, despite the work that has already been done, partially because Defendants' most recent IVC filter products suffer from the same defects as did their older ones, and thus are failing in the same or similar fashion and thus are causing the same or similar injuries. To that end, it is well understood that IVC filters suffer from proportionately higher failure and complication rates the longer they remain in the body. Defendants' Meridian and Denali filters have been on the market less than five (5) years, and thus the failures of these filters have more recently started to accumulate. With the benefit of hindsight regarding the Recovery and G2 litigation, this Court can look ahead with the necessary foresight to determine that MDL centralization can and will benefit both the advanced actions as well as the newer ones.

B. The Panel Should Assign This Consolidated Proceeding to Judge Kinkeade of the Northern District of Texas or Judge Jones of the District of Nevada

27. The ideal transferee judge is one with some existing knowledge of one of the cases to be centralized and who may already have some experience with complex cases, if the new docket appears to require it. P. 22240, T.L.R. Judge James E. Kinkeade, Northern District of Texas, has taken on the task of the DePuy Pinnacle Litigation (*In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation*; 3:11-md-02244) and has, in a little over two (2) years, streamlined the litigation involving over 6,000 cases, including presiding over a bellwether trial. Judge Kinkeade recently presided over the IVC filter case of *Jones v. C. R. Bard, Inc., et al.* (Civil Action No. 3:13-CV-0599; N.D. Texas) which was resolved on the eve of trial. Asked by one of the undersigned counsel, in the presence of counsel for the Bard Defendants in a pretrial matter less than two (2) months ago, Judge Kinkeade indicated that he would not be opposed to participating in the IVC filter litigation as a transferee judge, if requested. "The willingness and motivation of a particular judge to handle an MDL docket are ultimately the true keys to whether centralization will benefit the parties and the judicial system." 82 Tul.L.Rev. 2225 (2007-2008).

28. Judge Robert C. Jones, District of Nevada, has recently presided over the *Kevin Phillips vs. C.R. Bard, Inc., et al; Civil Action No. 3:12-cv-00344* matter, another IVC filter case which was resolved after two (2) weeks of trial. Given his experience with the complete work-up of the case, and two (2) weeks of trial, Judge Jones might well know the litigation and the documents better than any other judge in the country.

C. The Panel Has Been Down This Road Many Times, and Has Consistently Ruled in Favor of Consolidation Where, as Here, so Many Product Liability Personal Injury Actions are Pending in so Many Different Districts.

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

30. Although "swine flu" actions differed in certain respects, the 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.).

31. 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 U.S.C. § 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.).

32. 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.).

33. In this litigation, injuries are alleged to have occurred from product failure (filter fracture, tilt, perforation and/or migration) and the plaintiffs all allege that the defendants knew or should have known that the product would fail in such a manner. Such questions merit centralization for purposes of consolidating discovery to reduce judicial waste.

34. Here, twenty-five (25) actions arise out of allegations that Bard IVC filters are defective and that their marketing and manufacture were negligent. All cases focus on health hazards resulting from failure of the IVC filters and allegations of failure to warn doctors and consumers.

35. Here, there are a large number of Related Actions filed in numerous district courts across the country, all of which involve common questions of fact concerning the product (Defendants' IVC filters). Consequently transfer is necessary to prevent duplication and to eliminate risk of inconsistent rulings.

36. 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 *In re Kugel Mesh Hernia Patch Prods.Liab. Litig.*, 493 F.Supp 1371 (2007 Jud. Pan. Mult. Litig.).

37. Recently, the Panel determined that twenty-seven (27) product liability cases filed against another IVC Filter manufacturer, Cook Medical, in eleven (11) different jurisdictions with regard to alleged defects in its IVC filters warranted consolidation under an MDL. *In re: Cook Med., Inc. IVC Filters Mrkt., Sales & Practices & Prod. Liab. Litg. Litigation*, 2015 U.S. Dist. LEXIS 49174 (Jud. Pan. Mult. Litig, April 10, 2015).

WHEREFORE, Plaintiffs respectfully requests that this Honorable Panel order that the "Related Actions" and all tag-along actions be consolidated and coordinated for pretrial proceedings before Judge Kinkeade of the United States District Court for the Northern District Texas or, in the alternative, Judge Jones of the U.S. District Court for the District of Nevada.

Date: May 18, 2015

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BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

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

Proof of Service

I hereby certify that a copy of the foregoing Motion, Brief, Schedule of Actions (Exhibit "A"), and this Certificate of Service was served by Email and/or ECF and/or U.S. postal mail on this 18th day of May, 2015 to the following:

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