UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

ANTHONY PAYNE; and JOHNITA PAYNE,

Plaintiffs,

v. Case No. 6:11-cv-1582-Orl-37GJK

C.R. BARD, INC.; and BARD PERIPHERAL VASCULAR, INC.,

Defendants.

ORDER

This matter comes before the Court on the following:

1. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Dispositive *Daubert* Motion to Exclude the Expert Opinion and Testimony of Fredrick Hetzel, Ph.D. (Doc. 74), filed December 31, 2013;
2. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Dispositive *Daubert* Motion to Exclude the Expert Opinion and Testimony of Timothy Harward, M.D. (Doc. 75), filed December 31, 2013;
3. Plaintiffs' Response to Defendants' Dispositive *Daubert* Motion to Exclude the Expert Opinion and Testimony of Timothy Harward, M.D., and Incorporated Memorandum of Law (Doc. 93), filed January 24, 2014;
4. Plaintiffs' REDACTED Response Seeking to Oppose Defendants' Dispositive *Daubert* Motion to Exclude the Expert Opinion and Testimony of Frederick Hetzel, Ph.D, and Incorporated Memorandum of Law (Doc. 95), file January 24, 2013;

5. Plaintiffs' SEALED Response Seeking to Oppose Defendants' Dispositive *Daubert* Motion to Exclude the Expert Opinion and Testimony of Frederick Hetzel, Ph.D, and Incorporated Memorandum of Law (Doc. 97), file January 27, 2013;

6. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Unopposed Motion to Delete Duplicative Filing (Doc. 105), filed February 4, 2014;

7. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Reply in Support of Its Dispositive *Daubert* Motion to Exclude the Expert Opinion and Testimony of Frederick Hetzel, Ph.D (Doc. 107), filed February 6, 2014;

8. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Reply in Support of Its Dispositive *Daubert* Motion to Exclude the Expert Opinion and Testimony of Timothy Harward, M.D. (Doc. 108), filed February 6, 2014; and

9. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Reply Brief in Further Support of Defendants' Motion for Summary Judgment (Doc. 126), filed February 28, 2014.

For the reasons stated on the record during the *Daubert* Hearing on March 6, 2014 (Doc. 133), and for the reasons set forth below, the Court finds that Defendants' *Daubert* Motion to Exclude the Expert Opinion and Testimony of Fredrick Hetzel, Ph.D. (Doc. 74) is due to be granted, and Defendants' *Daubert* Motion to Exclude the Expert Opinion and Testimony of Timothy Harward, M.D. (Doc. 75) is due to be denied.

BACKGROUND

I. The G2 Filter

This is a medical device products liability action involving the failure of a Bard G2 inferior vena cava filter (the "G2 Filter"). (Doc. 11.) Made of nitinol (which is a metal alloy of nickel and titanium), and comprised of twelve struts that make up its six arms and six legs, the G2 Filter is designed to be placed in a person's inferior vena cava ("IVC") as a mechanical barrier to prevent thrombi from reaching the heart or lungs and becoming a life-threatening pulmonary embolism ("PE"). (Doc. 20, ¶ 20; Doc. 76, pp. 2–3; Doc. 76-2, pp. 20, 45–46; Doc. 74-14, p. 2.) The G2 Filter is part of a placement system that was manufactured and distributed by Defendants C.R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("Bard PV"). (Doc. 20, ¶¶ 5, 8, 18; Doc. 74-2.) The G2 Filter is designed to be retrievable, but it may also act as a permanent IVC filter. (Doc. 74-2, p. 2 ("The G2 Filter System – Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava . . . .").)

The G2 Filter is a Class III medical device under the Medical Device Amendments of 1976 ("MDA"). In accordance with the MDA, Defendants obtained clearance for the G2 Filter from the Food and Drug Administration ("FDA") pursuant to a § 510(k) application. *Carr v. C.R. Bard, Inc.*, No. 3:13-cv-824, 2014 WL 463347, at *1 (N.D. Ohio Feb. 5, 2014) (citing 21 U.S.C. § 360c(i)). In their application, Defendants represented that the G2 Filter was substantially equivalent to a predecessor device—the Recovery Filter. *Id.*; *Linsday v. C.R. Bard, Inc.*, No. 1:MC-10-441, 2011 WL 240104, at *1 (M.D. Pa. Jan. 24, 2011).

Before introducing the G2 Filter to the market in 2005, Defendants had received reports of adverse events in relation to the Recovery Filter. *Carr*, 2014 WL 463347, at

*1, *6 (finding that information about the Recovery Filter's design flaws may be relevant to products liability claims arising from a G2 Filter). In November 2004, Defendants drafted a Health Hazard Evaluation ("HHE") concerning reports of limb fractures in the Recovery Filter. (Doc. 120-16 (noting that based on limited data, "fracture rates for Recovery appear to be higher than those for other filters").) In December 2004, Defendants created a Remedial Action Plan due to the adverse data (Doc. No. 120-17), and they authored another HHE for the Recovery Filter. (Doc. 120-6, pp. 5–9 (noting that "Recovery reporting rates are significantly higher than those of other filters").)

Soon after the G2 Filter was introduced to the market, Defendants received adverse reports of migration (movement) of the filter in the IVC, and Defendants authored an HHE on the issue. (Doc. 120-9.) Further, early data indicated that the G2 Filter had perforation issues similar to the Recovery Filter (Doc. 120-11), and articles have been published concerning the failures of the two filters. (*See* Docs. 116-1 to 116-5 (providing copies of six journal articles).) Further, a number of lawsuits have been filed against Defendants related to the G2 Filter and the Recovery Filter.[1] Finally, in August 2010, the FDA issued an Alert that physicians and clinicians responsible for the care of patients with retrievable IVC filters should "consider removing the filter as soon as protection from PE is no longer needed." (Doc. 74-14, p. 2.) The Alert mentioned "filter fracture, filter migration, filter embolization and IVC perforation" as risks associated with IVC filters; however, it did not explicitly reference Defendants or the G2 Filter. (*See id.*)

[1] *See Brown v. C.R. Bard., Inc.*, 942 F. Supp. 2d 549 (E.D. Pa. 2013) (involving medical monitoring class action); *Bouldry v. C.R. Bard, Inc.*, 909 F. Supp. 2d 1371 (S.D. Fla. 2012) (same); *see also Carr*, 2014 WL 463447; *Phillips v. C.R. Bard, Inc.*, 290 F.R.D. 615, 671 (D. Nev. 2013); *Davis v. C.R. Bard, Inc.*, No. 11-12556, 2012 WL 6082993 (E.D. Mich. Dec. 6, 2012) (involving fracture and embolization of a strut from a G2 filter); *Linsday*, 2011 WL 240104 (M.D. Pa. Jan. 24, 2011).

II. Mr. Payne

In 2007, Plaintiff Anthony Payne was suffering from recurrent bilateral lower extremity deep vein thrombosis ("DVT"), which puts one at risk of suffering PE. (Doc. 115, p. 4.) On September 28, 2007, to manage this risk, Dr. Robert Schultz deployed a G2 Filter below the level of the renal veins in Mr. Payne's IVC. (*Id.*; Doc. 74-1; *see also* Doc. 93, ¶ 3.) A medical report related to the procedure provides that Mr. Payne and his wife discussed with Mr. Payne's physician "the procedure, indications, alternatives and possible complications including . . . filter failure, filter migration, perforation or fracture." (Doc. 74-1; *see also* Doc. 76-2, pp. 18–21, 25, 32–35, 39; Doc. 76-3.) Mr. Payne's physician wrote that the Paynes "understand it is permanent. They understood and consented." (Doc. 74-1; *see also* Doc. 76-2, pp. 34–35, 37–38 (identifying additional warnings that Mr. Payne received before the procedure).)[2]

In January 2008, an abdominal and pelvic computed tomography exam ("CT") of Mr. Payne revealed that struts of his G2 Filter had perforated his IVC. (Doc. 76-1, p. 12; Doc. 115, p. 4; Doc. 11, ¶ 13.) Testing also revealed a "filling defect" caudal to the G2 Filter, which may be "secondary to caval thrombosis," or a trapped clot. (Doc. 76-1, p. 12.) In February 2009, Mr. Payne "developed a one week history of left [lower extremity] swelling followed by sudden-onset chest pain and shortness of breath." (Doc. 115, p. 4; *see also* Doc. 74-3; Doc. 11, ¶ 15.) CT exams revealed that Mr. Payne had suffered both DVT and a right-sided PE. (Doc. 76-1, p. 12; *see also* Doc. 74-3.) In addition, the

[2] Mr. Payne's treating physician explained that he told Mr. Payne that the G2 Filter would likely be permanent because Mr. Payne "likely was going to have recurrent problems with deep venous thrombosis and pulmonary emboli." (Doc. 117, p. 5 (explaining that Mr. Payne "had evidence of significant venous thrombosis disease. He had recurrent disease in his lower extremities . . . he had pulmonary emboli, blood clots in the lung, despite the fact that he had been anticoagulated").)

G2 Filter was tilted in his IVC, and it had fractured. (Doc. 74-3; *see also* Doc. 76-1, p. 13; Doc. 76-4; Doc. 93, ¶¶ 4–5; Doc. 75, p. 1; Doc. 11, ¶ 16.) A fractured strut from the G2 Filter was seen in Mr. Payne's renal vein. (Doc. 115, p. 4; Doc. 11, ¶ 16.) An "unsuccessful attempt was made to retrieve" the G2 Filter and the fractured strut, and a second IVC filter was successfully placed in Mr. Payne's IVC cephalad to the G2 Filter. (Doc. 115, p. 4; *see also* Doc. 97, p. 2.) Later in 2009, Mr. Payne again experienced chest pain. (Doc. 115, p. 4.) A chest x-ray and CT angiogram revealed that the fractured strut from the G2 Filter had migrated to the lower lobe of Mr. Payne's left lung. (*Id.*; *see also* Doc. 74-4; Doc. 76-1, p. 12; Doc. 76-6, pp. 27, 35–36.) An unsuccessful attempt was made to remove the "strut from the posterior basilar branch of the left lower lobe pulmonary artery." (Doc. 115, p. 4.) Mr. Payne continues to have left-sided chest pain and shortness of breath. (Doc. 115.)

III. Instant Action

Plaintiffs assert three claims: (1) strict liability based on defective design (Doc. 11, ¶¶ 23–31); (2) strict liability based on defective manufacturing (*id.* ¶¶ 32–43); and (3) negligence (*id.* ¶¶ 44–55). Plaintiffs seek compensatory and punitive damages and their costs. (*Id.* ¶¶ 56–60.) Mrs. Payne alleges loss of consortium. (*Id.*) Plaintiffs have identified two expert witnesses—Drs. Hetzel and Harward. (*See* Docs. 74, 75.) Defendants filed motions challenging the admissibility of the opinion testimony of both experts. (Docs. 74, 75.) Defendants also filed a Motion for Summary Judgment. (Doc. 76.) Plaintiffs filed responses to all three motions (Docs. 93, 97, 120), and Defendants filed replies. (Docs. 107, 108, 126.) A *Daubert* hearing was held in this matter on March 6, 2014; however, Plaintiffs did not present live testimony from either of their proposed expert witnesses. The *Daubert* motions are now ripe for adjudication.

STANDARDS

Before permitting expert opinion testimony, the court must make certain that the expert employs "in the courtroom the same level of intellectual rigor that characterizes the practice of the expert in the field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). This requirement comes from Federal Rule of Evidence 702, which provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702; *see also McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1237 (11th Cir. 2005). Under Rule 702 and the Supreme Court decision governing its application, *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993), district courts must act as gatekeepers to prevent speculative and unreliable "expert" testimony from reaching the jury. *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005) (noting that the "task of evaluating the reliability of expert testimony is uniquely entrusted to the district court under *Daubert*"); *McClain*, 401 F.3d at 1237–38. The gatekeeping role is "significant" because an "expert's opinion 'can be both powerful and quite misleading.'" *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (quoting *Daubert*, 509 U.S. at 595).

As gatekeeper, the district court makes three inquiries: (1) first, whether the expert is qualified to testify competently regarding the matters that he intends to address; (2) second, whether the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) third, whether the testimony will assist the trier of fact, through the

application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. *See City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562–63 (11th Cir. 1998); *see also Cooper v. Marten Transp., Ltd.*, 539 F. App'x 963, 965–67 (11th Cir. 2013). The party offering the expert opinion testimony bears the burden of establishing, by a preponderance of the evidence, the expert's qualification, reliability, and helpfulness. *See Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010) (citing *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1256 (11th Cir. 2002)); *see also Sumner v. Biomet, Inc.*, 434 F. App'x 834, 841 (11th Cir. 2011); *Frazier*, 387 F.3d at 1260.

While stringent, the standards set forth in *Daubert* and Rule 702 are not guarantees of correctness. When the methodology is sound and the evidence relied upon is sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility. *See United States v. Ala. Power Co.*, 730 F.3d 1278, 1282–85 (11th Cir. Sept. 19, 2013) (explaining that the *Daubert* inquiry "is not intended to supplant" cross-examination and presentation of contrary evidence); *see also Costa v. Wyeth, Inc.*, No. 8:04-cv-2599-T-27MAP, 2012 WL 1069189, at *2 (M.D. Fla. Mar. 29, 2012).

DISCUSSION

I. Frederick Hetzel, Ph.D

Plaintiffs retained Dr. Hetzel in June 2011 to "assess (1) the device failure mode(s) implanted into Mr. Payne, (2) the adequacy of warnings and labeling for the implanted BARD G-2 IVC clot filter, (3) design/safety factors as related to the cause of the product failure(s), [and] (4) the adequacy of Bard's 510(k) for the G-2 device." (Doc. 74-8, p. 6.) On November 22, 2013, Dr. Hetzel produced a Supplemental Report. (*Id.*) Defendants deposed Dr. Hetzel on November 25, 2013 (Doc. 74-17), and they filed their *Daubert* Motion on December 31, 2013 (Doc. 74.) On January 27, 2014, Plaintiffs filed their Response and an Affidavit of Dr. Hetzel. (Doc. 97; Doc. 97-1.) Defendants filed their Reply on February 6, 2014. (Doc. 107.) Finally, on March 3, 2014, Plaintiffs filed an errata sheet for Dr. Hetzel's deposition. (Doc. 127-1.) During the *Daubert* hearing, Dr. Hetzel did not testify; however, Defendants exhibited excerpts of his videotaped deposition to the court. (Doc. 133.)

A. Supplemental Report

In the first three pages of Dr. Hetzel's thirteen-page Supplemental Report, he provides a summary of Mr. Payne's medical history starting in May 2007. (Doc. 74-8, pp. 2–4.) The fourth page of the Report is a brief summary of Dr. Hetzel's "Credentials." (*Id.* at 5.) Pages five through ten provide a "Background" section describing the G-2 Filter and summarizing certain evidence concerning product development, complaints, and Defendants' interaction with the FDA.[3] (*Id.* at 6–11.) Finally, pages eleven to

[3] This section contains mainly plaintiff-slanted summaries and characterizations of the evidence which should be excluded as unhelpful to the jury. *See In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1067–69 (D. Minn. 2007) (finding that expert's criticism of defendant "for inadequately evaluating the potential toxicity of Baycol, and

thirteen recite Dr. Hetzel's twenty "Opinions." (*Id.* at 12–14.) Generally, Dr. Hetzel opines that:

(a) high rates of G2 Filter failures were due to "flawed product design," and inadequate testing (*id.* ¶¶ 1, 4, 14);

(b) Defendants employed inadequate quality control and risk management techniques (*id.* ¶¶ 6–13);

(c) electropolishing would have resulted in "a safer product" (*id.* ¶¶ 13, 16);

(d) "[a]lternative designs and materials are available and described as specified in industry standards and identified in competitors' various regulatory submissions" (*id.* ¶ 18);

(e) "[a]dditional warnings either in IFUs, Package Inserts or instructive material are needed to adequately inform surgeons as to the design limits" of the G2 Filter (*id.* ¶ 19); and

(f) Defendants' "faulty" assurances and submissions to the FDA render the G2 Filter "adulterated within the meaning as applied by the FDA" (*id.* ¶¶ 17, 18).

Because they have been withdrawn, the foregoing omits Dr. Hetzel's opinions concerning manufacturing defects and Defendants' corporate misconduct, which were asserted by Dr. Hetzel and objected to by Defendants.[4] (Doc. 97, p. 2 (providing that Plaintiffs have withdrawn "Dr. Hetzel as an expert with respect to . . . the existence of a manufacturing defect" in the G2 Filter, and representing that Dr. Hetzel will "refrain from giving any opinions regarding his perceptions of [Defendants'] 'bad behavior'").)

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asserting that [defendant] ignored warnings is legal argument that does not qualify as expert testimony under Rule 702"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (holding that expert's "commentary on any documents and exhibits" would be limited to "drawing inferences that would not be apparent without the benefit of experience or specialized knowledge"); *see also In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1345–47 (S.D. Fla. 2010).

[4] During the *Daubert* hearing, Plaintiffs' counsel confirmed the remaining topics on which Dr. Hetzel would opine. (Doc. 133.)

B. Defendants' Motion

Defendants persuasively argue that the Court should completely preclude Dr. Hetzel from testifying in this action because: (1) he "lacks sufficient knowledge, skill, experience, training, and education to qualify as an expert regarding medicine; metallurgy; and [IVC] filter design, manufacturing and labeling" (Doc. 74, pp. 2, 4–9); (2) his opinions are unhelpful, plaintiff-slanted summaries (*id.* at 2, 9–11); and (3) his litigation-driven opinions are unreliable because they are "based on a cursory review of the barest materials" and do not satisfy the *Daubert* factors (*id.* at 2, 11–22). Defendants cite numerous pertinent medical device product liability cases where other federal courts precluded testimony in circumstances similar to those presented here—including two cases in which Dr. Hetzel was precluded from offering product-defect and deficient-labeling opinions because his qualifications were not sufficiently pertinent to the hip and knee implant products in those cases. (*Id.* (discussing *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737 (E.D. Pa. 2007), and *Swank v. Zimmer, Inc.*, No. 03-cv-60-B, 2004 WL 5254312 (D. Wyo. Apr. 20, 2004).)[5]

C. Plaintiffs' Response

Plaintiffs' Response is markedly unpersuasive. At the outset, Plaintiffs misstate the standard for assessing the admissibility of Dr. Hetzel's opinions. Rather than acknowledge Plaintiffs' obligation to establish admissibility by a preponderance of the evidence, Plaintiffs argue that the Court should deny Defendants' attempts to

[5] The *Swank* court held that "Dr. Hetzel is not qualified to testify on the alleged inadequacies in Defendant's warnings," and "[h]e is not qualified to testify on the design of the device because he has no experience or education in designing hip implants." *Swank*, 2004 WL 5254312, at *3. The *Soufflas* court similarly held that "Dr. Hetzel is not qualified to opine about the alleged inadequacies of Zimmer's warnings," and he "is not qualified as an expert to opine on" the common practices of those in the industry of "manufacturing prescription medical devices." *Soufflas*, 474 F. Supp. 2d at 744.

"disqualify" Dr. Hetzel because Defendants have "failed to demonstrate that Dr. Hetzel lacks the minimal qualifications to testify." (Doc. 97, pp. 2, 9 (arguing that Defendants have "fallen short of convincing this Honorable Court to believe that Dr. Hetzel . . . is 'unqualified' to opine regarding the defective design of the IVC filter").) Further, Plaintiffs cite only nine cases, including four cases cited in an unsuccessful attempt to distinguish them. The remaining cited cases are similarly unhelpful. Indeed, aside from *Daubert* and *Frazier*, Plaintiffs cite only insurance coverage cases concerning expert claims adjusters—not complex products liability actions involving defective device and causation experts.

D. Analysis

1. Qualifications

"[I]n determining whether a proffered expert is 'qualified' to offer an opinion, courts generally look to evidence of the witness's education and experience and ask whether the subject matter of the witness's proposed testimony is sufficiently within the expert's expertise." *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1367 (M.D. Ga. 2010). Here, Dr. Hetzel earned a B.S. in chemistry at Penn State University in 1964; three years later, he earned an M.S. in chemistry from Ohio State University; and in 1968, he earned a Ph.D. in organic chemistry from Ohio State University. (Doc. 74-11, p. 3.) Although impressive, Dr. Hetzel's education does not qualify him to testify in this case because chemistry is not implicated by Plaintiff's claims. The Court rejects Plaintiffs' argument that Dr. Hetzel's chemistry background somehow qualifies him to opine on metallurgy issues because "the materials in metallurgy are part of the periodic chart of the elements which

is what chemistry is all about."[6] (Doc. 97, p. 5; *see also* Doc. 94-17, p. 12.)

Because Dr. Hetzel's education does not fit with this case, Plaintiffs focus on his "experience" with "medical device technology" as rendering him "eminently qualified to testify." (Doc. 97, p. 4; *see also* Doc. 97-1.) In particular, Plaintiffs emphasize Dr. Hetzel's "experience in actually consulting specifically with [IVC] filters." (Doc. 97, pp. 7–8.) However, that project occurred more than twenty years ago, lasted only three to six months, and was only "conceptual." (Doc. 97, pp. 7–8; *see also* Doc. 74-17, pp. 20–21.) As such, it does not qualify him to render his opinions in this case.[7] *See Walker v. CSX Transp. Inc.*, 650 F.3d 1392, 1397 n.19 (11th Cir. 2011) (affirming exclusion of expert whose limited experience with the product at issue had "occurred over thirty to forty years" before the case arose).

Where, as here, a witness relies "primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Frazier*, 387 F.3d at 1261 (citing Fed. R. Evid. 702 advisory committee's note (2000 amends.)). Plaintiffs have failed to properly tie Dr. Hetzel's limited and dated experience as a consultant and his extensive experience as a plaintiff's expert in myriad product liability cases to the opinions that he has offered in this case. Therefore, Plaintiff has not established Dr. Hetzel's qualifications by a preponderance of the evidence. *See Walker*, 650 F.3d at 1397 n.19 (affirming exclusion of expert evidence who "may have extensive

[6] Plaintiffs' argument is at odds with Dr. Hetzel's testimony in another case that a metallurgical failure is one issue where he might be unqualified to render an opinion. (Doc. 74-9.)

[7] Defendants aptly note that Dr. Hetzel "admits that he has never designed an IVC filter, he has never tested an IVC filter, he has never manufactured an IVC filter, he has never taught any seminars regarding IVC filters, and he has never published any articles regarding IVC filters." (Doc. 74, p. 6.)

experience in the railway industry," but was "not qualified . . . to offer opinions regarding the design, operation, and alleged safety features of the subject bulkhead door system"); *see also Polston v. Boomershine Pontiac-GMC Truck, Inc.*, 952 F.2d 1304, 1309 (11th Cir. 1992) (agreeing with district court that mechanical engineer was not qualified to testify as to medical probabilities); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1241–43 (D. Colo. 1998) (holding that a chemist's "asserted expertise in biomaterials does not make him qualified in the many areas of medical science in which he opines" and the "design, manufacturing, marketing, or labeling of silicone breast implants").

2. Reliability & Helpfulness

The district court has substantial discretion in deciding how to assess whether an expert's "reasoning or methodology underlying the testimony is scientifically valid" and can be applied to the facts of the case. *Kilpatrick*, 613 F.3d at 1335; *see also Rink*, 400 F.3d at 1292. For instance, if appropriate, the Court may consider: "(1) whether the experts' methodology can be tested; (2) whether the expert's scientific technique has been subjected to peer review and publication; (3) whether the method has a known rate of error; and (4) whether the technique is generally accepted by the scientific community." *Rink*, 400 F.3d at 1292; *e.g.*, *Sumner*, 434 F. App'x at 841. A district court may find unreliable an expert's opinion that is "connected to existing date only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (explaining that if there is "too great an analytical gap between the data and the opinion proffered," then the opinion may be excluded); *see also Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cnty.*, 402 F.3d 1092, 1111 (11th Cir. 2005) (holding that opinions that are "imprecise and unspecific, or whose factual basis is not adequately explained" should

be excluded); *Rydzewski v. DePuy Orthopaedics, Inc.*, No. 11-80007-CIV, 2012 WL 7997961, at *6 (S.D. Fla. Aug. 14, 2012) (criticizing Dr. Hetzel for his "factually unsupported" opinions). Further, where an opinion is advanced solely for the purpose of litigation, the Court may weigh this fact "heavily against the admissibility" of the opinion. *Sumner*, 434 F. App'x at 842–43.

Here, the methodology that Dr. Hetzel applied in reaching his opinions does not support a finding of reliability. As noted by Defendants, Dr. Hetzel reviewed only three deposition transcripts, and he referenced only a small fraction of the scholarly articles concerning IVC filters and the G2 Filter in particular. (Doc. 74, pp. 13, 17–18; *see also* Doc. 74-12; Doc. 74-17, pp. 45, 57–58, 86–89, 129–31, 145.) Further, in his list of matters considered in forming his opinions, Dr. Hetzel lists largely inapplicable materials—including articles regarding hip implants. (Doc. 74, p. 13; *see also* Doc. 74-12, ¶¶ 11, 13, 14.) Defendants correctly characterize Dr. Hetzel's work in this matter as a "slipshod" approach that does not match the level of intellectual rigor that scientists typically employ. (Doc. 7, p. 4.) That Dr. Hetzel's opinions were developed solely in the context of this litigation provides further support for a finding that his opinions are unreliable and unhelpful. *See Sumner*, 434 F. App'x at 842–43 (affirming exclusion of opinion absent evidence that the proposed expert "developed his theory during research conducted independent" of the litigation).[8] Accordingly, even if Dr. Hetzel's qualifications were sufficient, his methodology is not. *See McCorvey*, 298 F.3d at 1256–57 (affirming

[8] *See also Lust ex rel. Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 597–98 (9th Cir. 1998) (finding it "not unreasonable to presume" that professional plaintiff's witness's opinions were unreliable); *Tokio Marine & Fire Ins. Co. v. Grove Mfg. Co.*, 958 F.2d 1169, 1173–75 (1st Cir. 1992) (noting that expert witness' "hired gun background as an expert in an astonishing number of other areas suggested he 'would not possess the professional safeguards ensuring objectivity'").

exclusion of expert opinion absent testing and a command of the pertinent literature). For all of the foregoing reasons, and for the reasons stated on the record during the hearing on March 6, 2014 (Doc. 133), Defendants' *Daubert* motion concerning Dr. Hetzel is due to be granted.

II. Timothy Harward, M.D.

Dr. Harward opines that Mr. Payne's symptoms are caused by an "inflammatory response" to the strut in his left lung and "chronic fibrosis in the pulmonary arteries," which was exacerbated by "recurrent pulmonary emboli" that occurred when Mr. Payne's IVC "was no longer properly covered" due to the failure of the G2 Filter. (*Id.* at 4–5.) Defendants' expert, Clement J. Grassi, M.D., opines that Mr. Payne's "pulmonary symptoms are most likely due to chronic pulmonary hypertension from chronic PE, acquired over a long period of time." (Doc. 76-1, pp. 14–15 (opining that the symptoms are not caused or aggravated by the strut or the body of the G2 Filter).) Defendants raise no challenge to Dr. Harward's qualifications; rather, they argue that his testimony should be excluded because he did not reliably apply a differential diagnosis in reaching his opinions. (Doc. 75, pp. 7–11.)

"Differential diagnosis 'is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.'" *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999)). While an expert need not "rule out all possible alternative causes" of an injury, she must "at least consider other factors that could have been the sole cause of the plaintiff's injury." *Guinn*, 602 F.3d at 1253. The expert also must "'provide a reasonable

explanation as to why he or she has concluded that [any alternative cause suggested by the defense] was not the sole cause' of the plaintiff's injury." *Id.* (quoting *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 179 (6th Cir. 2009)). Finally, an expert may not rely solely on the temporal proximity of an injury to establish medical causation. *See id.* (noting that in some circumstances, "temporal proximity may constitute probative evidence" of causation); *Kilpatrick*, 61 F.3d at 1343 (holding that plaintiff "cannot overcome the fact" that her expert's "causation testimony is rooted in a temporal relationship").

Here, Dr. Harward did not rely solely on the temporal relationship between the G2 Filter failure and the onset of Mr. Payne's symptoms as a basis for his causation opinion. (Doc. 75-3, p. 38.) Further, although Dr. Harward intimates that his opinions are, by necessity, based on speculation (*id.* at 37–39), there is no indication that Dr. Harward departed from his normal practice of diagnosis in his assessment of Mr. Payne. Further, Dr. Harward's opinion is consistent, in part, with Dr. Grassi's opinion. Accordingly, the Court is persuaded that Dr. Harward's opinions were reached through a reliable application of an accepted methodology—the differential diagnosis. *See Costa v. Wyeth, Inc.*, No. 8:04-cv-2599, 2012 WL 1069189, at *2 (M.D. Fla. Mar. 29, 2012) (permitting expert to opine regarding causation based on differential diagnosis). Defendants' *Daubert* motion regarding Dr. Harward is due to be denied.

III. Summary Judgment

Defendants seek summary judgment in their favor on numerous grounds—including that Plaintiffs cannot establish the requisite elements of defect and causation absent the opinion testimony of Dr. Hetzel. (Doc. 76.) During the *Daubert* Hearing, Plaintiffs conceded that summary judgment may be appropriate absent expert

testimony, and they moved *ore tenus* for leave to reopen the deadline to disclose an expert witness on the pertinent issues. (Doc. 133.) The Court advised that it would consider such a motion if filed, but Plaintiffs have not yet filed the motion. The Court will reserve ruling on Defendants' summary judgment motion pending a brief additional period of time for Plaintiffs to file their motion.

CONCLUSION

Accordingly, it is hereby **ORDERED AND ADJUDGED**:

1. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Unopposed Motion to Delete Duplicative Filing (Doc. 105) is **GRANTED**.
2. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Dispositive *Daubert* Motion to Exclude the Expert Opinion and Testimony of Fredrick Hetzel, Ph.D. (Doc. 74) is **GRANTED**.
3. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Dispositive *Daubert* Motion to Exclude the Expert Opinion and Testimony of Timothy Harward, M.D. (Doc. 75) is **DENIED**.
4. On or before **March 31, 2014**, Plaintiffs are granted leave to file a motion to reopen the deadline to disclose expert witnesses.
5. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion for Summary Judgment (Doc. 76) will be **TAKEN UNDER ADVISEMENT** on **March 31, 2014**.

DONE AND ORDERED in Chambers in Orlando, Florida, on March 12, 2014.

ROY B. DALTON JR.
United States District Judge

Copies:

Counsel of Record