UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

LESSIE TILLMAN,

Plaintiff,

vs. Case No. 3:13-cv-222-J-34JBT

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

Defendants.

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O R D E R

THIS CAUSE comes before the Court as a products liability action pertaining to an inferior vena cava filter, known as the G2®, designed and manufactured by Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc.[1] On February 19, 2008, a physician implanted a G2® Filter (the Filter) in Plaintiff Lessie Tillman (Tillman). Although the physician intended for the Filter to be retrieved later, it changed position within Tillman's body such that it cannot be removed safely. Tillman contends that the Filter is defective and, because it cannot be removed, exposes her to an ongoing risk of serious harm for which she requires medical monitoring. On March 19, 2013, Tillman filed an Amended Complaint for Damages (Doc. 10; Complaint) asserting a state law negligence claim, as well as strict liability claims for

[1] The Court will refer to the Defendants collectively in the singular as "Bard."

failure to warn, design defect, and manufacturing defect. See Complaint at 12-16.[2] This matter is presently before the Court on several motions.

On August 1, 2014, Bard filed four motions seeking to exclude the testimony of certain of Tillman's expert witnesses. See Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion to Exclude the Opinions of Michael Freeman, Ph.D. and Memorandum of Law in Support (Doc. 95; Motion to Exclude Freeman); Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion and Memorandum of Law to Exclude the Opinions of William A. Hyman (Doc. 96; Motion to Exclude Hyman)[3]; Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion to Exclude the Opinions of Robert McMeeking and Matthew Begley and Incorporated Memorandum of Law in Support Thereof (Doc. 99; Motion to Exclude McMeeking/Begley)[4]; Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion to Exclude the Opinions of Robert Ritchie, Ph.D. and Memorandum of Law in Support (Doc. 100; Motion to Exclude Ritchie).[5] Tillman filed responses in opposition to these Motions on August 22, 2014. See Plaintiffs' Opposition to Defendants' Motion to Exclude the Opinions of William Hyman and Brief in Support Thereof (Doc. 96; Hyman Response); Plaintiff's Opposition to Defendants' Motion to Exclude the Opinions of Michael Freeman, Ph.D. and Brief in Support Thereof (Doc. 120; Freeman

[2] Tillman also asserted claims for breach of implied warranty of merchantability and negligent misrepresentation, see Complaint at 16-20, but the parties stipulated to the dismissal of those claims on May 14, 2013. See Rule 41 Stipulation of Dismissal Without Prejudice (Doc. 17); Order (Doc. 18), entered May 16, 2013.

[3] Exhibit A to the Motion to Exclude Hyman is filed under seal at Document 110.

[4] Bard filed Exhibit A to the Motion to Exclude McMeeking/Begley under seal at Document 112.

[5] Exhibits A, D and E to Bard's Motion to Exclude Ritchie are located in the record under seal at Document 113.

Response)[6]; Plaintiff's Opposition to Defendants' Motion to Exclude the Opinions of Robert Richie [sic], Ph.D. and Brief in Support Thereof (Doc. 122; Ritchie Response)[7]; Plaintiff's Opposition to Defendants' Motion to Exclude the Opinions of Robert McMeeking and Matthew Begley as to Manufacturing and Legal Conclusions and Brief in Support Thereof (Doc. 123; McMeeking/Begley Response). With leave of Court, see Order (Doc. 141), Bard filed reply briefs on October 9, 2014. See Bard's Reply in Support of its Motion to Exclude the Opinions of Michael Freeman, Ph.D (Doc. 144; Freeman Reply); Bard's Reply in Support of its Motion to Exclude the Opinions of Robert McMeeking and Matthew Begley (Doc. 145; McMeeking/Begley Reply); Bard's Reply in Support of its Motion to Exclude the Opinions of William A. Hyman (Doc. 146; Hyman Reply); Bard's Reply in Support of Its Motion to Exclude the Opinions of Robert Ritchie, Ph.D. (Doc. 147; Ritchie Reply).

In addition, both parties filed motions for summary judgment on August 1, 2014. See Plaintiff's Motion for Partial Summary Judgment Against Defendant C.R. Bard and Bard Peripheral Vascular, Inc. (Doc. 93; Tillman Motion)[8]; Defendants' Motion for Summary Judgment (Doc. 98; Bard Motion).[9] The parties filed their respective responses in opposition to the summary judgment motions on August 22, 2014, and with the Court's permission, the

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[6] Exhibit A to the Freeman Response is filed under seal at Document 133.

[7] Exhibit A to the Ritchie Response is filed under seal at Document 135.

[8] The unsealed exhibits to Tillman's Motion for Partial Summary Judgment are located in the record at Document 97, and the sealed exhibits are filed at Documents 132 and 137. Tillman inadvertently omitted Exhibit R in her initial filing, and later filed this exhibit at Document 150. In addition, Tillman cites to Exhibit S in her Motion for Partial Summary Judgment as the deposition of Andrew Stockland, M.D. See, e.g., Tillman Motion at 7. However, the document she filed as Exhibit S in the record is not this deposition. See Doc. 132-9. Nonetheless, Stockland's complete deposition is in the record at Document 137-7.

[9] Exhibits F and Q to Bard's Motion for Summary Judgment are filed separately under seal at Document 111.

parties filed replies on October 9, 2014. See Defendants' Response in Opposition to Plaintiff's Motion for Partial Summary Judgment (Doc. 116; Bard Response); Plaintiff's Response to Defendants' Motion for Summary Judgment (Doc. 121; Tillman Response)[10]; Plaintiff's Reply to Defendant's Opposition to Plaintiff's Motion for Partial Summary Judgment Against Defendant C.R. Bard and Bard Peripheral Vascular, Inc. (Doc. 142; Tillman Reply); Bard's Reply in Support of its Motion for Summary Judgment (Doc. 143; Bard Reply). Accordingly, the various pending motions are ripe for review.

I. Background

This case concerns a medical device known as an inferior vena cava (IVC) filter. An IVC filter is a "device that's implanted into the inferior vena cava. . . . And its responsibility essentially is to capture a clot that may become dislodged from a [deep vein thrombosis] and potentially be a life-threatening pulmonary embolism to the patient." See Deposition of Andrew Stockland, M.D. (Doc. 137-7; Stockland Dep.) at 13. These filters originated in the 1960's and 1970's, and were first used as permanently implanted devices. See Bard Motion, Ex. A: Report of Clement J. Grassi, M.D. (Doc. 98-1; Grassi Report) at 2-3. With advances in technology and design, manufacturers began developing "retrievable" or "option" filters. Id. Bard's expert, Clement J. Grassi, M.D., a physician and interventional radiologist, explains that all IVC filters carry the risk of complications. See id. at 4. "Well known" filter complications include "filter migration, filter fracture, component embolization, access site thrombosis, IVC occlusion, filter tilt, penetration or perforation, and others." Id.; Stockland

[10] The sealed exhibits to the Tillman Response are located at Document 134 . However, Exhibit S to Tillman's Response was indecipherable as originally filed. Following the Court's Order, Tillman filed a more legible copy of this document at Document 163.

Dep. at 14-17. According to Grassi, "there is no perfect filter device available in the market today." Grassi Report at 4. Indeed, Matthew Begley, Ph.D., one of Tillman's engineering experts, concedes that it is not possible to design an IVC filter that never migrates, tilts, perforates, or fractures. See Bard Motion, Ex. I: June 19, 2014 Deposition of Matthew Begley, Ph.D. (Doc. 98-9; June Begley Dep.) at 43.

Bard originally marketed a permanent IVC filter known as the Simon Nitinol Filter (SNF), and later developed a retrievable filter named the Recovery. See Tillman Response, Ex. EE: Report of Jeffrey Hull, M.D. (Doc. 134-16; Hull Report) at 2. The FDA approved the Recovery filter as a permanent filter in November 2002, and as a retrievable filter in July 2003. See Tillman Response, Exs. F, G. Bard obtained this approval via the "§ 510(k) process," through which the FDA will clear a device for marketing if it is substantially equivalent to a predicate device.[11] Id. The Recovery's predicate device was the SNF. Id., Ex. F. Bard withdrew the Recovery from the market in 2005, and replaced it with the G2 filter. See Hull Report at 2. On August 29, 2005, Bard obtained FDA clearance to market the G2 filter through this same process by identifying the Recovery filter as a substantially equivalent predicate device. See Tillman Response, Ex. H.

[11] The "§ 510(k) process" is a means by which devices which are "substantially equivalent" to devices that were on the market prior to the enactment of the Medical Device Amendments of 1976 (MDA), 90 Stat. 539, may avoid the onerous premarket approval (PMA) process and be introduced into the market rapidly. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 477-78 (1996). The § 510(k) process "imposes a limited form of review on every manufacturer intending to market a new device by requiring it to submit a 'premarket notification' to the FDA . . . ." See id. at 478. "If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis . . . ." Id. "[I]n contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." Id. at 479. Moreover, it requires "little information, rarely elicits a negative response from the FDA, and gets processed very quickly." Id. (internal quotation omitted).

In early 2008, Tillman, who was in a rehabilitation center recovering from two knee replacement surgeries, woke up with leg pain. See Bard Motion, Ex. B: Deposition of Lessie Tillman (Doc. 98-2; Tillman Dep.) at 70-71. Testing revealed the pain was caused by a blood clot in her leg. Id. As a result, on February 19, 2008, Dr. Luis Anez ordered the implantation of an IVC filter. See Tillman Dep. at 71-72; Tillman Response, Ex. Z. According to Tillman, she was informed that the filter was needed to protect her from "the blood clot that was in my left leg to make sure that it didn't go all the way up." See Tillman Dep. at 80. Andrew Stockland, M.D., an interventional radiologist, performed the placement procedure that same day, implanting a G2 filter manufactured by Bard. See Tillman Response, Ex. Z; Stockland Dep. at 10, 32. Stockland states that the Filter was centered in the IVC when it was placed, and "was very vertical" in his opinion. See Stockland Dep. at 79.

In the Final Report following the implantation, Stockland notes that "[t]his filter may remain as a permanent device, or be potentially retrieved within 12 months. Given the patient's young age, consider retrieval in the very near future when her current medical issues have resolved." See Tillman Response, Ex. Z. Stockland explains that

> [t]he plan was to potentially take it out if possible . . . [b]ecause I think the filter served a purpose for [Tillman] in the current situation that she presented with, but when she was done with rehab and done with her getting back on anticoagulation and we felt it was safe and the risk of a [pulmonary embolism] was low, then we should seriously consider removing it.

See Stockland Dep. at 63. Stockland explains that "[t]he preference is to place a retrievable with the hope of getting it out. But unless I . . . was convinced that someone needed a permanent filter, I would place a temporary or a retrievable. But there's always an understanding that a retrievable can turn into a permanent device." Id. at 75.

Tillman saw Dr. Kedra Williams on June 18, 2008, "[t]o have some medications refilled and to follow up some labs that were done." See Bard Motion, Ex. D: Deposition of Kedra Williams, M.D. (Doc. 98-4; Williams Dep.) at 24. At that time, Tillman was taking Coumadin to treat her previous deep vein thrombosis (DVT), and Williams ordered a venous Doppler examination of Tillman's legs to see if the DVT had cleared. See id. at 24-25. Williams commented in Tillman's medical records on that visit that "[w]ill need to follow up with a vascular surgeon for the filter – Greenfield filter removal when Dopplers are negative." Id. at 25. On July 24, 2008, Williams assessed that the Doppler results were negative such that Tillman could stop taking Coumadin, and included a note in her records that Tillman was to talk to her surgeon about getting the Filter removed. Id. at 29-30. Although Williams does not recall whether she told Tillman to follow up with the surgeon that placed the Filter, it would have been her typical practice to do so. Id. at 25.

Tillman saw Williams again in October 2008, and February 2009. On the February 4, 2009 visit, Williams referred Tillman to a vascular surgeon for the removal of the Filter. Id. at 41. Tillman underwent a venous procedure on March 4, 2009, in an attempt to remove the Filter. The Final Report from that procedure states that "[a] scout film was obtained which demonstrated the previously placed G-2 Bard IVC filter to have slightly migrated and is now tilted to the left." See Bard Motion, Ex. F at 2.[12] The Final Report further states that "[t]he apex of the filter was noted to be incorporated into the left renal vein and no thrombus

[12] Bard disputes that the Filter has migrated and places great emphasis on the testimony of Tillman's medical expert, Jeffrey Hull, M.D., who states that he has not observed any migration of Tillman's Filter. See Bard Motion, Ex. C: May 20, 2014 Deposition of Jeffrey Hull, M.D. (Doc. 98-3; Hull Dep.) at 111. However, other evidence in the record indicates that the Filter has migrated. See Bard Motion, Ex. F; Stockland Dep. at 78, 101-02. As such, this is an issue of fact, and viewing the evidence in the light most favorable to Tillman, the Court will analyze Bard's Motions as if the Filter has migrated.

or filling defects were identified within the filter or within the vena cava." Id. Although multiple attempts were made at recovering the Filter with the Bard recovery device, "[d]ue to the extensive nature of tilting of the device, length of the duration of placement of the device and probable incorporation into the left renal vein further attempts at recovering filter were abandoned." Id.

Three days after the attempted retrieval, on March 7, 2009, Tillman returned to the hospital because she felt "sick and couldn't stand up." See Tillman Dep. at 137; Tillman Response, Ex. CC. According to Tillman, she was informed that she had a blood clot in her kidney "that came from the pulling up to try to get the filter out." See Tillman Dep. at 138. Tillman was treated with Coumadin, and by June 2009, the clot had cleared. Id. at 138-39; Williams Dep. at 53-54. Since that time, Tillman has not been diagnosed with another DVT or clot. See Tillman Dep. at 140. Tillman and her husband met with Williams in September 2013, to discuss their concerns about the Filter. See Williams Dep. at 58, 60-61; see also Bard Motion, Ex. G. An October 3, 2013 imaging diagnostic report on Tillman indicates that the IVC filter now "appears to extend outside the inferior vena cava . . . ." See Tillman Response, Ex. DD. In 2014, Tillman met with a specialist, Dr. Erin Moore, to discuss getting the Filter removed. See Tillman Dep. at 133-34, 145-46; Williams Dep. at 80. Williams explains that Moore noted in his records that:

> [b]ased on the independent visualization of the patient's imaging, I do not feel removal of the IVC filter is necessary and . . . only an open surgical repair is likely to be possible for achieving retrieval. I have assured the patient the risk of surgically intervening and removing of filter [sic] as comparatively greater than leaving it in place.

See Williams Dep. at 80. According to Tillman, Moore did not tell her that the Filter's tilted position or perforation of her IVC was causing any of her symptoms. See Tillman Dep. at 217.

When asked what injuries, damages, or problems she claims are caused by the Filter, Tillman responds that:

> I'm not saying I have anything that's caused by the filter. I'm just saying that the filter's there, and I don't know what's going to happen down the line. . . . It should be taken out, but now they can't take it out. So I got to live with the fact of it being there and hoping and praying that if I have a blood clot or something, that it work . . . .

See Tillman Dep. at 153. She further explains that "it's there, and it needs to be taken out. I just don't want anything to happen, like it rupture or something or fall apart or start pulling apart and moving around in my body or something like that . . . ." Id. at 166-67. Tillman also believes that "Dr. Moore said . . . that it needs to be watched to make sure that it doesn't break loose." Id. at 170. In addition, Tillman indicates that although she has not experienced any emotional problems or depression as a result of the Filter, she does worry "about what's going to happen with it being in." Id. at 171. After meeting with Dr. Moore, Tillman began to "really kind of start worrying about the rupture or coming apart or something like that or it's stretching out." Id. at 171-72. Tillman emphasizes that if she had known "that [the Filter] wasn't going to be able to be taken out, I would have never had it put in . . . ." See Tillman Dep. at 154, 208-09.

II. Motions to Exclude Expert Opinions

A. Standard of Review

Rule 702 of the Federal Rules of Evidence (Evidence Rule(s)) provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific technical or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.[13] In Daubert, the Supreme Court explained that Evidence Rule 702 imposes an obligation on a trial court to act as gatekeeper, to ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993). To determine the admissibility of expert testimony, a trial court must consider if:

> (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists 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 United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004). The burden of establishing qualification, reliability and helpfulness lies with the party offering the expert

[13] The language of Evidence Rule 702 was amended in December 2011. The Advisory Committee Notes accompanying this latest revision state that the changes are only stylistic and do not make any substantive change. Fed. R. Evid. 702 advisory committee's note (2011 amends.). Thus, case law interpreting and applying Evidence Rule 702 prior to the 2011 changes is still applicable.

opinion. See McClain v. Metabolife Int'l, Inc. 401 F.3d 1233, 1238 (11th Cir. 2005). For the purpose of conducting the reliability inquiry mandated by Daubert, the Supreme Court has suggested that a trial court consider a number of factors, which include: (1) whether the theory or technique can be, and has been, tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error; and (4) whether the theory has attained general acceptance in the relevant scientific community. See Daubert, 509 U.S. at 593-94. These factors are not exhaustive, and the Eleventh Circuit Court of Appeals has also considered whether an expert has relied on anecdotal evidence, such as case reports; temporal proximity; and improper extrapolation. See Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312 (11th Cir. 1999). The Court's inquiry under Evidence Rule 702 must focus on the methodology, not conclusions, but the Court is not required to admit opinion testimony only connected to existing data by an expert's unsupported assertion. See Daubert, 509 U.S. at 595; Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997).

In addition to determining the reliability of the proposed testimony, Daubert instructs that Evidence Rule 702 requires the Court to determine whether the evidence or testimony assists the trier of fact in understanding the evidence or determining a fact in issue. See Daubert 509 U.S. at 591. This consideration focuses on the relevance of the proffered expert testimony or evidence. The Court explained that to satisfy this relevance requirement, the expert testimony must be "relevant to the task at hand." Daubert, 509 U.S. at 591. Because scientific testimony does not assist the trier of fact unless it has a justified scientific relation to the facts, the Eleventh Circuit has opined that "there is no fit where a large

analytical leap must be made between the facts and the opinion." McDowell v. Brown, 392 F.3d 1283, 1289 (11th Cir. 2004) (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136 (1997), finding too great an analytical gap between data suggesting that one type of cancer was caused in mice and the conclusion or opinion that such data established causation of another type of cancer in humans).

The proponent of expert testimony need not show that the opinion proffered is scientifically correct, but only, based upon a preponderance of the evidence, that the opinion is reliable. See Allison, 184 F.3d at 1312. Thus, absolute certainty is not required. See Jones v. Otis Elevator Co., 861 F.2d 655, 662 (11th Cir. 1988). However, an expert must know "facts which enable him to express a reasonably accurate conclusion instead of mere conjecture or speculation," see id., and an expert's assurances that he has used generally accepted scientific methodology are insufficient, see McClain, 401 F.3d at 1244.

B. Discussion

i. Ritchie

Robert Ritchie, Ph.D. is the "H.T. & Jessie Chua Distinguished Professor of Engineering and Professor of Materials Science and Engineering and of Mechanical Engineering at the University of California, Berkeley." See Motion to Exclude Ritchie, Ex. A (Doc. 113; Ritchie Report) at 1. He has extensively researched "the problem of fracture and fatigue of metallic alloys and other structural materials" and has "extensive experience in the analysis of failures in a wide range of structures and components, in particular from the medical device industries." Id. Bard does not challenge Ritchie's qualifications as an expert. See generally Motion to Exclude Ritchie. Instead, Bard contends that Ritchie's

opinions regarding the causes of fracture in Bard's Recovery and G2 filters do not fit the facts of this case. Id. at 2. In addition, to the extent Ritchie does offer opinions specific to the complications Tillman experienced, Bard argues that those opinions are "neither the product of reliable scientific methodology nor based on sufficient data." See id.

Ritchie's opinions are "based on [his] personal knowledge, education, training and decades of experience." Ritchie Report at 1. He examined fourteen failed G2 filters, and has previously examined ten failed Recovery filters. Id. He also scrutinized four "exemplar" unimplanted filters of each type. Id. Of course, because Tillman's Filter remains implanted in her IVC, Ritchie has not been able to examine that specific device. Id. at 22. In addition, Ritchie reviewed various depositions pertaining to this case, as well as documentary evidence produced in discovery. Id. at 2. Ritchie is further informed by his knowledge of the fatigue and fracture of Nitinol (a Ni-Ti alloy from which the filters are made), obtained from twenty years of research on this material. Id. Based on his analysis of the foregoing, Ritchie concludes that Bard IVC filters "were inadequately and defectively designed and manufactured to withstand the physiological loading that they experienced in vivo," causing these filters to fail in service. Id. at 19.

Specifically, Ritchie addresses the causes of fracture in the Recovery and G2 filters. He asserts that fractures are caused by "cyclic fatigue failure involving fatigue cracks that initiated on the surface of the wire arms (and legs) . . . ." See Ritchie Report at 18. These cracks spread through the wire until it completely fractures "due to ductile overload failure (microvoid coalescence)." See id. Ritchie explains that the presence of "surface gouges" or other imperfections on the surface of the wires "could be directly identified with the

initiation of the fatigue crack that fractured the wire." Id. Ritchie maintains that these gouges and imperfections are defects which could have been removed by "electropolishing" or avoided by improved manufacturing procedures. Id. at 18-19. In addition, Ritchie asserts that fractures initiate where the wires emerge from the filter sleeve, specifically where the wire contacts the edge of the inner-diameter rim. Id. at 19. According to Ritchie, the inner rim of the filter sleeve is inadequately chamfered such that it has an exceedingly sharp radius of curvature. Id. Ritchie posits that this lack of chamfer "represents a severe design and/or manufacturing defect." Id. Ritchie also opines that fractures can occur when a filter tilts, migrates, or perforates the IVC. Id. Ritchie adds that Bard did not sufficiently analyze these diverse scenarios in their stress analyses, and that the filters "were inadequately tested prior to distribution, particularly with respect to their fatigue endurance." Id. Ritchie explains that the testing was inadequate "either because Bard inadequately estimated the severity of the loading condition in vivo in their testing protocol, and/or the duration of the tests was too short. Id. As such, Ritchie concludes that the Bard filters fail in service because they are inadequately designed and manufactured to withstand the stresses and strains experienced in the human body. Id.

Bard is correct that there is no evidence that the Filter implanted in Tillman's IVC has fractured. See, e.g., Ritchie Report at 22. Rather, the medical records demonstrate that the Filter has tilted and perforated her IVC such that it cannot be removed, and may or may not have slightly migrated. See Bard Motion, Ex. F; Tillman Response, Exs. DD, EE at 6; Stockland Dep. at 78, 101-102; see also Hull Dep. at 111. Ritchie, himself, acknowledges that "the medical reports do not provide evidence of the fracture of any specific arms or legs

in Mrs. Tillman's filter or of the migration of fragments . . . ." See Ritchie Report at 22. As such, Bard contends that Ritchie's opinions on filter fracture do not "fit" the facts of this case. However, Tillman argues that the defects Ritchie identifies create an increased risk of fracture such that she is exposed to an "on-going present danger with the G2 filter lodged in her body." See Ritchie Response at 7. Because of this risk, Tillman seeks the cost of medical monitoring necessary to detect the onset of physical harm, see Complaint ¶ 49, and absent any argument from Bard to the contrary, it appears such damages are recoverable under Florida law. See Petito v. A.H. Robins Co., Inc., 750 So. 2d 103, 104-06 (Fla. 3d Dist. Ct. App. 1999); see also Bouldry v. C.R. Bard, Inc., 909 F. Supp. 2d 1371, 1375-76 (S.D. Fla. 2012). Thus, evidence that G2 filters are prone to fracture due to design or manufacturing defects is relevant to Tillman's claim for medical monitoring damages. In addition, having found that Ritchie's fracture opinions are relevant to this case, the Court also rejects Bard's unsupported contention that these opinions are somehow unduly prejudicial. Therefore, the Court will deny Bard's Motion to Exclude Ritchie to the extent Bard requests the exclusion of Ritchie's fracture opinions.[14]

As to Tillman's current complications, Ritchie concedes that "[l]acking the failed filter itself, we do not have direct structural evidence for the cause of the migration, tilting and

[14] To the extent Bard challenges Ritchie's assumption that the Filter implanted in Tillman contains the same defects identified above, the Court rejects this challenge. See Motion to Exclude Ritchie at 9; Ritchie Report at 22. "An expert's opinion, where based on assumed facts, must find some support for those assumptions in the record." McLean v. 988011 Ontario, Ltd., 224 F.3d 797, 800 (6th Cir. 2000). Because Ritchie offers some support for his assumptions, the Court will not exclude this opinion. Counsel may attack any weaknesses in Ritchie's reasoning on cross-examination. Id. at 801 ("[M]ere weaknesses in the factual basis of an expert witnesses' opinion . . . bear on the weight of the evidence rather than on its admissibility." (internal quotation omitted)).

probable perforations of the struts of Mrs. Tillman's filter . . . ." Id. Nonetheless, Ritchie draws the following conclusion regarding the Filter:

> the evidence from other failed G2 filters described in this report does indicate fractures of the arms and of the legs and feet in failed filters which would interrupt the proper placement of the filter, leading to potential tilting and migration and would of course increase the load on the remaining anchored legs. Based upon my review and examination of these failed G2 filters, as well as the exemplar filters, it is my opinion that the likely causes of their malfunction are their design and/or manufacturing defects that I have observed. In this regard, the filter implanted in Mrs. Tillman would more likely than not have had the same characteristics as the filters that I have examined, namely a lack of proper chamfering of the interior edge of the Nitinol sleeve and a lack of an undamaged surface from surface gouges and grinding and draw markings, all of which represent manufacturing and/or design defects of the device, coupled with poor mechanical design, limited stress analysis and an inadequate assessment of their fatigue resistance during all modes of in vivo operation. These likely rendered Mrs. Tillman's filter unable to withstand the normal physiological stresses exerted upon it within the human body, causing problems of tiling, migration and perforation.

Id. at 22-23. However, Ritchie offers no explanation or analysis to support the leap from his contention that the identified defects cause fracture to his conclusion that the identified defects also cause tilt, migration and perforation. Id. Indeed, as Bard aptly points out, Ritchie's analysis of tilt, migration and perforation in the body of his Report is limited to the ways in which these events can lead to fracture, and includes no discussion of what or how the purported design or manufacturing defects can also cause tilt, migration or perforation. See Ritchie Report at 12, 19. A number of Daubert decisions "warn against leaping from an accepted scientific premise to an unsupported one." See Allison, 184 F.3d at 1314 (collecting cases). Here, Ritchie does precisely that in leaping from his scientifically supported opinions regarding the causes of filter fracture, to his unsupported conclusion that, absent any evidence of fracture, these same deficiencies cause tilt, migration and

perforation. Even accepting Ritchie's assumption that Tillman's Filter has the same surface defects and lack of chamfering that are present in the filters he examined, Ritchie offers nothing more than his own ipse dixit to conclude that those conditions also cause tilt, migration, and perforation. As such, the Court determines that Ritchie's opinion on the cause of tilt, perforation and migration is not sufficiently reliable under Daubert and will grant Bard's Motion to Exclude Ritchie as to that opinion only. See McDowell, 392 F.3d at 1289.

ii. McMeeking/Begley

Robert M. McMeeking, Ph.D. is a "Tony Evans Professor of Structural Materials and Professor of Mechanical Engineering," and Matthew R. Begley, Ph.D. is a "Professor of Mechanical Engineering and Professor of Materials," both at the University of California, Santa Barbara. See Motion to Exclude McMeeking/Begley, Ex. A (Doc. 112; McMeeking/Begley Report) at 1. McMeeking and Begley (the Engineers) have performed "extensive research" into "problems of mechanical failure in a wide range of structural components, including biomedical implants." Id. at 2. The Engineers issued a joint report based on their "personal examination of the Bard design and qualification documentation produced during discovery . . . in cases [they] previously worked on," and the Report describes "the design, mechanical analysis, finite element analysis (FEA) and testing of Bard filters." See McMeeking/Begley Report at 1. Bard seeks exclusion of the Engineers' opinions in their entirety. See Motion to Exclude McMeeking/Begley at 2. As with Ritchie, Bard argues that the Engineers' opinions on filter fatigue and fracture do not "fit" the facts of this case because Tillman's Filter did not fracture. Id. at 5-6, 15. Next, Bard challenges the Engineers' opinion that Bard inadequately tested the Recovery and G2 filter designs for the

risk of perforation, tilt and migration. Id. at 6. Bard asserts that these opinions are unhelpful to the jury because the Engineers "fail to identify any aspect of the Bard G2® Filter that is allegedly defective such that it caused [Tillman's] filter to tilt, perforate, or migrate." Id. at 7, 16. In addition, Bard argues that the Engineers' opinions regarding Bard's manufacturing process and quality controls should be excluded because the Engineers are not qualified to opine on manufacturing processes and the opinions are unreliable. Id. at 16-18. Last, Bard contends that the Court should exclude the Engineers' opinions characterizing Bard's conduct as reckless, negligent, incompetent, misleading, or unethical because such opinions constitute inappropriate legal conclusions, or purport to discern Bard's intent, matters about which the experts are not qualified to opine. See id. at 18-20.

First, the Engineers' opinions concerning filter fracture are relevant to Tillman's claims for the same reasons that Ritchie's opinions on fracture are relevant. As discussed above, Tillman contends that the Filter is defectively designed such that it poses an unreasonable risk of fracture and requires her to obtain ongoing medical monitoring. The Engineers' opinions with respect to whether G2 filters contain design defects which make them unreasonably prone to fracture, and whether Bard adequately tested its filters for this risk, are relevant to this claim. Bard does not challenge the Engineers' qualifications or the reliability of their opinions on this issue, thus, the Court finds no basis to exclude the Engineers' opinions on filter fracture, and will deny Bard's Motion to Exclude McMeeking/Begley in that respect.

Next, the Engineers opine that Bard failed to conduct adequate testing on the risk of tilt, perforation and migration. Bard argues that these opinions should be excluded as

unhelpful to the jury because the Engineers "cannot identify a single defect – or anything else – that allegedly caused [Tillman's] filter to tilt, perforation [sic], or migrate." See Motion to Exclude Begley/McMeeking at 16. Evidence Rule 702 requires that "the evidence or testimony 'assist the trier of fact to understand the evidence or determine a fact in issue.'" See Daubert, 509 U.S. at 591 (quoting Evidence Rule 702). However, "[t]he expert need not have an opinion on the ultimate question to be resolved by the trier of fact in order to satisfy this requirement." Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000). Indeed, "the testimony need only 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." City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 565 (11th Cir. 1998). The Engineers' "data and testimony need not prove [Tillman's] case by themselves, they must merely constitute one piece of the puzzle that [Tillman] endeavor[s] to assemble before the jury." Id.

Upon review, the Court finds that the Engineers' opinions regarding the adequacy of Bard's testing for the risk of perforation, tilt and migration would be helpful to a jury in determining a fact in issue, specifically whether Bard breached its duty of care in designing the G2 filter, or failing to issue adequate warnings, as alleged in Count One. See Adams v. G.D. Searle & Co., Inc., 576 So. 2d 728, 730-31 (Fla. 2d Dist. Ct. App. 1991) ("The duty to test . . . is a subpart of a manufacturer's duty to design a product with reasonable care, and thus is subsumed in the plaintiffs' claims for defective design and failure to warn."); Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517, 1528 (D. Minn. 1989) ("The duty to test is subpart of duties to design a product non-negligently, manufacture a product non-negligently, and

provide adequate warnings of dangers associated with its use."); see also Smith, 215 F.3d at 721. Although the Engineers do not offer opinions on the ultimate issue of whether the G2 filter's design was actually defective, or whether a specific defect caused Tillman's G2 filter to tilt, perforate and possibly migrate, their testimony need not be excluded simply because they do not opine on these ultimate factual issues.[15] See Dartey v. Ford Motor Co., 104 F. Supp. 2d 1017, 1024-25 (N.D. Ind. 2000) ("Relevant testimony is not excluded simply because the testimony does not relate to the ultimate issue in the case."). Because the Engineers' opinions on the adequacy of Bard's testing and whether Bard accurately determined the degree of risk associated with the G2 filter will be helpful to the trier of fact in determining whether Bard acted negligently in its design, manufacture, and marketing of the Filter, the Court will not exclude this testimony.

Bard also seeks to exclude the Engineers' opinion that Bard does not exert sufficient control over its manufacturing processes such that there is variability in certain aspects of the G2 filters leading to failure in some devices. See Motion to Exclude McMeeking/Begley at 9-10. Specifically, Bard challenges the Engineers' opinions that the magnitude of the bend

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[15] In their Report, the Engineers state that:

> [i]t is our opinion that the risk of migration is higher than suggested by Bard's analysis; given that Bard was aware that the predicate device to the G2 was prone to perforation, and design changes were made that lowered the radial force exerted by the legs, it is only reasonable to conclude that migration in the Tillman filter case is attributable to an inadequate design.

See McMeeking/Begley Report at 22. However, in his June 19, 2014 Deposition, Begley testified that he could not identify the specific factors that caused Tillman's Filter in particular to migrate. See June Begley Dep. at 39. Indeed, Begley explains that he "cannot state with certainty [as to Tillman's specific filter] whether or not the percentage was greater than 50 percent that these considerations were contributing factors or less than. It could be less than, it could be more than, and I've stated that it's the lack of the designers' awareness about whether or not these risks were less than or greater than 50 percent that I find objectionable." See id. at 83. As such, the Court does not consider the opinions in the McMeeking/Begley Report to pertain to the issue of specific causation, and the Engineers will not be permitted to offer an opinion on that issue.

in the arm of the G2 Filter is an "arbitrary outcome of the manufacturing process," and that "the radius of the sheath edge where it contacts the arms and legs is not controlled in the manufacturing process and therefore it can vary considerably." See McMeeking/Begley Report at 7, 11. As support for these opinions, the Engineers observe that "the radius of the bend is not specified in any of Bard's engineering drawings that we have reviewed." Id. at 7. In addition, the Engineers note differences in the radius of the sheath shown in micrographs obtained from other experts, but have not "cut open a filter to look at that" themselves. See Motion to Exclude McMeeking/Begley, Ex. C: April 22, 2014 Deposition of McMeeking (Doc. 99-3; McMeeking Dep.) at 146. However, McMeeking concedes that he "would not claim to know in detail what" the manufacturing controls are, and does not know in specific detail "how uncontrolled or how variable the filters coming off the line were" for the Recovery and G2 filters. See id. at 146-47. As such, Bard contends that these opinions "are unsupported by facts and are unreliable," and that the Engineers "have no qualifications that would provide them the expertise to proffer these opinions." See McMeeking/Begley Reply at 5.

It is Tillman's burden to demonstrate that the expert opinions on which she relies satisfy the Daubert standards. See McClain, 401 F.3d at 1238. In her Response, although she broadly discusses the Engineers' general qualifications, Tillman does not specifically explain how the Engineers are qualified to opine on Bard's manufacturing processes. See McMeeking/Begley Reponse at 3-5, 9. Indeed, she identifies the Engineers' particular area of expertise as "theoretical and computational stress/strain analysis." Id. at 9. Notably, she does not include these particular manufacturing opinions in her summary of the

Engineers' findings. See id. at 8. Likewise, Tillman does not rely on the Engineers' opinions on the variability of Bard's manufacturing process in her summary judgment briefing. See Tillman Response at 11-12. As such, it is unclear whether Tillman intends to offer the Engineers as experts on the manufacture of these devices. Nonetheless, upon review of the Report, the Court finds that while the Engineers are qualified to opine on mechanical failure and stress-strain analysis, they do not identify any qualifications specific to the area of manufacturing controls and processes. See McMeeking/Begley Report at 2. Moreover, the experts do not identify any documents or materials pertaining to Bard's manufacturing process that they reviewed in preparing their Report. Id. at 3. While McMeeking states that he has "read some of the documents that describe" Bard's manufacturing controls, he "would not claim to know in detail what those controls are." See McMeeking Dep. at 146. Rather, it appears McMeeking's opinion in this respect is based on his examination of Bard's finite element calculations. Id. at 146-47 ("[T]hey made a variety of assumptions about boundary conditions . . . . And that suggests to me that they realized that there was a variability in the constraint of the weld imposed on the wires, and that that was something they were accounting for in their calculations."). Accordingly, with respect to Bard's manufacturing process in particular, Bard's argument is well-taken and the Engineers will not be permitted to opine on Bard's manufacturing controls or lack thereof.[16]

[16] Although the Engineers may not opine that Bard should have exercised greater control over its manufacturing processes, this finding does not preclude the Engineers from noting the variations in the micrographs they reviewed, or the lack of specification in the design materials. The Engineers may properly identify these variables in explaining the bases for their calculations. See, e.g., McMeeking/Begley Report at 7.

Last, Bard argues that the Engineers' opinions characterizing Bard's conduct as reckless, negligent, incompetent, misleading, or unethical are legal conclusions which should be excluded. Tillman responds in a conclusory fashion that "Plaintiffs [sic] would simply assert that the use of such terms in the experts' reports does not constitute a proper basis for a Daubert challenge as these terms do not render the experts incompetent to testify nor does such language establish that the experts' testimony is not reliable." See McMeeking/Begley Response at 12. Tillman does not offer any legal authority in support of this argument. Id. Throughout their Report, the Engineers assert that Bard was incompetent, negligent and reckless in its failure to run certain tests or calculations, as well as in the manner in which it tested design features. See generally McMeeking/Begley Report. In addition, the Engineers opine that Bard acted "unethically, unprofessionally and recklessly" in asserting to the FDA, and stating in its marketing brochures, that the G2 filter was twelve times more resistant to fatigue failure than the Recovery model. See id. at 5. They explain that Bard's claim was premised on the results of only one test and that

> Bard has provided no evidence to support the claim that when the Recovery and G2 filters are subjected to expansion and contraction as occurs when they are in the vena cava, or subjected to repeated impacts as occurs when blood clots are arrested by the filter, or subjected to repeated drag loadings as occurs when blood flows by the filter in the vena cava, that the G2 filter will last 12 times as long as the Recovery filter.

Id. at 5-6. Based on an internal memorandum, the Engineers further opine that "Bard was fully aware that its claims regarding improved fatigue resistance for the G2 filter were false, misleading and reckless." Id. at 6.

Evidence Rule 704 provides that "[a]n opinion is not objectionable just because it embraces an ultimate issue." However, "courts must remain vigilant against the admission

of legal conclusions, and an expert witness may not substitute for the court in charging the jury regarding applicable law." See United States v. Milton, 555 F.2d 1198, 1203 (5th Cir. 1977)[17]; Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cnty., Fla., 402 F.3d 1092, 1112 n.8 (11th Cir. 2005) (noting that "testifying experts may not offer legal conclusions . . ."). As such, courts have excluded expert testimony that employs terminology with legal import, such as negligence. See Emp'rs Ins. of Wausau v. Latex Contr. Co., No. 1:01-CV-1909-BBM, 2003 WL 26087498, at *8 (N.D. Ga. Sept. 2, 2003) (excluding portions of expert's testimony which relate to "negligence"); Andrews v. Metro N. Commuter R.R. Co., 882 F.2d 705, 709 (2d Cir. 1989) (holding that trial court should have excluded expert's testimony that the defendant was negligent); Schober v. Maritz Inc., No. 07-CV-11922, 2008 WL 544948, at *3 (E.D. Mich. Feb. 26, 2008) ("Further, [the expert's] opinion that Defendant was 'negligent' amounts to a legal conclusion, and is therefore particularly problematic."); In re Rezulin Prods. Liab. Litig. (In re Rezulin), 309 F. Supp. 2d 531, 541, 547 (S.D.N.Y. 2004) ("[The expert's] opinion that [defendant's] conduct with respect to clinical trial data potentially constituted 'negligence' or 'something more serious' is excluded for the additional reason that it impermissibly embraces a legal conclusion." (internal footnote omitted)); see also Haney v. Mizell Mem'l Hosp., 744 F.2d 1467, 1473-74 (11th Cir. 1984). As the Sixth Circuit explained in Torres v. Cnty. of Oakland, 758 F.2d 147 (6th Cir. 1985), "[t]he problem with testimony containing a legal conclusion is in conveying the witness' unexpressed, and perhaps erroneous, legal standards to the jury. This 'invade[s] the province of the court to

[17] In Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as binding precedent all the decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

determine the applicable law and to instruct the jury as to that law.'" Torres, 758 F.2d at 150 (quoting F.A.A. v. Landy, 705 F.2d 624, 632 (2d Cir. 1983)) (alteration in original). The Sixth Circuit offered guidance that "[t]he best resolution of this type of problem is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular. If they do, exclusion is appropriate." Id. at 151.

Based on the foregoing, the Court will exclude the Engineers' opinions that Bard acted negligently or recklessly. These terms carry special meaning under the law and are contingent upon application of the appropriate standard of care. The Engineers do not indicate what standard of care they are applying to reach this opinion, and Tillman does not explain how these experts are qualified to opine on the standard of care applicable to the medical device design and manufacture industry. Accordingly, the Court will grant, in part, Bard's Motion to Exclude McMeeking/Begley to the extent the Court will not permit the Engineers to offer opinions on whether Bard was negligent or reckless.

However, throughout their Report the Engineers also identify flaws in Bard's testing of the Recovery and G2 filters' ability to withstand stresses and strains, and conclude that as a result of these flaws, Bard's engineering analyses were incompetent. The term incompetence does not carry with it a legal definition and is not contingent on a legal standard of care, but rather on the applicable principles of science and engineering. Bard does not dispute that the Engineers are qualified to testify regarding stress-strain analysis, nor does Bard contend that the engineering analyses performed by these experts is unreliable. Indeed, the Engineers explain that their assessment is "typical of those routinely

conducted during the design validation and verification of devices." See McMeeking/Begley Report at 2. The testimony that Bard performed its testing in a scientifically incompetent manner would be helpful to the trier of fact in determining whether Bard breached its duty of care and the Court does not find it to be unduly prejudicial. Accordingly, the Court will not exclude the Engineers' opinions that the testing performed was incompetent as a matter of engineering and design principles.

As to the Engineers' opinions on Bard's claim that G2 filters are twelve times more fatigue resistant than Recovery filters, the Court finds that the Engineers' may not opine that Bard's conduct was unethical and unprofessional. Tillman offers no argument or information to show that the Engineers are qualified to opine on the ethical or professional standards in the industry. Moreover, Tillman fails to demonstrate that these opinions are reliable or relevant to this case. The Engineers themselves do not purport to have any expertise on the relevant ethical or professional standards, and they do not identify the ethical or professional standard on which they base this opinion. As such, these opinions appear to be simply their subjective views on how a medical device manufacturing company should act, and therefore, are due to be excluded as unreliable. See In re Rezulin, 309 F. Supp. 2d at 543. Moreover, Bard's compliance with an unidentified standard of ethical or professional conduct is not relevant to the issues in this case. See id. at 543-44. Rather, the issues here are limited to whether the Filter is defective in its design, manufacture, or warnings, whether Bard breached a legal duty to Tillman in designing, manufacturing, or labeling the device, and whether the defects or breaches caused Tillman's damages. Id. at 544. "While [Bard] may be liable in

the court of public opinion, or before a divine authority for any ethical lapses, expert opinion as to the ethical character of their actions is not relevant" to this lawsuit. See id.

In addition, to the extent the Engineers offer opinions on Bard's intent, state of mind, or motivations, this testimony is outside the bounds of appropriate expert testimony. Id. at 546-47; In re Flonase Antitrust Litig., 884 F. Supp. 2d 184, 193 (E.D. Penn. 2012); Kaufman v. Pfizer Pharms., Inc., No. 1:02-CV-22692, 2011 WL 7659333, at *9 n.8 (S.D. Fla. Aug. 4, 2011); In re Seroquel Prods. Liab. Litig., No. 6:06-md-1769-Orl-22DAB, 2009 WL 3806436, at *5 (M.D. Fla. July 20, 2009); Baldonado v. Wyeth, No. 04 C 4312, 2012 WL 1802066, at *7-8 (N.D. Ill. May 17, 2012) (collecting cases). Based on their interpretation of a memorandum produced in discovery, the Engineers opine that "Bard was fully aware that its claims regarding improved fatigue resistance for the G2 filter were false, misleading and reckless." See McMeeking/Begley Report at 6. The Court finds that this opinion is due to be excluded as unhelpful in that a jury is fully capable of drawing its own inferences from this memorandum without assistance from an expert. See In re Rezulin, 309 F. Supp. 2d at 546-47. Indeed, the experts do not appear to rely on any of their scientific expertise in drawing conclusions about the import of the cited memorandum. Accordingly, the Court will grant Bard's Motion to Exclude McMeeking/Begley to the extent that it will exclude the Engineers' opinion that Bard acted unethically or unprofessionally, as well as their opinion regarding Bard's intent as extrapolated from the March 23, 2006 memorandum.

However, the Engineers also opine that it is misleading for Bard to claim that G2 filters are twelve times more fatigue resistant than Recovery filters, and upon consideration, the Court finds this opinion to be permissible. See Deutsch v. Novartis Pharms. Corp., 768 F.

Supp. 2d 420, 440 (E.D.N.Y. 2011). The Engineers reviewed the testing done to support Bard's claim and determined that the claim is misleading based on their analysis of what that testing actually showed. An opinion that Bard's claim was misleading because it was not supported by the tests performed does not relate to legal standards, nor is it a question of Bard's state of mind or intent. Whether the scientific data supported the claim made regarding the G2 filters is within the realm of the Engineers' expertise and would be helpful to a fact-finder. See In re Seroquel, 2009 WL 3806436, at *8 Accordingly, the Court will deny Bard's request for the exclusion of this opinion.

iii. Hyman

William A. Hyman, Sc.D., P.E., is an engineer with a masters and doctorate degree from Columbia University in engineering mechanics. See Motion to Exclude Hyman, Ex. A (Doc. 110; Hyman Report) at 1. He has extensive educational and professional experience in biomedical engineering, biomaterials, biomechanics, medical device design and system safety, and FDA regulatory processes. See Hyman Report at 1-2. He has spent a substantial amount of time researching, writing, teaching and consulting in these areas, and has published on topics of medical device design and system safety, as well as FDA regulatory issues. Id. To generate his Report, Hyman employed the following methodology:

> [reviewed] the underlying facts, [reviewed] the known failure modes of the device in question and similar devices, and [reviewed] the relevant medical literature. This information was then used, in combination with [his] existing knowledge of FDA regulations and medical device design and safety, to analyze Bard corporate documents . . . to compare the adequacy of their approach to regulatory matters and design to [his] understanding of what a prudent manufacturer should have done under the circumstances surrounding vena cave [sic] filters throughout Bard's involvement with such filters, and at least up to the time of Ms. Tillman [sic] implantation.

Id. at 3. Based on the foregoing qualifications and methodology, Hyman draws several conclusions regarding Bard's filters, including, inter alia, that the design of the G2 filter was defective, that Bard's design, testing, and marketing of the G2 filter was below industry standards, that Bard conducted inadequate testing on the G2 filter, that Bard's promotion of the G2 filter was misleading, that Bard did not adequately warn physicians of the risks associated with the G2 filters, and that, as a "direct result" of the foregoing, Tillman "received and suffered from, and continues to suffer from, a device that was defective and should not have been on the market as designed, at least at the time of [Tillman's] implantation." Id. at 31-32.

Bard maintains that the Court should exclude Hyman's opinions because Hyman "lacks sufficient knowledge, skill, experience, training, and education to qualify as an expert regarding Bard's [IVC] filter testing, design, and labeling." See Motion to Exclude Hyman at 1. In addition, Bard asserts that Hyman's opinions are unhelpful to the jury in that they are summaries of documents which do not require expertise to understand, regulatory opinions which are improper conclusions of law, improper opinions on corporate knowledge or intent, and irrelevant opinions on alleged fracture and migration complications. Id. at 1-2. Bard also maintains that Hyman's opinions are not based on sufficient facts or data, and that his opinions are not the product of reliable principles and methods. Id. at 2.

First, with respect to Hyman's qualifications, the Court finds that Hyman is qualified to testify regarding the applicable FDA regulations, as well as medical device design and testing. Bard challenges Hyman's qualifications to render opinions on the design and testing of the G2 filter because Hyman "lacks any meaningful training or experience with implantable

medical devices, let alone IVC filters." See Motion to Exclude Hyman at 4. In support, Bard relies on cases where courts have found experts unqualified due to their lack of expertise with the particular product at issue. See id. at 4-5. However, the cases on which Bard relies are distinguishable because, unlike Hyman, the experts in those cases had only general engineering or scientific backgrounds and lacked any expertise in the design of medical devices. See Cason v. C.R. Bard, Inc., 1:12-CV-1288-MHS, slip op. at 25-28 (N.D. Ga. Feb. 12, 2015) (discussing and distinguishing the cases Bard cited for this proposition).[18] Here, Hyman is not only a mechanical engineer but one with extensive experience in the design of medical devices. Accordingly, the Court agrees with the decision in Cason that Hyman is qualified to render an opinion on Bard's medical device design and testing. Id.; Compton v. Subaru of Am., Inc., 82 F.3d 1513, 1520 (10th Cir. 1996) ("As long as an expert stays within the reasonable confines of his subject area, . . . a lack of specialization does not affect the admissibility of [the expert] opinion, but only its weight." (internal quotation omitted) (second alteration in original)) reversed on other grounds by Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 146-47 (1999); DaSilva v. Am. Brands, Inc., 845 F.2d 356, 361 (1st Cir. 1988); see also In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 202 (S.D.N.Y. 2009).

However, with respect to Hyman's opinions on the adequacy of Bard's warnings, Tillman fails to establish that Hyman is qualified to opine on this issue. Although Hyman has had "input" into instructions for use (IFU) on a "few" occasions, he has never drafted an

[18] The Cason decision pertains to another product liability lawsuit against C.R. Bard based on the G2 filter. Hyman was offered as an expert in that case as well, and the court granted, in part, and denied, in part, a nearly identical motion to exclude Hyman's opinions. Bard filed a notice of supplemental authority (Doc. 160) attaching the Cason decision on February 12, 2015.

entire IFU. See Motion to Exclude Hyman, Ex. B: May 6, 2014 Deposition of William Hyman (Doc. 96-2; Hyman Dep.) at 26-27. Hyman has only "commented on pieces" of the complications section of an IFU, and has "commented on warnings" in the context of litigation, as well as "in writing" to inform a manufacturer of his "perception on their warnings." Id. at 136. Tillman does not present any evidence that Hyman has reviewed the warnings or labeling of other IVC filters, nor has Hyman drafted an alternative warning for the G2 filter. Indeed, Hyman's Report never specifically discusses the G2 filter's IFU as currently drafted. Without this experience, the Court finds that Hyman is not qualified to testify regarding the adequacy of the warnings accompanying the G2 filter. See Cason, 1:12-CV-1288-MHS, slip op. at 28-29; Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 969-70 (10th Cir. 2001). Moreover, the Court agrees with the reasoning in Cason that Hyman's lack of medical training or expertise in the relevant medical specialty renders him further unqualified to offer an opinion on the adequacy or appropriateness of the G2 filter's warning label. See Cason, 1:12-CV-1288-MHS, slip op. at 29; King v. Synthes (U.S.A.), 532 F. Supp. 2d 828, 833 (S.D. Miss. 2006) (excluding labeling opinion of medical technology expert because the expert had no medical training, had never drafted a label for the device, did not design an alternative label, or review the label of competitor devices); See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig., No. MDL 1203, 2001 WL 454586, at *9 (E.D. Penn. Feb. 1, 2001) ("[The expert] also lacks expertise in the medical specialties that would qualify a witness to testify about the accuracy and appropriateness of warning labels . . . ."). Accordingly, Hyman's opinions on the adequacy of the G2 filters' warning labels are due to be excluded.

Next, Bard seeks to exclude Hyman's opinions regarding "FDA regulations (including the 510(k) clearance process), FDA guidelines, and Bard's compliance or alleged non-compliance with these regulations and guidance documents." See Motion to Exclude Hyman at 7. Bard does not challenge Hyman's qualifications as an expert on the FDA regulation of medical devices, but contends that these opinions would not be helpful to the jury. Id. In addition, Bard argues that "[a]ny allegation that Bard misled the FDA or committed fraud on the FDA is preempted." Id. These arguments are unavailing. Hyman's testimony on FDA guidelines and regulations, and Bard's compliance therewith, is helpful to the trier of fact because "[a] lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the [medical device] industry." See In re Fosamax, 645 F. Supp. 2d at 191. Moreover, because Tillman is not alleging any claim for fraud on the FDA, Bard's preemption arguments are inapposite. Indeed, the court in Cason considered these same arguments and determined that Hyman's regulatory opinions were permissible. See Cason, 1:12-CV-1288-MHS, slip op. at 34-37. This Court agrees with the reasoning in Cason, and holds that Hyman "may testify regarding the regulatory process by which medical devices like the G2 Filter are brought to market, and he may express his opinion as to whether Bard complied with all FDA regulatory requirements applicable to the G2 Filter." Id. at 36; see also In re Fosamax, 645 F. Supp. 2d at 192. However, as in Cason, Hyman "will not be allowed to express any opinion as to whether Bard should have done more than was required by FDA regulations to address the hazards of the G2 Filter." Cason, 1:12-CV-1288-MHS, slip op. at 37.

To the extent Hyman offers opinions which amount to legal conclusions on Bard's recklessness or negligence, or opines on Bard's corporate intent, the Court will exclude such opinions for the same reasons discussed above regarding Begley and McMeeking. In addition, Bard argues that Hyman offers "under the guise of 'expert opinion,' plaintiff-slanted summaries of Bard documents that require no expertise to understand, and which will not assist the jury." See Motion to Exclude Hyman at 1-2, 12. This argument is well-taken. In his Report, Hyman "presents a narrative of select regulatory events through the summary or selective quotation from internal [Bard] documents . . . [and] regulatory filings." See In re Fosamax, 645 F. Supp. 2d at 192. "'[A]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence.'" Id. (quoting Highland Capital Mgmt., L.P. v. Schneider, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005)); Baldonado, 2012 WL 1802066, at *4. To the extent such evidence is admissible, it is "properly presented through percipient witnesses and documentary evidence." See In re Rezulin, 309 F. Supp. 2d at 551. Accordingly, Hyman's "'commentary on any documents and exhibits in evidence will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge.'" See Cason, 1:12-CV-1288-MHS, slip op. at 39 (quoting In re Fosamax, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009)). The Court will not permit Hyman to testify to "simple inferences drawn from uncomplicated facts that serve only to buttress plaintiff's theory of the case." In re Rezulin, 309 F. Supp. 2d at 551; see also In re Seroquel, 2009 WL 3806436, at *4 ("Plaintiffs' counsel may not simply use these expert witnesses to provide a narrative history

of [the manufacturer's] marketing and labeling practices, or to make points that are within the province of counsel, rather than an expert witness.").

Finally, Bard argues that Hyman's opinions on the testing, design and warnings should be excluded because they are based on inadequate facts or data, and are unreliable. Upon review, the Court again agrees with the well-reasoned decision in Cason, and holds that Hyman's opinions are not based on sufficient facts or data, and are not the product of reliable principles and methods. See Cason, 1:12-CV-1288-MHS, slip op. at 30-34. Hyman did not conduct any tests, examine a Bard G2 filter or any other type of IVC filter, and has never seen in person or touched an IVC filter. See Hyman Dep. at 23-24. Moreover, Hyman concludes that the G2 filter is defective without assessing the risks versus the benefits of the filter, the availability and safety profiles of other filters on the market, or the viability of a safer, alternative design. See McGee v. Evenflo Co., Inc., No. 5:02-CV-259-4(CAR), 2003 WL 23350439, at *5-6 (M.D. Ga. Dec. 11, 2003). Thus, based on the foregoing, and for the reasons discussed in Cason, the Court finds that Bard's Motion to Exclude Hyman is due to be granted, in part, as to Hyman's opinions on the design, testing and labeling of the G2 filter.

iv. Freeman

Michael Freeman, Ph.D. is an epidemiologist with a doctorate degree in public health. See Motion to Exclude Freeman, Ex. A (Doc. 95-1; Freeman Report) at 3. He is currently an Affiliate Professor of Epidemiology at the Oregon Health and Science University in Portland, Oregon, and has held this position since 2010. Id. at 26. Freeman offers two primary opinions in his expert report. First, Freeman opines that the "available data"

indicates that the G2 filter was "failing at a significantly increased rate relative to Bard's predicate permanent device, the SNF, as well as in comparison with both permanent and retrievable filters from other manufacturers," and in particular, "the rate of migration and perforation is significantly higher than for all other devices." See Freeman Report at 1. Second, Freeman posits that there were "early indicators prior to 2008" that the device was "failing and causing adverse events at a rate that was substantially elevated relative to other IVC filters on the market, including the predicate SNF filter." Id. at 2. As such, Freeman maintains that Bard would have had "a strong indication that G2 IVC filters were failing and causing adverse events at a relatively high rate within a matter of months of their release on the market." Id. at 5.

Bard moves to exclude Freeman's opinion that Bard filters were failing at an "alarmingly high" rate because it is based on data which, according to Bard, cannot be used to calculate rates for adverse events or complications. See Motion to Exclude Freeman at 2. As such, Bard maintains that Freeman's opinions are based on insufficient and unreliable data. Id. Bard also challenges Freeman's opinion that the G2 filter was fracturing and migrating at higher rates than filters manufactured by competitors as irrelevant. In addition, Bard argues that Freeman's opinions on Bard's corporate conduct should be excluded because Freeman has "no expertise in either IVC filters or corporate responsibility of a medical device company," such that he is not qualified to opine on this subject. Id. Last, Bard maintains that the probative value of Freeman's opinions is "substantially outweighed by a danger of unfair prejudice and confusing the issues for, or misleading, the jury." Id.

First, Bard challenges the reliability of the data underlying Freeman's opinions. Freeman's opinions on the failure rates of Bard's filters are based on his analysis of adverse event reporting data obtained from the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. See Freeman Report at 3. He then used "IMS (device sales) and Bard sales data in order to derive failure and event rates for each device that could then be compared." Id. Bard argues that "the MAUDE database does not accurately estimate the actual number of adverse events for a particular device, because what constitutes a reportable adverse event in the database is the subject of federal regulations . . . which can be interpreted differently by different doctors, hospitals, and device companies." See Motion to Exclude Freeman at 7. Bard cites to the FDA's warning that the MAUDE database "'cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices.'" Id. at 7-8 (citing MAUDE Database search page, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm). Bard also challenges the reliability of the IMS sales data. Id. at 8 n.2. In support, Bard cites several cases in which courts have rejected expert opinions premised on the anecdotal reports that make up adverse event data. See id. at 9 n.3, 10 n.4.

In his Report, Freeman acknowledges the weaknesses in the MAUDE data and explains his reasoning for finding this data to be a reliable source of information in the context of IVC filters. See Freeman Report at 4. Moreover, Freeman clarifies in his deposition that "as a broad overarching conclusion," his principal opinion in this case is that "at certain times, [as] delineated in [his] reports, [he] think[s] Bard had a signal about its

products based on whatever data it had pulled together." See Motion to Exclude Freeman, Ex. B: Deposition of Michael Freeman (Doc. 95-2; Freeman Dep.) at 67-68. Freeman explains that his opinion is limited to what the information in Bard's possession indicated to Bard. Id. at 68. As such, he is not opining on "how often this happens," or the "exact rate at which this happens," rather, he is stating only that "the information in front of Bard says, well, compared to the SNF and compared to other devices, it seems like these devices are failing at a really high rate." Id. at 94-95. Although Freeman reviewed medical literature "to get a good understanding of what was out there," he limited his analysis to "what the data that Bard had at the time demonstrated." Id. at 115-16. As such, Freeman explains that he is not giving any medical causation opinions in this case. Id. at 126.

Upon review, the Court determines that Bard's criticisms are more appropriately directed to the weight, rather than the admissibility of this evidence. See In re Chantix (Varenicline) Prods. Liab. Litig., 889 F. Supp. 2d 1272, 1282 (N.D. Ala. 2012); In re Fosamax, 645 F. Supp. 2d at 178 ("Under Daubert, an expert need not base his or her opinion on the best possible evidence, regardless of availability, but upon 'good grounds' based on what is known.'" (quoting Daubert, 509 U.S. at 590)). Bard does not identify an alternative source of data that would have been more accurate, and indeed, Freeman relies on the same MAUDE and IMS data that Bard used to analyze its products. See generally Lehmann Report. Moreover, the cases Bard cites generally address the use of adverse event reports to generate opinions on the effects of pharmaceutical drugs. Freeman acknowledges the "criticisms of the use of the FDA adverse event reporting system (AERS) as a basis for comparing the rate of adverse reactions to drugs," but explains that

this "is a much less significant issue when evaluating the relative failure rate of medical devices." See Freeman Report at 3. Freeman elaborates that "when used to track a device failure the MAUDE database is a highly reliable source of information, as a device failure is not attributable to any cause other than a failure of the device." See id. at 3.

In addition, Bard's cited authority discusses the unreliability of using this type of evidence to generate opinions specific to causation. See, e.g., In re Accutane Prods. Liab., 511 F. Supp. 2d 1288, 1298 (M.D. Fla. 2007) (stating that the adverse event reports were "unreliable as proof of causation because, in general, the events were not observed in such a way as to rule out coincidence or other potential causes"); McClain, 401 F.3d at 1250 (holding that adverse event reports were "one of the least reliable sources to justify opinions about both general and individual causation"); but see In re Baycol Prods. Liab. Litig., 532 F. Supp. 2d 1029, 1041-42 (excluding expert opinion that drug was the most toxic of its variety because expert's comparative analysis used adverse event data). However, Freeman explains in his deposition that he is not using the adverse event reports to generate an opinion as to causation. See Freeman Dep. at 126. Rather, Freeman draws inferences from the available data about the comparative failure rates among IVC filters, and he explains his reasoning for why the data is reliable to support his conclusions. See Freeman Report at 3-4. As such, the Court does not find the cited authority on causation to be persuasive in this context. Rather, Bard's arguments concerning the weaknesses of the underlying MAUDE and IMS data go to the weight rather than the admissibility of the opinion. See Deutsch, 768 F. Supp. 2d at 432, 441 (finding that objections to the factual bases for the experts' opinions on the incidence rate "go to the weight and not the admissibility of their

testimony"). Bard may explore these weaknesses in Freeman's opinions on cross-examination.[19] Accordingly, Bard's Motion to Exclude Freeman is due to be denied, in part, to the extent Bard seeks the exclusion of Freeman's opinions on the comparative rate of failure of Bard's filters. See Phillips v. C.R. Bard, Inc., 3:12-cv-00344-RCJ-WGC, slip op. at 11 (D. Nev. Dec. 16, 2014) (stating that the Court was inclined to allow Freeman to testify to the comparative failure rates at trial).[20]

Next, to the extent Freeman opines on Bard's corporate conduct or how Bard should have responded to the data in its possession, Tillman fails to establish that Freeman is qualified to opine on this subject. Freeman is an expert in the particular scientific discipline of epidemiology and forensic medicine. Freeman's areas of expertise do not include "knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig., No. MDL 1203, 2000 WL 876900, at *9 (E.D. Penn. June 20, 2000). Moreover, the Court finds that these opinions are not helpful to the jury. See In re Rezulin, 309 F. Supp. 2d at 547; In re Fosamax, 645 F. Supp. 2d at 192. Bard's intent or motivations are "lay matters which a jury is capable of understanding and deciding without the expert's help." In re Rezulin, 309 F. Supp. 2d at 546.

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[19] To the extent Bard challenges the relevance of these opinions because they pertain to fracture and migration, this argument is again rejected for the reasons expressed above. See supra Part II.B.i.

[20] Phillips, like Cason, is another lawsuit against Bard based on its IVC filters, although Phillips concerns a Recovery, rather than a G2, filter. Tillman filed a notice of supplemental authority (Doc. 158) attaching the Phillips decision on January 25, 2015.

However, to the extent Freeman merely discusses what information was available and possessed by Bard prior to Tillman's procedure, this testimony is helpful and relevant to determining whether Bard acted reasonably and does not improperly comment on Bard's "state of mind." In re Flonase, 884 F. Supp. 2d at 192-93. Thus, Freeman may opine on what information and knowledge was available to Bard, but may not go beyond that to offer opinions on Bard's intent, motive, or what it should have done with that information. Id.; see also In re Seroquel, 2009 WL 3806436, at *3-4; Deutsch, 768 F. Supp. 2d at 443 ("However, whether [the expert] can opine on [the manufacturer's] state of mind is distinct from whether [the expert] can opine on his interpretation of whether certain information contained in [the manufacturer's] internal documents indicated certain risks . . . .").

III. Summary Judgment Standard of Review

Under Rule 56, Federal Rules of Civil Procedure (Rule(s)), "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Rule 56(a). The record to be considered on a motion for summary judgment may include "depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." Rule 56(c)(1)(A).[21] An issue is genuine when the evidence is such that a reasonable jury

[21] Rule 56 was revised in 2010 "to improve the procedures for presenting and deciding summary-judgment motions." Rule 56 advisory committee's note 2010 Amendments.

> The standard for granting summary judgment remains unchanged. The language of subdivision (a) continues to require that there be no genuine dispute as to any material fact and that the movant be entitled to judgment as a matter of law. The amendments will not affect continuing development of the decisional law construing and applying these phrases.

could return a verdict in favor of the nonmovant. See Mize v. Jefferson City Bd. of Educ., 93 F.3d 739, 742 (11th Cir. 1996) (quoting Hairston v. Gainesville Sun Publ'g Co., 9 F.3d 913, 919 (11th Cir. 1993)). "[A] mere scintilla of evidence in support of the non-moving party's position is insufficient to defeat a motion for summary judgment." Kesinger ex rel. Estate of Kesinger v. Herrington, 381 F.3d 1243, 1247 (11th Cir. 2004) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986)).

The party seeking summary judgment bears the initial burden of demonstrating to the court, by reference to the record, that there are no genuine issues of material fact to be determined at trial. See Clark v. Coats & Clark, Inc., 929 F.2d 604, 608 (11th Cir. 1991). "When a moving party has discharged its burden, the non-moving party must then go beyond the pleadings, and by its own affidavits, or by depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." Jeffery v. Sarasota White Sox, Inc., 64 F.3d 590, 593-94 (11th Cir. 1995) (internal citations and quotation marks omitted). Substantive law determines the materiality of facts, and "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." Anderson, 477 U.S. at 248. In determining whether summary judgment is appropriate, a court "must view all evidence and make all reasonable inferences in favor of the party opposing summary judgment." Haves v. City of Miami, 52 F.3d 918, 921 (11th Cir. 1995) (citing Dibrell Bros. Int'l, S.A. v. Banca Nazionale Del Lavoro, 38 F.3d 1571, 1578 (11th Cir. 1994)).

Id. Thus, case law construing the former Rule 56 standard of review remains viable and is applicable here.

IV. Bard Motion for Summary Judgment

A. Strict Liability

"Strict liability is defined as negligence as a matter of law or negligence per se; it relieves the plaintiff of the burden of proving specific acts of negligence." Barrow v. Bristol-Myers Squibb Co., No. 96-689-CIV-ORL-19B, 1998 WL 812318, at *27 (M.D. Fla. Oct. 29, 1998). In West v. Caterpillar Tractor Co., Inc., 336 So. 2d 80, 87 (Fla. 1976), Florida adopted the strict products liability standard of the Restatement (Second) of Torts § 402A. See West, 336 So. 2d at 87; Jennings v. BIC Corp., 181 F.3d 1250, 1255 (11th Cir. 1999). "Under this standard, the manufacturer of a defective product can be held liable if the manufacturer made the product in question, if the product has a defect that renders it unreasonably dangerous, and if the unreasonably dangerous condition is the proximate cause of the plaintiff's injury." Jennings, 181 F.3d at 1255. Under Florida law, "'a product may be defective by virtue of a design defect, a manufacturing defect, or an inadequate warning.'" Id. (quoting Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167, 1170 (Fla. 4th Dist. Ct. App. 1998)). In this case, Tillman asserts all three defects.

i. Failure to Warn

A defendant is strictly liable for a failure to warn where a plaintiff proves that the defendant "(a) is a manufacturer or distributor of the product at issue, and (b) did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture and distribution." See Thomas v. Bombardier Recreational Prods., Inc., 682 F. Supp. 2d 1297, 1300 (M.D. Fla. 2010). Because the G2 filter is a prescription medical

device, the learned intermediary doctrine applies to Tillman's claim. See Rounds v. Genzyme Corp., 440 F. App'x 753, 755 n. 2 (11th Cir. 2011).[22] Under this doctrine, the manufacturer owes a duty to warn to the patient's physician, rather than the patient directly. See Barrow, 1998 WL 812318, at *30; Rounds, 440 F. App'x at 755 ("The manufacturer's duty to warn of a prescription product's hazards runs to the physician, not directly to the patient."). Moreover, the failure of the manufacturer to provide the physician with an adequate warning is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that an adequate warning should have communicated. See Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995).

In this case, because Bard did provide some warnings regarding its G2 filters, "the issue is whether the warning provided to the physician is adequate." Rounds, 440 F. App'x at 755. "When the warning is accurate, clear, and unambiguous, its adequacy is a question of law. When the warning is not accurate, clear, or unambiguous, its adequacy is a question of fact that a jury may resolve." Kaufman v. Wyeth, LLC, No. 1:02-CV-22692, 2011 WL 10483576, at *5 (S.D. Fla. Aug. 15, 2011) (internal citations omitted). In Upjohn Co. v. MacMurdo, 562 So. 2d 680 (Fla. 1990) the Florida Supreme Court set forth a general rule that, because the duty to warn of a prescription product's dangerous side effects is to the physician, not the patient, "the adequacy or inadequacy of the warning to inform a physician must, except in the more obvious situations, be proved by expert testimony." See Upjohn, 562 So. 2d at 683; see also Barrow, 1998 WL 812318, at *30; Beale v. Biomet, Inc., 492 F.

[22] "Although an unpublished opinion is not binding . . ., it is persuasive authority." United States v. Futrell, 209 F.3d 1286, 1289 (11th Cir. 2000) (per curiam); see generally Fed. R. App. P. 32.1; 11th Cir. R. 36-2 ("Unpublished opinions are not considered binding precedent, but they may be cited as persuasive authority.").

Supp. 2d 1360, 1369 (S.D. Fla. 2007); Kaufman, 2011 WL 10483576, at *5. As such, in Upjohn, the Florida Supreme Court found that the manufacturer was entitled to judgment on the patient's failure to warn claim where "no medical expert testified that the package insert was insufficient to put a doctor on notice that the symptoms displayed by [the patient] . . . could result from the use of [the drug]." See Upjohn, 562 So. 2d at 683.

Bard maintains that Tillman's failure-to-warn claims fail under the learned intermediary doctrine because "the evidence demonstrates that Bard adequately warned Dr. Stockland, the implanting physician, of the risk of relevant complications in the Filter." See Bard Motion at 19. Stockland testified that "[e]very time one of the new Bard devices came out I would review the new instruction booklet." See Stockland Dep. at 28. The IFU accompanying the G2 filter included warnings regarding filter fracture, movement or migration of filters, and the possibility that the complications described "may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted." See Bard Motion, Ex. P.[23] In addition, the list of potential complications in the IFU includes, among other things, the embolization of filter fragments, and the perforation or other acute chronic damage of the IVC. According to the IFU:

> [a]ll of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit for a patient who is at risk of pulmonary embolism without intervention.

[23] Tillman attaches several variations of the G2 filter's IFU to her Response, however, the revision dates on these documents indicate that they were issued after the date of Tillman's implantation. See Tillman Response, Exs. A-C. Exhibit P to the Bard Motion is an IFU with a last revision date of January 2008, prior to Tillman's February 2008 procedure, and thus, the IFU relevant to this case.

Id. In addition, the IFU references a clinical study of 100 patients in which 61 patients underwent the filter retrieval procedure and 58 patients had a successful retrieval. Id. Notably, the three failed retrievals "resulted from inability to engage the filter apex with the Recovery Cone® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall." Id. Indeed, Stockland testified that he was aware that IVC filters carried risks of fracture, migration, perforation, and tilt, as well as the risk that complications may make it impossible or unadvisable to remove a retrievable filter intended to be temporary. See Stockland Dep. at 15-18, 27, 38, 56-57.

Based on the foregoing, not only did the IFU accompanying the G2 filter warn of the specific complications that Tillman experienced, but Stockland was otherwise aware of these potential risks. Nonetheless, Tillman contends that these warnings were inadequate, and that the learned intermediary doctrine should not apply because Stockland was not fully informed of the risks and was misled by the language in the IFU.[24] See Tillman Response at 17-18. Specifically, Tillman argues that Bard failed to issue "a warning about the higher failure rates with the G2 Filter."[25] See id. at 6. In addition, Tillman maintains that the IFU

[24] Tillman also argues that 21 C.F.R. § 801.109(c) "imposes a duty on Defendants to warn the patient directly, and breach of this regulation gives rise to strict liability." See Tillman Response at 17. However, her contention is not supported by the text of the regulation and Tillman cites no case law in support of her position. As such, to the extent Tillman contends that Bard is liable because it did not warn her directly, this argument is without merit.

[25] Bard contends that it has no duty to warn of the comparative rates of complication for its filters. See Bard Motion at 20. "Although Bard frames this argument as one of duty, it actually relates to whether Bard's warnings were adequate, which is a question of breach." See Cisson v. C.R. Bard, Inc., No. 2:11-cv-00195, 2013 WL 5700513, at *7 (S.D.W.V. Oct. 18, 2013). Indeed, the Court finds persuasive authority from courts applying analogous principles under Georgia law that "a failure to warn about the rate or severity of potential injury creates a jury question over the adequacy of warnings." Id. (citing Watkins v. Ford Motor Co., 190 F.3d 1213, 1220 (11th Cir. 1999) ("The question that must be answered by the fact finder is whether the warning given was sufficient or was inadequate because it did not provide a complete disclosure of the existence and extent of the risk involved.")); Cason, 1:12-cv-1288-MHS, slip op. at 11-16; Davis v. C.R. Bard, Inc., No. 11-12556, 2012 WL 6082933, at * 9 (E.D. Mich. Dec. 6, 2012); In re Mentor Corp. ObTape Transobturator Sling

warnings used language that minimized or negated the risk. See id. at 18. Tillman relies on Zanzuri v. G.D. Searle & Co., 748 F. Supp. 1511 (S.D. Fla. 1990) in support of this argument. In Zanzuri, the court found that the manufacturer was not entitled to summary judgment on the plaintiff's failure to warn claim where medical experts testified that the warning was inadequate, in part, because "it did not present data to the physician or patient upon which they could make a judgment as to the comparative risk" of developing a particular complication when using this product as opposed to other types of contraceptive. Id. at 1517. In addition, the medical experts testified that the warnings did not adequately convey the information present in the medical literature about the risk, and in fact, used language which minimized or negated the warnings. Id. Based on this evidence, the court found an issue of fact with respect to whether the warnings were adequate. Id. Moreover, the court determined that the learned intermediary doctrine did not apply because, although the plaintiff's physician was aware of the risks, he was also exposed to the misrepresentative product warnings. Id. at 1518. While the Zanzuri court reasoned that it was not necessarily impossible for a manufacturer to show that a physician had "formed an accurate opinion as to a product's safety where the product warning contains misstatements from the manufacturer," the record presented in Zanzuri was "not sufficiently compelling to persuade [the court] that despite the presence of possible missstatements, [the physician] was nevertheless fully informed as to the risks associated with the [device]." Id. at 1518.

Prods. Liab. Litig., 711 F. Supp. 2d 1348, 1377-78 (M.D. Ga. 2010). Nonetheless, the Court need not resolve this issue because Florida law generally requires the testimony of an expert to establish the inadequacy of a medical warning, and as discussed below, Tillman fails to satisfy this requirement.

Tillman argues that this Court is faced with analogous facts. Tillman points to language in the IFU which refers to migration as a "known complication," as well as language that there have been "reports" of filter fracture but that "most cases of filter fracture, however, have been reported without any adverse clinical sequelae." See Tillman Response at 18. According to Tillman, such language is similar to the language found to be inadequate and misleading in Zanzuri. See Zanzuri, 748 F. Supp. at 1516-17 ("An increased risk of pelvic inflammatory disease associated with the use of IUDs has been reported. While unconfirmed, this risk appears to be greatest for young women who are nulliparous . . . ."). However, unlike Zanzuri, Tillman fails to cite to the opinion of any qualified expert who has analyzed the IFU and found that it "did not adequately convey the information . . . as reflected in medical literature," or that the language used misrepresented the actual risks. Compare Zanzuri, 748 F. Supp. at 1517 with Tillman Response at 17-18.[26] While Tillman argues that the IFU should have included information on the failure rates and comparative

[26] Although not specifically cited by Tillman to support her argument, the Court notes that Hyman does opine that "Bard did not adequately warn physicians about the actual risks of the Recovery and G2 filters, including, but not limited to, arm fracture, vena cave perforations, tilting and migration or that it did not know the specific causes of those failures or how to prevent them." See Hyman Report at 31. However, as discussed above, Hyman is not qualified to render an opinion on the adequacy of Bard's warnings and as such, this opinion is inadmissible. See supra Part II.B.iii.

Additionally, while Tillman does not rely on this evidence in her Response, she cites to the testimony of Christine L. Brauer, Ph.D. in the Tillman Motion. See Tillman Motion at 6-7. Brauer has a masters degree in microbiology and molecular biology, and a doctorate degree in women's health and research methods. See Tillman Motion, Ex. X: Deposition of Christine Brauer, Ph.D (Docs. 97-13 to 97-25; Brauer Dep.), Ex. 2. She has "worked in the regulation of medical devices for over 20 years, including positions within FDA, industry, and as a consultant." Id. Brauer testifies that "statements of increased migration resistance and enhanced fracture resistance" included in some of the G2 filter's advertising materials "are not accurate, if you're comparing G2 to the Simon Nitinol." See Brauer Dep. at 216-25. Nonetheless, this evidence is not sufficient to create an issue of fact on Tillman's failure to warn claim because Tillman cites to no evidence that Stockland was aware of these alleged misrepresentations. Moreover, Brauer does not testify that the warnings given in the IFU were insufficient as a result of these inaccuracies. Notably, Tillman does not explain if Brauer is qualified as an expert in FDA warning labels pertaining to G2 filters, and although Tillman states that Brauer is "designated as an expert in the case at bar," the citation given does not support this assertion. See Tillman Motion at 6, Ex. T.

risks and that it uses language which "minimizes or negates" the warnings given, these contentions are unavailing without any expert evidence to support them. See Upjohn, 562 So. 2d at 683. Because this is not a case where the inadequacy of the warning would be obvious to a lay person, Tillman's failure to provide admissible expert testimony on this issue is fatal to her claim. See Upjohn, 562 So. 2d at 683; Kaufman, 2011 WL 10483576, at *5. Accordingly, the Court will grant Bard's Motion for Summary Judgment on Tillman's strict liability failure to warn claim.[27]

ii. Design Defect

Bard offers three primary arguments in support of its request for summary judgment on Tillman's strict liability design defect claim. First, Bard contends that Tillman's claim is "precluded by application of comment k to § 402A of the Restatement (Second)." See Motion at 14-15. Second, Bard argues that Tillman's design defect claim must fail because she "has not provided any evidence pinpointing what exactly was defective about the Filter, or how any such alleged defect caused the Filter to tilt, migrate, or perforate [her] IVC." Id. at 15-16. Last, Bard contends that Tillman's claim must fail because Florida law requires her to identify a reasonable alternative design and she fails to provide any evidence of an alternative design the omission of which rendered the Filter unsafe. Id. at 16-17. Upon review, the Court finds that there is an issue of fact as to whether the design of the Filter is defective. Tillman presents evidence that the Filter, as designed, has a propensity to tilt, migrate, or perforate the IVC, complications which can also lead to fracture. In addition, the

[27] To the extent Tillman also asserts a negligent failure to warn claim, her failure to demonstrate the inadequacy of the warning entitles Bard to summary judgment on that theory of liability as well. See Kaufman, 2011 WL 10483576, at *5.

Filter's geometry and lack of chamfer on the inner-rim of the filter sleeve increase the Filter's risk of fracturing. In response to this evidence, Bard fails to demonstrate the absence of a question of fact as to whether the Filter is as safe as current testing and research permit, and that its benefits outweigh its risks, such that comment k is inapplicable. Finally, the Court determines that Florida law does not require Tillman to identify an alternative reasonable design in the context of a products liability action pertaining to a medical device.

The definition of design defect is in a "state of flux in Florida." See In re Standard Jury Instructions in Civil Cases - Report No. 09-10 (Prods. Liab.), 91 So. 3d 785, 789 (2012) (Pariente, J., concurring). Currently, the Florida jury instruction on design defect instructs that: "A product is unreasonably dangerous because of its design if [the product fails to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the manufacturer] [or] [the risk of danger in the design outweighs the benefits]." See Florida Standard Jury Instructions in Civil Cases - PL 5. Courts refer to the first parenthetical as the "consumer-expectation test" and the second parenthetical as the "risk-utility test." See Force v. Ford Motor Co., 879 So. 2d 103, 105 (Fla. 5th Dist. Ct. App. 2004). As addressed by Justice Pariente of the Florida Supreme Court, although the jury instruction contains both tests, the Supreme Court Committee on Standard Jury Instructions in Civil Cases "takes no position on whether the risk/benefit test is a standard for product defect . . . or an affirmative defense." See In re Standard Jury Instructions, 91 So. 3d at 789. In addition, Justice Pariente observes the lack of clarity regarding whether the Third Restatement of Torts applies in design defect cases. Id. Thus,

at present, the proper definition of design defect, and whether that definition varies depending on the type of product involved remains unclear in Florida law. Id.

The "consumer-expectation test" is derived from the strict liability doctrine set forth in section 402A of the Restatement (Second) of Torts. See Edic ex rel. Edic v. Century Prods. Co., 364 F.3d 1276, 1285 (11th Cir. 2004); Restatement (Second) of Torts § 402A (1965), cmt. i. However, "[d]ue to the difficulty in applying the consumer expectation standards to all types of product defects, many thoughtful commentators have suggested that it should be rejected, particularly as to those defects arising from design, in favor of a test that would weigh the utility of the design versus the magnitude of the inherent risk." See Cassisi v. Maytag Co., 396 So. 2d 1140, 1145 (Fla. 1st Dist. Ct. App. 1981). Although Florida courts generally continue to rely on the consumer-expectation test, some courts have observed that "there may . . . be products that are too complex for a logical application of the consumer-expectation standard." See Force, 879 So. 2d at 106; Tran v. Toyota Motor Corp., 420 F.3d 1310, 1314 (11th Cir. 2005). At least one District Court of Appeal in Florida has rejected the consumer-expectation test entirely. See Agrofollajes, S.A. v. E.I. Du Pont de Nemours & Co., Inc., 48 So. 3d 976, 997 (Fla. 3d Dist. Ct. App. 2010). Because this case pertains to a complex medical device, accessible to the consumer only through a physician, the Court finds that the consumer-expectation test is not applicable here. See Rydzewski v. DePuy Orthopaedics, Inc., No. 11-80007-Civ, 2012 WL 7997961, at *2 (S.D. Fla. Aug. 14, 2012) (rejecting the consumer-expectation test in a design defect claim pertaining to a medical device); In re Fosamax Prods. Liab. Litig., No. 1:06-MD-1789-JFK, 2010 WL 1257299, at *6

n.4 (S.D.N.Y. Mar. 26, 2010) (applying Florida law and rejecting consumer-expectation test in a design defect claim pertaining to a prescription drug).

Consistent with this well-reasoned authority, to analyze Tillman's design defect claims, the Court will apply a risk-utility test. However, the exact contours of the risk-utility test are also unclear under Florida law. Under one version of the test, a product is defective in design where "the plaintiff demonstrates that the product's design proximately caused his injury and the defendant fails to establish, in light of the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design." See Cassisi, 396 So. 2d at 1145-46. Under this test, "[o]nce the plaintiff establishes a prima facie case showing that his injuries were caused by a product's design, the burden is shifted to the defendant to prove the design was not defective by presenting evidence of factors, such as the gravity of the danger posed by the challenged design, the feasibility of a safer design, the financial cost of improved design, etc." Id. Although the Cassisi court did not decide whether this risk-utility test applied under Florida law, other courts have subsequently cited to this definition of the risk-utility test as a correct statement of Florida law. See Force, 879 So. 2d at 106; Rydzewski, 2012 WL 7997961, at *2 n.2; Kaufman, 2011 WL 10483576, at *6; Barrow, 1998 WL 812318, at *28 ("Although it has not done so yet, this Court believes that the Florida Supreme Court would adopt such risk-utility test." (citing Pulte Home Corp., Inc. v. Ply Gem Indus., Inc., 804 F. Supp. 1471, 1487 (M.D. Fla. 1992))).

Notably, the aforementioned risk-utility analysis appears to embody the intent of comment k in the Second Restatement. See Restatement (Second) of Torts § 402A, cmt. k. Comment k addresses "[u]navoidably unsafe products," described as "products which,

in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs." Id. The comment cites the treatment for rabies as an "outstanding example" of such a product because, while the treatment can lead to very serious and damaging consequences, the disease itself invariably leads to a dreadful death. Id. Thus, "the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve." Id. According to comment k, "[s]uch a product, properly prepared, and accompanied by proper directions and warnings, is not defective nor is it unreasonably dangerous." Id. As such:

> [t]he seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Id. The comment suggests that this reasoning applies to many other drugs, vaccines and the like which, because of their danger, can only be sold to physicians or under prescription. Id.

In Adams, Florida's Second District Court of Appeal explained that "by its terms comment k applies to products which current knowledge and technology cannot make safe for their ordinary use, but for which society has a need great enough to justify using the product despite its dangers." Adams, 576 So. 2d at 731. Noting that the comment "adopts a risk/benefit analysis," the court reasoned that the comment should not uniformly protect all prescription drugs or medical products. Id. at 732. Rather, only "a product which is as safe as current testing and research permits should be protected. The reverse is also true;

a product which is not as safe as current technology can make it should not be protected." Id. Accordingly, the court concluded that comment k "is an affirmative defense to a strict liability claim," such that "the seller has the burden to establish the application of comment k." Id. at 733. Whether comment k applies should be based on a risk-benefit analysis, and "if reasonable minds might differ, then the matter must be submitted to the jury." Id. Thus, to be protected under comment k, a defendant must show that the product is as safe as current testing and research permit, and that the product's benefits outweigh the known risks as of the date the product is distributed. Id. at 732-33. "If new information later tips the balance toward the risk of a product, or if new developments make possible a safer design, at that point further distributions of the product are not protected by comment k." Id. at 733; see also Zanzuri, 748 F. Supp. at 1518-20.

For the reasons discussed below in the causation portion of this decision, Tillman presents sufficient evidence to create an issue of fact as to whether her injuries were caused by the Filter's design. See infra Part IV.B. In sum, the evidence shows that tilt, perforation and migration are known risks of G2 filters, Grassi Report at 4, and Hull testifies that there is no indication that any outside factor caused the complications Tillman experienced. See Hull Report at 6. Moreover, Tillman presents evidence that the tendency to tilt, migrate or perforate the IVC, as well as the geometry of the device and its lack of a chamfer on the rim of the filter sleeve, make G2 filters prone to fracture. See Ritchie Report at 11-12; McMeeking/Begley Report at 10, 12. She also presents evidence that these aspects of the Filter's design have damaged her in that the resulting risk of fracture requires Tillman to obtain ongoing medical monitoring. Accordingly, the Court considers next whether Bard has

established that the benefits of the Filter outweigh these risks. Cassisi, 396 So. 2d at 1145-45

In support of its comment k defense, Bard relies on Stockland's testimony that IVC filters can be life-saving medical devices. See Stockland Dep. at 14. In addition, Stockland testified to his awareness of the risks associated with IVC filters, and explained that he decides whether to use a medical device by considering the risk-benefit ratio. Id. at 15-22, 27. Stockland states that "[i]f the device in any way aids the patient's outcome or health and that outweighs the risk of the device being implanted, that's how we decide." Id. at 12-13. Because Stockland implanted the filter in Tillman despite his awareness of the risks associated with the use of IVC filters, Bard maintains that the potentially life-saving benefits of the device outweigh the known risks. Id. at 15. In addition, Bard maintains that the IVC filter is incapable of being made safe and cites to Begley's testimony that it is impossible to design an IVC filter that never migrates, tilts or fractures. See id., Ex. I: Begley Dep. at 43.

Rather than respond to Bard's arguments directly, or cite to specific evidence that would create an issue of fact, Tillman unhelpfully responds, in summary fashion, that Bard "has presented no evidence establishing that the G2 Filter is such a special device needed to satisfy an exceptional social/medical need that the benefits exceed its risks, or that the device could not have been made safer at the time of manufacture and distribution." See Tillman Response at 14. Nonetheless, the Court finds that Bard fails to establish that it is entitled to protection under comment k. To receive the protection of comment k, Bard must show that "the product is as safe as current testing and research permit" at the time of distribution. Adams, 576 So. 2d at 732-33. Bard does not cite to any evidence in its Motion

to support a finding that the Filter was as safe as testing and research would permit at the time of distribution. See Bard Motion at 15. Indeed, Tillman presents expert opinions that Bard's testing was insufficient to demonstrate the safety of the device, and that certain design changes would have reduced the risk of fracture and made the device safer. See Ritchie Report at 10-11; McMeeking/Begley Report at 1, 10, 18-22. Of note, Ritchie opines that the lack of a chamfer on the rim of the filter cap, as well as the failure to electropolish the filters to remove surface defects increased the stresses and strains on the device leading to fatigue failure. See Ritchie Report at 6, 10. Thus, there is a question of fact whether the fracture risk of the Filter could have been reduced.

Additionally, Tillman submits evidence that the G2 filter experiences higher adverse event rates in certain categories than other IVC filters. The G2 filter's predecessor, the Recovery, had statistically significant higher reporting rates for death, filter migration (movement), IVC perforation, and filter fracture than all other removable filters. See Tillman Response, Ex. M. Although this data should be viewed with caution, it is corroborated, at least in part, by bench testing which also "revealed that the Recovery filter has the least ability to resist migration of all tested [IVC] filters at larger simulated IVC diameters." See Lehmann Report at 21. As to the G2 filter, Freeman states that "within 2 quarters the G2 matched or exceeded the rate of perforation and migration observed in the withdrawn Recovery filter." See Freeman Report at 5. Freeman opines that "within the first 2 quarters of sales of the Bard G2 filter in 2005," early signals indicated that the G2 filter was "failing at . . . a high rate for PE, fracture, migration and perforation relative to Bard's SNF permanent IVC filter, as well as in comparison with other manufacturer's permanent and

retrievable filters." Id. Internal Bard documents acknowledge that "[f]eedback from our customers, the field and our own clinical data have shown an increased frequency of migration in the caudal direction with the G2 and G2X filters as compared to Recovery." See Tillman Response, Ex. W; Ex. X: Deposition of Robert Carr (Doc. 134-15; Carr Dep.) at 97-98. Significantly, caudal migration can lead to tilt, "penetration," and fracture. See Carr Dep. at 98; 124-25 ("If the filter ends up in an orientation that imparts a stress that is not anticipated on it, that is the most likely cause of a potential fracture. . . . I am talking about a migration that causes a penetration that causes a stress to be in an arm in particular that wasn't ordinary."); see also Ritchie Report at 19 ("Indeed, the occurrence of tilting, migration and most certainly perforation more likely than not resulted in the fracture of specific struts in the failed filters.").

In light of the foregoing, Bard's reliance on Stockland's decision to implant the Filter as evidence that its benefits outweigh its risks is unavailing. Although Stockland's testimony suggests that IVC filters in general satisfy a medical need to protect against a life-threatening pulmonary embolism, this evidence does not establish that the G2 filter in particular provides benefits which outweigh its risks. Notably, Stockland testifies that he was unaware of the information indicating that the adverse event report rate for the Recovery in categories such as filter fracture, movement, embolization, and death, was significantly higher than with other retrievable IVC filters. See Stockland Dep. at 89-90; see Lehmann Report at 2; Freeman Report at 5. He states that such information would have been significant to him and could have influenced his decision to use the G2 filter on Tillman. See Stockland Dep. at 89-90. Stockland also stated that he was never provided the information that the safety profiles of

the Recovery and G2 filters were different than that of the predecessor filter, the SNF, and that such information could be very important to him in deciding whether to use a Bard filter. Id. at 93-95. Thus, while Stockland was aware of the general risks attendant with the use of IVC filters, he was not aware of the quantum of risk associated with the use of this Bard filter in particular. As such, the Court is not persuaded by Bard's argument that Stockland's decision to use the G2 filter establishes that its benefits outweigh its risks.

In addition, Hull, Tillman's medical expert, remarks from his observation of the Recovery filter in practice, that

> the device had an early perforation rate of 56%, and as time went on, a perforation rate of 100%. Recent literature studying the G2 filter has shown that the filter experiences a 'grade 3' perforation of the vessel 43.3% of the time. Of note is that the same study found that the G2's predecessor (Recovery) was found to have grade 3 perforation 52.2% of the time.

See Hull Report at 3. Because of the G2 filter's propensity to perforate the vessel wall, Hull finds that it "is at an increased risk of fracture." Id.; see also Ritchie Report at 19. In addition, Hull notes that "these filters do not have a common strut, wire or other instrument to connect the struts of the device to one another." See Hull Report at 3. As such, "when the device experiences fracture of one (or more) of the struts, the design of the filter allows fractured struts to independently embolize from their position through the vasculature to the body's vital organs (i.e., the heart, lungs, and other organs/anatomical locations)." Id. Hull maintains that in his professional opinion and the opinion of his colleagues in the field of interventional radiology, "fracture rates that result in embolization or potential embolization of the fractured portions of the device for vena cava filters should be well less than 1%, and, as close to zero % as possible." Id. at 6. According to Hull, "[t]he vena cava wall perforation,

limb fracture with embolization and migration through the body or to organs is a unique, dangerous and unexpected complication of having a vena cava filter." Id. at 5.

Hull concludes that "[b]ased upon my observations, review of the medical literature, and evidence adduced to date in this litigation, it is my opinion that the G2 filter presents risks of harm to patients that are unacceptable, and which outweigh the benefits provided by the device." See id. at 4. Hull adds that

> [w]hile [pulmonary embolism] is indeed a serious medical condition that can present serious risks to patients, there are preferred methods of preventing [pulmonary embolism], ... To suggest that an IVC filter is the sole, or best, method of choice for preventing [pulmonary embolism] does not take into account the reality that these other methods to treat [pulmonary embolism] exist.

Id. at 8. The Court expresses no opinion on whether the risks of the G2 filter outweigh its benefits, however it is enough at this stage in the proceedings to find that, based upon the evidence before the Court, "reasonable minds might differ" on the matter. See Adams, 576 So. 2d at 733. Therefore, in light of the foregoing evidence, the Court finds that Tillman has demonstrated an issue of fact as to whether the G2 filter is unreasonably dangerous, and therefore defectively designed, and Bard fails to establish that it is entitled to summary judgment pursuant to the comment k affirmative defense.

Alternatively, Bard relies on a slightly different version of the risk-utility test, described in the Restatement (Third) of Torts, to argue that Tillman's claim fails because she does not provide evidence of a reasonable alternative design. See Bard Motion at 16.[28] Section 2 of

[28] Bard also contends, as a "preliminary point," that it is "entitled to a rebuttable presumption of no liability under Florida law because the G2 filter complied with federal safety regulations." See Bard Motion at 16. This presumption, known as the Government Rules Defense, is set forth in section 768.1256(1) of the Florida Statutes, which provides:

the Third Restatement provides that a product is defective in design "when the foreseeable risk of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller . . . , and the omission of the alternative design renders the product not reasonably safe." Restatement (Third) of Torts: Products Liability § 2. It appears that some Florida courts have employed this version of the risk-utility test. See Tran, 420 F.3d at 1313-14 (explaining that the trial court erred by only instructing the jury on the Third Restatement's risk-utility test, and not also giving the consumer-expectation test as an independent basis for liability); Force, 879 So. 2d at 105-06, 110 (same). However, only Florida's Third District Court of Appeal has expressly adopted section 2 of the Third Restatement. See Union Carbide Corp. v. Aubin, 97 So. 3d 886, 893-94 (Fla. 3d Dist. Ct. App. 2012); Agrofollajes, S.A., 48 So. 3d at 997; Kohler Co. v. Marcotte, 907 So. 2d 596, 598-99 (Fla. 3d Dist. Ct. App. 2005); see also Warren ex. rel. Brassell v. K Mart

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> In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the product is not defective or unreasonably dangerous and the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm:
>
> (a) Complied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or injury;
>
> (b) The codes, statutes, rules, regulations, or standards are designed to prevent the type of harm that allegedly occurred; and
>
> (c) Compliance with the codes, statutes, rules, regulations, or standards is required as a condition for selling or distributing the product.

Fla. Stat. § 768.1256(1). "Florida's [Government Rules Defense] 'has not yet been thoroughly interpreted, and the contours and operation of the presumption are still largely unsettled.'" See Rydzewski, 2012 WL 7997961, at *2 (quoting Emerson v. Novartis Pharm. Corp., 446 F. App'x 733, 735 (6th Cir. 2011)). Bard simply states in a conclusory fashion that it is entitled to this presumption, but fails to offer any argument or citation to the record to demonstrate that Bard complied with the relevant statutes and regulations as required for application of the presumption. The Court could decline to apply the presumption on this basis alone. See Kaufman, 2011 WL 10483576, at *7. Nonetheless, even if the presumption applies, it is rebuttable by evidence that the Filter's design is defective or unreasonably dangerous. Id. For the reasons discussed above, the Court finds an issue of fact on this question, and will not grant summary judgment in favor of Bard based on the Government Rules Defense. Id.; Rydzewski, 2012 WL 7997961, at *2; In re Aredia & Zometa Prods. Liab. Litig, No. 3:06-MD-1760, 2010 WL 813459, at *2 (M.D. Tenn. Mar. 3, 2010).

Corp., 765 So. 2d 235, 237 (Fla. 1st Dist. Ct. App. 2000) (referencing favorably § 2 of the Third Restatement but not addressing the issue). Although the Fourth District Court of Appeal found the Third Restatement's version of the risk-utility test "instructive" in Scheman-Gonzalez v. Saber Mfg. Co., 816 So. 2d 1133, 1139 (Fla. 4th Dist. Ct. App. 2002), the court later limited the import of its prior reliance on the Third Restatement and emphasized that the Third Restatement "has not yet been adopted in Florida." See Liggett Grp., Inc. v. Davis, 973 So. 2d 467, 473, 475-76 (Fla. 4th Dist. Ct. App. 2007); McConnell v. Union Carbide Corp., 937 So. 2d 148, 151 n.4 (Fla. 4th Dist. Ct. App. 2006) ("We purposefully forbear from any reliance on the Restatement (Third) of Torts and its risk-benefit analysis until the supreme court has recognized it as correctly stating the law of Florida.").

Relying on this version of the risk-utility test, Bard argues that Tillman's claims must fail because she has not presented evidence of a reasonable alternative design. See Bard Motion at 16-17. The language of the Third Restatement does require a plaintiff with a design defect claim to prove the availability of a "reasonable alternative design." See Aubin, 97 So. 3d at 897.[29] In contrast, courts applying the Cassisi version of the risk-utility test identify the availability of an alternative design as merely one of the factors to consider in the analysis. See Kaufman, 2011 WL 10483576, at *6; Liggett, 973 So. 2d at 475 ("We find no case which holds that a plaintiff is required to show a safer alternative design in order to prevail on a strict liability design defect claim. Rather, it appears to be one factor which can

[29] The Aubin court recognizes an exception to this requirement where a plaintiff can show that "the product design at issue is 'manifestly unreasonable,'" meaning that "'the extremely high degree of danger posed by its use . . . so substantially outweighs its negligible social utility that no rational, reasonable person, fully aware of the relevant facts, would choose to use . . . the product.'" Aubin, 97 So. 3d at 897 (alterations in original) (quoting Restatement (Third) of Torts: Products Liability § 2, cmt. e). Tillman does not assert that the Filter's design is "manifestly unreasonable" within the meaning of the Third Restatement.

be demonstrated and argued to the jury."); see also Norton v. Snapper Power Equip, Div. of Fuqua Indus., Inc., 806 F.2d 1545, 1548-49 (11th Cir. 1987); Barrow, 1998 WL 812318, at *41-42. Indeed, in Radiation Technology, Inc. v. Ware Construction Co., 445 So. 2d 329 (Fla. 1983), the Florida Supreme Court indicated that whether a product is "unreasonably dangerous" within the meaning of the Second Restatement is contingent on a weighing of factors. See Radiation Tech., 445 So. 2d at 331. Specifically, the Florida Supreme Court instructed that this term

> balances the likelihood and gravity of potential injury against the utility of the product, the availability of other, safer products to meet the same need, the obviousness of the danger, public knowledge and expectation of the danger, the adequacy of instructions and warnings on safe use, and the ability to eliminate or minimize the danger without seriously impairing the product or making it unduly expensive.

Id. Thus, unless Florida has now adopted section 2 of the Third Restatement, the availability of an alternative design is merely one of the factors to be considered in determining whether a product is "unreasonably dangerous."

Upon careful consideration, the Court finds that regardless of whether the Third Restatement applies under Florida law in other contexts, in a medical device case such as this, Florida law does not apply this standard. The Florida cases in which courts have applied or acknowledged the test set forth in section 2 of the Third Restatement did not concern pharmaceutical drugs or medical devices. See Aubin, 97 So. 3d at 890 (construction materials including chrysotile asbestos); Kohler Co., 907 So. 2d at 598 (small engines); Agrofollajes, S.A., 48 So. 3d at 980 (fungicide); see also Scheman-Gonzalez, 816 So. 2d at 1136 (tire and wheel rim); Tran, 420 F.3d at 1312 (seatbelt); Force, 879 So. 2d at 105 (seatbelt). This is significant because the Third Restatement actually contains a

separate provision specifically tailored to medical devices. See Restatement (Third) of Torts: Products Liability § 6(c). Section 6 of the Third Restatement instructs that a medical device has a design defect if it is not reasonably safe in that "the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients." Id. Thus, even if the Third Restatement applied under Florida law, the reasonable alternative design test advocated by Bard is not the appropriate standard for a medical device case such as this. As no court in Florida has adopted section 6 of the Third Restatement, the Court determines that the risk-utility test articulated in Cassisi and embodied in comment k is the appropriate standard. Thus, to the extent Bard argues that the Court should enter summary judgment on Tillman's design defect claim because she fails to identify a reasonable alternative design, this request is due to be denied. Rather, because it is disputed whether the risks of the Filter outweigh the benefits, the Court finds an issue of fact as to whether the Filter is unreasonably dangerous due to its design.[30]

iii. Manufacturing Defect

Bard asserts that Tillman's manufacturing defect claim fails because Tillman does not provide any evidence that "the Filter varied from other G2® filters in its lot." See Bard Motion at 18. Absent evidence that the Filter deviated from its intended design, Bard contends that summary judgment is appropriate in its favor on this claim. In Response,

[30] Bard also argues that it is entitled to summary judgment on this Count because Tillman fails to present any evidence of causation. The Court will address Bard's causation arguments below. See infra Part IV.B.

Tillman argues that the Court should infer the existence of a manufacturing defect based on a principle of Florida law known as the Cassisi inference. See Tillman Response at 16-17 (citing Cassisi v. Maytag Co., 396 So. 2d at 1148). Specifically, Tillman argues that because the Filter cannot be removed and examined, it is appropriate to infer that a manufacturing defect exists based on the Filter's malfunction during normal use. See Tillman Response at 16-17. Alternatively, Tillman contends, without elaboration, that her experts and Dr. Robert Carr, Jr., the designer/patent holder of the original SNF filter technology, "have unequivocally established a defect and have shown that the G2® Filter 'does not conform to its intended design' in that it 'fails to perform as safely as the intended design would have performed.'" Id. at 17. Tillman then cites the Court to "supra" and provides no specific citation as to what evidence purportedly supports this proposition or where in the extensive record and lengthy expert reports it is located.

First, Tillman's argument that the Court should infer the existence of a manufacturing defect based on the Cassisi inference is unavailing. This inference provides that "when a product malfunctions during normal operation, a legal inference, which is in effect a mirror reflection of the Restatement's standard of product defect, arises, and the injured plaintiff thereby establishes a prima facie case for jury consideration." See Cassisi, 396 So. 2d at 1148. For the inference of a defect to apply, a plaintiff must demonstrate "two essential predicate facts . . . (1) a malfunction (2) during normal operation." See Hall v. Sunjoy Indus. Grp., Inc., 764 F. Supp. 2d 1297, 1302 (M.D. Fla. 2011). In an unpublished decision, a panel of the Eleventh Circuit has explained that the Cassisi inference applies "where a 'product malfunctions that would not malfunction but for the defect,' . . . ." Beauregard v. Cont'l Tire

N. Am., Inc., 435 F. App'x 877, 880 (11th Cir. 2011). However, a malfunction is not established merely because a product breaks. Rather, a plaintiff "must present evidence, through expert testimony, that [the product] did not perform properly under the circumstances." Id. As such, to demonstrate a malfunction, Tillman must show that "based on the design of the unit, it should not have [performed as it did]." See Edic, 364 F.3d at 1285-86.

Upon review, the Court finds that Tillman fails to submit any evidence that the Filter, as designed, should not have performed as it did. Indeed, tilt, perforation, and migration are all well-known potential complications with the use of IVC filters, including G2 filters. Grassi Report at 4. Thus, it is entirely possible that Tillman's Filter migrated, tilted, and perforated her IVC, despite the lack of any intervening manufacturing defect. In Cassisi, the court applied the inference to a dryer which, if manufactured as designed and used properly, should not have spontaneously caught fire. See Cassisi, 396 So. 2d at 1146 ("[The fire in the clothes dryer] differs either from the manufacturer's intended result or from other units of the same product line. . . . Moreover, the alleged offending product before us is not one required to be excepted from the standard, such as one that is unavoidably unsafe."). Similarly, in McCorvey, the court inferred the existence of a manufacturing defect because a catheter, if manufactured as designed and used properly, should not have spontaneously exploded as it did. See McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1258-59 (11th Cir. 2002). Thus, in those cases, it was the uncharacteristic malfunction that warranted the inference that the product deviated from its design by virtue of a manufacturing defect. In contrast, a G2 filter, if manufactured as designed and used properly, may still experience tilt,

migration, or perforation. Because these risks are inherent in the design of the G2 filters, the occurrence of these known complications does not give rise to an inference that Tillman's Filter deviated from its design due to a manufacturing defect.

Nonetheless, the Court finds that there is sufficient evidence in the record of a manufacturing defect in G2 filters to create an issue of fact on this claim. "Under Florida law, a manufacturing defect requires (1) a product that 'does not conform to its intended design' such that it (2) 'fails to perform as safely as the intended design would have performed.'" See Citizens Prop. Ins. Corp. v. Simkar LLC, 813 F. Supp. 2d 1356, 1363 (M.D. Fla. 2011) (quoting Fla. Std. Jury Instr. (Civil) PL 4). "Manufacturing defects are generally limited to situations where something goes wrong in the manufacturing process . . . ." See Benitez v. Synthes, Inc., 199 F. Supp. 2d 1339, 1344 (M.D. Fla. 2002). These are "aberrational" defects or "unintended configurations," as opposed to defects occurring throughout an entire line of products, or intended configurations that produce unintended results. Id. In this case, Ritchie examined several G2 filters, both used and unused, and noted

> [t]he presence of draw markings, scratches, pock-marks and deeper gouges, the latter resulting from the shape-setting procedures during manufacture, represents defects which due to their stress and strain concentrating effect would markedly elevate the stresses and strains locally at the surface, which is exactly where fatigue cracks are most likely to initiate . . . .

See Ritchie Report at 11. Ritchie explains that these defects "could have been readily removed by electropolishing (or in the case of the gouges avoided by improved manufacturing procedures and/or quality control) . . . ." Id. at 18-19.[31] As such, a jury could

[31] Ritchie also opines that some G2 filters have a "very sharp corner edge at the inner diameter of the sleeve . . . where the wires emerge and contact the rim of the sleeve . . . ." See Ritchie Report at 11. According to Ritchie, the rim of the sleeve "should have been chamfered to reduce the stress concentration there," and that the absence of a chamfer "represents an apparent departure from prototype design specifications . . . ."

reasonably conclude that the surface defects on the G2 filters are the sort of unintended flaws that are characterized as manufacturing defects. See Benitez, 199 F. Supp. 2d at 1344. Ritchie further states that "the filter implanted in Mrs. Tillman would more likely than not have had the same characteristics as the filters that I have examined, namely . . . a lack of an undamaged surface from surface gouges and grinding and draw markings . . . ." See Ritchie Report at 22. Tillman has submitted evidence that the presence of the surface defects on G2 filters may indicate that they do not conform to their intended design. Because she also presented evidence that these defects elevate the stresses and strains on the device leading to fracture, a jury could conclude that G2 filters do not perform as safely as the intended design would have performed. In light of the foregoing, the Court finds sufficient evidence of a manufacturing defect for the claim to survive summary judgment on this basis.

B. Causation[32]

Bard next argues that it is entitled to summary judgment on Tillman's negligence and strict liability claims because Tillman "has not provided admissible evidence of causation–that, but for the presence of a design, manufacturing defect, or inadequate warnings, she would not have been damaged." See Bard Motion at 24. Bard maintains that Tillman "cannot provide any evidence pinpointing what exactly was defective about the Filter, let alone that she suffered injury caused by such a defect." Id. at 25. As discussed above, there is

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Id. Although Ritchie characterizes the lack of a chamfer as a manufacturing defect, his Report states that "[s]ubsequent Bard specifications, however, for both the Recovery and G2 filters call for no such chamfer." Id. at 9. As such, it appears the lack of a chamfer is, if anything, a defect in the design of G2 filters.

[32] Tillman also brings a claim for negligence in Count I of the Complaint. However, Bard does not separately move for summary judgment on the negligence claim except to challenge Tillman's ability to prove causation on all of her claims. See Bard Motion at 24. Accordingly, the Court will not separately consider Tillman's negligence claim.

sufficient evidence to support a finding that the Filter is unreasonably dangerous due to its design because its propensity to migrate, tilt, perforate the IVC, and fracture outweigh its benefits. As such, an issue of fact exists as to whether the G2 Filter is defectively designed. In addition, the Court has determined that there is an issue of fact concerning whether the Filter is defectively manufactured in light of the surface defects present on the device. Thus, the Court turns to the question of whether there is a triable issue as to the question of whether these defects caused damage to Tillman.

Bard maintains that Tillman has failed to produce evidence that the Filter caused her any injury. See Bard Motion at 25. Bard contends that Tillman has not identified any physical injury, emotional distress, pain or other symptom caused by the Filter. Id. In her Response, Tillman asserts that the Filter migrated, tilted, and perforated her IVC such that it cannot be removed leading to "renal vein thrombosis, pain, hospitalization, expense of hospitalization and continued risk of filter fracture and injury and the need for ongoing medical monitoring." See Tillman Response at 19. Thus, the Court must determine whether there is sufficient evidence to demonstrate that the alleged defects caused the Filter complications in Tillman, and whether those complications have resulted in any damages. As to the first step in the analysis, the parties do not dispute that migration, tilt, and perforation, are inherent risks in the use of Bard's G2 filter. See Grassi Report at 4; Bard Motion, Ex. P: IFU. In addition, Tillman offers the Hull Report in which Hull opines that Tillman:

> had a Bard G2 filter placed in the inferior vena cava for acceptable medical use. The filter was properly placed by the implanting physician. I have reviewed the available and relevant medical records, reports and imaging studies relative to the placement, indwell and retrieval of [Tillman's] filter in this

> case. I see no evidence of 1) improper placement 2) contraindications to placement or 3) other outside intervention that served to cause the observed failures of the Bard G2 filter in this case.

See Hull Report at 6. Thus, in sum, Tillman's causation evidence is that these complications are inherent in the design of the G2 filters, she experienced these complications, and there is no evidence that any other factor caused the complications she experienced. A factfinder could conclude from the foregoing evidence that the complications Tillman claims to have experienced with her Filter were the result of the Filter's defective design. See C.R. Bard, Inc. v. Mason, 247 So. 2d 471, 471-72 (Fla. 2d Dist. Ct. App. 1971) (finding sufficient evidence of causation where evidence showed some devices contained defect which caused fracture, plaintiff's device fractured, and all other possible causes excluded); Worsham v. A. H. Robins Co., 734 F.2d 676, 683-84 (11th Cir. 1984) ("Elimination of alternative causes is one of several accepted types of proof for establishing product defect.").

The Court next considers whether Tillman has presented evidence that the Filter caused damaging complications. Tillman argues that she experienced renal vein thrombosis, pain, and subsequent hospitalization as a result of the failed removal, which was caused by the Filter's complications. However, Tillman does not cite to any evidence in the record that the failed removal actually caused those damages. Although the medical records indicate that the Filter could not be removed due to "the extensive nature of the tilting of the device, length of the duration of placement of the device and probable incorporation into the left renal vein," see Tillman Response, Ex. BB, Tillman presents no probative evidence that the failed removal then caused the renal vein thrombosis, pain, and subsequent hospitalization. Indeed, Tillman cites only to her own deposition testimony that after the attempted removal

"I had to go back to Mayo, because I didn't know what was going on. I was just sick and couldn't stand up. And then when I went back, that's when they said I had a blood clot in the kidney from trying to remove the filter." See Tillman Dep. at 137. Tillman does not identify who the "they" who told her this information are, and without any medical or expert testimony to demonstrate a causative link between the failed removal and the subsequent blood clot, Tillman cannot recover those damages. See Jacob v. Korean Air Lines Co., Ltd., No. 12-CV-62384, 2014 WL 1584444, at *6 (S.D. Fla. Mar. 20, 2014) ("Although causation is an issue generally left to a jury, medical causation falls beyond the scope of a layperson's knowledge and requires competent medical testimony.") (collecting cases).

In addition, Tillman argues that design and manufacturing defects in the Filter expose her to an ongoing medical risk of filter fracture and require medical monitoring. Although Tillman cannot recover damages merely for an "increased risk" of harm, her experts opine that the design and manufacturing defects in the G2 Filter make it prone to fracture. See Ritchie Report at 10-11; McMeeking/Begley Report at 10-12. Notably, the fact that Tillman's Filter has tilted and perforated her IVC appears to increase the risk that the Filter will fracture. See Ritchie Report at 12, 22 ("[E]vidence strongly suggests that [perforations] are a prime reason that motivates the fracture of the struts of these filters; in many cases this has resulted in the migration of fragments of the broken struts to other parts of the body, and are often with associated serious medical complications."); Carr Dep. at 94-95. As a result of this propensity and the fact that the Filter cannot be removed, Tillman argues that she requires ongoing medical monitoring. In his Report, Hull opines that:

> patients who have the G2 filter (either the entire filter, or, portions thereof) should undergo regular clinical and radiological surveillance to monitor the

> placement, location and structural integrity of the filter, or portions thereof. I hold this opinion concerning the patient/plaintiff involved in this litigation and will offer testimony that the patient should undergo medical surveillance in order to monitor the portions of the filter retained within her body.

See Hull Report at 4-5. Hull bases this opinion on his observation of fractured/embolized limbs of Bard filters migrating from one position to another within the body. Id. Hull adds that a patient who has a G2 filter remaining inside her body should undergo a "CT scan of the abdomen annually," so long as the device remains implanted, and that "regularly scheduled physician's visits with a primary care physician, or the like, is reasonable and necessary to monitor the condition of the filter, or portions thereof." Id. at 5. Bard offers no argument or evidence to dispute Tillman's contention that she requires such medical monitoring as a result of the Filter's permanent presence in her body and propensity to fracture.

In light of the foregoing, the Court finds that Tillman presents sufficient evidence to permit a factfinder to conclude that her Filter tilted, migrated, and perforated her IVC as a result of its defective design. Because the Filter malfunctioned in this way, it cannot be removed, and as a result of its defective design and manufacturing defects, a jury could conclude that the Filter exposes her to a real risk that it will fracture and cause potentially life-threatening harm. Tillman maintains that due to this risk she requires ongoing medical monitoring and offers evidence to support this contention. The Court finds that this evidence is sufficient to create an issue of fact on causation, and as such, will deny Bard's Motion for Summary Judgment on Tillman's strict liability design and manufacturing defect claims, as well as her negligence claim, to the extent Tillman seeks medical monitoring damages.

C. Punitive Damages

Florida law provides that "[a] defendant may be held liable for punitive damages only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of misconduct or gross negligence." See Fla. Stat. § 768.72(2). The statute defines "intentional misconduct" to mean that "the defendant had actual knowledge of the wrongfulness of the conduct and the high probability that injury or damage to the claimant would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage." Fla. Stat. § 768.72(2)(a). In addition, "'[g]ross negligence' means that the defendant's conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct." Fla. Stat. § 768.72(2)(b).

Bard argues that Tillman's claim for punitive damages fails "because she cannot provide any 'clear and convincing evidence' that Bard acted with 'intentional misconduct or gross negligence' with regard to the Filter." See Bard Motion at 26. Bard maintains that Tillman fails to present any evidence that it had "actual knowledge" of a high probability that the Filter would cause Tillman harm, or any evidence that "Bard reacted to the information available to it in a grossly negligent manner or acted in away that could constitute intentional misconduct." Id. In Response, Tillman contends that she "has established evidence of Bard's knowledge that the G2® Filter is inherently dangerous, but nevertheless continued to market the product without a recall, making feasible modifications to eliminate the danger or making adequate disclosure and warning of the gravity of such danger." See Tillman Response at 21.

Upon review, the Court finds sufficient evidence to warrant sending this issue to the jury. Evidence in the record shows that Bard had data in its possession indicating the dangerous propensities of its retrievable filter design. See Freeman Report at 5; Lehmann Report at 2, 22; McMeeking/Begley Report at 16-17 ("[T]his [May 22, 2007] report warned Bard that the stresses and strains in the filter could exceed safe levels and that therefore the G2 filter would be prone to fatigue failaure. [sic]."). In addition, Tillman's experts opine that Bard conducted insufficient and incompetent testing on its devices to assess these risks. See generally McMeeking/Begley Report; see also Ritchie Report at 19. Indeed, a jury could find that although Bard was aware of the problems with its Recovery filter design, Bard released the "enhanced" G2 filter without conducting adequate testing to determine whether these problems had been adequately improved or resolved. See McMeeking/Begley Report at 14, 19-22. Soon after the G2 filter's release in 2005, Bard had information in its possession signaling tht the new G2 filter suffered from many of the same problems as the Recovery. See Freeman Report at 5. Viewed in the light most favorable to Tillman, the jury could conclude that this evidence supports a conscious disregard or indifference to Tillman's safety. See Domke v. McNeil-P.P.C., Inc., 939 F. Supp. 849, 852 (M.D. Fla. 1996) ("[P]unitive damages may be imposed when the defendant knows of the defect but chooses not to remedy the dangerous condition."); see also Cason, 1:12-CV-1288-MHS, slip op. at 16-18; Phillips, 3:12-cv-344-RCJ-WGC, slip op. at 18-19. Accordingly, the Court will deny Bard's request for summary judgment on Tillman's claim for punitive damages.

V. Tillman Partial Motion for Summary Judgment

Tillman moves for partial summary judgment on Bard's affirmative defenses set forth in paragraphs 4, 16, 25, and 38 of the Answer and Defenses of Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. and Demand for Trial by Jury (Doc. 15; Answer). See Tillman Motion at 1. Paragraphs 4 and 25 set forth an affirmative defense of assumption of risk and comparative negligence. See Answer at 19, 22-23. In paragraph 16, Bard asserts that it "neither had nor breached any alleged duty to warn with respect to the product, with the result that [Tillman] is not entitled to recover in this cause." Id. at 21. In paragraph 38, Bard maintains that "[n]o act or omission of [Bard] was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred." Id. at 25. In its Response, Bard states that it will withdraw the assertions in paragraphs 16 and 38 "to the extent they are viewed as 'affirmative defenses,' because they simply deny or rebut the elements that [Tillman] must prove for a prima facie claim for negligent failure to warn and for punitive damages." See Bard Response at 1; see also Home Design Servs., Inc. v. Hibiscus Homes of Fla., Inc., No. 603CV1860ORL19KRS, 2005 WL 3445522, at *6 (M.D. Fla. Dec. 14, 2005) ("Defenses which seek to negate an element of the plaintiff's prima facie case are excluded from the definition of an affirmative defense in Federal Rule of Civil Procedure 8(c)."). Bard emphasizes that it "is not waiving its right – and is, in fact, expressly reserving its right – to assert at the summary judgment stage or at trial that Plaintiff has failed to carry her burden with respect to her claims for negligent failure to warn and for punitive damages." Bard Response at 1-2. Indeed, the Court addressed Bard's arguments that Tillman has not met her burden on those claims in its consideration

of Bard's Motion for Summary Judgment set forth above. As the Court concurs that the assertions in paragraphs 16 and 38 are not affirmative defenses, the Court will consider only whether summary judgment is appropriate on Bard's affirmative defenses of assumption of risk and comparative negligence.[33]

Tillman argues that the implied assumption of risk affirmative defense is not available to Bard because this defense "does not exist" in Florida. See Tillman Motion at 10. According to Tillman, the implied assumption of risk defense has merged into "the defense of contributory negligence and the principles of comparative negligence," and those principles apply in any case where assumption of risk is asserted. Id. at 11. Thus, with regard to Bard's comparative negligence defense, Tillman contends that she "could not have avoided the inherent danger of the G2 IVC Filter since she understood the filter to be temporary." Id. She maintains that she "neither consented to a severely tipped risk-benefit profile nor contributed in any way to her current condition of having a perforated inferior vena cava. Moreover, she neither consented to nor contributed to the long term risk to her health." Id. at 12. Accordingly, Tillman requests summary judgment in her favor on these defenses.

Bard agrees with Tillman that the implied assumption of risk doctrine is merged into the defense of contributory negligence. See Bard Response at 8. However, Bard contends that Tillman "voluntarily exposed herself to the risk that the G2® Filter could not be retrieved and could become a permanent implant, and, thus, under the principles of comparative

[33] Tillman does not challenge Bard's contention that paragraphs 16 and 38 do not constitute true affirmative defenses, and raises no argument in response to Bard's statement that it withdraws those defenses without waiving the right to reassert them on summary judgment or at trial. See Tillman Reply at 2 n.1, 5.

negligence, her recovery, if any, should be barred or reduced." Id. at 8-9. Bard maintains that Tillman "should have known that the G2® Filter may not be able to be retrieved and, thus, become a permanent filter." Id. at 10. Bard contends that a jury could also "find that [Tillman] failed to exercise reasonable care by agreeing to have a potentially permanent medical device implanted, given her alleged fear and desire not to have a permanent implant." Id. at 10.

In Blackburn v. Dorta, 348 So. 2d 287 (Fla. 1977), the Florida Supreme Court discussed the doctrine of assumption of risk at length, in an attempt to unravel this "enigma wrapped in a mystery." Id. at 290 (internal quotation omitted). First, the court addressed "primary assumption of risk," and explained that this term "is simply another means of stating that the defendant was not negligent, either because he owed no duty to the plaintiff in the first instance, or because he did not breach the duty owed." Id. at 290. For example, "[i]t can be said that a passenger assumes the risk of lurches and jerks which are ordinary and usual to the proper operation of the train, but that he does not assume the risk of extraordinary or unusual lurches and jerks resulting from substandard operation of the train." Id. at 291. Although articulated in terms of assuming the risk, this concept is more appropriately framed in terms of the standard of care, i.e.

> the railroad owes a duty to operate its train with the degree of care of an ordinary prudent person under similar circumstances which include some lurching and jerking . . . . So long as the lurching or jerking is not extraordinary due to substandard conduct of the railroad, there is no breach of duty and, hence, no negligence on the part of the railroad.

Id. Thus, "primary assumption of risk," rather than an affirmative defense, is instead an attempt to negate that any breach of a duty occurred.

The affirmative defense version of the assumption of risk doctrine precludes recovery where a plaintiff voluntarily and unreasonably exposes herself to a known risk, albeit a risk created by a defendant's negligence. Id. The Florida Supreme Court offers the example of a landlord who has negligently permitted his tenant's premises to become highly flammable and a fire ensues. Id. If the tenant returns from work to find the premises ablaze, but unreasonably rushes into the fire to retrieve his favorite hat, his claims against the landlord would be subject to the assumption of risk doctrine. Id. Because the tenant's conduct is clearly unreasonable, the Blackburn court explains that "this conduct can just as readily be characterized as contributory negligence. . . . It is the failure to exercise the care of a reasonably prudent man under similar circumstances." Id. As such, the court found no reason "to maintain a distinction between the affirmative defense of contributory negligence and assumption of risk." Id. at 292. Thus, under Florida law, "the affirmative defense of implied assumption of risk is merged into the defense of contributory negligence and the principles of comparative negligence . . . shall apply in all cases where such defense is asserted." Id. at 293.[34]

In the context of a products liability action such as this, "'the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense'" to strict

[34] The Florida Supreme Court also acknowledged a form of the defense which would bar a plaintiff's recovery where the plaintiff acted reasonably in encountering the known risk. Id. at 291. For example, from the scenario described above, where the plaintiff rushes in to the fire to save her child. Id. Under the "pure" or "strict" form of the doctrine, the plaintiff is still barred from recovery for encountering the known risk, notwithstanding the fact that her conduct was entirely reasonable under the circumstances. Id. However, this strict assumption of risk doctrine does not apply in Florida, and the court found "no reason supported by law or justice in this state to give credence to such a principle of law." Id.

liability. See West, 336 So. 2d at 90 (quoting Restatement (Second) of Torts § 402A, cmt. n). Thus, "[c]ontributory negligence of the consumer or user by unreasonable use of a product after discovery of the defect and the danger is a valid defense." Id. (emphasis added). Significantly, contributory negligence is a defense in a strict liability action only if "based upon grounds other than the failure of the user to discover the defect in the product or the failure of the user to guard against the possibility of its existence." Id. at 92. Moreover, because Florida has adopted principles of comparative negligence, the defense of contributory negligence, including negligence in the form of assuming the risk, is available to apportion "the negligence of the manufacturer of the alleged defective product and the negligent use made thereof by the consumer." Id. at 90.

In considering this defense, the Court notes that comparative negligence is an issue in this case only if a jury determines that the Filter is, in fact, defective. If a jury finds that the Filter is not defective, i.e., not unreasonably dangerous, then Bard is not liable and the inquiry would end. In the event the jury does find a defect, to prevail on its assumption of risk defense, Bard must show that Tillman knew and appreciated the risk of having the defective Filter implanted in her body. See Bartholf v. Baker, 71 So. 2d 480, 483 (Fla. 1954) ("Appreciation of the danger is . . . essential to the defense of assumption of risk, or of contributory negligence, as is knowledge of the condition which creates the peril."); West, 336 So. 2d at 90.

Here, the evidence shows that Tillman signed an informed consent document prior to implantation. See Bard Motion, Ex. Q; Tillman Dep. at 83-84. The document states:

> My physician has also discussed the benefits, substantial risks and hazards inherent in the procedure, including the risks of damage to blood vessels,

> nerves, internal organs, infection, bleeding, perforation, additional surgeries and death. Medically acceptable alternatives to this procedure and their risks have been explained. The risks of not undergoing this procedure have also been explained. All my questions have been asked and answered to my satisfaction.

See Bard Motion, Ex. Q. In addition, as summarized in Part IV.A.i., Stockland was aware of the risk that Tillman's G2 Filter could tilt, perforate, migrate, fracture, or become unavailable for removal. Stockland read the IFU issued with G2 filters, and the IFU warned of these potential complications as well. See Bard Motion, Ex. P; see supra Part IV.A.i. However, Bard presents no evidence that either Tillman or Stockland were aware that the Filter was unreasonably dangerous, that is, that the design or manufacture of the Filter made it unreasonably prone to these complications. See supra Part IV.A.ii. As such, Tillman did not know of the conditions that created the peril, nor did she appreciate the danger that she was encountering. Stated another way, because Tillman did not know of the conditions which made the Filter unreasonably dangerous, Bard fails to show that she acted negligently in encountering the danger by agreeing to the implantation of the Filter. See Riegel v. Beilan, 788 So. 2d 990, 991 (Fla. 2d Dist. Ct. App. 2000). In the absence of any evidence that Tillman discovered the defective condition of the Filter, Bard cannot maintain its contributory negligence and assumption of risk defense. See West, 336 So. 2d at 90.

Indeed, upon review of Bard's Response, it appears that Bard fails to acknowledge that the assumption of risk defense applies only to the extent that the G2 Filter is found to be defective. Bard's argument is essentially that Tillman assumed the reasonable risks associated with the use of IVC filters. This argument is akin to the Blackburn court's train hypothetical. Like the passenger on the train who assumes the risk of lurching and jerking,

Tillman assumed the reasonable risks associated with the use of an IVC filter. If those reasonable risks are the only ones involved, then it is not a matter of assumption of risk, but rather, Bard would prevail because it did not breach its duty to design a non-defective device. However, the Court is denying Bard's request for summary judgment on the design and manufacturing defect claims because there are issues of fact as to whether the Filter's risks are unreasonable as a result of its arguably defective design or manufacture. Bard presents no evidence to suggest that Tillman had knowledge of the excessive risk accompanying the use of a defective Filter, and as such, she did not assume this risk or act negligently in agreeing to its implantation. Accordingly, the Court finds that Tillman's Motion for Summary Judgment is due to be granted.

VI. Preparing for Trial

The instant Order resolves various Daubert motions as well as competing summary judgment motions. During the pendency of these motions, the parties have been working diligently to prepare for trial as evidenced by their filing of motions relating to their preparation of a pretrial stipulation as well as their respective motions in limine. Recognizing that the Court's Order would narrow the issues for trial, the Court postponed the applicable deadlines and has denied certain motions without prejudice to renewal if necessary. In order to address the parties' concerns and to assist in the preparation of a pretrial stipulation now that the parties have notice of the issues to be tried, the Court will schedule a telephonic status conference for Wednesday, April 1, 2015, at 3:00 p.m. In advance of the status conference, the parties are encouraged to confer with regard to any matters that should be addressed and attempt to reach an agreed upon resolution. The filing of a joint notice of issues by 4:00

p.m. on March 31, 2015, would be appreciated but, in light of the short notice is not required.

In accordance with the foregoing, it is

ORDERED:

1. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion to Exclude the Opinions of Michael Freeman, Ph.D. and Memorandum of Law in Support (Doc. 95) is **GRANTED, in part, and DENIED, in part**. The Motion is **GRANTED** to the extent set forth in the body of this Order, and otherwise **DENIED.**

2. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion and Memorandum of Law to Exclude the Opinions of William A. Hyman (Doc. 96) is **GRANTED, in part, and DENIED, in part**. The Motion is **GRANTED** to the extent set forth in the body of this Order, and otherwise **DENIED.**

3. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion to Exclude the Opinions of Robert McMeeking and Matthew Begley and Incorporated Memorandum of Law in Support Thereof (Doc. 99) is **GRANTED, in part, and DENIED, in part**. The Motion is **GRANTED** to the extent set forth in the body of this Order, and otherwise **DENIED.**

4. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion to Exclude the Opinions of Robert Ritchie, Ph.D. and Memorandum of Law in Support (Doc. 100) is **GRANTED, in part, and DENIED, in part**. The Motion is **GRANTED** to the extent set forth in the body of this Order, and otherwise **DENIED.**

5. Plaintiff's Motion for Partial Summary Judgment Against Defendant C.R. Bard and Bard Peripheral Vascular, Inc. (Doc. 93) is **GRANTED**.

6. Defendants' Motion for Summary Judgment (Doc. 98) is **GRANTED, in part, and DENIED, in part**.

   A. Defendants' Motion is **GRANTED** as to Plaintiff's claim for failure to warn.

   B. Defendants' Motion is further **GRANTED** to the extent Plaintiff's compensatory damages are limited to her request for the cost of medical monitoring.

   C. In all other respects, Defendants' Motion is **DENIED**.

7. A telephonic status conference is set for **Wednesday, April 1, 2015, at 3:00 p.m.** Counsel for Plaintiff shall initiate the telephonic status conference by first contacting counsel for Defendants and then conferencing the Court at (904) 301-6812.

DONE AND ORDERED in Jacksonville, Florida, this 30th day of March, 2015.

Marcia Morales Howard

MARCIA MORALES HOWARD
United States District Judge

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Copies to:

Counsel of Record