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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC
Sherr-Una Booker, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00474-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. The MDL Plaintiffs have received implants of Bard IVC filters and claim that they are defective and have caused Plaintiffs to suffer serious injury or death. Plaintiffs assert numerous state law claims and seek both compensatory and punitive damages.

One of the MDL cases is brought by Plaintiff Sherr-Una Booker, who had a Bard filter implanted ten years ago. Plaintiff's case has been selected as one of several

bellwether cases and is set for trial in March 2018. Defendants have filed a motion for partial summary judgment on Plaintiff's claims. Doc. 7456. The motion is fully briefed, and the Court heard oral arguments on November 17, 2017. For reasons set forth below, the Court will grant the motion in part and deny it in part.[1]

I. Factual Background.

[*The factual background section of this order has been redacted because it sets forth Plaintiff's personal medical information protected from public disclosure under the provisions of HIPPA and orders sealing documents in this case. See Doc. 7787. An unredacted version of this order has been filed under seal. See Doc. 8873.*]

II. Plaintiff's Claims.

The Court was assigned this MDL in August 2015. Doc. 1. Three months later, the MDL Plaintiffs filed a long-form master complaint that asserts seventeen causes of action. Doc. 303-1. The master complaint alleges that Bard filters, including the G2, were negligently designed and manufactured and are more dangerous than other IVC filters. The complaint further alleges that Defendants concealed adverse information and otherwise failed to warn about increased risks posed by Bard filters. Defendants dispute the allegations of concealment and high risk levels, contending that complication rates associated with Bard filters are low and comparable to those of other IVC filters.

In her short-form individual complaint filed on February 22, 2016, Plaintiff asserts the following claims under Georgia law: manufacturing defects (Master Complaint Counts I and V), failure to warn (Counts II and VII), design defects (Counts III and IV), failure to recall or retrofit (Count VI), misrepresentation (Counts VIII and XII), negligence per se (Count IX), breach of warranties (Counts X and XI), and punitive

[1] Defendants' motion redacts information concerning Plaintiff's personal medical history. Defendants have filed a sealed unredacted version of the motion. Doc. 7460. The Court will cite to this unredacted document in addressing Defendants' summary judgment arguments.

damages. Doc. 1, CV-16-00474-PHX-DGC. Plaintiff agreed not to pursue the breach of warranty claims before the present motion was filed. Doc. 7460 at 2 n.1.[2]

Defendants seek summary judgment on all claims other than design defects. *Id.* at 1. In her response to Defendants' motion, Plaintiff concedes the insufficiency of her manufacturing defect and failure to recall or retrofit claims. Doc. 8167 at 2 n.1. The Court will grant summary judgment on these claims and the breach of warranty claims.

The remaining claims on which Defendants seek summary judgment are failure to warn, misrepresentation, negligence per se, and punitive damages. The Court will deny summary judgment on the failure to warn and punitive damages claims and grant summary judgment on the claims for misrepresentation and negligence per se.

III. Summary Judgment Standard.

A party seeking summary judgment "bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence of the nonmoving party, however, is to be believed, and all justifiable inferences drawn in that party's favor because "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions[.]" *Id.* at 255.

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[2] Plaintiff does not assert claims for fraudulent concealment (Master Complaint Count XIII), consumer fraud and unfair trade practices (Count XIV), loss of consortium (Count XV), wrongful death (Count XVI), or survival claims (Count XVII). *See id.*; Doc. 303-1 ¶¶ 267-338.

IV. Failure to Warn (Counts II and VII).

The parties agree that Georgia law applies because the alleged injuries occurred in Georgia and Plaintiff lived there when the complaint was filed. Doc. 7460 at 6. To establish a failure to warn claim under Georgia law, "the plaintiff must show the defendant had a duty to warn, the defendant breached that duty and the breach was the proximate cause of the plaintiff's injury." *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999). "[A] manufacturer has a duty to warn of nonobvious foreseeable dangers from the normal use of its product." *Thornton v. E.I Du Pont de Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994) (citations omitted). The duty to warn arises "whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994). The duty generally is "breached by (1) failing to adequately communicate the warning to the ultimate user or (2) failing to provide an adequate warning of the product's potential risks." *Thornton*, 22 F.3d at 289.

In cases involving prescription drugs and medical devices, Georgia applies the "learned intermediary" doctrine. Under this doctrine, the manufacturer has no "duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and manufacturer." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) (citing *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1279-80 (11th Cir. 2002)). The manufacturer's warnings to the physician, however, "must be adequate or reasonable under the circumstances of the case." *Id.*

In this case, the G2 filter's Instructions for Use ("IFU") were available to Dr. D'Ayala when he decided to implant the filter in Plaintiff, but he did not have information about any increased risks associated with Bard filters. Doc. 7462-2 at 5-6. Plaintiff alleges that the instructions Bard provided failed to adequately warn about the device's known defects and high complication rates, including the filter's propensity to tilt, fracture, and perforate the IVC. *See* Doc. 303-1 ¶¶ 174-78, 211-16. Plaintiff claims

that this failure to warn constitutes a breach of Bard's duty to adequately warn of the dangers presented by its IVC filters, and proximately caused her injuries. *Id.* ¶¶ 177-81, 215-17. Plaintiff asserts strict liability and negligence claims for the alleged failure to warn. *Id.* ¶¶ 171-81, 202-09; *see* Doc. 1 at 3, CV-16-00474-PHX-DGC.

Defendants contend that the warnings contained in the IFU were adequate as a matter of law because they included the risks of filter movement, fracture, and perforation – the very complications Plaintiff experienced. Doc. 7460 at 9-11. Defendants further contend that proximate cause is lacking because Dr. D'Ayala implanted the G2 filter with knowledge of its potential risks, and there is no evidence that additional warnings would have made him choose a different filter or treatment. *Id.* at 11-12. For purposes of summary judgment, Defendants do not dispute that Plaintiff has presented evidence that Bard knew its IVC filters had complication rates higher than other filters at the time Plaintiff was implanted with the G2 filter. See Doc. 8167 at 4-7.

A. Adequacy of the Warnings.

The IFU for the G2 filter included the following warnings under the bold heading of "Potential Complications":

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.

- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.

- Perforation or other acute or chronic damage of the IVC wall.

- All 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 ratio for a patient who is at risk of pulmonary embolism without intervention.

Doc. 7457-1 at 2.

Plaintiff concedes that the IFU warned about G2 filters tilting, fracturing, and perforating the IVC, but notes that these complications exist for all IVC filters. Doc. 8167 at 13. Plaintiff argues that the warnings were inadequate because they did not include risk rates or disclose that the risks associated with the G2 filter were higher than those of other filters, including Bard's own Simon Nitonol filter ("SNF"). *Id.* at 12.

Framing the issue as one of duty, Defendants contend that Georgia law imposes no duty on a manufacturer to provide comparative complication rates for its product and those of competitors. Doc. 7460 at 10 n.4; *see* Doc. 7351 at 9-10. Plaintiff counters that the issue is one of breach, not duty, and that there is a triable issue as to whether Defendants' failure to warn about increased risks constitutes a breach of their duty to provide an adequate warning.

This very issue was addressed in *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513 (S.D. W. Va. Oct. 18, 2003). *Cisson*, which applied Georgia law, found that "[a]lthough Bard frames the issue as one of duty, it actually relates to whether Bard's warnings were adequate, which is a question of breach." *Id.* at *7. The Court agrees with this conclusion. Under Georgia law, a duty to warn arises "whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Batten*, 450 S.E.2d at 211. Defendants cite no authority to suggest that this duty arises only on a fact-by-fact basis. The duty arises when dangers are known or reasonably known, and the factual detail that must then be disclosed is then addressed in the adequacy of the disclosure. The duty to warn is breached by "failing to provide an *adequate warning of the product's potential risks*." *Thornton*, 22 F.3d at 289 (emphasis added). After concluding that the question was one of breach, *Cisson* denied judgment on the failure to warn claim, noting that other courts have held that a failure to warn

about the rate or severity of potential injuries raises a jury question over the adequacy of the warnings. 2013 WL 5700513 at *7.

The exact warning at issue in this case was considered recently in *Cason v. C. R. Bard, Inc.*, No. 1:12-CV-1288-HMS, 2015 WL 9913809 (N.D. Ga. Feb. 9, 2015). In *Cason*, as in this case, there was evidence that the G2 filter has a greater propensity to migrate, fracture, and perforate the IVC, and that Bard had knowledge of such increased risks at all relevant times. *Id*. at *4-5. Given this evidence, and the fact that Bard did not warn the plaintiff's doctor about the increased risks, *Cason* concluded that a jury reasonably could find that "the IFU did not contain an adequate warning regarding the G2 Filter." *Id.* at *5. The Court finds this ruling by a Georgia-based federal judge, applying Georgia law, to be highly persuasive. Other cases applying Georgia law have reached similar conclusions. *See Cisson*, 2013 WL 5700513, at *8 (rejecting Bard's argument that warnings were adequate as a matter of law because the IFU identified as a possible adverse reaction each of the complications the plaintiff experienced); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1378 (M.D. Ga. 2010) (rejecting similar argument where the product at issue had a greater propensity to cause complications and was associated with more severe complications than other products); *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1219-20 (11th Cir. 1999) (denying summary judgment on failure to warn claim where Ford's internal documents showed that the Bronco II had a rollover fatality rate more than three times that of other SUVs and the vehicle was rated last in government stability tests).[3]

The Court notes that some of the warnings in the G2 filter's IFU are limited in scope. Although filter movement and migration are identified as known complications,

[3] Defendants asserted at oral argument that *Cisson* and *Cason* were causation cases that did not address duty and breach. To the contrary, *Cisson* made clear that "Bard had a duty to warn about 'any potential dangers that may result' from use of the product[,]'" and that the adequacy of Bard's warnings was a question of breach, not duty. 2013 WL 5700513, at *6-7 (citation omitted). Similarly, *Cason* discussed at length Bard's arguments that it had no duty to warn about increased risks and that its warnings were adequate as a matter of law. 2015 WL 9913809, at *3-6. The issue of causation was discussed only briefly in the last paragraph addressing the failure to warn claim. *Id.* at *6.

the IFU states that "[t]his may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU." Doc. 7457 ¶ 5. The IFU notes that migration of filters to the heart or lungs has been reported, but only "in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens." *Id.* The IFU discloses reports of serious adverse events associated with the use of IVC filters, including death, but only in "morbidly obese patients." *Id.* With respect to filter fracture, the IFU states that most cases had "been reported without any adverse clinical sequelae." *Id.* Plaintiff has presented evidence to the contrary, along with other evidence from which a jury reasonably could find that the warnings contained in the IFU were not adequate. *See Cisson*, 2013 WL 5700513, at *8 (denying motion for judgment as a matter of law where the plaintiff presented evidence that Bard's IFU "downplayed risks by stating that 'potential adverse reactions are those typically associated with surgically implantable materials'").

Defendants argue that they cannot be held liable for failure to warn because the complications Plaintiff experienced – filter tilting, fracture, and perforation – were well documented and known to medical professionals, including Dr. D'Ayala. Doc. 7460 at 10. But this argument misses the mark. As Defendants themselves note, Plaintiff claims that the general warning about complications associated with all IVC filters was inadequate given the G2 filter's *higher* complication rates. *Id.* at 10 n.4. Plaintiff presents evidence that the G2 filter involved substantially greater risks of failure than competitor filters and even Bard's own SNF filter, and that evidence must be accepted as true for purposes of this summary judgment motion.[4]

Defendants state that including warnings about comparative risk rates "is almost certainly precluded by FDA regulations," but they cite no specific regulation in support

[4] Defendants cite *Presto v. Sandoz Pharmaceuticals Corp.*, 487 S.E.2d 70, 73 (Ga. Ct. App. 1997), for the proposition that warning the physician about a product's potential risks is sufficient. Doc. 7460 at 10. The warning, however, must be adequate or reasonable under the circumstances. *See McCombs*, 587 S.E.2d at 595. *Presto* is inapposite because the plaintiffs in that case "ma[de] no argument that the warning given [the doctor] was inadequate." 487 S.E.2d at 73.

of this assertion. Doc. 8574 at 4. The opinion of Defendants' regulatory expert in this regard creates a fact issue for the jury. Defendants' reliance on cases involving prescription drugs is misplaced because those cases concern a specific FDA regulation not applicable to medical devices such as the G2 filter. *See* 21 C.F.R. § 201.57(c)(7) (providing that "any claim comparing [a prescription drug] with other drugs in terms of frequency, severity, or character of adverse reactions must be based on adequate and well-controlled studies").

Defendants contend that Georgia law does not require a manufacturer to provide comparative rates of complications for its products. Doc. 7460 at 10 n.4; Doc. 7351 at 9-10 (citing *Dixie Grp., Inc. v. Shaw Indus. Grp., Inc.*, 693 S.E.2d 888, 892 (Ga. Ct. App. 2010); *Hoffman v. AC & S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001)). But the cases cited by Defendants concern very different questions: whether a manufacturer can be liable for injuries caused by modifications another party made to its product, *Dixie Grp.*, 693 S.E.2d at 892, and whether a plaintiff must show that it was the defendant's asbestos product – as opposed to an asbestos products generally – that caused her mesothelioma, *Hoffman*, 548 S.E.2d at 382. "Nothing in these cases suggests that a manufacturer's warning is adequate even if it fails to warn that the product is significantly more dangerous than other similar products on the market." *Cason*, 2015 WL 9913809, at *5.

"The general rule in Georgia is that the adequacy of the warning is an issue for the jury [unless] . . . the facts support only one conclusion, that is, the warning and its communication were adequate." *Thornton*, 22 F.3d at 289 (citations omitted). In this case, there are facts from which a jury reasonably could conclude that the warnings contained in the IFU were not "adequate or reasonable under the circumstances of the case." *McCombs*, 587 S.E.2d at 595. 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.'"

Watkins, 190 F.3d at 1220 (quoting *Thornton*, 22 F.3d at 289); *see Cason*, 2015 WL 9913809, at *4-5; *Cisson*, 2013 WL 5700513, at *7-8.

The Court is not holding, as a matter of Georgia law, that manufacturers must always disclose how the risks of their product compare to the risks of other products. But presumably there is a point where the risks of a product so depart from the norm that a failure to disclose them constitutes an inadequate warning. Whether that point was reached in this case will be for the jury to decide. *See Cason*, 2015 WL 99913809, at *6 (the question "is not whether [D]efendants are able to provide completely up-to-date failure rate comparisons but whether, prior to [Plaintiff's] surgery, they had sufficient information such that they knew or should have known that use of the G2 Filter involved a significantly increased risk of complications as compared to other IVC filters.").

Finally, Defendants contend that summary judgment is warranted because Plaintiff never identifies the precise information the G2 warnings should have contained. Doc. 7460 at 7 (citing *Nolley v. Greenlee Textron, Inc.*, No. 1:06-CV-228-MHS, 2007 WL 5369405, at *7 (N.D. Ga. Dec. 6, 2007)). To the contrary, Plaintiff makes clear that the IFU should have disclosed that the "risks associated with Bard's devices were higher than those of competitor devices or the SNF." Doc. 8167 at 12. The jurors in this case, unlike in *Nolley*, will be presented with proposed warnings and will have a means by which to determine whether the actual warnings were adequate. The Court will consider the parties' proposed jury instructions on the issue of inadequate warnings.

B. Causation.

To prevail on a failure to warn claim, a plaintiff must show that the deficient warning caused her injury. *See Wheat*, 46 F. Supp. at 1362. "Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that . . . the causal link is broken and the plaintiff cannot recover." *Id.* at 1363.

Defendants contend that any failure to warn Dr. D'Ayala that IVC filters may tilt, fracture, and perforate the IVC wall was not the proximate cause of Plaintiff's injuries because Dr. D'Ayala was aware of these risks when he implanted the G2 filter in Plaintiff. Doc. 7460 at 11. But as explained above, Plaintiff's position is that Defendants failed to warn Dr. D'Ayala about significantly higher complication rates posed by Bard filters. Doc. 8167 at 12-16. The fact that Dr. D'Ayala knew about the existence of complications for all IVC filters does not preclude a showing of causation.

Dr. D'Ayala testified that when he implanted the G2 filter in Plaintiff in June 2007 he was not aware of the high number of adverse events associated with Bard's Recovery filter, the predicate device for the G2. Doc. 8169 ¶ 332-33 (Tr. 33:10-34:5). Nor was he aware of certain Bard documents showing higher complication rates in the Recovery device compared to other filters, including Bard's 2004 crisis management plan, the 2004 health hazard evaluation, the 2005 migration remedial action plan, and the adverse event reports contained in the FDA's Manufacture and User Facility Device Experience ("MAUDE") database. *Id.* ¶¶ 334-336 (Tr. 34:7-40:2). Dr. D'Ayala testified that this information would have influenced his prescribing habits and he would have liked to have known about the high number of adverse events before implanting the G2 filter in Plaintiff. *Id.* Regarding his decision to use a Bard filter, Dr. D'Ayala stated:

> With regards to the Bard filter, would I have used a different device if I knew at the time that the Bard filter was not ideal or as good as some of the other implants? The answer would have to be yes. . . . I would have used a different filter if there was a different filter that I knew of that was better, in terms of its safety profile.

Id. ¶ 338; Docs. 7462-2 at 3, 8169-1 at 32-33 (Tr. 62:25-63:1-9). Consistent with this testimony, Dr. D'Ayala also stated: "If I knew that one filter was better than another, as I said before, absolutely, I would use it." Doc. 8574-1 at 21 (Tr. 76:25-77:2).

Defendants note that Dr. D'Ayala testified that it was "[d]ifficult to say with certainty" whether he would have used a G2 filter in light of internal Bard documents showing higher complication rates because "[it] would depend upon what other filters

[they] had at the time and what their problems would have been." Doc. 7462-2 at 3 (Tr. 63:21-25). Dr. D'Ayala also stated that some filter has to be used in treating difficult patients like Plaintiff, and "it becomes a matter of deciding which filter is best[.]" *Id.* (Tr. 70:20-25). Dr. D'Ayala made clear, however, that information about higher complication rates "would have been a very important piece of information to have, as far as making a decision regarding [Plaintiff]." *Id.* at 4 (Tr. 63:25-64:1-3).

Defendants assert in their reply brief that Dr. D'Ayala's testimony about what he may or may not have done constitutes mere conjecture and speculation that is insufficient to establish causation as a matter of law. Doc. 8574 at 9 & n.8. The Court does not agree. Dr. D'Ayala stated that information about higher complication rates would have influenced his decision, and that he would have used a different device had he known the Bard filter was not as good as other available devices. Doc. 8169-1 at 25-28, 32-33. Indeed, Dr. D'Ayala ultimately stopped using Bard filters due to reports of migration and fragmentation in the MAUDE database and medical literature. *Id.* at 22 (Tr. 31:13-25). Although it is true that Dr. D'Ayala also made more equivocal statements during his deposition, Plaintiff must prove her case by a preponderance of the evidence, not with absolute certainty. Construing Dr. D'Ayala's testimony in Plaintiff's favor, as required at the summary judgment stage, the Court finds that it creates a question of fact on the issue of causation.

Defendants note that Dr. D'Ayala does not rely on a manufacturer's internal documents when deciding which filter to use because such documents are unreliable. Doc. 8574 at 9. But this says nothing about whether Dr. D'Ayala would have implanted a different filter had Defendants warned about higher complication rates in the IFU for the G2 device or in other public documents. Stated differently, the question is not what Dr. D'Ayala would have done had he been aware of Defendant's internal documents, but what he would have done had Defendants provided adequate public warnings.

Under Georgia law, summary judgment is warranted on the issue of causation only where the physician testifies unequivocally that he would have made the same decision

despite the proposed warning. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) (doctor provided "explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed [anti-depressant]"); *Porter v. Eli Lilly & Co.*, No. 1:06-CV-1297-JOF, 2008 WL 544739, at *13 (N.D. Ga. Feb. 25, 2008) (doctor "unequivocally testified that even if he had read the warning that [plaintiff] asserts should have been given, he still would have prescribed [anti-depressant] to the decedent"). Defendants cite no such testimony from Dr. D'Ayala. *See Watkins v. Eli Lilly & Co.*, No. 1:08-CV-1665, 2010 WL 11493785, at *9 (N.D. Ga. Mar. 31, 2010) (denying summary judgment where the defendant failed to "nail[] this matter down" through deposition testimony).

In summary, the Court concludes that Dr. D'Ayala's testimony "is sufficient evidence of causation at the summary judgment stage, because 'it can be inferred that [he] would not have implanted the G2 Filter'" had he been warned about its higher complication rates. *Cason*, 2015 WL 9913809, at *6 (quoting *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. CV 2:10-cv-01224, 2013 WL 2431975, at *7 (S.D. W. Va. June 4, 2013)); *see Cisson*, 2013 WL 5700513, at *9-10 (denying summary judgment where there was sufficient evidence for a jury to find that the proposed warnings would have prevented the doctor from implanting a Bard device). The Court will deny summary judgment on Plaintiff's failure to warn claims.

V. Misrepresentation (Counts VIII and XII).

"In Georgia, the plaintiff must show actual reliance to support both negligent misrepresentation and fraud claims." *Fanelli v. BMC Software, Inc.*, No. 1:11-cv-00436-JOF, 2013 WL 12190241, at *10 (N.D. Ga. July 29, 2013) (citations omitted). Summary judgment is warranted, Defendants argue, because Plaintiff has presented no evidence showing that either she or Dr. D'Ayala relied on any representation made by Defendants. Docs. 7460 at 7-8 n.3, 8574 at 11. Plaintiff does not address this argument in her response brief (*see* Doc. 8167 at 16-17), and at oral argument stated only that Dr. D'Ayala should have been told about the G2 filter's higher complication rates.

But Plaintiff asserts claims for misrepresentation, not concealment. Doc. 1 at 3-4, CV-16-00474-PHX-DGC. Although Dr. D'Ayala had access to the G2 filter's IFU at the time of Plaintiff's surgery (Doc. 7462-2 at 5-6), Plaintiff has pointed to no evidence showing that Dr. D'Ayala relied on the IFU or any other representation made by Defendants. The Court therefore will grant summary judgment on the misrepresentation claims. *See Celotex*, 477 U.S. at 324 (summary judgment warranted where "the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof").[5]

VI. Negligence Per Se (Count IX).

"In Georgia, 'the violation of a statute, ordinance or mandatory regulation that imposes a legal duty for the protection of others constitutes negligence per se." *Ashton Park Trace Apartments, LLC v. W. Oilfields Supply Co.*, No. 14-CV-4056-MHC, 2015 WL 12469074, at *6 (N.D. Ga. July 16, 2015) (citation omitted). This theory of liability is codified in a Georgia statute: "When the law requires a person to perform an act for the benefit of another or to refrain from doing an act which may injure another, although no cause of action is given in express terms, the injured party may recover for the breach of such legal duty if he suffers damage thereby." Ga. Code Ann. § 51-1-6. Defendants are liable for negligence per se, Plaintiff alleges, because they violated various provisions of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and related regulations by misbranding Bard filters, making false and misleading statements about the filters, failing to notify the FDA when the filters were no longer safe and effective, failing to recall the devices, and not maintaining accurate adverse event reports.

[5] It also appears that, under Georgia law, there are no misrepresentation claims for products liability distinct from failure to warn claims. *See Gaddy v. Terex Corp.*, 1:14-cv-1928-WSD, 2017 WL 3476318, at *5 (N.D. Ga. May 5, 2017); *Brazil v. Janssen Research & Dev. LLC*, 249 F. Supp. 3d 1321, 1340 (N.D. Ga. 2016); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008). For reasons they did not explain, however, Defendants withdrew this position at oral argument.

Doc. 303-1 ¶ 231.[6]

Defendants argue that this claim is impliedly preempted under 21 U.S.C. § 337(a) because no private right of action exists under the FDCA and all proceedings to enforce or restrain violations of the statute must be brought by the FDA. The Court agrees.

Plaintiff alleges no violation of any state ordinance, regulation, or statute in support of her negligence per se claim. The master complaint cites statutory provisions of more than 40 states, but Georgia is not one of them (*see* Doc. 303-1 at 56-60), and Plaintiff otherwise does not assert statutory claims for consumer fraud or unfair trade practices (*see* Doc. 1 at 4, CV-16-00474-PHX-DGC). Thus, Plaintiff's negligence per se claim exists solely because of alleged violations of the FDCA and its implementing regulations. Doc. 303-1 at 56-60.

Courts have held that "no private right of action exists for a violation of the FDCA." *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002). "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001). Indeed, § 337(a) expressly provides that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Thus, "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist." *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011) (citation omitted).

In *Buckman*, the Supreme Court held that a state law claim that a defendant made fraudulent statements to the FDA, in violation of FDCA, was impliedly preempted by § 337(a) because the claim "exist[ed] solely by virtue" of FDCA requirements and therefore "would not be relying on traditional state tort law which had predated the

[6] Specifically, Plaintiff alleges violations of 21 U.S.C. §§ 321, 331, 352, and 21 C.F.R. §§ 1.21, 801, 803, 807, 820. *Id.* at 46-48.

[FDCA]." 531 U.S. at 353. The same is true here. Plaintiff's "claim of negligence per se would not exist prior to the enactment of the FDCA . . . because the claim only alleges violation of that law." *Leonard*, 2011 WL 3652311, at *8. Thus, "as in *Buckman*, Plaintiff's negligence per se claim (or, more appropriately characterized, [her] negligence claim based solely on violations of the FDA-Imposed Requirements or other FDA regulations) is impliedly preempted by the FDCA." *Grant v. Corin Grp. PLC*, No. 3:15-CV-169-CAB-BLM, 2016 WL 447523, at *4 (S.D. Cal. Jan. 15, 2016).

Plaintiff notes that Georgia common law and § 51-1-6 recognize that laws which do not create a private right of action may nonetheless support a claim for damages. Doc. 8167 at 18-19. While it is true that courts generally have allowed a negligence per se claim based on violation of a federal statute, including those that may not expressly provide for a private right of action, "the plain language of § 337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails." *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014). Even if state law recognizes such claims, federal law preempts them.

Plaintiff asserts that *Leonard* is inapposite because, unlike Bard IVC filters, the medical device at issue in *Leonard* had been approved by the FDA through the rigorous premarket approval process. Doc. 8167 at 18. But this was not the basis for *Leonard*'s implied preemption finding. *Leonard* found implied preemption because "all proceedings to enforce or restrain violations of the FDCA 'shall be by and in the name of the United States.'" 2011 WL 3652311, at *7 (quoting § 337(a)). Moreover, preemption under § 337(a) is not limited to devices approved through the premarket approval process. As Defendants note, the device at issue in *Buckman* – like the G2 filter in this case – was cleared for market under 510(k) review. Doc. 8547 at 13.

Plaintiff's reliance on *McClellan v. I-Flow Corp.*, 776 F.3d 1035 (9th Cir. 2015), is misplaced. In that case, the plaintiff's state law failure-to-warn claim had "little to do with direct regulatory interaction with the FDA." 776 F.3d at 1041. The Ninth Circuit found that a negligence per se jury instruction therefore would not usurp the FDA's

exclusive enforcement power over the MDA. *Id.* at 1041 & n.6. In this case, by contrast, Plaintiff's claim exists solely because of alleged FDCA violations and Defendants' interaction with the FDA. The claim clearly is preempted under § 337(a) and *Buckman*.

The Court will grant summary judgment on Plaintiff's negligence per se claim because allowing the claim to go forward would authorize an impermissible action to enforce provisions of the FDCA and its implementing regulations. *See Leonard*, 2011 WL 3652311, at *7-8; *Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-EJD, 2017 WL 361962, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim preempted where it was "based entirely on violations of the FDCA and its implementing regulations"); *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) ("[T]o the extent that Plaintiff seeks to ground her negligence per se and misrepresentation claims on allegations that Defendant violated the FDCA – namely, by selling a misbranded and adulterated product – these claims are impliedly preempted pursuant to 21 U.S.C. § 337(a)."); *see also Mink v. Smith & Nephew*, 860 F.3d 1319, 1330 (11th Cir. 2017) (failure-to-report claim preempted because the duty was owed to the FDA and the "theory of liability is not one that state tort law has traditionally occupied"); *Perez v. Nidek Co.*, 711 F.3d 1109, 1119-20 (9th Cir. 2013) (fraud-by-omission claim "impliedly preempted because it conflicts with the FDCA's enforcement scheme").

This holding is not inconsistent with the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). *Riegel* addressed the scope of 21 U.S.C. § 360k(a), which expressly preempts any state requirement concerning a medical device that "is different from, or in addition to," a federal requirement relating to the device. *Riegel* held that this provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" where "the state duties in such a case 'parallel,' rather than add to, federal requirements." 552 U.S. at 329; *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) ("Nothing in § 360k denies [a state]

the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.").

In this case, however, Plaintiff relies on no parallel state duty in support of her negligence per se claim. The claim cites no Georgia statute. It relies exclusively on alleged violations of the FDCA and its implementing regulations. Plaintiff is not suing under state law for conduct that happens to violate the FDCA, but instead is suing solely "*because* the conduct violates the FDCA." *Perez*, 711 F.3d at 1120 (emphasis in original). Such claims are impliedly preempted under *Buckman* and § 337(a). *See id.*

VII. Punitive Damages.

Under Georgia law, punitive damages may be awarded only where "it is shown by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b). Defendants contend that punitive damages are not warranted because there is no evidence they acted with the requisite state of mind and they otherwise complied with all applicable FDA regulations. Doc. 7460 at 14-15. "Compliance with federal regulations, however, is not sufficient to automatically preclude an award of punitive damages." *Cason*, 2015 WL 9913809, at *6 (citing *Cisson*, 2013 WL 5700513, at *11-12). This is particularly true where, as in this case, the device at issue was cleared by the FDA under 510(k) review which focuses primarily on equivalence with other products, not safety. *Cisson*, 2013 WL 5700513, at *12.

Plaintiff claims that Defendants' actions constitute an entire want of care that shows a "conscious indifference" to the dangerous consequences posed by the Recovery filter and its successor, the G2. Doc. 8167 at 19-22. Plaintiff argues that a jury reasonably could award punitive damages because there is evidence that Defendants knew the G2 filter was less safe than the SNF and was failing at a higher rate than competitor devices, and yet never identified the root cause of the failures, provided

adequate warnings, recalled or suspended sales of Bard filters, or implemented known design improvements to address filter migration and perforation. *Id.* at 22.

Under the conscious indifference standard, "[n]umerous Georgia cases have held that punitive damages are available where a manufacturer knows that its product is potentially dangerous and chooses to do *nothing* to make it safer or to warn consumers." *Cisson*, 2013 WL 5700513, at *13 (citations omitted) (emphasis in original). Plaintiff has presented evidence that the Recovery filter had failed internal tests and performed worse than the SNF and competitor devices, and that Bard did not have a full understanding of the filter's design elements before full market release. Doc. 7950 ¶¶ 29, 33-39. Bard began receiving complaints of filter migration and fractures in 2003, and reports of failures resulting in death by April 2004. *Id.* ¶¶ 28, 31. Rather than warning physicians or recalling the filter, Plaintiff alleges that Bard hired a public relations firm to prepare a "Crisis Management Plan" and help Bard "manage controversial or negative stories surrounding the Recovery [filter]." *Id.* ¶ 44, Ex. 38. Bard's bottom line message to the public was: "good filter, severe case, bad outcome, deep regret." *Id.* ¶ 45. Bard viewed this as a "simple story" to be repeated "again and again." *Id.* Significantly, Bard found "[c]omparison with other filters [to be] problematic in many ways," and yet chose to "avoid/downplay this as much as possible." *Id.* Bard continued to sell the Recovery filter even though it had information that the filter was fracturing at a rate higher than other filters, was tilting in nearly a third of all patients, and was significantly less safe than the SNF and competitor devices. *Id.* ¶¶ 47-48, 60-61. Despite this information, Bard provided its employees with a Q&A "script" to follow stating that the Recovery filter's "overall complication rates are comparable to those reported in literature and in the MAUDE database for other IVC filters." *Id.* ¶ 54.

Plaintiff claims that instead of pulling the Recovery filter off the market and starting over, Bard began marketing the next generation G2 filter without adequate testing to determine whether underlying design problems had been fixed. Doc. 8167 at 21-22. By late 2005, Bard was aware that there was no significant change in

perforation rates between the Recovery and G2 filters and that G2 failure rates needed to be investigated. Doc. 7950 ¶¶ 77-78. Bard also was aware that the G2 did not have increased migration resistance over the Recovery and SNF, despite its representations to the contrary. *Id.* ¶ 79. Bard later learned during a clinical study that the G2 tended to tilt at an excessive rate and nearly half the patients had reported an adverse event. *Id.* ¶ 91. With respect to fractures, Bard engineers did not conduct thorough testing because they concluded that the data "would still fall outside the acceptable range" and would not support the G2's "design change as a viable option." *Id.* ¶ 76.

This description of the evidence is made in the light most favorable to Plaintiff, as required for a summary judgment ruling, and is disputed vigorously by Defendants. But if believed by the jury at trial, this evidence is sufficient to support a finding that Defendants "knew the G2 Filter was failing at a significantly higher rate than other IVC filters but did nothing to correct the problem or to warn doctors or patients of the increased risk." *Cason*, 2015 WL 9913809, at *6. A jury reasonably could "conclude that Bard acted with an entire want of care such that Bard was consciously indifferent to the consequences of its actions." *Cisson*, 2013 WL 5700513, at *14; *see Weilbrenner v. Teva Pharms. USA, Inc.*, 696 F. Supp. 2d 1329, 1344 (M.D. Ga. 2010) (punitive damages appropriate for jury consideration where drug manufacturer knew risks of adverse effects in adolescents but did nothing to warn about the dangers); *Mack Trucks, Inc. v. Conkle*, 436 S.E.2d 635, 640 (Ga. 1993) (punitive damages appropriate where truck manufacturer failed to notify purchasers of frame problems); *Ford Motor Co. v. Sasser*, 618 S.E.2d 47, 58 (Ga. Ct. App. 2005) (punitive damages warranted where manufacturer was aware of danger from seat latching system but failed to warn consumers).

Defendants contend that incidents involving the Recovery filter are irrelevant because Plaintiff cannot show a "substantial similarity" between that device and the G2 filter. Doc. 8574 at 14-16. "To show substantial similarity, the plaintiff must come forward with evidence that the other 'incidents share a common design, common defect,

and common causation with the alleged design defect at issue.'" *Chrysler Grp., LLC v. Walden*, 792 S.E.2d 754, 740 (Ga. Ct. App. 2016) (quoting *Colp v. Ford Motor Co.*, 630 S.E.2d 886, 889 (Ga. 2006)). Plaintiff clearly has met this burden.

It is undisputed that the Recovery filter was the predicate device for the G2 and that the two filters share a common design. Indeed, Defendants themselves acknowledge that they filed a 510(k) notice in March 2005 "seeking clearance for a modified Recovery Filter (subsequently known as the G2 Filter)[.]" Doc. 5396 at 8. The FDA cleared the G2 as a permanent filter after finding it to be "substantially equivalent" to the Recovery filter. *Id.* at 9. A device is "substantially equivalent" to a predicate device if it has the same intended use and the same technological characteristics as the predicate device, or any differences do not raise different safety issues. 21 U.S.C. § 360c(i)(1)(A).

What is more, Plaintiff has presented evidence that the two devices share common design defects that have caused similar adverse events, namely, filter migration, fracture, and perforation resulting in serious injury or death. Contrary to Defendants' contention, Plaintiff has shown a "substantial similarity" between the Recovery and G2 filters.[7]

Defendants contend that punitive damages are not warranted for any failure to make design changes before June 2007 given the extensive design, testing, and regulatory clearance processes that were required before any design changes could be implemented. Doc. 8574 at 17. But the same cannot be said about providing warnings for Bard filters. Indeed, Defendants acknowledge that the FDA previously has cleared labeling changes to Bard IVC filters and in one instance found that no 510(k) clearance was even needed. Doc. 5396 at 33.

Defendants claim that Georgia courts have denied punitive damages in circumstances more egregious than those alleged here. Doc. 8574 at 18. The cases Defendants cite, however, are distinguishable. *See Hernandez v. Crown Equip. Corp.*, 92 F. Supp. 3d 1325, 1357 (M.D. Ga. 2015) (forklift manufacturer was not consciously

[7] Defendants' reliance on *Ray v. Ford Motor Co.*, 514 S.E.2d 227 (Ga. Ct. App. 1999), is misplaced. The plaintiff in that case did not argue that the prior incidents were similar to her accident, and the evidence otherwise was unreliable. *Id.* at 231.

indifferent to the risk of leg or foot injuries in part because it "placed warnings on the forklifts and in the operator's manual relating to this danger"); *Moore v. Wright Tech., Inc.*, No. 1:14-cv-62, 2016 WL 1298975, at *6 (S.D. Ga. Mar. 31, 2016) (summary judgment warranted where the plaintiff cited no legal authority and merely referenced the defendant's misconduct in general in support of punitive damages); *Stuckey v. N. Propane Gas Co.*, 874 F.2d 1563, 1575 (11th Cir. 1989) (affirming denial of motion to add punitive damages claim at trial and merely noting that the evidence did not justify an award of punitive damages).

The Court will deny summary judgment on Plaintiff's claim for punitive damages.

IT IS ORDERED:

1. Defendants' motion for partial summary judgment (Doc. 7456) is **granted in part** and **denied in part**. The motion is granted with respect to Plaintiff's claims for manufacturing defects (Counts I and V), failure to recall or retrofit (Count VI), misrepresentation (Counts VIII and XII), negligence per se (Count IX), and breach of warranty (Counts X and XI). The motion is denied with respect to Plaintiff's claims for failure to warn (Counts II and VII) and punitive damages. These claims, along with the design defect claims (Counts III and IV), remain for trial.

2. A final pretrial conference is set for **February 23, 2018 at 2:00 p.m.** The trial is set to begin on **March 13, 2018 at 9:00 a.m**. *See* Docs. 8104, 8858.

Dated this 22nd day of November, 2017.

David G. Campbell
United States District Judge