IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2187

THIS DOCUMENT RELATES TO CIVIL ACTION NUMBERS:

Cisson, et al. v. C. R. Bard, Inc.	2:11-cv-00195
Queen, et al. v. C. R. Bard, Inc.	2:11-cv-00012
Rizzo, et al. v. C. R. Bard, Inc.	2:10-cv-01224
Jones v. C. R. Bard, Inc.	2:11-cv-00114

MEMORANDUM OPINION AND ORDER
(Bard's Partial Motions for Summary Judgment on Plaintiffs' Punitive Damages Claims)

Pending before the court are the defendant C. R. Bard's ("Bard") four motions for summary judgment on the bellwether plaintiffs' punitive damages claims (*Cisson*, 2:11-cv-00195 [Docket 141], *Queen*, 2:11-cv-00012 [Docket 144], *Rizzo*, 2:10-cv-01224 [Docket 171], *Jones*, 2:11-cv-00114 [Docket 153]).[1] The plaintiffs have responded, Bard has replied, and the motions are ripe for review.[2] As set forth below, Bard's motions for summary judgment on the plaintiffs' punitive damages claims are **DENIED**.

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[1] Citations to the docket are to the *Cisson* case unless otherwise noted. Both parties make substantially similar, if not identical, arguments in support of each motion and, as a result, this Memorandum Opinion and Order applies to the pending motion in each bellwether case.

[2] Bard argues that the plaintiffs' forty page response violates Local Rule of Civil Procedure 7.1(a)(2) and PTO # 72. The court consented to the length of this response and moreover, the plaintiffs effectively submitted a single response to the four motions for summary judgment on this issue.

I. Background

These cases are four of several thousand assigned to me by the Judicial Panel on Multidistrict Litigation and currently set for trial pursuant to Pretrial Order # 32.[3] These MDLs involve use of transvaginal surgical mesh to treat pelvic organ prolapse or stress urinary incontinence. The four bellwether cases involve implantation of one or more products, but only the pelvic organ prolapse products are at issue. The plaintiffs in these cases allege injuries suffered as a result of Avaulta products implanted in Ms. Cisson, Ms. Queen, Ms. Rizzo, and Ms. Jones. In each case, the Complaint includes a claim for and allegations in support of punitive damages. In the instant motions, Bard moves for summary judgment on each of the plaintiff's punitive damages claims.

II. Legal Standards

A. *Summary Judgment*

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*,

[3] Originally, there was a fifth case, *Smith v. C. R. Bard*, No. 2:10-cv-01355, which was terminated on February 22, 2013 pursuant to a Stipulation of Dismissal/Order.

477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds*, 490 U.S. 228 (1989).

B. *Choice of Law*

Under 28 U.S.C. § 1407, this court has authority to rule on pre-trial motions. In multidistrict litigation cases such as this, the choice-of-law for these pre-trial motions depends on whether they involve federal or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re*

Air Crash Disaster Near Chicago, Ill., 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

Three of the four cases, *Cisson*, *Queen*, and *Rizzo*, originally were filed in the Northern District of Georgia. The fourth, *Jones*, originally was filed in the Northern District of Mississippi. Therefore, I apply Georgia choice-of-law rules to *Cisson*, *Queen*, and *Rizzo*, and Mississippi choice-of-law rules to *Jones*.

i. *Cisson*, *Queen*, and *Rizzo*

Under Georgia law, the traditional *lex loci delicti* rule generally applies to tort actions. *Dowis v. Mud Slingers, Inc.*, 621 S.E.2d 413, 419 (Ga. 2005) (holding that "[t]he rule of *lex loci delicti* remains the law of Georgia"). Under this rule, the law of the place where the tort or wrong occurred governs the substantive rights of the parties. *See Federated Rural Elec. Ins. Exch. v. R.D. Moody & Assocs., Inc.*, 468 F.3d 1322, 1325 (11th Cir. 2006) (applying Georgia law). In addition, Georgia's choice-of-law system has an unusual characteristic: "the application of another jurisdiction's laws is limited to statutes and decisions construing those statutes." *Frank Briscoe Co., Inc. v. Georgia Sprinkler Co., Inc.*, 713 F.2d 1500, 1503 (11th Cir. 1983) (citing *Budget Rent-A-Car Corp. v. Fein*, 342 F.2d 509 (5th Cir. 1965) and *White v. Borders*, 123 S.E.2d 170 (Ga. Ct. App. 1961)). "When no statute is involved, Georgia courts apply the common law as developed in Georgia rather than foreign case law." *Id.*; *accord Kirkpatrick v. J.C. Bradford & Co.*, 827 F.2d 718, 725 n.6 (11th Cir. 1987) ("If a particular state does not have a controlling statute, however, the Georgia choice of law rule requires application of the common law as construed by the courts of Georgia); *Briggs & Stratton Corp. v. Royal Globe Ins. Co.*, 64 F. Supp. 2d 1340, 1343-44 (M.D. Ga. 1999) (gathering post-*Frank Briscoe* cases from appellate

courts of Georgia and concluding that rule from *Frank Briscoe* remains valid Georgia choice-of-law rule).

With respect to the Cissons, the surgery to implant Ms. Cisson's Avaulta product was performed in Georgia and any alleged injuries occurred in Georgia. Accordingly, Georgia law applies to the *Cisson* case. With respect to the Queens, the surgery to implant Ms. Queen's Avaulta product was performed in North Carolina and any alleged injuries occurred in North Carolina. North Carolina recognizes punitive damages by statute. *See* N.C. Gen. Stat. § 1D-1. Accordingly, North Carolina law applies to the *Queen* case. With respect to the Rizzos, the surgery to implant Ms. Rizzo's Avaulta product was performed in Wisconsin and any alleged injuries occurred in Wisconsin. Wisconsin recognizes punitive damages by statute. *See* Wis. Stat. § 895.043(3). Accordingly, Wisconsin law applies to the *Rizzo* case.

ii. *Jones*

Mississippi applies the "most significant relationship" test as stated in the Restatement (Second) of Conflicts of Law. *McDaniel v. Ritter*, 556 So. 2d 303, 310 (Miss. 1989); *see also Boardman v. United Servs. Auto. Ass'n*, 470 So. 2d 1024, 1031-32 (Miss. 1985); *Mitchell v. Craft*, 211 So. 2d 509, 515 (Miss. 1968). The Restatement (Second) § 145 provides:

> (1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.
>
> (2) Contacts to be taken into account in applying the principles of § 6 to determine the law applicable to an issue include:
>
> (a) the place where the injury occurred,
>
> (b) the place where the conduct causing the injury occurred,
>
> (c) the domicile, residence, nationality, place of incorporation and place of business of the parties,

(d) the place where the relationship, if any, between the parties is centered.

These contacts are to be evaluated according to their relative importance with respect to the particular issue.

Restatement (Second) of Conflicts of Laws § 145. Ms. Jones was and is a resident of the State of Mississippi, the surgery to implant Ms. Jones's Avaulta product was performed in Mississippi, and any alleged injuries occurred in Mississippi. Accordingly, Mississippi law applies to the *Jones* case.

iii. *Punitive Damages Standards*

Georgia's punitive damages statute provides, in relevant part:

(b) Punitive damages may be awarded only in such tort actions in which it is proven 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).

North Carolina's punitive damages statute provides, in relevant part:

(a) Punitive damages may be awarded only if the claimant proves that the defendant is liable for compensatory damages and that one of the following aggravating factors was present and was related to the injury for which compensatory damages were awarded:

(1) Fraud.

(2) Malice.

(3) Willful or wanton conduct.

(b) The claimant must prove the existence of an aggravating factor by clear and convincing evidence.

N.C. Gen. Stat. § 1D-15.

Wisconsin's punitive damages statute provides, in relevant part: "The plaintiff may receive punitive damages if evidence is submitted showing that the defendant acted maliciously toward the plaintiff or in an intentional disregard of the rights of the plaintiff." Wis. Stat. § 895.043(3).

Finally, Mississippi's punitive damages statute provides, in relevant part:

> (a) Punitive damages may not be awarded if the claimant does not prove by clear and convincing evidence that the defendant against whom punitive damages are sought acted with actual malice, gross negligence which evidences a willful, wanton or reckless disregard for the safety of others, or committed actual fraud.

Miss. Code Ann. § 11-1-65(1)(a).

In sum, the Georgia, North Carolina, and Mississippi statutes regarding punitive damages effectively set similar standards: a plaintiff must show, by clear and convincing evidence, that the defendant's actions showed willful or wanton conduct, or an intentional disregard to the plaintiff's rights. However, the Wisconsin statute, when coupled with case law, establishes that the plaintiffs must produce clear and convincing evidence of outrageous conduct by intentionally disregarding their rights. *See City of W. Allis v. Wis. Elec. Power Co.*, 635 N.W.2d 873, 881 (Wis. App. 2001). This involves: "(1) a subjective awareness on the part of the defendant (2) that his conduct is practically certain to result in (3) the plaintiff's rights being disregarded." *Boomsma v. Star Transp., Inc.*, 202 F. Supp. 2d 869, 881 (E.D. Wis. 2002) (emphasis omitted). In requiring intentional disregard, Wisconsin law is more stringent than that of the states allowing punitive damages for reckless disregard or conscious indifference. I will address Bard's motion for partial summary judgment on the four bellwether plaintiffs' punitive damages claims as one below and then apply the states' standards for punitive damages to the extent that they differ.

III. Discussion – Punitive Damages

The question before the court is whether the plaintiffs have produced enough evidence to create a genuine issue of material fact as to whether Bard engaged in culpable conduct that meets each state's punitive damages standard. Bard asserts that the plaintiffs "cannot meet the clear and convincing evidence standard required to prove a punitive damages claim as a matter of law." (Def. Bard's Mem. of Law in Supp. of Mot. for Partial Summ. J. on Pls.' Punitive Damages Claim, or in the Alternative to Bifurcate the Trial with a Separate Punitive Damages Phase [Docket 142], at 3) [hereinafter Bard's Mem.]. It contends that "none of the fact evidence or expert testimony in this case could conceivably constitute clear and convincing evidence of willful misconduct, malice, fraud, wantonness, oppression or an intentional disregard of the rights of another." (*Id.* at 4) (internal quotation marks omitted).[4] In support, Bard argues that:

> (1) Bard affirmatively undertook significant efforts to warn physicians of the risks associated with the Avaulta Systems; (2) Bard complied with FDA regulatory and industry standards and was never subject to any enforcement action in relation to its Avaulta Systems; and (3) even if Plaintiffs' design defect claim survives summary judgment, Plaintiffs can by no means show that any design defect was so obvious that punitive damages would be warranted.

(*Id.* at 5). As discussed below, Bard's arguments fail, and the cases it cites are simply inapposite.

A. *Inadequate Warnings*

First, with respect to warnings, Bard argues that "the mere fact that Bard may have failed to sufficiently warn about a specific risk is not adequate to authorize punitive damages." (*Id.* at 6). In other words, Bard argues that because it provided a warning in the instructions for use ("IFU"), punitive damages should not go to the jury. Bard also points to Dr. Brian Raybon's, Dr. Lennox Hoyte's, and Dr. Bernd Klosterhalfen's testimony to suggest that Bard's IFUs were

[4] Bard argues similarly under each of the state's punitive damages standards.

adequate. (*Id.* at 7). Finally, Bard argues that it facilitated training and educational programs for physicians, even though it was not required by the FDA. (*Id.* at 8).

The plaintiffs respond by arguing that "[t]he mere inclusion of *some* warning with a product does not absolve the manufacturer of potential punitive damage liability where there is otherwise evidence demonstrating willful or wanton misconduct, conscious indifference or intentional disregard." (Pls.' Resp. in Opp'n to Def. Bard's Mot. for Partial Summ. J. on Pls.' Punitive Damages Claim, or in the Alternative to Bifurcate the Trial with a Separate Punitive Damages Phase [Docket 200], at 30) [hereinafter Pls.' Resp.]. The plaintiffs contend that (1) Bard knew that the mesh arm design, collagen component, and pore size and density of the mesh arms created heightened risks, but failed to take any action to warn or address these known risks; (2) Bard knew that the material was subject to degradation *in vivo*, through oxidation and thermal processing, but never warned about it and subjected it to thermal processing anyway; (3) Bard knew it was manufacturing Avaulta products using a material expressly prohibited by the manufacturer against permanent implantation in humans, but never warned of, and in fact took steps to conceal, this fact; (4) Bard never conducted any clinical studies despite recommendations from one of its chief medical advisors to do so; and (5) Bard never disclosed the results of its animal testing, which revealed adverse risks and did not support the safety of the material used.

Bard cites a number of cases to support its argument that punitive damages are precluded when a product manufacturer warns of a particular type of danger and the plaintiff is subsequently injured through the danger about which the manufacturer warned of. In *Richards v. Michelin Tire Corp.*, the Eleventh Circuit stated, "in terms of wantonness, the issue is whether [the defendant] consciously and intentionally failed to give reasonable and adequate warnings

with knowledge of, or reckless indifference to, the fact that the lack of warnings made [the plaintiff's] injury likely or probable." 21 F.3d 1048, 1058 (11th Cir. 1994). The court held that "the issue of punitive damages should not go to the jury when a manufacturer takes steps to warn the plaintiff of the potential danger that injured him; such acts bar a finding of wantonness." *Id.* at 1059. Other courts have held similarly. *See, e.g.*, *Heston v. Taser Int'l, Inc.*, 431 F. App'x 586, 589 (9th Cir. 2011); *Dudley v. Bungee Int'l Mfg. Corp.*, No. 95-1204, 1996 WL 36977, at *3 (4th Cir. 1996) (unpublished table decision); *DeLuryea v. Winthrop Labs., a Div. of Sterling Drug, Inc.*, 697 F.2d 222, 230-31 (8th Cir. 1983); *Ilosky v. Michelin Tire Corp.*, 307 S.E.2d 603, 619 (W. Va. 1983); *Kritser v. Beech Aircraft Corp.*, 479 F.2d 1089, 1096-97 (5th Cir. 1973).

In *Richards*, the manufacturer knew of very few incidents—the "actual incidence of mismatches" during the tire mounting process being "roughly one in millions." 21 F.3d at 1058. Furthermore, the Eleventh Circuit found that the manufacturer's "compliance with both federal regulations and industry practices is some evidence of due care." *Id.* at 1059. The court found that "[a]s shown, [the plaintiff] has not demonstrated sufficient evidence of wantonness on his failure to warn claim." *Id.*

In *Dudley*, the defendant specifically warned against stretching a cord "greater than Seventy Five (75%) Percent of its stretchable length," and it was undisputed that the plaintiff stretched the cord over 75% of its stretchable length. 1996 WL 36977, at *3. Accordingly, the Fourth Circuit found that an award of punitive damages was not warranted under a failure to warn theory. Similarly, in *Ilosky*, the defendant specifically warned against mixing radial and conventional tires—which is exactly what the plaintiff did. 307 S.E.2d at 607, 619.

In *DeLuryea*, the Eighth Circuit found that the defendant drug manufacturer failed to adequately warn of dangers concerning tissue damage and drug dependence, but that punitive

damages were not warranted because "warnings were given concerning both tissue damage and drug dependence." 697 F.2d at 230. The court went on to distinguish the matter from *Hoffman v. Sterling Drugs*, 485 F.2d 132 (3d Cir. 1973), where "[t]he evidence showed that defendant, knowing that its drug could cause serious retinal changes, knew or should have known that its attempted warnings would not effectively reach the medical profession." *DeLuryea*, 697 F.2d at 231. In sum, the court found that "[t]he evidence in *Hoffman* was substantially different from that presented in this case. DeLuryea relied almost exclusively on expert opinion evidence and did not present the devastating documentary evidence presented in *Hoffman*." *Id.*

In *Heston*, the Ninth Circuit found that the defendant "made efforts, albeit insufficiently, to warn its customers about the risks posed by prolonged TASER [device] deployment. While this may amount to negligence, it does not rise to the level [of] 'willful or wanton' conduct." 431 F. App'x at 589. Finally, in *Kritser*, the Fifth Circuit found that the defendant took some steps to inform the plaintiff of potential danger and punitive damages were therefore unwarranted, but went onto state that "[t]he defendant did not exhibit the conscious indifference toward the public which generally typifies gross negligence, and there is no evidence that it committed any wilful act or omission." 479 F.2d at 1097 (internal citation omitted).

In each of these cases, the plaintiffs simply were unable to demonstrate sufficient evidence to meet the appropriate standard for punitive damages. As stated above, for example, in *Richards*, the ultimate conclusion was that the plaintiff failed to demonstrate sufficient evidence of wantonness. 21 F.3d at 1059. In *DeLuryea*, the court's review concluded that there was "no evidence" to support punitive damages and "no indication of malice, wantonness, or reckless indifference to the consequences from which malice could be inferred." 697 F.2d at 231.

Similarly, in *Kritser*, the court found "no evidence that [the defendant] committed any wilful act or omission." 479 F.2d at 1097.[5]

In the instant matters, the fact that Bard provided warnings regarding certain issues is simply not dispositive. The court must still necessarily inquire whether the plaintiffs have presented other evidence creating a genuine issue of material fact as to whether Bard's actions rose to a level amounting to culpable behavior. As discussed *infra*, Section D, unlike the cases cited by Bard, the plaintiffs here have done so.

B. *Compliance with FDA and Industry Standards*

Second, Bard argues that under Georgia law, "punitive damages are not generally appropriate in cases where a manufacturer complies with industry and regulatory standards," and that it complied with FDA and industry standards. (Bard's Mem. [Docket 142], at 8). With respect to FDA standards, Bard argues that it "repeatedly disclosed information pertaining to its Avaulta Systems to the FDA, and never received an indication that the labeling or design for the products was anything but satisfactory." (*Id.* at 10). According to Bard, the FDA never took any enforcement actions against Bard with respect to Avaulta products and cleared the Avaulta products to be marketed in the United States. Additionally, Bard argues that the FDA does not generally require human or clinical data for 510(k) submissions. With respect to industry standards, Bard argues that it submitted "undisputed expert evidence showing that its regulatory

[5] *Dudley* applied Virginia law which specifically "precludes a finding of willful and wanton negligence when a defendant has shown some care for the safety of others." 1996 WL 36977, at *2. *Ilosky* held that the facts in that case—inadequate warnings, without more—did not meet the willfulness, wantonness, or malice standard, but makes no mention of whether inadequate warnings *in addition to* other, more egregious conduct, would meet the standard. *See* 307 S.E.2d at 619.

I note that Bard cites several additional cases in its Replies. I draw the same conclusions about these cases as the ones cited above. For example, in *Drabik v. Stanley-Bostitch, Inc.*, the Eighth Circuit found that "[t]he evidence clearly shows that when Bostitch became aware of the inadvertent discharge problem, it immediately took steps to make the product safer," and such actions are inconsistent with a finding of "complete indifference" to the safety of others. 997 F.2d 496, 510 (8th Cir. 1993). The plaintiffs have provided evidence here—which must be viewed in the light most favorable to them—that Bard knew of certain risks and deliberately decided *not* to take steps to make the product safer.

submissions, labeling, testing, and promotional materials reflected current industry standards." (*Id.* at 11).

The plaintiffs first argue that any compliance with the FDA would not preclude punitive damages because there is other evidence of wrongful conduct in this case. The plaintiffs then argue that while the Avaulta products were cleared through the 510(k) process, this process does not demonstrate the safety or efficacy of the device because the process focuses on equivalence, not safety.

Bard again cites a number of cases to support its contentions. *See Mims v. Wright Med. Tech., Inc.*, No. 1:11-CV-213-TWT, 2012 WL 1681810, at *5 (N.D. Ga. May 11, 2012); *Taylor v. Mooney Aircraft Corp.*, 464 F. Supp. 2d 439, 449 (E.D. Pa. 2006); *Welch v. Gen. Motors Corp.*, 949 F. Supp. 843, 845 (N.D. Ga. 1996); *Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993); *Barger v. Garden Way, Inc.*, 499 S.E.2d 737, 743 (Ga. Ct. App. 1998). A close reading of these cases reveals that punitive damages are improper *as a general rule* where a defendant has complied with applicable regulations. However, these cases also state unambiguously that "[c]ompliance with the regulations will not prevent the imposition of punitive damages *if other evidence is presented showing culpable behavior*." *Taylor*, 464 F. Supp. 2d at 448 (emphasis added). *Taylor* cited *Welch*—another case Bard itself cited—for this proposition. *Welch* states that "nothing in *Stone Man* precludes an award of punitive damages where, notwithstanding the compliance with applicable safety regulations, there is other evidence showing culpable behavior." 949 F. Supp. at 844 (quoting *Gen. Motors Corp. v. Moseley*, 447 S.E.2d 302, 311 (Ga. Ct. App. 1994), *abrogated on other grounds by Webster v. Boyett*, 496 S.E.2d 459 (Ga. 1998)).

Bard's reliance on *Montgomery v. Mitsubishi Motors Corp.*, No. 04-3234, 2006 WL 1030272, at *4 (E.D. Pa. Apr. 19, 2006) is similarly unavailing for its argument that failure to conduct tests not mandated by regulations is insufficient to warrant punitive damages. *Montgomery* ultimately concluded that the record before the court "presents no dispute of a material fact on the punitive damages issue and is devoid of any evidence from which a reasonable jury could find that [the manufacturer] acted with an evil motive or with reckless indifference." *Id.* One such factor that the court considered in reaching this conclusion was that the product complied with safety standards, one of which was certain vehicle testing accepted and conducted by the automobile industry. When the vehicle at issue was designed, one of the tests that the plaintiffs alleged should have been done was not conducted because industry standards did not require it. However, as the court found, "the record present[ed] nothing more on this issue." *Id.* In sum, even if the court were to accept Bard's arguments as true—that Bard followed the 510(k) process and that the process addresses safety and efficacy—the court must still necessarily inquire whether the plaintiffs have presented other evidence creating a genuine issue of material fact as to whether Bard's actions rose to a level amounting to culpable behavior under each state's punitive damages standard. As discussed *infra*, Section D, the plaintiffs here have done so.

C. *Design Defects*

Third, Bard argues that it "had good faith bases for believing that its devices were adequately designed" and that the plaintiffs "cannot demonstrate that it is beyond dispute that Bard's design of its Avaulta Systems was so obviously defective" that it would satisfy the standard for awarding punitive damages. (Bard's Mem. [Docket 142], at 12). In sum, Bard

argues that "there is at a bare minimum a genuine dispute as to whether the Avaulta Systems were defectively designed," and therefore punitive damages are not warranted. (*Id.* at 13).

The plaintiffs argue that Bard misstates the standard for punitive damages. According to the plaintiffs, if Bard's stated standard were correct, then "there could never be a punitive damages award in any design defect products liability action" because the design defect would always be disputed. (Pls.' Resp. [Docket 200], at 37). The plaintiffs contend that Bard has conceded "the dangerous flaws inherent in the Avaulta mesh design, and that its choice of materials was the cause of women's injuries," citing many internal Bard documents. (*Id.* at 38).

Bard cites to various cases in support of its contentions. *See, e.g.*, *Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1317 (5th Cir. 1995); *Riley v. Ford Motor Co.*, No. 2:09-CV-148-KS-MTP, 2011 WL 2938107, at *3 (S.D. Miss. July 19, 2011); *Loitz v. Remington Arms Co.*, 138 Ill. 2d 404, 426 (1990); *Owens-Corning Fiberglas Corp. v. Garrett*, 682 A.2d 1143, 1163-68 (Md. App. 1996). In each of these cases, the court simply looked at the facts and found no clear and convincing evidence of the culpable conduct required for an award of punitive damages. For example, the Southern District of Mississippi in *Riley* found that "the only evidence to support Plaintiffs' claim for punitive damages is the testimony that Ford knew the buckle stalk would bend if enough pressure was applied to it." 2011 WL 2938107, at *6. In *Loitz*, the court found that the evidence before it, including the disagreement among experts, did not provide "sufficient proof that [the defendant] had the requisite degree of culpability that would warrant imposition of a sanction that is intended to punish and deter." 138 Ill. 2d at 427.

In sum, these cases merely hold that when the *only* evidence before the court is a genuine dispute as to whether a product was defectively designed—and perhaps that the defendant knew about it—then the plaintiff has not shown by clear and convincing evidence the culpable conduct

required for an award of punitive damages. The mere fact that there may be a genuine dispute of material fact as to whether the Avaulta products were defectively designed does not compel the conclusion that the plaintiffs are not entitled to punitive damages. Again, the inquiry is whether the plaintiffs have presented evidence sufficient to create a genuine issue of material fact as to whether Bard's actions rose to a level that warrants an imposition of punitive damages under each state's standard. And again, as discussed *infra*, Section D, the plaintiffs here have done so.

D. ***The Plaintiffs' Evidence in this Case***

In this case, construing the facts in the light most favorable to the plaintiffs, I **FIND** that there are genuine issues of material fact as to whether Bard's actions meet each state's punitive damages standard. The plaintiffs provide evidence that (1) Bard had the Material Safety Data Sheet ("MSDS") which expressly prohibited the use of the material for permanent human implantation;[6] (2) Bard concealed from the resin manufacturer that Bard was using the material for the purposes of human implantation; and that (3) Bard concealed, from a company performing a part of the polypropylene processing for Bard, that the material was being used in a

[6] The warning on the material—polypropylene resin used to manufacture the Avaulta products—stated:

> MEDICAL APPLICATION CAUTION: Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

(Material Safety Data Sheet [Docket 200-1]). Bard has not challenged the admissibility of the MSDS on any grounds in its summary judgment pleadings. The court is in receipt of a motion *in limine* as to the MSDS and will rule on that motion when it is ripe.

medical device.[7] (*See* Internal Emails [Docket 200-2, 200-3, 200-6]).

Moreover, there is evidence from Bard's internal documents indicating it knew that inadequate pore size and high density of mesh arms cause problems and that the mesh design and material are responsible for problems experienced by patients. (*See* PowerPoint Slides [Dockets 200-14, 200-15, 200-16, 200-17, 200-21, 200-22]; Pore Size Measurements [Docket 200-23]; Pore Density Measurements [Docket 200-24]; Inter-Office Correspondence [Dockets 200-18, 200-25]; Internal Email [Docket 200-26]). The MSDS for the polypropylene resin states that it "[m]ay react with oxygen and strong oxidizing agents," and there is evidence that peer-reviewed literature shows that polypropylene degrades *in vivo*. (Material Safety Data Sheet [Docket 200-1], at 5; *see* Journal Articles [Dockets 200-27; 200-28; 200-29; 200-30; 200-31; 200-33]). There is evidence that Bard's sales personnel and physicians knew that the mesh arms can cause tissue tearing when the mesh is being implanted. (*See* Internal Emails [Dockets 200-38, 200-44]; Cadaver Lab Notes [Docket 200-39]; Interoffice Memo [Docket 200-45]; Phase Initiation Form

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[7] Bard argues that under *State Farm Mutual Automobile Insurance Co. v. Campbell*:

> The [Utah] courts awarded punitive damages to punish and deter conduct that bore no relation to the [plaintiffs'] harm. A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages. A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business.

538 U.S. 408, 422-23 (2003). As one district court has summarized, *Campbell* requires "that the jury base its award of punitive damages on the defendant's wrongful conduct only as it relates to the specific conduct giving rise to the plaintiff's underlying claims." *Burton v. Wyeth-Ayerst Labs. Div. of Am. Home Prods. Corp.*, 513 F. Supp. 2d 708, 718 (N.D. Tex. 2007) (internal citation omitted).

Here, the plaintiffs' claims include design defect and failure to warn. (*See, e.g.*, Compl. [Docket 1]). Bard's actions with respect to the MSDS at issue are relevant insofar as they could show that Bard *knew* that use of the polypropylene resin in the design of the product was improper and *actively took steps* to conceal this knowledge such that it ultimately harmed the bellwether plaintiffs. Bard's actions with respect to the MSDS at issue also are relevant insofar as they could show that Bard never warned anyone of the dangers stated on the polypropylene resin MSDS. *See Zeigler v. CloWhite Co.*, 507 S.E.2d 182, 184-85 (Ga. Ct. App. 1998) (holding that trial court erred in granting summary judgment for defendants where evidence showed that defendants failed to warn of dangers contained in MSDS for a component of its product).

[Docket 200-46]). There is evidence from Bard's internal documents indicating it knew that the collagen component of its Avaulta Plus product causes a problem referred to as "persistent delayed healing." (*See* Internal Document on Persistent Delayed Healing [Docket 200-48]; Email to Doctor [Docket 200-49]).

According to the plaintiffs' evidence, with respect to testing, Bard "chose not to conduct full biocompatibility testing on the finished Avaulta Plus/Solo mesh product before the products were released for sale." (Pls. Resp. [Docket 200], at 19; Bard Memorandum [Docket 200-50]; Emails [Dockets 200-53, 200-54]; Response to UK Medicines and Healthcare Products Regulatory Agency (MHRA) on Bard Synthetic Vaginal Mesh Devices [Docket 200-55], at 6). Moreover, Bard performed certain animal testing which failed to support the safety of the products, and chose to market the products anyway. (Internal Memorandum on Emory Rat Studies [Docket 200-56]; Abdominal Wall Hernia Model in a Rat [Docket 200-59]; A Novel Mesh/Tissue Combination for Vaginal Prolapse in a Sheep Model – A Pilot Study [Docket 200-60]; Mercuri Dep. [Docket 200-58], at 213:12-215:14). Finally, there is evidence that Bard chose not to conduct clinical studies of the Avaulta mesh products, notwithstanding advice from one of its chief medical advisors and its own medical director. (*See* Ross Dep. [Docket 200-61], at 119:9-120:3; 145:25-146:21; Email [Docket 200-62]; Delaney Dep. [Docket 200-63], at 29:3-30:20; 139:15-140:4). As discussed in my Memorandum Opinions and Orders on Bard's motion for partial summary judgment against the plaintiffs, there are genuine issues of material fact as to whether the warnings provided by Bard were adequate. Accordingly, the evidence provided by the plaintiffs, viewed in the light most favorable to them, clearly raises a genuine issue of

material fact as to whether Bard failed to address or warned of the known design issues with the Avaulta products.[8]

I **FIND** that the above evidence offered by the plaintiffs creates a genuine issue of material fact as to whether Bard's actions meet each state's punitive damage standards. In particular, evidence of Bard's concealment of the MSDS and Bard's intended use of the polypropylene mesh for human implantation, viewed in the light most favorable to the plaintiffs, raises a genuine issue of material fact about whether Bard was aware its conduct was practically certain to cause injuries to the plaintiffs under Wisconsin law. Likewise, this evidence further raises a genuine issue of material fact as to whether Bard engaged in willful misconduct, wantonness, or conscious indifference to the consequences sufficient to meet the Georgia, North Carolina, and Mississippi standards. Additionally, evidence of Bard's lack of testing or otherwise addressing issues related to inadequate pore size, high density of mesh arms, polypropylene degradation, and collagen, combined with evidence of its knowledge further creates issues of material fact. Accordingly, Bard's motion for partial summary judgment on the issue of punitive damages is **DENIED**.

IV. Discussion – Bifurcation or Trifurcation

Bard requests bifurcation or trifurcation of the trial under Federal Rule of Civil Procedure 42(b). The plaintiffs do not oppose bifurcation as long as the first phase is on liability and compensatory damages and the second phase is limited only to the amount of punitive damages.

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[8] Bard cites to several cases to support its contention that a failure to test does not provide support for punitive damages. A review of these cases reveals that they simply find that a failure to test, *without more*, provides no support for an award of punitive damages. *See, e.g.*, *Mosser v. Fruehauf Corp.*, 940 F.2d 77, 86 (4th Cir. 1991) ("Factors relevant to the reasonableness of any failure to test . . . bear primarily on the question of negligence and provide no support for an award of punitive damages *in the absence of some evidence of conscious disregard of public safety*.") (emphasis added); *see id.* at 87 ("Many cases from other jurisdictions upholding punitive awards based in part on a failure to test involved aggravating circumstances including, significantly, the manufacturer's failure to act in the face of notice or knowledge of a defect.").

I agree. Bard's motion to bifurcate the trial is **GRANTED in part** insofar as it seeks bifurcation with the first phase on liability and compensatory damages and the second phase on punitive damages. To the extent that Bard seeks to trifurcate the trial or to preclude evidence regarding its liability for punitive damages in the first phase of the bifurcated trial, the motion is **DENIED**.[9]

V. Conclusion

For the reasons stated above, it is **ORDERED** that Bard's motions for summary judgment on the plaintiffs' punitive damages claims (*Cisson*, 2:11-cv-00195 [Docket 141], *Queen*, 2:11-cv-00012 [Docket 144], *Rizzo*, 2:10-cv-01224 [Docket 171], *Jones*, 2:11-cv-00114 [Docket 153]) are **DENIED**. The Clerk is instructed to file a copy of this Memorandum Opinion and Order in *Cisson*, *Queen*, *Rizzo*, and *Jones*.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: June 4, 2013

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

[9] It is not entirely clear which issues Bard seeks to bifurcate. Bard discusses introduction of evidence "relating to Bard's financial status," which is relevant only towards the amount of punitive damages. (Bard's Mem. [Docket 142], at 16). However, it also seeks to preclude "improper motive evidence," which is relevant towards its liability for punitive damages. (*Id.*).