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

CHARLESTON DIVISION

DONNA CISSON, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:11-cv-00195

C. R. BARD, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER

Pending before the court is Defendant C. R. Bard, Inc.'s Renewed Motion for Judgment as a Matter of Law [Docket 439]. Plaintiffs have responded [Docket 440], making the matter ripe for decision. For the reasons stated below, the defendant's motion is **DENIED**.

I. Factual and Procedural History

A. Factual History and Trial Summary

This is the first bellwether case tried to a jury involving allegations of design defect and failure to warn related to the Avaulta Plus product, manufactured by C. R. Bard, Inc. ("Bard"). The Avaulta Plus is a synthetic mesh product designed and distributed by Bard to treat pelvic organ prolapse in women. The plaintiffs, Donna and Dan Cisson, filed this action against Bard on March 10, 2011, alleging a number of different claims against Bard regarding its Avaulta Plus product. (*See* Compl. [Docket 1]). The plaintiffs eventually presented three claims to the jury: design defect, failure to warn, and loss of consortium. With respect to their design defect claim, the plaintiffs asserted that the arms contained in the device, the small pore size used in the mesh, and the use of polypropylene to create the product all constituted design defects. On their failure to

warn claim, the plaintiffs argued that Bard inadequately warned about the risk and severity of the complications Ms. Cisson eventually experienced.

Dr. Brian Raybon, Ms. Cisson's treating physician, implanted the Avaulta Plus in Ms. Cisson in May of 2009. Ms. Cisson testified that after the device was implanted, she experienced pain during intercourse, while sitting, and during gynecological exams. (*See* Tr. 8/5/13, 85:8-86:2, 86:3-13, 87:18-88:5, 88:24-89:1, 104:17-21, 111:1-9).[1] The evidence indicated Ms. Cisson also experienced extrusion, erosion, excessive scarring, and inflammation as a result of the implant. (*See* Pls.' Ex. 1227A, Miklos T., 43:11-44:4, 46:1-13, 52:15-53:1, 71:15-72:01; Tr. 7/30/13, 74:7-13, 74:22-24, 82:10-13, 84:15-18, 113:10-22; Tr. 8/1/13, 75:14-13). After continuing to experience pain, Ms. Cisson underwent surgery to have the Avaulta Plus removed in March of 2011. However, the "arms" of the device could not be removed and remain inside Ms. Cisson. (*See, e.g.*, Tr. 7/31/13, 42:24-43:6). Ms. Cisson testified that she continued to experience pelvic pain from the time the device was implanted through the time of trial. (*See* Tr. 8/5/13, 104:24-25).

The plaintiffs presented testimony from a number of experts to support their claims that the Avaulta Plus was defectively designed. Dr. Lennox Hoyte, a urogynecologist, testified that the arms on the Avaulta Plus were a design defect. (*See* Tr. 7/30/13, 266:19-267:5; Tr. 7/31/13, 18:17-19:5). Dr. Hoyte also testified that the arms on the Avaulta Plus cause pain in patients. (*See* Tr. 7/30/13, 261:25-262:9, 266:19-267:5, 277:7-18; Tr. 7/31/13, 18:17-19:5, 22:19-23:9, 23:10-24:6). Dr. Hoyte testified that the arms in the Avaulta Plus caused Ms. Cisson's pain. (*See* Tr. 7/31/13, 31:13-32:15, 32:23-34:12, 35:2-24, 37:1-38:2, 42:24-43:6). Dr. John Miklos, one of Ms. Cisson's treating physicians, also testified that the arms in the Avaulta Plus caused Ms.

[1] Citations to the record throughout this Memorandum Opinion and Order are not intended as exhaustive lists of the evidence presented at trial.

Cisson's pain. (*See* Pls.' Ex. 1227A, Miklos T., 44:23-46:23, 70:22-72:01).

The plaintiffs also presented evidence that the device's pore size was inadequate. Dr. Bernd Klosterhalfen, a pathologist, testified that an inadequate pore size can cause a rigid scar plate and an inflammatory reaction. (*See* Tr. 8/1/13, 46:20-47:17, 50:6-13). Dr. Klosterhalfen stated that an inadequate pore size can cause the mesh to shrink. (*See id.* at 54:18-56:8). Dr. Jim Ross testified that a larger pore size decreases scarification and small pore size can create a rigid scar plate. (*See* Pls.' Ex. 1216A, Ross T., 61:2-4, 64:25-65:5).

Additionally, the plaintiffs presented evidence that the device was defective because it was constructed with polypropylene. Suppliers such as Chevron Phillips produce polypropylene resin in pellet form. The resin is purchased and extruded by Bard's supplier, Red Oaks, into monofilament. Bard then knits the monofilament into mesh that makes up the Avaulta Plus. The plaintiffs produced a Chevron Phillips Material Data Safety Sheet ("MSDS") in Bard's possession that included the following warning: "MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." (Pls.' Ex. 482, at 1). Dr. Anthony Brennan, a professor of materials science and biomedical engineering, testified that polypropylene degrades and cannot perform its intended function. (*See* Tr. 8/2/13, 84:9-86:24, 109:24-111:6). He testified that polypropylene triggers an inflammatory response in patients and that degradation of a medical device contributes to inflammation. (*See id.* at 85:25-86:24, 112:9-16, 113:11-18). Dr. Klosterhalfen testified that polypropylene is not biocompatible for long-term implantations because it can degrade and create an inflammatory response. (*See* Tr. 8/1/13, 91:25-92:23, 95:23-96:14). Dr. Raybon testified that Ms. Cisson's mesh degraded. (*See* Tr. 7/30/13, 113:10-22). Dr. Klosterhalfen also specifically looked at Ms. Cisson's

pathology and explained to the jury that the polypropylene implanted in Ms. Cisson gave her an inflammatory reaction and a scar plate. (*See* Tr. 8/1/13, 76:4-79:15).

B. Jury Verdict and Rule 50 Motions

On August 15, 2013, the jury returned a verdict in favor of Ms. Cisson on her design defect and failure to warn claims.[2] The jury awarded Ms. Cisson $250,000 in compensatory damages. (*See* Verdict Form [Docket 404]). The jury also awarded Ms. Cisson $1,175,000 in punitive damages. (*See* Verdict Form [Docket 404]; Verdict Form [Docket 406]).

Bard orally moved for judgment as a matter of law pursuant to Federal Rule of Civil Procedure 50(a) at the conclusion of the plaintiffs' case on August 7, 2013. (*See* Tr. 8/7/13, 104:22-128:8). I deferred ruling. (*See id.* at 129:2-13). Bard renewed its motion on the same grounds at the close of its case on August 13, 2013, and I again deferred ruling. (*See* Tr. 8/13/13, 167-75, 181). I now consider Bard's post-verdict motion for judgment as a matter of law pursuant to Rule 50(b).

II. Legal Standard

A court may grant judgment as a matter of law pursuant to Federal Rule of Civil Procedure 50 "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a). When considering a party's motion for judgment as a matter of law, the court must "view the evidence in the light most favorable" to the non-moving party and "draw all reasonable inferences in his [or her] favor without weighing the evidence or assessing the witnesses' credibility." *Baynard v. Malone*, 268 F.3d 228, 234-35 (4th Cir. 2001). Judgment as a

[2] The jury found that Mr. Dan Cisson had not proven his loss of consortium claim by a preponderance of the evidence.

matter of law is inappropriate if a reasonable jury could find in favor of the non-moving party. *Id.* at 235. However, a court may grant judgment as a matter of law if the "evidence presented supports only one reasonable conclusion as to the verdict." *Bank of Montreal v. Signet Bank*, 193 F.3d 818, 831 (4th Cir. 1999).

Rule 50 also states that "[i]f the court does not grant a motion for judgment as a matter of law made under Rule 50(a), the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion." Fed. R. Civ. P. 50(b). After the matter is submitted to the jury, the Rules allow a movant to file a renewed motion for judgment as a matter of law. *Id.* "When a jury verdict has been returned, judgment as a matter of law may be granted only if, viewing the evidence in a light most favorable to the non-moving party (and in support of the jury's verdict) and drawing every legitimate inference in that party's favor, the only conclusion a reasonable jury could have reached is one in favor of the moving party." *Int'l Ground Transp. v. Mayor & City Council of Ocean City, Md.*, 475 F.3d 214, 218-19 (4th Cir. 2007).

While courts should not simply rubber stamp a jury's verdict, judgment as a matter of law is a remedy to be applied sparingly and only in the most extraordinary circumstances. 9B Charles Wright & Arthur Miller, *Federal Practice and Procedure* § 2524 (3d ed. 2008); *see, e.g.*, *Sawyer v. Asbury*, 861 F. Supp. 2d 737, 743-44 (S.D. W. Va. 2012) (submitting case to a jury despite "deep concerns" but granting post-verdict motion for judgment as a matter of law where video evidence contradicted trial testimony). "A court . . . may not disturb the [jury] verdict where there was sufficient evidence for a reasonable jury to find in the non-movant's favor." *Dotson v. Pfizer, Inc.*, 558 F.3d 284, 292 (4th Cir. 2009).

III. Discussion

A. Design Defect

Bard moved for judgment as a matter of law under Rule 50(a) at the close of the plaintiffs' case. This motion was renewed under Rule 50(b) after the jury rendered a verdict. Rule 50(b) provides that "[i]f the court does not grant a motion for judgment as a matter of law made under Rule 50(a), . . . the movant may file a renewed motion for judgment as a matter of law" after the verdict is received. "However, the district court only can grant the Rule 50(b) motion on the grounds advanced in the preverdict motion, because the former is conceived of as only a renewal of the latter." Wright & Miller, *supra*, § 2537.

In Bard's Rule 50(a) motion, defense counsel explicitly waived any objection to a Rule 50 challenge of the plaintiffs' evidence regarding the arms of the Avaulta Plus constituting a design defect. (*See* Tr. 8/7/13, 106:18-107:6 ("So, I would concede, on behalf of Bard, that that issue, that is, the alleged defect related to the arms and causation to Ms. Cisson, should go to the jury based on Dr. Hoyte's testimony."); *id.* at 122:14-16 ("I did concede that arms . . . should go to the jury[.]")). I therefore **FIND** that because Bard conceded in its Rule 50(a) motion that the design defect claim with regard to the arms should go to the jury, it may not raise arguments that evidence about the arms was insufficient in its Rule 50(b) motion.

Even if Bard had not conceded on the arms issue, I would nonetheless find that the plaintiffs presented sufficient evidence that a reasonable jury could find that the arms in the Avaulta Plus constituted a design defect and that the defect proximately caused Ms. Cisson's injuries. (*See, e.g.*, Tr. 7/31/13, 18:17-19:5; Pls.' Ex. 1227A, Miklos T., 70:22-72:01; Tr. 7/31/13, 42:24-43: 6). Bard claims that "[t]he only specific causation opinion that Dr. Hoyte offered was that Ms.Cisson's pain was caused by the Avaulta's arms being implanted into the levator ani

muscles," and he "did not express this causation opinion to a reasonable degree of medical certainty, as is required by Georgia law." (Def. C. R. Bard, Inc.'s Renewed Mot. for J. as a Matter of Law [Docket 439], at 23). However, a simple review of the transcript indicates that this is patently false. In fact, Dr. Hoyte testified two separate times to a reasonable degree of medical certainty that Ms. Cisson's pain was caused by the mesh, and specifically by the placement of the arms. (*See* Tr., 7/31/13, 37:1-38:2 (stating to a reasonable degree of medical certainty that Ms. Cisson's pain during intercourse was "related to the mesh via the levator ani inserts"); *id.* at, 42:24-43:4 (stating to a reasonable degree of medical certainty that Ms. Cisson's complaints of vaginal pain are permanent in nature "because they're related to the placement of the mesh arms," and that "as long as the arms remain in . . . her symptoms will be present")).[3]

Despite the fact that Bard conceded there was sufficient evidence for a jury to consider whether the Avaulta Plus arms constituted a design defect, Bard nonetheless argues that the plaintiffs failed to prove that polypropylene or pore size constituted design defects. Bard is correct that defense counsel limited the concession to only the arms on the Avaulta Plus, and not the other potential design defects that the plaintiffs were attempting to prove. (*See* Tr. 8/7/13, 106:12-13, 107:7-8, 113:11-19, 122:24-123:2). However, the plaintiffs were not required to separate the alleged defects as Bard now attempts to do. Georgia law provides that in a products liability case "it is not necessary for the plaintiff to specify precisely the nature of the defect." *Trickett v.*

[3] Additionally, Bard argues that pursuant to my Memorandum Opinion and Order on *Daubert* Motions [Docket 274], Ms. Cisson's treating physicians, Dr. Raybon and Dr. Miklos, were not permitted to render opinions concerning the Avaulta product's design, and therefore neither could testify regarding whether any specific defect caused Ms. Cisson's injuries. (Def. C. R. Bard, Inc.'s Reply Mem. of Law in Supp. of Renewed Mot. for J. as a Matter of Law [Docket 443], at 11). However, in the Memorandum Opinion and Order, on the very page Bard references, I explicitly stated that Ms. Cisson's treating physicians were permitted to offer "causation opinions, if formed in the course of treatment," because those "opinions fall within the realm of proper testimony from treating physicians." (Mem. Op. & Order [Docket 274], at 30). Dr. Raybon and Dr. Miklos were therefore permitted to testify regarding the cause of Ms. Cisson's injuries.

Advanced Neuromodulation Sys., Inc., 542 F. Supp. 2d 1338, 1345 (S.D. Ga. 2008); *see also, e.g.*, *Williams v. Am. Med. Sys.*, 548 S.E.2d 371, 374 (Ga. Ct. App. 2001); *Waddy v. Globus Med., Inc.*, No. 407CV075, 2008 U.S. Dist. LEXIS 73030, at *12 (S.D. Ga. Aug. 18, 2008). What a plaintiff must show is that "the device did not operate as intended and this was the proximate cause of [the plaintiff's] injuries." *Trickett*, 542 F. Supp. 2d at 1345.

Using this logic, it was not necessary for the plaintiffs to specify the exact defect in the Avaulta Plus that injured Ms. Cisson, as long as they presented evidence to demonstrate that the device did not function as intended, and that it proximately caused Ms. Cisson's injuries. Therefore, if the plaintiffs presented evidence of *any* design defect in the Avaulta Plus and presented evidence to show that the defect proximately caused Ms. Cisson's injuries, the case must go to the jury. The plaintiffs did not allege three separate design defect claims related to the arms, polypropylene, and pore size; they argued that the Avaulta Plus was defectively designed. Similarly, there was one jury instruction for design defect, not three.

The issue of whether the arms in the Avaulta Plus constitute a design defect cannot be separated from the design defect claim as a whole, as Bard now attempts to assert. Where a plaintiff has presented *any* evidence of a design defect, judgment as a matter of law rarely will be granted. *See, e.g.*, *Ogletree v. Navistar Int'l Transp. Corp.*, 522 S.E.2d 467, 470 (Ga. 1998) (stating that the risk-utility test used in Georgia to determine whether a product was defectively designed "increased the burden of a defendant, in seeking a judgment as a matter of law, to show plainly and indisputably an absence of any evidence that a product as designed is defective"); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010) ("In general, weighing the risk-utility factors is left to the jury. Judgment as a matter of law will rarely be granted in design defect cases when any of the elements is disputed."). Here, the

plaintiffs presented evidence showing that, because of the arms on the device, the Avaulta Plus was defectively designed. This was conceded by Bard in its Rule 50(a) motion. Therefore, judgment as a matter of law is not appropriate on the design defect claim.

I **FIND** that Bard conceded that sufficient evidence existed to submit to the jury whether the Avaulta Plus arms constituted a design defect. I also **FIND** that the plaintiffs presented evidence to send the issue of design defect to the jury. Because Georgia law does not require plaintiffs to specify the precise nature of the design defect alleged, I need not determine whether the plaintiffs presented sufficient evidence and expert testimony regarding whether polypropylene and pore size constituted design defects. For the reasons discussed above, Bard's renewed motion for judgment as a matter of law is **DENIED** with regard to the design defect claim.

B. Failure to Warn

In their failure to warn claim, the plaintiffs allege that Bard should have given a number of warnings to Ms. Cisson's implanting physician, Dr. Raybon. (*See* Pls.' Resp. to Bard's Post-Verdict Mot. for J. as a Matter of Law [Docket 440], at 22-23). Among these were (1) that the Avaulta Plus's small pore size increased the risk and severity of scarring, (2) that the Avaulta Plus's shrinkage rate was 30-50%, (3) that the Avaulta Plus porcine layer increased the risk of delayed healing, extrusion, and rejection, and (4) that Bard was warned not to use polypropylene in implanted medical devices. (*See* Pls.' Resp. to Bard's Post-Verdict Mot. for J. as a Matter of Law [Docket 440], at 20, 22-23).

1. Legal Standard

Under Georgia law, the elements of a failure to warn claim are as follows: (1) the defendant had a duty to warn, (2) the defendant breached that duty, and (3) the breach caused the plaintiff's

injury. *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1352 (N.D. Ga. 1999). "[T]he duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Hunter v. Werner Co.*, 574 S.E.2d 426, 431 (Ga. Ct. App. 2002). However, there is no duty "to warn of a product-connected danger which is obvious or generally known." *Moore v. ECI Mgmt.*, 542 S.E.2d 115, 121 (Ga. Ct. App. 2000) (quoting *Yaeger v. Stith Equip. Co.*, 341 S.E.2d 492, 493 (Ga. Ct. App. 1986)).

In cases involving prescription drugs or medical devices, Georgia law provides that a manufacturer does not have a duty to warn end users of its product. *See McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003). Instead, the manufacturer has a duty to warn only the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. *Id.* Further, "there is no duty to give warning to the members of a profession against generally known risks. There need be no warning to one in a particular trade or profession against a danger generally known to that trade or profession." *Niles v. Bd. of Regents of Univ. Sys. of Georgia*, 473 S.E.2d 173, 175 (Ga. Ct. App. 1996).

Where a duty to warn arises, it "may be breached in either of two ways: (1) failure to take adequate measures to communicate the warning to the ultimate user, or (2) failure to provide a warning that, if communicated, was adequate to apprise the user of the product's potential risks." *Rhodes v. Interstate Battery Sys. of Am., Inc.*, 722 F.2d 1517, 1519 (11th Cir. 1984).

Finally, a plaintiff's injuries must have been caused by the failure to warn. This requires a showing that the failure to warn was a cause-in-fact of the plaintiff's injuries. *See R&R Insulation Servs., Inc. v. Royal Indem. Co.*, 705 S.E.2d 223, 233 (Ga. Ct. App. 2010). Additionally, the plaintiff must show that the failure to warn proximately caused his or her injuries. This necessarily means that the warning the plaintiff alleges should have been given would have addressed the

plaintiff's injuries. *See* 2 Dan B. Dobbs et al., *The Law of Torts* 972 (2d ed. 2011).

2. Analysis

a. Bard's Duty to Warn

As a manufacturer of a medical device, Bard had a duty to warn Ms. Cisson's physician, Dr. Raybon, about non-obvious product-related dangers that were not generally known. Bard contends that its duty to warn did not extend to (1) product characteristics or raw materials or (2) the rates and severity of potential complications.

i. Product Characteristics and Raw Materials

Bard argues that its duty was limited to warning about the potential risks associated with the Avaulta Plus's use. (*See* Def. C. R. Bard, Inc.'s Renewed Mot. for J. as a Matter of Law [Docket 439], at 6). Bard contends that it did not have a duty to warn about particular product characteristics, such as pore size, or particular raw materials, such as polypropylene. (*Id.*). Bard misconstrues its duty to warn about risks associated with the Avaulta Plus. Bard had a duty to warn about "any potential dangers that may result" from use of the product. *Singleton v. Airco, Inc.*, 314 S.E.2d 680, 682 (Ga. Ct. App. 1984). That pores are a particular size or that the product used particular raw materials are not necessarily risks associated with product use. In other words, Bard did not have to warn Dr. Raybon that the Avaulta Plus's pores were 3 millimeters. However, if these characteristics caused the Avaulta Plus to be more dangerous or risky than the product's Instructions for Use suggested, then Bard had a duty to warn about the dangers associated with them, and it is for the jury to decide whether Bard breached that duty.

ii. Rates and Severity of Complications

Bard argues that its duty was limited to warning about possible complications, not their rate

or severity. (*See* Def. C. R. Bard, Inc.'s Renewed Motion for J. as a Matter of Law [Docket 439], at 8-9). The Avaulta Plus's Instructions for Use stated that, *inter alia*, erosion, inflammation, dyspareunia (pain during intercourse), scarification, and extrusion were possible adverse reactions. (Pls.' Ex. 834, at 5). There is evidence that Ms. Cisson experienced each of these complications. Nonetheless, the plaintiffs argue that Bard failed to warn about the rate and severity of those complications. (*See* Pls.' Resp. to Bard's Post-Verdict Mot. for J. as a Matter of Law [Docket 440], at 17-18).

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. As I stated above, it was for the jury to decide whether Bard's warnings to Dr. Raybon were adequate. Other courts have found that a failure to warn about the rate or severity of potential injury creates a jury question over the adequacy of warnings. *See 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.") (internal quotation omitted); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1377 (M.D. Ga. 2010) (where medical device manufacturer's warning stated that the plaintiffs' injuries could occur "very rarely," holding that there was "a genuine issue of material fact as to whether such complications were indeed 'very rare'"); *Sands v. Kawasaki Motors Corp.*, No. CV608–009, 2009 WL 3152859, at *5 (S.D. Ga. Sept. 30, 2009) (holding that jury was not precluded from finding that manufacturer failed to warn end user "of both the extent of the danger and the severity of any injury"). Thus, it was for the jury to decide whether Bard adequately warned Dr. Raybon about rates and severity of complications associated with the Avaulta Plus.

b. Breach of Duty – Adequacy of Bard's Warnings

Because Bard had a duty to warn Dr. Raybon about dangers associated with the Avaulta Plus, I will now determine whether the plaintiffs presented sufficient evidence at trial for a reasonable jury to determine that Bard breached this duty.

Bard argues that its warnings were adequate as a matter of law because Bard warned Dr. Raybon about each of the injuries Ms. Cisson experienced. As noted *supra*, the Avaulta Plus's Instructions for Use, which served as Bard's warning to Dr. Raybon, included warnings about erosion, inflammation, dyspareunia, scarification, and extrusion. (*See* Pls.' Ex. 834, at 5). The plaintiffs allege that Ms. Cisson experienced each of these injuries. Therefore, Bard argues that it did not breach its duty to warn; its warning was adequate as a matter of law. (*See* Def. C. R. Bard, Inc.'s Reply Mem. of Law in Supp. of Renewed Mot. for J. as a Matter of Law [Docket 443], at 3); *see, e.g.*, *Copeland v. Ashland Oil, Inc.*, 373 S.E.2d 629, 629-30 (Ga. Ct. App. 1988) (warning was adequate as a matter of law where label on drum of flammable chemical included illustration of flames and large, bold print stating "FLAMMABLE LIQUID," and plaintiff died from explosion precipitated by dragging metal scraper across the floor).

However, Bard's warnings were adequate as a matter of law only if "a reasonable jury would not have a legally sufficient evidentiary basis" to find against Bard. Fed. R. Civ. P. 50. At trial, the plaintiffs produced evidence of an MSDS in Bard's possession that specifically warned against using polypropylene resin for permanent implantation in the human body. (*See* Pls.' Ex. 482, at 2). They presented evidence that Bard knew the presence of a porcine sheet on the Avaulta Plus created a higher risk of complications (*see* Pls.' Ex. 607) and that the product's inadequate pore size increased the risk of inflammation and scarring (Tr. 7/30/13, 106:22-24; 8/1/13, 51:6-12; 54:12-56:8). Dr. Raybon was never warned about these risks. (*See* Tr. 7/30/13, 109:14-110:6

(polypropylene); Tr. 7/31/13, 109:6-9 (porcine sheet); Tr. 7/30/13, 104:19-23, 105:2-20 (pore size)). Further, the plaintiffs produced evidence that Bard's Instructions for Use for the Avaulta Plus downplayed risks by stating that "potential adverse reactions are those typically associated with surgically implantable materials[.]" (Pls.' Ex. 834, at 5). Accordingly, when viewing evidence most favorably to the plaintiffs and drawing every legitimate inference in their favor, I **FIND** that there was sufficient evidence to create a jury question as to whether Bard's warning was adequate.

c. Causation

Bard argues the plaintiffs failed to proffer evidence that the lack of any warnings caused Ms. Cisson's injuries. Under Georgia law,

> the plaintiff must demonstrate that the deficient warning proximately caused the alleged injury to prevail. Therefore, in cases 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.

Dietz v. Smithkline Beecham Corp., 598 F.3d 812, 816 (11th Cir. 2010) (internal citations and quotations omitted). Proving causation consists of two components. First, the failure to warn must have been the cause-in-fact of the plaintiff's injuries. That is, the plaintiffs must show that Dr. Raybon would not have implanted the Avaulta Plus if Bard had provided the warnings the plaintiffs allege should have been provided. *See R&R Insulation Servs., Inc. v. Royal Indem. Co.*, 705 S.E.2d 223, 233 (Ga. Ct. App. 2010). Second, the failure to warn must have proximately caused the plaintiff's injuries. In other words, the proposed warning must have addressed Ms. Cisson's injuries. *See* Dobbs et al., *supra*, at 972 ("[T]he injury suffered must be within the class of injury that the warning requirement was meant to avoid.").

As required, the plaintiffs alleged that a number of specific warnings should have been given to Dr. Raybon. *See* 1 David G. Owen et al., *Madden & Owen on Products Liability* § 9:11, at 586 (3d ed. 2000) ("[The] plaintiff should not prevail in a warnings suit if the record is bereft of evidence as to what type of warning might have prevented the accident."). Each missing warning addresses different, yet related, risks associated with the Avaulta Plus. Each of these risks allegedly contributed to the injuries that Ms. Cisson experienced, including extrusion, excessive scarring, inflammation, pain during intercourse, and pelvic pain.

I will examine the alleged warnings to determine if there was sufficient evidence for a reasonable jury to find that they would have prevented Dr. Raybon from implanting the Avaulta Plus. I will also determine whether there was sufficient evidence for a jury to find that the warnings addressed the injuries Ms. Cisson suffered.

i. Mesh Pore Size

Dr. Raybon testified that he did not know that the Avaulta Plus's "pore size results in formation of a scar plate that is rigid and does not integrate well with the host tissue." (Tr. 7/30/13, 104:19-23). Dr. Raybon would not have implanted the device had he known this information. (Tr. 7/30/13, 105:2-8). He further expressed concern that Robert Orr, Head of Product Development for Bard's Urology Department, recommended an optimal pore size of 2.5 to 3 millimeters. (Tr. 7/30/13, 105:9-20). Accordingly, I **FIND** that there was sufficient evidence for a jury to believe that Dr. Raybon would not have implanted the device had Bard warned him that Robert Orr recommended a larger pore size for the Avaulta Plus.

The plaintiffs produced evidence that large pore size reduces rates of scarring and inflammation. (Tr. 7/30/13, 106:22-24; Tr. 8/1/13, 51:6-12; 54:12-56:8). However, Bard argues that the plaintiffs failed to prove that this warning proximately caused Ms. Cisson's injuries

because there is no direct testimony that Ms. Cisson developed a "rigid scar plate." (*See* Def. C. R. Bard, Inc.'s Reply Mem. of Law in Supp. of Renewed Motion for J. as a Matter of Law [Docket 443], at 9). The plaintiffs presented testimony from three doctors that Ms. Cisson experienced excessive scarring and inflammation. (*See* Tr. 7/30/13 (Dr. Raybon), 84:15-18 (inflammation), 74:7-13 ("band" of scar tissue), 74:22-24 (scarring), 82:10-13 ("thick band of scar tissue"); Tr. 8/1/13 (Dr. Klosterhalfen), 76:10-13 ("chronic inflammatory response to that mesh"), 78:12-79:15 ("scar plate"); Pls.' Ex. 1227A (Dr. Miklos), 46:1-13 (mesh arms "scarring down"), 71:15-72:01 ("scar tissue")). From this testimony, a jury could legitimately infer that Ms. Cisson developed a "rigid scar plate" that a warning would have prevented. Thus, I **FIND** that there was sufficient evidence for a reasonable jury to find that the failure to warn about inadequate pore size proximately caused Ms. Cisson's scarring and inflammation.

ii. Mesh Shrinkage Rate

Dr. Raybon testified that he did not know that Robert Orr said the shrinkage rate for Avaulta mesh was 30-50%. (Tr. 7/30/13, 102:22-103:3). Had he known this, Dr. Raybon would either not have implanted the mesh, or he would have implanted it differently. (Tr. 7/30/13, 103:18-104:11; 105:2-8). I **FIND** that there was sufficient evidence for a jury to believe that Dr. Raybon would not have implanted the device had Bard warned him about the Avaulta Plus's higher shrinkage rate.

According to the plaintiffs' experts, scarring causes tissue shrinkage which can place undue tension on the mesh. Scar tissue may shrink, causing the mesh to wrinkle and contract with it. (*See* Tr. 8/1/13, 32:12-20; 55:19-56:8). Dr. Raybon testified to a reasonable degree of medical certainty that Ms. Cisson's "adhesion band" and erosion of the mesh were caused by "contraction" of the "distal arms of the mesh that produced this band along the distal edge." (Tr. 7/30/13,

113:10-22). Dr. Miklos testified that the presence of the arms on the Avaulta Plus caused excessive tension as a result of scar tissue formation. (Pls.' Ex. 1227A, Miklos T., 71:15-72:01 ("The pain is—we see was not due to mesh extrusion but instead due to the amount of tension on the mesh. . . . [I]f you put in meshes with arms you're increasing the likelihood that these arms are pulling and putting excessive tension due to scar tissue and integration of that scar tissue into the arms and pulling on this mesh creating pain.")). He further stated that "undue tension" on Ms. Cisson's mesh was caused by "pulling at the arms and pulling across the mesh due to scar tissue in the arms and pulling on the central body of the mesh." (*Id.* at 66:13-14; 66:17-19; 46:8-13 ("[W]hen I hit the area where I feel . . . banding effect on both sides like a guitar string[,] it leads me to believe that tension is created by those arms scarring down and pulling on the center of the mesh.)).

I **FIND** that there was sufficient evidence for a jury to determine that failure to warn about the high mesh shrinkage rate proximately caused Ms. Cisson's injuries.

iii. Higher Risk of Delayed Healing, Extrusion, Rejection Because of Porcine Sheet

Dr. Raybon testified that he would not have implanted the Avaulta Plus in Ms. Cisson had he known that a Bard marketing representative stated that the porcine sheet increased the risk of delayed healing, extrusion, and rejection. (Tr. 7/30/13, 108:10-17). Dr. Miklos, who examined Ms. Cisson after implantation, testified that the Avaulta Plus mesh had extruded through the vaginal wall, causing pain. (Pls.' Exhibit 1227A, Miklos T., 43:11-44:4; 52:15-53:1).

Thus, I **FIND** that there was sufficient evidence for a jury to believe that Dr. Raybon would not have implanted the device had Bard warned him about the Avaulta Plus's higher risk of rejection and extrusion as a result of the porcine sheet. I also **FIND** that there was sufficient evidence for a jury to believe that the lack of this warning proximately caused Ms. Cisson's

extrusion injury.

iv. Warning Against Permanent Implantation of Polypropylene

Dr. Raybon testified that he would not have implanted the Avaulta Plus had he known that Bard had been warned against using polypropylene resin for permanent implantation in the human body. (Tr. 7/30/13, 109:14-110:2). As discussed above, Bard only had an obligation to warn about potential risks associated with the Avaulta Plus. The MSDS itself is not a risk associated with the product; however, the fact that polypropylene may not be safe for permanent implantation in the human body is a risk associated with the product. Therefore, it was for the jury to determine whether Bard had an obligation to warn Dr. Raybon that polypropylene, and therefore the Avaulta Plus, may be unsafe for permanent human implantation.

To establish that polypropylene harmed Ms. Cisson, the plaintiffs presented evidence from Dr. Bernd Klosterhalfen, the plaintiffs' expert pathologist. When examining pathology slides containing samples from Ms. Cisson's tissues, Dr. Klosterhalfen explained that macrophages, or inflammatory cells, were attaching themselves to the polypropylene in Ms. Cisson's mesh. (Tr. 8/1/13, 76:4-79:15). Because the polypropylene did not biodegrade, Dr. Klosterhalfen stated that macrophages continued to build up around it, forming a "fibrotic reaction" or a scar plate. (*Id.*). Further, he stated that Ms. Cisson's reaction was a typical reaction to polypropylene meshes. (Tr. 8/1/13, 84:20-85:5).

The plaintiffs also offered Dr. Anthony Brennan, a materials expert, to testify on this issue. Dr. Brennan testified that peroxides in the body form free-radicals that attack polypropylene. (Tr. 8/2/13, 91:14-92:8). Dr. Brennan opined that polypropylene is not biocompatible for long-term use because it reacts with the body's natural chemistry. (*Id.*). He further testified to a reasonable

degree of scientific certainty that polypropylene degrades in the human body, which triggers an inflammatory response by the body. (*See* Tr. 8/2/13, 109:24-110:5; 112:5-16).

Neither Dr. Klosterhalfen nor Dr. Brennan states directly that polypropylene caused Ms. Cisson's injuries. However, the plaintiffs are not required to prove every fact by direct evidence. Juries can draw legitimate inferences from the evidence, and I must give the plaintiffs the benefit of every legitimate inference that can be drawn from the evidence. *See* Wright & Miller, *supra*, § 2528; *see also Int'l Ground Transp.*, 475 F.3d at 218 (on Rule 50 motion, district court should draw "every legitimate inference" in favor of the non-moving party).

I **FIND** that a jury could legitimately infer from Dr. Klosterhalfen's and Dr. Brennan's testimony that polypropylene caused inflammation and scarring in Ms. Cisson. Accordingly, I **FIND** that there was sufficient evidence for a jury to find that Bard's failure to warn Dr. Raybon about polypropylene hazards proximately caused injury to Ms. Cisson.

3. Conclusion

In sum, Bard had a duty to warn Dr. Raybon about non-obvious risks associated with the Avaulta Plus that were not generally known. The plaintiffs presented sufficient evidence for a reasonable jury to conclude that Bard did not adequately warn about a number of product dangers. Finally, there was sufficient evidence for a reasonable jury to conclude that the failure to warn about those dangers caused Ms. Cisson's injuries.

C. Punitive Damages

Bard argues that I should set aside the jury's award of punitive damages as a matter of law. In Georgia, 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.

1. Compliance with federal regulations and industry and international standards does not automatically preclude punitive damages

Bard first argues that punitive damages cannot be awarded because its conduct complied with all federal regulations and all industry and international standards. *See Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993) (holding punitive damages award in nuisance action not supported by clear and convincing evidence where quarry operator complied with state, county, and federal regulations). Bard maintains that punitive damages are generally inappropriate where a defendant complied with industry-wide practices, the state of the art, or federal regulations. *See Barger v. Garden Way, Inc.*, 499 S.E.2d 737, 743 (Ga. Ct. App. 1998).

Bard is correct that punitive damages are *generally* inappropriate under those circumstances. A plaintiff ordinarily cannot show by clear and convincing evidence that a defendant who complied with federal and industry standards is culpable under the Georgia punitive damages statute. However, punitive damages may still be available against a defendant who complied with federal and industry standards based on the entirety of the evidence. Indeed, the court in *Barger* affirmed a jury instruction that read, "compliance with applicable industry standards will not preclude an award of punitive damages if you find *by clear and convincing evidence* that the manufacturer engaged in a deliberate course of conduct which knowingly endangered those using the product." *Id.* (emphasis added). There, the defendants had unsuccessfully argued for instructions that stated, "[g]enerally, if you find that [the defendant] complied with the applicable industry standard, then you should not award punitive damages." *Id.* Therefore, an award of punitive damages is not precluded "where, notwithstanding the compliance

with applicable safety regulations, there is other evidence showing culpable behavior." *Gen. Motors Corp. v. Moseley*, 447 S.E.2d 302, 311 (Ga. Ct. App. 1994), *abrogated on other grounds*, 496 S.E.2d 459 (Ga. 1998).

Bard has consistently maintained that its compliance with the FDA's 510(k) process precludes a judgment for punitive damages. However, as I have previously ruled (*see* Mem. Op. & Order [Docket 302], at 3-4; Mem. Op. & Order [Docket 356], at 12-13), the 510(k) process does not address product safety and efficacy and therefore is not relevant to Bard's obligations under Georgia state tort law. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) ("the 510(k) process is focused on *equivalence*, not safety") (quotation marks omitted); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) ("While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence. . . . [D]evices that enter the market through § 510(k) have never been formally reviewed under the [Medical Device Amendments] for safety or efficacy.") (citations and quotation marks omitted). This evidence was properly excluded under Federal Rule of Evidence 403 because of its tendency to mislead the jury and confuse the issues.

Bard also cites its compliance with "industry standards" as evidence that should have precluded the jury from awarding punitive damages. However, this evidence is extremely general and would not preclude a reasonable jury, considering all evidence presented, from awarding punitive damages. (*See, e.g.*, Tr. 8/8/13, 72:21-73:3 ("Q: Did you comply with all industry standards in developing the design of the Avaulta Plus? A: Yes, we did.")). Similarly, evidence that Bard complied with standards set by the International Standards Organization (ISO) would not preclude the jury from awarding punitive damages. This evidence shows that Bard conducted biocompatibility and risk analysis tests in accordance with ISO standards. (*See* Tr. 8/2/13, 123:12-16; Tr. 8/7/13, 160:10-161:3; Tr. 8/12/13, 153:19-154:17). While evidence of Bard's

compliance with ISO standards is relevant, it does not preclude a jury from awarding punitive damages under Georgia law as long as the plaintiffs presented additional evidence of culpable conduct.

2. Punitive damages are available where a defendant acts with an "entire want of care which would raise the presumption of conscious indifference"

The plaintiffs have not argued that Bard's conduct amounted to willful misconduct, malice, fraud, wantonness, or oppression. Thus, punitive damages are available in this case only if the plaintiffs showed by clear and convincing evidence that Bard's conduct amounted to "that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1. "A conscious indifference to consequences relates to an intentional disregard of the rights of another. [Willful] and intentional misconduct is not essential." *Tyler v. Lincoln*, 527 S.E.2d 180, 182-83 (Ga. 2000) (emphasis, internal citations, and quotation marks omitted).

For punitive damages to be appropriate, Bard's misconduct must have exceeded gross negligence. *See Colonial Pipeline Co. v. Brown*, 365 S.E.2d 827, 830 (Ga. 1988) ("Negligence, even gross negligence, is inadequate to support a punitive damages award."). In Georgia, gross negligence is equivalent to the "failure to exercise even a slight degree of care." *Gliemmo v. Cousineau*, 694 S.E.2d 75, 80 (Ga. 2010) (quoting *Pottinger v. Smith*, 667 S.E.2d 659, 661 (Ga. Ct. App. 2008) (construing Ga. Code Ann. § 51-1-4)). Thus, even if Bard's conduct amounted to slight—although legally inadequate—care, punitive damages are inappropriate. *Cf. Brooks v. Gray*, 585 S.E.2d 188, 189 (Ga. Ct. App. 2003) ("Negligence, even gross negligence, is inadequate to support a punitive damage award. Something more than the mere commission of a tort is always

required for punitive damages. There must be circumstances of aggravation or outrage.") (quotation marks and punctuation omitted).

Numerous 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. *See, e.g.*, *Weilbrenner v. Teva Pharms. USA, Inc.*, 696 F. Supp. 2d 1329, 1344 (M.D. Ga. 2010) (punitive damages appropriate for jury consideration where evidence showed drug manufacturer knew of risk of pseudotumor cerebri in adolescents, but did *nothing* to warn about those dangers); *Mack Trucks, Inc. v. Conkle*, 436 S.E.2d 635, 640 (Ga. 1993) (punitive damages appropriate where evidence showed truck manufacturer ignored or rejected advice to reinforce frames, vetoed proposals to reinforce frames on new trucks, and failed to notify purchasers of frame problems); *Ford Motor Co. v. Stubblefield*, 319 S.E.2d 470, 481 (Ga. Ct. App. 1984) (manufacturer's "conscious decisions to defer implementation of safety devices in order to" save $20 million supported punitive damages); *Ford Motor Co. v. Sasser*, 618 S.E.2d 47, 58 (Ga. Ct. App. 2005) (manufacturer was aware of danger from seat latching system, but "chose to do *nothing* to warn consumers" such as the plaintiff) (emphasis added); *Reid v. BMW of N. Amer.*, 430 F. Supp. 2d 1365, 1374 (N.D. Ga. 2007) ("If the BMW defendants did know of a defect in the radiator and did *nothing* about it, punitive damages may be appropriate.") (emphasis added). These cases suggest that a defendant's conduct will exhibit "that entire want of care" in excess of gross negligence where a defendant does *nothing* to prevent injury from a known risk. Any care taken to prevent injuries would not rise to an "entire want of care" and could not, by definition, exceed gross negligence.

3. With respect to MSDS warning, evidence shows that Bard acted with entire want of care raising the presumption of conscious indifference to the consequences

Viewing the evidence most favorably to the plaintiffs, I **FIND** that a reasonable jury could find by clear and convincing evidence that Bard's conduct exhibited an entire want of care raising the presumption of conscious indifference to the consequences. Bard was aware of the Phillips MSDS warning not to use "this Chevron Phillips Chemical Company LP material [polypropylene resin] in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." (Pls.' Ex. 482). Bard was thus on notice that products made from polypropylene resin should not be permanently implanted in the human body. However, Bard failed to ask Phillips about the MSDS warning. (*See* Tr. 8/7/13, 61:8-18). In fact, Bard intentionally avoided alerting Phillips that it was surreptitiously purchasing Phillips's polypropylene resin via third parties. (*See id.* at 68:13-70:4; Pls.' Ex. 613). Roger Darois, vice president of Davol, a Bard division, stated in an internal email that Bard's supplier, Red Oaks, "purchases the Phillips Marlex resin without Phillips[']knowledge for its use in a medical device. We need to keep this proprietary." (Pls.' Ex. 492). When asked to recommend potential polypropylene suppliers, Mr. Darois advised that Phillips

> will likely not be interested in a medical application due to product liability concerns. We purchase our polypropylene monofilament from an extrusion supplier who purchases the resin directly from the resin manufacturers. Thus, it is likely that they do not know of our implant application. Please do NOT mention Davol's name in any discussions with these manufacturers. In fact, I would advise purchasing the resin through a 3rd party, not the resin supplier to avoid a supply issue once the medical application is discovered.
>
> If you need the resin we use for samples or trials, we can get you any amount you need so you do not have to talk to the resin manufacturer.

(Pls.' Ex. 613). Bard believed Phillips would stop supplying polypropylene resin if it discovered that Bard was using polypropylene in medical devices. (*Id.*; Tr. 8/7/13, 69:11-70:4).

Bard's fears were not unfounded. Bard purchased polypropylene monofilament from Shakespeare Co., LLC. (*See* Pls.' Ex. 492; Tr. 8/7/13, 65:2-66:21). When Shakespeare independently became aware of the Phillips MSDS warning (Tr. 8/7/2013, 66:14-16, 66:22-25), it declined to supply monofilament to Bard. (*See* Pls.' Ex. 492; Tr. 8/7/13, 66:22-67:4). Shakespeare continued to decline even after Bard agreed to completely indemnify Shakespeare. (*See* Pls.' Ex. 492; Tr. 8/7/13, 66:5-9). Shakespeare explained that they would supply monofilament for medical devices "under no circumstances." (*See* Pls.' Ex. 492).

Finally, there is evidence to suggest that Bard understood the dangers of using polypropylene for tissue repair, including a higher risk of erosion and infection; a greater amount of scar tissue formation around the mesh; and a tendency "to unravel, creating a sharp 'fishing line' effect, which can slice through the patient's tissue." (Pls.' Ex. 375). However, even with this knowledge, Bard conducted no human tests before placing the Avaulta Plus on the market. (Pls.' Ex. 1213A, Orr T., 37:2-23; 38:2-12). Bard overruled suggestions that it should conduct premarket human trials. (*Id.* at 38:13-17; 38:19; 39:14-16; 39:18-19; Pls.' Ex. 1216A, Ross T., 47:20-48:8; 48:21-49:17; 51:12-21; 119:12-22).

To be sure, Bard presented evidence that it conducted its own "biocompatibility" tests on the Avaulta Plus, including animal tests, mechanical tests, and cadaver tests. (*See* Tr. 8/7/13, 155:3-156:8; Def.'s Ex. 1070, 1071, 1072). Even so, the fact remains that Bard—at the executive level—was warned not to use polypropylene resin for permanent implantation in the human body. If the plaintiffs' evidence is to be believed, Bard did not heed this warning, seek an explanation from Phillips, or conduct human tests. Rather, Bard consciously employed subterfuge to procure

polypropylene resin from Phillips, who would not provide it otherwise. This combination of evidence was sufficient for a reasonable jury to conclude that Bard acted with an entire want of care such that Bard was consciously indifferent to the consequences of its actions.

As I have explained above, the jury could legitimately infer from the testimony of Dr. Klosterhalfen and Dr. Brennan that polypropylene caused Ms. Cisson's injuries. Accordingly, I **FIND** that a reasonable jury could conclude that, with respect to the use of polypropylene, Bard acted with an entire want of care raising the presumption of conscious indifference to the consequences.

III. Conclusion

For the reasons stated above, the defendant's motion is **DENIED**. The court **DIRECTS** the Clerk to send a copy of this Order to the all counsel of record.

ENTER: October 18, 2013

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE