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

CHARLESTON DIVISION

ROSEANNE SANCHEZ, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-05762

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(Motions for Summary Judgment on Substantive Claims and Punitive Damages)

Pending before the court is Boston Scientific Corporation's Motion for Summary Judgment [Docket 60], the Plaintiffs' Motion for Summary Judgment [Docket 62], and Boston Scientific Corporation's Motion for Partial Summary Judgment on Plaintiffs' Punitive Damages Claim [Docket 64]. For the reasons stated below, Boston Scientific Corporation's Motion for Summary Judgment [Docket 60] is **GRANTED in part** and **DENIED in part**, the Plaintiffs' Motion for Summary Judgment [Docket 62] is **GRANTED in part** and **DENIED in part**, and Boston Scientific Corporation's Motion for Partial Summary Judgment on Plaintiffs' Punitive Damages Claim [Docket 64] is **DENIED**.

I. Background

This case is one of more than 60,000 assigned to me by the Judicial Panel on Multidistrict Litigation. These cases involve the use of transvaginal surgical mesh to treat pelvic organ prolapse and stress urinary incontinence. In this particular case, plaintiff Roseanne Sanchez was implanted

with two products manufactured by defendant Boston Scientific Corporation ("BSC"): the Pinnacle Pelvic Floor Repair Kit (the "Pinnacle") to treat pelvic organ prolapse and the Advantage Transvaginal Mid-Urethral Sling System (the "Advantage") to treat stress urinary incontinence. The plaintiffs allege that as a result of implantation with these products Ms. Sanchez experienced several complications, including vaginal discharge, painful intercourse, bleeding, pelvic pain, and cramping. (*See* Pls.' Mem. in Supp. of Pls.' Mot. for Partial Summ. J. [Docket 63], at 1). The plaintiffs currently advance the following claims: negligence, strict liability (defective design, manufacturing defect, and failure to warn), loss of consortium, breach of express and implied warranties, fraudulent concealment, and punitive damages. (*See* Short Form Compl. [Docket 1] ¶ 13).

The parties have filed several motions for summary judgment. I have already denied BSC's motion for summary judgment on the statute of limitations. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 202787 (S.D. W. Va. Jan. 17, 2014). Currently before me are motions by BSC for summary judgment on all claims, and the plaintiffs' motions for summary judgment on express preemption, implied preemption, and the learned intermediary doctrine.

II. Legal Standard

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. 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*, 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. Commc'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds, Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

III. Choice of Law

While this case was filed directly into this multidistrict litigation, I have already decided that California choice-of-law rules apply here. *See Sanchez*, 2014 WL 202787, at *4. The parties agree that California law applies to the substantive claims in this case. Therefore, I will apply California law to the plaintiffs' substantive claims. The parties disagree, however, whether to apply California law or Massachusetts law to the punitive damages claim. As I explain below, California law also applies to the punitive damages claim.

IV. Analysis

A. Failure to Warn

The plaintiffs allege that BSC failed to warn about particular risks associated with the Pinnacle and Advantage devices. BSC moves for summary judgment, contending that the

plaintiffs have failed to adduce any evidence that inadequate or absent warnings caused their injuries. In a separate motion, the plaintiffs move for summary judgment by arguing that the learned intermediary doctrine is inapplicable in this case. I will address each motion separately, beginning with the plaintiffs' contention that the learned intermediary doctrine is inapplicable.

1. Learned Intermediary Doctrine

The plaintiffs argue that the learned intermediary doctrine "does not apply when a plaintiff alleges that a manufacturer failed to adequately warn a plaintiff's doctor of a device's risks." (*See* Pls.' Mem. of Law in Supp. of Pls.' Mot. for Partial Summ. J. [Docket 63], at 7). They contend that the learned intermediary doctrine is inapplicable where it is alleged that product warnings were inadequate. (*See id.* at 8). The plaintiffs are incorrect, but they are not at fault. In my opinion, several courts applying California law have recently confused this issue.

In order to establish a claim for failure to warn, whether in strict liability or in negligence, a plaintiff must prove that the defendant's warnings were inadequate, and that the inadequate warnings were a substantial factor in causing the plaintiff's harm. *See Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991) (stating that both negligence and strict liability require showing that warnings were inadequate); *Rosa v. City of Seaside*, 675 F. Supp. 2d 1006, 1011 (N.D. Cal. 2009) (listing elements of negligence and strict liability failure-to-warn claims). It is the plaintiff's burden to demonstrate that he or she would have acted differently if provided with adequate warnings. *See, e.g.*, *Ramirez v. Plough, Inc.*, 863 P.2d 167, 177 (Cal. 1993) (holding that plaintiff failed to produce evidence of causation in failure-to-warn claim where plaintiff could not read English-language warning).

The learned intermediary rule is part and parcel of a failure-to-warn analysis in California. Under the learned intermediary rule, manufacturers of prescription drugs and medical devices

satisfy their duty to warn if they provide adequate warnings to prescribing physicians, rather than patients. *See Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996) ("[I]n the case of prescription drugs, the duty to warn runs *to the physician*, not to the patient."); *Brown v. Superior Court*, 751 P.2d 470, 477 n.9 (Cal. 1988) ("It is well established that a manufacturer fulfills its duty to warn if it provides adequate warning to the physician."). A pharmaceutical manufacturer is not required to warn anybody other than prescribing physicians about the dangerous propensities of their prescription drugs and medical devices. Period.

In order to satisfy the element of causation under the learned intermediary doctrine, a plaintiff must demonstrate that the prescribing physician would have acted differently had he or she received adequate warnings. *See Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 995 (C.D. Cal. 2001) ("Pfizer may prevail in its motion for summary judgment if Ms. Motus has failed to adduce evidence that Dr. Trostler would have acted differently had Pfizer provided an adequate warning[.]"); *Georges v. Novartis Pharm. Corp.*, 988 F. Supp. 2d 1152, 1157-58 (C.D. Cal. 2013) (holding that plaintiff was required to prove that her injuries "resulted from Defendant's inadequate warnings" and upholding jury verdict for plaintiff where treating physician "testified that he changed his treatment practices once he was aware of the [product] risk"); *Plummer v. Lederle Labs., Div. of Am. Cyanamid Co.*, 819 F.2d 349, 358 (2d Cir. 1987) (applying California law) (noting that plaintiff had failed to prove proximate causation where he "failed to prove that a proper warning would have altered the doctor's conduct"); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 308-09 (Ct. App. 2008) (denying summary judgment where plaintiff produced evidence that prescribing doctor "probably read" manufacturer's warnings, creating dispute of fact whether the warnings were "a substantial factor" in his prescribing decision).

The plaintiffs assert that the learned intermediary rule "does not apply" to their claims because they allege that BSC failed to adequately warn Dr. Kerri Wiltchik, the prescribing physician. (Pls.' Mem. of Law in Supp. of Pls.' Mot. for Partial Summ. J. [Docket 63], at 7). The plaintiffs cite several cases in support of this proposition. *See, e.g.*, *Hatherley v. Pfizer, Inc.*, No. CIV. 2:13-00719 WBS, 2013 WL 3354458, at *4 (E.D. Cal. July 3, 2013) (stating that the learned intermediary doctrine "appears to be inapplicable" where plaintiffs alleged that warnings were inadequate); *Hill v. Novartis Pharm. Corp.*, 944 F. Supp. 2d 943, 954 (E.D. Cal. 2013) (stating that if plaintiff proffered evidence of inadequate warnings, plaintiff could argue that prescription drug manufacturer had a duty to warn individuals other than her prescribing physician); *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 624 F. Supp. 2d 396, 419 (E.D. Pa. 2009) (applying California law) ("the learned intermediary defense simply does not apply where a plaintiff alleges that the manufacturer failed to adequately warn doctors of the danger of the drug") (internal quotation omitted); *In re Fosamax Prods. Liab. Litig.*, No. 1:06-MD-1789, 2008 WL 2940560, at *7 (S.D.N.Y. July 29, 2008) (holding that the learned intermediary doctrine did not "operate to preclude recovery" where plaintiff alleged warnings were inadequate); *Stewart v. Union Carbide Corp.*, 117 Cal. Rptr. 3d 791, 797-98 (Ct. App. 2010) (learned intermediary doctrine, "where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary").

To the extent that these cases suggest that the learned intermediary doctrine has no effect where plaintiffs allege that warnings are inadequate, I respectfully believe that these cases are incorrect. The learned intermediary rule merely holds that the "the prescribing doctor . . . in reality stands in the shoes of 'the ordinary consumer'" to receive a manufacturer's warnings. *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 401 (Ct. App. 1971). There are several policies behind the rule:

(1) The doctor is intended to be an intervening party in the full sense of the word.

> Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.

Id. at 400-01. For these reasons, California holds that in the case of prescription drugs and medical devices, "the duty to warn runs *to the physician*, not to the patient." *Carlin*, 920 P.2d at 1354.

It does not withstand scrutiny to say that the learned intermediary doctrine suddenly becomes inapplicable when a plaintiff alleges that warnings are inadequate. If the learned intermediary doctrine became inapplicable when a plaintiff alleged that warnings were inadequate, the doctrine would never operate in California. Plaintiffs could simply plead around the doctrine by alleging inadequate warnings—*which they must necessarily do to state a claim for failure to warn*. Every time a plaintiff brings a claim for failure to warn, he or she must allege that warnings were inadequate. Cases involving prescription pharmaceuticals are no different: a plaintiff must allege that the product's warnings were inadequate.

Even where a plaintiff *proves* that warnings were inadequate, the learned intermediary doctrine still applies. A plaintiff must prove that inadequate warnings altered the prescribing physician's decision to prescribe. Anything to the contrary would violate the California Supreme Court's clear holding that "the duty to warn runs to the physician, not to the patient." *Carlin*, 920 P.2d at 1354.

California courts, apart from the ones cited above, consistently apply the learned intermediary rule even when a plaintiff alleges and proves that warnings were inadequate. *See, e.g., Stanley v. Novartis Pharm. Corp.*, --- F. Supp. 2d ---, No. CV 11-03191-JGB, 2014 WL

1316217, at *11 (C.D. Cal. Apr. 2, 2014); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991, 995-98 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659 (9th Cir. 2004); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 307-08 (Ct. App. 2008); *Valentine v. Baxter Healthcare Corp.*, 81 Cal. Rptr. 2d 252, 263 (Ct. App. 1999); *Plenger v. Alza Corp.*, 13 Cal. Rptr. 2d 811, 819 (Ct. App. 1992).

For instance, in *Conte*, the plaintiff contended that Wyeth's information provided for the Physician's Desk Reference was inadequate. *See* 85 Cal. Rptr. 3d at 307. The court applied the learned intermediary rule and held that "Wyeth's duty to warn of risks associated with its [product's] usage runs to the physician, not the patient." *Id.* at 308 n.5. The court then found a genuine dispute of fact as to whether the prescribing physician read and relied on the Physician's Desk Reference in prescribing the drug. *Id.* at 308-09. If the law were as the plaintiffs here argue, the *Conte* court should have ignored the learned intermediary rule altogether and held that Wyeth's duty to warn ran to the plaintiff directly. But the court correctly recognized that the duty to warn in that case ran to the physician, not the patient.

Similarly, in *Motus*, the parties and the court assumed for the purposes of argument that Pfizer's warnings were inadequate. *See* 196 F. Supp. 2d at 991 ("Pfizer tacitly concedes for purposes of this summary judgment motion that its warning about the risk of suicide was inadequate."). Again, the court applied the learned intermediary rule. *See id.* 990-991. The court found that the plaintiff "failed to adduce evidence that Dr. Trostler [the prescribing physician] would have acted differently had Pfizer provided an adequate warning about the risk of suicide associated with the ingestion of Zoloft." *Id.* at 995. The Ninth Circuit affirmed and again applied the learned intermediary rule. *See Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004). The Ninth Circuit held that "[b]ecause the doctor testified that he did not read the warning label that accompanied Zoloft or rely on information provided by Pfizer's detail men before prescribing the

drug to Mr. Motus, the adequacy of Pfizer's warnings is irrelevant to the disposition of this case." *Id.*

Thus, the plaintiffs' assertion that the learned intermediary rule "does not apply" in this case is without merit. In a failure-to-warn claim, the manufacturer of a prescription drug or medical device owes a duty to the plaintiff to warn the prescribing physician about the potential dangers associated with a product. The plaintiffs in this case must prove at trial that BSC's warnings were inadequate and that the inadequate warnings affected the prescribing physician's decision. If they do not, the learned intermediary rule will preclude recovery on their failure-to-warn claim. The plaintiffs' motion for summary judgment on the learned intermediary doctrine is **DENIED**.

2. Causation

Having determined that the learned intermediary rule applies in this case, I now move to BSC's arguments that the plaintiffs have failed to present evidence that inadequate warnings caused their injuries. BSC contends that there is no evidence that Ms. Sanchez's treating physician, Dr. Wiltchik, read or relied on BSC's product warnings. I disagree.

BSC's argument extends to both the strict liability failure-to-warn claim and the negligent failure-to-warn claim. As I have explained, for both the negligence and strict liability claims, the plaintiffs must prove that BSC's warnings were inadequate, and that the inadequate warnings were a substantial factor in causing the plaintiffs' harm. The plaintiffs must prove that Dr. Wiltchik would have acted differently had she received adequate warnings. *See Latiolais v. Merck & Co., Inc.*, 302 F. App'x 756, 757 (9th Cir. 2008) (affirming summary judgment for defendant where deposition testimony of prescribing physician indicated that drug warnings "did not play a role in his decision to prescribe" the drug); *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 995 (C.D. Cal.

2001). Summary judgment is inappropriate where there is evidence that "stronger warnings would . . . have altered the conduct of the prescribing physician." *Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004).

Despite BSC's contentions, there is at least a dispute of fact whether Dr. Wiltchik read each product's Directions for Use ("DFU"). Although Dr. Wiltchik could not pinpoint exactly when she read the DFUs, she clearly testified that she had read them at some point:

> Q. Do you remember the first time you saw a directions for use with the Pinnacle?
>
> A. No.
>
> Q. And do you remember the first time you would have seen directions for use for the Advantage Fit?
>
> A. No.
>
> Q. But you have read both of those; is that right?
>
> A. At some point.

(Wiltchik Dep. [Docket 75-2], at 117:4-13).[1]

Further, there is at least a dispute of fact whether Dr. Wiltchik relied on the DFUs accompanying the Pinnacle device. Dr. Wiltchik testified that she would not have used the Pinnacle device had the Pinnacle DFU characterized dyspareunia as a "warning/potential complication" rather than as an "adverse event." (*See id.* at 21:13-15; 22:10-14; 25:14-26:8). Dr. Wiltchik also stated that the Pinnacle DFU did not warn about the rates of certain complications, including pain, infection, erosion and exposure of the mesh, failure of the implantation procedure,

[1] The plaintiffs' attachment containing Dr. Wiltchik's deposition is frustrating. It consists of dozens of small portions of the deposition removed from context and chronological order. For instance, the exhibit starts with one-page excerpts of pages 137, 117, and 21. It then jumps to a four-page exchange on pages 34-38. It then jumps to a one-page, heavily redacted excerpt of page 43. And it goes on like this. The court was forced to manually reconstruct much of the 165-page exhibit in order to review (where possible) relevant portions of the deposition in context.

and recurrence of prolapse and incontinence. (*See id.* at 23:8-23). She then testified that she wanted to know this information because it would affect her "risk/benefit analysis" in prescribing the Pinnacle device. (*See id.* at 23:25-24:23). Accordingly, I **FIND** that there is a genuine dispute of fact whether inadequate warnings on the Pinnacle DFU caused the plaintiffs' injuries.

The result is different with respect to the Advantage device. The plaintiffs have failed to point to evidence that Dr. Wiltchik relied on the Advantage DFU. Although the plaintiffs argue that Dr. Wiltchik "relied on each [product's] DFU," (*see* Pls.' Resp. in Opp. to BSC's Mot. for Summ. J. Against Pls. Rosanne Sanchez and Rod Sanchez [Docket 75], at 10), their briefing fails to point to anything showing that Dr. Wiltchik specifically relied on the Advantage DFU. Further, as far as the court can tell, none of the plaintiffs' citations to Dr. Wiltchik's deposition relate to Dr. Wiltchik's reliance on the Advantage DFU. The citations relate only to the Pinnacle DFU.

Accordingly, as it relates to the Pinnacle device, BSC's motion for summary judgment on the failure-to-warn claims is **DENIED**. As it relates to the Advantage device, BSC's motion for summary judgment on the failure-to-warn claims is **GRANTED**.

B. Design Defect

The plaintiffs also bring claims for strict liability for defective design and for negligent design. (*See* Short Form Compl. [Docket 1], at 4). California does not recognize strict liability for defective design of implantable medical devices. *See Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 382 (Ct. App. 1992); *see also Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 772 (Ct. App. 1996) ("In the context of medical devices, design defects must be pursued under a negligence theory."). In light of these authorities, plaintiffs concede their strict liability defective design claim. (*See* Pls.' Resp. in Opp. to BSC's Mot. for Summ. J. Against Pls. Rosanne Sanchez and Rod Sanchez [Docket 75], at 1 n.1). Accordingly, BSC's motion on the strict liability defective design

claim is **GRANTED** and this claim is **DISMISSED**.

Although California does not recognize strict liability for defective design, the plaintiffs may still pursue defective design under a negligence theory. BSC's arguments to the contrary are unavailing and lack legal support. BSC argues that *Brown v. Superior Court*, 751 P.2d 470, 483 (Cal. 1988), forecloses negligence actions against medical device manufacturers. In *Brown*, the California Supreme Court abolished strict liability actions against prescription drug manufacturers. *See Brown*, 751 P.2d at 480. The court reasoned that prescription drugs are often unavoidably unsafe even though they serve the public welfare by saving lives and reducing pain and suffering. *See id.* at 478-480. The court noted that imposing strict liability on drug manufacturers might cause them to be "reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments." *Id.* at 479.

The court then exempted drug manufacturers from strict liability for design defect, but clarified that such manufacturers could still be liable under the ordinary principles of negligence. *See id.* at 483 n.12 ("Our conclusion does not mean, of course, that drug manufacturers are free of all liability for defective drugs. They are subject to liability for manufacturing defects, *as well as under general principles of negligence*, and for failure to warn of known or reasonably knowable side effects.") (emphasis added).

Several California appellate courts have made clear that *Brown* did not abolish ordinary negligence actions against drug manufacturers. *See, e.g.*, *Garrett v. Howmedica Osteonics Corp.*, 153 Cal. Rptr. 3d 693, 699 (Ct. App. 2013) ("The California Supreme Court in *Brown* . . . held that a manufacturer of prescription drugs cannot be strictly liable for a design defect and that the appropriate test for determining a prescription drug manufacturer's liability for a design defect

involves an application of the ordinary negligence standard."); *Armstrong*, 57 Cal. Rptr. 2d at 772; *Hufft*, 5 Cal. Rptr. 2d at 382 ("*Brown* does not exempt a drug manufacturer from . . . liability for negligence or failure to warn of known or reasonably knowable side effects."). Several federal courts applying California law also agree that manufacturers of medical devices may be liable for ordinary negligence for the design of their products. *See, e.g.*, *Dilley v. C.R. Bard, Inc.*, No. 2:14-cv-01795-ODW, 2014 WL 2115233, at *3-4 (C.D. Cal. May 21, 2014) (granting plaintiff leave to amend complaint to add design defect negligence claim); *Tucker v. Wright Med. Tech., Inc.*, No. 11-cv-03086-YGR, 2013 WL 1149717, at *7-10 (N.D. Cal. Mar. 19, 2013) (denying device manufacturer's motion for summary judgment on negligent design claim).

Accordingly, I **FIND** that medical device manufacturers may be liable for design defects under the ordinary principles of negligence. BSC's motion for summary judgment on the plaintiffs' negligence claim is **DENIED**.

C. Loss of Consortium

BSC contends that it is entitled to summary judgment on Mr. Sanchez's loss of consortium claim. BSC's only argument is that loss of consortium is a derivative claim that cannot survive without Ms. Sanchez's personal injury claims. *See Vanhooser v. Superior Court*, 142 Cal. Rptr. 3d 230, 233 (Ct. App. 2012) ("A cause of action for loss of consortium is, by its nature, dependent on the existence of a cause of action for tortious injury to a spouse.") (quotation omitted). As noted, the plaintiffs' claims for failure to warn about the Pinnacle device survive summary judgment, as well as the plaintiffs' negligent design claim. Therefore, Mr. Sanchez's loss of consortium claim is not improper, and BSC's motion on this issue is **DENIED**.

D. Punitive Damages

BSC additionally moves for summary judgment on the plaintiffs' punitive damages claim.

BSC argues that Massachusetts law applies to the punitive damages claim and bars recovery of punitive damages in this case. BSC alternatively argues that under California law, the plaintiffs have failed to present sufficient evidence in support of their punitive damages claim. The plaintiffs assert that California punitive damages law should apply because California has the greatest interest in seeing its law applied to injuries occurring within its borders. For the reasons that follow, I hold that California law applies to the punitive damages claim and that the plaintiffs have proffered sufficient evidence to sustain their punitive damages claim at this stage.

California's choice-of-law rules apply to this case. *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014). Therefore, I use California's choice-of-law rules to determine which state's law to apply to the punitive damages claim. California courts apply a three-step governmental interest approach to resolve choice-of-law disputes. *See Kearney v. Salomon Smith Barney, Inc.*, 137 P.3d 914, 922 (Cal. 2006); *Hurtado v. Superior Court*, 522 P.2d 666, 669 (Cal. 1974). Under the first step, the court should determine whether the laws of each potential jurisdiction actually differ. *Kearney*, 137 P.3d at 922. Second, where the laws of each jurisdiction differ, the court must determine whether a "true" conflict exists by determining whether each state has an interest in applying its law in this case. *Id.* Finally, if a true conflict exists, the court will determine "which state's interest would be more impaired if its policy were subordinated to the policy of the other state" and apply that state's law. *Id.* (quoting *Bernhard v. Harrah's Club*, 546 P.2d 719, 723 (Cal. 1976)). California law will presumptively apply unless there are compelling reasons to do otherwise. *Browne v. McDonnell Douglas Corp.*, 504 F. Supp. 514, 517 (N.D. Cal. 1980) (citing *Kasel v. Remington Arms Co.*, 101 Cal. Rptr. 314, 327 (Ct. App. 1972)).

The parties agree that the first step—whether the laws of California and Massachusetts

actually differ—is satisfied. California permits awards of punitive damages where a plaintiff proves by "clear and convincing evidence" that the defendant is "guilty" of "oppression, fraud, or malice[.]" Cal. Civ. Code § 3294(a); *see also Boeken v. Philip Morris Inc.*, 26 Cal. Rptr. 3d 638, 675 (Ct. App. 2005). Massachusetts, however, prohibits awards of punitive damages "unless expressly authorized by statute." *Flesner v. Technical Commc'ns Corp.*, 575 N.E.2d 1107, 1112 (Mass. 1991). The parties agree that Massachusetts law does not permit recovery of punitive damages in this case. I therefore **FIND** that the punitive damages laws of California and Massachusetts differ.

Having determined that the punitive damages laws of California and Massachusetts actually differ, I now move to the second step. Under the second step, I must determine whether both states have an interest in having their respective laws applied in this case. In other words, I must decide whether "only one of the states has an interest in having its law applied." *Wash. Mut. Bank, FA v. Superior Court*, 15 P.3d 1071, 1081 (Cal. 2001). If only one state has an interest in having its law applied here, I will apply the law of that state. *See id.* ("[T]he trial court may properly find California law applicable without proceeding to the third step in the analysis if the foreign law proponent fails to identify any actual conflict or to establish the other state's interest in having its own law applied."). BSC must therefore demonstrate that Massachusetts has a legitimate interest in having its law applied to the punitive damages claim in this case. As I explain below, I find that Massachusetts does not.

California has a clear interest in applying its punitive damages law. California's punitive damages law serves the important purposes of punishing and deterring harmful conduct. *See* Cal. Civ. Code § 3294(a) (punitive damages recoverable "for the sake of example and by way of punishing the defendant"); *Simon v. San Paolo U.S. Holding Co.*, 113 P.3d 63, 80 (Cal. 2005)

(state has interest in "punishing [defendant's conduct] and deterring its repetition"); *Stonewall Surplus Lines Ins. Co. v. Johnson Controls, Inc.*, 17 Cal. Rptr. 2d 713, 720 (Ct. App. 1993) ("California's paramount interest is in protecting its residents by deterring tortfeasors."). According to the California Supreme Court, punitive damages "are not intended to compensate the injured party, but rather to punish the tortfeasor whose wrongful action was intentional or malicious, and to deter him and others from similar extreme conduct." *Ferguson v. Lieff, Cabraser, Heimann & Bernstein*, 69 P.3d 965, 970 (Cal. 2003) (internal quotation omitted). "Perhaps nowhere is this clearer than in the punitive damages jurisprudence established by California courts in products liability actions." *Hill v. Novartis Pharm. Corp.*, No. 1:06-cv-00939-AWI, 2012 WL 967577, at *3 (E.D. Cal. Mar. 21, 2012) (citing *Johnson v. Ford Motor Co.*, 113 P.3d 82 (Cal. 2005); *Bullock v. Philip Morris USA, Inc.*, 131 Cal. Rptr. 3d 382, 399-406 (Ct. App. 2011)).

In contrast, Massachusetts has no legitimate interest in applying its prohibition on punitive damages to injuries occurring outside of Massachusetts. BSC contends that Massachusetts has an interest in protecting its citizens from excessive financial liability. BSC is a Delaware Corporation with its principle place of business in Massachusetts. (BSC's Mem. of Law in Supp. of Mot. for Partial Summ. J. on Pls.' Punitive Damages Claim [Docket 65], at 4). BSC asserts that the decisionmaking and conduct for which the plaintiffs seek punitive damages, including designing, marketing, and distributing the devices, all occurred in Massachusetts. (*See id.*).

First, BSC is incorrect that the conduct at issue here—the wrongs giving rise to the plaintiffs' claim for punitive damages—occurred in Massachusetts. California considers the "place of the wrong to be the state where the last event necessary to make the actor liable occurred." *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 593-94 (9th Cir. 2012) (internal

quotation marks omitted). The last event necessary to make BSC liable is Ms. Sanchez's implantation surgery, which occurred in California. Therefore, for our purposes, BSC's wrongful conduct occurred in California.

Second, BSC points to no Massachusetts legal authority supporting its proposition that Massachusetts has an interest in protecting its citizens from excessive liability, let alone liability for wrongs occurring outside of Massachusetts. Likewise, I am unable to locate any Massachusetts cases articulating the state's interest in prohibiting punitive damages at common law. Each case simply restates the Massachusetts rule without providing an explanation of the policy behind it. *See, e.g.*, *Pine v. Rust*, 535 N.E.2d 1247, 1249 (Mass. 1989) ("Punitive damages are not favored in Massachusetts, and we have long followed the principle that, absent statutory authorization, punitive damages may not be awarded."); *Santana v. Registrars of Voters of Worcester*, 502 N.E.2d 132, 135 (Mass. 1986) ("Punitive or exemplary damages are not allowed in Massachusetts except under statutory authority."); *Int'l Fid. Ins. Co. v. Wilson*, 443 N.E.2d 1308, 1317 n.20 (Mass. 1983) ("Under Massachusetts law, punitive damages may be awarded only by statute."); *Boott Mills v. Boston & M.R.R.*, 106 N.E. 680, 683 (Mass. 1914) ("In this commonwealth there is no such thing known to the common law as the recovery of punitive damages in addition to compensatory damages."); *Ellis v. Brockton Pub. Co.*, 84 N.E. 1018, 1020 (Mass. 1908) ("In this commonwealth the damages recoverable in actions of tort have always included only compensation for those injuries, which flow from the wrong as a natural result."); *Burt v. Advertiser Newspaper Co.*, 28 N.E. 1, 5 (Mass. 1891) ("Vindictive or punitive damages are never allowed in this state.").

Even assuming Massachusetts's punitive damages prohibition is based on a policy of shielding its residents from excessive liability, Massachusetts has no legitimate interest in

enforcing this policy outside of its borders. Two recent California cases are instructive on this point. In the first case, *Scott v. Ford Motor Co.*, 169 Cal. Rptr. 3d 823, 835-36 (Ct. App. 2014), the court found that California law applied to a punitive damages claim because Michigan had no legitimate interest applying its laws to injuries occurring outside of Michigan. Ford argued that Michigan law should apply to the punitive damages claim because the conduct underlying the plaintiff's failure-to-warn claim allegedly occurred at Ford's Michigan headquarters. *See id.* at 834. Ford asserted that Michigan had an interest in regulating "the legal consequences of conduct" that occurred within its borders and that Michigan's ban on punitive damages represented "a declaration that corporate conduct occurring in Michigan should not be subject to punitive damages[.]" *Id.* at 836. The court disagreed and found that Michigan had no legitimate interest in imposing its punitive damages policy on other states. The court wrote that

> Ford effectively argues it should be found to carry a nationwide shield from punitive damage liability because the state in which it maintains its headquarters has decided punitive damages are poor public policy. We cannot agree, any more than we expect a Michigan court would yield to a plaintiff's plea to impose punitive damages on a California-based corporation because its home state has made the opposite policy judgment.

Id. at 834.

The court then wrote that even if Michigan had intended to protect resident businesses from punitive damages outside of the state, Michigan "would have no legitimate interest in imposing that intent in California." *Id.* at 835. A foreign state such as Michigan "has no interest in shielding its resident corporations from punitive damages when those corporations chose to do business in states permitting the imposition of such damages." *Id.* at 835-36.

The second case demonstrating that Massachusetts has no legitimate interest in applying its punitive damages rule here is *Sullivan v. Oracle Corp.*, 254 P.3d 237 (Cal. 2011). In that case, the

California Supreme Court held that Arizona and Colorado had no legitimate interest in applying their wage laws to work performed by their residents in California. The plaintiffs were residents of Arizona and Colorado and were employed by Oracle, a California corporation. *See id.* at 239. Their jobs required them to travel to work in several states, including California. *Id.* They argued that they were required to be paid overtime in accordance with California laws for work performed in California. *Id.* Oracle contended that the laws of the employees' home states controlled. *See id.* at 244.

To determine which state's law to apply, the court conducted the governmental interest choice-of-law analysis. On the second step of the governmental interest analysis, the court determined that neither Colorado nor Arizona had a legitimate interest in shielding Oracle from the requirements of California wage laws for work performed in California. *See id.* at 246. The court rejected Oracle's argument that Arizona and Colorado "have an interest in shielding their own businesses from more costly and burdensome regulatory environments in other states." *Id.* The court explained:

> We do not doubt the premise that a state can properly choose to create a business-friendly environment within its own boundaries. The federal system contemplates that individual states may adopt distinct policies to protect their own residents and generally may apply those policies to businesses that choose to conduct business within that state. However, *every* state enjoys the same power in this respect. Therefore, it follows from this basic characteristic of our federal system that, at least as a general matter, a company that conducts business in numerous states ordinarily is required to make itself aware of and comply with the law of a state in which it chooses to do business.

Id. (quotations and citations omitted). The court then held that California law applied to the plaintiffs' wage claims.

The reasoning in *Sullivan* and *Scott* is equally applicable here. Massachusetts undeniably has an interest in crafting economic policies that benefit its residents and encourage corporations

to relocate there. This interest extends to shielding corporations from liability for harms occurring in Massachusetts. But in this case, Massachusetts has no legitimate interest in shielding BSC from punitive damages liability for injuries occurring in California.

BSC additionally argues that applying Massachusetts law would provide a "uniform rule so that those who market their product outside of Massachusetts might know what risks they are subject to when they make and sell their products." (BSC's Mem. of Law in Supp. of Mot. for Partial Summ. J. on Pls.' Punitive Damages Claim [Docket 65], at 12). BSC asserts that this uniformity interest is especially important because this case is one of many thousands in multidistrict litigation. (*See id.*). BSC fails to demonstrate how *Massachusetts's* interests are advanced by simplifying the legal issues in multidistrict litigation. In any event, as I explained above, this same argument was dispatched in *Scott*. *See Scott*, 169 Cal. Rptr. 3d at 834 ("[S]tates have the prerogative to establish a uniform rule applicable to all enterprises that elect to do business there, but they have no legitimate interest in imposing that policy decision on the courts of a sister state."). Further, there already exists a uniform rule. Companies that conduct business in different states are generally required to comply with the laws of those states. *See Sullivan*, 254 P.3d at 346.

For these reasons, I **FIND** that no true conflict exists between the punitive damages law of California and Massachusetts. Therefore, I need not conduct the final step of the governmental interest analysis, and I will apply California law to the punitive damages claim in this case.

Having found that California law applies to this claim, I now examine whether the plaintiffs have proffered sufficient evidence to survive summary judgment. I find that they have. Punitive damages are available in tort claims "where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice[.]" Cal. Civ. Code § 3294(a).

Because there are no allegations of fraud in this case, my analysis will focus on whether there is evidence of malice or oppression. Malice is statutorily defined as "conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others." *Id.* § 3294(c)(1). Malice does not require intent to harm. *Pfeifer v. John Crane, Inc.*, 164 Cal. Rptr. 3d 112, 135 (Ct. App. 2013). Rather, malice can be shown by conscious disregard for the safety of another "where the defendant is aware of the probable dangerous consequences of his or her conduct and he or she willfully fails to avoid such consequences." *Id.* Oppression means "despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person's rights." Cal. Civ. Code § 3294(c)(2).

Here, the plaintiffs argue that BSC was aware that the polypropylene used to construct the Pinnacle device was not intended to be implanted in the human body. The plaintiffs point to a material data safety sheet ("MSDS") issued by BSC's supplier of polypropylene that warned BSC not to implant the material into the human body. The Pinnacle device is constructed using a polypropylene resin supplied by Chevron Phillips Chemical Company, LP. Chevron Phillips authored the MSDS that accompanied the resin. The MSDS 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.

(MSDS [Docket 77-3], at 38[2]). Despite this warning, BSC used Chevron Phillips polypropylene in its Pinnacle devices.

Additionally, the plaintiffs argue that BSC knew it needed to conduct long-term safety studies of the polypropylene material in the Pinnacle device. The plaintiffs point to the written

[2] Pagination here is the court-stamped page number at the top of the exhibit pages.

agreement between BSC and its polypropylene supplier. The agreement cautioned BSC to make its own determination of the safety and suitability of the polypropylene material in BSC's products. The agreement stated:

> BOSTON SCIENTIFIC IS ADVISED AND CAUTIONED TO MAKE ITS OWN DETERMINATION AND ASSESSMENT OF THE SAFETY AND SUITABILITY OF THE . . . POLYPROPYLENE PRODUCT FOR USE BY, FOR OR ON BEHALF OF BOSTON SCIENTIFIC. IT IS THE ULTIMATE RESPONSIBILITY OF BOSTON SCIENTIFIC TO ENSURE THAT THE . . . POLYPROPYLENE PRODUCT IS SUITED TO BOSTON SCIENTIFIC'S SPECIFIC APPLICATION.

(Agreement [Docket 77-9], at 3-4[3]).

Despite the MSDS warning and the admonition from BSC's polypropylene supplier to conduct its own tests, there is evidence that BSC conducted no clinical studies on the safety or efficacy of the Pinnacle device. (*See* Berry Dep. [Docket 77-5], at 69:19-23 ("There were no clinical studies.")). An internal BSC document indicated that "[n]o pre-clinical studies have been conducted and there are no future studies planned." (*See* Pinnacle Clinical Risk/Benefit Analysis [Docket 77-6], at 10).

In light of this evidence, I **FIND** that there is a genuine dispute of material fact whether BSC's actions with respect to the Pinnacle device were malicious under California Civil Code § 3294. A reasonable jury could find that by ignoring a warning on the MSDS and failing to conduct clinical testing, BSC's actions were "despicable conduct" with willful and conscious disregard of the safety of consumers. Cal. Civ. Code § 3294(c). Accordingly, BSC's motion for summary judgment on the issue of punitive damages is **DENIED** with respect to the Pinnacle device.

The plaintiffs failed to proffer arguments or evidence on the issue of punitive damages in relation to the Advantage device. Therefore, BSC's motion for summary judgment on the issue of

[3] Pagination here is the court-stamped page number at the top of the exhibit pages.

punitive damages is **GRANTED** with respect to the Advantage device.

E. Preemption Defenses

The plaintiffs contend that their state law claims are not barred by federal preemption and that they are entitled to summary judgment as to BSC's federal preemption affirmative defenses. BSC asserts two preemption-based affirmative defenses: express preemption and implied preemption by the Federal Food, Drug, and Cosmetic Act ("FDCA"). I have repeatedly addressed preemption issues throughout this multidistrict litigation, and I have consistently found that federal preemption does not apply. *See, e.g.*, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362287, at *8-14 (S.D. W. Va. July 8, 2014); *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361920, at *3-9 (S.D. W. Va. July 8, 2014); *Lewis v. Johnson & Johnson*, No. 2:12-cv-04301, 2014 WL 152374, at *6-10 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc.*, No. 2:10-cv-01224, 2013 WL 2431975, at *11 (S.D. W. Va. June 4, 2013). Here, too, preemption is not available to BSC.

The United States Supreme Court has foreclosed the possibility of an express preemption defense in this case. The Medical Device Amendments ("MDA") to the FDCA contain an express preemption provision. The provision provides that, with respect to medical devices, state law may not impose any requirement "which is different from, or in addition to" the requirements of the FDCA, or any requirement "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." 21 U.S.C. § 360k(a).

The FDCA's preemption provision does not apply to product liability claims regarding medical devices that underwent 510(k) clearance rather than the premarket approval process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501-02. In *Lohr*, the Court found that because the 510(k)

requirements did not relate to the safety or efficacy of the device, they did not preempt state tort claims. *Id.* As the Court noted,

> The generality of [the 510(k)] requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at 501. Because of this, the Court reasoned, the FDCA's express preemption provision does not apply to products that received clearance through the 510(k) process. Therefore, BSC's express preemption defense must fail.

BSC's affirmative defense of implied preemption also must fail. The FDCA impliedly preempts private claims that seek to enforce FDCA provisions against a manufacturer. *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("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[.]"). Thus, plaintiffs may not bring claims based on "a mere violation" of the FDCA. *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 900 (D. Minn. 2006).

The plaintiffs here admit that they do not assert any claim that BSC violated the FDCA or committed fraud on the FDA. (*See* Pls.' Mem. of Law in Supp. of Pls.' Mot. for Partial Summ. J. [Docket 63], at 7). Nonetheless, BSC contends that the plaintiffs will introduce evidence that BSC failed to comply with the FDCA by (1) knowingly mislabeling its products and (2) failing to report

adverse product events to the FDA. BSC thus argues it is entitled to assert the implied preemption defense. BSC's fears are unfounded. As I have repeatedly ruled in relation to this multidistrict litigation, and as I now hold in this case, no party will be permitted to introduce evidence relating to the FDA or the 510(k) clearance process. *See, e.g.*, *Lewis v. Johnson & Johnson*, No. 2:12-cv-04301, 2014 WL 152374, at *4-6 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL 2187, 2013 WL 3282926, at *2 (S.D. W. Va. June 27, 2013). As I stated in *Lewis*,

> Evidence regarding the 510(k) process poses a substantial risk of misleading the jury and confusing the issues. That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law. Admission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims. The prejudicial value of evidence regarding the 510(k) process far outweighs its probative value.

Lewis, 2014 WL 152374, at *4-6. Accordingly, the plaintiffs' motion for summary judgment on BSC's preemption defenses is **GRANTED**.

F. Conceded Claims

The plaintiffs concede their claims for manufacturing defect in strict liability, breach of express and implied warranties, and fraudulent concealment. (*See* Pls.' Resp. in Opp. to BSC's Mot. for Summ. J. Against Pls. Rosanne Sanchez and Rod Sanchez [Docket 75], at 1 n.1). Accordingly, BSC's motion for summary judgment on these claims is **GRANTED** and these claims are **DISMISSED**.

V. Conclusion

For the reasons explained above, Boston Scientific Corporation's Motion for Summary Judgment [Docket 60] is **GRANTED in part** and **DENIED in part**, the Plaintiffs' Motion for Summary Judgment [Docket 62] is **GRANTED in part** and **DENIED in part**, and Boston

Scientific Corporation's Motion for Partial Summary Judgment on Plaintiffs' Punitive Damages Claim [Docket 64] is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party. The court further **DIRECTS** the Clerk to post a copy of this published opinion on the court's website, www.wvsd.uscourts.gov.

ENTER: August 18, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE