IN THE SUPERIOR COURT OF THE STATE OF DELAWARE
IN AND FOR NEW CASTLE COUNTY

DEBORAH A. BARBA and THOMAS BARBA, her husband,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. N11C-08-050 MMJ
BOSTON SCIENTIFIC CORPORATION, A DELAWARE CORPORATION,	)	
Defendant.	)	

Submitted: July 20, 2015
Decided: October 9, 2015

On Defendant's Motion for New Trial
DENIED
On Defendant's Renewed Motion for Judgment as a Matter of Law
DENIED
On Defendant's Motion for Remittitur
GRANTED

OPINION

Fidelma L. Fitzpatrick, Esq. (Argued), Fred Thompson, III, Esq. (Argued), Jonathan D. Orent, Esq., Motley Rice LLC, Phillip T. Edwards, Esq., Lauren A. Cirrinicone, Esq., Murphy & Landon, Attorneys for Plaintiffs

Matthew D. Keenan, Esq. (Argued), Shook, Hardy & Bacon LLP, Colleen Shields, Esq. (Argued), Eric Aneilak, Esq., Krista Reale Samis, Esq., Eckert, Seamans, Cherin & Mellott, Esq., Stephen P. Casarino, Esq. (Argued), Casarino Christman Ransom & Doss, P.A., Attorneys for Defendant

JOHNSTON, J.

FACTUAL AND PROCEDURAL CONTEXT

This products liability action arises from allegations that Boston Scientific Corporation designed and manufactured defective implantable pelvic mesh devices. Plaintiffs Deborah and Thomas Barba contend that the Pinnacle Pelvic Floor Repair Kit ("Pinnacle") and the Advantage Fit Mid-Urethral Sling System ("Advantage Fit") (collectively "Devices") caused physical injury to Deborah Barba. Boston Scientific filed its motions following the conclusion of a fourteen-day jury trial.

Prior to the start of trial, Boston Scientific filed a Motion for Summary Judgment, and made the following arguments:

- All of Plaintiffs' claims premised on failure to warn are barred by the learned intermediary doctrine.
- There is no evidence that either of the Devices departed from their respective manufacturing specification.
- Plaintiffs' negligent product design claim must be dismissed for failure to identify a safer alternative design.
- Plaintiffs' claims for breaches of implied warranty of merchantability, implied warranty of fitness for a particular purpose, and express warranty all fail for lack of notice and evidence.

- Plaintiffs' fraud, fraudulent concealment, and consumer protection statute claims all fail for lack of evidence.
- Thomas Barba's loss of consortium claim must be dismissed because it is derivative of Deborah Barba's claims.
- Massachusetts law should govern the issue of punitive damages because Massachusetts is the location of the alleged misconduct that forms the basis for Plaintiffs' punitive damages claim.
- Massachusetts law prohibits punitive damages in the absence of wrongful death or special statutory provisions, neither of which are implicated in this case.

The Court dismissed Plaintiff's claim Breach of Express Warranty, and denied summary judgment for the remainder of Boston Scientific's claims. The Court found that Plaintiffs demonstrated a *prima facie* case for all claims presented.

Trial in the Superior Court began on May 11, 2015. Plaintiffs presented testimony from fifteen witnesses for its case-in-chief. Nine were experts and three were presented by video deposition. Boston Scientific presented evidence from five witnesses for its case-in-chief. Four were experts and two were presented by video deposition.

At the close of trial, the jury was presented with a Special Verdict Form, consisting of eight questions. Question 1 asked if the jury found Boston Scientific was negligent in the design and manufacture of the Pinnacle and/or Advantgae Fit, and whether Boston Scientific fulfilled its duty to provide warnings to Dr. Carlson about the devices.

Question 2 asked if the jury found that Boston Scientific breached an implied warranty of merchantability.

Question 3 asked if the jury found that Boston Scientific committed fraud or fraudulently concealed a material fact.

Question 4 asked if the jury found that Boston Scientific violated the Delaware Consumer Fraud Act.

Question 5 asked if the jury found that Boston Scientific's conduct was a proximate cause of Mrs. Barba's harm in any of the previous questions, and if so, what amount of damages should Ms. Barba be awarded.

Question 6 asked if the jury would award Thomas Barba damages for loss of consortium, and in what amount.

Question 7 asked if the jury found that Boston Scientific's conduct in the sale and distribution of the Pinnacle and/or Advantage Fit was willful, wanton, and/or reckless in a manner proximately causing injuries to Ms. Barba.

During deliberations, the jury had a question regarding punitive damages. After discussions among the Court and counsel, the attorneys consulted with their clients. The parties agreed to add an eighth question, allowing the jury to consider punitive damages, and to award a specific dollar amount should punitive damages be found to be warranted.

The jury returned a verdict on May 28, 2015. The jury answered "yes" to each of the questions posed on the Special Verdict Form, with the exception of Question 6, for Mr. Barba's loss of consortium claim. The jury awarded Plaintiffs $25 million in compensatory damages and $75 million in punitive damages.

Following trial, Boston Scientific filed its motions for renewed judgment as a matter of law, new trial, and remittitur. Oral argument for the motions was heard on July 20, 2015.

ANALYSIS

Defendant's Motion for a New Trial, or in the Alternative, it's Renewed Motion for Judgment as a Matter of Law

Standards of Review

Motion for New Trial & Renewed Motion for Judgment as a Matter of Law

Superior Court Civil Rule 50(b)[1] permits a motion for judgment as a matter of law to be renewed after the entry of a judgment. "[B]arring exceptional circumstances, a trial judge should not set aside a jury verdict . . . unless . . . the

[1] All "Rules" referred to hereinafter will be the Superior Court Civil Rules.

evidence preponderates so heavily against the jury verdict that a reasonable jury could not have reached the result."[2] Therefore, the Court must consider whether "under any reasonable view of the evidence the jury could have justifiably found for the non-moving party."[3]

In contrast to Rule 50, when considering a Rule 59 motion for a new trial, the Court "weighs the evidence in order to determine if the verdict is one which a reasonably prudent jury would have reached."[4] The Court should only set aside a verdict if it is clear that the "verdict was the result of passion, prejudice, partiality, corruption, or if it is clear that the jury disregarded the evidence or law."[5] A jury's verdict with respect to damages is presumed to be correct, "unless it is so grossly disproportionate to the injuries suffered so as to shock the Court's conscience and sense of justice."[6]

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[2] *Himes v. Liu*, 2008 WL 4147579, at *1 (Del. Super.) (citing *Storey v. Camper*, 401 A.2d 458, 465 (Del. 1979)).
[3] *Mazda Motor Corp. v. Lindahl*, 706 A.2d 526, 530 (Del. 1998).
[4] *Burgos v. Hickok*, 695 A.2d 1141, 1145 (Del.).
[5] *Cooke v. Murphy*, 2014 WL 3764177, at *2 (Del.). *See also Burgos v. Hickok*, 695 A.2d 1141, 1145 (Del. 1997) ("[T]he trial judge should set aside a jury verdict pursuant to a Rule 59 motion only when the verdict is manifestly and palpably against the weight of evidence, or for some reason, justice would miscarry if the verdict were allowed to stand.").
[6] *Cooke*, 2014 WL 3764177, at *2.

Fraud

Parties' Contentions

Boston Scientific

Boston Scientific contends that Plaintiffs failed to establish the requisite elements of their claims of common law fraud, fraud by concealment, and violation of the Delaware Consumer Fraud Act. Boston Scientific argues that it never communicated with Ms. Barba. No representations were made by Boston Scientific to Ms. Barba on which she could rely in deciding to have the Pinnacle and Advantage Fit implanted. Rather, Ms. Barba relied on the facts presented to her by Dr. Carlson in electing to proceed with the surgery.

Boston Scientific also argues that Plaintiffs did not offer any evidence that Boston Scientific made a false representation to Dr. Carlson or that he took any action in justifiable reliance on a specific false representation. Further, Boston Scientific contends that Plaintiffs failed to offer evidence establishing that Boston Scientific deliberately concealed information regarding the Pinnacle's complication rate or the differences between Advantage Fit and TVT, a similar mesh sling device manufactured by Ethicon.

With regard to the Delaware Consumer Fraud Act, Boston Scientific argues that there is no evidence that it made any false representation or omitted any material fact with the intention of inducing Ms. Barba's reliance. Boston Scientific

asserts that it did not market the Pinnacle or Advantage Fit directly to consumers. Further, Boston Scientific claims that the advertisements sent to physicians did not contain any false representations or omissions of material fact.

Barba Plaintiffs

Plaintiffs contend that Ms. Barba should prevail on her fraud claims because Dr. Carlson relied on false representations or omissions of material fact made to him by Boston Scientific regarding the safety and effectiveness of the Pinnacle and Advantage Fit. Plaintiffs argue that Boston Scientific was silent about the high complication rate that arose in the first year of selling the Pinnacle. Plaintiffs state that despite the high rate and the overwhelming numbers of complaints, "Boston Scientific ***chose to do nothing*** but to continue to sell the Pinnacle—without so much as mentioning the most common types of complaints to doctors, including Dr. Carlson." Further, they state that Dr. Carlson justifiably relied on Boston Scientific's false representation that the Pinnacle was safe and effective, and such reliance was a substantial factor in causing Ms. Barba's injuries.

Plaintiffs argue that Boston Scientific falsely represented to Dr. Carlson that the Advantage Fit was identical to Ethicon's TVT. Plaintiffs claim that Boston Scientific did not disclose the fact that the Advantage Fit was twice as stiff as the TVT, which increased the likelihood of erosions to the bladder and urethra. Plaintiffs state that Dr. Carlson relied on this representation, and if he had known

that the Advantage Fit was twice as stiff, he would have inquired about this difference from the TVT and how it might affect his patients.

Discussion

The Court instructed the jury on fraud, fraudulent concealment, and the Delaware Consumer Fraud Act. With respect to fraud, the jury was told: "Fraud consists of the following five elements: (1) the false representation of fact that is important to another; (2) the knowledge or belief that this representation was false or was made with reckless indifference to the truth; (3) the intent to induce Deborah Barba to act on the false representation, or to decline to act; (4) the fact that Deborah Barba acted or declined to act in justifiable reliance on the false representation; and (5) damages to Deborah Barba as a result of this reliance. A false representation may be asserted by words or by conduct. A fact is important [if it would] cause a reasonable person to decide to act in a particular way or if the maker of the representation knew another person would regard it as important." Boston Scientific did not request an alternative fraud instruction.

Boston Scientific argues that the evidence was insufficient to prove fraud because there were no misrepresentations made to Ms. Barba. During closing arguments, counsel for Boston Scientific stated:

> There's instructions here about fraud and the important thing here that I want to point out is, Ms. Barba testified she didn't have any contact or connection with Boston Scientific, whatsoever. She dealt with Dr. Carlson.

> That's not unusual because these products were not marketed directly to consumer, there weren't ads on TV for these products, but I mention that because there is an instruction about fraud and the absence of any connection she had with Boston Scientific should nullify any claim that she got something [from] us that was false or misleading or wrong.

Plaintiffs objected to Boston Scientific's statement to the jury that a claim for fraud must fail if there was no direct representation to Ms. Barba. The Court held that the inducement did not have to be made directly to Ms. Barba—the inducement may be direct or indirect as a matter of law. The Court stated that:

> The statement . . . does not have to be made directly to [Ms. Barba]. It must be made with the intent to induce someone in her position to act. So if it is made with the intent to induce a physician to use this product, then fraud may lie because the intended person that will be affected by the fraud would be the patient, so the statement that the fraud must be made directly to the patient is not a correct statement of the law. If there is a fraud made to a learned intermediary, fraud will lie.

The issue of whether the learned intermediary doctrine applies to a claim for fraud is one of first impression for this Court. While the learned intermediary doctrine has yet to be considered in the context of fraud, Delaware courts have applied the doctrine to failure to warn claims. As a general rule, the manufacturer owes a duty to warn the consumer directly concerning the risks associated with any product.[7] However, where a product is available only by means of a prescription

[7] *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399 (Del. 1989).

issued by a licensed physician, the physician is deemed a "learned intermediary" between the manufacturer or seller, and the patient.[8] The duty shifts to the physician to become informed about the qualities and characteristics of the prescribed products.[9]

The learned intermediary physician must exercise independent judgment, taking into account the specific needs of the patient.[10] It is presumed that the patient can reasonably rely on the physician's judgment.[11] If the product is properly labeled and is accompanied by instructions and warnings sufficient to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer is relieved of any duty to warn or advise the consumer patient.[12]

Federal courts have held that a patient can prevail on a common law fraud claim by showing that her physician relied on a manufacturer's fraudulent statements or omissions regarding medical devices. In *Taylor v. Danek Medical, Inc.*,[13] plaintiff sued the manufacturers and distributors of a bone screw that was surgically implanted in plaintiff's spine. Plaintiff alleged that defendants made fraudulent representations to plaintiff's surgeon regarding the safety and

[8] *Id.*
[9] *Id.*
[10] *Id.* at 400.
[11] *Id.*
[12] *Id.* at 399–400.
[13] 1998 WL 962062 (E.D. Pa.).

effectiveness of the bone screw, and that absent the false representations, the surgeon would have not proceeded with the implantation of the device in plaintiff.[14] The *Taylor* Court stated: "[T]he fact that the alleged misrepresentations were made to the surgeon and not directly to Mrs. Taylor is not a bar to her claim."[15] The Court followed Section 310 of the Restatement (Second) of Torts, which makes clear that "an actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by . . . a third person in reliance upon the truth of the representation . . . ."[16] Similarly, the Court in *Car Sense, Inc. v. American Special Risk, LLC*[17] found: "To be liable for an indirect fraudulent statement, the defendant must have made a representation to a third person with the intent or a reason to expect that 'its terms will be repeated or its substance communicated [to the plaintiff], and that it will influence [the plaintiff's] conduct in the transaction . . . .'"[18]

This Court finds that a defendant may be liable for fraud even if the false representations or omissions were not made directly to the plaintiff. The learned intermediary doctrine is not a bar insulating a party who perpetrates a fraud from liability. When the party engaging in fraudulent conduct is aware that the learned

[14] *Id*. at *5.
[15] *Id*.
[16] Restatement (Second) of Torts § 310 (1965).
[17] 56 F. Supp 3d 686 (E.D. Pa. 2014).
[18] *Id*. at 695.

intermediary may act in reliance on the representations in treating a consumer patient, an injured patient may have a cause of action for fraud.

At trial, evidence was presented that if Dr. Carlson had known about the complication rate of the Pinnacle, he would not have used the device. Further, Dr. Carlson testified that if he had known that the Advantage Fit was twice as stiff as the TVT, he would have inquired about the differences between the two and how they might affect his patients. Consequently, there was evidence that created questions of fact appropriate for jury resolution. The Court holds that a reasonable jury could find that Boston Scientific knowingly made fraudulent representations and/or omissions to Dr. Carlson, upon which Boston Scientific knew he would rely, and which were communicated to and justifiably relied on by Ms. Barba to her detriment.

Proximate Cause/Causation

Parties' Contentions

Boston Scientific

Boston Scientific contends that it is entitled to a new trial, or in the alternative, judgment as a matter of law, because Plaintiffs failed to put forth sufficient evidence of causation. Boston Scientific argues that in order to establish causation for a failure to warn claim, which is governed by the learned intermediary doctrine, a plaintiff must show that a different warning would have

changed the physician's prescribing decision. This includes demonstrating that the physician read and relied upon the applicable warnings, and that had different warnings been given, the physician would have acted differently.

Boston Scientific argues that it warned Dr. Carlson of the potential complications of the Pinnacle and Advantage Fit, including the precise injuries Ms. Barba has claimed. Even if Plaintiffs could demonstrate any inadequacy in the warnings, Dr. Carlson's course of treatment would not have differed because he did not testify that he read or relied upon the Pinnacle or Advantage Fit Directions for Use ("DFUs"). Further, Boston Scientific contends that there was no evidence that Dr. Carlson would have acted differently if he had known additional information.

Boston Scientific next argues that the only relevant failures of the device are those that have proximately caused Ms. Barba's injuries. Other known or possible defects in the Pinnacle or Advantage Fit are irrelevant if such defects did not injure Ms. Barba.

Finally, Boston Scientific argues that Plaintiffs put forth no evidence to prove that the defects observed in mesh samples were present in Ms. Barba's mesh and that they caused Ms. Barba's injuries. Several experts testified that Boston Scientific's mesh often degraded and that the mesh contained black specs, irregular

edges, and low molecular weight. However, there was no testimony that connected these defects to the mesh that was implanted in Ms. Barba.

Barba Plaintiffs

Plaintiffs contend that the learned intermediary doctrine cannot shield Boston Scientific from liability where the warnings and information provided by Boston Scientific to physicians were inadequate. Plaintiffs argue that they met their burden to demonstrate that additional information would have made a difference to a reasonable intermediary, and therefore would have made a difference to Dr. Carlson.

Plaintiffs also argue that the DFUs were inadequate and failed to identify and explain complications associated with the device, including the complications that Ms. Barba experienced. Further, Plaintiffs contend that Boston Scientific failed to warn Dr. Carlson about the high complication rate of the Pinnacle as well as the stiffness of the Advantage Fit as compared to the TVT. With respect to the Pinnacle, Dr. Carlson testified that if he knew about the complication rate, he would not have used the product. In regards to the Advantage Fit, Dr. Carlson testified that if he had known that the Advantage Fit was stiffer than the TVT, he would have inquired about the differences between the products to determine if there were any clinical ramifications.

Discussion

The learned intermediary doctrine states that "a manufacturer of a prescription drug satisfies its duty to provide an appropriate warning about the drug when it gives the patient's physician the necessary information to be disseminated to the patient."[19] The Delaware Supreme Court in *Lacy* relied on the rationale for the rule as stated by the Washington Supreme Court in *Terhune v. A.H. Robins Co.*:[20]

> Where a product is available only on prescription or through the services of a physician, the physician acts as a "learned intermediary" between the manufacturer or seller and the patient. *It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product.* The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.[21]

[19] *Lacy*, 567 A.2d at 399.
[20] 577 P.2d 975 (Wash. 1978).
[21] *Id*. at 978 (emphasis added).

The test takes into account what information was communicated to a particular physician.[22] The evidence in this case demonstrates that a reasonable jury could find that the warnings provided to Dr. Carlson were inadequate and that additional information would have altered his decision to implant the Pinnacle and Advantage Fit in Ms. Barba. Dr. Carlson stated that if he had known about the complication rate of the Pinnacle, he would have used that information to further inquire into the safety and efficacy of the device. He stated that if the complication rate was associated with the Capio portion of the Pinnacle, he would not use that device. With regard to the Advantage Fit, Dr. Carlson testified that he was not aware that the Advantage Fit was twice as stiff as the TVT. Dr. Carlson testified that if he were aware of this difference, he would have inquired further into the effect that difference in stiffness may have on patients.

The evidence presented at trial was sufficient for a reasonable jury to find that the defects identified in Boston Scientific mesh samples also were present in Ms. Barba's mesh and caused her injuries. Dr. Dunn testified that, although he never examined Ms. Barba's mesh, he examined other Boston Scientific mesh samples and observed that the mesh contained black specs, irregular edges, and low molecular weight. Dr. Dunn stated that these defects are evidence of oxidation

[22] The learned intermediary doctrine employs a subjective test–that adequate information was communicated to *this* physician. This finding shall clarify and supersede any apparent contradictory ruling in *Barba v. Carlson*, 2014 WL 1678246 (Del. Super.).

in the mesh. Similarly, Dr. Guelcher and Dr. Galloway testified about polypropylene degradation, but each stated that they had not examined Ms. Barba's mesh for degradation. Dr. Guelcher also explained that oxidation causes polypropylene to degrade, embrittle, and become hard.

Dr. Iakovlev examined Ms. Barba's Pinnacle mesh and opined that the pathology of the explanted mesh and tissue was consistent with the degradation, foreign body response, pelvic pain, nerve pain, and urinary problems from which Ms. Barba suffered. Dr. Wright opined that Ms. Barba's urethral obstruction and erosion were caused by the Advantage Fit.

Considering the testimony of learned intermediary Dr. Carlson, along with the testimony of the expert witnesses, the evidence presented was sufficient to allow the jury to reasonably conclude that the defects found in mesh samples were present in the mesh implanted in Ms. Barba, and that she suffered injuries as a result of these defects. In other words, the expert testimony served to complete the causal connection between product defects—which were not disclosed to Dr. Carlson—and the injuries suffered by Ms. Barba. The totality of the evidence demonstrates that a reasonable jury could find: product defects caused problems with the mesh after implantation; problems with the mesh after implantation caused injuries; and injuries were caused by wadding and bunching.

FDA Evidence

Parties' Contentions

Boston Scientific

Boston Scientific argues that the Court erred in admitting evidence regarding fraud on the FDA. Boston Scientific relies on the United States Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Comm.*[23] The Supreme Court in *Buckman* held that federal law preempts any state law fraud on the FDA claims, and that the FDA is the only party authorized to police fraud on the FDA.[24] The *Buckman* analysis also applies to cases where a plaintiff attempts to prove fraud or negligence with evidence of alleged fraud on the FDA.[25] Courts have found these claims to be disguised fraud on the FDA claims and will exclude evidence "when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA."[26] Boston Scientific argues that Plaintiffs sought testimony from Dr. Brauer to support Plaintiffs' claim that Boston Scientific intentionally misled the FDA. Boston Scientific also alleges that the purpose for Plaintiffs' questioning of Dr. Parisian was to prove that Boston Scientific misled the FDA or intentionally concealed information.

[23] 531 U.S. 341 (2001).
[24] *Id*. at 348–50.
[25] *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424–25 (6th Cir. 2005).
[26] *Bouchard v. Am. Home Prods. Corp.*, 213 F.Supp 2d 802, 812 (N.D. Ohio 2002).

Boston Scientific further argues that Plaintiffs alleged that Boston Scientific misled the FDA in regard to labeling. Boston Scientific contends that Plaintiffs' arguments are premised on the idea that had Boston Scientific not misled the FDA, the device would not have been cleared, and Dr. Carlson would not have used the device—a premise that directly conflicts with the holding in *Buckman*. Boston Scientific asserts that the FDA evidence proffered by Plaintiffs had no other case-specific purpose than as a disguised fraud on the FDA claim. Thus, Boston Scientific argues that such evidence was admitted in violation of the law and resulted in a verdict based on prejudice, and a new trial is required.

Barba Plaintiffs

Plaintiffs argue that Boston Scientific opened the door by introducing evidence about the FDA and the 510(k) clearance process, thus allowing Plaintiffs to introduce evidence related to these topics. Plaintiffs contend that Boston Scientific sought to prove that it acted with due care by introducing evidence at trial to demonstrate that it had complied with the 510(k) requirements in order to receive clearance from the FDA for the Pinnacle and Advantage Fit. Plaintiffs argue that they acted within the scope of the law and the Court's previous rulings by introducing evidence related to the FDA to rebut Boston Scientific's claim that it acted with due care.

Plaintiffs next argue that their claims were not based on a fraud on the FDA theory, thus, *Buckman* is inapplicable. Plaintiffs concede that evidence offered solely to show that the FDA was misled would be improper. However, where, as here, evidence is submitted for other purposes, such as to support Plaintiffs' state law claims or to rebut Boston Scientific's affirmative defense, the evidence is admissible.[27] Plaintiffs claim that evidence relating to the FDA was introduced to show that Boston Scientific did not exercise due care in the manufacturing, marketing, and sales of the Pinnacle and Advantage Fit. Evidence relating to the FDA was also introduced to show Boston Scientific's intent, knowledge, and notice of adverse effects of the Pinnacle and Advantage Fit, which are of paramount relevance in this litigation.

Discussion

The Supreme Court in *Buckman* held that federal law preempts any state law fraud on the FDA claims, and that the FDA is the only party authorized to police fraud on the FDA.[28] The Sixth Circuit in *Cupek v. Medtronic, Inc.*, expanded on the *Buckman* analysis and held that a cause of action will not stand if it is a disguised action for fraud on the FDA.[29] However, the Court in *Bouchard v. American Home Products Corporation*, distinguished between purposes for which

[27] *Wyeth v. Levine*, 555 U.S. 555, 581 (2009); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd sub nom. Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008).
[28] *Buckman*, 531 U.S. at 348–50.
[29] *Cupek*, 405 F.3d at 424.

the evidence is offered. The *Bouchard* Court stated: "If . . . [Plaintiff's] claims are based on direct fraud against her and her healthcare provider, rather than the FDA, then her claims are not preempted, and evidence concerning what information was an[d] was not provided to the FDA might still be relevant."[30]

The Second Circuit in *Desiano v. Warner-Lambert & Co.*, further validated the ability to introduce evidence relating to the FDA as long as the claim is not a disguised fraud on the FDA cause of action.[31] The *Desiano* Court stated:

> Finding preemption of traditional common law claims where fraud is not even a required element—but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law—would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect.[32]

Here, Plaintiffs have not alleged a fraud on the FDA claim. The Court is not persuaded that Plaintiffs' fraud and failure to warn claims are actually disguised fraud on the FDA claims. The evidence relating to the FDA was relevant to other issues, such as Boston Scientific's knowledge and notice of defects in the Pinnacle

[30] *Bouchard*, 213 F.Supp 2d at 812.
[31] *Desiano*, 467 F.3d at 96.
[32] *Id*.

and Advantage Fit, as well as whether it exercised due care in labeling, marketing, and selling the Pinnacle and Advantage Fit.

The Court finds that Boston Scientific opened the door by seeking admission of evidence that Boston Scientific obtained FDA approval. Prior to trial, the parties presented arguments to the Court about whether any evidence pertaining to the FDA would be admissible. Plaintiffs sought to exclude all FDA evidence from the case. Boston Scientific vigorously opposed Plaintiffs' motion and stated that "the FDA and rules are at the center of this case." The Court explicitly warned Boston Scientific that presenting FDA evidence would open the door to Plaintiffs arguing that Boston Scientific manipulated the FDA approval process, did not provide all necessary information, or provided false or misleading information. Despite the Court's warning, Boston Scientific pursued a trial strategy that included introducing FDA evidence. Thus, Plaintiffs' evidence was admitted for purposes of fairness and completeness.

Plaintiffs' closing argument, taken as a whole, is not a disguised fraud on the FDA claim. In response to Boston Scientific's FDA approval process evidence, the Court admitted other relevant evidence of the sequence of events before the FDA.

Further, the Court excluded evidence of the FDA's subsequent request to Boston Scientific to remove the Devices from the market. Over Plaintiffs'

strenuous and repeated objections, the Court held that the FDA's request constituted an inadmissible subsequent remedial measure.

In short, Boston Scientific elected its trial strategy after having been warned by the Court of the consequences. The jury chose to resolve factual issues of fraud in favor of Plaintiffs. The Court finds no reason to disturb that finding.

Defendant's Motion for Remittitur, or in the Alternative, a New Trial

Standard of Review

In the absence of exceptional circumstances, the jury's award of damages should be deemed appropriate. Under Delaware law, enormous deference is given to jury verdicts. Reasonable differences of opinion are resolved in favor of the jury's opinion. The court will set aside a jury's verdict only in the rare case where it is "clear that the award is so grossly out of proportion to the injuries suffered, as to shock the court's conscience and sense of justice."[33] Remittitur is required only when the award of damages is so excessive that it must have been based on passion, prejudice or misconduct, rather than on objective consideration of evidence presented at trial.

[33] *Mitchell v. Haldar*, 2004 WL 1790121, at *3 (Del. Super.).

Compensatory Damages

Parties' Contentions

Boston Scientific

Boston Scientific contends that the jury's award of $25 million in compensatory damages bears no reasonable relationship to Plaintiffs' economic and physical damages. Such a grossly excessive award should shock the Court's conscience and sense of justice. Boston Scientific argues that an award must be proportional to the damages. The only economic damages presented at trial were medical expenses, totaling $45,259.90. Further, the evidence presented at trial demonstrated that Ms. Barba has not sought treatment for her pain in more than four years and she did not present a claim for lost wages or future medical expenses. While it is hard to quantify a person's pain and suffering, Boston Scientific argues that an award of $25 million in compensatory damages is immensely disproportional to the damages suffered by Plaintiffs.

Boston Scientific also argues that the excessive nature of the compensatory damages award indicates that punitive damages are wrapped into the compensatory award. Boston Scientific contends that the award bears no reasonable relationship to Plaintiffs' economic and physical damages, suggesting that the jury included a punitive magnifier. Boston Scientific states that this impermissible intermingling of damages should shock the Court's conscience and sense of justice.

Boston Scientific next argues that the Court should grant remittitur, or in the alternative, a new trial, because the verdict was not based on the facts or law presented to the jury, but rather upon passion, partiality, prejudice, mistake, or misapprehension. Boston Scientific recognizes that courts are usually hesitant to review the amount of a jury verdict, but submits that this is a rare case where there has been a recognizable injustice in rendering the verdict.

Barba Plaintiffs

Plaintiffs contend that the jury, after considering all of the evidence, assessed Ms. Barba's physical and emotional injuries and delivered a proper award of compensatory damages. Plaintiffs rely on the Delaware Supreme Court's holding in *Storey v. Costner*.[34] "Recognizing that it would be remiss in its duties to invade an area within the exclusive province of the jury, the courts will yield to the jury where any margin for reasonable difference of opinion exists in the matter of a verdict."[35]

Plaintiffs contend that the jury's compensatory damages award was not the result of any passion, prejudice, partiality, or corruption on the part of the jury, and thus, the award has not risen to the level of shocking the Court's conscience. Plaintiffs argue that because of the fact-specific nature of personal injury cases, it is impossible for courts to base an award in one action on what courts did in

[34] 314 A.2d 187 (Del. 1973).
[35] *Id*. at 193.

another action. Plaintiffs also argue that the jury spent weeks listening to testimony, received and followed careful instructions from the Court, and decided that Ms. Barba should be properly compensated in the amount of $25 million for the years of nearly-constant pain she endured, numerous surgical procedures, and the pain and mental anguish caused by her complete inability to engage in sexual relations with her husband, all resulting from defects in the Pinnacle and Advantage Fit devices that were implanted in her. Plaintiffs claim that where damages are not subject to mathematical certainty, the jury's award should not be set aside, as it expresses the view of the community. Plaintiffs contend that the Court should not find its conscience shocked just because the award is a sizeable one.

Punitive Damages

Parties' Contentions

Boston Scientific

Boston Scientific argues that the Court's instruction to the jury regarding punitive damages omitted critical language intended to guide the jury on the method for calculating punitive damages, thus constituting plain error and requiring a new trial. The omitted language directs that an award of punitive damages must bear a reasonable relationship to the plaintiff's compensatory damages. Boston Scientific argues that the omitted language constitutes a

deficiency that "undermined the ability of the jury to intelligently perform its duty in returning a verdict,"[36] thus warranting a new trial.

Boston Scientific contends that even if punitive damages were warranted in this case, the jury's award of $75 million in punitive damages is grossly excessive. Boston Scientific argues that when a punitive award is grossly excessive, it rises to a level of arbitrariness that violates the Due Process clause of the Fourteenth Amendment.[37]

Boston Scientific relies on *State Farm Mut. Auto. Ins. Co. v. Campbell*.[38] In *State Farm*, the United States Supreme Court stated that "punitive damages should only be awarded if the defendant's culpability, after having paid compensatory damages, is so reprehensible as to warrant the imposition of further sanctions to achieve punishment or deterrence."[39] The Supreme Court went on to state that "When compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee."[40] Boston Scientific argues that the $25 million in compensatory damages awarded in this case is substantial. Therefore, Boston Scientific asserts that the punitive damages award should be adjusted so that there is, at most, a 1:1 ratio of punitive damages to compensatory damages.

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[36] *Russell v. K-Mart Corp.*, 761 A.2d 1, 5 (Del. 2000).
[37] *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996).
[38] 538 U.S. 408 (2003).
[39] *Id*. at 419.
[40] *Id*. at 425.

Barba Plaintiffs

Plaintiffs contend that the jury's award of punitive damages is justified by Boston Scientific's own reprehensible conduct and is completely within the acceptable parameters for punitive damage awards. Plaintiffs also rely on *State Farm*. The Supreme Court stated that it "decline[s] to impose a bright-line ratio which a punitive damages award cannot exceed."[41] The Supreme Court went on to state that single-digit ratios usually will satisfy due process.[42] Therefore, Plaintiffs argue that the 3:1 ratio between punitive damages and compensatory damages cannot be held to violate due process.

Plaintiffs argue that the $75 million punitive damage award should not be disturbed because it achieves the purpose of punitive damages—to punish and deter. Plaintiffs contend that the large size, alone, is not enough to prove prejudice and passion in the jury's award determination, especially when considering Boston Scientific's net worth.

Discussion

The Court instructed the jury on personal injury damages. The jury was told:

> If you find your verdict for Mrs. Barba, then in determining the damages to which she is entitled, you shall consider any of the following which you believe by a preponderance of the evidence was caused by the negligence of Boston Scientific Corporation:

[41] *State Farm Mut. Auto. Ins. Co.*, 538 U.S. at 425.
[42] *Id*.

(1) compensation for pain and suffering that Deborah Barba has suffered to date;
(2) compensation for pain and suffering that it is reasonably probable that Deborah Barba will suffer in the future;
(3) compensation for permanent impairment; and
(4) compensation for reasonable and necessary medical expenses incurred to date.

In evaluating pain and suffering, you may consider its mental as well as its physical consequences. You may consider such things as discomfort, anxiety, grief, or other mental or emotional distress that may accompany any depravation of usual pleasurable activities and enjoyments.

In evaluating impairment or disability, you may consider all the activities that Deborah Barba used to engage in, including those activities for work and pleasure, and you may consider to what extent these activities have be impaired because of the injuries and to what extent they will continue to be impaired for the rest of her life expectancy. [It has been agreed that a person of Deborah A. Barba's age and sex would have a life expectancy of 33.6 years.]

The law does not prescribe any definite standard by which to compensate an injured person for pain and suffering or impairment, nor does it require that any witness should have expressed an opinion about the amount of damages that would compensate for such injury. Your award should be just and reasonable in light of the evidence and reasonably sufficient to compensate Deborah Barba fully and adequately.

The Court also instructed the jury on punitive damages:

If you decide to award compensatory damages to Deborah Barba, you must determine whether Boston Scientific Corporation is also liable to Deborah Barba for punitive damages.

Punitive damages are different from compensatory damages. Compensatory damages are awarded to compensate the plaintiff for

> the injury suffered. Punitive damages, on the other hand, are awarded in addition to compensatory damages.
>
> You may award punitive damages to punish a party for outrageous conduct and to deter a party, and others like it from engaging in similar conduct in the future. To award punitive damages, you must find by a preponderance of the evidence that Boston Scientific Corporation acted intentionally or recklessly. Punitive damages cannot be awarded for mere inadvertence, mistake, errors of judgment and the like, which constitute ordinary negligence.
>
> Intentional conduct means it was the person's conscious object to engage in conduct of that nature. Reckless conduct is a conscious indifference that amounts to an "I don't care" attitude. Reckless conduct occurs when a person, with no intent to cause harm, performs an act so unreasonable and dangerous that it knows or should know that the there is an imminent likelihood of harm that can result. Each requires that the defendant foresee that its conduct threatens a particular harm to another.
>
> The law provides no fixed standards for the amount of punitive damages. In determining an award of punitive damages, you may consider the nature of Boston Scientific Corporation's conduct and the degree to which the conduct was reprehensible.

After the jury was charged and began deliberations, the Court received the following question from the jury: "Jury verdict form. Does Question 5 include punitive damages? Guidance needed in rewarding damages." Question 5 of the Special Verdict Form reads: "If you found that Boston Scientific's conduct was a proximate cause of Mrs. Barba's harm in 1(D), 2(B), 3(C) or 4(B) above, what amount of damages do you award Deborah Barba?"

The Court conferred with counsel about the appropriate way to answer the jury's question. After the Court permitted counsel time to consult with their

clients, the parties agreed to allow the jury to consider and award punitive damages during their current deliberations, instead of conducting a second trial phase to determine punitive damages.

The jury was brought into the courtroom and was instructed:

> The answer to your question is . . . Question 5 does not include punitive damages. For your consideration, I suggest that if you need additional information on the answer to Question 5, you should take a look at the instruction on damages/personal injury, which talks about compensatory damages. And it gives you four categories of damages and talks about that. You may very well have already re-reviewed that particular instruction. That instruction needs to be taken into consideration, of course, with all other instructions.
>
> * * *
>
> Now, in response to the question as it relates to punitive damages, I have, through handwriting, amended the verdict form. I have added a Question No. 8, which says, "If you answered yes to Question 7,[43] what amount of punitive damages do you award Mrs. Barba?"
>
> And, again, by putting this question on the verdict form I am in no way suggesting whether or not you should decide that punitive damages are appropriate. You must consider all of the other instructions I have given you on that. I'm simply outlining the form that your analysis should take.

The sequence of events demonstrates that, when faced with a jury question regarding punitive damages, the parties agreed on the proper course of action. An

[43] Question 7 on the Special Verdict Form read: "Was Boston Scientific Corporation's conduct in the sale and distribution of the Pinnacle and/or Advantage Fit willful, wanton, and/or reckless in a manner promimately causing injuries to the plaintiff Deborah Barba?"

additional question was added that specifically dealt with an amount to be awarded for punitive damages. The Court instructed the jury that Question 5 does not include punitive damages. Therefore, there is no evidence to support Boston Scientific's contention that the jury's compensatory damages award included a punitive magnifier.

Boston Scientific also argues that the punitive damages instruction should have contained the following language: "Any award of punitive damages must bear a reasonable relationship to Deborah Barba's compensatory damages." Boston Scientific contends that the absence of this language constituted a deficiency that undermined the ability of the jury to intelligently perform its duty in returning a verdict. However, Boston Scientific failed to object to the instruction when it was given to the jury. The instruction was challenged for the first time in Boston Scientific's post trial motions. When a party fails to timely object, it must rely on the principles of plain error.[44]

The Delaware Supreme Court discussed jury instructions in *Russell v. K-Mart Corp*:

> In evaluating the propriety of a jury charge, the jury instructions must be viewed as a whole. Although a party is not entitled to a particular jury instruction, a party does have the unqualified right to have the jury instructed with a correct statement of the substance of the law. Even if the jury instructions contain some

[44] *Riggins v. Mauriello*, 603 A.2d 827, 830 (Del. 1992).

> inaccuracies, however, this Court will reverse the decision below only if the deficiencies undermined the ability of the jury to intelligently perform its duty in returning a verdict, thus excusing the failure to object at trial.[45]

Reading the punitive damage instruction in its entirety, the Court finds no error of law. Boston Scientific's objection as to the "missing" language pertains to the ratio of punitive damages to compensatory damages, rather than to a correct statement of the substance of the law. The instruction advised the jury that punitive damages are different from compensatory damages and that the purpose of punitive damages is "to punish a party for outrageous conduct and to deter a party, and others like it from engaging in similar conduct in the future." Thus, the instruction accurately reflects Delaware law on punitive damages.

Under Rule 50(b), the Court has reviewed the evidence to determine whether under any reasonable view, the jury could have justifiably found in favor of Boston Scientific. Under Rule 59, the Court has weighed the evidence in order to determine whether the verdict is one that a reasonably prudent jury could have reached. Further, the Court has examined the evidence in consideration of whether it is clear that the verdict was the result of passion, prejudice, partiality, corruption, or in clear disregard of the evidence or the law. The Court viewed the damages

[45] *Russell v. K-Mart Corp.*, 761 A.2d 1, 5 (Del. 2000).

award to determine whether it is so grossly disproportionate to the injuries suffered so as to shock the Court's conscience and sense of justice.

After considering all of the relevant factors, the Court concludes that remittitur must be granted because the verdict is sufficiently out of proportion to the injury so as to shock the Court's conscience and sense of justice.

Plaintiffs presented medical evidence supporting injuries resulting from the implantation of the Pinnacle and Advantage Fit devices. After the Pinnacle and Advantage Fit were implanted, Ms. Barba suffered from recurrent bladder infections, underwent two surgeries to remove the implanted mesh, was forced to self-catheterize for over five months because of her inability to urinate, and was unable to engage in sexual relations with her husband. Ms. Barba currently suffers from pelvic and abdominal pain, bladder pressure, and pain and mental anguish because of her inability to engage in sexual relations with her husband. Nevertheless, Ms. Barba has neither sought nor received medical treatment in over four years. There was no claim for future medical expenses, lost wages, or the expenses of any future surgery. Plaintiff incurred past medical expenses in the amount of $45,259.90.

When determining whether a jury's verdict shocks the conscience, it is instructive to look at jury verdicts in similar pelvic mesh cases. While the Court recognizes that each case is fact-specific and heavy reliance should not be placed

on any particular award, the Court finds it informative to examine other relevant verdicts. A Texas jury returned a verdict for compensatory damages in the amount of $23,465,000. Other cases have resulted in compensatory damages ranging from $250,000 to $6,722,222. In the Texas case, the jury awarded $50,000,000 in punitive damages, but the statutory cap reduced punitive damages to $11,180,000. The pelvic mesh cases in other jurisdictions in which compensatory damages were awarded did not all find punitive damages appropriate. In cases awarding punitive damages, the amounts ranged from $1,750,000 to $7,760,000.

In assessing remittitur, "tribute is still paid to the very jury whose verdict is being set aside."[46] "[U]nder the Delaware policy to highlight the role of the jury, our practice should be [in remittitur] to grant the plaintiff every reasonable factual inference from the record and determine what the record justifies as an absolute maximum."[47]

The purpose of remittitur is to remove the portion of the verdict that shocks the Court's conscience and sense of justice. Remittitur cannot be used to replace the jury's verdict with what the Court, sitting as a trier of fact, would have imposed. Nor is remittitur imposed to reduce the award to what an objectively reasonable jury might have determined. Out of the respect and deference which

[46] *Carney v. Preston*, 683 A.2d 47, 56 (Del. Super. 1996).
[47] *Id*. (quoting *Stewart v. Genesco, Inc*., 406 A.2d 25, 27 (Del. Super. 1979)).

must be accorded to the jury, remittitur functions to reduce a verdict to the high end of the spectrum of reasonableness.

Even when viewed in the light most favorable to Plaintiffs, Ms. Barba's injuries cannot justify a monetary award for compensatory damages in the amount of $25 million. Having considered the nature and extent of Ms. Barba's injuries, past and future pain and suffering, her life expectancy, and past and future impairment of activities, the maximum just and reasonable compensation to Plaintiffs is $2,500,000.

The Court finds that the jury properly determined that punitive damages should be awarded in this case. Nevertheless, punitive damages of $75 million shock the Court's conscience, and remittitur must be granted. "The most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct."[48] In determining the reprehensibility of Boston Scientific, the Court considers the physical harm caused to Ms. Barba, and Boston Scientific's deficiencies in its warnings for the Pinnacle and Advantage Fit. Punitive damages are warranted in this case in order to punish Boston Scientific and deter it from permitting other products to enter the market without first taking steps to ensure the product's safety and efficacy.

[48] *State Farm Mut. Auto. Ins. Co.*, 538 U.S. at 419.

While the jury's punitive damages award will be lowered, the Court finds that the 3:1 ratio of punitive damages to compensatory damages was not improper. In *State Farm*, the United States Supreme Court stated that single-digit ratios usually will satisfy due process.[49] Because the maximum just and reasonable amount to award in compensatory damages is $2,500,000, the Court, utilizing the jury's 3:1 ratio, will assess punitive damages in the amount of $7,500,000.

CONCLUSION

Trial in this case lasted for fourteen days. The jury was attentive and diligent throughout the trial, and conducted lengthy deliberations. The Special Verdict Form contained eight questions, five of which contained subparts. The jury appeared to the Court to have a good understanding of the issues and evidence presented.

The Court finds that the jury's liability determinations are reasonable and consistent with the evidence. Having weighed the evidence, the Court holds that the liability verdict is one that a reasonably prudent jury could have reached.

The Court finds that compensatory damages in the amount of $25 million and punitive damages in the amount of $75 million are grossly disproportionate to the injuries suffered and shock the Court's conscience and sense of justice. The

[49] *Id*. 425.

Court grants remittitur and reduces the award of compensatory damages to $2,500,000, and punitive damages to $7,500,000.

THEREFORE:

Boston Scientific's Motion for Judgment as a Matter of Law is hereby **DENIED**;

Boston Scientific's Motion for a New Trial is hereby **DENIED**;

Boston Scientific's Motion for Remittitur is hereby **GRANTED**.

IT IS SO ORDERED.

/s/ *Mary M. Johnston*_____
The Honorable Mary M. Johnston