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

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| DEBORAH A. BARBA and THOMAS D. BARBA, her husband,<br><br>Plaintiff,<br>v.<br><br>JOHN C. CARLSON, D.O., MATERNITY ASSOCIATES, P.A. and BOSTON SCIENTIFIC CORPORATION, a Delaware Corporation,<br><br>Defendants. | ) | C.A. No. N11C-08-050 MMJ |

Submitted: March 12, 2014
Decided: April 8, 2014

On Defendant Boston Scientific's Motion for Summary Judgment
Against Plaintiffs Deborah and Thomas Barba
**DENIED Except that the Breach of Express Warranty Claim is DISMISSED**

On Boston Scientific's Motion for Partial Summary Judgment
on Plaintiffs' Punitive Damages Claim
**DENIED**

## MEMORANDUM OPINION

Colleen D. Shields, Esquire (argued), Eckert Seamans Cherin & Mellott, LLC, Attorney for Defendant Boston Scientific

Jonathan D. Orent, Esquire (argued Summary Judgment), Motley Rice LLC, Philip T. Edwards, Esquire (argued Partial Summary Judgment), Lauren A. Cirrinicione, Esquire, Murphy & Landon, Attorneys for Plaintiff

**JOHNSTON, J.**

## FACTUAL AND PROCEDURAL CONTEXT

This products liability action alleges that Boston Scientific Corporation ("Boston Scientific") designed and manufactured defective implantable pelvic mesh devices. Plaintiffs Deborah and Thomas Barba contend that the Pinnacle Pelvic Floor Repair Kit and the Advantage Fit Mid-Urethral Sling System ("Devices") caused physical injury to Deborah Barba. Plaintiffs assert causes of action against Boston Scientific for: breach of implied warranty of merchantability, breach of implied warranty of fitness for particular purpose, breach of express warranty, fraud, fraud by concealment, violations of the Delaware consumer protection laws, loss of consortium, and punitive damages.

Defendant John Carlson, D.O. implanted the Boston Scientific Devices during surgery he performed on Deborah Barba. The Devices were used to treat Ms. Barba's pelvic organ prolapse and stress urinary incontinence. Following surgery, Deborah Barba alleges that she suffered pelvic and abdominal pain, urinary dysfunction, urinary infections, urinary retention, dyspareunia, sexual dysfunction, fecal incontinence, urinary incontinence, recurrent prolapse, and erosion. To address these problems, she was required to undergo corrective surgery.

The Devices only are available by prescription issued by a licensed physician. Each Device is accompanied by Directions for Use ("DFU"). The DFUs state certain precautions that must be taken by the surgeon. The DFUs also list possible "Adverse Events."

For purposes of this motion, it is undisputed that Dr. Carlson does not recall reading the DFU for either Device. However, Dr. Carlson testified at deposition that he attended many different training and educational opportunities on implanting pelvic mesh devices.

In addition to the claims against Boston Scientific, Plaintiffs have sued Dr. Carlson for medical negligence and lack of informed consent, and Defendant Maternity Associates, P.A. for negligence.

Boston Scientific has moved for summary judgment. Boston Scientific has 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 fails 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.

Oral argument on these motions was held on March 12, 2014. Trial is set to begin in a few weeks. Following are the Court's findings, intended to enable the parties to timely prepare for alternative dispute resolution and trial.

## ANALYSIS

### *Summary Judgment Standard*

Summary judgment is granted only if the moving party establishes that there are no genuine issues of material fact in dispute and judgment may be granted as a matter of law.[1] All facts are viewed in a light most favorable to the non-moving party.[2] Summary judgment may not be granted if the record indicates that a material fact is in dispute, or if there is a need to clarify the application of law to the specific circumstances.[3] When the facts permit a reasonable person to draw only one inference, the question becomes one for decision as a matter of law.[4] If the non-moving party bears the burden of proof at trial, yet "fails to make a showing sufficient to establish the existence of an element essential to that party's case," then summary judgment may be granted against that party.[5]

### *Learned Intermediary Doctrine*

As a general rule, the manufacturer owes a duty to warn the consumer directly concerning the risks associated with any product. However, where a product is available only by means of a prescription issued by a licensed

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[1] Super. Ct. Civ. R. 56(c).

[2] *Hammond v. Colt Indus. Operating Corp.*, 565 A.2d 558, 560 (Del. Super. 1989).

[3] Super. Ct. Civ. R. 56(c).

[4] *Wootten v. Kiger*, 226 A.2d 238, 239 (Del. 1967).

[5] *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

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

The learned intermediary physician must exercise independent judgment, taking into account the specific needs of the patient. It is presumed that the patient can reasonably rely on the physician's judgment. 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 directly warn or advise the consumer patient.[6]

Boston Scientific argues that it warned Dr. Carlson of the precise injuries Plaintiffs now claim. Further, even if Plaintiffs could demonstrate any inadequacy in the warnings, Dr. Carlson's course of treatment would not have been different because he neither read nor relied upon the warnings and instructions contained in the DFUs. Thus, Boston Scientific contends, any alleged failure to warn cannot have proximately caused Plaintiff's injuries.

The Court finds that the proper analysis must begin with whether there is a genuine issue of material fact about whether the warnings were adequate. A

[6] *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399-400 (Del. 1989).

manufacturer or seller, who has failed in its duty to warn, cannot insulate itself from all liability simply by the serendipitous circumstance that a learned intermediary is interposed between itself and the ultimate consumer. If the warnings and information are inadequate as a matter of law, the learned intermediary doctrine cannot apply. However, an injured party cannot prosecute a cause of action against a manufacturer or seller when liability is more properly imposed on the learned intermediary physician.

If the warnings and information are not insufficient as a matter of law, or, in other words, if there is a genuine issue of material fact about the adequacy of the warnings and information, the analysis will proceed to the next issue. This issue is whether additional information or warnings would have made a difference to a ***reasonable*** learned intermediary. If the warnings and information are found to be adequate, ***and*** additional warnings or information would not have affected the medical decisions of a reasonable physician, then the learned intermediary insulates the manufacturer from liability.[7] If further information or warnings would have made a difference to a reasonable physician, in a way that could have prevented injury, then the learned intermediary doctrine does not apply. The

[7] *Id.* at 400 ("Thus, if the manufacturer of prescription products provides the physician with the legally appropriate information, it has satisfied its duty to warn.").

learned intermediary doctrine "places the task of making an informed choice on the physician as the medical expert."[8] A reasonable learned intermediary cannot make an informed choice in the absence of adequate warnings and information.

For purposes of summary judgment, the Court finds that Plaintiffs have demonstrated genuine issues of material fact regarding the adequacy of Boston Scientific's warnings, sufficient to proceed to the issue of whether additional warnings or information would have made a difference to a reasonable learned intermediary.

In this case, Dr. Carlson has testified that he attended three Boston Scientific training courses prior to implanting the Devices in Deborah Barba.[9] Additionally, Dr. Carlson stated that it was his normal practice to review videos of procedures. Dr. Carlson admitted that he has no specific recollection of reviewing the DFUs for the implanted Devices.

The Court also finds that it there are genuine issues of material fact as to whether the information provided in the DFUs was different from, and supplemental to, the information provided to Dr. Carlson as part of the training courses and procedure videos. If the Boston Scientific warnings (other than those

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[8] *Crookshank v. Bayer Healthcare Pharms.*, 2009 WL 1622828, at *3 (Del. Super.).

[9] May 2003, June 2005 and September 2008.

contained in the DFUs) were adequate, and if the DFU information was not different, or would not have made a difference to a reasonable physician, the learned intermediary doctrine applies. If the DFU information was different and would have made a difference to a reasonable physician, and Dr. Carlson failed to review the DFUs, the learned intermediary doctrine would apply. However, if the warnings and information provided by Boston Scientific as part of training courses, procedure videos, and DFUs were not adequate, the learned intermediary doctrine cannot insulate Boston Scientific from liability, regardless of whether or not Dr. Carlson reviewed the DFUs.

Boston Scientific relies upon decisions issued by the Multidistrict Litigation ("MDL") Court in transvaginal mesh litigation. The Court finds these cases distinguishable from the facts present in this action. For example, in *In re C.R. Bard, Inc.*,[10] the MDL Court found that plaintiff had failed to offer sufficient evidence to meet the burden of showing that additional or different warnings would have prevented the physician from implanting defendant's product.

[10] 2013 WL 5591948 (S.D. W.Va.).

Because the doctor did not review the directions for use, the Court held that no warnings contained therein could have caused the doctor to act any differently.[11]

There was no evidence in the cited MDL cases that the physicians had information from defendants other than that contained in the directions for use. The evidence merely demonstrated that those doctors did not rely on the warnings in the directions. Under those circumstances, the MDL Court found that plaintiffs had failed to offer sufficient evidence that additional or different warnings could have affected the physicians' decisions.

In this case, Dr. Carlson testified that he was relying on extensive information specifically provided by Boston Scientific. This creates questions of fact, including credibility, for the trier of fact. The jury must determine whether additional or different information provided in the DFUs would have made a difference to a reasonable physician, in a way that could have prevented injury to Plaintiffs. The inquiry in this case does not automatically end simply because the learned intermediary states that he never read certain warnings.

The Court cannot grant summary judgment to Boston Scientific on the basis of the learned intermediary doctrine. There are genuine issues of material fact.

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[11] *Id*. at *6; *see In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2014 WL 186869, at *4 (S.D. W.Va.) (evidence of physician reliance on warnings in directions for use or patient brochures required for plaintiffs to prevail on summary judgment).

These include: whether the warnings and information provided by Boston Scientific were adequate; whether the warnings and information provided to Dr. Carlson, outside the DFUs, were different or additional to other information reviewed by Dr. Carlson; and whether any different or additional warnings or information contained in the DFUs would have made a difference to a reasonable learned intermediary physician.

***Negligent Manufacture***

A manufacturing defect exists when a product is properly designed, but the item was manufactured incorrectly.[12] If the alleged defect is outside the common knowledge of a lay person, expert testimony is required to establish a *prima facie* case.[13]

Plaintiffs have offered an expert witness on the alleged manufacturing defects of the Devices. These include: contaminated monofilaments; non-uniform monofilaments with sharp edges; Devices are easily permanently deformed due to extreme flexibility; inconsistent molecular weight of polypropylene affecting important polymer properties; significant oxidation levels on the polypropylene surface; and deficient quality controls.

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[12] *DiIenno v. Libbey Glass Div., Owens-Illinois, Inc.*, 668 F.Supp. 373, 377 (D. Del. 1987).

[13] *Reybold Grp., Inc. v. Chemprobe Technologies, Inc.*, 721 A.2d 1267, 1270 (Del. 1998).

The Court finds that Plaintiffs have presented expert testimony establishing a *prima facie* case of negligent manufacture.

***Negligent Product Design***

Expert testimony also is necessary to support allegations of negligent product design.[14] "The proper test is whether the design has created a risk of harm which is so probable that an ordinarily prudent person, acting as a manufacturer, would pursue a different available design which would substantially lessen the probability of harm."[15]

Plaintiffs have offered expert testimony that Boston Scientific's procedure design is dangerous to patients receiving the Devices. These design defects include: inability to prevent contamination in the surgical field is a contraindication for permanent placement; permanent placement creates increasing inflammation and pain; removal of the mesh is difficult, if not impossible; numerous serious adverse events; erosion of the mesh into the bladder muscle; failure of the mesh to support the bladder as intended; and urethra obstruction. Plaintiffs' negligent design expert opines that the design defects proximately caused Deborah Barba's injuries.

Boston Scientific argues that in order to prevail on a negligent design claim, Plaintiffs also must present expert testimony that an alternative design would

[14] *Polaski v. Dover Downs, Inc.*, 2012 WL 3291783, at *2 (Del.).

[15] *Nacci v. Volkswagen of America, Inc.*, 325 A.2d 617, 620 (Del. Super. 1974).

substantially lessen the likelihood of injury. Because Plaintiffs have failed to propose an alternative design, Boston Scientific asserts that the negligent design claim must fail.

The Court finds that Boston Scientific's proposed legal standard is incorrect. It is legally possible for a plaintiff to prove defective design even if no alternative design has been identified. Clearly, the finder of fact may consider the availability and feasibility of any alternative design in determining negligence. However, common sense dictates that a product may be defectively designed in the absence of any alternative.

For example, if a mask designed to protect miners from coal dust did not filter out any harmful particles, then the design would be defective, even if the alternative would be for the miners to work without any protective apparatus.

Evidence of safer or more effectively designed products is relevant. Nevertheless, expert testimony or other evidence about the existence of an alternative design, is not a necessary prerequisite to a negligent design claim in Delaware.

***Breach of Warranties***

To recover for breach of a warranty, Delaware law requires that the buyer must notify the seller of the breach within a reasonable time after discovery of the breach.[16]

[16] 6 *Del. C.* § 2-607(3)(a).

Boston Scientific asserts that it received no notice of Plaintiffs' dissatisfaction with the Devices until served with this lawsuit, nearly two years after Plaintiffs' surgery.

Plaintiffs' have the burden of demonstrating that reasonable notice was given. The sufficiency of notice may be determined as a matter of law.[17]

In this case, the Court finds that whether or not Plaintiffs' provided reasonable and timely notice, is a question of fact.

Express Warranties

Plaintiffs have failed to identify any specific express warranties. In order to pursue a claim for breach of express warranty, the consumer must produce evidence of reliance on the express warranty.[18] Deborah Barba has testified that she neither received nor relied upon any Boston Scientific materials. Therefore, Plaintiffs' breach of express warranty claim must be dismissed.

Implied Warranty of Merchantability

The Court has found that Plaintiffs have presented expert testimony establishing a *prima facie* case of negligent manufacture, and a *prima facie* case of negligent product design. This expert testimony also provides a *prima facie* basis for Plaintiffs' claim for breach of the implied warranty of merchantability.

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[17] *Klein v. Am. Luggage Works, Inc.*, 158 A.2d 814, 819 (Del. 1960).

[18] *DiIenno*, 668 F.Supp. at 376; 6 *Del. C.* § 2-313(1).

Implied Warranty of Fitness for a Particular Purpose

An implied warranty of fitness for a particular purpose arises when the seller or manufacturer has reason to know that the consumer is relying on the seller's skill or judgment to select or furnish a suitable product. The consumer does not need to provide the seller with actual knowledge of the particular purpose for which the product is intended, if the seller has reason to perceive the purpose intended or that reliance exists.[19] It is not necessary that the plaintiff claim that there was some unusual use for the product. The crucial element is that the buyer relies on the seller's superior knowledge and expertise in selecting suitable goods.[20]

In this case, Plaintiffs, through Dr. Carlson, relied upon the representations made by Boston Scientific during training sessions and videos. This reliance establishes a *prima facie* case for the breach of implied warranty of fitness for a particular purpose claim.

***Fraud***

[19] *Neilson Bus. Equip. Ctr., Inc. v. Italo Monteleone, M.D., P.A.*, 524 A.2d 1172, 1175-76 (Del. 1987).

[20] *In re Asbestos Litig. (Mergenthaler)*, 542 A.2d 1205, 1214 (Del. Super. 1986).

Plaintiffs have asserted claims against Boston Scientific for common law fraud, fraudulent concealment and violations of the Delaware Consumer Fraud Act ("DCFA").

Common law fraud has five elements:

1. defendant's false representation;
2. made knowingly or with reckless indifference to the truth;
3. intent to induce plaintiff to act or to refrain from acting;
4. plaintiff's action or inaction taken in justifiable reliance upon the representation; and
5. damages resulting from reliance.[21]

Fraudulent concealment requires:

1. defendant's deliberate concealment of a material fact, or silence when there is a duty to speak;
2. scienter;
3. intention to induce plaintiff's reliance upon the concealment;
4. causation; and
5. damages resulting from concealment.[22]

In order to prove a violation of the DCFA, plaintiff must prove:

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[21] *Stephenson v. Capano Dev., Inc.*, 462 A.2d 1069, 1074 (Del. 1983).

[22] *Nicolet, Inc. v. Nutt*, 525 A.2d 146, 149 (Del. 1987).

1. defendant's advertisement contained a false representation or omitted a material fact;
2. defendant intended that plaintiff rely upon the misrepresentation or omission; and
3. damages.[23]

The DCFA was enacted for the purpose of protecting consumers from unfair or deceptive merchandising practices. The DCFA is designed to be "liberally construed and applied to promote its underlying purposes and policies."[24]

Plaintiffs allege that Boston Scientific has engaged in "active misconduct." Such purported conduct includes: actions to mitigate negative press regarding the FDA's Public Health Notification; and lobbying activities. Additionally, the fraud claims overlap with allegations of inadequate warnings. Finally, Plaintiffs' fraud contentions relate to the duty to provide accurate information to the learned intermediary.

The Court need not rule on the propriety of the fraud claims at this stage of the proceedings. Because the evidence is so intertwined with other claims, it does not appear that permitting fraud to remain as an issue for trial will prolong or

[23] 6 *Del. C.* § 2513(a).

[24] 6 *Del. C.* § 2512.

complicate the proceedings unnecessarily. Therefore, the Court will hold the ruling on these claims until after the evidence is presented at a trial.

***Loss of Consortium***

It is undisputed that Thomas Barba's loss of consortium claims are derivative. Therefore, to the extent Deborah Barba's underlying claims have been maintained or dismissed, the loss of consortium claims will follow suit.

***Punitive Damages***

In Delaware, punitive damages may be awarded only "where the defendant's conduct, though unintentional, has been particularly reprehensible, *i.e.* reckless, or motivated by malice or fraud. Thus, the imposition of punitive damages is sustainable for persistent distribution of an inherently dangerous product with knowledge of its injury-causing effect among the consuming public . . . "[25]

The penal aspect and public policy considerations underlying punitive damages require proof that the defendant has acted outrageously, with an evil motive, or with reckless indifference to the rights of others. "Mere inadvertence, mistake or errors of judgment which constitute mere negligence will not suffice . . . It is not enough that a decision be wrong. It must result from a conscious

[25] *Jardel Co., Inc. v. Hughes*, 523 A.2d 518, 529 (Del. 1987).

indifference to the decision's foreseeable effect."[26]

Boston Scientific argues that Massachusetts law applies to Plaintiffs' punitive damages claim. It contends that where a conflict of law exists, the "most significant relationship" test applies. Boston Scientific asserts that Massachusetts is the place where the alleged injury-causing conduct occurred. Massachusetts law only permits punitive damage awards authorized by statute.

It is undisputed that Massachusetts law bars punitive damages unless brought along with a wrongful death claim[27] or under the Massachusetts consumer protection statute.[28] Plaintiffs have not pled a claim under the Massachusetts Regulation of Business Practices for Consumers Protection statute. Additionally, Plaintiffs did not file the demand letter at least 30 days before filing suit, as prerequisite to a Massachusetts consumer protection action seeking punitive damages.

There is no Delaware authority supporting the proposition that in a product liability action, Delaware law applies to every issue except punitive damages. Such a conclusion would require a finding that Delaware had the most significant relationship to everything, except the conduct underlying punitive damages. It is

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[26] *Id.* (citing Restatement (Second) of Torts § 908, cmt. b (1979)).

[27] Mass. Gen. Laws ch. 229 § 2.

[28] Mass. Gen. Laws ch. 93A.

difficult to posit a case in which the conduct supporting compensatory damages is not inextricably intertwined with actions giving rise to punitive damages.

In *Yoder v. Delmarva Power & Light Company*,[29] this Court declined to apply the Maryland cap on non-economic damages where the automobile accident occurred in Maryland. The Court concluded that Delaware had the most significant relationship to the occurrence and the parties. The Court ruled that a cap on non-economic damages would be contrary to Delaware's public policy.[30]

In this case, the Court finds that there is no basis for a finding that Massachusetts has the most significant relationship to everything except punitive damages. Further, prohibiting Plaintiffs from seeking punitive damages would be contrary to Delaware's public policy against limiting damages on the basis of the law of another jurisdiction. Therefore, Plaintiffs' punitive damages claim is not barred by Massachusetts law in this action.

## CONCLUSION

The Court cannot grant summary judgment to Boston Scientific on the basis of the learned intermediary doctrine. This issue involves genuine issues of material fact.

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[29] 2003 WL 26066796 (Del. Super.).

[30] *Id*. at *5.

The Court finds that Plaintiffs have presented expert testimony establishing a *prima facie* case of negligent manufacture and of negligent product design. Evidence of safer or more effectively-designed products is relevant. However, expert testimony or other evidence of alternative design is not a necessary prerequisite to a negligent design claim in Delaware.

The expert testimony also provides a *prima facie* basis for Plaintiffs' claims for breach of the implied warranty of merchantability, and for breach of implied warranty of fitness for a particular purpose.

The Court declines to rule on the propriety of the fraud claims at this stage of the proceedings. The Court will hold ruling on these claims until after the evidence is presented at a trial.

To the extent Deborah Barba's underlying claims have been maintained or dismissed, the loss of consortium claims also are maintained or dismissed.

Plaintiffs' punitive damages claim is not barred by Massachusetts law in this action.

Plaintiffs having failed to identify any express warranties, Plaintiffs' breach of express warranty claim must be dismissed.

**THEREFORE,** Defendant Boston Scientific's Motion for Summary Judgment Against Plaintiffs Deborah and Thomas Barba is **DENIED, except that the breach of express warranty claim is DISMISSED.**

Boston Scientific's Motion for Partial Summary Judgment on Plaintiffs' Punitive Damages Claim is hereby **DENIED.**

**IT IS SO ORDERED.**

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