Luna v. Atrium Medical Corporation et al Doc. 268

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

Martha Luna

v.

Civil No. 16-cv-372-LM
Opinion No. 2021 DNH 083 P

Atrium Medical Corporation

O R D E R

Plaintiff Martha Luna brings this product liability action against defendant Atrium Medical Corporation ("Atrium").[1] Luna's action is a member and bellwether case of In re Atrium Medical Corporation C-QUR Mesh Products Liability Litigation, 16-md-2753-LM. As in all the cases of this Multi-District Litigation, the plaintiff in this action asserts that Atrium designed, manufactured, and sold an unreasonably dangerous surgical mesh product intended for permanent implantation in the human body in connection with hernia repair surgeries. Plaintiff Luna alleges that she suffered injury after undergoing umbilical hernia repair surgery using Atrium's surgical mesh product.

Now before the court is defendant's motion for summary judgment (doc. no. 217) to the extent it seeks dismissal of plaintiff's claims for violation of New Hampshire and California consumer protection law.[2] Defendant argues that plaintiff lacks standing to bring a claim under

[1] Plaintiff voluntarily withdrew all of her claims to the extent asserted against former defendant Maquet Cardiovascular US Sales, LLC on April 26, 2021.

[2] A summary of the convoluted path of this summary judgment litigation is in order. Plaintiff's amended complaint (doc. no. 176) asserts claims of negligence, design defect, manufacturing defect, failure to warn, breach of express warranty, breach of implied warranty, and violation of New Hampshire and California consumer protection laws. Defendant filed this motion for summary judgment as to all of plaintiff's claims on October 14, 2020. In a prior order, the court denied certain portions of this motion based on overlapping claims and rulings in the Barron bellwether case. See doc. no. 258 at 9-11. After the court's order partially denying this motion for summary judgment, there were four sets of plaintiff's claims still pending a

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New Hampshire's Consumer Protection Act ("NHCPA") because any advertising or representations received by the plaintiff or her medical care providers regarding the surgical mesh product would have been received, if at all, outside of New Hampshire. Defendant further argues that plaintiff lacks standing to bring a claim under California's Consumer Legal Remedies Act ("CCLRA") because plaintiff did not personally select Atrium's surgical mesh product for use in her surgery and had not personally seen any advertising or other statements regarding the product prior to her surgery. Plaintiff opposes the motion on both grounds.

For the reasons set forth below, the court grants defendant's summary judgment motion as to plaintiff's NHCPA claim and denies it as to her CCLRA claim.

LEGAL STANDARD

Summary judgment is proper only if the moving party can demonstrate "that there is no evidence in the record to support a judgment for the nonmoving party." Celotex Corp. v. Catrett, 477 U.S. 318, 332 (1986); see also Fed. R. Civ. P. 56(a). If the moving party succeeds in making that showing, "the burden shifts to the nonmoving party, who must, with respect to each issue on which she would bear the burden of proof at trial, demonstrate that a trier of fact could reasonably resolve that issue in her favor." Borges v. Serrano-Isern, 605 F.3d 1, 5 (1st Cir. 2010). The nonmoving party's failure to meet that burden by reference to "significantly probative" materials "of evidentiary quality" entitles the moving party to summary judgment.

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ruling: strict liability/manufacturing defect (Count III), express warranty (Count V), implied warranty (Count VI), and consumer protection claims (Count VII). By motion filed on April 26, 2021, counsel jointly filed a stipulation of dismissal of the remaining claims other than the consumer protection claims. To the extent the motion for summary judgment seeks adjudication of Counts III, V, and VI, it is therefore denied as moot. The only count that remains subject to the motion for summary judgment is Count VII, plaintiff's consumer protection claims.

Flovac, Inc. v. Airvac, Inc., 817 F.3d 849, 853 (1st Cir. 2016) (citations omitted). In evaluating a motion for summary judgment, the courts must view the evidence in the light most favorable to the nonmoving party, must draw all reasonable inferences in that party's favor, and may neither make credibility determinations nor weigh the evidence. See, e.g., Lytle v. Household Mfg., Inc., 494 U.S. 545, 554-555 (1990); Harris v. Scarcelli, 835 F.3d 24, 29 (1st Cir. 2016).

BACKGROUND

The following factual summary is drawn from plaintiff's medical records (doc. nos. 241-4, 241-6), plaintiff's response to defendant's statement of undisputed facts (doc. no. 241-11), and the deposition testimony of the following persons:

- Plaintiff Luna (doc. nos. 218-1, 241-10);
- Dr. John Husted (the surgeon who performed plaintiff's hernia repair surgery) (doc. nos. 218-2, 241-3);
- Dr. Stephen A. Dada (the surgeon who removed defendant's surgical mesh product from plaintiff's body after she suffered post-surgical complications) (doc. nos. 218-3, 241-5);
- Dr. Howard Langstein (plaintiff's specific medical causation expert) (doc. nos. 218-4, 241-2);
- Dr. Prof. Uwe Klinge (plaintiff's general medical causation expert) (doc. no. 241-7);
- Dr. Russell F. Dunn (plaintiff's chemical engineering expert) (doc. no. 241-8); and
- Dr. Scott Guelcher (plaintiff's biomedical engineering expert) (doc. no. 241-9).

Atrium designed, manufactured, and marketed a surgical mesh product known as the "C-Qur V-Patch." The C-Qur V-Patch is intended for permanent implantation in the human body in connection with hernia repair surgeries. Plaintiff's medical, chemical engineering, and

biomedical engineering experts have offered their opinions that a product with the characteristics of the C-Qur V-Patch could cause an array of post-surgical complications, including infection. See doc. nos. 241-2 (Dr. Langstein), 241-7 (Dr. Klinge), 241-8 (Dr. Dunn), 241-9 (Dr. Guelcher).

On August 9, 2013, plaintiff Luna underwent repair of an umbilical hernia at Parkview Community Hospital in Riverside, California. Dr. Husted performed the surgery, during which he implanted the C-Qur V-Patch in plaintiff's abdomen.

On October 23, 2015, more than two years later, plaintiff was hospitalized after experiencing fevers and abdominal pain for at least a week. Doc. no. 241-4. A CT scan revealed an abdominal abscess that was later confirmed to be infected with staphylococcus aureus. Doc. nos. 241-4, 241-6. Plaintiff's specific medical causation expert, Dr. Langstein, has testified to his opinion that plaintiff's infection was caused by implantation of the C-Qur V-Patch in plaintiff's body. Doc. no. 241-2. Dr. Dada recommended that the C-Qur V-Patch be removed due to the risk that, if left inside her body, it could cause her infection to recur. Doc. no. 241-5, 27:6-9. Dr. Dada removed the mesh product the following day, October 24, 2015.

Plaintiff testified that she had no knowledge of the C-Qur V-Patch before it was implanted in her body and had never seen any television commercials about it or read any information about it before her surgery. See doc. no. 218-1, 102:11-18, 104:3-23. She further testified that she trusted her physicians to tell her the risks and benefits of any medical device that would be used in connection with her health care and to use such a device appropriately. See id., 95:5-16. Plaintiff also testified that, had she known prior to her surgery of an increased risk of infection from use of the C-Qur V-Patch, she would not have consented to its implantation in her body. See doc. no. 241-10, 156-158.

Dr. Husted, who performed plaintiff's first surgery, testified that he has "the final say" in whether to use a particular surgical mesh product when conducting a hernia repair. Doc. no. 241-3, 16:10-14. In making the decision to use a particular surgical mesh product, he generally relies on his own "surgical judgment" and "working knowledge" derived from his "years of practice" and "training," id., 17:15-22, 18:5-8, except that he "usually" learns specific "information on a particular mesh" product from the manufacturer's sales representatives, id., 18:8-11. It is Dr. Husted's practice to consider "[e]verything" when making such a decision, including, in particular, "everything about the patient." Id., 16:15-19. Among the factors Dr. Husted considers when making such a decision are whether surgery to repair the hernia is the best approach, and if so, whether there is a need for a surgical mesh product and whether use of a mesh product would result in increased risk of infection. See id., 16:19 - 7:9.[3]

However, Dr. Husted testified that he does not make the decision whether to use a particular mesh product entirely on his own. See id., 23:16 - 24:7. That is, Dr. Husted does not conduct his own "risk-benefit analysis" before making the decision to use a particular medical device, but rather relies on the "working assumption" that someone with purchasing authority at the hospital where he performs surgeries has conducted some form of such an analysis before he chooses whether to use the device. Id. At least With respect to devices with which he already

[3] Dr. Husted explained that, when selecting a surgical mesh product, he reviews the appearance and general description of the product to determine whether it is of the "class" of surgical mesh products appropriate for the needs of the particular surgical patient. Id., 110:15—111:5. In Dr. Husted's view, "coated meshes"—like the C-Qur V-Patch—"in general are . . . within the same class and generally used for the same indications because they kind of generally have the same degree of risk." Id., 111:13-16. That is, it is Dr. Husted's practice to treat mesh products within a given "class" as "equivalent" to one another. Id., 112:13-14.

has a degree of familiarity, he assumes that if his hospital has made a medical device available for use in surgeries "it must be okay if it looks okay." Id., 24:2-7.

At his deposition, Dr. Husted testified that, "[o]ff the top of [his] head," he did not have any specific recollection of contacts with defendant's sales representatives, id., 18:19-21, and he did not specifically recall having read the C-Qur V-Patch "instructions for use" or any other written materials included with the C-Qur V-Patch packaging before using the product in plaintiff's surgery, id., 112:15-23. In fact, Dr. Husted testified that he did not know if he had "ever even read the warnings part of any packing" or "read anything about warnings on any packages" associated with surgical mesh products. Id., 111:22-25. Dr. Husted also testified, however, that he "would never knowingly expose a patient to an unnecessary risk," id., 42:7-8, and that if he received "new information about the risk of a particular product," he would take that information into account in deciding whether to implant it in a patient, id., 24:8-11.

Dr. Husted specifically testified that if had he been told that "there were doctors throughout the country who were reporting increased rates of infection" associated with use of the C-Qur V-Patch, such information would have gotten his "attention" and made him "[l]ess likely" to use that product. Id., 82:13 - 83:9, 89:2-4. Similarly, Dr. Husted would have been less likely to choose to use defendant's product had he been told that physicians were reporting increased "infections with the V-Patch in multiple countries," that "the increased risk of infection was perceived across different medical centers and different surgeons," or that "Atrium's consultants were telling [Atrium] the[] mesh was causing infections." Id., 87:6-16; 88:12 - 89:4; 98:2-14. Dr. Husted did not recall anyone at Atrium ever advising him regarding any such reports of increased rates of infection. Id., 82:6-11; 87:6-10. And when asked whether he would have used the C-Qur V-Patch if he had known that "the company that makes the polypropylene"

used in manufacturing the mesh product "prohibited its use in permanent implantation in the body," Dr. Husted said that he would have had questions as to why his hospital would have purchased such a product. Id., 102:6-18. Dr. Husted expressed surprise verging on disbelief that his hospital would have purchased a surgical mesh product made from a material not intended for permanent implantation. Id., 102:11-18 ("If it's sitting on the shelf, how would we get it there if it's prohibited. I just wouldn't know.").

DISCUSSION

Under New Hampshire's consumer protection statute, it is "unlawful for any person to use any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within" the State of New Hampshire. RSA 358-A:2. In relevant part, such proscribed conduct includes, but is not limited to:

> V. Representing that goods . . . have . . . characteristics, ingredients, uses, benefits, or quantities that they do not have; [and]
>
> * * *
>
> IX. Advertising goods . . . with intent not to sell them as advertised. . . .

Id. California's consumer protection statute is identical in all material respects. See Cal. Civ. C. § 1770(a)(5), (9).

Plaintiff alleges that defendant violated the NHCPA and CCLRA "by knowingly and falsely representing" in marketing and promotional materials that the Defendant's C-Qur V-Patch "was fit to be used for the purpose for which it was intended while in fact it was defective and dangerous." Doc. no. 176, ¶ 164.

I. Plaintiff's NHCPA Claim

Defendant argues that plaintiff lacks standing to bring her NHCPA claim because the alleged misrepresentations or false advertising would have been received in California, where plaintiff's care providers (Dr. Husted and Parkview Community Hospital) are located.

Although the New Hampshire Supreme Court "has yet to address the territorial limitations" of the NHCPA, several decisions of this court have held that a NHCPA misrepresentation claim cannot be brought where premised on misrepresentations allegedly made in New Hampshire but received or heard by a consumer outside of New Hampshire. See BAE Sys. Info. & Elecs. Sys. Integration Inc. v. SpaceKey Components, Inc., No. 10-CV-370-LM, 2011 WL 1705592, at *4-5 (D.N.H. May 4, 2011) (holding that an out-of-state consumer cannot state a claim under New Hampshire's consumer protection law based on "conduct originating in New Hampshire that has an extraterritorial effect" where the consumer resides); Fujifilm N. Am. Corp. v. M&R Printing Equip., Inc., No. 20-CV-492-LM, 2021 WL 722861, at *8-9 (D.N.H. Feb. 24, 2021) (applying the rule announced in BAE to dismiss a NHCPA misrepresentation claim premised on misrepresentations regarding the characteristics of goods made by a New Hampshire entity in New Hampshire but received by consumers outside New Hampshire); Ortiz v. Sig Sauer, Inc., 448 F. Supp. 3d 89, 107-108 (D.N.H. 2020) (applying the rule announced in BAE to dismiss a NHCPA misrepresentation claim premised on misrepresentations made in New Hampshire and received by a consumer in Arizona).

Plaintiff does not dispute that Dr. Husted and the hospital that employed him made the decisions to purchase and use the C-Qur V-Patch in California. As a matter of law, it is therefore immaterial that defendant may have made misrepresentations or falsely advertised the C-Qur V-Patch in New Hampshire. A consumer who receives misrepresentations of goods or false

advertising outside of New Hampshire cannot state a claim under the NHCPA. See Fujifilm, 2021 WL 722861 at *8; Ortiz, 448 F. Supp. 3d at 107-108. It follows that defendant is entitled to summary judgment in its favor as to plaintiff's NHCPA claim.

II. Plaintiff's CCLRA Claim

As a matter of California law, to establish standing to bring a consumer protection law claim a consumer must show that she "suffered injury in fact . . . as a result of unfair competition." Veera v. Banana Republic, LLC, 6 Cal. App. 5th 907, 915 (2016) (quoting Kwikset Corp. v. Superior Court, 51 Cal. 4th 310, 320-321 (2011)) (discussing California's Unfair Competition Law ("UCL") but affirming that the CCLRA's standing requirements "are essentially identical to" those of the UCL). For purposes of establishing CCLRA standing, "[t]he phrase 'as a result of' . . . means 'caused by' and requires a showing of a causal connection or reliance on the alleged misrepresentation." Id.; see also Durell v. Sharp Healthcare, 183 Cal. App. 4th 1350, 1363 (2010) (the reliance requirement of consumer protection law standing "applies equally" when the claim is premised on misrepresentation or deception).

Defendant asserts that plaintiff lacks standing to pursue her CCLRA claim because she cannot prove the element of reliance. The sole argument defendant offers in support of its standing theory is that plaintiff could not have relied on any false representations because she did not make the decision to use the C-Qur V-Patch and did not see any advertising or representation regarding the product prior to her surgery, see doc. no. 218-1, 102:11-18, 104:3-23. The court agrees with defendant that plaintiff cannot establish that she personally relied on any advertising or representation regarding the C-Qur V-Patch but disagrees that the reliance inquiry begins and ends with the plaintiff herself.

In connection with plaintiff's failure to warn claim, defendant argues that the so-called "learned intermediary doctrine" necessarily governs its responsibility to provide warnings regarding the risks associated with the C-Qur V-Patch. Indeed, defendant takes plaintiff to task for offering argument regarding her testimony that she "would have . . . refused C-Qur V-Patch mesh if she knew more about its risks," criticizing such argument as an improper and unavailing "attempt to avoid the learned intermediary rule." Doc. no. 254 at 3, n. 4. However, defendant fails to acknowledge that to the extent it was plaintiff's medical providers who made the decision on plaintiff's behalf to purchase and use Atrium's product, it was those medical providers' reliance (if any) on defendant's advertising or representations that is at issue in connection with her CCLRA claim.

Where applicable, the learned intermediary doctrine holds that a manufacturer's duty to warn regarding the risks associated with a product runs to a patient's treating physician (or other learned intermediary) rather than directly to the patient. The parties and the court agree that, as a matter of New Hampshire law, the learned intermediary doctrine applies to duties owed by pharmaceutical manufacturers. See Bartlett v. Mut. Pharm. Co., 731 F. Supp. 2d 135, 145 (D.N.H. 2010), aff'd, 678 F.3d 30 (1st Cir. 2012), rev'd on other grounds, 570 U.S. 472 (2013); see also State v. Purdue Pharma, LP, No. 217-2017-CV-00402, 2018 N.H. Super. LEXIS 24, at *15 (Sep. 18, 2018). And while plaintiff argues that there is an unresolved question as to whether the doctrine applies to medical device manufacturers, plaintiff offers no rationale for distinguishing between the pharmaceutical and the medical device contexts for purposes of the doctrine. Courts that have considered the matter have uniformly found that the doctrine is applicable with equal force in both contexts. See, e.g., O'Connell v. Biomet, Inc., 250 P.3d 1278, 1281 (Colo. Ct. Appeal. 2010); Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1368 (S.D. Fla.

2007) (surveying cases). There being no principled ground for distinguishing pharmaceuticals from medical devices in this context, the court assumes for the purposes of this motion that the learned intermediary doctrine applies to a medical device manufacturer's duty to warn regarding risks associated with its products.

Dr. Husted, plaintiff's implanting surgeon, did not consider any advertising or affirmative representations regarding the C-Qur V-Patch before making the decision to use it in plaintiff's surgery. See doc. no. 241-3, 111:13-16, 111:22-25, 112:13-23. However, viewing the evidence in the light most favorable to plaintiff, a jury could reasonably find on the basis of Dr. Husted's testimony that he "usually" received "information on a particular mesh" from manufacturers' sales representatives, id., 18:8-11, and that, notwithstanding Dr. Husted's lack of specific recollection of contacts with defendant's sales representatives, id., 18:19-21, defendant had opportunities to convey any reasonably necessary warnings regarding the C-Qur V-Patch to Dr. Husted prior to plaintiff's surgery. And a jury could also reasonably find both that defendant failed to warn Dr. Husted regarding any increased infection risk and that Dr. Husted relied on that omission[4] when he elected to use defendant's surgical mesh product. A jury could so find based on Dr. Husted's testimony that warnings regarding increased rates of infection associated with the C-Qur Patch would have gotten his "attention" and made him "less likely" to use it, id.,

[4] An omission is actionable under the CCLRA "if the omitted fact is (1) contrary to a material representation actually made by the defendant or (2) is a fact the defendant was obliged to disclose." Gutierrez v. Carmax Auto Superstores Cal., 19 Cal. App. 5th 1234, 1258 (2018) (citations, internal quotation marks, and modifications omitted). A defendant is obliged to disclose a fact if the defendant "has exclusive knowledge of material facts not known or reasonably accessible to the plaintiff," "actively conceals a material fact," or "makes partial representations that are misleading because some other material fact has not been disclosed." Id. (citations and internal quotation marks omitted). For purposes of the CCLRA, a fact is material "if a reasonable consumer would deem it important in determining how to act in the transaction at issue." Id.

82:13 - 83:9, 89:2-4, 87:6-16; 88:12 - 89:4; 98:2-14, that he "would never knowingly expose a patient to an unnecessary risk," id., 42:7-8, and that if he received "new information about the risk of a particular product," he would take that information into account in deciding whether to implant it in a patient, id., 24:8-11. Similarly, a jury could reasonably find that, in choosing the defendant's product, Dr. Husted also relied on defendant's failure to disclose the polypropylene manufacturer's warning that its product should not be permanently implanted in a human body. Dr. Husted testified that he "wouldn't even know where to go with that" information and seemed surprised at the suggestion that a hospital would have put such a product on the shelf for doctors like himself to use. Id., 102:6-18.

Moreover, the record establishes that Dr. Husted did not make the decision to purchase the C-Qur V-Patch for the use of surgeons at Parkview Community Hospital. See id., 23:16 - 23:7. That decision was made by a person or persons not identified in the record now before the court. The record further establishes that when Dr. Husted decides whether to use a surgical mesh product for a specific surgery, he relies in part on a "risk-benefit analysis" that he assumes was performed by someone at Parkview Community Hospital at the time the product was originally purchased. Id., 23:16 - 24:1-7. The testimony of Dr. Husted raises the reasonable inference that he (or whomever at the hospital exercised authority to purchase surgical products for the hospital) would not have chosen defendant's product had it been accompanied by appropriate warnings (i.e., that its use was associated with increased risk of infection or that the material used in its manufacturer was not intended for permanent implantation in the body).

At trial, plaintiff will need to establish the element of reliance in connection with her CCLRA claim. The record does not conclusively show that she will persuade a jury on this issue on at trial. However, in light of Husted's testimony that he would have been less likely to choose

defendant's product had defendant warned him about its risks, and in the absence of material evidence regarding the basis for the hospital's decision to purchase the C-Qur V-Patch, the court cannot find that defendant has established its entitlement to summary judgment.

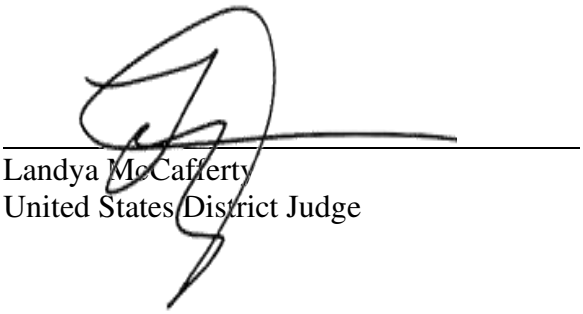
For all of these reasons, the court denies defendant's motion as to plaintiff's CCLRA claim.

CONCLUSION

For the reasons discussed above, the court (1) grants defendant's summary judgment motion (doc. no. 217) as to plaintiff's New Hampshire Consumer Protection Act claim, (2) denies the motion as to plaintiff's California Consumer Legal Remedies Act claim, and (3) denies the motion as moot to the extent it addresses plaintiff's strict liability/manufacturing defect (Count III), express warranty (Count V), and implied warranty (Count VI) claims.

Remaining for trial are the following claims: negligence (Count I), strict liability/design defect (Count II), strict liability/failure to warn (Count IV), and California Consumer Legal Remedies Act (Count VII).

SO ORDERED.



Landya McCafferty
United States District Judge

May 14, 2021

cc: Counsel of Record.