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FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

IN RE: ALLODERM® LITIGATION

CASE CODE 295

MICHAEL SIMINERI and KAREN SIMINERI, h/w,

Plaintiffs,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-5972-11 CM

Civil Action

ORDER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order granting summary judgment and dismissing plaintiffs' product liability claim based on a failure to warn, and the Court having considered all papers submitted by the parties, and for good cause and the reasons in the attached memorandum of decision, ~~stated on the record by the Court~~,

It is on this the 14th day of August, 2015,

ORDERED that defendant's motion is hereby ~~granted~~ denied*; and it is further

~~ORDERED that plaintiffs' product liability claim based on a failure to warn is dismissed with prejudice and without costs~~; and it is further

* for the reasons set forth in the court's memorandum of decision dated August 14, 2015

ORDERED that a copy of this Order be ~~served~~ posted online by on all counsel of record within 7 days hereof.

8/14/18

Hon. Jessica R. Mayer, J.S.C.

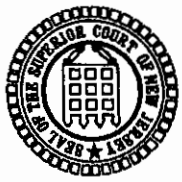
OPPOSED

PAPERS CONSIDERED

	Yes	No	Date
Notice of Motion	✓		
Movant's Affidavits	✓		
Movant's Brief	✓		
Answering Affidavits	✓		
Answering Brief	✓		
Cross Motion	✓		
Movant's Reply			
Other			

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.
JUDGE



MIDDLESEX COUNTY COURTHOUSE
P.O. BOX 964
NEW BRUNSWICK, NEW JERSEY 08903-964

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendant's Motion for Summary Judgment as to Plaintiffs' Claim for Failure-to-Warn

In Re: AlloDerm® Litigation, Case Code 295

Michael Simineri and Karen Simineri v. LifeCell Corporation

Docket No. MID-L-5972-11 CM

For Plaintiffs: Lawrence R. Cohan, Esq., Adrianne W. Webb, Esq., Joseph J. Fantini, Esq., Paola Saneaux, Esq., Sol H. Weiss, Esq., Anapol Schwartz.

For Defendant: David W. Field, Esq., Stephen R. Buckingham, Esq., Joseph A. Fischetti, Esq., Lowenstein Sandler LLP.

Dated August 14, 2015

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves for summary judgment as to the claim asserted by plaintiffs Michael and Karen Simineri ("Plaintiffs") for failure-to-warn. The court, in addressing Defendant's motion, reviewed the parties' filed submissions and the written arguments of counsel. Counsel agreed to waive oral argument and consented to the court's disposition of the motion on the papers submitted. The following memorandum of decision sets forth the court's disposition of LifeCell's motion.[1]

[1] The parties signed a consent order stipulating that New Jersey law governs all issues in the AlloDerm® cases. See Consent Order dated January 15, 2015.

I. Background

Defendant, LifeCell, manufactures and sells AlloDerm® Regenerative Tissue Matrix ("AlloDerm®"). AlloDerm® is a type of soft tissue graft derived from human cadaver skin.[2] LifeCell originally developed AlloDerm® in the 1990s for use in the treatment of burn victims.[3] LifeCell was later used by surgeons and sold by LifeCell for other applications including periodontal and breast reconstruction surgery.[4] In the late 1990s, some surgeons began using AlloDerm® for complex hernia repairs and, thereafter, LifeCell began promoting AlloDerm® for hernia repair.[5]

Plaintiff, Michael Simineri, is a 54-year-old Pennsylvania resident with a long history of obesity.[6] Mr. Simineri also has a history of diabetes, hyperlipidemia, and hypertension.[7] In 2002, Mr. Simineri underwent a gastric bypass surgery in an effort to control his weight.[8] In April 2005, Mr. Simineri was diagnosed with a small incisional hernia at the same location as his previous gastric bypass surgery.[9] Incisional hernias are a common medical problem occurring in patients' abdominal walls at the site of prior surgical incisions.[10] Incisional hernias may be repaired in a variety of ways including just suturing, known as primary closure, or with the reinforcement of a

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[2] Brief in Support of Defendant's Motion for Summary Judgment ("Def.'s Br.") 1.
[3] Ibid.
[4] Ibid.
[5] Plaintiffs' Brief in Opposition to Summary Judgment ("Pls.' Opp.") 3; Certification of Joseph Fantini ("Fantini Cert."), Ex. M.
[6] Certification of David Field ("Field Cert."), Ex. A, Deposition of Michael Simineri ("Simineri Dep.") 9:13-15; Ex. B.
[7] Field Cert., Ex. E, Deposition of Dr. Gerardo Garcia ("Garcia Dep.") 109:1-21.
[8] Pls.' Opp. 5.
[9] Ibid.
[10] Field Cert., Ex. C, Expert Report of Dr. Gregory Dumanian, 3–4.

synthetic mesh or a biologic graft such as AlloDerm®.[11] For Mr. Simineri's first hernia surgery, his surgeon, Dr. Gerardo Garcia, performed a primary repair, meaning that the surgeon closed the hernia solely with sutures.[12]

In August of 2007, Mr. Simineri began experiencing abdominal pain and returned to Dr. Garcia.[13] Dr. Garcia diagnosed Mr. Simineri with a recurrent hernia and gallstones.[14] Dr. Garcia planned to repair the hernia using either synthetic mesh or AlloDerm® and, at the same time, to perform a cholecystectomy to remove the gallstones.[15] On October 24, 2007, Dr. Garcia performed a laparoscopic cholecystectomy to remove the gallstones and then repaired Mr. Simineri's recurrent hernia using AlloDerm®.[16] Dr. Garcia implanted the AlloDerm® graft using an underlay technique by placing the AlloDerm® inside the abdomen and closing the tissues, muscle and fascia over the AlloDerm®, with the AlloDerm® reinforcing the repair.[17]

Dr. Garcia testified that he used AlloDerm® rather than a synthetic mesh due to the risk of infection inherent with a simultaneous gallstone surgery.[18] At his deposition, Dr. Garcia explained: "When we are doing surgery on the biliary tree, it usually is contaminated with bacteria. If we put a synthetic mesh, then it's a potential infection for the synthetic mesh. AlloDerm doesn't cause that infection, at least it will not cause an infection in a contaminated field."[19]

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[11] Ibid.
[12] Pls.' Opp. 5.
[13] Field Cert., Ex. I.
[14] Ibid.
[15] Ibid.
[16] Pls.' Opp. 5.
[17] Field Cert., Ex. E, Garcia Dep. 34:8-16, 58:14-59:9.
[18] Id. at 48:17-49:24.
[19] Ibid.

Prior to the October 2007 surgery, Mr. Simineri discussed the procedure with Dr. Garcia and signed a consent form which stated:

> I am aware that there exists in any operation and/or diagnostic procedure some degree of risk and incidence of complications in spite of all reasonable and customary precautions taken by the physician . . . . I ACKNOWLEDGE THAT NO GUARANTEE OR ASSURANCE HAS BEEN MADE TO ME AS TO THE RESULT OF THE ABOVE NAMED PROCEDURE.[20]

Mr. Simineri also signed a form titled "PROCEDURE EDUCATION LITERATURE" which stated in part: "The majority of hernia repairs are successful and last forever. With time, however, any hernia can recur. Recurrence is more common with: large hernia repairs, re-do repairs, in obese patients, and perhaps even in diabetics or in patients with immune disorders."[21]

Following his October 2007 surgery, Mr. Simineri returned for follow-up visits with Dr. Garcia on November 8, 2007, and December 11, 2007, at which time he expressed no problems as a result of the hernia surgery.[22] In April of 2010, Mr. Simineri returned to Dr. Garcia complaining of a painful bulge "for approximately four weeks" which Mr. Simineri first noticed "after doing some lifting at work."[23] Dr. Garcia diagnosed Mr. Simineri with a recurrent incisional hernia at the same location as the previous hernia repaired in October of 2007.[24] Dr. Garcia advised Mr. Simineri that he should undergo a laparoscopic repair of the recurrent hernia.[25] Mr. Simineri asked to postpone the surgery because of his work schedule.[26] Dr. Garcia ultimately repaired the recurrent

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[20] Field Cert., Ex. G. (emphasis in original).
[21] Field Cert., Ex. F, 2; Field Cert., Ex. E, Garcia Dep. 116:16-118:11.
[22] Fantini Cert., Ex. C, Garcia Dep. 68:8-71:7.
[23] Id. at 78:5-14.
[24] Id. at 80:3-23.
[25] Field Cert., Ex. K.
[26] Id.

January 3, 2011, using a synthetic mesh.[27] Dr. Garcia decided to use a synthetic mesh during this operation because, unlike the October 2007 surgery, there was no risk of infection: "Like I mentioned before, typically, when I do involve either biliary or bowel surgery, I don't use synthetic. I will use a biologic. In this situation, it was just a straightforward hernia repair, so I usually use just synthetic."[28] Mr. Simineri's January 2011 hernia repair was apparently successful as he has not experienced hernia recurrence.[29]

Plaintiffs filed a complaint based on the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. § 2A:58C-1 et seq., alleging, in part, that LifeCell failed to adequately warn Plaintiffs of the risks associated with the use of AlloDerm® in abdominal ventral hernia repair.[30] Plaintiffs allege that LifeCell failed to warn that AlloDerm® presents a significantly higher risk of recurrence than other hernia repair products on the market at the time of Mr. Simineri's October 2007 surgery. Plaintiffs also allege that LifeCell failed to warn of the risks of painful bulging resulting from the purported tendency of AlloDerm® grafts to thin and stretch in the patient post-operatively. Mr. Simineri's alleged injuries include the pain resulting from the bulging of the AlloDerm® leading up to his 2010 hernia surgery as well as the pain and attendant difficulties resulting from the need for an additional hernia surgery in 2011.[31]

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[27] Field Cert., Ex. E, Garcia Dep. 90:7-14.
[28] Fantini Cert., Ex. C, Garcia Dep. 87:12-18.
[29] Fantini Cert., Ex. D, Dr. Huckfeldt's Specific Causation Report on behalf of Michael Simineri ("Huckfeldt Specific Causation Report") 2.
[30] Pls.' Opp. 1.
[31] Pls.' Opp. 1.

II. Legal Analysis

A. Defendant's Motion

Defendant LifeCell seeks summary judgment on Plaintiffs' failure-to-warn claim based on two theories. First, LifeCell argues that Plaintiffs are unable to establish proximate cause under New Jersey law because they are unable to prove that additional warnings provided to Mr. Simineri's implanting surgeon would have changed the decision to use AlloDerm® in 2007.[32] It is LifeCell's position that Plaintiffs' claim is premised solely on a failure to warn of a risk of hernia recurrence and thus, because there is a risk of recurrence with any hernia procedure—regardless of the product used—and because Dr. Garcia knew of the risk, discussed the risk with Mr. Simineri, presented literature and a consent form to Mr. Simineri and still chose to use AlloDerm® despite the risk, Plaintiffs are unable to establish that any stronger warnings would have deterred Dr. Garcia from using AlloDerm® for Mr. Simineri's hernia repair.

Secondly, LifeCell argues that Plaintiffs allege "nothing more than lack of efficacy, and not any unsafe property of AlloDerm®.[33]" LifeCell contends that because a failure-to-warn claim under the NJPLA must be premised on a failure to warn of a "danger" or "side effect" posed by a product, Plaintiffs' claim must fail because Plaintiffs merely allege that AlloDerm® was unsuccessful in treating Mr. Simineri's recurrent hernia.[34] Thus, LifeCell argues that Mr. Simineri's recurrence is not the type of "danger" contemplated by the NJPLA. See N.J.S.A. § 2A:58C-4.

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[32] Def.'s Br. 9.
[33] Def.'s Br. 14.
[34] Def.'s Br. 15.

B. Plaintiffs' Opposition

Plaintiffs oppose LifeCell's motion, contending that LifeCell fails to appreciate the multitude of risks against which Plaintiffs allege LifeCell failed to warn.[35] Plaintiffs dispute LifeCell's argument that their claim is only the failure-to-warn of the risk of hernia recurrence.[36] Rather, Plaintiffs allege that LifeCell failed to warn of a risk of recurrence "significantly higher than other biologic materials."[37] Furthermore, Plaintiffs contend that LifeCell failed to warn of the alleged mechanisms of AlloDerm® failure, i.e. thinning, bulging, and stretching, and that these mechanisms could result in painful bulging preceding the onset of recurrence.[38] Plaintiffs counter that despite Dr. Garcia's general awareness of the risk of recurrence, LifeCell failed to "provide anywhere near the amount of evidence" to overcome New Jersey's "heeding presumption." Thus, according to Plaintiffs, LifeCell's motion must be denied as a jury should determine whether a stronger warning would have changed Dr. Garcia's decision to use AlloDerm® in Mr. Simineri's hernia repair.[39]

C. Summary Judgment Standard

"A party seeking any affirmative relief may . . . move for a summary judgment or order on all or any part thereof or as to any defense." R. 4:46-1. Summary judgment may be rendered as to "any issue in the action . . . although there is a genuine factual dispute as to any other issue . . . ." R. 4:46-2(c). Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no

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[35] Pls.' Opp. 1.
[36] Ibid.
[37] Ibid.
[38] Id. at 1–2.
[39] Pls.' Opp. 2.

genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." Ibid. In considering a motion for summary judgment, the court should determine whether "the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 540 (1995). "If there exists a single, unavoidable resolution of the alleged disputed issue of fact, that issue should be considered insufficient to constitute a 'genuine' issue of material fact for purposes of Rule 4:46-2." Ibid.

D. The New Jersey Products Liability Act

In New Jersey, all products liability actions are governed by the New Jersey Products Liability Act, N.J.S.A. § 2A:58C-1 et seq. The NJPLA encompasses "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C-1(b)(3). Under the NJPLA:

> [a] manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.
>
> [N.J.S.A. § 2A:58C-2]

With respect to failure to warn claims, generally, the NJPLA explains:

> [i]n any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonable should discover after the product leaves its control, if the manufacturer or seller provides

> an adequate warning or instruction. An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.
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> [N.J.S.A. § 2A:58C-4 (emphasis added).]

This subsection of the NJPLA incorporates New Jersey's "learned intermediary" doctrine, whereby the manufacturer fulfills its obligation by providing the appropriate warning to the prescribing physician or surgeon.[40] See Banner v. Hoffmann-La Roche Inc., 383 N.J. Super. 364, 375–76 (App. Div. 2006), certif. denied, 190 N.J. 393 (2007); Niemiera v. Schneider, 114 N.J. 550, 559 (1989).

Under New Jersey case law, a manufacturer has a duty to warn of all adverse effects of a prescription medical product "of which they know or should have known on the basis of reasonably obtainable or available knowledge." See Feldman v. Lederle Lab., 97 N.J. 429, 434 (1984); see also In re Diet Drug Litig., 384 N.J. Super. 525, 534 (Law Div. 2005). "Causation is a fundamental requisite for establishing any product-liability action." James v. Bessemer Processing Co., 155 N.J. 279, 297 (1998) (quoting Coffman v. Keene Corp., 133 N.J. 581, 594 (1993)). Thus, to succeed on a claim for failure-to-warn, in addition to demonstrating inadequacy of the warning,[41] a plaintiff must also prove that an adequate warning or instruction would have prevented his

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[40] This court determined that the learned intermediary doctrine applies to human tissue products such as AlloDerm®. See Order and Memorandum of Decision in Simineri v. LifeCell Corporation, dated, May 8, 2015. Based upon that ruling, LifeCell was required to warn Mr. Simineri's implanting surgeon, Dr. Garcia, as to the risks associated with the use of AlloDerm®.

[41] Although LifeCell disputes Plaintiffs' claim that the warnings and instructions for AlloDerm® were inadequate, LifeCell does not argue that the court should find the AlloDerm® warnings and instructions were adequate as a matter of law. Thus, the court will not address this issue and Plaintiffs ultimately bear the burden of proving that the warnings and instructions accompanying AlloDerm® were insufficient to apprise Mr. Simineri and Dr. Garcia of the risks associated with AlloDerm®.

injuries. Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 209 (1984). In a pharmaceutical product liability action, a plaintiff must "demonstrate so-called product-defect causation – that the defect in the product was a proximate cause of the injury. When the alleged defect is the failure to provide warnings, a plaintiff is required to prove that the absence of a warning was a proximate cause of his harm." James, supra, 155 N.J. at 297 (quoting Coffman, supra, 133 N.J. at 594). In other words, a plaintiff must prove that an adequate warning, if provided, would have prevented the plaintiff from using the prescription drug or product in question. See Perez v. Wyeth Labs. Inc., 161 N.J. 1, 28 (1999). It follows that regardless of the warning provided, a defendant will not be liable if "the prescribing physician either did not read the warning at all, and thus did not rely on any information from the manufacturer in prescribing the product, or if the physician was aware of the risk from other sources and considered the risk in prescribing the product." Ibid. (quoting Richard J. Heafey & Don M. Kennedy, Products Liability: Winning Strategies and Techniques § 10.03 (1999) (footnotes omitted)).

However, "[d]ue to the individualized nature of the inquiry into what warning would have caused the plaintiff to alter her behavior . . . predicting how additional information would have affected any given individual may be well nigh impossible." Ibid. (quoting Lloyd C. Chatfield II, Medical Implant Litigation and Failure to Warn: A New Extension for the Learned Intermediary Rule, 82 Ky. L.J. 575, 582–83 (1993-94) (footnotes omitted)). To counter this difficulty, New Jersey adopted the "heeding presumption." See Coffman, supra, 133 N.J. at 597–98. The heeding presumption "provides the plaintiff with a rebuttable presumption on the issue of proximate cause [that], if a[n] [adequate] warning or instruction had been given, such warning or instruction would have been heeded by the plaintiff." Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 68 (App. Div. 1998), aff'd o.b., 158 N.J. 329 (1999). Where the heeding presumption applies:

> [T]he burden of production on the issue of proximate cause shifts to the defendant to come forward with rebuttal evidence. In essence, the defendant's burden of production requires evidence sufficient to demonstrate . . . that a warning would have made known to the plaintiff the danger of the product and, notwithstanding the knowledge imparted by the warning, the plaintiff would have proceeded voluntarily and unreasonably to subject him or herself to the dangerous product. . . . If the defendant fails to meet its burden of production to the trial court's satisfaction, the trial judge is required to direct a verdict in favor of the plaintiff on the issue of proximate causation. If, however, the defendant presents rebuttal evidence such that reasonable minds could differ as to whether the warning, if given, would have been heeded by the plaintiff, the defendant has satisfied its burden of production and the plaintiff loses the benefit of the presumption. The plaintiff must then carry the burden of persuasion as to proximate cause.
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> [Sharpe, supra, 314 N.J. Super. at 68–69 (internal citations and quotations omitted).]

Even in cases in which the prescribing physician did not know of the risk, summary judgment for the manufacturer may be appropriate where the physician testifies that, if provided with an adequate warning, the physician would still have used the product and would not have communicated the risks to the patient. See In re Diet Drug, supra, 384 N.J. Super. at 545. However, where the physician indicates that he would have communicated the risk to the patient, there remains a factual question regarding proximate cause. Ibid.

E. Proximate Cause

LifeCell's argument for summary judgment on Plaintiffs' failure-to-warn claim is premised on the incorrect assertion that the only injury Mr. Simineri alleges is hernia recurrence. According to LifeCell, the only warnings relevant to Plaintiffs' claims are warnings regarding the risk of recurrence.[42] Because Dr. Garcia was aware of a risk of recurrence in any hernia surgery, LifeCell

[42] Def.'s Br. 11.

argues that no warning would have changed Dr. Garcia's decision to use AlloDerm® for Mr. Simineri's surgery. Thus, according to LifeCell, Plaintiffs cannot prove proximate cause.

In support of its motion, LifeCell relies on Dr. Garcia's testimony that he used AlloDerm® instead of a synthetic mesh because Mr. Simineri's simultaneous gallbladder surgery presented a potential for bacterial contamination. As Dr. Garcia explained at his deposition:

> Q. So are you able to tell us why it is that at this time, in August of 2007, that you are recommending to Mr. Simineri that AlloDerm® potentially would be used for his repair?
>
> A. Yes. In this case, it's because of the gallstones. When we are doing surgery on the biliary tree, it usually is contaminated with bacteria. If we put a synthetic mesh, then it's a potential infection for the synthetic mesh. AlloDerm® doesn't cause that infection, at least it will not cause an infection in a contaminated field.
>
> Q. So I am sorry. I missed the first part of your answer. So what was the bacteria from that you were concerned about?
>
> A. When we were doing surgery for the gallbladder –
>
> Q. Okay.
>
> A. – if there is any spillage of the bile, it's potentially contaminated with bacteria. So if I am going to put a synthetic mesh, potentially it can get infected, and it will be a disaster for the patient. So I wrote there AlloDerm® because of that fact, that he might ending up having a spillage of bile, and said I will not use synthetic, I will use the AlloDerm® or the biologic.[43]

Dr. Garcia further testified:

> Patients with an infected mesh, they get a lot of complications. They can develop sepsis, they can develop a fistula, they can develop an abdominal wall infection that we have to intervene, go back, remove the infected mesh and try to repair the best we can, not necessarily with any type of mesh, just with their own tissues. And in those

[43] Field Cert., Ex. E, Garcia Dep. 48:17-49:24.

> situations, in my, you know, sixteen years of practice, it is not a pretty picture.[44]

Thus, it was Dr. Garcia's medical judgment that the use of a synthetic hernia mesh was not a viable option for Mr. Simineri.[45] Because of the potential for infection, LifeCell argues that Dr. Garcia would not have used another product regardless of AlloDerm®'s warning.

LifeCell further notes that Dr. Garcia was well aware of the risk of recurrence in hernia repairs and explained that risk to Mr. Simineri. Indeed, at his deposition, Dr. Garcia conceded that recurrences can occur with any hernia repair:

> Q. Is it a fair conclusion that you intend every one of your hernia repairs to be a permanent solution?
>
> A. Yes.
>
> Q. But in your experience of 20-plus years as a surgeon, you know hernias recur, correct?
>
> A. Yes.[46]

Additionally, LifeCell relies on the "PROCEDURE EDUCATION LITERATURE" form Mr. Simineri signed before his 2007 hernia surgery.[47] That form states, in a box titled "Expectations for Outcome":

> There may be significant swelling or bruising (black and blue discoloration) at the area of incision and in the surrounding area. Recovery time varies from patient to patient and is dependent on the size, location, and complexity of the repair. The majority of hernia repairs are successful and last forever. With time, however, any hernia can recur. Recurrence is more common with: large hernia repairs, re-do repairs, in obese patients, and perhaps even in diabetics or in patients with immune disorders (or on steroids) in which tissue healing may be somewhat compromised.[48]

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[44] Id. at 128:16-129:2.

[45] Def.'s Br. 11.

[46] Field Cert., Ex. E, Garcia Dep. 111:17-24.

[47] Field Cert., Ex. E.

[48] Field Cert., Ex. F (emphasis added).

LifeCell argues because synthetic mesh was not a viable option and because Dr. Garcia understood that there is always a risk of recurrence and communicated that risk to Mr. Simineri, no warning would have changed the decision to use AlloDerm® to repair Mr. Simineri's hernia. Therefore, according to LifeCell, summary judgment must be granted because Plaintiffs are unable to prove that any failure-to-warn was a proximate cause of Mr. Simineri's injury.[49]

Plaintiffs, on the other hand, dispute LifeCell's characterization and limitation of their claims. Plaintiffs contend that LifeCell not only had an obligation to provide warnings regarding the risk of recurrence typical of any hernia repair, but that LifeCell had an obligation to warn of the allegedly "significantly higher" risk of recurrence for AlloDerm® as compared to other biologic materials used for hernia repairs.[50] Additionally, Plaintiffs contend that LifeCell had an obligation to warn of the alleged risk that AlloDerm® could thin and stretch post-operatively leading to painful bulging.[51] Plaintiffs claim that AlloDerm®'s purported thinning and stretching led to Mr. Simineri's painful bulge which became a recurrent hernia and resulted in "unnecessary, invasive, additional surgery" as well as scarring, mental pain, increased risk for future hernias, and other injuries.[52]

Plaintiffs note that before Dr. Garcia determines the appropriate treatment and medical product for a given patient, he performs a risk-benefit analysis:

> Q. As a doctor, before you recommend a prescription or a product, do you perform a risk benefit analysis to determine whether the product or prescription is appropriate for a particular patient?

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[49] Def.'s Br. 11.
[50] Pls.' Opp. 11.
[51] Ibid.
[52] Ibid.

A. I typically do.[53]

In considering what medical product to use for a particular patient, Dr. Garcia testified that he considers "the patient's conditions . . . if he has any comorbidities, and any potential factors that may influence in my decision what products I am going to use. And I will explain that to the patient ahead of time.[54]" Dr. Garcia further testified that in conducting his risk-benefit analysis he relies on material from seminars, websites, and from information provided by the manufacturers' sales representatives.[55] Dr. Garcia also testified that although he cannot specifically recall reading the instructions for AlloDerm®, he typically does read the instructions for use ("IFU") before using a medical product.[56]

In sum, Plaintiffs argue that: (1) although Dr. Garcia was aware of a risk of recurrence generally, he was not aware of the significantly higher risks of thinning, stretching, and recurrence presented by AlloDerm®; (2) Dr. Garcia would have read the IFU accompanying AlloDerm®; (3) an adequate warning may have changed Dr. Garcia's decision to use AlloDerm®; and (4) LifeCell has not presented sufficient evidence to overcome New Jersey's heeding presumption in this case.

Considering the evidence in the light most favorable to Plaintiffs, the court cannot conclude that LifeCell is entitled to summary judgment on the issue of proximate cause as a matter of law. While LifeCell has come forward with evidence tending to rebut the heeding presumption as part of its burden of production that Dr. Garcia was aware of a risk of hernia recurrence and prefers using biologics in hernia repairs when there is a risk of infection—this creates a factual dispute as

[53] Fantini Cert., Ex. C, Garcia Dep. 98:8-14.
[54] Id. at 98:19-99:1.
[55] Id. at 99:5-10.
[56] Id. at 33:16-34:4.

to proximate cause returning the burden to Plaintiffs to prove their claims by presenting evidence to a jury on their failure-to-warn claim.

Dr. Garcia indicated that it was his "preference" to use a biologic when there is a risk of infection in a hernia repair.[57] However, Dr. Garcia did not testify that AlloDerm® was the only option for Mr. Simineri's surgery or that Dr. Garcia would never have considered using a different biologic material. In fact, there were other biologic hernia repair products on the market that Dr. Garcia might have used instead of AlloDerm®.[58] Additionally, although Dr. Garcia was aware of the risk of recurrence with hernia repair and communicated that risk to Mr. Simineri, there is a genuine factual dispute as to the specific risks inherent in the use of AlloDerm® for hernia repair. Plaintiffs claim that there was a significantly higher risk of recurrence for AlloDerm® as compared with other biologic products available at the time of Mr. Simineri's surgery.[59] Furthermore, Plaintiffs assert injuries beyond mere hernia recurrence due to the alleged mechanisms of AlloDerm® failure—post-operative thinning and stretching—which purportedly caused painful bulging in Mr. Simineri's abdomen prior to his 2011 surgery.

LifeCell's motion cites cases in which the treating doctors' clear and unequivocal testimony demonstrated that no different warning would have changed the doctors' decisions to

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[57] Fantini Cert., Ex. C, Garcia Dep. 29:24-30.

[58] Fantini Cert., Ex. D, Huckfeldt Specific Causation Expert Report.

[59] In its reply papers, LifeCell asserts that because Dr. Garcia knew that AlloDerm® carried some risk of recurrence, the manufacturer is not required to warn as to the extent or likelihood of recurrence. For this proposition, LifeCell relies on Calabrese v. Trenton State Coll., 162 N.J. Super. 145 (App. Div. 1978), aff'd, 82 N.J. 321 (1980). However, such reliance is misplaced. In Calabrese, the plaintiff suffered debilitating effects from a rabies vaccine which was administered after a dog bite. At the time, it was unknown whether the dog actually had rabies. The plaintiff argued that, due to the statistical rarity of rabies and the extreme nature of the side effects of the vaccine, the manufacturer should have included statistical data on the incidence of rabies. The court rejected this claim. However, there was no discussion of a requirement to report the incidence of the side effects. LifeCell cites no other New Jersey cases to support its argument.

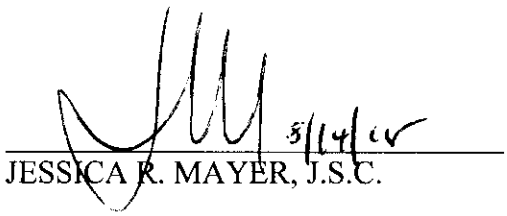
use the product in question. See, e.g., Strumph v. Schering Corp., 256 N.J. Super. 309, 328 (App. Div. 1992), rev'd on dissent, 133 N.J. 33 (1993). In the present case, neither Dr. Garcia nor Mr. Simineri presented such unequivocal testimony that would lead the court to conclude, as a matter of law, that no stronger warning would have affected Dr. Garcia's decision to use AlloDerm®. Considering the evidence in the light most favorable to Plaintiffs, and assuming for the purpose of this motion, as this court must, that Plaintiffs may be able to prove that AlloDerm® poses risks of thinning, stretching, and recurrence above and beyond that which Dr. Garcia understood to be inherent in any hernia repair product, the court cannot say as a matter of law that a stronger warning would not have persuaded Dr. Garcia to use something other than AlloDerm® in Mr. Simineri's hernia repair.

F. Efficacy

Alternatively, LifeCell argues that Plaintiffs' failure-to-warn claim alleges nothing more than that AlloDerm® was ineffective in repairing Mr. Simineri's hernia. However, the court finds that Plaintiffs' claim goes beyond simply alleging that AlloDerm® was an ineffective treatment for his hernia. The court finds that lack of efficacy is not a separate claim advanced Plaintiffs in their complaint. Plaintiffs claim that AlloDerm® poses significantly higher risks of recurrence as compared to other hernia repair products and presents risks of post-operative thinning and stretching leading to additional pain and injuries. The lack of efficacy is a part of Plaintiffs' claims that LifeCell failed to warn of the risks associated with AlloDerm®. Thus, LifeCell's lack-of-efficacy argument fails for the same reasons as LifeCell's failure-to-warn argument.

Conclusion

For the reasons set forth above, Defendant's motion for summary judgment as to Plaintiffs' failure-to-warn claim is **DENIED.**



JESSICA R. MAYER, J.S.C.

#01623
05-07-15

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LifeCell Corporation

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

IN RE: ALLODERM® LITIGATION

CASE CODE 295

PATRICIA JULIEN,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-507-12 CM

Civil Action

ORDER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order granting summary judgment dismissing plaintiff's product liability claim based on failure to warn, and the Court having considered all papers submitted by the parties, and for good cause and the reasons ~~stated on the record by the Court~~ in the attached memorandum of decision,

It is on this the 14th day of August, 2015,

ORDERED that defendant's motion is hereby granted*; and it is further

ORDERED that plaintiff's product liability claim based on failure to warn is hereby dismissed with prejudice and without costs; and it is further

* for the reasons set forth in the court's memorandum of decision dated August 14, 2015.

ORDERED that a copy of this Order be served on all counsel of record within 1 days hereof.

8/14/14

Hon. Jessica R. Mayer, J.S.C.

OPPOSED

PAPERS CONSIDERED

	Yes	No	Date
Notice of Motion	✓		
Movant's Affidavits	✓		
Movant's Brief	✓		
Answering Affidavits	✓		
Answering Brief	✓		
Cross Motion			
Movant's Reply	✓		
Other			

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.

MIDDLESEX COUNTY COURT HOUSE
P.O. Box 964
NEW BRUNSWICK, NEW JERSEY 08903-64

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendant's Motion for Summary Judgment as to Plaintiff's Claim for Failure-to-Warn

In re: AlloDerm® Litigation, Case Code 295

Patricia Julien v. LifeCell Corporation,
Docket No. MID-L-507-12 CM

For Plaintiffs: Lawrence R. Cohan, Esq., Adrianne W. Webb, Esq., Joseph J. Fantini, Esq., Paola Saneaux, Esq., Sol H. Weiss, Esq., Anapol Schwartz.

For Defendant: David W. Field, Esq., Stephen R. Buckingham, Esq., Joseph A. Fischetti, Esq., Lowenstein Sandler LLP.

Dated August 14, 2015

Defendant LifeCell ("LifeCell" or "Defendant") moves for summary judgment dismissing the product liability claim of Plaintiff Patricia Julien ("Plaintiff") based on failure-to-warn. The court has considered the written arguments and exhibits submitted by counsel. Counsel agreed to waive oral argument and consented to the court's disposition of the motion on the papers submitted. The following memorandum sets forth the court's disposition of Defendant's motion.

I. BACKGROUND

AlloDerm® is a human tissue product derived from processed human cadaver skin.[1] LifeCell initially developed AlloDerm® in the 1990s to treat skin burns.[2] Over time, surgeons began using AlloDerm® for a number of purposes, including rotator cuff surgery, oral surgery, breast reconstruction, and hernia repair.[3] In the early 2000s, LifeCell began marketing AlloDerm® specifically for hernia repair. AlloDerm® is regulated by the Food and Drug Administration ("FDA") as a banked human tissue product.[4] Human tissue products are regulated separately by the FDA from medical devices and prescription drugs. See 21 C.F.R. § 1271 et seq.

An abdominal hernia occurs when there is an opening in the abdominal wall.[5] An incisional hernia is a hernia that occurs at the site of an incision from a prior surgery.[6] A hernia may be repaired surgically using synthetic mesh, animal-derived biologic mesh, human-derived biologic mesh, or by certain surgical techniques without the use of mesh. All methods of hernia repair carry some level of recurrence risk.[7] Plaintiff in this action asserts that LifeCell marketed AlloDerm® as a permanent hernia solution, and failed to warn Plaintiff and Plaintiff's physician "of the increased risks associated with Alloderm[sic] including but not limited to stretching, expanding, thinning out, pulling, sagging, loosening, spreading, and/or dissolving" and the "high failure rate of the product and high likelihood of reherniation" of AlloDerm® when used for hernia repair.[8]

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[1] Defendant's Brief in Support of its Motion for Summary Judgment on Failure-to-Warn ("Def.'s Br.")1; Plaintiff's Brief in Opposition to Defendant's Motion for Summary Judgment ("Pl.'s Opp.") 1.
[2] Def.'s Br. 1; Pl.'s Opp. 1.
[3] Def.'s Br. 1; Pl.'s Opp. 1.
[4] Pl.'s Opp. 1.
[5] Pl.'s Opp. 2.
[6] Ibid.
[7] Def.'s Statement of Material Uncontroverted Facts ("SMUF") ¶9.
[8] Long Form Complaint, Pl.'s Opp. Ex.1, ¶¶ 65-66.

Plaintiff, Patricia Julien, is a 68 year old woman who is retired.[9] In December of 2003, Plaintiff underwent surgery for a bowel obstruction.[10] Approximately a year and a half later, Plaintiff noticed a "large balloon in [her] abdomen]."[11] When Plaintiff presented to her gynecologist, her gynecologist referred her to Dr. Joubin Khorsand. Dr. Khorsand is a general surgeon.[12] Dr. Khorsand diagnosed Plaintiff with an incisional hernia.[13] Dr. Khorsand discussed with Plaintiff that the hernia could be repaired with either AlloDerm® (a biologic material) or a synthetic mesh.[14] Dr. Khorsand performed Plaintiff's hernia repair surgery on January 17, 2006.[15] Because of the suspected presence of bowel content and/or fluid in the hernia sac, Dr. Khorsand believed that Plaintiff was "a high risk for wound infections," and the use of a synthetic mesh would be "risky." He therefore elected to repair the hernia with AlloDerm®.[16] In August of 2007, Plaintiff had a CT scan which revealed laxity at the site of her 2006 AlloDerm® hernia repair.[17] On August 10, 2009, Plaintiff returned to Dr. Khorsand and was diagnosed with a "recurrent large incisional hernia."[18] Dr. Khorsand noted this as an "Alloderm meltdown."[19] On June 10, 2010, Dr. Khorsand performed a hernia repair surgery using a synthetic mesh.[20] To date, Plaintiff has not reported any hernia recurrence.

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[9] Def.'s SMUF ¶1.
[10] Def.'s SMUF ¶2.
[11] Julien Dep., Def.'s Br. Ex. A, 89-92.
[12] Khorsand Dep., Def.'s Br. Ex. B, 12.
[13] Julien Dep., Def.'s Br. Ex. A, 95; Julien Medical Record, Def.'s Br. Ex. Q.
[14] Julien Dep., Def.'s Br. Ex. A, 96; Julien Dep., Pl.'s Opp. Ex. 37, 101-103; Khorsand Dep., Def.'s Br. Ex. B, 62. While there is conflicting testimony as to the exact nature of this conversation, both Plaintiff and Dr. Khorsand testified that a basic discussion of synthetic mesh versus biologic (AlloDerm®) took place.
[15] Def.'s SMUF ¶10.
[16] Def.'s SMUF ¶5.
[17] Pl.'s Opp.3.
[18] Def.'s SMUF ¶13; Khorsand Dep., Pl.'s Opp. Ex. 38, 82:12-21.
[19] Pl.'s Opp. Counterstatement of Additional Material Facts ("CAMF") ¶24; Khorsand Dep. Pl.'s Opp. Ex. 38, 82:4-21.
[20] Def.'s SMUF ¶15.

II. LEGAL STANDARDS

A. SUMMARY JUDGMENT

"A party seeking any affirmative relief may . . . move for a summary judgment or order on all or any part thereof . . . ." R. 4:46-1. Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to judgment as a matter of law." R. 4:46-2(c). In determining whether there are disputed issues of material fact, the court must "consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 540 (1995). It is not the court's function "to weigh the evidence and determine the truth of the matter but [rather] to determine whether there is a genuine issue for trial." Id.

B. PRODUCT LIABILITY/FAILURE TO WARN

1. Duty to Warn

All product liability cases in New Jersey are governed by the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. § 2A:58C-1 et seq.[21] Under the NJPLA:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it. . . b. failed to contain adequate warnings or instructions. . . .
> [N.J.S.A. § 2A:58C-2.]

[21] Pursuant to a consent order dated January 15, 2015, the parties stipulated that this litigation is governed exclusively by New Jersey statutory and common law. (Consent Order Stipulating Choice of Law, Jan. 15, 2015). Thus, the court need not look beyond New Jersey law in evaluating the parties' arguments.

Recognizing that certain products may be "unavoidably unsafe" while still serving a useful purpose, the NJPLA exempts from liability manufacturers who adequately warn of the dangers of an unavoidably unsafe product. N.J.S.A. § 2A:58C-4 ("In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction . . . ."); See also Feldman v. Lederle Labs., 97 N.J. 429, 446–49 (1984). The adequacy of a warning is determined in part by considering the "the characteristics of, and the ordinary knowledge common to" the party to whom the warning is directed. Id.

2. The Learned Intermediary Doctrine

In accordance with the NJPLA:

> [a]n adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.
>
> [N.J.S.A. § 2A:58C-4 (emphasis added)]

This subsection of the NJPLA incorporates New Jersey's "learned intermediary" doctrine ("LID") whereby the manufacturer fulfills its obligation by providing the appropriate warning to the prescribing physician or surgeon.[22] See Banner v. Hoffmann-La Roche Inc., 383 N.J. Super. 364, 375–76 (App. Div. 2006), certif. denied, 190 N.J. 393 (2007); Niemiera v. Schneider, 114 N.J. 550, 559 (1989) ("In New Jersey, as elsewhere, we accept the proposition that a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by

[22] By order dated May 8, 2015, this court determined that the learned intermediary doctrine applies to human tissue products such as AlloDerm®. See Order and Memorandum of Decision in Simineri v. LifeCell Corporation, dated May 8, 2015. Based upon that ruling, LifeCell was required to warn Mrs. Julien's implanting surgeon, Dr. Khorsand, as to the risks associated with the use of AlloDerm®.

supplying physicians with information about the drug's dangerous propensities."); In re Diet Drug Litig., 384 N.J. Super. 525, 540 (Law Div. 2005) ("Because the physician is in the best position to receive and assess risk information, it is appropriate that warnings or other risk information be provided to him or her."). The treating physician, in turn, "as the learned intermediary assumes a responsibility to warn the patient of the risks involved in [using the product]." Niemiera, supra, 114 N.J. at 552.

Under New Jersey case law, a manufacturer has a duty to warn of all adverse effects of a prescription medical product "of which they know or should have known on the basis of reasonably obtainable or available knowledge." See Feldman v. Lederle Lab., 97 N.J. 429, 434 (1984); see also In re Diet Drug Litig., 384 N.J. Super. 525, 534 (Law Div. 2005). "Causation is a fundamental requisite for establishing any product-liability action." James v. Bessemer Processing Co., 155 N.J. 279, 297 (1998) (quoting Coffman v. Keene Corp., 133 N.J. 581, 594 (1993)). Thus, to succeed on a claim for failure-to-warn, in addition to demonstrating inadequacy of the warning,[23] a plaintiff must also prove that an adequate warning or instruction would have prevented his injuries. Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 209 (1984). In a pharmaceutical product liability action, a plaintiff must "demonstrate so-called product-defect causation – that the defect in the product was a proximate cause of the injury." James, supra, 155 N.J. at 297 (quoting Coffman, supra, 133 N.J. at 594). In other words, a plaintiff must prove that an adequate warning, if provided, would have prevented the plaintiff from using the prescription drug or product in question. See Perez v. Wyeth Labs. Inc., 161 N.J. 1, 28 (1999). It follows that regardless of the

[23] Although LifeCell disputes Plaintiffs' claim that the warnings and instructions for AlloDerm® were inadequate, LifeCell does not argue that the court should find the AlloDerm® warnings and instructions were adequate as a matter of law. Thus, the court will not address this issue and Plaintiffs ultimately bear the burden of proving that the warnings and instructions accompanying AlloDerm® were insufficient to apprise Ms. Julien and Dr. Khorsand of the risks associated with AlloDerm®.

warning provided, a defendant will not be liable if "the prescribing physician either did not read the warning at all, and thus did not rely on any information from the manufacturer in prescribing the product, or if the physician was aware of the risk from other sources and considered the risk in prescribing the product." Ibid. (quoting Richard J. Heafey & Don M. Kennedy, Products Liability: Winning Strategies and Techniques § 10.03 (1999)(footnotes omitted)).

3. Proximate Cause and the Heeding Presumption

In all product liability actions, "[t]he plaintiff must demonstrate . . . that the defect in the product was a proximate cause of the injury. When the alleged defect is the failure to provide warnings, a plaintiff is required to prove that the absence of a warning was a proximate cause of his harm." Coffman v. Keene Corp., 133 N.J. 581, 594 (1993) (internal citations omitted). New Jersey courts apply a "heeding presumption" in product liability failure-to-warn cases, whereby a plaintiff is entitled to the presumption that if the product at issue had contained an adequate warning, the plaintiff would have heeded that warning. Coffman, supra, 133 N.J. at 600-03 ("[A] jury determination of whether, if a warning had been provided, it would have been followed would most likely be highly speculative. A jury, in effect, would be invited to imagine whether a plaintiff, given the various facets of his or her personality . . . would have heeded a warning. . . . The heeding presumption accords with the manufacturer's basic duty to warn; it fairly reduces the victim's burden of proof; and it minimizes the likelihood that determinations of causation will be based on unreliable evidence.").

However, if a defendant produces "sufficient evidence to rebut the presumption," the heeding presumption falls away, and the plaintiff must proceed with the original burden of proving all elements of proximate cause by a preponderance of the evidence. Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 67 (App. Div. 1998) aff'd. o.b. 158 N.J. 329 (1999). In cases involving a learned

intermediary, if the defendant "produces evidence that [the plaintiff's physician], if provided with the warning information, would have prescribed [the product] anyway and would not have communicated the [additional] risk information to the plaintiffs . . . summary judgment for [the defendant] may be appropriate." In re Diet Drug Litig., supra, 384 N.J. Super. at 544-45 (emphasis added). If the plaintiff's physician would have prescribed the product anyway but also passed on the additional warnings to the plaintiff, "a more complex inquiry is necessary. If the plaintiff denies that he or she would have [used the product] based on those warnings, then the matter will be presented to a jury with the plaintiff bearing the burden of proof on this causation issue." Id.

III. THE PARTIES' ARGUMENTS

Defendant's moving papers focus on the issue of proximate cause, asserting a four-part argument: 1) Plaintiff's only injury was a hernia recurrence, therefore only warnings regarding the risk of recurrence are relevant; 2) Plaintiff's surgeon, Dr. Khorsand, chose AlloDerm® out of necessity, and with full awareness of the risk of recurrence, such that any additional warnings about recurrence risk would not have affected his decision to use AlloDerm®; 3) Dr. Khorsand did not read the Instructions for Use ("IFU") included with AlloDerm® (and in fact, did not know there were any), so even the strongest of warnings on the IFU would not have affected his decision-making; and 4) that Plaintiff's claim boils down to a complaint about efficacy, rather than "any unsafe property of AlloDerm®," and thus is not appropriate for a product liability action.[24]

Plaintiff responds by first noting that the complaint in this matter identifies injuries beyond just the hernia recurrence, including "abdominal bulging (from thinning and stretching of the Alloderm graft) that was disfiguring and painful as well as other injuries such as loss of enjoyment

[24] Def.'s Br. 6, 12-17. The court finds that the lack of efficacy is not a claim advanced by Plaintiff in her complaint but is really part of Plaintiff's claim that LifeCell failed to warn of the risks associated with AlloDerm®.

of life."[25] Plaintiff further argues that: 1) Defendant's production of evidence rebutting the heeding presumption necessitates a jury determination on proximate cause, precluding summary judgment; and 2) in the alternative, Defendant has not adequately rebutted the heeding presumption, and there is a genuine dispute as to whether Dr. Khorsand and/or Plaintiff would have elected not to use AlloDerm®, had they properly been warned.

The crux of Plaintiff's claim is that Dr. Khorsand relied on advertising by LifeCell promoting AlloDerm® as a "permanent" repair for complex hernias, and that if he had been warned of the high risk of recurrence and laxity, he would not have used it in Plaintiff's hernia repair. In support of her claim, Plaintiff cites Dr. Khorsand's deposition testimony that he cannot remember LifeCell providing any information as to long term efficacy studies, and this is information he would want to know.[26] He makes similar statements regarding recurrence rates, lack of clinical trials, and reports of bulging.[27] Plaintiff also notes that Dr. Khorsand only found out AlloDerm® stretches "after following up with [his] patients,"[28] and that he stopped using AlloDerm® in his practice specifically because of the stretching, thinning, and high recurrence rate associated with its use.[29] Plaintiff further argues that there were other biologic products on the market at the time of Plaintiff's surgery, such that Dr. Khorsand could have "requested a different product or ordered an alternative hernia repair product and simply rescheduled Plaintiff's surgery."[30] Finally, Plaintiff's opposition brief claims that Plaintiff herself "would have sought an alternative if she had known about such hazardous risks [of AlloDerm®]."[31]

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[25] Pl.'s Opp. 4.
[26] Pl.'s Opp. CAMF ¶ 13.
[27] Khorsand Dep., Pl.'s Opp. Ex. 38, 37-39.
[28] Pl.'s Opp. Ex. 38, 35:10-13; 37-38
[29] Pl.'s Opp. 10, Ex. 38, 34-35. Dr. Khorsand testified that the "melting or thinning" occurred in every patient he repaired with AlloDerm®.
[30] Pl.'s Opp. 12.
[31] Pl.'s Opp. 12; Julien Dep. Ex. 37, 229-230.

IV. ANALYSIS

A. THE ASSERTED INJURIES AND RELEVANT WARNING INFORMATION

Plaintiff asserts in her opposition brief that her injuries are not limited to the hernia recurrence, and include "abdominal bulging (from thinning and stretching of the Alloderm graft) that was disfiguring and painful as well as other injuries such as loss of enjoyment of life."[32] However, Plaintiff's own deposition testimony indicates that the only injury she incurred from the use of AlloDerm® was hernia recurrence, necessitating a second surgery.

> Q: Is it fair to say that the entire time that the Alloderm was in you, you experienced no pain?
>
> A: Yes, I don't—I don't remember any.
>
> . . .
> Q: Did the Alloderm that was put in you cause you to suffer any abnormality or deformity in your abdomen?
>
> A: No.
>
> Q. Did it cause you any pain?
>
> A: No.
>
> Q: Other than five or so days that you were in the hospital for that surgery, did it cause you any kind of disability?
>
> A: No.
> . . .
>
> Q: Do you have any damages that you can quantify for us that you know an amount and can explain what it is you're seeking in this lawsuit as a result of Alloderm being implanted in you?
>
> MR. FANTINI: Objection. You can answer.
>
> A: No, I don't.

[32] Pl.'s Opp. 4. Defendant argues in its Reply Brief that these injuries are not distinct from the hernia, but rather, are merely the various symptoms and side effects of the hernia. For reasons explained in footnote 24 of this memorandum, the court rejects Defendant's argument on this point.

Q: In what way do you believe the Alloderm was defective or ineffective?

MR. FANTINI: Objection. You can answer.

A: I had to have the surgery over again, so it didn't work.

Q: Again, the recurrence is the reason why?

A: Right.[33]

Accepting the unequivocal testimony of Plaintiff herself that her sole injury is the hernia recurrence, the court will focus its analysis on the failure to warn as to recurrence.[34]

B. SUMMARY JUDGMENT IN FAILURE TO WARN CASES

Plaintiff relies on Sharp, supra 314 N.J. Super. 54, for the proposition that if a defendant presents evidence rebutting the heeding presumption, the issue of proximate cause must go to the jury.[35] This, however, is a misreading of the case. In Sharpe, the court discussed the effect of the heeding presumption on thc burdens of production and persuasion, stating: "[i]n the absence of evidence produced by the defendant rebutting the heeding presumption, the plaintiff is entitled to a directed verdict on the proximate cause element of a failure to warn cause of action." Sharpe, supra, 314 N.J. Super. at 64. Conversely, where the defendant does present rebuttal evidence, directed verdict is avoided, and in the context of a trial, the issue would then go to the jury. See id.

[33] Julien Dep., Pl.'s Opp. Ex. 37, 195:18-22; 226-229.

[34] Defendant, in its Reply Brief, asserts that because Dr. Khorsand knew that AlloDerm® carried some risk of recurrence, the manufacturer is not required to warn specifically as to the extent or likelihood of recurrence. For this proposition, it relies on Calabrese v. Trenton State Coll., 162 N.J. Super. 145 (App. Div. 1978), aff'd. Calabrese v. Trenton State Coll., 82 N.J. 321, 322 (1980). However, such reliance is misplaced. In Calabrese, the plaintiff suffered debilitating effects from a rabies vaccine which was administered after a dog bite. At the time, it was unknown whether the dog actually had rabies. Plaintiff argued that, due the statistical rarity of rabies and the extreme nature of the side effects of the anti-rabies vaccine, the vaccine manufacturer should have included statistical data on the incidence of rabies. The court rejected this claim. However, there was no discussion of a requirement to report the incidence of the vaccine's side effects. Defendant cites no other New Jersey cases to support its argument.

[35] Pl.'s Opp. 7.

This is not necessarily the case in a pretrial posture. Sharpe made clear that a defendant's production of rebuttal evidence would shift the burden back to the plaintiff, "who must then carry the burden of persuasion as to proximate cause." Id. at 69. Thus, when the defendant presents rebuttal evidence in a motion for summary judgment, the heeding presumption falls away, and the plaintiff's burden of proof on proximate cause is the same as to any other aspect of the claim, and equally subject to summary judgment in the absence of disputed material facts. See, e.g., Strumph v. Schering Corp., 133 N.J. 33, 34 (1993) (upholding the trial court's grant of summary judgment for defendant in a failure to warn case, where the plaintiff's doctor testified that the proposed warnings would not have altered his decision to prescribe the drug to plaintiff); R. 4:46-1 ("A party seeking any affirmative relief may . . . move for a summary judgment or order on all or any part thereof . . . ." (emphasis added)).

C. PROXIMATE CAUSE

1. Dr. Khorsand

Plaintiff argues that Defendant failed to produce rebuttal evidence sufficient to overcome the heeding presumption. Essentially, she argues that because Dr. Khorsand was not informed about the lack of clinical evidence for AlloDerm®'s long-term efficacy, and because he no longer uses AlloDerm® due to its high recurrence rate in his patients, there is sufficient evidence for a trier of fact to find that Dr. Khorsand would not have used AlloDerm® if proper warnings had been given. While appealing on its face, Plaintiff's argument contains a critical flaw. A claim of failure-to-warn rests on what the treating doctor would have done at the time of treatment, if given the proper warnings proposed by the plaintiff. The fact that a doctor no longer uses a product at the time of litigation is not dispositive of a failure-to-warn inquiry. The record in this case makes clear that no warning would have changed Dr. Khorsand's decision.

Dr. Khorsand is a general surgeon with significant experience in hernia repair. At the time of Plaintiff's 2006 hernia surgery, Dr. Khorsand understood that all methods of hernia repair, and all products used in hernia repair, whether synthetic or biologic, carry a risk of recurrence.[36] If a synthetic mesh is used in the presence of an infection, Dr. Khorsand testified "you can get infection and that synthetic material has to be removed."[37] Prior to the availability of AlloDerm®, Dr. Khorsand's method of treating hernias in patients with infection risk was to "[j]ust give antibiotics and – and pray."[38] According to Dr. Khorsand, the complications from an infected mesh include sepsis, and may necessitate subsequent surgeries. AlloDerm® was the first biologic mesh that Dr. Khorsand used.[39] Dr. Khorsand understood that, "as a rule, you expect any biological mesh to stretch or dissolve."[40] In his current practice, Dr. Khorsand still uses a biologic product for hernia patients with a high infection risk, despite his knowledge that biologic products tend to "melt down."[41]

> Q: Now, around 2006, what product did you most commonly use when you used a hernia repair product to assist you during surgery?
>
> A: We always used to use synthetic material 'til biological mesh becomes available—became available. And then any time that I felt the patient's a high risk for infection, I chose the biological mesh when they're available.[42]
>
> * * *
>
> Q:. . . [C]an you give us an estimate how often or what percentage of the time you would use a biologic versus a synthetic?

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[36] Def.'s SMUF ¶9.
[37] Khorsand Dep., Def.'s Br. Ex. B, 24:15-25:8.
[38] Khorsand Dep., Def.'s Br. Ex. B, 177:8-9.
[39] Khorsand Dep., Def.'s Br. Ex. B, 29:13-16.
[40] Def.'s SMUF ¶7.
[41] Dr. Khorsand now uses Strattice®--LifeCell's porcine mesh--rather than AlloDerm®. Def.'s SMUF ¶11.
[42] Khorsand Dep., Def.'s Br. Ex. B, 28:20-29:6.

A: As I said, that depends on the particular case. Any time I felt that a patient's high risk for having wound infection—and mesh gets infected is a big complication—I use biological mesh . . . .[43]

* * *

Q: Okay. Do you still use biologic product – products like the porcine when there's a high risk of infection?

A: Yes.

Q: And you do that notwithstanding your knowledge that there is the propensity of this melt-down?

A: We understanding that, yes.[44]

* * *

Q: Right. So notwithstanding the fact that [Strattice is] thicker, it still melts down, but to a different degree.

A: Correct.

Q: And that's still the product that surgeons like yourself use when there's a high risk of infection.

A: Correct.

Q: And it's for the same reason that you told us earlier that it's better to avoid the infection of the synthetic mesh than it is to worry about the long-term viability of the biologic.

A: Correct

MR. VOTOVA: Object to the form[45]

* * *

Q: . . . What is the fundamental difference between synthetic and biologic materials?

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[43] Khorsand Dep., Def.'s Br. Ex. B, 30:23-31:9.
[44] Khorsand Dep., Def.'s Br. Ex. B, 163:6-14.
[45] Khorsand Dep., Def.'s Br. Ex. B, 166:11-24.

A: I'm not a specialist on that, but the only thing I know that we use biological mesh, less chance of post-operative infection.[46]

Dr. Khorsand testified that at the time of Plaintiff's hernia surgery, he believed that she was at a high risk for infection and thus was not a candidate for synthetic mesh.

Q: Now, was Patricia Julien also a candidate to have synthetic mesh to repair her hernia in January 2006 if you had chosen to do—to do that?

A: If she was, I would have used it.

. . .

A: As I explained to you earlier, there was some fluid in the hernia sac I thought could increase the chance of infection of the synthetic mesh. That's why I chose to use biological mesh.[47]

* * *

Q: What was your concern about her that she might have a wound infection?

A: I don't recall the detail, but maybe there was a—when you have a bowel content in the hernia and there's fluid in there, sometimes that fluid can be infected and increase the chance of infection. Sometimes we culture this fluid to prove it, but that doesn't help, because they cannot give you answer right away. So, therefore, you choose to use the biological mesh, rather than synthetic mesh, on the basis of what you see in the surgery.

Q: Had you decided to use Alloderm before surgery?

A: No.[48]

* * *

Q: Okay. So your decision to use the biologic was to avoid the likelihood or chance, rather . . . of an infection that would require a second surgery.

A: Correct.

Q: And that was your medical judgment.

A: Correct, and consequence of infection afterwards. It's not just reoperation. It could be patient become septic and – and other –

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[46] Khorsand Dep., 116:7-13.
[47] Khorsand Dep., Pl.'s Opp. Ex. 38, 99:13-100:7.
[48] Khorsand Dep., Pl.'s Opp. Ex. 38, 63:1-19.

Q: Things worse than a second operation.

A: Correct.

Q: And if they—certainly, if they became septic, they'd be looking at a second operation anyway. Correct?

A: Correct.[49]

Plaintiff asserts in her opposition brief that other biologic products were on the market in 2006, and thus were "available" to Dr. Khorsand in place of AlloDerm®. However, Dr. Khorsand unequivocally stated that at the time of Plaintiff's surgery, AlloDerm® was the only biologic available to him. Plaintiff's claim that Dr. Khorsand could have "requested a different product or ordered an alternative hernia repair product" is unsupported speculation. There is no testimony that Dr. Khorsand had any say in which products his hospital carried. There is no testimony that Dr. Khorsand was even aware that other biologic products existed at the time. To the contrary, Dr. Khorsand testified that he had no say in the products ordered or available at his hospital.

Q: Did you have any biologic alternatives for use of hernia repair in 2006 besides Alloderm?

A: No.

Q: That's the only product they provided?

A: Yes

. . .

Q: And "they" is Advocate Lutheran?

A: Correct. If they did, I was not aware of it. [50]

* * *

[49] Khorsand Dep., 139:23-140:18.
[50] Khorsand Dep., Pl.'s Opp. Ex. 38, 101:8-23.

Q: Do you recall ever reviewing any marketing materials from LifeCell regarding Alloderm?

A: No. I used biological mesh because it was the only thing available at Lutheran General.[51]

* * *

Q: Is it your understanding that the product was supposed to provide a lasting or long-term hernia repair?

A: I don't recall.

Q: Well, was it your understanding Alloderm was not just a temporary fix?

A: All I can say is that was the only product available at that time for me to use as a biological mesh.

Q: Let me ask it this way: When you used Alloderm for the hernia repairs that you did, you didn't use it with the intention that I'll be back doing this again in one year, did you?

A: Not in one year, but later, we found out this is not a permanent solution. It's for temporary fix. Because when you have an abdomen full of infections or you expect that, you have to close the abdomen. That was the only thing available to do it.[52]

* * *

Q: You told us earlier today that the material manager at the Advocate Lutheran Hospital was the one who put the product on the shelf, so to speak.

A: Yes.

Q: Was that a person, a committee? What was it – what was that?

A: Committee.

Q: Okay. And were you on the committee?

A: No.

Q: And did that committee make the decision as to decide what was on the shelf?

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[51] Khorsand Dep., Pl.'s Opp. Ex. 38, 46:2-8.

[52] Khorsand Dep., Pl.'s Opp. Ex. 38, 36:3-24. (emphasis added).

A: It decide what to provide – what they decide what material to provide to surgeons.

Q: Okay. Did the surgeons have a vote?

A: No.[53]

Plaintiff alternately proposes that, to avoid infection, Dr. Khorsand could have rescheduled Plaintiff's surgery. However, this was not a situation where the presence of infection was caused by a secondary condition, such as an inflamed appendix. Rather, the risk of infection in 2006 was due to the location of the hernia near the bowel, so no passage of time would have reduced that risk. Most importantly, Dr. Khorsand himself testified that, because of the dangers of infection, additional warnings would not have affected his decision to implant AlloDerm® into Plaintiff.

Q: Is it correct that you would not have used Alloderm for Ms. Julien's hernia repair in January 2006 if you were told there was no long-term data suggesting its long-term ability to provide a repair?

MR. FIELD: Object to the form.

A: I can't answer that question, because on the basis of surgical complications, sometimes we prefer local recurrence on long term versus synthetic mesh infection.[54]

Finally, Dr. Khorsand testified that he did not read any Instructions For Use ("IFU") prior to implanting Plaintiff with AlloDerm® and, in fact, was under the (mistaken) impression that AlloDerm® did not come with instructions.[55] Accordingly, even if additional warnings could have theoretically made a difference (though Dr. Khorsand testified they could not), Dr. Khorsand would not have received any such warnings as he did not read the IFU.

[53] Khorsand Dep., Pl.'s Opp. Ex. 38, 113:12-114:6.
[54] Khorsand Dep., Pl.'s Opp. Ex. 38, 100:15-101:4.
[55] Khorsand Dep., Pl.'s Opp. Ex. 38, 64:10-65:3.

2. Patricia Julien

Plaintiff asserts that, even if Dr. Khorsand would have still recommended AlloDerm® had he been given an adequate warning, summary judgment is not warranted because Plaintiff herself would have elected a different option if properly warned. This argument fails for two reasons: 1) Plaintiff herself did not deny that she would have allowed Dr. Khorsand to implant AlloDerm® even if given a stronger warning; and 2) Dr. Khorsand testified emphatically that he would not have left such a decision up to his patient.

Plaintiff testified that prior to her surgery, she had a consultation with Dr. Khorsand where they discussed the differences between AlloDerm® and synthetic mesh. To the extent that Plaintiff believed this conversation was for the purpose of having her elect which hernia repair product to use (which Dr. Khorsand disputes), she testified that she decided on AlloDerm®, in part, because it was what Dr. Khorsand recommended.

> Q: Do you recall whether you did any type of investigation to get more information from any other source, the internet, another doctor, anyone, to help you decide what you were going to do?
>
> A: No. Let me say this, I believe that my husband and I felt that Dr. Khorsand leaned a little bit towards the Alloderm. I don't know that that's true, but it felt that way. That that was almost like what he was recommending, and which is one of the reasons why we chose that.[56]

On the day of her surgery, Plaintiff signed a surgery consent form stating:

> I understand the nature of my condition, the nature and purpose of the procedure(s) described above, the risks and consequences of the proposed procedure(s), the feasible alternative methods of treatment, the probability that the proposed treatment will be successful and the prospect of recovery if no treatment is received. I have had an opportunity to discuss the procedure(s) with the doctor(s) concerned and have received answers to all the questions I have asked. No guarantee has been given to me as the results that may be expected.[57]

[56] Julien Dep., Pl.'s Opp. Ex. 37, 111:22-112:7.
[57] Def.'s Br. Ex. H, ¶2.

Although Plaintiff gave conflicting testimony as to how she would react to a warning that AlloDerm® alone might lead to recurrence, she failed to testify that she would have declined AlloDerm® if informed that recurrence was possible with all hernia repair options, and implied that she would rely on Dr. Khorsand's judgment.

> Q: If the doctor had told you that there was a risk of recurrence, would that have affected your decision to use Alloderm?
>
> MR. FANTINI: Objection. You can answer.
>
> A: No, I don't think so.[58]
>
> * * *
>
> Q: If your doctor had told you at the time or before Alloderm was implanted that there was a chance of there being a recurrence and you still went forward anyway, would you agree that you don't have a claim against Alloderm because it did exactly what he said it would do?
>
> MR. FANTINI: Objection. Calls for speculation and asked and answered. You can answer.
>
> A: I don't think I would have gone ahead with it.
>
> Q: Okay. What would you have done instead?
>
> A: Gone with the other.
>
> Q: The mesh product that you have in yourself now?
>
> A: Yes.
>
> . . .
>
> Q: If Dr. Khorsand had told you that there was potential for recurrence for both Alloderm and synthetic mesh, what would you have done?
>
> MR. FANTINI: Objection. You can answer.

[58] Julien Dep., Def.'s Br. Ex. A, 131:16-21 (emphasis added).

A: I don't know. I would ask him which one he would recommend and ask him how long I can expect it to last, I guess. I don't know. That's a tough one.[59]

Even setting aside Plaintiff's failure to testify that an adequate warning would have led her to refuse AlloDerm®, Dr. Khorsand testified explicitly that he would not have left this option to Plaintiff because it is a decision he makes during surgery.

Q: Okay. If Patricia Julien said that you let her choose whether she was going to have Alloderm or synthetic mesh for that surgery in January of 2006, do you disagree with her? Or is there a chance you're just remembering—misremembering how that selection of repair was chosen?

A: I don't think any patient can say that, because they're not familiar with the product. It's a decision you make on the base of the operative findings. So you don't put the pressure on the patients. I have never had that discussion with any patient in 25 years, 30 years in practice.[60]

Thus, Dr. Khorsand would not have passed on any additional warnings to Plaintiff, placing this case squarely into the category of cases that In re Diet Drug identified as appropriate for summary judgment. In re Diet Drug Litig., supra, 384 N.J. Super. at 544-45 ("[I]f [defendant] produces evidence that [the plaintiff's physician], if provided with the warning information, would have prescribed [the product] anyway and would not have communicated the [additional] risk information to the plaintiffs . . . summary judgment for [the defendant] may be appropriate.").

V. CONCLUSION

A defendant manufacturer in a product liability action may be entitled to summary judgment on failure to warn upon a showing that, even if given the proposed additional warnings, the treating doctor would not have altered his course of treatment or differently advised the plaintiff. Strumph v. Schering Corp., 256 N.J. Super. 309 (App. Div. 1992) (Skillman, J.A.D.,

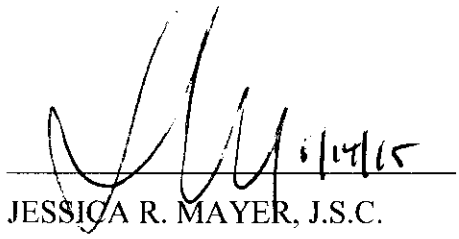
[59] Julien Dep., Pl.'s Opp. Ex. 37, 229:12-232:19 (emphasis added).
[60] Khorsand Dep., Pl.'s Opp. Ex. 38, 181:15-182:7 (emphasis added).

dissenting), rev'd on dissent, 133 N.J. 33 (1993); In re Diet Drug Litig., 384 N.J. Super. 525 (Law Div. 2005). At the summary judgment phase, mere unsupported allegations are insufficient to present genuine disputes of material fact. R. 4:46-5 ("When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the pleading, but must respond . . . setting forth specific facts showing that there is a genuine issue for trial."). While Plaintiff has provided voluminous documentation relating to AlloDerm® promotional materials and various scientific articles debating the merits of AlloDerm®, she has failed to produce any evidence that disputes the critical facts relating to proximate cause.

In this case, Dr. Khorsand's uncontroverted testimony is as follows: Patricia Julien was at high risk for wound infection, making synthetic meshes unsuitable for implantation. At the time of the surgery, AlloDerm® was the only biologic product available to Dr. Khorsand. He was well aware that all hernia repair methods carry a risk of recurrence, and specifically, that biologic products tend to "melt down." Dr. Khorsand evaluated the risk of recurrence as less severe than the risk of infection with a synthetic product. Although Dr. Khorsand had informed Plaintiff during the surgical consultation that both AlloDerm® and synthetic mesh were options, the ultimate decision was up to Dr. Khorsand based on the surgical findings during the actual surgery. Furthermore, Plaintiff failed to assert unequivocally that she would have declined AlloDerm® if given different warnings.

The testimony is clear that no amount of warnings would have altered Dr. Khorsand's decision to use AlloDerm® or to advise Plaintiff differently prior to her surgery. Accordingly, the undisputed evidence in this case precludes a rational trier of fact from finding that any inadequacies in AlloDerm®'s warning were the proximate cause of Plaintiff's injuries.

For the above reasons, Defendant's motion for summary judgment on Plaintiff's failure-to-warn claim is **GRANTED**.



JESSICA R. MAYER, J.S.C.

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FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

IN RE: ALLODERM® LITIGATION

CASE CODE 295

THOMAS DUTCHER,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-1469-12 CM

Civil Action

ORDER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order granting summary judgment and dismissing plaintiff's product liability claim based on a failure to warn, and the Court having considered all papers submitted by the parties, and for good cause and the reasons in the attached memorandum of decision ~~stated on the record by the Court~~,

It is on this the 14th day of August, 2015,

ORDERED that defendant's motion is hereby ~~granted~~ denied; * and it is further

~~ORDERED that plaintiff's product liability claim based on a failure to warn is dismissed with prejudice and without costs;~~ and it is further

* For the reasons set forth in the court's memorandum of decision dated August 14, 2015.

ORDERED that a copy of this Order be served on all counsel of record within 7 days hereof.

Hon. Jessica R. Mayer, J.S.C.

OPPOSED

PAPERS CONSIDERED

	Yes	No	Date
Notice of Motion	✓		
Movant's Affidavits	✓		
Movant's Brief	✓		
Answering Affidavits	✓		
Answering Brief	✓		
Cross Motion			
Movant's Reply	✓		
Other			

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.
JUDGE

MIDDLESEX COUNTY COURTHOUSE
P.O. BOX 964
NEW BRUNSWICK, NEW JERSEY 08903-964

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendant's Motion for Summary Judgment as to Plaintiff's Claim for Failure-to-Warn

In Re: AlloDerm® Litigation, Case Code 295

Thomas Dutcher v. LifeCell Corporation

Docket No. MID-L-1469-12 CM

For Plaintiffs: Lawrence R. Cohan, Esq., Adrianne W. Webb, Esq., Joseph J. Fantini, Esq., Paola Saneaux, Esq., Sol H. Weiss, Esq., Anapol Schwartz.

For Defendant: David W. Field, Esq., Stephen R. Buckingham, Esq., Joseph A. Fischetti, Esq., Lowenstein Sandler LLP.

Dated August 14, 2015

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves for summary judgment as to the claim asserted by plaintiff Thomas Dutcher ("Plaintiff") for failure-to-warn. The court, in addressing Defendant's motion, reviewed the parties' filed submissions and the written arguments of counsel. Counsel agreed to waive oral argument and consented to the court's

disposition of this motion on the papers submitted. The following memorandum of decision sets forth the court's disposition of LifeCell's motion.[1]

I. Background

Defendant, LifeCell, manufactures and sells AlloDerm® Regenerative Tissue Matrix ("AlloDerm®"). AlloDerm® is a type of soft tissue graft derived from human cadaver skin.[2] LifeCell originally developed AlloDerm® in the 1990s for use in the treatment of burn victims.[3] LifeCell was later used by surgeons and sold by LifeCell for other applications including periodontal and breast reconstruction surgery.[4] In the late 1990s, some surgeons began using AlloDerm® for complex hernia repairs and thereafter LifeCell began promoting AlloDerm® for hernia repairs.[5]

Plaintiff, Thomas Dutcher, is a 52-year-old resident of the State of Washington.[6] Plaintiff has a history of obesity and, in 2003, underwent gastric bypass surgery in an attempt to control his weight.[7] Thereafter, Plaintiff developed a ventral incisional hernia and, in February 2004, Plaintiff underwent surgery to repair the hernia.[8] Incisional hernias are a common medical problem occurring in patients' abdominal walls at the site of prior surgical incisions.[9] Incisional hernias may be repaired in a variety of ways including just suturing, known as primary closure, or with

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[1] The parties signed a consent order stipulating that New Jersey law governs all issues in the AlloDerm® cases. See consent order dated January 15, 2015.
[2] Brief in Support of Defendant's Motion for Summary Judgment ("Def.'s Br.") 1; Plaintiff's Brief in Opposition to Defendant's Motion for Summary Judgment ("Pl.'s Opp.") 3.
[3] Def.'s Br. 1.
[4] Ibid.
[5] Ibid.; Pl.'s Opp. 4.
[6] Def.'s Br. 2.
[7] Ibid.
[8] Pl.'s Opp. 5.
[9] Certification of David Field ("Field Cert."), Ex. L, Expert Report of Dr. Huckfeldt on General Causation ("Huckfeldt General Causation Report"), 2–3.

the reinforcement of a synthetic mesh or a biologic graft such as AlloDerm®.[10] Plaintiff's hernia was repaired using a synthetic mesh.[11] After Plaintiff's hernia surgery, he developed a wound infection initially treated with antibiotics.[12] However, the antibiotics were ineffective and Plaintiff continued to suffer from infection and drainage of purulent fluids.[13]

On April 28, 2005, Dr. Jeffrey Hunter, a general surgeon, and Dr. Keith Paige, a plastic surgeon, operated on Plaintiff to remove the infected synthetic mesh, repair the ventral hernia with AlloDerm®, and reconstruct the abdominal wall.[14] Dr. Hunter, who performed the hernia repair, used AlloDerm® rather than synthetic mesh because synthetic mesh is contraindicated for placement in an infected abdomen.[15] Dr. Hunter placed the AlloDerm® underneath Plaintiff's abdominal wall in order to reinforce the hernia repair.[16]

In September 2005, a CT scan revealed a small ventral hernia.[17] In October 2005, Plaintiff visited Virginia Mason Medical Center and discussed the CT findings with Physician Assistant Redmon ("PA Redmon").[18] At that time, Plaintiff noticed a bulge but told PA Redmon that he was not experiencing any pain in his abdomen.[19] The plan was to monitor Plaintiff's hernia and Plaintiff was advised to return for follow-ups as needed.[20] In May of 2006, Plaintiff returned to PA Redmon

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[10] Id. at 2–5.
[11] Pl.'s Opp. 5.
[12] Ibid.
[13] Ibid.
[14] Def.'s Br. 2; Pl.'s Opp. 5.
[15] Def.'s Br. 2.
[16] Ibid.
[17] Field Cert., Ex. D.
[18] Field Cert., Ex. E, Oct. 2005 Outpatient Clinic Note.
[19] Ibid.
[20] Ibid.

after experiencing pain in his right lower abdomen.[21] Plaintiff was advised that his pain was caused by weight lifting and was told by PA Redmon to adjust his weight lifting.[22]

Plaintiff again returned to PA Redmon in December of 2007, after experiencing continuing pain in his right lower quadrant.[23] At that time, Plaintiff had a "considerable bulge" in his right lower quadrant.[24] PA Redmon decided to order a CT scan and discuss Plaintiff's care with Drs. Hunter and Paige.[25] Plaintiff was diagnosed with a recurrent hernia and, in March of 2008, Dr. Hunter repaired the hernia with synthetic mesh because there was no infection or risk of infection present.[26] Plaintiff has not experienced hernia recurrence since that time.[27]

II. Legal Analysis

A. Defendant's Motion

LifeCell seeks summary judgment on Plaintiff's failure-to-warn claim based on two arguments. First, LifeCell contends that Plaintiff is unable to prove proximate cause. LifeCell argues that the only warnings relevant to Plaintiff's failure-to-warn claim are related to hernia recurrence.[28] Because both of Plaintiff's treating surgeons, Drs. Hunter and Paige, were aware of the risk of recurrence in hernia repairs, generally, and because Plaintiff's surgeons testified that "even if they had received different warnings . . . they still would have used AlloDerm®," LifeCell claims Plaintiff is unable to prove that any warning would have prevented his harm.[29] Second, LifeCell argues that Plaintiff's failure-to-warn claim is nothing more than a claim that the

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[21] Field Cert., Ex. F, May 2006 Outpatient Clinic Note.
[22] Ibid.
[23] Field. Cert., Ex. G, Dec. 2007 Outpatient Clinic Note.
[24] Ibid.
[25] Ibid.
[26] Def.'s Br. 4; Pl.'s Opp. 5.
[27] Pl.'s Opp. 5.
[28] Def.'s Br. 8.
[29] Ibid.

AlloDerm® was ineffective in repairing his hernia.[30] According to LifeCell, because Plaintiff fails to complain of any "danger" or "side effect" as contemplated by the New Jersey Products Liability Act, his claim must fail.[31]

B. Plaintiff's Opposition

Plaintiff opposes LifeCell's motion and argues that LifeCell mischaracterizes the injuries alleged by Plaintiff.[32] Plaintiff alleges that LifeCell not only failed to warn of the risk of recurrence generally, but that LifeCell failed to warn of the "high failure rate" and the "high likelihood of recurrence" of AlloDerm® as well as AlloDerm®'s propensity to thin and stretch post-operatively leading to further injury and the need for additional surgery.[33] Plaintiff further argues that there were other products available to repair Plaintiff's hernia and that, contrary to LifeCell's position, the testimony of Dr. Hunter suggests that a different warning may have affected Dr. Hunter's decision to use AlloDerm®.[34]

C. Summary Judgment Standard

"A party seeking any affirmative relief may . . . move for a summary judgment or order on all or any part thereof or as to any defense." R. 4:46-1. Summary judgment may be rendered as to "any issue in the action . . . although there is a genuine factual dispute as to any other issue . . . ." R. 4:46-2(c). Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment

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[30] Def.'s Br. 14.
[31] Id. at 14–15.
[32] Pl.s' Opp. 18.
[33] Pl.'s Opp. 19–20.
[34] Pl.'s Opp. 22–23.

or order as a matter of law." Ibid. In considering a motion for summary judgment, the court should determine whether "the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 540 (1995). "If there exists a single, unavoidable resolution of the alleged disputed issue of fact, that issue should be considered insufficient to constitute a 'genuine' issue of material fact for purposes of Rule 4:46-2." Ibid.

D. The New Jersey Products Liability Act

In New Jersey, all products liability actions are governed by the New Jersey Products Liability Act, N.J.S.A. § 2A:58C-1 et seq. ("NJPLA"). The NJPLA encompasses "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C-1(b)(3). Under the NJPLA:

> [a] manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.
>
> [N.J.S.A. § 2A:58C-2]

With respect to failure-to-warn claims, generally, the NJPLA explains:

> [i]n any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonable should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. An adequate product warning or

> instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.
>
> [N.J.S.A. § 2A:58C-4 (emphasis added).]

This subsection of the NJPLA incorporates New Jersey's "learned intermediary" doctrine, whereby the manufacturer fulfills its obligation by providing the appropriate warning to the prescribing physician or surgeon.[35] See Banner v. Hoffmann-La Roche Inc., 383 N.J. Super. 364, 375–76 (App. Div. 2006), certif. denied, 190 N.J. 393 (2007); Niemiera v. Schneider, 114 N.J. 550, 559 (1989).

Under New Jersey case law, a manufacturer has a duty to warn of all known adverse effects of a prescription medical product "of which they know or should have known on the basis of reasonably obtainable or available knowledge." See Feldman v. Lederle Lab., 97 N.J. 429, 434 (1984); see also In re Diet Drug Litig., 384 N.J. Super. 525, 534 (Law Div. 2005). "Causation is a fundamental requisite for establishing any product-liability action." James v. Bessemer Processing Co., 155 N.J. 279, 297 (1998) (quoting Coffman v. Keene Corp., 133 N.J. 581, 594 (1993)). Thus, to succeed on a claim for failure-to-warn, in addition to demonstrating inadequacy of the warning,[36] a plaintiff must also prove that an adequate warning or instruction would have

[35] This court determined that the learned intermediary doctrine applies to human tissue products such as AlloDerm®. See Simineri v. LifeCell Corporation, Order and Memorandum of Decision, May 8, 2015. Based upon that ruling, LifeCell was required to warn Mr. Dutcher's implanting sugeon, Dr. Hunter, as to the risks associated with the use of AlloDerm®.

[36] Although LifeCell disputes Plaintiff's claim that the warnings and instructions for AlloDerm® were inadequate, LifeCell does not argue that the AlloDerm® warnings and instructions were adequate as a matter of law. Thus, the court need not address this issue and Plaintiff ultimately bears the burden of proving that the warnings and instructions accompanying AlloDerm® were insufficient to apprise Plaintiff and his doctors of the risks associated with AlloDerm®.

prevented his injuries. Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 209 (1984). In a pharmaceutical product liability action, a plaintiff must "demonstrate so-called product-defect causation – that the defect in the product was a proximate cause of the injury. When the alleged defect is the failure to provide warnings, a plaintiff is required to prove that the absence of a warning was a proximate cause of his harm." James, supra, 155 N.J. at 297 (quoting Coffman, supra, 133 N.J. at 594). In other words, a plaintiff must prove that an adequate warning, if provided, would have prevented the plaintiff from using the prescription drug or product in question. See Perez v. Wyeth Labs. Inc., 161 N.J. 1, 28 (1999). It follows that regardless of the warning provided, a defendant will not be liable if "the prescribing physician either did not read the warning at all, and thus did not rely on any information from the manufacturer in prescribing the product, or if the physician was aware of the risk from other sources and considered the risk in prescribing the product." Ibid. (quoting Richard J. Heafey & Don M. Kennedy, Products Liability: Winning Strategies and Techniques § 10.03 (1999)(footnotes omitted)).

However, "[d]ue to the individualized nature of the inquiry into what warning would have caused the plaintiff to alter her behavior . . . predicting how additional information would have affected any given individual may be well nigh impossible." Ibid. (quoting Lloyd C. Chatfield II, Medical Implant Litigation and Failure to Warn: A New Extension for the Learned Intermediary Rule, 82 Ky. L.J. 575, 582–83 (1993-94) (footnotes omitted)). Thus, to counter this difficulty, New Jersey adopted the "heeding presumption." See Coffman, supra, 133 N.J. at 597–98. The heeding presumption "provides the plaintiff with a rebuttable presumption on the issue of proximate cause [that], if a[n] [adequate] warning or instruction had been given, such warning or instruction would have been heeded by the plaintiff." Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 68 (App. Div. 1998), aff'd o.b., 158 N.J. 329 (1999). Where the heeding presumption applies:

> [T]he burden of production on the issue of proximate cause shifts to the defendant to come forward with rebuttal evidence. In essence, the defendant's burden of production requires evidence sufficient to demonstrate . . . that a warning would have made known to the plaintiff the danger of the product and, notwithstanding the knowledge imparted by the warning, the plaintiff would have proceeded voluntarily and unreasonably to subject him or herself to the dangerous product. . . . If the defendant fails to meet its burden of production to the trial court's satisfaction, the trial judge is required to direct a verdict in favor of the plaintiff on the issue of proximate causation. If, however, the defendant presents rebuttal evidence such that reasonable minds could differ as to whether the warning, if given, would have been heeded by the plaintiff, the defendant has satisfied its burden of production and the plaintiff loses the benefit of the presumption. The plaintiff must then carry the burden of persuasion as to proximate cause.
>
> [Sharpe, supra, 314 N.J. Super. at 68–69 (internal citations and quotations omitted).]

Even in cases wherein the prescribing physician did not know of the risk, summary judgment for the manufacturer may be appropriate where the physician testifies that, if provided with an adequate warning, the physician would still have used the product and would not have communicated the risks to the patient. See In re Diet Drug, supra, 384 N.J. Super. at 545. However, where the physician indicates that he would have communicated the risk to the patient, there remains a factual question regarding proximate cause. Ibid.

E. Proximate Cause

LifeCell's argument for summary judgment on Plaintiff's failure to warn claim is that Plaintiff is unable to prove proximate cause because a different warning would not have changed the course of Plaintiff's treatment.[37] In support of its argument, LifeCell cites a portion of Dr. Hunter's deposition in which he indicated that the addition of certain warnings would not have changed his decision to use AlloDerm®:

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[37] Def.'s Br. 6.

> Q. So if the AlloDerm instructions for use in 2005 that came with the AlloDerm that you used in Mr. Dutcher's operation had a specific warning stating that the AlloDerm graft once implanted might not prevent the recurrence, would that have changed your decision to use AlloDerm in your operation on Mr. Dutcher?
>
> A. No, it would not.
>
> Q. If the AlloDerm instructions for use in 2005 had a specific warning stating that the AlloDerm graft could possibly stretch after it was implanted and contribute to a bulge in the patient's abdomen, would that have changed your decision to use AlloDerm in your operation on Mr. Dutcher?
>
> A. No, it would not have.
>
> Q. And I'll ask, if the AlloDerm instructions for use in 2005 had a specific warning stating that the AlloDerm graft could possibly become lax after it was implanted and contribute to a sagging or lax abdomen, would that have changed your decision to use AlloDerm in Mr. Dutcher's operation?
>
> A. No, it would not have.[38]

LifeCell also notes that both of Plaintiff's treating surgeons were aware of the risk of hernia recurrence and they communicated that risk to Plaintiff. Indeed, Dr. Hunter testified that there is a high risk of recurrence when repairing incisional hernias:

> Q. Why is it that you would use synthetic mesh more often in incisional versus ventral?
>
> A. Because they're going to have a high risk of recurrence, because it's already been operated on at least twice and the tissues are distorted and weakened, and often there are multiple defects as opposed to a primary ventral hernia where it's usually one solitary defect with surrounding good tissue.[39]

Dr. Hunter also testified that the general approximate rate of recurrence for incisional hernia repairs is between 10 and 20%.[40] Additionally, although Dr. Paige conceded he is not an expert on

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[38] Field Cert., Ex. B, Hunter Dep. 78:23-79:23.
[39] Id. at 15:24-16:7.
[40] Id. at 17:22-25.

hernia repair, Dr. Paige testified there is a risk of hernia recurrence with any hernia repair and that the risk is heightened in patients such as Plaintiff who have an infected synthetic mesh.[41]

Dr. Paige testified that he typically defers to Dr. Hunter regarding to the specific products and techniques used in a hernia repair.[42] As the plastic surgeon, Dr. Paige is primarily concerned with reconstruction of the abdominal wall, while the general surgeon handles the hernia repair portion of the surgery.[43] Consequently, the court focused primarily on Dr. Hunter's testimony and whether Dr. Hunter's testimony demonstrates that no additional warnings would have changed his decision to use AlloDerm®. Dr. Hunter testified that additional warnings specifically indicating recurrence, stretching, bulging, and laxity would not have affected his decision to use AlloDerm® for Plaintiff's hernia repair.[44] Standing alone, this testimony might have been sufficient evidence that additional warnings would not have changed Dr. Hunter's decision to use AlloDerm®. However, as Plaintiff notes in his opposition brief, Dr. Hunter also testified that he was unaware that AlloDerm® can stretch under tension:

> Q. Were you aware that AlloDerm stretches?
>
> A. I don't believe so.[45]
>
> * * *
>
> Q. Did you know that AlloDerm could expand or its expected expansion would be up to 50% under moderate tension?
>
> A. No, I would not have known that.[46]
>
> * * *

[41] Field Cert., Ex. C, Paige Dep. 24:1-21, 41:10-19.
[42] Id. at 39:25-40:7.
[43] Id. at 27:19-28:4.
[44] Field Cert., Ex. B, Hunter Dep. 78:23-79:23.
[45] Fantini Cert., Ex. I, Hunter Dep. 136:13-14
[46] Id. at 142:17-20.

> Q. When you implanted the AlloDerm in Mr. Dutcher, if I understand your testimony, you were unaware that it could expand as much as 50 percent under moderate tension; is that correct?
>
> A: That's correct.[47]

LifeCell's assertion that no additional warnings would have changed Dr. Hunter's decision to use AlloDerm® is further questioned when the court considers the surgeon's direct testimony to the contrary:

> Q. If you had been informed that AlloDerm could expand as much as 50% under moderate tension, would you have taken that into account in your surgery on April of 2005 on Mr. Dutcher?
>
> A. Yes.
>
> Q. So this would have caused you to in some fashion alter your surgical procedure?
>
> A. It might have.
>
> Q. When you say "might have," in what way would it? Taking the "might" as an indication that you would, in what way would you have altered your surgical procedure?
>
> A. I would have inquired into the need to stretch the mesh. If there was a need to do that when it was placed, I would have considered using another mesh if there was another available.[48]

Although the Instructions for Use ("IFU") included with the AlloDerm® actually used in Plaintiff's surgery did not indicate that AlloDerm® can expand approximately 50%, later IFU revisions included just such an indication.[49] Furthermore, although Dr. Hunter testified that he would never consider using a synthetic mesh in a patient with infection such as Plaintiff, Dr. Hunter never testified that there were no alternative hernia repair products available to him as of April

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[47] Id. at 157:1-5.
[48] Id. at 159:3-20.
[49] See Certification of Joseph Fantini ("Fantini Cert."), Ex. U, AlloDerm® IFU, Revision E; Fantini Cert., Ex. X, AlloDerm® IFU, Revision G.

2005. In fact, Dr. Hunter testified that Surgisis®—a porcine-based biologic graft—was an alternative product available at the time of Plaintiff's surgery.[50]

Plaintiff contends that LifeCell had a duty to warn Plaintiff's surgeons of AlloDerm®'s allegedly higher risk of recurrence and AlloDerm®'s purported tendency to thin and stretch post-operatively.[51] Given Dr. Hunter's testimony that such a warning might have changed his decision to use AlloDerm® for Plaintiff's hernia surgery, the court cannot conclude, as a matter of law, that Plaintiff is unable to establish proximate cause. There is testimony from Plaintiff's implanting surgeon suggesting that additional warnings might have affected his decision to use AlloDerm®. Therefore, there is a genuine factual dispute on the question of proximate cause that must be resolved by a jury.

F. Efficacy

Alternatively, LifeCell argues that Plaintiff's failure-to-warn claim alleges nothing more than that AlloDerm® was ineffective in repairing his hernia. However, the court finds that Plaintiff's claim goes beyond simply alleging that AlloDerm® was an ineffective treatment for his hernia. The court finds that lack of efficacy is not a separate claim advanced by Plaintiff in his complaint. Plaintiff claims that AlloDerm® poses significantly higher risks of recurrence as compared to other hernia repair products and presents risks of post-operative thinning and

[50] Fantini Cert., Ex. I, Hunter Dep. 158:21-159:2.

[51] In its reply papers, LifeCell asserts that because Drs. Hunter and Paige knew that Alloderm® carried some risk of recurrence, the manufacturer is not required to warn as to the extent or likelihood of recurrence. For this proposition, LifeCell relies on Calabrese v. Trenton State Coll., 162 N.J. Super. 145 (App. Div. 1978), aff'd, 82 N.J. 321 (1980). However, such reliance is misplaced. In Calabrese, the plaintiff suffered debilitating effects from a rabies vaccine that was administered after a dog bite. At the time, it was unknown whether the dog actually had rabies. The plaintiff argued that, due to the statistical rarity of rabies and the extreme nature of the side effects of the vaccine, the manufacturer should have included statistical data on the incidence of rabies. The court rejected this claim. However, there was no discussion of a requirement to report the incidence of the side effects. LifeCell cites no other New Jersey cases to support its argument.

stretching leading to additional pain and injuries. The lack of efficacy is a part of Plaintiff's claim that LifeCell failed to warn of the risks associated with AlloDerm®. Thus, LifeCell's lack-of-efficacy argument fails for the same reasons as LifeCell's failure-to-warn argument.

III. Conclusion

For the reasons set forth above, Defendant's motion for summary judgment as to Plaintiff's failure-to-warn claim is **DENIED.**

8/14/15

JESSICA R. MAYER, J.S.C.

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08-0775

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FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

IN RE: ALLODERM® LITIGATION

CASE CODE 295

DEBBIE FOSTER and DAVID FOSTER, w/h,

Plaintiffs,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-6841-12 CM

Civil Action

ORDER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order granting summary judgment and dismissing plaintiffs' product liability claim based on a failure to warn, and the Court having considered all papers submitted by the parties, and for good cause and the reasons ~~stated~~ in the attached memorandum of decision, on the record by the Court,

It is on this the 14th day of August, 2015,

ORDERED that defendant's motion is hereby granted*; and it is further

ORDERED that plaintiffs' product liability claim based on failure to warn is hereby dismissed with prejudice and without costs; and it is further

* For the reasons set forth in the court's memorandum of decision dated August 14, 2015.

ORDERED that a copy of this Order be ~~served on~~ Posted online by all counsel of record within 7 days hereof.

OPPOSED

8/14/15
Hon. Jessica R. Mayer, J.S.C.

PAPERS CONSIDERED

	Yes	No	Date
Notice of Motion	✓		
Movant's Affidavits	✓		
Movant's Brief	✓		
Answering Affidavits	✓		
Answering Brief	✓		
Cross Motion			
Movant's Reply	✓		
Other			

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.

MIDDLESEX COUNTY COURT HOUSE
P.O. Box 964
NEW BRUNSWICK, NEW JERSEY 08903-64

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendant's Motion for Summary Judgment as to Plaintiff's Claim for Failure-to-Warn

In re: AlloDerm® Litigation, Case Code 295

Debbie Foster and David Foster v. LifeCell Corporation, Docket No. MID-L-6841-12 CM

For Plaintiffs: Lawrence R. Cohan, Esq., Adrianne W. Webb, Esq., Joseph J. Fantini, Esq., Paola Saneaux, Esq., Sol H. Weiss, Esq., Anapol Schwartz.

For Defendant: David W. Field, Esq., Stephen R. Buckingham, Esq., Joseph A. Fischetti, Esq., Lowenstein Sandler LLP.

Dated August 14, 2015

Defendant LifeCell ("Defendant") moves for summary judgment dismissing the product liability claim of Plaintiffs Debbie Foster and David Foster[1] ("Plaintiffs') based on failure-to-warn. The court has considered the written arguments and exhibits submitted by counsel. Counsel agreed to waive oral argument and consented to disposition of the motion on the papers submitted. The following memorandum sets forth the court's disposition of Defendant's motion.

[1] David Foster is suing for loss of consortium separate and apart from Debbie Foster's claim.

I. BACKGROUND

AlloDerm® is a human tissue product derived from processed human cadaver skin.[2] LifeCell initially developed AlloDerm® in the 1990s to treat skin burns.[3] Over time, surgeons began using AlloDerm® for a number of purposes, including rotator cuff surgery, oral surgery, breast reconstruction, and hernia repair.[4] In the early 2000s, LifeCell began marketing AlloDerm® specifically for hernia repair. AlloDerm® is regulated by the Food and Drug Administration ("FDA") as a banked human tissue product.[5] Human tissue products are regulated separately by the FDA from medical devices and prescription drugs. See 21 C.F.R. § 1271 et seq.

An abdominal hernia occurs when there is an opening in the abdominal wall. An incisional hernia is a hernia that occurs at the site of an incision from a prior surgery. A hernia may be repaired surgically using synthetic mesh, animal-derived biologic mesh, human-derived biologic mesh, or by certain surgical techniques without the use of mesh.[6] All methods of hernia repair carry some level of recurrence risk.[7] Plaintiffs in this action assert that LifeCell marketed AlloDerm® as a permanent hernia solution, and failed to warn Mrs. Foster and her physician "of the increased risks associated with Alloderm[sic] including but not limited to stretching, expanding, thinning out, pulling, sagging,

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[2] Defendant's Brief in Support of its Motion for Summary Judgment on Plaintiffs' Failure-to Warn Claim ("Def.'s Br.") 1; Plaintiffs' Brief in Opposition to Defendants' Motion for Summary Judgment ("Pls.' Opp.") 1.
[3] Def.'s Br. 1, Pls.' Opp. 1.
[4] Def.'s Br. 1, Pls.' Opp. 1.
[5] AlloDerm® Product Insert, Pls.' Opp. Ex. 5, 7.
[6] Gupta Dep., Def.'s Br. Ex. B, 10-13.
[7] Huckfeldt Dep., Def.'s Br. Ex. D, 297:14-298:14.

loosening, spreading, and/or dissolving" and the "high failure rate of the product and high likelihood of reherniation."[8]

Plaintiff, Debbie Foster, is a 62-year old woman who is retired.[9] She married Plaintiff David Foster in 1978.[10] Mrs. Foster suffers from many medical conditions, including morbid obesity, asthma, bronchitis, chronic pneumonia, chronic obstructive pulmonary disease, hypothyroidism, gastroesophageal reflux disease, arthritis, neuropathy, chronic back pain, and multiple recurrent incisional hernias.[11] Mrs. Foster's relevant and extensive surgical history prior to her AlloDerm® implantation is as follows: in July of 1981, she underwent gastric bypass surgery. In February of 2001, she was diagnosed with an incisional hernia, which was repaired with Gore-tex synthetic mesh. In March of 2006, Mrs. Foster underwent a gastric bypass revision. In September of 2007, she was diagnosed with an incisional hernia, which was repaired with Parietex synthetic mesh.[12]

In June of 2008, Mrs. Foster saw Dr. Samir Gupta for issues with "persistent draining from an abdominal wound that was in – what was felt to be infected mesh" from her previous hernia repairs.[13] Dr. Gupta is a general surgeon who has been in practice since 1999. Approximately 40% of his practice is hernia repair. [14] In June of 2008, Dr. Gupta explanted the infected synthetic meshes and repaired Mrs. Foster's hernia with AlloDerm® biologic mesh. Due to the presence of infection in Mrs. Foster's abdomen, Dr. Gupta

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[8] Long Form Complaint, Pls.' Opp. Ex. 1, ¶¶ 65-66.
[9] Def.'s Statement of Material Uncontroverted Facts ("SMUF") ¶1; Huckfeldt Report, Pls.' Opp. Ex. 43, 2.
[10] Foster Dep., Pls.' Opp. Ex. 40, 12:12-13.
[11] Foster Medical Records, Def.'s Br. Exs. F, G, H.
[12] Huckfeldt Report, Pls.' Opp. Ex. 43 at 2-3; Foster Dep., Def.'s Br. Ex. A, 36:14-18.
[13] Gupta Dep., Def.'s Br. Ex. B, 28:18-24; 31:14-18. In her deposition, Mrs. Foster mentioned seeing Dr. Gupta as early as February 2001, but Dr. Gupta's deposition and Mrs. Foster's medical records indicate that Dr. Gupta did not perform surgery on Mrs. Foster until 2008. Foster Dep., Def.'s Brief Ex. A, 53:24-54:15; Foster Medical Records, Def.'s Brief Exs. E, F, G, H, I, J, K.
[14] Gupta Dep., Def.'s Br. Ex. B, 6:18-7:24.

elected to use AlloDerm® to repair her hernia, as synthetic mesh is contraindicated in an infected field.[15] In December of 2008, Mrs. Foster sought medical treatment for a severe coughing fit, asserting she was "coughing up pieces of her lung."[16] The physician who saw Mrs. Foster ordered a CT scan to rule out a pulmonary embolism.[17] The CT scan revealed a "small ventral hernia."[18] In June of 2009, Mrs. Foster returned to Dr. Gupta complaining of nausea and pain.[19] A CT scan revealed an "incarcerated incisional ventral hernia containing colon."[20] In April of 2011, Dr. Gupta performed an incisional hernia repair with Sepra Mesh synthetic mesh. Within a year, the hernia had recurred, and in April of 2012, Mrs. Foster underwent an incisional hernia repair with Ventralight synthetic mesh.[21] At the time of Mrs. Foster's deposition for this case in July of 2014, she reported another hernia recurrence.[22]

II. LEGAL STANDARDS

A. SUMMARY JUDGMENT

"A party seeking any affirmative relief may . . . move for a summary judgment or order on all or any part thereof . . . ." R. 4:46-1. Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to judgment as a matter of law." R. 4:46-2(c). In

[15] Gupta Dep., Def.'s Br. Ex. B, 37:8-23. Although Mrs. Foster did not present in June of 2008 with a hernia recurrence, the infected mesh needed to be explanted, which necessitated the use of an alternate hernia repair product to close the hernia after explanting the mesh.
[16] Gupta Dep., Def.'s Br. Ex. B, 54:20-24.
[17] Gupta Dep., Def.'s Br. Ex. B, 57:9-24.
[18] Gupta Dep., Def.'s Br. Ex. B, 58:1-3.
[19] Foster Medical Record, Def.'s Br. Exs. H, I.
[20] Foster Medical Record, Def.'s Br. Exs. H, I.
[21] Huckfeldt Report, Pls.' Opp. Ex. 43, 2-3; Foster Dep., Def.'s Br. Ex. A, 36:14-18.
[22] Foster Dep., Def.'s Br. Ex. A, 60:19-20.

determining whether there are disputed issues of material fact, the court must "consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 540 (1995). It is not the court's function "to weigh the evidence and determine the truth of the matter but [rather] to determine whether there is a genuine issue for trial." Id.

B. PRODUCT LIABILITY/FAILURE TO WARN

1. Duty to Warn

All product liability cases in New Jersey are governed by the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. § 2A:58C-1 et seq.[23] Under the NJPLA:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it. . . b. failed to contain adequate warnings or instructions. . . .
>
> [N.J.S.A. § 2A:58C-2.]

Recognizing that certain products may be "unavoidably unsafe" while still serving a useful purpose, the NJPLA exempts from liability manufacturers who adequately warn of the dangers of an unavoidably unsafe product. N.J.S.A. § 2A:58C-4 ("In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction . . . ."); See also Feldman v. Lederle Labs., 97 N.J. 429, 446–49 (1984). The adequacy of a warning is determined in

[23] Pursuant to a consent order dated January 15, 2015, the parties stipulated that this litigation is governed exclusively by New Jersey statutory and common law. (Consent Order Stipulating Choice of Law, Jan. 15, 2015). Thus, the court need not look beyond New Jersey law in evaluating the parties' arguments.

part by considering the "the characteristics of, and the ordinary knowledge common to" the party to whom the warning is directed. Id.

2. The Learned Intermediary Doctrine

In accordance with the NJPLA:

> [a]n adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.
>
> [N.J.S.A. § 2A:58C-4 (emphasis added).]

This subsection of the NJPLA incorporates New Jersey's "learned intermediary" doctrine ("LID") whereby the manufacturer fulfills its obligation by providing the appropriate warning to the prescribing physician or surgeon.[24] See Banner v. Hoffmann-La Roche Inc., 383 N.J. Super. 364, 375–76 (App. Div. 2006), certif. denied, 190 N.J. 393 (2007); Niemiera v. Schneider, 114 N.J. 550, 559 (1989) ("In New Jersey, as elsewhere, we accept the proposition that a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities."); In re Diet Drug Litig., 384 N.J. Super. 525, 540 (Law Div. 2005) ("Because the physician is in the best position to receive and assess risk information, it is appropriate that warnings or other risk information be provided to him or her."). The treating physician, in turn, "as the learned intermediary assumes a responsibility

[24] By order dated May 8, 2015, this court determined that the learned intermediary doctrine applies to human tissue products such as AlloDerm®. See Order and Memorandum of Decision in Simineri v. LifeCell Corporation, dated May 8, 2015. Based upon that ruling, LifeCell was required to warn Mrs. Foster's implanting surgeon, Dr. Gupta, as to the risks associated with the use of AlloDerm®.

to warn the patient of the risks involved in [using the product]." Niemiera, supra, 114 N.J. at 552.

Under New Jersey case law, a manufacturer has a duty to warn of all adverse effects of a prescription medical product "of which they know or should have known on the basis of reasonably obtainable or available knowledge." See Feldman v. Lederle Lab., 97 N.J. 429, 434 (1984); see also In re Diet Drug Litig., 384 N.J. Super. 525, 534 (Law Div. 2005). "Causation is a fundamental requisite for establishing any product-liability action." James v. Bessemer Processing Co., 155 N.J. 279, 297 (1998) (quoting Coffman v. Keene Corp., 133 N.J. 581, 594 (1993)). Thus, to succeed on a claim for failure-to-warn, in addition to demonstrating inadequacy of the warning,[25] a plaintiff must also prove that an adequate warning or instruction would have prevented his injuries. Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 209 (1984). In a pharmaceutical product liability action, a plaintiff must "demonstrate so-called product-defect causation – that the defect in the product was a proximate cause of the injury." James, supra, 155 N.J. at 297 (quoting Coffman, supra, 133 N.J. at 594). In other words, a plaintiff must prove that an adequate warning, if provided, would have prevented the plaintiff from using the prescription drug or product in question. See Perez v. Wyeth Labs. Inc., 161 N.J. 1, 28 (1999). It follows that regardless of the warning provided, a defendant will not be liable if "the prescribing physician either did not read the warning at all, and thus did not rely on any information from the manufacturer in prescribing the product, or if the physician was aware of the risk from

[25] Although LifeCell disputes Plaintiffs' claim that the warnings and instructions for AlloDerm® were inadequate, LifeCell does not argue that the court should find the AlloDerm® warnings and instructions were adequate as a matter of law. Thus, the court will not address this issue and Plaintiffs ultimately bear the burden of proving that the warnings and instructions accompanying AlloDerm® were insufficient to apprise Mrs. Foster and Dr. Gupta of the risks associated with AlloDerm®.

other sources and considered the risk in prescribing the product." Ibid. (quoting Richard J. Heafey & Don M. Kennedy, Products Liability: Winning Strategies and Techniques § 10.03 (1999) (footnotes omitted)).

3. Proximate Cause and the Heeding Presumption

In all product liability actions, "[t]he plaintiff must demonstrate . . . that the defect in the product was a proximate cause of the injury. When the alleged defect is the failure to provide warnings, a plaintiff is required to prove that the absence of a warning was a proximate cause of his harm." Coffman v. Keene Corp., 133 N.J. 581, 594 (1993) (internal citations omitted). New Jersey courts apply a "heeding presumption" in product liability failure-to-warn cases, whereby a plaintiff is entitled to the presumption that if the product at issue had contained an adequate warning, the plaintiff would have heeded that warning. Coffman, supra, 133 N.J. at 600-03 ("[A] jury determination of whether, if a warning had been provided, it would have been followed would most likely be highly speculative. A jury, in effect, would be invited to imagine whether a plaintiff, given the various facets of his or her personality . . . would have heeded a warning. . . . The heeding presumption accords with the manufacturer's basic duty to warn; it fairly reduces the victim's burden of proof; and it minimizes the likelihood that determinations of causation will be based on unreliable evidence.").

However, if a defendant produces "sufficient evidence to rebut the presumption," the heeding presumption falls away, and the plaintiff must proceed with the original burden of proving all elements of proximate cause by a preponderance of the evidence. Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 67 (App. Div. 1998) aff'd. o.b., 158 N.J. 329 (1999). In cases involving a learned intermediary, if the defendant "produces

evidence that [the plaintiff's physician], if provided with the warning information, would have prescribed [the product] anyway and would not have communicated the [additional] risk information to the plaintiffs . . . summary judgment for [the defendant] may be appropriate." In re Diet Drug Litig., supra, 384 N.J. Super. at 544-45 (emphasis added). If the plaintiff's physician would have prescribed the product anyway but also passed on the additional warnings to the plaintiff, "a more complex inquiry is necessary. If the plaintiff denies that he or she would have [used the product] based on those warnings, then the matter will be presented to a jury with the plaintiff bearing the burden of proof on this causation issue." Id.

III. THE PARTIES' ARGUMENTS

Defendant's moving papers focus on the issue of proximate cause, asserting a two-part argument. First, LifeCell contends Mrs. Foster's only injury was a hernia recurrence, therefore only warnings regarding the risk of recurrence are relevant. In this case, LifeCell argues that Mrs. Foster's surgeon, Dr. Gupta, chose AlloDerm® out of necessity, and with full awareness of the risk of recurrence, such that any additional warnings about recurrence risk would not have altered his decision to use AlloDerm®.

Second, LifeCell argues that Plaintiffs' failure-to-warn claim is nothing more than a claim that the AlloDerm® was ineffective in repairing Mrs. Foster's hernia.[26] According to LifeCell, because Plaintiffs fail to complain of any "danger" or "side effect" as contemplated by the NJPLA, Mrs. Foster's claim must fail. Id. at 14–15.

Plaintiffs respond first by noting that the complaint in this matter lists injuries beyond just the hernia recurrence, including "abdominal bulging, pain, and loss of

[26] Def.'s Br. 14.

enjoyment of life,"[27] so LifeCell had a duty to warn as to all of these alleged side-effects.[28] Plaintiffs further argue that: 1) Defendant's production of evidence rebutting the heeding presumption necessitates a jury determination on proximate cause, precluding summary judgment; and 2) in the alternative, Defendant has not adequately rebutted the heeding presumption, leaving a genuine dispute as to whether Dr. Gupta would have elected not to use AlloDerm® had he been adequately warned.[29]

The heart of Plaintiffs' claim is that Dr. Gupta relied on advertising by LifeCell promoting AlloDerm® as a "permanent" repair for complex hernias, and that if he had been warned of the high risk of recurrence and laxity, he would not have used AlloDerm® to repair Mrs. Foster's hernia. In support of their claim, Plaintiffs cite Dr. Gupta's deposition testimony that he no longer uses AlloDerm® in his practice specifically because it is "too thin," "too pliable," and "doesn't meet the factors" necessary for hernia repair surgery.[30] Plaintiffs argue that, because there were other biologic products on the market in June of 2008, Dr. Gupta could have "performed the surgery with a different hernia repair product from the start or ordered an alternative hernia repair product and simply rescheduled Plaintiff's surgery."[31] Notably, Plaintiffs do not put forth any evidence that Mrs. Foster herself would have refused AlloDerm® if properly warned.

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[27] Pls.' Opp. 7.
[28] Plaintiffs alternately pose this as a requirement to warn of the "mechanisms of how [Alloderm] fails," in hernia repair, not just the rate at which it is likely to fail. Pls.' Opp. 9.
[29] Pls.' Opp. 6-16.
[30] Gupta Dep., Pls.' Opp. Ex. 14, 50:14-19.
[31] Pls.' Opp. 14-15.

IV. ANALYSIS

A. THE ASSERTED INJURIES AND RELEVANT WARNING INFORMATION

Plaintiffs argue that LifeCell's failure to warn extends beyond the risk of hernia recurrence because Mrs. Foster's injuries are not limited to recurrence. Plaintiffs' expert report from Dr. Roger Huckfeldt defined Mrs. Foster's injuries as follows:

> [A]side from the need for reoperation, her resulting injuries include pain and discomfort consistent with an additional hernia repair procedure. She is also at greater risk for developing abdominal scar tissue, adhesions, and associated abdominal pain that comes from these issues as she ages. Additionally, the failed June 2008 hernia repair put her at greater risk for subsequent hernia recurrences due to weakened fascia strength."[32]

Plaintiffs claim in their opposition brief that "the abdominal bulging from [Mrs. Foster's] stretched and thinned out Alloderm graft resulted in disfigurement and pain"[33] as well as "loss of enjoyment of life."[34] Mrs. Foster also asserts "disability" as a result of the failed AlloDerm® repair.[35]

Defendant argues in its reply brief that Mrs. Foster's alleged injuries are in fact part and parcel of a hernia recurrence, such that only warnings as to recurrence risk are relevant. "Plaintiff's [sic] attempt to separate the development of a hernia into distinct problems is the equivalent of saying a runny nose, coughing, and sneezing are distinct injuries from having the flu."[36] For support, Defendant cites information from The American College of

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[32] Huckfeldt Report, Pls.' Opp. Ex. 43, 3 (emphasis added).
[33] Pls.' Opp. 3-4.
[34] Pls.' Opp. 7.
[35] Foster Short Form Complaint, Pls.' Opp. Ex. 2, ¶4.
[36] Def.'s Reply 2-3. Defendant, in its reply brief, also asserts that because Dr. Gupta knew that AlloDerm® carried some risk of recurrence, the manufacturer is not required to warn specifically as to the extent or likelihood of recurrence. For this proposition, it relies on Calabrese v. Trenton State Coll., 162 N.J. Super. 145 (App. Div. 1978), aff'd, Calabrese v. Trenton State Coll., 82 N.J. 321, 322 (1980). However, such reliance is misplaced. In Calabrese, the plaintiff suffered debilitating effects from a rabies vaccine which was administered after a dog bite. At the time, it was unknown whether the dog actually had rabies. Plaintiff argued that, due the statistical rarity of rabies and the extreme nature of the side effects of the anti-rabies vaccine, the vaccine manufacturer should have included statistical data on the incidence of rabies. The court

Surgeons describing abdominal bulging and pain as "common hernia symptoms."[37] For reasons explained below, the court need not resolve this particular dispute to rule on this motion.

As to Dr. Huckfeldt's claims that Mrs. Foster is now "at risk" for a myriad of other injuries and side effects, the NJPLA only covers actual physical injuries. See Sinclair v. Merck & Co., Inc., 195 N.J. 51, 64 (2008) ("We read our PLA to require a physical injury. Prior to the enactment of the PLA, we adopted generally the view of Restatement . . . in which strict liability in tort for defective products spoke only in terms of physical harm. Nothing in the legislative history of the PLA suggests that the Legislature intended to eliminate that physical component." (internal citations omitted)).[38]

B. SUMMARY JUDGMENT IN FAILURE TO WARN CASES

Plaintiffs rely on Sharp, supra 314 N.J. Super. 54, for the proposition that if a defendant presents evidence rebutting the heeding presumption, the issue of proximate cause must go to the jury.[39] However, this is a misreading of that case. In Sharpe, the court discussed the effect of the heeding presumption on the burdens of production and persuasion, stating: "[i]n the absence of evidence produced by the defendant rebutting the heeding presumption, the plaintiff is entitled to a directed verdict on the proximate cause element of a failure to warn cause of action." Sharpe, supra 314 N.J. Super. at 64. Conversely, where the defendant presents rebuttal evidence, a directed verdict is avoided, and in the context of a trial, the issue would then go to the jury. See id.

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rejected this claim. However, there was no discussion of a requirement to report the incidence of the vaccine's side effects. Defendant cites no other New Jersey cases to support its argument.

[37] Def.'s Reply 3 n.1.

[38] While New Jersey courts have recognized an exception to the physical injury rule with certain toxic torts, that exception is inapplicable in this case. See, e.g., Ayers v. Township of Jackson, 106 N.J. 557 (1987).

[39] Pls.' Opp. 7.

This is not necessarily the case in a pretrial posture. Sharpe made clear that a defendant's production of rebuttal evidence would shift the burden back to the plaintiff, "who must then carry the burden of persuasion as to proximate cause." Id. at 69. Thus, when the defendant presents rebuttal evidence in a motion for summary judgment, the heeding presumption falls away, and the plaintiff's burden of proof on proximate cause is the same as to any other aspect of the claim, and equally subject to summary judgment in the absence of disputed material facts. See, e.g., Strumph v. Schering Corp., 133 N.J. 33, 34 (1993) (upholding the trial court's grant of summary judgment for defendant in a failure to warn case, where the plaintiff's doctor testified that the proposed warnings would not have altered his decision to prescribe the drug to plaintiff); R. 4:46-1 ("A party seeking any affirmative relief may . . . move for a summary judgment or order on all or any part thereof . . . ." (emphasis added)).

C. PROXIMATE CAUSE

1. Dr. Gupta

Plaintiffs argue that there is sufficient evidence for a trier of fact to find that Dr. Gupta would not have used AlloDerm® if proper warnings had been given, because Dr. Gupta no longer uses AlloDerm® and does not believe it to be appropriate for hernia repair. While appealing on its face, Plaintiffs' argument contains a critical flaw. A claim of failure to warn rests on what the treating doctor would have done at the time of treatment, if given the warnings proposed by the plaintiff. The fact that a doctor no longer uses a product at the time of litigation is not dispositive of a failure-to-warn inquiry. Furthermore, a closer inspection of the record reveals that, while Dr. Gupta does not currently believe AlloDerm® is fit for hernia "repair," he distinguishes the conccpts of repair and

reinforcement, noting that "repair" to him implies a permanence that he never intended with his own use of AlloDerm®.[40]

Dr. Gupta testified that, although his techniques and options have evolved over time, AlloDerm® was the only option at the time of Mrs. Foster's surgery. Because of the severe infection of the synthetic mesh, Dr. Gupta was not going to implant another synthetic mesh. Dr. Gupta also would not have employed a surgical technique to repair the hernia without the use of some type of product. He repeatedly categorized Mrs. Foster's 2008 surgery and his use of AlloDerm® as a "get out of Dodge" situation where there were simply no other options.

> Q: With respect to the biologic and synthetic products, is there some set of circumstances when a biologic is either preferred or is the only option?
>
> A: I think that, in general – and this is my bias. I think that the biologic is the best in those situations where I thought that the patient was heavily contaminated with bacteria, either due to an infection in the area or through peritonitis with intestinal rupture, and I didn't feel comfortable putting a synthetic graft in because that would become infected because it doesn't dissolve, it doesn't go away, and it doesn't have good in-growth of blood vessels and doesn't allow white blood cells to get into the area. So typically, at least in my practice, when I've used biologics, it's because of a contaminated field or for an emergency operation where the risk of infection is quite high. And so the literature has changed on that, but not significantly. I think, for grossly contaminated fields, you still want to use a biologic, or you want to use native tissue. Or you may want to delay the operation completely and just wait and try to do something different.
>
> Q: When you say the literature has "changed," what do you mean by that?
>
> A: Well, it used to be that we had biologics as an option to "get out of Dodge." You know, you put it in, and you close the muscles over it, and then you get out.[41]

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[40] Gupta Dep., Def.'s Br. Ex. B, 73:12-21. Plaintiffs appear to concede that AlloDerm® is suitable for temporary repairs. Pls.' Opp. 3 ("The use of Alloderm in Plaintiff's hernia repair all but guaranteed that he [sic] would have a hernia recurrence. AlloDerm is better suited as a temporary repair product rather than a definitive repair product (as it was advertised).").

[41] Gupta Dep., Def.'s Br. Ex. B, 19:9-20:15.

* * *

Q: So this is – you used the phrase several times, "get out of Dodge."

A: Yes.

Q: Meaning it's a problematic situation.

A: It's a problematic situation

. . .

Q: Why does mesh have to be explanted when it's infected?

A: Again, these are mesh-related factors. But synthetic mesh particularly, when it gets infected, it will not attach to the surrounding tissue, so it's already weakened by that fact. The particular kind of mesh that was in Mrs. Foster is a multifilament mesh; and so it can actually hold onto bacteria within those filaments where white blood cells can't get in to clean that area out. So these patients, particularly with this kind of mesh that she has in, can have a very difficult time healing any kind of wound over it because the mesh continues to stay infected. So it's a situation where you're going to end up taking the entire mesh out instead of leaving pieces of it in if it was well attached. And this will not be well attached.

Q: So at this point, biologic is the only choice you usually have?

A: Yeah. It's either biologic or autologous, and that's what I say in my note.

Q: What do you mean by "autologous"?

A: Autologous means using her own tissues to do a primary repair.

Q: Off the thigh?

A: Not necessarily, no, just primarily repairing it. I don't do tissue transfers, so that's not going to happen.[42]

Dr. Gupta testified that although there may have been other biologic products available at the time, he had been unhappy with those alternatives and did not use them.

Q: Going into this operation, did you consider other biologic products?

[42] Gupta Dep., Def.'s Br. Ex. B, 37:24-40:4 (emphasis added).

A: Yes.

Q: Do you recall any specifically?

A: At the time, Surgisis and – what was the other one? I don't think Xenaderm was out or whatever that Bard product is. There were a couple of other biologics that were out. I had utilized them previously, and I hadn't really been happy with them.

Q: How long had you been using Alloderm in ventral wall surgery?

A: You know, I don't recall as of this time how long I'd been using it. But I will say that the Alloderm product, I utilized it for several repairs – again, the "get out of dodge" situation – but switched to Stratus [sic], the porcine dermal graft, after it came out because I liked the strength of it better.[43]

Dr. Gupta further testified that due to the severity of Mrs. Foster's infection and the pain she was experiencing incidental to it, simply delaying or cancelling the surgery was also not an option.

Q: If Ms. Foster had not undergone this surgery, what was her prognosis?

MR. FANTINI: Objection. You can answer.

A: Well, I mean, she would continue to stay in this state of infection. The mesh would continue to stay secondarily infected, and she has risk of developing sepsis and having worsening infection if the abdominal wall was to get infected. So it couldn't be left in place as is . . . . In her case, she was having a lot of pain associated with this as well.[44]

Thus, while it is undisputed that Dr. Gupta no longer uses AlloDerm®, the record in this case indicates that in 2008, Dr. Gupta believed AlloDerm® to be the only feasible option in grossly contaminated cases such as Mrs. Foster's medical situation. In fact, even though Dr. Gupta now prefers LifeCell's Strattice® biologic product, he still does not believe

[43] Gupta Dep., Pls.' Opp. Ex. 14, 49:20-50:19.
[44] Gupta Dep., Pls.' Opp. Ex. 14, 52:22-53:18.

AlloDerm® was a bad choice before Strattice® came along--depending on the intended use.

> Q: Could you estimate or approximate for us how many times you used Alloderm in those complex ventral hernia repairs?
>
> A: It was very infrequent. Again, my partners used it. I've used it. And we all had the same issues with it, which was that it was a little too light and a little too pliable. It was really only re-enforcement [sic]. I don't think any of us felt that we were going to use it for anything but those really grossly contaminated cases. . . .[45]
>
> * * *
>
> A: It's a thin graft. It's highly elastic. But, again, the use was in highly contaminated fields. That's where we felt we had no other real options. Some of the other meshes that we tried had all melted. And part of that may have been just the way we learned to put it in initially and then how we changed our practice.[46]
>
> * * *
>
> Q: So how did you learn that [AlloDerm®] didn't work for your practice?
>
> A: I wouldn't say that it didn't work. That's not how I would quantitate this. I was not using it as a repair. I was using it as a re-enforcement [sic], which is not – that was my purpose with it. It was to help me in a situation where I have a complex problem and I'm using is as a reinforcing mesh.
>
> Q: So it was adequate for that purpose?
>
> A: Right.[47]
>
> * * *
>
> Q: So [bulging] was a criticism in a repair situation but not in a re-enforcement [sic] situation?
>
> MR. FANTINI: Objection.

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[45] Gupta Dep., Pls.' Opp. Ex. 14, 84:17-24.
[46] Gupta Dep., Pls.' Opp. Ex. 14, 85:13-19 (emphasis added).
[47] Gupta Dep., Def.'s Br. Ex. B, 73:12-21.

A: Yeah. Again, because I never used it in a repair situation. . . .[48]

* * *

Q: And you told us that, when you used Alloderm, you always use [sic] it as a re-enforcement [sic] instead of a permanent repair, right?

A: Yes.[49]

In addition to Dr. Gupta's uncontroverted testimony that he believed AlloDerm® was his only option for Mrs. Foster's 2008 surgery,[50] and that he never believed it would be a permanent repair, he also testified that he was well aware of the risk of recurrence. Although Plaintiffs repeatedly assert in their papers that Dr. Gupta relied on representations by LifeCell that AlloDerm® was a permanent repair, and that Dr. Gupta was unaware of AlloDerm®'s "harmful propensities,"[51] this assertion is unfounded and unsupported by the record. To the contrary, Dr. Gupta testified emphatically that he never believed AlloDerm® to be a permanent repair, and in no way relied on any such representation by LifeCell.

Q: In these marketing materials, do you ever recall LifeCell promoting Alloderm as a permanent repair?

A: I just don't recall, and I wouldn't have believed them anyway.

Q: Why wouldn't you have believed them?

A: Because [biologic meshes] disappear. If the native tissue is what's replacing it, then there's no way that the strength of the native tissue is

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[48] Gupta Dep., Def.'s Br. Ex. B, 75:7-11.

[49] Gupta Dep., Def.'s Br. Ex. B, 87:18-21.

[50] To the extent Plaintiffs argues that Dr. Gupta could have chosen a two-stage repair or that Mrs. Foster's surgery was not a true "emergency," the argument is misplaced. A failure-to-warn claim must be based on what the surgeon would have done if given a different warning. If the surgeon did not believe he had other options, a challenge to the surgeon's judgment would be as a medical malpractice claim, which is not asserted in this case. Had AlloDerm® had different warnings, Dr. Gupta would not have altered his course of treatment as he believed there were no other options possible or feasible for Mrs. Foster in June of 2008. Nor would a different warning have convinced Dr. Gupta that Ms. Foster's situation was not an emergency.

[51] Pls.' Opp. 3.

improved with a nonsynthetic. And that was consistent across all biologics for a long time.[52]

* * *

Q: And do you recall if the sales reps ever told – or any of the marketing material – that Alloderm can successfully treat difficult cases in a single repair, which ultimately saves the health care system money, saves surgeons time, and improves the patient's care and quality of life?

A: I don't independently recall a rep ever telling me that and me not laughing at him.

Q: What do you mean by that?

A: Well, because I've just never bought this premise, and I've told LifeCell that. . . . That's why I take it all with a grain of salt. There's a lot of people that come by and are presenting information. You have to use it appropriately.[53]

* * *

Q: What type of information would you rely on from a sales rep?

A: More as far as comparison literature and how the biologic is absorbed, some basic scientific stuff. The reason to use a product I don't base on what they're telling me. I usually base that on cost, availability, indication. And those are not things I rely on from the reps. It's nice if the reps tell me. But there's a hernia mesh coming around the corner every month. I really don't care what they tell me because there's always a guy with a better product coming around the table.[54]

In fact, Dr. Gupta well understood the increased hernia recurrence risk with biological products.

Q: And do you have an understanding as to how the difference, if any, of the synthetic works and the biologic works?

A: Yeah. Both have different characteristics that we use as surgeons. Synthetic will not disappear, generally; but there are synthetic meshes that do absorb. Biologic meshes, as a rule, are not permanent.[55]

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[52] Gupta Dep., Def.'s Br. Ex. B, 87:18-88:8 (emphasis added).
[53] Gupta Dep., Def.'s Br. Ex. B, 90:9-91:2.
[54] Gupta Dep., Def.'s Br. Ex. B, 71:24-72:12.
[55] Gupta Dep., Def.'s Br. Ex. B, 13:13-21.

* * *

> Q: Well, presently, what level or percentage [for recurrence risk] are you comfortable telling the patient . . . [with] biologic?
>
> A: To be frank, I've never said that a biologic would not lead to recurrence. In fact, when I've used biologics, I've used them in an emergency case. So I have always told my patients that they're going to get a recurrence because I'm using it in a field where it is a "get out of Dodge" technique. . . . When I put a biologic in, I don't know what the tensile properties are going to be once it's reabsorbed. So there's no way I can tell the patient that that's going to be a permanent repair because I don't assume it.
> . . .
>
> Q: Have you ever felt comfortable guaranteeing a patient that he or she won't get a recurrence?
>
> A: Never. [56]

While Plaintiffs attempt to use their own expert, Dr. Huckfeldt, to opine on what Dr. Gupta thought or believed, that is improper speculation and unsupported by any evidence. The uncontroverted testimony is that Dr. Gupta, with full knowledge that AlloDerm® would likely lead to a recurrence, used AlloDerm® to "reinforce" Mrs. Foster's hernia in 2008 as a "get out of Dodge" emergency technique.

2. Debbie Foster

Absent the benefit of the heeding presumption, Plaintiffs have the burden of producing evidence as to each element of their claim. As noted above, Plaintiffs have not put forth any testimony that a stronger warning on AlloDerm® would have caused Mrs. Foster to refuse implantation. While Mrs. Foster indicated in her deposition that she could not recall the details of any specific pre-surgery conversation she had with Dr. Gupta,[57] the

[56] Gupta Dep., Def.'s Br. Ex. B, 26:12-28:17 (emphasis added).
[57] Foster Dep., Def.'s Br. Ex. A, 60:4-20

record does reveal that Mrs. Foster signed a surgery consent form prior to the 2008 surgery, which stated:

> My physician has explained to me the following: . . . C. The potential benefits, risks, and side effects, including potential problems related to recuperation. . . . I have received no warranties or guarantees with respect to the benefits to be realized or consequences of the aforementioned procedure(s)/treatment(s).[58]

As noted above, Dr. Gupta testified that he always tells patients getting a biologic product that they will (not might) get a recurrence.[59] While Plaintiffs argue that an adequate warning would also include the specific mechanisms of failure and symptoms of a hernia—such as bulging and pain—Mrs. Foster's long history with hernias prior to the 2008 surgery made her well aware of the varying complications from hernias. In discussing her first hernia, Mrs. Foster described it as a bulge in her abdomen "the size of your head."[60] By the time of her 2007 hernia, Mrs. Foster understood the precise mechanism of hernia and its accompanying pain.

> Q: Were you in pain—
>
> A: Oh, yes.
>
> Q: Let me just finish – or was it just a cosmetic issue that you could see?
>
> A: No, it's painful.
>
> Q: Okay. And what type of pain or what type of activities caused the pain?
>
> A: Because, what they do is your intestines break through the wall of your stomach, and if pressure is put on that in any way, shape or form, it causes great pain.[61]

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[58] Consent Form signed June 23, 2008, Def.'s Br. Ex. E, ¶¶2-3, "Ventral hernia repair with Alloderm."
[59] Gupta Dep., Def.'s Br. Ex. B, 26:12-28:17.
[60] Foster Dep., Def.'s Br. Ex. A, 59:14-19.
[61] Foster Dep., Def.'s Br. Ex. A, 76:18-77:4.

Although a plaintiff's understanding of product risks does not alleviate a manufacturer of its duty to warn, "a plaintiff's knowledge of a certain risk, irrespective of the existence of a warning, may directly affect the issue of causation." Coffman v. Keene Corp., 133 N.J. 581, 603 (1993). In this case, the record is replete with evidence that Mrs. Foster understood that hernia repairs may fail (since she had two failed repairs prior to her surgery with AlloDerm®), and that hernia recurrences can entail bulging, laxity, and pain.

V. CONCLUSION

A defendant manufacturer in a product liability action may be entitled to summary judgment on failure to warn upon a showing that, even if given the proposed additional warnings, the treating doctor would not have altered his course of treatment or differently advised the plaintiff. Strumph v. Schering Corp., 256 N.J. Super. 309 (App. Div. 1992) (Skillman, J.A.D., dissenting), rev'd on dissent, Strumph v. Schering Corp., 133 N.J. 33 (1993); In re Diet Drug Litig., 384 N.J. Super. 525 (Law Div. 2005). At the summary judgment phase, mere unsupported allegations are insufficient to present genuine disputes of material fact. R. 4:46-5 ("When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the pleading, but must respond . . . setting forth specific facts showing that there is a genuine issue for trial."). While Plaintiffs have provided a voluminous amount of documentation relating to AlloDerm® promotional materials and various scientific articles debating the merits of AlloDerm®, they have failed to produce any evidence that puts into dispute the critical facts relating to proximate cause.

In this case, Dr. Gupta's uncontroverted testimony is as follows: he does not recall ever being told by LifeCell that AlloDerm® was appropriate for permanent hernia repair,

and he would not have believed such a claim anyway. Dr. Gupta knew that, as a rule, biologics are temporary. Although there were several other biologics on the market in 2008, Dr. Gupta was not happy with other biologics, and did not use them. He also did not perform autologous repairs in infected fields without the use of mesh. Because of Mrs. Foster's presentation with infected synthetic mesh, Dr. Gupta used AlloDerm® as a "get out of Dodge," emergency repair. Dr. Gupta used AlloDerm® as a "reinforcement," rather than a permanent repair. In accordance with his understanding of biologic products, Dr. Gupta always tells his patients getting a biologic product that they will have a recurrence. The record also shows that Mrs. Foster had numerous failed hernia repairs prior to 2008, some of which resulted in significant bulging and pain.

The testimony is clear that no different or better warning would have altered Dr. Gupta's decision to use AlloDerm®. It is equally clear that the warning Dr. Gupta gave to Mrs. Foster—that she will have hernia recurrence—is as strong a warning as one can give or receive. Accordingly, the undisputed evidence in this case precludes a rational trier of fact from finding that any inadequacies in AlloDerm®'s warnings were a proximate cause of Mrs. Foster's injuries. As Mr. Foster's loss of consortium claim is derivative of Mrs. Foster's claims, his claim similarly fails as a matter of law.

For the above reasons, Defendant's motion for summary judgment on Plaintiffs' claim for failure-to-warn is **GRANTED**.

8/14/17

JESSICA R. MAYER, J.S.C.