#0311
08-07-15

David W. Field (00378-1984)
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973.597.2500
Attorneys for Defendant
LifeCell Corporation

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
PATRICIA JULIEN, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-507-12 CM
THOMAS DUTCHER, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-1469-12 CM

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 Actions **ORDER**

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order barring plaintiffs' experts from offering any opinions or related evidence at trial relating to the amount of tension to be applied to AlloDerm pre-operatively, 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~~ denied*; and it is further

~~ORDERED that Drs. Billiar, Dumanian, Huckfeldt, Gouge and LeBlanc may~~ not ~~offer at trial any opinions or other evidence related to the amount of tension to be applied~~ to ~~AlloDerm pre-operatively or the sufficiency of LifeCell's warnings or instructions~~ on ~~tension~~; and it is further

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

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

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

OPPOSED

0312
08-07-15

David W. Field (00378-1984)
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973.597.2500
Attorneys for Defendant
LifeCell Corporation

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
PATRICIA JULIEN, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-507-12 CM
THOMAS DUTCHER, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-1469-12 CM

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 Actions **ORDER**

FILED

AUG 14 2015

JUDGE JESSICA R. MAYER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order barring plaintiffs' experts from offering any opinions or related evidence at trial relating to the amount of tension to be applied to AlloDerm pre-operatively, and the Court having considered all papers submitted by the parties, and for good cause and the reasons ~~stated on the record by the~~ in the attached memorandum of decision 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 Drs. Billiar, Dumanian, Huckfeldt, Gouge and LeBlanc may not offer at trial any opinions or other evidence related to the amount of tension to be applied to AlloDerm pre-operatively or the sufficiency of LifeCell's warnings or instructions on tension; and it is further

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

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

OPPOSED

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

#0313
08-0715

David W. Field (00378-1984)
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973.597.2500
Attorneys for Defendant
LifeCell Corporation

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
PATRICIA JULIEN, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-507-12 CM
THOMAS DUTCHER, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-1469-12 CM

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 Actions **ORDER**

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order barring plaintiffs' experts from offering any opinions or related evidence at trial relating to the amount of tension to be applied to AlloDerm pre-operatively, 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~~ denied*; and it is further

~~ORDERED that Drs. Billiar, Dumanian, Huckfeldt, Gouge and LeBlanc may not offer at trial any opinions or other evidence related to the amount of tension to be applied to AlloDerm pre-operatively or the sufficiency of LifeCell's warnings or instructions on tension~~; and it is further

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

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

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

OPPOSED

David W. Field (00378-1984)
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973.597.2500
Attorneys for Defendant
LifeCell Corporation

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
PATRICIA JULIEN, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-507-12 CM
THOMAS DUTCHER, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-1469-12 CM

0314
08-07-15

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 Actions **ORDER**

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order barring plaintiffs' experts from offering any opinions or related evidence at trial relating to the amount of tension to be applied to AlloDerm pre-operatively, 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~~ denied; * and it is further

~~ORDERED that Drs. Billiar, Dumanian, Huckfeldt, Gouge and LeBlanc~~ may not ~~offer at trial any opinions or other evidence related to the amount of tension to be applied~~ to ~~AlloDerm pre-operatively or the sufficiency of LifeCell's warnings or instructions on tension~~; and it is further

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

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

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

OPPOSED

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 *In Limine* to Exclude Evidence and Testimony

In Re: AlloDerm® Litigation, Case Code 295

Thomas Dutcher v. LifeCell Corporation

Docket No. MID-L-1469-12 CM

Debbie Foster and David Foster v. LifeCell Corporation

Docket No. MID-L-6841-12 CM

Patricia Julien v. LifeCell Corporation

Docket No. MID-L-507-12 CM

Michael Simineri and Karen Simineri v. LifeCell Corporation

Docket No. MID-L-5972-11 CM

Dated August 14, 2015

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

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

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves to bar Plaintiffs'[1] experts – Dr. Kristen Billiar, Dr. Gregory Dumanian, Dr. Thomas Gouge, Dr. Roger Huckfeldt,

[1] Counsel for the parties selected four cases out of approximately 350 currently pending AlloDerm® matters as "bellwether" trials. The selected cases are: Thomas Dutcher, Debbie and David Foster, Patricia Julien, and Michael and Karen Simineri (collectively "Plaintiffs").

and Dr. Karl LeBlanc – from offering evidence or testimony regarding the amount of tension to be applied to AlloDerm® preoperatively or the sufficiency of LifeCell's warnings or instructions concerning tension.[2] Counsel agreed to waive both oral argument on the motion and a hearing pursuant to N.J.R.E. 104 and consented to the court's disposition of the matter on the papers submitted. Upon considering the legal memoranda, exhibits and relevant case law,[3] the court determines that LifeCell's motion to bar Plaintiffs' experts from offering tension testimony is **DENIED.**

I. BACKGROUND

Plaintiffs each assert a claim against Defendant for failure-to-warn under the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. § 2A:58C-1 et seq.[4] As part of this claim, Plaintiffs allege that "LifeCell knew, or should have known, that AlloDerm could stretch, expand, thin out, pull, sag, loosen, spread and/or dissolve . . . [and] that an AlloDerm graft must be pre-stretched before it can be used in a hernia repair or abdominal wall reconstruction surgery."[5] Plaintiffs further allege "Defendant failed to provide full and accurate warnings and/or instructions . . . that Alloderm would stretched [sic] if not pre-stretched before it was implanted or implanted under the appropriate tension."[6] Finally, Plaintiffs allege that "once implanted, AlloDerm stretches, expands,

[2] The court notes that LifeCell's motion to bar certain testimony is not a dispositive motion. The court deems a motion to bar portions of an expert's testimony to be an *in limine* motion. In accordance with Paragraph 13 of Case Management Order No. 6, only dispositive motions and motions related to the admissibility of expert testimony were to be filed and served at this time. Motions *in limine* limited to the trial selected case are due on October 16, 2015 in accordance with Paragraph 17 of Case Management Order No. 6. In the future, the court will not address motions that are filed contrary to the timeframes specified in the court's case management orders.

[3] The parties signed a consent order stipulating that New Jersey law governs all issues in the AlloDerm® cases. See Consent Order Stipulating Choice of Law, Jan. 15, 2015.

[4] This court dismissed the failure-to-warn claims of Plaintiffs Julien and Foster in separate Orders and Memoranda of Decision dated August 14, 2015. Accordingly, the court will only discuss records and arguments of counsel relating to the remaining plaintiffs, Dutcher and Simineri, in deciding the instant motion.

[5] Long Form Complaint, Plaintiffs' Opposition Brief ("Pls.' Opp. Br.") Ex. A, ¶¶30-31.

[6] Long Form Complaint, Pls.' Opp. Br. Ex. A, ¶69.

thins out, pulls, sags, loosens, spreads, dissolves or otherwise fails, resulting in serious injury to the user's abdominal area and/or requiring additional surgery."[7]

Plaintiff Thomas Dutcher underwent hernia repair surgery with AlloDerm® in April of 2005. Mr. Dutcher alleges the AlloDerm® graft "completely failed," resulting in hernia recurrence, abdominal deformity, pain, disability, and the need for additional surgery.[8] Plaintiff Michael Simineri underwent hernia repair surgery with AlloDerm® in October of 2007. Mr. Simineri alleges that "By January 3, 2011, the AlloDerm® [used in his repair] had completely failed, resulting in a hernia recurrence" which necessitated another surgery.[9]

LifeCell included Instructions For Use ("IFUs") with each package of AlloDerm®. The IFUs were revised several times since 2004.[10] Some of the changes in these revisions include instructions as to the appropriate amount of tension to apply to AlloDerm®, and the extent to which AlloDerm® can stretch when placed under "significant" tension.[11]

II. LEGAL STANDARDS

A. PRODUCT LIABILITY/FAILURE 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. 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. . . .

---

[7] Long Form Complaint, Pls.' Opp. Br. Ex. A, ¶45.
[8] Dutcher Short Form Complaint, Pl.'s Opp. Br. Re: Dutcher Failure to Warn/Summary Judgment, Ex. R ¶¶3-4.
[9] Simineri Complaint, Pls.' Opp. Br. Re: Simineri Failure to Warn/Summary Judgment, Ex. T ¶48.
[10] Pl.'s Opp. Br. 6.
[11] AlloDerm® 2008 IFU, Pls.' Opp. Br. Ex. G, 9.

[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 part, by considering the "the characteristics of, and the ordinary knowledge common to" the party to whom the warning is directed. Id. 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.[12] 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

[12] 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.

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 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, 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 v. Bessemer Processing Co., Inc., 155 N.J. 279, 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).

B. ADMISSIBILITY OF EXPERT TESTIMONY

N.J.R.E. 702, which governs the admissibility of scientific expert testimony in New Jersey, provides that:

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of a opinion or otherwise.
>
> [Ibid.]

In order to assist the trier of fact in understanding evidence or determining a fact in issue, the proffered testimony must be relevant to the evidence or facts in issue. See Muise v. GPU, Inc., 371 N.J. Super. 13, 59 (App. Div. 2004) ("Because expert testimony must assist the trier of fact, its admissibility depends in part on the connection between the evidence to be presented and the disputed factual issues in the case." (citing In re TMI Litig., 193 F.3d 613, 665 (3d Cir. 1999)). Evidence is considered relevant if there is a logical connection between the proffered evidence and what the party seeks to prove. See Furst v. Einstein Moomjy, Inc., 182 N.J. 1, 15 (2004) (citing State v. Hutchins, 241 N.J. Super. 353, 358, (App. Div. 1990)); N.J.R.E. 401 ("'Relevant evidence' means evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action."). As the New Jersey Supreme Court has explained,

> [r]elevancy consists of probative value and materiality. Probative value is the tendency of the evidence to establish the proposition that it is offered to prove. A material fact is one which is really in issue in the case. Thus, our inquiry focuses on the logical connection between the proffered evidence and a fact in issue. Evidence need not be dispositive or even strongly probative in order to clear the relevancy bar. It need only have some tendency to prove a material fact. The inquiry is whether the thing sought to be established is more logical with the evidence than without it.
>
> [State v. Buckley, 216 N.J. 249, 261 (2013) (emphasis added) (internal citations and quotation marks omitted)]

III. THE PARTIES' ARGUMENTS

Defendant's argument against the admission of tension testimony focuses entirely on the issue of relevance. Defendant cites to Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 62-63 (App. Div. 1998), for the proposition that "Plaintiffs cannot establish their failure-to-warn claims merely by pointing out **any** alleged inadequacy in LifeCell's warnings and instructions. Instead, they are required to demonstrate that their alleged injuries would not have occurred if proper instructions had been conveyed."[13] Defendant argues that none of the Plaintiffs' experts specifically opined that it was the tension applied when the AlloDerm® was implanted that was the cause of Plaintiffs' respective injuries. Therefore, according to LifeCell, any testimony regarding pre-stretching or tension will not tend to prove or disprove proximate cause, rendering tension testimony irrelevant. Defendant further notes that Dr. Huckfeldt specifically did not take issue with the surgical techniques of the implanting surgeons.[14]

Plaintiffs respond by arguing that evidence about LifeCell's instructions on tension "goes to the very heart of Plaintiffs' failure to warn claims."[15] Plaintiffs cite testimony from their experts which Plaintiffs assert establishes a causal connection between tension and AlloDerm®'s failure.[16] Additionally, Plaintiffs refer to Defendant's internal communications indicating LifeCell's own belief of a potential connection between implantation tension, pre-stretching, and graft failure.[17]

---

[13] See Defendant's Brief in support of motion to bar tension testimony ("Def.'s Br.") 6.
[14] See Defendant's Reply Brief in support of motion to bar tension testimony ("Def.'s Reply Br.") 5.
[15] Pls.' Opp. Br. 1.
[16] Pls.' Opp. Br. 6-11.
[17] Pls.' Opp. Br. 5.

IV. ANALYSIS

The court reiterates that Defendant's sole objection to Plaintiffs' experts' tension testimony is grounded on the issue of relevance, and not any other aspect of scientific testimony admissibility under N.J.R.E. 702.[18] Thus, the court addresses only the issue of relevance concerning tension testimony by Plaintiffs' experts. The record before the court is replete with evidence connecting pre-stretching and tension to the alleged AlloDerm® failures entailing laxity, bulging, and recurrence. Dr. Billiar testified, "when they say 'high tension,' the unit is some sort of a force or force per length or force per area. And what happens to the material is it deforms to a certain percentage . . . ."[19] Dr. Huckfeldt stated, "AlloDerm has demonstrated, by its extensive laxity and hernia recurrence rate, an inability to provide prolonged in vivo strength." LifeCell's own employees repeatedly link tension to post-surgical bulging in discussing reports of high recurrence rates and proposed IFU changes as noted in the following corporate testimony and LifeCell documents:

> [O]f note is that the time period for these procedures [reporting a 60% recurrence rate] was January 2004 to December 2005 before we had migrated to our "significant tension/wide underlay" message. . . . [W]e are recommending wide underlay and putting AlloDerm under significant tension . . . . Additional technique advancements include . . . [a]llowing for complete rehydration of the AlloDerm to ensure that all stretch is out of the material before closure. . . . We will continue to stay the course with our focused message on the clinical benefits of AlloDerm and the technique tips to avoid bulging and laxity . . . .
>
> [LifeCell Corporation Interoffice Memorandum, Pls.' Opp. Br. Ex. D (emphasis added).]

* * *

[18] To the extent Defendant objects to specific testimony proffered by Plaintiffs' experts on the basis of other aspects of admissibility, it may file an appropriate *in limine* motion on October 16, 2015 in accordance with Paragraph 17 of Case Management Order No. 6.

[19] Billiar Dep., Pls.' Opp. Br. Ex. K, 112:5-8 (emphasis added).

Q: You had a study at the time that showed a hundred percent failure rate. And one of the problems that you yourself, I mean LifeCell raised, was that hundred percent was in the absence of significant tension being used, correct?

A: One, one of the things.

[Jankiewicz Dep., Pls.' Opp. Br. Ex. E, 307:21-308:2.]

* * *

[When surgeons are] presented with a biological material, their tendency would be to put it in a lax configuration because that's the way they're trained. . . . That's contrary to what happens with a biological material such as AlloDerm that grows into the body and heals to the edges. That doesn't heal by contraction like the synthetic materials do. So conventional training would say put it in tension-free, and when they learned this was not the case, by surgeons who began using it, you can see that the evolution of that approach, that mentality, thinking would have to go someplace to get to putting it under stretch.

[Harper Dep., Pls.' Opp. Br. Ex. B, 63:5-24 (emphasis added).]

* * *

Marketing indicated that Key Opinion Leaders believe that a significant amount of tension must be applied to avoid a bulging effect post-surgery. . . . My initial thought was to avoid any type of qualifier and just state "tension" since I cannot determine what "moderate" or "significant" means. However, Marketing feels this is not sufficient in relaying the message that a great deal of tension must be applied to get the best results.

[Email from Ray Librojo Dated June 8, 2006, Pls.' Opp. Br. Ex. I (emphasis added).]

While Defendant argues that Plaintiffs' experts explicitly disclaim surgical technique as a cause for AlloDerm® failure, the court views the record differently. Dr. Huckfeldt stated that "Thomas Dutcher's AlloDerm graft was implanted in accordance with contemporaneous product indications, promotional materials and sales representations by LifeCell."[20] He similarly noted, "Michael Simineri's AlloDerm graft was implanted in accordance with contemporaneous product

[20] Huckfeldt Dutcher Report, Pls.' Opp. Br. Ex. N, 4.

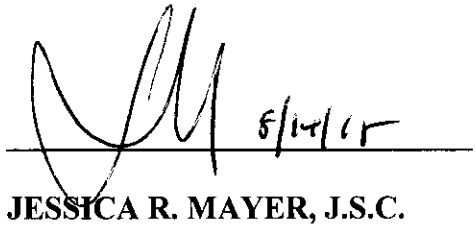
indications and representations by LifeCell." The court reads Dr. Huckfeldt's statements to mean that the implanting surgeons' techniques were "appropriate" in that the surgeons followed the information supplied by LifeCell at the time, not that the surgical technique had no impact on the later issues with laxity, bulging, and hernia recurrence. Indeed, the surgeons' techniques in following LifeCell's instructions for AlloDerm® at the time is indeed an essential component of Plaintiffs' failure-to-warn claim.

V. CONCLUSION

Defendant argues the absence of an explicit statement that inadequate tension caused Plaintiffs' injuries renders any tension testimony irrelevant. The legal standard in barring testimony for lack of relevance is not a bright line. Relevant evidence is evidence that may prove any fact of consequence in the action. In these cases, Plaintiffs describe AlloDerm®'s failure in terms of tension issues, such as "laxity" and "bulging." Defendant's own discussions on tension's potential role in graft failure are particularly relevant to the question of what LifeCell "knew or should have known" in the context of a failure-to-warn claim. The court agrees with Plaintiffs that tension issues are relevant and testimony related to tension is relevant to Plaintiffs' claims and Plaintiffs shall not be barred from presenting such testimony at trial.[21]

[21] Pls.' Opp. Br. 1.

For the foregoing reasons, Defendant's motion to bar Plaintiffs' experts from offering evidence or testimony regarding the amount of tension to be applied to AlloDerm® preoperatively, or the sufficiency of LifeCell's warnings or instructions on tension, is **DENIED.**



JESSICA R. MAYER, J.S.C.