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

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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 barring plaintiff from introducing from introducing expert testimony on certain failure-to-warn theories at the time of trial, and the Court having considered all papers submitted by the parties, and for good cause and the reasons set forth in the attached memorandum of decision ~~stated on the record by the Court,~~

It is on this the 20th day of November, 2015,

ORDERED that defendant's motion is hereby granted in part; and it is further ~~, and it is further~~

ORDERED that plaintiffs are barred from introducing expert testimony on the following failure-to-warn theories: ~~(a) that Dr. Garcia applied an improper amount of tension to the AlloDerm he implanted in plaintiff on October 24, 2007, (b) that LifeCell provided~~ Dr. ~~Garcia with inadequate warnings and instructions on the amount of tension to be applied to AlloDerm~~ pre-surgery, ~~(c) Dr. Garcia's application of inadequate pre-surgery tension was a~~

~~proximate cause of plaintiff's alleged injuries at the time of trial and,~~ (d) the IFUs and warnings should have ~~to~~ informed Dr. Garcia that ~~(i) AlloDerm takes 18 to 24 months to remodel~~, (ii) patients should not go back to normal activities for at least 18 to 24 months ~~and (iii) that patients with co-morbidities such as obesity had greater risk of recurrence~~; and it is further

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

4/21/17

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NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS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 *In Limine* to Bar Plaintiffs from Introducing Expert Testimony on Certain Failure-to-Warn Theories

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., Joseph J. Fantini, Esq., and Sol H. Weiss, Esq., Anapol Weiss.

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

Dated November 20, 2015

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves to preclude Plaintiffs' experts from testifying about "certain failure-to-warn theories." Counsel agreed to waive oral argument on this motion and consented to the court's disposition of the matter on the papers submitted. Upon considering the legal memoranda, exhibits and relevant case law,[1] the court determines that LifeCell's motion to bar Plaintiffs' experts from testifying about pre-surgery tension, remodeling time, and comorbidities is **GRANTED IN PART**.

[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.

Defendant moves under Rule 4:17-4(e) to preclude failure-to-warn theories which LifeCell alleges were not disclosed in the expert reports authored by Plaintiffs' expert, Dr. Roger Huckfeldt. Specifically, Defendant moves to preclude evidence and testimony relating to pre-surgery tension, remodeling time, and comorbidities.[2] Plaintiffs oppose the motion, essentially arguing that all three of these elements do appear in Dr. Huckfeldt's expert reports.

New Jersey Court Rule 4:17-4(e) dictates that an expert report "shall contain a complete statement of that person's opinions and the basis therefor ... ." R. 4:17-4(e). The trial judge has the discretion to preclude expert testimony on subjects or opinions not disclosed through the discovery process. Mauro v. Owens-Corning Fiberglas Corp., 225 N.J. Super. 196, 206 (App. Div. 1988) (affirming trial court's preclusion of expert testimony on certain statistics which were not disclosed in the expert's report "or in other discovery furnished to defendants"), aff'd sub nom Mauro v. Raymark Industries, Inc., 116 N.J. 126 (1989).

The court notes that Defendant previously moved to bar evidence and testimony regarding pre-surgery tension, and that motion was denied by this court on August 14, 2015.[3] While the prior motion was based on a purported lack of relevance, it belies Defendant's current argument that such a failure-to-warn theory was not previously disclosed by Plaintiffs or their expert. It is evident from Defendant's earlier motion that LifeCell was well aware that Plaintiffs intended to put pre-surgery tension at issue as part of their failure-to-warn claim. In fact, this court noted previously that the tension issue is stated in Plaintiffs' Long Form Complaint: "Defendant failed to provide full and accurate warnings and/or instructions . . . that Alloderm would stretched [sic] if not pre-

[2] Defendant's Brief in Support of Motion *In Limine* to Bar Plaintiffs from Introducing Expert Testimony Regarding Certain Failure-to-Warn Theories ("Def.'s Br.") 1-2.

[3] Order and Memorandum of Decision on Defendant's Motion *In Limine* to Exclude Evidence and Testimony Regarding Tension, dated August 14, 2015.

stretched before it was implanted or implanted under the appropriate tension."[4] Additionally, Dr. Huckfeldt raised the issue of tension instructions during his deposition.[5] Although there is not a dedicated section of the expert report entitled "tension," the court finds sufficient evidence in the record that Defendant was on notice of the tension issue raised by Plaintiffs during discovery. While a majority of the Defendant's brief on the instant motion questions the validity of Dr. Huckfeldt's assertions regarding tension, that is a matter for the finder of fact, not a reason for preclusion of tension testimony.

As to Defendant's motion to bar argument that LifeCell failed to warn Dr. Garcia that patients should refrain from normal everyday activities "for at least 18 to 24 months," the court finds that this specific assertion was never revealed in Plaintiffs' expert's reports or anywhere else in the discovery process. Rather, it was an argument made by Plaintiffs' counsel in opposition to a prior summary judgment motion. Because the assertion was not identified during discovery, Plaintiffs' expert is precluded from making this specific argument at trial. However, the court shall not apply a broad rule precluding testimony on the issues of graft degradation and remodeling completely, as the court understands that such issues may relate to scientific background information on how AlloDerm® works.

Regarding comorbidities, Dr. Huckfeldt identifies this issue in both his general and specific causation reports. In section H of his general causation report, Dr. Huckfeldt states:

> The LifeCell AlloDerm IFUs, promotional materials, and sales representatives failed to adequately warn patients, and their surgeons, of the inherent risks in using the graft for definitive and lasting ventral hernia repair. ... Promotional materials are very specific as to indications for use, recommended patient demographics and comorbidities in the definitive hernia repair despite the complete lack of supporting evidence. There are no discussions in the promotional materials about the significant risk of stretch, thinning, laxity and reherniation despite LifeCell awareness. ... It was made very clear that AlloDerm was recommended for use in

[4] Long Form Complaint ¶69.

[5] Certification of Joseph F. Fantini ("Fantini Cert.") Ex. C, 106:17-23.

> complex patients including … significant comorbidities (obesity, diabetes, etc.) as a definitive, rather than a staged repair of ventral hernias.
>
> [Huckfeldt General Causation Report, Fantini Cert. Ex. A, 12-13 (emphasis added).]

The report continues,

> LifeCell sold and marketed AlloDerm as a definitive and lasting ventral hernia repair product for patients with infections and various comorbidities despite the fact that it contains numerous characteristics that make it unsuitable for hernia repair. These characteristics include … reliance on patient's healing process to repair hernia but targeting patients with poor-healing comorbidities; and propensity to stretch, bulge, thin, attenuate, and/or reherniate over time.
>
> [Id. at 13.]

In his specific causation report, Dr. Huckfeldt notes that "LifeCell promoted AlloDerm as suitable for hernia repair in patients like Michael Simineri who … suffered from comorbidities … ."[6] Thus, Defendant was apprised through Dr. Huckfeldt's expert reports of Plaintiffs' intent to raise comorbidities as part of their claim. Therefore, Plaintiffs are not barred from presenting such testimony through their expert witness.

For the foregoing reasons, Defendant's motion to bar expert testimony regarding pre-surgery tension is **DENIED**. Defendant's motion to bar expert testimony regarding graft degradation and remodeling is **GRANTED IN PART**. Defendant's motion to bar expert testimony regarding comorbidities is **DENIED**.

4/20/16

Jessica R. Mayer, J.S.C.

[6] Huckfeldt Specific Causation Report, Fantini Cert. Ex. B, 3.