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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 arguments and evidence regarding LifeCell's marketing materials at the time of trial, and the Court having considered all papers submitted by the parties, and the arguments of counsel and for good cause and the reasons ~~stated on the record by the Court~~ set forth in the attached memorandum of decision,

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

ORDERED that defendant's motion is hereby ~~granted; and it is further~~ DENIED without prejudice

~~ORDERED that plaintiffs are barred from introducing (1) LifeCell's marketing materials which were not provided to and relied on by Dr. Garcia and (2) argument or evidence that AlloDerm was marketed by LifeCell as a "permanent repair", "permanent solution," "one time solution" or the equivalent phrase or language at the time of trial~~; and it is further

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

4/21/11

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NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS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 Arguments and Evidence Regarding LifeCell's Marketing Materials

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 evidence and argument concerning LifeCell's marketing materials. 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 evidence and testimony about LifeCell's marketing materials is **DENIED WITHOUT PREJUDICE.**

[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.

Plaintiffs allege that LifeCell failed to adequately warn of the risks associated with the use of AlloDerm® in abdominal hernia repair. Defendant seeks to bar Plaintiffs from introducing LifeCell marketing materials that were not provided to and relied upon by Mr. Simineri's surgeon, Dr. Gerardo Garcia, as well as to bar Plaintiffs from arguing that AlloDerm® was marketed as a "permanent repair," "permanent solution," "one time solution," or such similar language. Defendant argues that, absent any testimony from Dr. Garcia identifying LifeCell documents he received and his reliance on those documents, LifeCell's marketing material is irrelevant and highly prejudicial. Defendant further argues that since Dr. Garcia testified that he did not specifically recall AlloDerm® being marketed as a permanent repair, Plaintiffs should be precluded from using such a term. Defendant argues that "permanent repair" is a term of art meaning a hernia repair done in one surgery, rather than a two-stage repair, and that the use of such a term will be confusing to a jury, who may presume it to mean a recurrence-free repair.

Plaintiffs respond by asserting that (1) Dr. Garcia could not recall which specific documents he viewed, but testified that he did receive and review LifeCell marketing materials; (2) the consistency of LifeCell's marketing message means that essentially any LifeCell marketing material was likely to have been seen by or communicated to Dr. Garcia, regardless of whether he can recall the specific item; and (3) "permanent repair" is not a term of art.

Plaintiff Michael Simineri underwent a hernia repair surgery with AlloDerm® on October 24, 2007. Mr. Simineri's surgeon, Dr. Garcia, testified at his deposition that he determines the appropriate treatment and medical product for a given patient using 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?

A: I typically do.

[Certification of Joseph J. Fantini ("Fantini Cert."), Ex. B, 98:8-14.]

Dr. Garcia further testified that in conducting his risk-benefit analysis, he relies on information from seminars, websites, and materials provided by the manufacturers' sales representatives.[2] Dr. Garcia also testified that although he cannot specifically recall reading the instructions for AlloDerm®, he typically reads the instructions for use ("IFU") before using a medical product.[3] Jeffrey Klecatsky, the LifeCell representative who serviced Dr. Garcia's practice at the time of Mr. Simineri's surgery, testified at deposition that he relied on marketing materials provided by LifeCell in making presentations to doctors.

Q: You said you relied upon the marketing materials when you're meeting with the surgeons out in the field, right?

A: Correct.

. . .

Q: Okay. Do you – what – what type of materials do you recall in this promotional material?

A: You know, the brochures that you showed me earlier, some of the papers or case studies that were done that were published by LifeCell.

. . .

Q: So what other studies or papers did you rely upon when you're meeting with the surgeons such as Dr. Garcia and his practice group?

. . .

[2] Id. at 99:5-10.

[3] Id. at 33:16-34:4.

A: Whatever the marketing material the company provided and/or the IFU, I suppose.

[Fantini Cert., Ex. C, 176:6-13; 176:21-177:3; 151:23-152:10.]

Unless subject to specific exclusions, "all relevant evidence is admissible." N.J.R.E. 402. Under the New Jersey Rules of Evidence, "'[r]elevant evidence' means evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. 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). Evidence which is relevant to the action may nonetheless be excluded "if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury . . . ." N.J.R.E. 403. The trial judge may preclude testimony consisting of terms of art, where such testimony is so overly technical that it would confuse the jury, rather than assisting it. State v. Dreher, 302 N.J. Super. 408, 496 (App. Div. 1997), overruled in part, on other grounds, State v. Brown, 190 N.J. 144 (2007).

Dr. Garcia's inability to recall which specific materials he received is not the same as testimony that he never received or read any marketing materials. To the contrary, Dr. Garcia testified that he did receive and review LifeCell materials. That Dr. Garcia could not specifically identify which documents he received while testifying at a deposition conducted nearly seven years after Mr. Simineri's surgery does not render all LifeCell marketing materials inadmissible. Rather, subject to the proper foundation, any marketing material provided to or relied upon by Dr. Garcia is relevant and probative as to the adequacy of the warning given by LifeCell to Dr. Garcia. Similarly, LifeCell representative Jeffrey Klecatsky stated that he relied upon certain

LifeCell materials in communicating with doctors about AlloDerm®. Subject to establishing a proper foundation, marketing material relied upon by Mr. Klecatsky in speaking with Dr. Garcia is relevant and probative as to the adequacy of the warning given by LifeCell to Dr. Garcia.

As for Defendant's motion to bar the term "permanent" as a technical term of art, the cases cited by Defendant are inapposite. In those cases, testimony was precluded because it was so overly technical that it would not assist the jury in understanding any aspect of the case. Dreher, supra, 302 N.J. Super. 408; State v. Conway, 193 N.J. Super. 133, 170-71 (App. Div. 1984) (precluding scientific testimony for failing to meet the Frye admissibility standard, and also noting that the testimony "contained technical terms and was the source of potential confusion"). Here, the phrase "permanent repair" is not so complicated or overly technical as to be more confusing than probative to the jury. Defendant is free to argue its proposed meaning by way of expert testimony or cross-examination of Plaintiffs' experts at trial. To the extent any admissible marketing materials contain the terms "permanent" or "one-time solution," it would be unreasonable to bar Plaintiffs from using such terminology.

For the foregoing reasons, Defendant's motion to bar evidence and testimony regarding LifeCell's marketing materials is **DENIED WITHOUT PREJUDICE.**

11/20/15

Jessica R. Mayer, J.S.C.