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11-30-15

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LifeCell Corporation

NOV 20 2015

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 evidence or argument about alleged misstatements made by LifeCell sales representatives who did not speak or otherwise communicate with plaintiff's implanting surgeon, Dr. Garcia, at the time of trial, and the Court having considered all papers submitted by the parties, and for good cause and the reasons <sup>set forth in the attached memorandum of decision</sup> ~~stated on the record by the Court,~~

It is on this the 20<sup>th</sup> day of November, 2015,

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

ORDERED that plaintiffs are barred from introducing evidence or argument about alleged misstatements made by LifeCell sales representatives who did not speak or otherwise communicate with plaintiff's implanting surgeon, Dr. Garcia, at the time of trial; and it is further

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NOT FOR PUBLICATION WITHOUT THE  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 Evidence or Arguments About  
Alleged Misrepresentations Made by Sales Representatives of LifeCell who did not Speak  
or Otherwise Communicate with Plaintiff's Surgeon**

**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 alleged misrepresentations made by LifeCell sales representatives who did not speak or otherwise communicate with Mr. Simineri's surgeon, Dr. Gerardo Garcia. 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,<sup>1</sup> the court determines that LifeCell's motion to bar evidence and testimony relating to

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<sup>1</sup> 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.

alleged misrepresentations by LifeCell sales representatives who did not speak or otherwise communicate with Dr. Garcia is **GRANTED**.

Plaintiffs 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. Specifically, Plaintiffs allege that LifeCell failed to adequately warn Mr. Simineri and his treating surgeon, Dr. Garcia, of certain health risks and recurrence rates associated with the use of AlloDerm® in ventral hernia repair. Defendant seeks to preclude any evidence or argument regarding allegedly misleading statements made by LifeCell representatives to doctors other than Dr. Garcia; specifically, alleged false and misleading statements regarding the efficacy and safety of AlloDerm® when used in hernia repair. Defendant argues that any statements made by LifeCell representatives which were not communicated to or relied upon by Dr. Garcia are irrelevant and unduly prejudicial.

Defendant asserts that “absent a foundation that a statement had also been made to Dr. Garcia by a LifeCell sales representative, statements made by other LifeCell sales representatives to plaintiff’s [sic] experts are irrelevant . . . . If an allegedly misleading or inaccurate statement was not made or delivered to Dr. Garcia, then the fact that the statement was made to plaintiff’s [sic] experts is irrelevant to determining either the adequacy of the warning delivered to Dr. Garcia or whether Dr. Garcia’s [sic] relied upon it.”<sup>2</sup> Defendant further notes that Dr. Garcia and the sales representative who communicated with Dr. Garcia during the relevant time period have been deposed, and that “none of th[e] alleged misstatements were identified in either deposition.”<sup>3</sup>

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<sup>2</sup> Defendant’s Brief in Support of Motion *In Limine* to preclude Plaintiffs’ Experts from Testifying Regarding Alleged Misleading Representations Made to Surgeons Other than Dr. Garcia (“Def.’s Br.”) 1, 3.

<sup>3</sup> Id. at 4.

Plaintiffs oppose Defendant's motion, arguing: (1) statements made by LifeCell representatives to other doctors are probative as to what LifeCell knew or should have known regarding AlloDerm®, and (2) LifeCell's overall consistency in its marketing message indicates that statements made to other doctors were likely made to Dr. Garcia. In support of the first argument, Plaintiffs cite several statements by Plaintiffs' expert, Dr. Roger Huckfeldt, regarding complaints and concerns that he had reported to LifeCell employees prior to the time of Mr. Simineri's surgery.<sup>4</sup> In support of their second argument, Plaintiffs draw a connection between a LifeCell representative (Kim Baker) who spoke with Dr. Huckfeldt and the LifeCell representative (Jeffrey Klecatsky) who spoke with Dr. Garcia, noting that Ms. Baker trained Mr. Klecatsky, and both representatives gave information to their respective doctors based on the same LifeCell internal marketing documents and guides.<sup>5</sup>

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.

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<sup>4</sup> Plaintiffs' Response to Defendant's Motion *In Limine* to Preclude Plaintiffs' Experts From Testifying Regarding Alleged Misleading Representations Made to Surgeons Other than Dr. Garcia ("Pls.' Opp.") 7.

<sup>5</sup> Pls.' Opp. 5-6; Certification of Joseph J. Fantini, Esq. ("Fantini Cert."), Ex. C.

Under New Jersey case law, a manufacturer has a duty to warn of 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). “When the alleged defect is the failure to provide warnings, a plaintiff is required to prove that the absence of a[n adequate] warning was a proximate cause of his harm.” James v. Bessemer Processing Co., 155 N.J. 279, 297 (1998) (quoting Coffman v. Keene Corp., 133 N.J. 581, 594 (1993)).

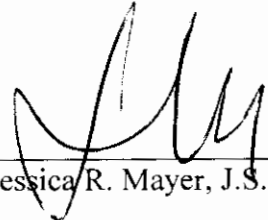
Plaintiffs argue that statements made by LifeCell representatives to Dr. Huckfeldt are relevant as to what LifeCell knew or should have known about AlloDerm® when used for hernia repair. This is correct as far as it concerns statements by LifeCell representatives mentioning the alleged problems and/or dangerous propensities of AlloDerm® about which Plaintiffs assert LifeCell failed to warn. Likewise, any statements made by Dr. Huckfeldt to LifeCell representatives regarding these same issues would be relevant to what LifeCell knew or should have known. Plaintiffs may introduce evidence of statements made by Dr. Huckfeldt or other testifying witnesses to LifeCell representatives communicating the alleged defects and dangers of AlloDerm®, as well as any such statements made by LifeCell representatives to Dr. Huckfeldt or other testifying witnesses.

However, the same cannot be said for allegedly misleading statements or inadequate warnings made by LifeCell representatives to doctors other than Dr. Garcia, which allegedly fail to identify the dangers of AlloDerm®, or overstate its safety or efficacy. Any allegedly inadequate warnings given to doctors who did not treat Mr. Simineri have no tendency to prove or disprove the adequacy of the warning given to Dr. Garcia, nor whether Dr. Garcia relied on such a warning

in deciding to use AlloDerm® for Mr. Simineri's hernia repair, nor whether Defendant knew about certain allegedly dangerous characteristics of AlloDerm®.

Plaintiffs assert that the warnings given to surgeons other than Dr. Garcia are probative as to the type of warnings given to Dr. Garcia himself. However, Plaintiffs' connection is too speculative to present to a jury. The sales representative who met with Dr. Garcia was not the same representative who met with Dr. Huckfeldt, and there is no testimony that the two sales representatives relied on an identical script or single message when visiting their respective doctors. At most, both representatives indicate that they relied on materials and presentations provided by LifeCell. The fact that one representative trained the other one does not establish that each provided their respective doctors with identical messaging. Such testimony would be overly prejudicial in relation to its low probative value, and would have a tendency to confuse the jury as to whom LifeCell had a duty to warn. Plaintiffs are free to use testimony from Mr. Klecatsky, the LifeCell representative who actually met with Dr. Garcia, as well as any material he relied upon when speaking to Dr. Garcia,<sup>6</sup> to present evidence of LifeCell's allegedly misleading marketing message.

For the foregoing reasons, Defendant's motion to preclude Plaintiffs' experts from testifying regarding allegedly misleading representations made to surgeons other than Dr. Garcia is **GRANTED**.



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Jessica R. Mayer, J.S.C.

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<sup>6</sup> Subject to the proper foundation.