

#0018  
11-20-15

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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 any evidence or argument regarding medical literature, e-mails or other documents which are dated after plaintiff Michael Simineri's October 24, 2007 surgery at the time of trial, and the Court having considered all papers submitted by the parties, <sup>and the arguments of counsel</sup> 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,  
<sup>GRANTED IN PART,</sup>  
ORDERED that defendant's motion is hereby ~~granted~~; and it is further

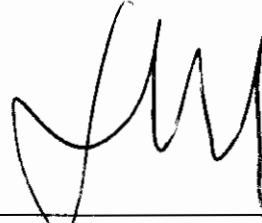
ORDERED that plaintiffs are barred from introducing any evidence or argument regarding medical literature, ~~e-mails or other documents~~ which are dated after plaintiff Michael Simineri's October 24, 2007 surgery at the time of trial; ~~and it is further~~ <sup>where such evidence relies exclusively on data gathered after October 24, 2007</sup>

*The admissibility at trial of any other*

ORDERED that ~~to the extent that plaintiffs contend that (a) the medical literature, e-mails or other documents reflect LifeCell's actual knowledge of the risks of AlloDerm before October 24, 2007 and/or (b) LifeCell had actually access to that information and therefore should have known about those risks of AlloDerm, plaintiffs shall bear the burden of proof to establish the admissibility of any medical literature, e-mails or other documents dated after~~ *is reserved for trial*

After October 24, 2007; and it is further

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



*4/20/11 r*

**OPPOSED**

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

**PAPERS CONSIDERED**

	<u>Yes</u>	<u>No</u>	<u>Date</u>
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 Evidence or Argument at Trial  
Regarding Medical Literature, Emails, or Other Documents Which are Dated After  
Plaintiff Michael Simineri's October 24, 2007 Surgery

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 bar evidence and argument regarding medical literature, emails, or other documents which are dated after Plaintiff Michael Simineri's October 24, 2007 hernia repair surgery with AlloDerm®. Counsel for the parties presented oral argument on this motion during a case management conference held on November 17, 2015. Upon considering the arguments of the parties, legal memoranda, exhibits and relevant case law,<sup>1</sup> the court determines that LifeCell's motion to bar evidence and argument

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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.

regarding medical literature, emails, or other documents dated after Mr. Simineri's October 24, 2007 AlloDerm® hernia repair surgery is **GRANTED IN PART**.

Defendant seeks to bar all documents published or created after the date of Mr. Simineri's AlloDerm® surgery, unless the documents contain or refer to information known to LifeCell before October 24, 2007. Defendant argues that any documentation issued subsequent to Mr. Simineri's surgery date that contains information not previously known to LifeCell is irrelevant, as it would not contain information that LifeCell knew or should have known at the time the warning was issued. In opposition, Plaintiffs argue that (1) many of the documents published after Mr. Simineri's 2007 surgery contain or summarize information which was available prior to that date, and (2) in a failure-to-warn case, a manufacturer may be held to constructive knowledge of information contained in subsequent medical literature.

Under New Jersey law, a manufacturer has a duty to warn of the adverse effects of a prescription medical product "of which they know or should have known on the basis of reasonably obtainable or available knowledge." Feldman v. Lederle Lab., 97 N.J. 429, 434 (1984). 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 primary issue is whether documents created or published after Mr. Simineri's AlloDerm® surgery are probative as to what LifeCell knew or should have known prior to the date of the surgery. While evidence that relates solely to information not available prior to Mr. Simineri's surgery is likely incapable of making any fact of consequence more or less probable, employing a bright line admissibility rule based on publication date alone would be over-inclusive and imprecise. This court finds the reasoning espoused in Mahaney v. Novartis Pharms. Corp., 835 F. Supp. 2d 299 (W.D. Ky. 2011), while not controlling, is instructive on the issue:

[Defendant] seeks to exclude arguments and evidence surrounding its corporate activities after [Plaintiff] was prescribed and began taking Zometa on October 24, 2003. It insists its actions following this date are inapposite since the prescribing physician could only have considered Zometa's warnings prior to the start of her therapy. [Defendant] affirms that whatever subsequent knowledge or notice it possessed about the drug's alleged connection to [osteonecrosis of the jaw ("ONJ")] would be similarly irrelevant since it would have arisen after [Plaintiff] began her treatment. ...

Conceptually, this request makes sense; practically, it does not. No matter which date the Court chooses, documents or actions by [Defendant] after that date could bear (or may be interpreted by a jury as bearing) on [Defendant]'s earlier knowledge about ONJ and Zometa. To ensure legitimate evidence was not excluded simply as a result of the date it was created, the Court would have to review all evidence dated after the temporal dividing line and determine whether it implicates [Defendant]'s knowledge at an earlier stage in Zometa's development. ... [T]o conduct such a review before trial would embroil the Court and parties in a pitched battle over countless documentary exhibits.

[Mahaney v. Novartis Pharms. Corp., 835 F. Supp. 2d 299, 313-14 (W.D. Ky. 2011) (internal citations omitted).]

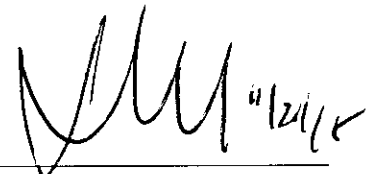
The court declines to make a broad ruling barring evidence based solely upon its publication date. Although Defendant acknowledges that any documents published or created after October 24, 2007 which "reflect events or LifeCell's knowledge prior to October 24, 2007"<sup>2</sup> could be relevant, it is unclear how Defendant proposes to identify such documents, nor what process

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<sup>2</sup> Defendant's Brief in Support of Motion *in Limine* to Preclude the Use at Trial of Post-Surgery Medical Literature, Emails, and Other Documents ("Def.'s Br.") 3.

Defendant proposes if the parties disagree on whether or not a certain document reflects LifeCell's knowledge before October 24, 2007. To the extent that a medical publication or study relies exclusively on data gathered after October 24, 2007 (for example, a study where all subjects were implanted with AlloDerm® after Mr. Simineri's AlloDerm® surgery date), it is barred as irrelevant. The court is aware that certain medical articles may refer to studies done both before and after Mr. Simineri's October 24, 2007 surgery;<sup>3</sup> where it is not possible to parse the article based on the studies done before October 24, 2007, the parties are encouraged to utilize the cited pre-2007 studies instead. For all other materials, the admissibility of specific items published after October 24, 2007, shall be reserved for trial.

For the foregoing reasons, LifeCell's motion to bar evidence and argument regarding medical literature, emails, or other documents which are dated after Plaintiff Michael Simineri's October 24, 2007 AlloDerm® hernia repair surgery is **GRANTED IN PART**.

A handwritten signature in black ink, appearing to read 'JM 12/1/11', is written above a horizontal line.

Jessica R. Mayer, J.S.C.

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<sup>3</sup> E.g., Fantini Cert. Ex. B, the 2011 Silverman article.