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11-20-15

IN RE: ALLODERM® LITIGATION

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: MIDDLESEX COUNTY

CASE CODE NO. 295

NOV 20 2015

CIVIL ACTION

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

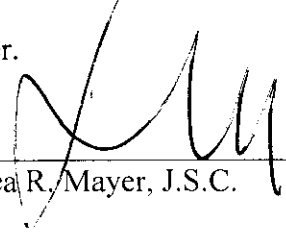
ORDER

The above matter having been opened to the Court by Anapol Weiss attorneys for Plaintiffs, on application for an Order granting Plaintiff's Motion *in Limine* to Exclude Irrelevant and Prejudicial Evidence, Testimony and Argument Related to Consent Forms Signed By Plaintiff Michael Simineri Prior to Hernia Repair Surgery Involving AlloDerm, and the Court having considered all papers submitted by the parties, and for good cause and the reasons <sup>set forth</sup> ~~stated~~ in the attached memorandum of decision, on the record by the Court,

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

**ORDERED** that Plaintiffs' motion is hereby **GRANTED** <sup>IN PART</sup> as to the gastric bypass surgery consent form, and **DENIED IN PART** as to the "Procedure Education" form and the hernia repair surgery consent form.  
**IT IS FURTHER ORDERED** that a copy of this Order be posted online and served on

all counsel of record within seven (7) days of the date of this order.

  
\_\_\_\_\_  
Jessica R. Mayer, J.S.C.

**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**NOT FOR PUBLICATION WITHOUT THE  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 Plaintiffs'  
Motion *In Limine* to Exclude Evidence and Testimony**

**In Re: AlloDerm® Litigation, Case Code 295**

**Michael Simineri and Karen Simineri v. LifeCell Corporation**

Docket No. MID-L-5972-11 CM

Dated November 20, 2015

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

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

Plaintiffs Michael Simineri and Karen Simineri seek an order barring Defendant LifeCell Corporation ("LifeCell" or "Defendant") from offering evidence, testimony or argument related to consent forms signed by Mr. Simineri prior to his AlloDerm® hernia repair surgery. Defendant opposes Plaintiffs' motion. For the reasons set forth in this memorandum of decision, Plaintiffs' motion is **GRANTED IN PART** and **DENIED IN PART**.

Plaintiffs claim that Defendant proposes to offer testimony regarding three consent forms signed by Mr. Simineri prior to his AlloDerm® hernia repair surgery. Plaintiffs argue that such testimony is irrelevant and prejudicial, and thus barred by New Jersey Rules of Evidence ("N.J.R.E.") 401 and 403. Specifically, Plaintiffs contend that the gastric bypass surgery consent

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MIDDLESEX COUNTY CLERK

form signed by Mr. Simineri on March 1, 2002 is irrelevant because it does not contain any warnings related to grafts used in hernia repair surgery. Plaintiffs additionally contend that the “Procedure Education” form signed by Mr. Simineri on August 23, 2007 is irrelevant because it only discusses hernia repair surgery performed using synthetic mesh, without reference to biologic hernia repair products such as AlloDerm®. Lastly, Plaintiffs contend that the hernia repair surgery consent form signed by Mr. Simineri on August 23, 2007 does not contain any warnings related to hernia recurrence.<sup>1</sup> Defendant counters that the consent forms addressed all methods of hernia repair, were directly relevant to Mr. Simincrici’s AlloDerm® hernia repair surgery and warned Mr. Simineri of the danger of hernia recurrence.

Evidence is relevant if the party seeking to proffer it demonstrates that it has a “tendency in reason to prove or disprove any fact of consequence to the determination of the action.” N.J.R.E. 401. In determining whether evidence is relevant under Rule 401, the inquiry focuses upon “the logical connection between the proffered evidence and a fact in issue.” Furst v. Einstein Moomjy, Inc., 182 N.J. 1, 15 (2004) (quoting State v. Hutchins, 241 N.J. Super. 353, 358 (App. Div. 1990)). Put differently, “[t]o say that ‘evidence is irrelevant in the sense that it lacks probative value’ means that it ‘does not justify any reasonable inference as to the fact in question.’” Verdicchio v. Ricca, 179 N.J. 1, 33-34 (2004) (quoting State v. Allison, 208 N.J. Super. 9, 17 (App. Div. 1985)). The admissibility of relevant evidence is governed by Rule 403, which provides that relevant evidence should be excluded “[i]f the probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury, or (b) undue delay, waste of time, or needless presentation of cumulative evidence.” N.J.R.E. 403; see State v. Thompson, 59 N.J. 396,

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<sup>1</sup> Plaintiffs did not make a separate argument as to why the introduction of the consent forms would be “highly prejudicial.”

421 (1971) (evidence is unduly prejudicial when its probative value is “so significantly outweighed by [its] inherently inflammatory potential as to have a probable capacity to divert the minds of the jurors from a reasonable and fair evaluation.”).

Here, Mr. Simineri’s gastric bypass surgery consent form is irrelevant. However, Mr. Simineri’s “Procedure Education” form and hernia repair surgery consent form are relevant and admissible.

Mr. Simineri acknowledged the gastric bypass surgery consent form on March 1, 2002, five years prior to his AlloDerm® hernia repair surgery. The only reference the form makes to hernias is: “Specific risks associated with gastric bypass surgery include the following: . . . 5. Hernias of the wounds needing operative repair.”<sup>2</sup> Defendant contends that Mr. Simineri’s acknowledgment of this warning is relevant to his knowledge of the risk of hernia recurrence at the time of his AlloDerm® hernia repair surgery. Yet, the statement is specific to hernias occurring at the site of a surgical wound where surgeons performed a gastric bypass surgery without the use of a graft. It does not discuss any of the potential risks to Mr. Simineri of hernia repair surgery or the use of grafts, let alone the use of AlloDerm® in hernia repair surgery. It is therefore irrelevant. Further, even assuming, *arguendo*, that Mr. Simineri’s acknowledgment that hernias occur at surgical sites has *de minimis* probative value, it is substantially outweighed by the risk of confusing the jury by introducing a consent form neither related to hernia repair surgery, nor issued by LifeCell.

Mr. Simineri acknowledged the “Procedure Education” form on August 23, 2007, immediately prior to his AlloDerm® hernia repair surgery. The form reviews the definition of a

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<sup>2</sup> Plaintiffs’ Brief (“Pls.’ Br.”) Ex. A.

hernia and discusses the steps taken during hernia repair surgery. In addition, the form contains a black box warning that states, in pertinent part:

The majority of hernia repairs are successful and last forever. With time, however, any hernia can recur. Recurrence is more common with: large hernia repairs, re-do repairs, in obese patients, and perhaps even in diabetics or in patients with immune disorders (or on steroids) in which tissue healing may be somewhat compromised.<sup>3</sup>

Later, the form reiterates: “Recurrence or persistence: As previously mentioned, hernias can return (read above).<sup>4</sup> The warnings in the “Procedure Education” form are probative of Mr. Simineri’s knowledge of the risk of hernia recurrence following hernia repair surgery. Plaintiffs’ argument that the form is irrelevant because it does not discuss AlloDerm® specifically goes to its weight, not its admissibility. Additionally, while the form states that a mesh is “an artificial material or screen,” the hernia recurrence warnings are not associated with any specific type of repair.<sup>5</sup>

Mr. Simineri acknowledged the contents of the hernia repair surgery consent form on August 23, 2007, immediately prior to his AlloDerm® hernia repair surgery. In it, Mr. Simineri’s consent to perform “repair incisional hernia w/ AlloDerm” is handwritten.<sup>6</sup> The form further states, in typewritten font, that:

[t]he benefits and purpose of the operation and/or procedure have been explained to me in language I understand by Dr. Garcia as well as the risks alternatives and complications pertaining to the above procedure/surgery . . . .<sup>7</sup>

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<sup>3</sup> Pls.’ Br. Ex. C.

<sup>4</sup> Id.

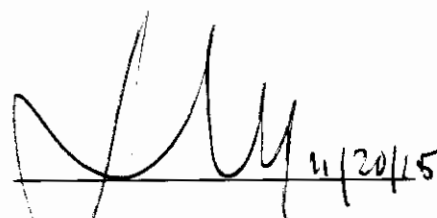
<sup>5</sup> Id. (In fact, the full sentence is: “In many repairs, a piece of mesh (an artificial material or screen as many call it) will be used in the repair.” Thus, when the form later refers to repairs, the warning is not limited to only artificial mesh procedures.)

<sup>6</sup> Id. Ex. D.

<sup>7</sup> Id.

While the court notes that the risks enumerated in the consent form did not include hernia recurrence, the quoted statement suggests that patient and doctor had a discussion of the risks inherent to an AlloDerm® hernia repair surgery. Evidence of that conversation is probative of whether Mr. Simineri was warned of the alleged risk of hernia recurrence when using AlloDerm®. Whether that risk was actually discussed by Mr. Simineri and Dr. Garcia is a question for the jury and a matter for cross-examination.

Therefore, Plaintiffs' motion to bar Defendant from introducing evidence of Mr. Simineri's informed consent forms is **GRANTED IN PART** as to the gastric bypass surgery consent form, and **DENIED IN PART** as to the "Procedure Education" form and the hernia repair surgery consent form.



Handwritten signature of Jessica R. Mayer, dated 4/20/15.

JESSICA R. MAYER, J.S.C.