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11-20-15

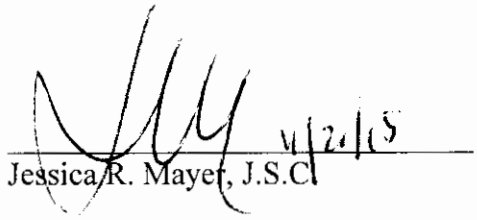
IN RE: ALLODERM® LITIGATION	**SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY** **CASE CODE NO. 295** **CIVIL ACTION**
MICHAEL SIMINERI and KAREN SIMINERI, h/w, **Plaintiffs,** **v.** **LIFECELL CORPORATION** **Defendant.**	**SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY** **Docket 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 Plaintiffs' Motion in Limine to Exclude Evidence, Testimony, and Argument Regarding Luijendijk and Burger Primary Repair and Synthetic Mesh Studies 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 20th day of November, 2015,

ORDERED that Plaintiffs' motion is hereby ~~**GRANTED**~~; DENIED.

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NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS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

NOV 20 2015

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., Adrianne 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 the Luijendijk and Burger suture and synthetic mesh studies. Defendant opposes Plaintiffs' motion. For the reasons set forth in this memorandum of decision, Plaintiffs' motion is **DENIED**.

Plaintiffs claim that Defendant proposes to offer testimony regarding the Luijendijk and Burger suture and synthetic mesh studies.[1] Plaintiffs argue that such evidence is irrelevant and prejudicial, and thus barred by New Jersey Rules of Evidence ("N.J.R.E.") 401 and 403.

[1] Plaintiffs' Brief ("Pl.s' Br.") Exs. A, B.

Specifically, Plaintiffs contend evidence of the studies is irrelevant because the patients included in the trials underwent suture or synthetic mesh hernia repair, rather than biologic hernia repair. Plaintiffs additionally contend the evidence is irrelevant because the studies only considered patients with midline hernias smaller than the hernia suffered by Mr. Simineri. Finally, Plaintiffs argue the underlying data is outdated because all patients incorporated in the studies underwent hernia repair between 1992 and 1998.[2] Defendant counters that the studies are relevant because the jury must learn the hernia recurrence rates for alternative methods of hernia repair in order to determine whether the AlloDerm® hernia repair recurrence rate is "high," as alleged by Plaintiffs. Defendant additionally contends that while the patients in the trial underwent surgery between 1992 and 1998, the Luijendijk and Burger studies were published in 2000 and 2004, respectively, and thus are not too remote in time to Mr. Simineri's AlloDerm® hernia repair surgery; further, the results of the studies have not been subsequently invalidated or superseded. Finally, Defendant argues that the studies constitute valuable background evidence and are cited by the parties' experts and in medical literature.

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.

[2] Plaintiffs do not advance a separate argument as to why introduction of the Luijendijk and Burger studies would mislead or confuse the jury, or cause undue prejudice to Plaintiffs.

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, 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.").

The Luijendijk study, A Comparison of Suture Repair with Mesh Repair for Incisional Hernia, consisted of a medical trial in which 200 randomly-assigned suture or synthetic mesh repair patients suffering from midline hernias six centimeters in diameter or smaller were tracked at six month intervals to determine rates of hernia recurrence after suture and synthetic mesh hernia repair surgery.[3] The study determined the three-year rate of hernia recurrence to be 43% for suture repair patients and 24% for mesh repair patients.[4] In 2000, the Luijendijk study was published in the New England Journal of Medicine.[5]

The Burger study, Long-term Follow-up of a Randomized Controlled Trial of Suture Versus Mesh Repair of Incisional Hernia, was a follow-up in 2003 to the Luijendijk study consisting of a survey of 126 original Luijendijk patients.[6] The Burger study determined the ten-

[3] Defendant's Opposition Brief ("Def.'s Opp. Br.") Ex. A at 1.
[4] Id.
[5] Id.
[6] Id. Ex. B at 579.

year *cumulative* rate of hernia recurrence to be 63% for suture repair patients and 32% for mesh repair patients.[7] In 2004, the study was published in the Annals of Surgery.[8]

Preliminarily, both parties' experts and medical literature support the continuing validity of the Luijendijk and Burger studies. Plaintiffs' expert, Dr. Roger Huckfeldt, testified at his deposition that the Luijendijk study is "reputable" with "reliable figures," and "one of the few randomized prospective clinical trials for hernia repair that's ever been done."[9] Dr. Huckfeldt also relied on the Luijendijk study in his expert report when discussing hernia recurrence rates in patients with suture and synthetic mesh repairs.[10] Plaintiffs additionally subpoenaed the testimony of Dr. Jose Jesus Diaz. Dr. Diaz testified that the Luijendijk and Burger studies are "the gold standard" for scientific inquiry regarding hernia recurrence rates in patients with suture and synthetic mesh repairs.[11]

Defendant's expert, Dr. Robert Langstein, also referenced the Burger study. In his expert report, Dr. Langstein cited the study to establish the hernia recurrence rate in patients with suture hernia repairs.[12] Finally, three peer-reviewed medical articles published between 2005 and 2007 regarding the efficacy of AlloDerm® cite the Luijendijk study to establish hernia recurrence rates in patients with suture and synthetic mesh repairs. [13] Thus, Plaintiffs' contention that the Luijendijk and Burger studies are outdated is belied by reliance upon these studies by current medical literature and the experts in this case.[14]

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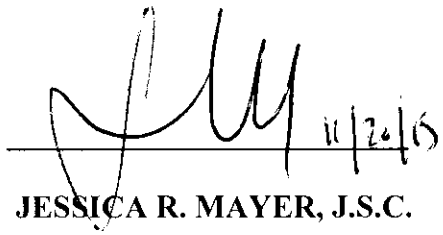
[7] Id. Ex. B at 578.
[8] Id.
[9] Id. Ex. C at 194:1-12, 223: 1-4.
[10] Id. Ex. G at 6.
[11] Id. Ex. N at 106:6-107:5.
[12] Id. Ex. O at 5.
[13] Id. Exs. I, J, K.
[14] In addition, none of the sources citing the Luijendijk and Burger studies suggest that the results of those studies are inapplicable to hernia repairs performed on patients suffering from hernias larger than six centimeters. Plaintiffs have

The Luijendijk and Burger studies are relevant and admissible for purposes of proving or disproving Plaintiffs' allegations that AlloDerm® has a "high failure rate . . . and high likelihood of re-herniation . . . ."[15] Evidence of hernia recurrence rates for hernia repair products other than AlloDerm® is probative of whether AlloDerm®'s risk of recurrence is relatively "high." The Luijendijk and Burger studies establish rates of recurrence for sutures and synthetic mesh used in hernia repair and are therefore probative of that risk. Whether Plaintiffs intend to establish AlloDerm's degree of risk by expert opinion or by comparative evidence (such as the Lujendijk and Burger study results) is immaterial; the existence of alternative avenues of proof does not deprive otherwise probative evidence of relevance.[16]

Therefore, because the Luijendijk and Burger studies are relevant, and because their probative value is not outweighed by the risk of undue prejudice or confusion, Plaintiffs' motion is **DENIED**.[17]



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not submitted expert opinion or medical literature to the contrary. However, Plaintiffs are free to raise this disparity during examination of the witnesses.

[15] Complaint ¶ 66, filed June 16, 2011.

[16] The court's conclusion is reinforced by Plaintiffs' additional allegation in their complaint. In the same paragraph in which Plaintiffs allege Defendant failed to warn that AlloDerm® has a high failure rate, Plaintiffs allege Defendant failed to warn that AlloDerm® has a "*comparative* severity" of adverse effects. Complaint ¶ 66 (emphasis added). Evidence establishing the adverse effects of hernia repair products other than AlloDerm® is probative of whether AlloDerm's adverse effects were comparatively severe. The Luijendijk and Burger studies fall within that category of probative evidence.

[17] The Luijendijk and Burger studies, however, are *not* probative of AlloDerm®'s absolute rate of hernia recurrence. The studies' results solely concern suture and synthetic mesh rates of hernia recurrence, and there is no expert opinion or medical literature establishing that those rates are directly applicable to AlloDerm®'s rate of recurrence. For the same reason, the Luijendijk and Burger studies are not independently probative of Dr. Garcia's knowledge of AlloDerm®'s risk of hernia recurrence prior to Mr. Simineri's hernia repair surgery. For those purposes, the studies are not relevant, and are inadmissible.