\$100475 08-07-15

David W. Field (00378-1984)

## LOWENSTEIN SANDLER LLP

65 Livingston Avenue Roseland, New Jersey 07068 973.597.2500 Attorneys for Defendant LifeCell Corporation

AUG 1 4 2015

JUDGE JESS H. MAYED

IN RE: ALLODERM® LITIGATION

CASE CODE 295

MICHAEL SIMINERI and KAREN SIMINERI, h/w,

Plaintiffs,

٧.

LIFECELL CORPORATION,

Defendant.

PATRICIA JULIEN,

Plaintiff.

٧.

LIFECELL CORPORATION,

Defendant.

THOMAS DUTCHER,

Plaintiff,

٧.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-5972-11 CM

SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-507-12 CM

DEBBIE FOSTER and DAVID FOSTER, w/h,	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY
Plaintiffs,	
v.	Civil Actions  Civil Actions  ORDER  ORDER  ORDER  ORDER
LIEDGELL GODDODATION	Civil Actions AUG, ED
LIFECELL CORPORATION,	ORDER UDGE 4 2015
Defendant.	ESS/CA
	ORDER JOGE JESSICAR MAYER
The above matter having been of	pened to the Court by Lowenstein Sandler LLP,
attorneys for defendant LifeCell Corporation, or	n application for an Order barring the testimony
of Dr. Karl LeBlanc in any of the four bell	wether plaintiffs' trials, and the Court having
considered all papers submitted by the parties, a memo: and om of decision record by the Court,	and for good cause and the reasons stated on the
It is on this the 14th day ofA	1945+ , 2015,
	ion is hereby granted; and it is further
ORDERED that the testimony of	of Dr. Karl A. LeBlanc is barred in the trials of
each of the four bellwether cases; and it is further	
ORDERED that a copy of this	Order be served on all counsel of record within
days hereof.	
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* For the reasons set firth in the	
For the reasons set forth in the	Hon. Jessica R. Mayer, J.S.C.
August 14, 2015.	\ 1
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Yes	No <u>Date</u>
Notice of Motion	<del></del>
Movant's Affidavits  Movant's Brief	
Movant's Brief Answering Affidavits Answering Brief	
Answering Brief	
Cross Motion	
Movant's Reply	

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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

AUG 1 4 20,3

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

FILED AUG 1 4 2015

JUDGE JESSICA R MAYER

PATRICIA JULIEN.

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THOMAS DUTCHER,

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LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-507-12 CM

DEBBIE FOSTER and DAVID FOSTER, w/h, Plaintiff's,	SUPERIOR COURT OF NEW LAW DIVISION: MIDDLESE: Docket No. MID-L-6841-12 CM	X COUNTY
v.  LIFECELL CORPORATION,  Defendant.	Civil Actions  ORDER	FILED AUG 1 4 2015 UDGE JESSICA R. MAYER
The above matter having been of	pened to the Court by Lowenstei	in Sandler LLP,
of Dr. Karl LeBlanc in any of the four bell considered all papers submitted by the parties, a memicandment decision.	wether plaintiffs' trials, and the	e Court having
It is on this the III day of Ave ORDERED that defendant's mot ORDERED that the testimony of	ion is hereby granted; and it is fur	
ORDERED that a copy of this of days hereof.  For the reasons set fith in the lowest memorialism of decision dated		
Agot 14, 2015.	ONSIDERED	OPPOSED
Notice of Motion Movant's Affidavits Movant's Brief Answering Affidavits Answering Brief Cross Motion Movant's Reply Other	No Date	

David W. Field (00378-1984)

# LOWENSTEIN SANDLER LLP

65 Livingston Avenue Roseland, New Jersey 07068 973.597.2500 Attorneys for Defendant LifeCell Corporation \$6249 08-07-15

FILED

AUG 1 4 2015
UDGE JESSICA R. MAYER

IN RE: ALLODERM® LITIGATION

CASE CODE 295

MICHAEL SIMINERI and KAREN SIMINERI, h/w,

Plaintiffs,

v.

LIFECELL CORPORATION,

Defendant.

PATRICIA JULIEN,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

THOMAS DUTCHER,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-5972-11 CM

SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-507-12 CM

DEBBIE FOSTER and DAVID FOSTER, w	LAW DIVISIO	OURT OF NEW J N: MIDDLESEX	COUNTY
Plaintiffs,	Docket No. MI	D-L-6841-12 CM	Δ.
V.		Civil Actions	AUG K
LIFECELL CORPORATION,		ORDER	OGE A
Defendant.			AUG 1 2013
			MAYER
The above matter having bee	en opened to the Cou	art by Lowenstein	Sandler LLP,
attorneys for defendant LifeCell Corporatio	n, on application for	an Order barring	the testimony
of Dr. Karl LeBlanc in any of the four	bellwether plaintiffs	s' trials, and the	Court having
considered all papers submitted by the partimeter addm of decision, record by the Court,	es, and for good cau	ise and the reasons	s stated on the
It is on this the 14th day of _	Augist ,201	5,	
ORDERED that defendant's	V	⊈-	her
ORDERED that the testimor	ny of Dr. Karl A. L	eBlanc is barred i	in the trials of
each of the four bellwether cases; and it is for			
ORDERED that a copy of t	his Order be served	on all counsel of	record within
days hereof.  * For the reasons set forth in the memoriandom of decision dated Argust 14		R. Mayer, J.S.C.	
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Yes	<u>No</u>	<u>Date</u>	
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Movant's Brief			
Answering Affidavits			
Answering Brief Cross Motion			
Movant's Reply			
Other			

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DEBBIE FOSTER and DAVID FOSTER, w/h,	SUPERIOR COURT OF NEW JERSEY
Plaintiffs,	LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-6841-12 CM
v. LIFECELL CORPORATION,	Civil Actions
Defendant.	Civil Actions  ORDER  ORDER  AUG 1 4 2015  Dened to the Court by Lowenstein Sandler LLP,
The above matter having been of	pened to the Court by Lowenstein Sandler LLP,
attorneys for defendant LifeCell Corporation, or	n application for an Order barring the testimony
	wether plaintiffs' trials, and the Court having
	and for good cause and the reasons stated on the
It is on this the it is day of	485 ± , 2015,
	on is hereby granted; and it is further
ORDERED that the testimony o	f Dr. Karl A. LeBlanc is barred in the trials of
each of the four bellwether cases; and it is furthe	
· · · · · · · · · · · · · · · · · · ·	Order be served on all counsel of record within
7 days hereof.	
* For the leasons set forth in the Cavil memorandum of decision detal Argent 14.	Hon. Jessica R. Mayor, J.S.C.
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Notice of Motion Movant's Affidavits	
Movant's Brief	
Answering Affidavits Answering Brief	
Cross Motion Movant's Reply	
Other	

David W. Field (00378-1984)

# LOWENSTEIN SANDLER LLP

65 Livingston Avenue Roseland, New Jersey 07068 973.597.2500 Attorneys for Defendant LifeCell Corporation

IN RE: ALLODERM® LITI	GATION
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CASE CODE 295

MICHAEL SIMINERI and KAREN SIMINERI, h/w,

Plaintiffs,

v.

LIFECELL CORPORATION,

Defendant.

PATRICIA JULIEN,

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Defendant.

THOMAS DUTCHER,

Plaintiff,

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SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-5972-11 CM



SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-507-12 CM

#### 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 to Bar the Testimony of Dr. Karl LeBlanc

In Re: AlloDerm® Litigation, Case Code 295

Thomas Dutcher v. LifeCell Corporation

Docket No. MID-L-1469-12 CM

**Debbie Foster and David Foster v. LifeCell Corporation** 

Docket No. MID-L-6841-12 CM

Patricia Julien v. LifeCell Corporation

Docket No. MID-L-507-12 CM

Michael Simineri and Karen Simineri v. LifeCell Corporation

Docket No. MID-L-5972-11 CM

Dated August 14, 2015

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

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

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves to bar the testimony of Dr. Karl LeBlanc ("Dr. LeBlanc"), as a specific causation expert in the above matters. In accordance with case management orders entered by the court, the above four (4) cases were selected by counsel for "bellwether" trials in the AlloDerm® litigation. The plaintiffs in the cases selected by counsel are as follows: Thomas Dutcher ("Dutcher"), Debbie and David Foster



("Foster"), Patricia Julien ("Julien") and Michael and Karen Simineri ("Simineri") (collectively "Plaintiffs"). The court issues this opinion in response to LifeCell's motion to exclude the specific causation testimony of Dr. LeBlanc. Counsel agreed to waive both oral argument on the motion and a hearing pursuant to N.J.R.E. 104 and consented to the court's disposition of this matter on the papers submitted. Upon considering the legal memoranda, exhibits (including Dr. LeBlanc's written reports dated February 23, 2015 and February 24, 2015 issued for each Plaintiff), deposition testimony of Dr. LeBlanc and relevant case law<sup>1</sup>, the court determines that LifeCell's motion to exclude the specific causation testimony of Dr. LeBlanc is **GRANTED**.

## I. BACKGROUND/LEGAL STANDARDS

To establish liability in these cases, Plaintiffs must prove through expert testimony that implantation of AlloDerm® caused them to develop hernia recurrence, stretching of the graft used in the hernia repair, thinning of the graft used in the hernia repair, as well as other claimed injuries related to implantation of AlloDerm®. Kemp ex rel. Wright v. State, 174 N.J. 412, 417 (2002). Hence, the expert testimony of Dr. LeBlanc has been proffered by Plaintiffs to establish that Plaintiffs' injuries were caused by the use of AlloDerm® for their hernia repair.

N.J.R.E. 702, which governs the admissibility of scientific expert testimony in New Jersey, provides that:

[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of a opinion or otherwise.

<sup>&</sup>lt;sup>1</sup> The parties signed a consent order stipulating that New Jersey law governs all issues in the AlloDerm® litigation. See Consent Order dated January 15, 2015.

[Ibid.]2

Under N.J.R.E. 702, for an expert to be admitted:

(1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony.

[Kemp, supra, 174 N.J. at 424 (quoting Landrigan v. Celotex Corp., 127 N.J. 404, 413 (1992)).]

Defendant challenges the second requirement in its motion to exclude the testimony of Dr. LeBlanc on specific causation. LifeCell contends that the testimony of Dr. LeBlanc is not sufficiently reliable in the field of hernia repair surgery.

In certain contexts, an expert's testimony has to be "generally accepted within the relevant scientific community." <u>State v. Chun</u>, 194 <u>N.J.</u> 54, 91 (2008); (discussing New Jersey's continued use of the standard from <u>Frye v. United States</u>, 293 <u>F.</u> 1013 (D.C. Cir. 1923), for evaluating scientific tests in criminal cases). See also State v. Harvey, 151 N.J. 117, 167-70 (1997). However,

<sup>&</sup>lt;sup>2</sup> While the New Jersey version of <u>Rule</u> 702 tracks the original version of <u>Federal Rule of Evidence</u> 702, it does not incorporate the language added to the Federal Rule in 2000, which permits an expert to testify only "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the methods reliably to the facts of the case." The federal rule was amended for the purpose of codifying the principles of <u>Daubert v. Merrell Dow Pharms.</u>, 509 <u>U.S.</u> 579 (1993) (outlining the federal requirements for scientific expert testimony).

In January 2009, the Jersey Supreme Court Committee on the Rules of Evidence explicitly declined to amend N.J.R.E. 702, Testimony by Experts, to follow the 2000 amendment to F.R.E. 702. 2007 – 2009 Report of the Supreme Court Committee on the Rules of Evidence, p. 3. The Committee reasoned that, "if the exact language of F.R.E. 702 was adopted, since the federal rule was intended to incorporate Daubert, it would create the erroneous impression that the Daubert standard governed the admission of expert testimony in New Jersey." Ibid. "Further, the Committee was concerned that New Jersey judges would be too inclined to be guided by the federal case law interpreting F.R.E. 702 and Daubert[,]" which the committee expressed "are sometimes overly restrictive in the admission of expert testimony, tending to exclude evidence that, under current New Jersey law, would be properly admitted as having a reliable basis. Ibid. (citing Edward K. Cheng & Albert H. Yoon, Does Frye or Daubert Matter? A Study of Scientific Admissibility Standards, 91 Va. L. Rev. 471, 473 (2005)).

Recently, the New Jersey Supreme Court tasked its Committee on the Rules of Evidence with revisiting adoption of the <u>Daubert</u> standard. The New Jersey Supreme Court has yet to render a decision on the matter. Thus, this court remains bound by the Court's decision in <u>Kemp</u>.

New Jersey applies a more relaxed standard for expert testimony in civil cases. Rather than requiring expert testimony to be generally accepted in the profession, "a scientific theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field." Rubanick v. Witco Chem. Corp., 125 N.J. 421, 449 (1991); accord Kemp, supra, 174 N.J. at 430.<sup>3</sup>

Hence, even if an expert's opinion is not generally accepted in the scientific community, it can still be admitted as evidence, so long as the methodology and reasoning underlying that opinion is sound. See Clark v. Safety-Kleen Corp., 179 N.J. 318, 337-38 (2004). The Supreme Court of New Jersey has specifically noted that, in the case of pharmaceutical litigation "in which a medical cause-effect relationship has not been confirmed by the scientific community but compelling evidence nevertheless suggests that such a relationship exists," such evidence may be admissible. Kemp, supra, 174 N.J. at 430.

Under this standard, a trial judge must assess "the soundness of the proffered methodology and the qualifications of the expert." <u>Id.</u> at 426 (quoting <u>Rubanick</u>, <u>supra</u>, 125 <u>N.J.</u> at 454) (internal quotations omitted). The role of the trial court is to "determine whether the expert's opinion is derived from a sound and well-founded methodology that is supported by some expert consensus in the appropriate field." <u>Id.</u> at 427 (quoting <u>Landrigan</u>, <u>supra</u>, 127 <u>N.J.</u> at 417) (internal quotations omitted). An expert's methodology can be properly supported by "professional journals, texts,

<sup>&</sup>lt;sup>3</sup> This is particularly applicable to "tort cases involving novel theories of causation offered to connect a plaintiffs injuries to a drug or a toxic substance." Biunno, <u>Current N.J. Rules of Evidence</u>, comment 3 on <u>N.J.R.E.</u> 702 (2015); see <u>Kemp</u>, supra, 174 <u>N.J.</u> at 430-31 (involving defective vaccine); <u>Landrigan</u>, <u>supra</u>, 127 <u>N.J.</u> at 413 (involving exposure to asbestos); <u>Rubanick</u>, <u>supra</u>, 125 <u>N.J.</u> at 449 (involving exposure to a chemical).

conferences, symposia, or judicial opinions accepting the methodology," and "[c]ourts also may consider testimony from other experts in the field who use similar methodologies." <u>Ibid.</u>

Flaws in an expert's causation testimony are not fatal. Even where an expert draws only a tenuous relationship between "the studies and literature on which [the expert] relied and [his] opinions," the expert's causation testimony may still be admitted, so long as the expert sufficiently provides the "why and wherefore" underlying his conclusions. Hisenaj v. Kuehner, 194 N.J. 6, 24 (2008) (reinstating the trial judge's admission of defense's biomechanical engineer expert's testimony despite plaintiff's contention that the expert employed flawed methodology; defendant's expert allegedly relied on studies consisting of subjects who were dissimilar from plaintiff in age and physical characteristics, overlooked other factors that would play a causal role in producing plaintiff's alleged chronic injury, and conducted no independent testing of his own); see also Rosenberg v. Tavorath, 352 N.J. Super. 385, 401-02 (App. Div. 2002). As the Hisenai Court emphasized, flaws in an expert's reasoning may be explored by opposing counsel on crossexamination, but such flaws do not compel exclusion of an expert opinion under N.J.R.E. 702. Hisenaj, supra, 194 N.J. at 24; see also Rosenberg, supra, 352 N.J. Super. at 402 ("The failure of an expert to give weight to a factor thought important by an adverse party does not reduce his testimony to an inadmissible net opinion .... Rather, such omission merely becomes a proper subject of exploration and cross-examination at trial." (quoting Rubanick v. Witco Chem. Corp., 242 N.J. Super. 36, 55 (1990), modified by 125 N.J. 421 (1991)) (internal quotations omitted)).

Moreover, the Supreme Court of New Jersey has indicated that "[a]lthough trial courts are expected to act as gatekeepers to the proper admission of expert testimony, trial courts [are not expected] to investigate *sua sponte* the extent to which the scientific community holds in esteem the particular analytical writings or research that a proponent of testimony advances as

foundational to an expert opinion." <u>Hisenaj</u>, <u>supra</u>, 194 <u>N.J.</u> at 16; <u>see also Landrigan</u>, <u>supra</u>, 127 <u>N.J.</u> at 414. ("[T]he trial court should not substitute its judgment for that of the relevant scientific community.") <u>Rubanick</u>, <u>supra</u>, 125 <u>N.J.</u> at 451 ("[T]he trial court should [not] directly and independently determine as a matter of law that a . . . complex scientific methodology is sound.") Instead, "[t]he court's function is to distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs." <u>Landrigan</u>, <u>supra</u>, 127 <u>N.J.</u> at 414.

In New Jersey, an expert proffered to establish specific causation must show that the product caused the harm specifically suffered by the plaintiff, not simply that the product may, generally, cause harm. Further, a reliable scientific methodology must be used by the expert in these cases to determine that the AlloDerm® was more likely than not the cause of Plaintiffs' hernia recurrences. The court relies on Creanga v. Jardal, 185 N.J. 345 (2005), in ruling on LifeCell's motion. In Creanga, the Supreme Court of New Jersey ruled that the plaintiff's expert's testimony was admissible and sufficiently reliable, as the expert in that case considered numerous alternative causes for the plaintiff's premature labor and explained how he arrived at the ultimate conclusion that it was the plaintiff's automobile accident, and not some other cause, that caused the premature labor resulting in the unfortunate death of one twin child.

Under New Jersey law, in order for an expert's methodology to be proper so as to be accepted by the court, the expert must first "rule[] in' all plausible causes for the patient's condition by compiling 'a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration." <u>Id.</u> at 356 (quoting <u>Clausen v. M/V New Carissa</u>, 339 <u>F.</u>3d 1049, 1057 (9th Cir. 2003)). In doing so, the expert must look to "which of the competing causes are generally capable of causing the patient's symptoms or mortality." <u>Ibid.</u> (quoting <u>Clausen</u>,

supra, 339 F.3d at 1057-58) (internal quotations and emphasis omitted). Thus, if an expert "rule[s] in a potential cause that is not so capable or fails to consider a plausible hypothesis that would explain the condition," that expert's methodology has not been properly conducted. <u>lbid.</u> (quoting <u>Clausen</u>, supra, 339 F.3d at 1058) (internal quotations omitted)). As such, the expert's flawed methodology would be scientifically unreliable, and thus, inadmissible.

In addition, "after the expert 'rules in' plausible causes, the expert then must rule out those causes that did not produce the patient's condition by engaging in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case." <u>Ibid.</u> (quoting <u>Clausen, supra, 339 F.3d at 1058</u>) (internal quotations omitted). The court notes that an expert "need not conduct every possible test to rule out all possible causes of a patient's [injury], so long as he or she employed sufficient . . . techniques to have good grounds for his or her conclusion." <u>Ibid.</u> (quoting <u>Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999)</u> (internal quotations omitted); <u>see also In re Paoli R.R. Yard PCB Litig.</u>, 35 <u>F.3d 717, 760-61 (3d Cir. 1994)</u>, <u>cert. denied, 513 U.S. 1190 (1995)</u>.

Furthermore, when "ruling out" other factors as part of an expert's scientific methodology, an expert need not establish that the alleged cause of a plaintiff's injuries is the only single contributing factor to those injuries; there can be other contributing causes. Under New Jersey law, "[a]ll that is required is that the plaintiff show that a defendant's conduct or defective product was a proximate cause of the condition, i.e., a substantial factor in bringing the condition about."

Grassis v. Johns-Manville Corp., 248 N.J. Super. 446, 457 (App. Div. 1991) (citing Brown v. United States Stove Co., 98 N.J. 155, 171 (1984)); see also Jones v. Owens-Corning Fiberglas Corp., 288 N.J. Super. 258, 267 (App. Div. 1996) (admitting expert's testimony that plaintiff's

exposure to asbestos remained a significant factor in causing his colon cancer even where other risk factors, such as diet, genetic factors, rare diseases, and sedentary lifestyle could have also contributed); Sholtis v. American Cyanamid Co., 238 N.J. Super. 8, 21 (App. Div. 1989)).

# II. ANALYSIS

Here, there is no scientific explanation given by Dr. LeBlanc in his expert reports or his deposition testimony was to why AlloDerm® was a cause in bringing about Plaintiffs' alleged injuries.<sup>4</sup> The premise of Dr. LeBlanc's expert reports and deposition testimony, as understood by the court, is that Dr. LeBlanc himself was allegedly misled by LifeCell's representatives regarding the use of AlloDerm® and LifeCell's marketing material purportedly touting AlloDerm® as a long-lasting, one-time, "permanent" solution for hernia repair. However, the issue for a specific causation expert in a product liability case involving a medical product is why the product, and not some other factor, caused the plaintiff's alleged injury. It is the function of the specific causation expert to explain the "methodology" as to how the expert arrived at the opinion that the product caused the harm allegedly suffered by the patient.<sup>5</sup>

As to the particular methodology employed by Dr. LeBlanc in rendering his opinions regarding the specific causal link between Plaintiffs' implantation with AlloDerm® and their alleged injuries, the court is uncertain as to the methodology employed by Dr. LeBlanc to formulate his opinions. Dr. LeBlanc relies exclusively on what he was personally told about AlloDerm® by LifeCell representatives and Dr. LeBlanc's own interpretation of the LifeCell's

<sup>&</sup>lt;sup>4</sup> For purposes of this motion, the court finds that Dr. LeBlanc is qualified to offer opinions in these cases as he has been a general surgeon since 1983, has had "a high volume" of hernia surgeries during his career and devotes approximately "65 to 70 percent of his practice" at the present time to the treatment of hernias. See Plaintiffs' Brief in Opposition to LifeCell's Motion to Bar the Testimony of Dr. LeBlanc ("Pls." Opp.") 7.

<sup>&</sup>lt;sup>5</sup> Even Plaintiffs' counsel recognizes it is the obligation of the specific causation expert to "explain his methodology." See Pls.' Opp. 15.

promotional materials. If Dr. LeBlanc intended to employ some type of differential diagnosis or other accepted methodology, such as "weight-of-the-scientific-evidence," to establish a causal link between AlloDerm® and Plaintiffs' injuries, the court did not find such an analysis in either Dr. LeBlanc's expert reports or his deposition testimony. The failure to establish even a single methodology by which Dr. LeBlanc weighed the evidence and rendered his specific causation opinions is clearly not scientifically reliable. More importantly, it is evident that Dr. LeBlanc's specific causation opinions are based solely on his own purported communications with LifeCell representatives and his own reading of LifeCell's promotional material. Dr. LeBlanc's use of medical terminology to present his own unsubstantiated personal beliefs is not a scientifically reliable methodology and therefore his testimony would not assist the jury in these cases.

Nowhere in the scant number of pages constituting his expert reports does Dr. LeBlanc discuss any scientific studies regarding the use of AlloDerm® in hernia repair surgery. Yet, counsel for both parties provided the court with numerous peer reviewed medical journal articles interpreting scientific studies involving hernia repair products and the various risk factors when using such products for surgery. Significantly, Dr. LeBlanc failed to cite a single one of the many articles that were identified for the court by both counsel in these cases. The articles provided to the court by counsel identified several risk factors associated with various hernia repair products including the co-morbidities of the patients, such as diabetes, morbid obesity, wound healing delay, previous abdominal surgery, and other factors. Additionally, the peer reviewed medical journal articles provided by counsel suggest that surgeon technique and medical judgment in the repair of a hernia may factor in the calculus for success with any hernia repair product.

<sup>&</sup>lt;sup>6</sup> Nor were any scientific studies or medical journal articles interpreting scientific studies discussed by Dr. LeBlanc during his deposition.

Nowhere in his deposition testimony or his expert reports does Dr. LeBlanc state why he opines that AlloDerm®, as opposed to surgeon technique or each plaintiff's co-morbidities, was a cause of the injuries allegedly suffered by Plaintiffs. The focus of Dr. LeBlanc's opinion that AlloDerm® caused the Plaintiffs' alleged injuries is that Dr. LeBlanc, personally, was misled by LifeCell's representatives and promotional material as to permanency of AlloDerm® in hernia repair. However, what Dr. LeBlanc may or may not have been told by LifeCell's representatives is irrelevant to the court's analysis of Dr. LeBlanc's specific causation opinion. It might have been relevant to the court's analysis of Dr. LeBlanc's testimony for him to identify what, if anything, LifeCell may have told Plaintiffs' implanting surgeons about AlloDerm®. While Dr. LeBlanc claimed to have read the deposition testimony of each implanting surgeon for Plaintiffs, it is clear that Dr. LeBlanc never read the entirety of each surgeon's deposition testimony.<sup>7</sup> In these cases, at least two of Plaintiffs' implanting surgeons testified that they never spoke to LifeCell's representatives or, if they spoke with a LifeCell representative, such discussions were limited to preparation/hydration of the product for surgery. Nor did any of Plaintiffs' implanting surgeons recall reading LifeCell's promotional material for AlloDerm®, let alone testify that they relied on such material in making the decision to use the product for each Plaintiff.

Dr. LeBlanc's role in this litigation is to determine, in light of the fact that AlloDerm® was implanted into Plaintiffs and considering Plaintiffs' other risk factors, that AlloDerm® was, in fact, a substantial contributing factor to the development of Plaintiffs' alleged injuries. In order for Dr. LeBlanc's testimony as to specific causation to be admitted as scientifically reliable, he must set forth a scientifically reliable methodology in rendering his opinions. Creanga, supra, 185

<sup>&</sup>lt;sup>7</sup> When asked during his deposition to identify the alleged "unfounded representations" made by LifeCell to each of Plaintiffs' implanting surgeons, Dr. LeBlanc conceded that he did not know what was said by LifeCell representatives to any implanting surgeon or what promotional material any implanting surgeon may have received from LifeCell.

N.J. at 358. For the reasons set forth above, the court finds that Dr. LeBlanc failed to set forth a reliable methodology, or even identify a methodology, as to the reason it was AlloDerm® and not some other factor that caused Plaintiffs' injuries. Dr. LeBlanc's specific causation opinions amount to nothing more than his "subjective belief [] or unsupported speculation." Id. (quoting Claar v. Burlington N. R.R. Co., 29 F. 3d 499, 502 (9th Cir. 1994)). Because Dr. LeBlanc failed to articulate his methodology in arriving at the conclusion that AlloDerm® was a substantial contributing factor in the development of Plaintiffs' alleged injuries, his testimony will not assist the trier of fact to determine whether Plaintiffs have met the burden of establishing that AlloDerm® substantially contributed to their alleged injuries. See N.J.R.E. 702. Dr. LeBlanc's lack of an articulated methodology in arriving at his specific causation opinions is not consistent with sound scientific principles and must be excluded under N.J.R.E. 702 and Kemp.

For the foregoing reasons, LifeCell's motion to bar the specific causation testimony of Dr. LeBlanc is **GRANTED**. <sup>8</sup>

JESSICA R. MAYER, J.S.C.

<sup>8</sup> The court notes that Plaintiffs proffer specific causation testimony from other experts. Therefore, the court's decision to bar the testimony of Dr. LeBlanc is not fatal to Plaintiffs' claims in these cases.