

#0241
0827-15

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LifeCell Corporation

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

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

PATRICIA JULIEN,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

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

THOMAS DUTCHER,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-1469-12 CM

DEBBIE FOSTER and DAVID FOSTER, w/h,

Plaintiffs,

v.

LIFECCELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-6841-12 CM

Civil Actions

ORDER

GRANTED IN PART

FILED
AUG 14 2015

JUDGE JESSICA R. MAYER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order barring the testimony of Dr. Thomas Gouge at trial in any of the four bellwether cases, and the Court having considered all papers submitted by the parties, and for good cause and the reasons ^{in the attached} stated on the ~~memorandum of decision,~~ ^{record by the Court,}

It is on this the 14th day of August, 2015,

ORDERED that defendant's motion is hereby granted, ^{in part and denied in part,} and it is further

~~ORDERED that the testimony of Dr. Thomas Gouge is hereby barred at any of the four bellwether trials; and it is further~~

ORDERED that a copy of this Order be ^{posted online for} served on all counsel of record within

7 days hereof.

* For the reasons set forth in the court's memorandum of decision dated August 14, 2015

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

PAPERS CONSIDERED

OPPOSED

	<u>Yes</u>	<u>No</u>	<u>Date</u>
Notice of Motion	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____
Movant's Affidavits	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____
Movant's Brief	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____
Answering Affidavits	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____
Answering Brief	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____
Cross Motion	<input type="checkbox"/>	<input type="checkbox"/>	_____
Movant's Reply	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____
Other _____	<input type="checkbox"/>	<input type="checkbox"/>	_____

#2042
08-07-15

David W. Field (00378-1984)
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Attorneys for Defendant
LifeCell Corporation

FILED

AUG 14 2015

JUDGE JESSICA R. MAYER

IN RE: ALLODERM® LITIGATION

CASE CODE 295

MICHAEL SIMINERI and KAREN
SIMINERI, h/w,

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LIFECCELL CORPORATION,

Defendant.

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

PATRICIA JULIEN,

Plaintiff,

v.

LIFECCELL CORPORATION,

Defendant.

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

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SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-1469-12 CM

DEBBIE FOSTER and DAVID FOSTER, w/h,

Plaintiffs,

v.

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Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-6841-12 CM

Civil Actions

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Cross Motion	_____	_____	_____
Movant's Reply	✓	_____	_____
Other _____	_____	_____	_____

0243
08-07-15

David W. Field (00378-1984)
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973.597.2500
Attorneys for Defendant
LifeCell Corporation

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

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

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Plaintiff,

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LIFECELL CORPORATION,

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

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Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-1469-12 CM

DEBBIE FOSTER and DAVID FOSTER, w/h,
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 v.
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SUPERIOR COURT OF NEW JERSEY
 LAW DIVISION: MIDDLESEX COUNTY
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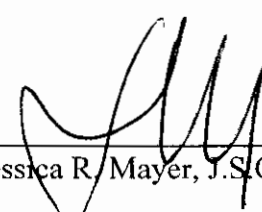
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0244
05-07-15

DEBBIE FOSTER and DAVID FOSTER, w/h,

Plaintiffs,

v.

LIFECCELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-6841-12 CM

Civil Actions

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AUG 14 2015
JUDGE JESSICA R. MAYER

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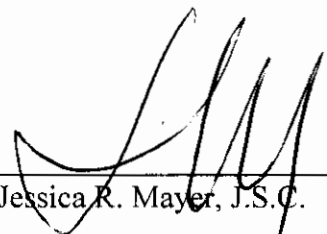
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Hon. Jessica R. Mayer, J.S.C.

PAPERS CONSIDERED

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David W. Field (00378-1984)
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Attorneys for Defendant
LifeCell Corporation

FILED
AUG 14 2015
JUDGE JESSICA R. MAYEF

IN RE: ALLODERM® LITIGATION
CASE CODE 295

MICHAEL SIMINERI and KAREN
SIMINERI, h/w,

Plaintiffs,

v.

LIFECCELL CORPORATION,

Defendant.

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

PATRICIA JULIEN,

Plaintiff,

v.

LIFECCELL CORPORATION,

Defendant.

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

THOMAS DUTCHER,

Plaintiff,

v.

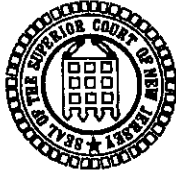
LIFECCELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-1469-12 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. Thomas Gouge**

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

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

For Plaintiffs: Lawrence R. Cohan, Esq., Joseph J. Fantini, Esq., Paola Saneaux, Esq., Adrienne 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"), filed a motion to exclude the testimony of Dr. Thomas Gouge.¹ The four bellwether Plaintiffs ("Plaintiffs") offer the expert report of Dr.

¹ Defendant's Brief in Support of Its Motion to Bar the Testimony at Trial of Dr. Thomas Gouge ("Def.'s Br.") 1.

Gouge and intend to offer the expert testimony of Dr. Gouge at trial in support of their claims that: (1) AlloDerm® for use in ventral hernia repair is a defective product; and (2) LifeCell failed to provide adequate warnings for AlloDerm® for use in ventral hernia repairs.² After considering the parties' moving papers, as well as the deposition testimony and expert report of Dr. Gouge, the court determines that Defendant's motion to exclude the opinion of Dr. Gouge is **GRANTED IN PART** and **DENIED IN PART**.

I. Background

Defendant argues that Dr. Gouge should be barred from testifying at trial because: (1) his opinion is irrelevant as LifeCell did not market AlloDerm® as a "permanent" solution; (2) none of Plaintiffs' implanting surgeons testified that they believed AlloDerm® would be a "permanent" solution for hernia repair; and (3) Dr. Gouge's testimony constitutes an inadmissible net opinion as he assumed that the implanting surgeons were misled into believing that AlloDerm® was a "permanent" solution.³

Plaintiffs respond by noting Dr. Gouge's "impressive" credentials as a "Board Certified general surgeon with over 38 years of clinical experience with a practice concentration in abdominal and gastrointestinal surgery."⁴ Plaintiffs aver that Dr. Gouge's expert opinion is reliable as it rests on "his extensive personal experience, medical and scientific training, review of pertinent literature and interactions with LifeCell's sales representatives"⁵ Plaintiffs argue that Dr. Gouge's opinion is relevant because Dr. Gouge's testimony will assist the jury in understanding the use of AlloDerm® in hernia repairs and AlloDerm®'s instructions and warnings provided by

² Plaintiffs' Brief in Opposition to Defendant LifeCell Corporation's Motion to Bar the Testimony at Trial of Dr. Thomas Gouge ("Pls.' Opp.") 9.

³ Def.'s Br. 1.

⁴ Pls.' Opp. 9.

⁵ Id. at 9-10.

LifeCell based upon Dr. Gouge’s personal experiences with LifeCell representatives and his reading of the relevant documents and literature.⁶ Plaintiffs further contend that Defendant’s entire argument in support of barring Dr. Gouge’s opinion is his use of the word “permanent” but that LifeCell “conveniently fails to reveal the entire content of Dr. Gouge’s expert report or his deposition testimony.”⁷

II. Relevant Law

To establish liability in these cases, Plaintiffs must prove through expert testimony that AlloDerm® was “not reasonably fit, suitable or safe” for use in hernia repairs because it either “failed to contain adequate warnings or instructions” or it “was designed in a defective manner.” Kemp ex rel. Wright v. State, 174 N.J. 412, 417 (2002); N.J.S.A. § 2A:58C-2. Hence, the expert testimony of Dr. Gouge has been proffered by Plaintiffs to support their claims that AlloDerm® was designed in a defective manner for use in hernia repair and that LifeCell failed to provide adequate warnings or instructions for the use of AlloDerm® in hernia repairs.⁸

N.J.R.E. 702, which governs the admissibility of 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 an opinion or otherwise.

[Ibid.]⁹

⁶ Id. at 17-18.

⁷ Id. at 9.

⁸ Ibid.

⁹ While the New Jersey version of Rule 702 tracks the original version of Federal Rule of Evidence 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

Under N.J.R.E. 702, for an expert's testimony 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., supra, 127 N.J. at 413)]

N.J.R.E. 703 addresses the foundation for expert testimony. It requires that expert opinions be grounded in “‘facts or data derived from (1) the expert's personal observations, or (2) evidence admitted at the trial, or (3) data relied upon by the expert which is not necessarily admissible in evidence but which is the type of data normally relied upon by experts.’” Polzo v. Cnty. of Essex, 196 N.J. 569, 583 (2008) (quoting State v. Townsend, 186 N.J. 473, 494 (2006)), rev'd on other grounds, 209 N.J. 51 (2012).

The net opinion rule is a “corollary” of N.J.R.E. 703. Townsend v. Pierre, 221 N.J. 36, 54 (2015). The rule “forbids the admission into evidence of an expert's conclusions that are not supported by factual evidence or other data.” Ibid. (quoting Polzo, supra, 196 N.J. at 583). Under the net opinion rule, “the expert is required to ‘give the why and wherefore’ that supports the opinion, ‘rather than a mere conclusion.’” Pomerantz Paper Corp. v. New Community Corp., 207

codifying the principles of Daubert v. Merrell Dow Pharms., 509 U.S. 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 Daubert 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 Kemp.

N.J. 344, 372 (2011) (quoting Polzo, *supra*, 196 N.J. at 583). The rule does not require perfection and an expert is not required to organize his opinion in a manner that opposing counsel finds preferable. Townsend v. Pierre, *supra*, 221 N.J. at 55.

An expert's opinion is "not inadmissible simply 'because it fails to account for some particular condition or fact which the adversary considers relevant.'" Creanga v. Jardal, 185 N.J. 345, 360 (2005) (quoting State v. Freeman, 223 N.J. Super. 92, 116 (App. Div. 1988)). "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 if he otherwise offers sufficient reasons which logically support his opinion." Rosenberg v. Tavorath, 352 N.J. Super. 385, 402 (App. Div. 2002) (quoting State v. Freeman, 223 N.J. Super. 92, 115-16 (App. Div. 1988), *certif. denied*, 114 N.J. 525 (1989)). However, under the net opinion rule, experts must be able to "identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and the methodology are reliable." Landrigan, *supra*, 127 N.J. at 413. An expert's opinion is inadmissible if it is based on mere speculation or "unquantified possibilities." Grzanka v. Pfeifer, 301 N.J. Super. 563, 580 (App. Div. 1997) (quoting Vuocolo v. Diamond Shamrock Chem. Co., 240 N.J. Super. 289, 300 (App. Div.), *certif. denied*, 122 N.J. 333 (1990)). "Given the weight that a jury may accord to expert testimony, a trial court must ensure that an expert is not permitted to express speculative opinions or personal views that are unfounded in the record." Townsend v. Pierre, *supra*, 221 N.J. at 55.

III. Analysis

As a preliminary matter, the court dismissed Plaintiffs' design defect claims for the reasons set forth in this court's Memorandum of Decision on Defendant's Motions for Summary Judgment

on Plaintiffs' Design Defect Claims, dated August 14, 2015. Accordingly, any testimony that relates solely to Plaintiffs' design defect claims is irrelevant to the Plaintiffs' remaining claims. Therefore, to the extent that Dr. Gouge is offered by Plaintiffs to opine on any issues related to the alleged defective design of AlloDerm®, that specific testimony is barred. Furthermore, this court dismissed the failure-to-warn claims of Plaintiffs Patricia Julien and Debbie and David Foster for the reasons set forth in this court's Memorandum of Decision on Defendant's Motion for Summary Judgment on Plaintiff Patricia Julien's Failure-to-Warn Claim, dated August 14, 2015 and Memorandum of Decision on Defendant's Motion for Summary Judgment on Plaintiffs Debbie and David Foster's Failure-to-Warn Claim, dated August 14, 2015. Thus, the only claims relevant to this motion are the failure-to-warn claims brought by Plaintiffs Michael and Karen Simineri and Thomas Dutcher.

Additionally, this court ruled that all evidence and testimony related to AlloDerm®'s regulation by the Food and Drug Administration ("FDA") is barred as set forth in this court's Memorandum of Decision on Defendant's Motion *In Limine* to Exclude FDA Evidence and Testimony, dated August 14, 2015. In his expert report and at his deposition, Dr. Gouge offered some commentary regarding the FDA's regulation of AlloDerm®.¹⁰ Thus, to the extent that Dr. Gouge is being offered for opinions on the FDA's regulation and classification of AlloDerm®, or LifeCell's compliance (or lack thereof) with those regulations, Dr. Gouge's testimony on that subject is also barred. Therefore, the court need only rule on the admissibility of Dr. Gouge's opinions regarding the remaining Plaintiffs' failure-to-warn claims.

¹⁰ Field Cert., Ex. A, Gouge Report.

Dr. Gouge is a Board Certified general surgeon with over thirty-eight years of clinical experience.¹¹ The focus of Dr. Gouge's practice is abdominal and gastrointestinal surgery.¹² Additionally, Dr. Gouge is currently Vice Chairman of the Department of Surgery at Lenox Hill Hospital and Professor of Surgery in the New York University School of Medicine. From 1973 to 2014, the repair of ventral hernias was a routine aspect of Dr. Gouge's practice and Dr. Gouge continues to teach residents and medical students regarding the appropriate techniques in these types of operations.¹³

At his deposition, Dr. Gouge estimated that he has performed between 500 and 1,500 ventral hernia repairs.¹⁴ Of those hernia repairs, approximately three-quarters involved the use of some type of mesh or graft product.¹⁵ Dr. Gouge estimated that approximately 10 to 20 of the ventral hernia repairs he has performed in his practice involved the use of biologic meshes.¹⁶ Defendant has not challenged Dr. Gouge's expert opinions on the basis that he is unqualified and the court finds that based on his professional knowledge and expertise, Dr. Gouge is well-qualified to provide expert opinions regarding the type of ventral hernia repairs at issue in these cases.

Defendant's argument is that Dr. Gouge's expert opinion is wholly irrelevant to the issues before this court. Defendant emphasizes the sections of Dr. Gouge's expert report wherein he describes LifeCell's marketing of AlloDerm® as a "long term, permanent solution."¹⁷ LifeCell contends that because LifeCell's marketing materials did not use the word "permanent" and because the implanting surgeons for Mr. Simineri and Mr. Dutcher understood that there is always

¹¹ Field Cert., Ex. A, Gouge Report.

¹² ibid.

¹³ ibid.

¹⁴ Field Cert., Ex. B, Gouge Dep. 11:20-25.

¹⁵ Id. at 12:19-22.

¹⁶ Id. at 18:6-9.

¹⁷ Def.'s Br. 4.

a risk of recurrence in hernia repairs, Dr. Gouge's opinion is irrelevant.¹⁸ Furthermore, Defendant contends that Dr. Gouge's opinion is an inadmissible net opinion because it "counter-factually assumes that the implanting surgeons were misled into believing that AlloDerm was a 'permanent' solution to repair a ventral hernia."¹⁹

The court finds LifeCell's argument to be misplaced. Defendant is correct that the implanting surgeons for Mr. Simineri and Mr. Dutcher did, in fact, agree that there is always a risk of recurrence in hernia surgery. In reviewing the numerous motions filed with the court, it is apparent that every implanting surgeon and every expert witness offered by both parties in these matters agrees that there is always a risk of recurrence in any hernia surgery regardless of the technique or product used. Defendant's argument attempts to characterize Dr. Gouge's use of the word "permanent" as an unsupported allegation that LifeCell marketed AlloDerm® with a 100% guarantee that AlloDerm® was recurrence-free. However, Defendant's argument oversimplifies the nature of Plaintiffs' claims. Plaintiffs allege that Defendant failed to warn Plaintiffs' surgeons of a significantly higher risk of recurrence with AlloDerm® as compared with other hernia repair products. Additionally, Plaintiffs allege that Defendant failed to warn Plaintiffs' surgeons of the risk of post-operative thinning and stretching leading to abdominal bulging, recurrence, and the need for additional surgeries. Plaintiffs' claims do not stand or fall on whether LifeCell 100% guaranteed that AlloDerm® would be recurrence-free.

Defendant's argument that none of the Plaintiffs' implanting surgeons believed that AlloDerm® would provide "permanent" repair is directly contradicted by the testimony of Plaintiff

¹⁸ Id. at 3-4.

¹⁹ Id. at 1.

Simineri's treating surgeon, Dr. Gerardo Garcia. Dr. Garcia agreed that there is always a risk of recurrence, but also testified that he intended his repair of Mr. Simineri's hernia to be permanent:

Q. And when you repaired Mr. Simineri with this AlloDerm in October of '07, was it your intention that would be a permanent solution?

A. Yes.²⁰

Thus, it is clear that Dr. Garcia does not necessarily equate the word "permanent" as used in hernia repair with an expectation of zero risk of recurrence. Dr. Gouge also concedes that there is always a risk of recurrence in any hernia repair.²¹ It is evident that Dr. Gouge's use of the word "permanent" is not intended to imply that AlloDerm® was marketed to be 100% recurrence-free. In fact, Dr. Gouge's deposition testimony elucidates his understanding of the word "permanent" in hernia repairs:

Q. You told us before there were two categories of surgery; one that was intended to be permanent and one that was intended to be temporary.

Tell us under what situations a repair would be intended to be temporary.

A. Yes, sir, so if you cannot safely reconstitute the patient's abdominal wall or if local conditions make that an inappropriate thing to do, the goal would be to reestablish a biologic closure of the abdominal wall and to leave definitive repair to a later date if it was ever going to be done at all.²²

Thus, Dr. Gouge's testimony clarifies his use of the word "permanent" as intended to differentiate two-stage hernia repairs in which a surgeon does a temporary repair and then later performs a second procedure once any infection has cleared, from those in which the surgeon intends to

²⁰ Fanini Cert., Ex. C, Garcia Dep. 73:22-74:2.

²¹ Field Cert., Ex. B, Gouge Dep. 32:22-33:10.

²² Field Cert., Ex. B, Gouge Dep. 40:3-16.

perform a single procedure. This context for the word “permanent” is further supported by the description of AlloDerm® offered by Kim Baker, a LifeCell Territory Manager, as “definitive (not temporary).”²³ The court finds that Dr. Gouge’s expertise as a surgeon familiar with hernia repairs and the techniques used in those repairs may aid the jury in understanding “permanency” in hernia repair. As a Board Certified surgeon with thirty-eight years of experience treating ventral hernias, Dr. Gouge is qualified to educate a jury on the repair of ventral hernias, including the surgical techniques, potential complications, and use of biologic grafts involved in repairing hernias relevant to Plaintiffs’ remaining claims.

Furthermore, the court finds that Dr. Gouge is qualified to testify, based on his extensive experience as a surgeon, regarding the type of information and instruction a surgeon expects a manufacturer to provide. For example, at his deposition, Dr. Gouge described the information he relies on when using a medical product like AlloDerm®:

Q. Other than a surgeon’s own surgical experience in the operating room, is discussing surgical technique with surgeons the second most informative source of information?

A. So in some ways, it’s the most informative, it’s the least scientific, that is, you’re getting a subjective impression of somebody, what works, what doesn’t, how they do it, but rather than the literature or a presentation at a meeting, discussion offers the opportunity to investigate the nuances of what to do.

You’re basically dependent upon [,] with a product with which you are not familiar, on what the company present to you about how it is to be used, that is, the whole spectrum of used, how it needs to be stored, how it needs to be prepared for use in the operating room, how it needs to be oriented, how it needs to be incorporated into the surgery and you are dependent upon the company for that. The company, meaning, both their printed materials and their representatives and then you’re dependent upon what information is

²³ Fantini Cert., Ex. F, LifeCell letter promoting AlloDerm® for use in hernia repairs.

available in the literature that backs that up or gives you additional information.

The technical aspects of use of a product such as AlloDerm are basically dependent upon what is communicated to you by the company.²⁴

Accordingly, although the adequacy or inadequacy of the AlloDerm® instructions and warnings is an issue that must be decided by the jury, the court finds that Dr. Gouge's "specialized knowledge" regarding hernia repairs, surgical techniques, and hernia repair products may assist the jury in understanding the evidence in these cases. N.J.R.E. 702.

Furthermore, the court finds that Dr. Gouge's opinions—insomuch as they are based on his own personal experiences and expertise as a surgeon, his reading of the AlloDerm® Instructions for Use and other literature, and his experiences with AlloDerm® sales representatives—are not inadmissible net opinions. However, the court agrees with Defendant that Dr. Gouge's opinions regarding what Plaintiffs' surgeons or any other surgeons understood about the use of AlloDerm® are merely speculative. Dr. Gouge conceded at his deposition that he has no personal knowledge of Plaintiffs' surgeons' understandings of AlloDerm® or any representations made to them by LifeCell employees.²⁵ Yet, Dr. Gouge's expert report repeatedly offers speculative opinions regarding what Plaintiffs' surgeons or other surgeons thought or intended.²⁶ To the extent Plaintiffs intend to offer Dr. Gouge's opinion as to the Plaintiffs' surgeons' knowledge, beliefs, or experiences regarding AlloDerm®, Dr. Gouge has no basis for such an opinion and any such testimony is barred.

²⁴ Fantini Cert., Ex. B, Gouge Dep. at 83:7-84:15.

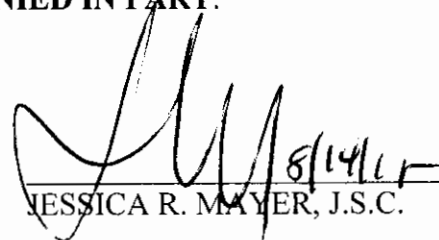
²⁵ Id. at 49:17-19, 56:20-57:16, 105:11-14.

²⁶ See, e.g. Field Cert., Ex. A, Gouge Report ("A surgeon's decision to use Alloderm was based on misleading marketing by LifeCell prompting [sic] its efficacy Surgeons used Alloderm thinking it provided a permanent repair without the problem of mesh infection.")

In sum, Dr. Gouge is permitted to testify regarding the general principles and concepts surrounding hernias and hernia repairs, as well as the type of information surgeons expect concerning the instructions and warnings accompanying products used in those repairs.²⁷ In providing those opinions, Dr. Gouge is entitled to rely on his own personal experiences and expertise as a surgeon as well as the materials and instructions provided with AlloDerm®. However, Dr. Gouge is not permitted to speculate regarding what other surgeons knew, believed or intended regarding their use of AlloDerm®. Additionally, in accordance with this court's decisions on other motions in these cases, Dr. Gouge will not be permitted to offer opinions regarding the purported defective design of AlloDerm® or its regulation by the FDA.

IV. Conclusion

For the foregoing reasons, Defendant's Motion to Exclude the Testimony at Trial of Dr. Thomas Gouge is **GRANTED IN PART** and **DENIED IN PART**.


JESSICA R. MAYER, J.S.C.

²⁷ Based on Plaintiffs' motion papers, it is difficult for the court to discern the exact issues for which Dr. Gouge's testimony is being offered. Dr. Gouge is permitted to testify as to his own experiences and expertise regarding hernia surgeries and hernia repair products insofar as they are relevant to Plaintiffs' failure-to-warn claims. To the extent Plaintiffs are offering Dr. Gouge's testimony for any other purpose, Plaintiffs must provide a proffer to Defendant and to this court so that the relevance and admissibility of Dr. Gouge's opinion may be determined. Furthermore, the court notes that Plaintiffs appear to offer a number of medical experts with overlapping knowledge and expertise regarding hernia repairs. Counsel for both parties are cautioned that this court will not allow cumulative expert testimony.