#0124
08-07-15

IN RE: ALLODERM® LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY CASE CODE NO. 295 CIVIL ACTION
MICHAEL J. SIMINERI and KAREN SIMINERI, *Plaintiffs*, v. LIFECELL CORPORATION *Defendant.*	DOCKET NO. L 5972-11 CM

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

ORDER GRANTING PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT DAVID FEIGAL, M.D.

This matter, having been opened to the Court by counsel for Plaintiffs on their Motion to Exclude Testimony of Defendant, LifeCell Corporation's ("LifeCell") Expert David Feigal, M.D., ~~the parties having had an opportunity to be heard~~ for the reasons in the attached memorandum of decision, and for good cause shown;

IT IS, on this 14th day of August, 2015, hereby **ORDERED** as follows:

Plaintiffs' Motion is **GRANTED** for the reasons set forth in the court's ~~Dr. Feigal shall not testify about or offer conclusions~~: memorandum of decision dated August 14 2015
1) that AlloDerm used in abdominal hernia repair is a homologous use for FDA classification as a human tissue product ~~versus a medical device; and 2) that the AlloDerm IFU provided adequate warning to the implanting surgeons for each bellwether case~~.

IT IS FURTHER ORDERED that a copy of this Order be posted online ~~and served on~~ by all counsel of record within seven (7) days of the date of this order.

Jessica R. Mayer, J.S.C.

OPPOSED

#0124
28-07-15

IN RE: ALLODERM® LITIGATION	**SUPERIOR COURT OF NEW JERSEY** **LAW DIVISION: MIDDLESEX COUNTY** **CASE CODE NO. 295** **CIVIL ACTION**
PATRICIA JULIEN, ***Plaintiff,*** **v.** **LIFECELL CORPORATION** ***Defendant.***	**DOCKET NO. L 507-12 CM**

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

ORDER GRANTING PLAINTIFF'S MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT DAVID FEIGAL, M.D.

This matter, having been opened to the Court by counsel for Plaintiff on her Motion to Exclude Testimony of Defendant, LifeCell Corporation's ("LifeCell") Expert David Feigal, M.D., ~~the parties having had an opportunity to be heard~~ for the reasons in the attached memorandum of decision, and for good cause shown;

IT IS, on this 14th day of August, 2015, hereby **ORDERED** as follows:

Plaintiffs' Motion is **GRANTED**, ~~Dr. Feigal shall not testify about or offer conclusions:~~ for the reasons set forth in the court's memorandum of decision dated August 14, 2015

~~1.) that AlloDerm used in abdominal hernia repair is a homologous use~~ for ~~FDA classification~~ as a human tissue product versus a medical device; and 2) that the ~~AlloDerm IFU~~ provided adequate warning to the implanting surgeons for each bellwether ~~case~~.

IT IS FURTHER ORDERED that a copy of this Order be posted online ~~and served on~~ for all counsel of record within seven (7) days of the date of this order.

Jessica R. Mayer, J.S.C.

OPPOSED

IN RE: ALLODERM® LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY CASE CODE NO. 295 CIVIL ACTION
THOMAS DUTCHER, *Plaintiff,* v. LIFECELL CORPORATION *Defendant.*	DOCKET NO. L 1469-12 CM

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

ORDER GRANTING PLAINTIFF'S MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT DAVID FEIGAL, M.D.

This matter, having been opened to the Court by counsel for Plaintiff on his Motion to Exclude Testimony of Defendant, LifeCell Corporation's ("LifeCell") Expert David Feigal, M.D., t~~he parties having had an opportunity to be hear~~d, and for good cause shown; for the reasons in the attached memorandum of decision

IT IS, on this 14 day of August, 2015, hereby **ORDERED** as follows:

for the reasons set forth in the court's

Plaintiffs' Motion is **GRANTED**. ~~Dr. Feigal shall not testify about or offer conclusions:~~

memorandum of decision dated August 14, 2015

1) that AlloDerm used in abdominal hernia repair is ~~a homologous use for FDA~~ classification as a ~~human tissue product versus a medical device; and 2) that the AlloDerm IFU~~ provided adequate warning to the implanting ~~surgeons for each bellwether case~~.

for

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.

OPPOSED

Jessica R. Mayer, J.S.C.

0129
~ 08.07.14

IN RE: ALLODERM® LITIGATION	**SUPERIOR COURT OF NEW JERSEY** **LAW DIVISION: MIDDLESEX COUNTY** **CASE CODE NO. 295** **CIVIL ACTION** FILED AUG 14 2015 JUDGE JESSICA R. MAYER
DEBBIE FOSTER and DAVID FOSTER, ***Plaintiffs,*** **v.** **LIFECELL CORPORATION** ***Defendant.***	**DOCKET NO. L 6841-12 CM**

ORDER GRANTING PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT DAVID FEIGAL, M.D.

This matter, having been opened to the Court by counsel for Plaintiffs on their Motion to Exclude Testimony of Defendant, LifeCell Corporation's ("LifeCell") Expert David Feigal, M.D., the ~~parties having had an opportunity to be heard~~, for the reasons set in the attached memorandum of decision, and for good cause shown;

IT IS, on this 14th day of August, 2015, hereby **ORDERED** as follows:

Plaintiffs' Motion is **GRANTED** for the reasons set forth in the court's memorandum of decision dated August 14 2015 ~~Dr. Feigal shall not testify about or offer~~ conclusions: 1) that ~~AlloDerm used in abdominal hernia repair is~~ a homologous use for ~~FDA classification as~~ a ~~human tissue product versus a medical device; and 2) that the AlloDerm IFU provided~~ adequate ~~warning to the implanting surgeons for each bellwether~~ case.

IT IS FURTHER ORDERED that a copy of this Order be posted online for ~~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 Defendant's Motion to Bar the Testimony of Dr. David Feigal

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.

Plaintiffs[1] move to bar the testimony of Dr. David Feigal, Jr., ("Dr. Feigal"), expert witness for the Defendant LifeCell Corporation ("LifeCell" or "Defendant"), in the above matters. Counsel

[1] Counsel for the parties selected four cases out of approximately 350 currently pending AlloDerm® matters as "bellwether" trials. The selected cases are: Thomas Dutcher, Debbie and David Foster, Patricia Julien, and Michael and Karen Simineri (collectively "Plaintiffs").

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 written arguments of counsel, all filed documents and exhibits (including Dr. Feigal's written report dated May 8, 2015 and deposition testimony of Dr. Feigal), and relevant case law,[2] the court determines that Plaintiffs' motion to exclude the testimony of Dr. Feigal is **GRANTED**.

I. BACKGROUND

Defendant proffers Dr. David Feigal, Jr., as a Food and Drug Administration ("FDA") expert to opine on the FDA's classification of AlloDerm® – specifically, whether AlloDerm®'s use in hernia repair constitutes a "homologous use" per the FDA "human cells, tissues, and cellular and tissue-based product" ("HCT/P") regulations, 21 C.F.R. § 1271.3(c) – and as a rebuttal expert to opine on the adequacy of AlloDerm®'s Instructions for Use ("IFUs"). Although neither party submitted a resume or curriculum vitae for Dr. Feigal in connection with this motion, the court gleans the following from Dr. Feigal's expert report: Dr. Feigal earned a medical degree from Stanford University in 1976 and a Master of Public Health degree in epidemiology and biostatistics from the University of California, Berkeley, in 1983.[3] He is board certified in Internal Medicine.[4] Dr. Feigal worked in various positions at the FDA from 1992-2004.[5] After leaving the FDA, Dr. Feigal worked for two biotech-pharmaceutical companies, focusing on regulatory issues, safety and labeling, and post-market surveillance.[6] Currently, Dr. Feigal is an adjunct professor at the

[2] The parties signed a consent order stipulating that New Jersey law governs all issues in the AlloDerm® cases. See Consent Order Stipulating Choice of Law, Jan. 15, 2015.
[3] Expert Report of Dr. David Feigal, Jr., dated May 8, 2015 ("Feigal Report"), Plaintiffs' Brief in Support of Motion to Exclude Testimony of Defendant's Expert David Feigal ("Pls.' Br.") Ex. B, 1.
[4] Feigal Report, Pls.' Br. Ex. B, 1.
[5] Id. at 2-5.
[6] Id. at 4-5.

Arizona State School of Law, teaching a course on Food and Drug law.[7] For the past ten years, Dr. Feigal has also served as an expert witness (on both the plaintiff and defense side) and professional consultant on FDA regulations and enforcement, epidemiology, and biostatistics.[8]

Dr. Feigal offered seven ultimate opinions in his expert report which, for the sake of brevity, the court qualifies as follows: opinions (1)-(4) and (6)-(7) deal with FDA regulations, AlloDerm®'s status in the FDA regulatory classification scheme, and LifeCell's compliance with FDA regulations; opinion (5) states, "[t]he applicable AlloDerm Instructions for Use provided adequate warnings to surgeons of patient factors and adverse events that could lead to poor tissue regeneration and result in graft failure risks, such as, bulging, stretching, laxity, and recurrence."[9]

Plaintiffs move to bar Dr. Feigal's testimony on the basis that it is speculative, unscientific net opinion and that Dr. Feigal lacks the requisite expertise to opine on adequacy of the AlloDerm® IFUs.[10] Specifically, Plaintiffs assert that Dr. Feigal's failure to read all of the IFU versions as revised throughout AlloDerm®'s existence[11] renders his method for determining the adequacy of the IFUs "questionable and unscientific."[12] Plaintiffs argue that, in addition to reading the IFU included with each Plaintiff's respective AlloDerm® graft, Dr. Feigal should have also evaluated the IFU version in effect at the time of each Plaintiff's respective surgery.[13] Plaintiffs argue that absent a "better understanding of the AlloDerm IFU evolution," Dr. Feigal's opinions on adequacy

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[7] Id. at 4.
[8] Id. at 5.
[9] Id. at 21-22.
[10] Pls.' Br. 1, 4-6, 12-17.
[11] Plaintiffs concede that Dr. Feigal read the IFU versions which were included in the packaging for the AlloDerm® that was implanted into each Plaintiff respectively. Pls.' Br. 13.
[12] Pls.' Br. 14.
[13] Id. at 13-14. Due to the passage of time between a hospital's purchase of AlloDerm® and the use of such AlloDerm® for implantation, there are occasions where the IFU included in a patient's AlloDerm® is not the "current" IFU included with AlloDerm® manufactured at that time.

are speculative personal opinions that are "scientifically flawed and unreliable."[14] Further, Plaintiffs question Dr. Feigal's expertise for the purpose of opining on adequacy of the IFUs. Plaintiffs note that Dr. Feigal is not a surgeon, has never participated in a hernia repair surgery, and has not been involved in direct patient care in over twenty years.[15] As such, Plaintiffs claim Dr. Feigal "lacks the required expertise to know the risks of AlloDerm when used in hernia repair surgery or grasp the importance of other product risks surgeons would want to be advised of."[16] For reasons explained in this Memorandum, the court need address Plaintiffs' arguments as to Dr. Feigal's FDA-related opinions, nor Defendant's opposition to same.

Defendant, in its opposition papers, argues that Plaintiffs' criticism of Dr. Feigal's methodology amounts to nothing more than a claim that Dr. Feigal failed to consider factors that the Plaintiffs find relevant, which is properly the subject of cross-examination, not the basis for preclusion.[17] See Rosenberg v. Tavorath, 352 N.J. Super. 385, 401-02 (App. Div. 2002) ("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)). Defendant argues that in evaluating the adequacy of a warning, the expert need only refer to the actual warning that was provided with the product used by the plaintiff, and not any prior or subsequent warnings. This is because only the adequacy of the warning actually provided can have

[14] Pls.' Br. 14, 17.
[15] Pls.' Br. 17.
[16] Ibid.
[17] Defendant's Brief in Opposition to Plaintiffs' Motion to Bar Testimony of Defendant's expert Dr. David Feigal ("Def.'s Br.") 9.

any impact on the issue of proximate cause; in other words, whether a prior or subsequent label was adequate is of no consequence to the impact of the warning given to the Plaintiffs' surgeons.[18]

As to Dr. Feigal's expertise, Defendant counters that "Dr. Feigal has acquired th[e] requisite expertise from his education, training as a medical doctor, [and] twelve years of experience employed as a senior regulator at the FDA (where he . . . reviewed and approved product labels, and was involved in the evaluation of safety and efficacy of . . . medical devices and biological products . . . [)]."[19] Defendant also argues that any analysis or discussion of the IFUs should be barred as irrelevant, because (Defendant asserts) none of the Plaintiffs' implanting surgeons actually read the IFUs prior to implanting the Plaintiffs' AlloDerm®.[20] While that statement by LifeCell is refuted by the record,[21] the court notes that such an argument would favor precluding Dr. Feigal's testimony on the adequacy of the IFUs.

II. LEGAL STANDARDS

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.
>
> [Ibid.][22]

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[18] Id. at 9-11.
[19] Id. at 4-5.
[20] Id. at 12-15.
[21] See Memorandum of Decision Denying Summary Judgment on Thomas Dutcher's Failure-to-Warn Claim, dated August 14, 2015; Memorandum of Decision Denying Summary Judgment on Michael and Karen Simineri's Failure-to-Warn Claim, dated August 14, 2015.
[22] 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

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 ex rel. Wright v. State, 174 N.J. 412, 424 (2002) (quoting Landrigan v. Celotex Corp., 127 N.J. 404, 413 (1992)).]

Relevance

In order to assist the trier of fact in understanding evidence or determining a fact in issue, the proffered testimony must be relevant to the evidence or facts in issue. See Muise v. GPU, Inc., 371 N.J. Super. 13, 59 (App. Div. 2004) ("Because expert testimony must assist the trier of fact, its admissibility depends in part on the connection between the evidence to be presented and the disputed factual issues in the case." (citing In re TMI Litig., 193 F.3d 613, 665 (3d Cir. 1999)). 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)); N.J.R.E. 401 ("'Relevant evidence'

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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 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.

means evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action."). As the New Jersey Supreme Court has explained,

> [r]elevancy consists of probative value and materiality. Probative value is the tendency of the evidence to establish the proposition that it is offered to prove. A material fact is one which is really in issue in the case. Thus, our inquiry focuses on the logical connection between the proffered evidence and a fact in issue. Evidence need not be dispositive or even strongly probative in order to clear the relevancy bar. It need only have some tendency to prove a material fact. The inquiry is whether the thing sought to be established is more logical with the evidence than without it.
>
> [State v. Buckley, 216 N.J. 249, 261 (2013) (internal citations and quotations omitted).]

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.

Expertise

In determining an expert's qualifications, the court must look to whether the expert possesses "the minimal technical training and knowledge essential to the expression of a meaningful and reliable opinion." Hake v. Manchester Twp., 98 N.J. 302, 314 (1985) (quoting Sanzari v. Rosenfeld, 34 N.J. 128, 136 (1961)). Likewise, an expert's opinion "need not necessarily be limited to the narrowest scope of his expert qualifications," so long as the opinion is founded on the expert's "peculiar knowledge or experience." Bahrle v. Exxon Corp., 279 N.J. Super. 5, 32 (App. Div. 1995), aff'd, 145 N.J. 144 (1996). Thus, an expert does not have to practice or be licensed in every discipline encompassed in his opinion so long as he has the "education, knowledge, training, and experience in the specific field" to which he is testifying. Clark v. Safety-Kleen Corp., 179 N.J. 318, 338 (2004).

In Clark, the Supreme Court held that an expert chemist, qualified to offer an opinion regarding the chemical composition and properties of cresylic acid, could testify to the medical effect the acid had on human skin. Ibid. The Court held that, although the expert was a non-physician, his "education, experience, and research broadly qualified him to address the subject of the effect of cresylic acid on human skin." Ibid. The Court also indicated that "the admissibility of expert testimony will depend on the facts," and a trial court must examine the circumstances surrounding an expert's education and experience to determine if the expert's opinion is proper. Ibid.

III. ANALYSIS

Plaintiffs in this case assert claims against Defendant for failure-to-warn and defective design under the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. § 2A:58C-1 et seq. This court dismissed Plaintiffs' defective design claims for the reasons set forth in the court's Memorandum of Decision on Defendant's Motions for Summary Judgment on Plaintiffs' Design Defect Claims, dated August 14, 2015. This court also barred testimony that AlloDerm® should be classified as a medical device, what regulations would apply if AlloDerm® were a medical device, and whether LifeCell violated FDA regulations, for the reasons set forth in this court's Memorandum of Decision barring certain FDA-related Testimony, dated August 14, 2015. Accordingly, testimony that relates to FDA classification, regulations, or requirements, or to Plaintiffs' defective design claims, is irrelevant to the Plaintiffs' remaining failure-to-warn claims. Dr. Feigal's expert report is primarily dedicated to analysis of LifeCell's communications with the FDA and whether or not AlloDerm®, as used in hernia repair, is a "homologous use" as defined by the FDA. Because this court is barring such FDA-related testimony in these cases, Dr. Feigal's testimony on such matters is similarly barred as irrelevant.

As to the IFUs, Dr. Feigal opines:

> An IFU for a surgical product is intended to provide a concise summary of necessary information to allow surgeons to assess the risks and benefits of the product for specific patients for specific intended uses. The purpose of the IFU is not to provide a textbook on surgery and it is not intended to be the sole source of information about the use of a product. ... It is not necessary for a manufacturer to provide warnings and risks as to well-known and common risks of hernia repair surgery such as post-operative graft failure, recurrence, bulging, lax abdomen, etc."[23]

The court reads such testimony not as offering an opinion on the adequacy of the IFU, but rather, offering an explanation of the FDA standards generally governing IFUs. Indeed, Dr. Feigal even cites to the HCT/P regulations in support of this proposition.[24] As such, this testimony is barred as irrelevant. Dr. Feigal further opines:

> The versions of the IFU at issue clearly describe adverse effects that could result in poor outcomes, such as a failed hernia repair. ... These adverse effects warnings clearly apprise the surgeon of the risk that the AlloDerm graft may not properly integrate with the patient's host tissue, leading to failure of the graft and a failed hernia repair. It is common surgical knowledge that the failure mode of a hernia repair can include a lax abdomen, bulging and/or recurrence, so it is my opinion that LifeCell's warnings regarding graft failure, resorption, dehiscence and similar language adequately conveyed risk information to surgeons.[25]

Defendant argues that Dr. Feigal is qualified to make such a statement because of his "education, training as a medical doctor, [and] twelve years of experience employed as a senior regulator at the FDA ... ."[26] However, being a medical doctor does not automatically qualify an expert to speak on all medically-related issues. See McDarby v. Merck & Co., Inc., 401 N.J. Super. 10, 76 (App. Div. 2008) (citing Tormenia v. First Investors Realty Co., 251 F.3d 128, 136 (3d Cir. 2000) (an expert's Master's degree in civil engineering and experience as a professor do not

[23] Feigal Report, Pls.' Br. Ex. B, 18-19.
[24] Id. at 18, n.32.
[25] Id. at 18 (emphasis added).
[26] Id. at 4-5.

"qualify him to provide expert testimony on any subject associated, however tangentially, with such engineering disciplines.")), certif. denied 196 N.J. 597 (2009). Dr. Feigal is not a surgeon and has never performed or participated in a hernia repair surgery.[27] While Dr. Feigal has a medical degree and appears to board certified (although the year(s) and status of such certification have not been provided to the court), he has not treated a patient in over twenty years[28] – since before commercial biologic hernia repair products even existed.[29] Furthermore, despite referring to "common surgical knowledge" in his expert report, Dr. Feigal explicitly admitted at his deposition that he does not have a foundation for such knowledge.

> Q: Now, do you agree that hernia graft thinning and attenuation is not a common surgical knowledge?
>
> A: I don't know what common surgical knowledge is one way or the other.
>
> Q: I thought you just said you had common – common surgical knowledge from your review of medical literature.
>
> A: Yes, but that's – I guess, I'm not offering opinions about what surgeons know or – or – or don't know. I guess, I'm speaking about my own knowledge about – that I would expect a – a physician to know in terms of what are the things that happen with ventral hernias over time.[30]
>
> * * *
>
> Q: When was the last time you took care of a patient with a recurrent hernia?
>
> A: In the 19 – 1980s, probably.[31]
>
> * * *

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[27] Feigal Dep., Pls.' Br. Ex. D, 133:1-2.

[28] The court notes that Plaintiffs' moving brief lists Dr. Feigal's last year of direct patient care as 1991, but does not provide a citation to the record. Dr. Feigal testified at his deposition that his last hernia patient was in the 1980s.

[29] Feigal Dep., Pls.' Br. Ex. D, 133:6-9; see also History of Biologic Prostheses, Plaintiffs' Brief in Opposition to Defendant's Motion to Dismiss Michael and Karen Simineri's Design Defect Claims, Ex. R (earliest product available in 2001).

[30] Feigal Dep., Pls.' Br. Ex. D, 133:9-21 (emphasis added).

[31] Id. at 133:6-9.

Q: AlloDerm® used in hernia repair serves as a patch or covering of the hernia; is that true?

A: I think that's a question more for a surgeon.[32]

* * *

Q: The repair of an abdominal hernia involves repair of the abdominal fascia; is that correct?

A: Well, I'm not – I'm not offering any opinions about abdominal repair … .[33]

* * *

Q: Do you know the mechanical properties of AlloDerm?

A: At a high level, not – not as an engineer would.

Q: Do you know the mechanical properties of abdominal fascia?

A: No. I was not asked to evaluate that.[34]

* * *

Q: When AlloDerm® is used for hernia repair, there are no additional tissues to support the repair, correct?

A: I don't – I don't know if that's – if that's correct. It's certainly – there are certainly other things in the layers of the hernia repair than – than Alloderm and including, eventually, the – the skin covering, but I wasn't asked to look at the technical aspects of hernia repair.

Q: So, as to whether or what additional tissues help support a hernia repair besides AlloDerm, you don't know.

A: That's correct.[35]

While Dr. Feigal is undoubtedly qualified to offer an opinion on the regulatory workings of the FDA in reference to HCT/Ps and medical devices, he lacks the "peculiar knowledge or

[32] Feigal Dep., Pls.' Reply Br. Ex. D, 48:12-14 (emphasis added).
[33] Id. at 64:9-12.
[34] Id. at 65:16-22.
[35] Id. at 72:16-73:3.

experience" necessary to opine as to what kind of product risks and patient morbidities a surgeon would want to know to conduct a proper risk-utility analysis of the appropriateness of a particular hernia repair product for a particular patient. See Bahrle, supra, 279 N.J. Super. at 32. Dr. Feigal has never made such an analysis, nor is there any evidence that he even participated in the process. Dr. Feigal stated repeatedly at his deposition that he is not a surgeon and cannot render an opinion on the technical aspects of hernia repair. Then, logically, Dr. Feigal cannot opine as to what information a surgeon would need with respect to performing hernia repair. Cf. Clark, supra, 179 N.J. at 325 (expert chemist qualified to render causation testimony where he worked with acid compound and observed its effect on human tissue).

IV. CONCLUSION

Based upon Dr. Feigal's expert report and deposition testimony, and the written arguments of counsel for the parties, the court finds that: (1) Dr. Feigal's testimony relating to FDA regulations, classifications, and requirements is barred as irrelevant pursuant to this court's Memorandum of Decision Barring FDA-Related Testimony, dated August 14, 2015; and (2) Dr. Feigal lacks the qualifications necessary to testify as to the adequacy of LifeCell's warnings, specifically, the AlloDerm® IFUs.

For the reasons stated above, Plaintiffs' motion to bar the testimony at trial of Dr. David Feigal is **GRANTED.**

8/14/15

JESSICA R. MAYER, J.S.C.