#017
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

GRANTED IN PART

ORDER ~~GRANTING~~ ON PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT STEPHEN F. BADYLAK, DVM, PH.D., 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 Stephen F. Badylak, DVM, Ph.D., 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** in part and denied in part for the reasons set forth in the court's memorandum of decision dated August 14, 2015. ~~Dr. Badylak shall not testify about or offer conclusions: 1) that AlloDerm is a safe and effective repair material for use in complex ventral~~ hernia repair; 2) there were and are no feasible alternative biologic or synthetic materials that were or are safer and notably more effective than AlloDerm for use in complex ventral hernia repair; 3) the design of AlloDerm as a minimally-processed extracellular matrix intended to elicit a constructive repair response and avoid a foreign body response was an appropriate design choice for prompting cell ingrowth, re-vascularization, and functional tissue remodeling. This design philosophy resulted in an extracellular matrix that is appropriate for use in complex ventral hernia repair; 4) the design philosophy for AlloDerm was to adequately decellularize a human dermal matrix to the fullest extent possible without disturbing its natural design, structure and compositing, based on the belief that preserving the natural properties of the matrix would result in the best constructive remodeling ability; 5) chemical crosslinking does not add any benefit to an extracellular matrix in terms of the long-term durability of the surgical repair; 6) chemically cross-linking biologic scaffolds do not increase the biologic scaffolds strength and is counterproductive and harmful to the known advantages and remodeling processes associated with biologic scaffold materials; 7) the biomechanical properties of AlloDerm exceed those of the tissue at the intended anatomic site for use, and are appropriate for complex ventral hernia repair; 8) the negative effects of chemical cross-linking can be severe and was considered by LifeCell scientist, and was considered in product design and manufacturing; 9) that any non-trivial amount of cross-linking cannot be applied without adversely impacting ECM performance; 10) there is no accepted basis for concluding that crosslinking an ECM confers any ~~benefits in terms of extending graft strength; 11) acellular dermal matrix will transition into~~

~~tissue with properties needed for the environment in which it is placed, such as fascia~~ when used ~~in ventral hernia repair; and 12) AlloDerm used in abdominal wall repair does not reduce scar formation and encapsulation, but instead elicits the formation of new collagen organized in a manner similar to native fascia~~.

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

#0119
08-07-15

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

GRANTED IN PART

ON

ORDER ~~GRANTING~~ PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT STEPHEN F. BADYLAK, DVM, PH.D., 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 Stephen F. Badylak, DVM, Ph.D., 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** in part and denied in part for the reasons set forth in the court's memorandum of decision dated August 14, 2015. ~~Dr. Badylak shall not testify about or offer conclusions: 1) that AlloDerm is a safe and effective repair material for use in complex ventral~~ hernia repair; 2) there were and are no feasible alternative biologic or synthetic materials that were or are safer and notably more effective than AlloDerm for use in complex ventral hernia repair; 3) the design of AlloDerm as a minimally-processed extracellular matrix intended to elicit a constructive repair response and avoid a foreign body response was an appropriate design choice for prompting cell ingrowth, re-vascularization, and functional tissue remodeling. This design philosophy resulted in an extracellular matrix that is appropriate for use in complex ventral hernia repair; 4) the design philosophy for AlloDerm was to adequately decellularize a human dermal matrix to the fullest extent possible without disturbing its natural design, structure and compositing, based on the belief that preserving the natural properties of the matrix would result in the best constructive remodeling ability; 5) chemical crosslinking does not add any benefit to an extracellular matrix in terms of the long-term durability of the surgical repair; 6) chemically cross-linking biologic scaffolds do not increase the biologic scaffolds strength and is counterproductive and harmful to the known advantages and remodeling processes associated with biologic scaffold materials; 7) the biomechanical properties of AlloDerm exceed those of the tissue at the intended anatomic site for use, and are appropriate for complex ventral hernia repair; 8) the negative effects of chemical cross-linking can be severe and was considered by LifeCell scientist and was considered in product design and manufacturing; 9) that any non-trivial amount of cross-linking cannot be applied without adversely impacting ECM performance; 10) there is no accepted basis for concluding that crosslinking an ECM confers any benefits in terms of extending graft strength; 11) acellular dermal matrix will transition into ~~tissue with properties needed for the environment in which it is placed, such as fascia when used~~

in ventral hernia repair; and 12) AlloDerm used in abdominal wall repair does not reduce scar formation and encapsulation, but instead elicits the formation of new collagen organized in a manner similar to native fascia.

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

#0122
08-07-15

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~~ DENYING PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT STEPHEN F. BADYLAK, DVM, PH.D., 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 Stephen F. Badylak, DVM, Ph.D., 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:

DOCUMENT IS NOT FINAL

Plaintiffs' Motion is **GRANTED** in part and denied in part for the reasons set forth in the court's memorandum of decision dated August 14, 2015. ~~Dr. Badylak shall not testify about or offer conclusions: 1) that AlloDerm is a safe and effective repair material for use in complex ventral~~ hernia repair; 2) there were and are no feasible alternative biologic or synthetic materials that were or are safer and notably more effective than AlloDerm for use in complex ventral hernia repair; 3) the design of AlloDerm as a minimally-processed extracellular matrix intended to elicit a constructive repair response and avoid a foreign body response was an appropriate design choice for prompting cell ingrowth, re-vascularization, and functional tissue remodeling. This design philosophy resulted in an extracellular matrix that is appropriate for use in complex ventral hernia repair; 4) the design philosophy for AlloDerm was to adequately decellularize a human dermal matrix to the fullest extent possible without disturbing its natural design, structure and compositing, based on the belief that preserving the natural properties of the matrix would result in the best constructive remodeling ability; 5) chemical crosslinking does not add any benefit to an extracellular matrix in terms of the long-term durability of the surgical repair; 6) chemically cross-linking biologic scaffolds do not increase the biologic scaffolds strength and is counterproductive and harmful to the known advantages and remodeling processes associated with biologic scaffold materials; 7) the biomechanical properties of AlloDerm exceed those of the tissue at the intended anatomic site for use, and are appropriate for complex ventral hernia repair; 8) the negative effects of chemical cross-linking can be severe and was considered by LifeCell scientist, and was considered in product design and manufacturing; 9) that any non-trivial amount of cross-linking cannot be applied without adversely impacting ECM performance; 10) there is no accepted basis for concluding that crosslinking an ECM confers any benefits in terms of extending graft strength; 11) acellular dermal matrix will transition into ~~tissue with properties needed for the environment in which it is placed, such as fascia~~ when used

~~in ventral hernia repair; and 12) AlloDerm used in abdominal wall repair does not reduce scar formation and encapsulation, but instead elicits the formation of new collagen organized in a manner similar to native fascia.~~

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

#0121
08-07-15

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

GRANTED IN PART

ORDER GRANTING PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT STEPHEN F. BADYLAK, DVM, PH.D., 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 Stephen F. Badylak, DVM, Ph.D., M.D., for the reasons in the attached memorandum of decision, ~~the parties having had an opportunity to be heard~~, and for good cause shown;

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

Plaintiffs' Motion is **GRANTED** in part and denied in part for the reasons set forth in the court's memorandum of decision dated August 14 2015. ~~Dr. Badylak shall not testify about or offer conclusions: 1) that AlloDerm is a safe and effective repair material for use in complex ventral~~ hernia repair; 2) there were and are no feasible alternative biologic or synthetic materials that were or are safer and notably more effective than AlloDerm for use in complex ventral hernia repair; 3) the design of AlloDerm as a minimally-processed extracellular matrix intended to elicit a constructive repair response and avoid a foreign body response was an appropriate design choice for prompting cell ingrowth, re-vascularization, and functional tissue remodeling. This design philosophy resulted in an extracellular matrix that is appropriate for use in complex ventral hernia repair; 4) the design philosophy for AlloDerm was to adequately decellularize a human dermal matrix to the fullest extent possible without disturbing its natural design, structure and compositing, based on the belief that preserving the natural properties of the matrix would result in the best constructive remodeling ability; 5) chemical crosslinking does not add any benefit to an extracellular matrix in terms of the long-term durability of the surgical repair; 6) chemically cross-linking biologic scaffolds do not increase the biologic scaffolds strength and is counterproductive and harmful to the known advantages and remodeling processes associated with biologic scaffold materials; 7) the biomechanical properties of AlloDerm exceed those of the tissue at the intended anatomic site for use, and are appropriate for complex ventral hernia repair; 8) the negative effects of chemical cross-linking can be severe and was considered by LifeCell scientist, and was considered in product design and manufacturing; 9) that any non-trivial amount of cross-linking cannot be applied without adversely impacting ECM performance; 10) there is no accepted basis for concluding that crosslinking an ECM confers any benefits in terms of extending graft strength; 11) acellular dermal matrix will transition into ~~tissue with properties needed for the environment in which it is placed, such as fascia~~ when used

~~in ventral hernia repair; and 12) AlloDerm used in abdominal wall repair does not reduce scar formation and encapsulation, but instead elicits the formation of new collagen organized in~~ a ~~manner similar to native f~~ascia.

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 to Bar the Testimony of Dr. Stephen Badylak

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. Stephen Badylak, ("Dr. Badylak"), expert witness for the Defendant LifeCell Corporation ("LifeCell" or "Defendant"), in the above matters. Counsel agreed to waive both oral argument on the motion and a hearing pursuant to N.J.R.E. 104

[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").

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. Badylak's written report dated May 8, 2015 and deposition testimony of Dr. Badylak), and relevant case law,[2] the court determines that Plaintiffs' motion to exclude the testimony of Dr. Badylak is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

Defendant proffers Dr. Stephen Badylak as a tissue engineering expert to rebut the testimony of Plaintiffs' experts, Dr. Kristen Billiar, Dr. Roger Huckfeldt, and Dr. Gregory Dumanian, on Plaintiffs' defective design claims as well as the scientific properties of biologic scaffolds as they relate to remodeling and graft failure.[3] Dr. Badylak earned a Doctor of Veterinary Medicine degree from Purdue University in 1976, a Master of Science degree in Clinical Pathology from Purdue University in 1978, a Doctor of Philosophy (Ph.D.) degree in Anatomic Pathology from Purdue University in 1981, and a Doctor of Medicine (M.D.) degree from Indiana University in 1985.[4] He is currently a professor in the Department of Surgery and the Department of Bioengineering at the University of Pittsburgh, as well as Deputy Director of the McGowan Institute for Regenerative Medicine and Director for the McGowan Center for Preclinical Studies.[5]

Dr. Badylak has held various research and teaching positions related to biomedical engineering since 1985, with a particular focus on biomaterials and extracellular matrices ("ECMs").[6] He has authored over 300 peer-reviewed articles on the topic of tissue engineering and

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[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. Stephen Badylak, dated May 8, 2015 ("Badylak Report"), Plaintiffs' Brief in Support of the Motion to Bar the Testimony of Dr. Stephen Badylak ("Pls.' Br.") Ex. C.

[4] Curriculum Vitae of Dr. Stephen Badylak ("Badylak C.V."), Defendant's Brief in Opposition to Plaintiffs' Motion to Bar the Testimony of Dr. Stephen Badylak ("Def.'s Opp. Br.") Ex. A, 1.

[5] Badylak C.V., Def.'s Opp. Br. Ex. A, 2.

[6] Ibid.

regenerative medicine.[7] He has served as a consultant for numerous biotech pharmaceutical companies on matters of research, development, and manufacturing of ECMs.[8] He is a past president of the Tissue Engineering and Regenerative Medicine International Society, and was the principal investigator for over 250 research projects in this area of study.[9] Dr. Badylak holds over fifty patents for biomedical related devices and methods, including an "extracellular matrix based gastroesophageal junction reinforcement device," "conditioned decellularized native tissues for tissue restoration," a "graft for promoting autogenous tissue growth," and a "tissue graft for surgical reconstruction of a collagenous meniscus and method therefore."[10] Dr. Badylak has also lectured internationally on matters of tissue engineering and regeneration.[11]

Dr. Badylak's expert report focuses primarily on rebutting the Plaintiffs' defective design claims, and specifically, Dr. Billiar's opinions regarding alleged alternative safer designs and Dr. Huckfeldt's theory that AlloDerm® is defectively designed because of its high elastin content.[12] Dr. Badylak also rebuts Dr. Dumanian's opinion that AlloDerm® does not become new fascia, but rather, simply forms scar tissue.[13] Dr. Badylak also opines generally on the basics of ECMs, how they work, and the "method of action of biologic scaffolds used as surgical material."[14]

Plaintiffs move to bar Dr. Badylak's testimony on the basis that it is speculative, unscientific net opinion. For reasons explained in this Memorandum, the court need not address Plaintiffs' arguments as to Dr. Badylak's opinions relating to defective design, nor Defendant's opposition to same. Plaintiffs' remaining arguments are that Dr. Badylak lacks any scientific

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[7] Badylak Report, Pls.' Br. Ex. C, 2.
[8] Id. at 2-3.
[9] Id. at 2.
[10] Badylak C.V., Def.'s Opp. Br. Ex. A, 5-7.
[11] Id. at 20-24.
[12] Badylak Report, Pls.' Br. Ex. C, 11-20, 23-24.
[13] Id. at 21-23.
[14] Id. at 7.

foundation for his opinions that (1) AlloDerm® does not scar, but rather, becomes fascia or fascia-like tissue, and (2) AlloDerm® is effective for complex hernia repair.[15]

As to the first point, Plaintiffs argue that Dr. Badylak only cites to two scientific publications in support of his opinion – Glasberg et al., Use of Regenerative Human Acellular Tissue (AlloDerm) to Reconstruct the Abdominal Wall Following Pedicle TRAM Flap Breast Reconstruction, 118 Plastic and Reconstructive Surgery 8 (July 2006)(hereinafter "Glasberg study") and Eberli et al., In Vivo Evaluation of Acellular Human Dermis for Abdominal Wall Repair, 93A J. Biomedical Materials Res. 1527 (2010)(hereinafter "Eberli study") – and that neither publication is scientifically reliable.[16] Plaintiffs argue that the Glasberg study involved a certain surgical technique that was not used in any of Plaintiffs' surgeries, thus the article is inapplicable and cannot support any conclusions about AlloDerm®'s remodeling process in Plaintiffs' hernia repairs.[17] Plaintiffs criticize the Eberli study because it was done on rabbits, not humans, and thus cannot support any conclusions on how AlloDerm® may remodel in humans.[18] Plaintiffs then cite deposition testimony by LifeCell employee John Harper, Ph.D., that each patient heals differently and the transition from AlloDerm® to fascia or fascia-like tissue is affected by various factors, for the proposition that there is no evidence that AlloDerm® remodels into fascia or fascia-like tissue in every use.[19] Plaintiffs thus conclude that Dr. Badylak's opinion that AlloDerm® remodels into fascia-like tissue when used in hernia repair is merely speculative personal opinion unsupported by reliable scientific evidence or methods.[20]

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[15] Pls.' Br. 13-15, 19-21.
[16] Ibid.
[17] Id. at 20.
[18] Id. at 20-21.
[19] Id. at 20.
[20] Ibid.

Plaintiffs also argue that Dr. Badylak cannot opine that AlloDerm® is "effective" for complex ventral hernia repair. Plaintiffs assert that Dr. Badylak has never personally studied the effectiveness of AlloDerm® for hernia repair as compared to other hernia repair products, and does not know the recurrence rate for AlloDerm® or any other hernia repair product.[21] Dr. Badylak also acknowledged at his deposition that he does "not know the strength over time of the remodeling site for AlloDerm®."[22] Finally, Plaintiffs criticize Dr. Badylak for not reviewing two scientific studies that Plaintiffs contend proves AlloDerm®'s ineffectiveness, "or any other study for that matter" that analyzes AlloDerm®'s recurrence rates.[23] Therefore, Plaintiffs conclude that Dr. Badylak lacks a reliable scientific foundation for his opinion that AlloDerm® is effective for complex ventral hernia repair.

Defendant, in its opposition papers, categorizes Plaintiffs' assertion that Dr. Badylak lacks scientific support for his conclusion that AlloDerm® remodels into fascia-like tissue as "preposterous." Defendant notes that, per his curriculum vitae, Dr. Badylak has "written numerous papers and published textbooks on the subject of tissue regeneration and remodeling, including a recent paper documenting the remodeling of biologic scaffold material onto functional skeletal muscle in human patients."[24] Defendant further argues that Plaintiffs' criticisms of the Glasberg and Eberli studies are misinterpretations of those studies, and that Plaintiffs have failed to prove that those studies are unreliable.[25]

As to Dr. Badylak's opinions on the effectiveness of AlloDerm® for complex hernia repair, Defendant argues that although Dr. Badylak has never conducted a study directed at comparing

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[21] Id. at 12-14.
[22] Badylak Dep., Pls.' Br. Ex. A, 139:14-17.
[23] Pls.' Br., 14-16.
[24] Def.'s Opp. Br. 16.
[25] Id. at 2, 16-17.

AlloDerm®'s recurrence rates with those of other hernia repair products, he has worked with AlloDerm® in his laboratory while studying hernia repair.[26] Dr. Badylak stated at his deposition, "We've done a lot of studies wanting to evaluate ... surgical mesh materials for ... ventral hernia repair. And when we do such studies, we have various controls. And because AlloDerm is one of the recognized effective mesh materials in that application, we would – we commonly used it as a control."[27] While acknowledging a lack of surgical experience performing hernia repairs, and not knowing the specific recurrence rate for AlloDerm®, Dr. Badylak testified that his "opinions will speak to the mechanisms that can contribute to recurrence. ... I want to be clear and not overstate my qualifications or have the answer misconstrued. But I can tell you that I do have a good understanding of the things that contribute to recurrence which obviously relates to recurrence rates."[28] Accordingly, Defendant argues that any alleged lack of support from scientific papers is not dispositive, as an expert may be qualified by his "training or experience."[29] See Rosenberg v. Tavorath, 352 N.J. Super. 385, 403 (App. Div. 2002). Further, Defendant notes that the failure to rely on one particular factor or article the other party deems relevant is not a basis for preclusion of expert testimony, but rather, should be the subject of cross-examination.[30] See id. at 401. In their reply brief, Plaintiffs reiterate their objections to the reliability of the Glasberg and Eberli studies, and argue that Dr. Badylak has no foundation for claiming that AlloDerm® is

[26] Id. at 8-9; Badylak Dep., Def.'s Opp. Br. Ex. B, 26:3-27:23, 34:9-37:23.
[27] Badylak Dep., Def.'s Opp. Br. Ex. B, 27:8-15.
[28] Def.'s Opp. Br. 10 (citing Badylak Dep., Def.'s Opp. Br. Ex. B at 145:4-17). In comparing the Badylak deposition excerpts as between Plaintiffs' and Defendant's exhibits, it appears that the parties are using different versions of Dr. Badylak's deposition transcript, leading to a conflict between the page and line numbers. This is not an issue as long as the citations to each respective version are accurate. However, the page 145 transcript citation included with Defendant's brief does not contain the cited quotation. The last few words of this quotation do appear on page 145 in Plaintiffs' version of the deposition. However, Plaintiffs did not include all of page 145 in their exhibit. Thus, the court will rely on counsel for the Defendant as to the accuracy of the cited quotation.
[29] Def.'s Opp. Br. 10.
[30] Def.'s Opp. Br. 12.

"appropriate" for ventral hernia repair, because he cannot cite to a long-term study proving AlloDerm®'s effectiveness for such a use.[31]

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.][32]

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

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[31] Plaintiffs Reply Brief in Further Support of the Motion to Bar the Testimony of Dr. Stephen Badylak ("Pls.' Reply Br.") 14-16, 18-19.

[32] 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 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.

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' 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.

Reliability

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). This 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 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.

An expert's methodology can be properly supported by "professional journals, texts, 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." Ibid. 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 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, supra, 352 N.J. Super. 385, 401-02 (App. Div. 2002). As the Hisenaj Court emphasized, flaws in an expert's reasoning may be explored by opposing counsel on cross-examination, 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." Hisenaj, supra, 194 N.J. at 16; see also Landrigan, supra, 127 N.J. at 414. ("[T]he trial court should not substitute its judgment for that of the relevant scientific community.") Rubanick, supra, 125 N.J. 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." Landrigan, supra, 127 N.J. at 414.

III. ANALYSIS

Plaintiffs 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 excluded testimony that AlloDerm® is defective due to its high elastin content for the reasons set forth in this court's Memorandum of Decision Barring Testimony that AlloDerm® is Defective Due to High Levels of Elastin, dated August 14, 2015. Accordingly, testimony that relates to Plaintiffs' defective design claims or Dr. Huckfeldt's testimony on elastin is barred as irrelevant to the Plaintiffs' remaining failure-to-warn claims.

Dr. Badylak's expert report appears to be Defendant's rebuttal to the testimony of Plaintiffs' design defect experts. Because this court dismissed Plaintiffs' defective design claims,

Dr. Badylak's testimony on such matters, including his rebuttal to the expert reports of Drs. Billiar and Huckfeldt, is barred as irrelevant. All that remains is Dr. Badylak's testimony that AlloDerm® remodels into fascia or fascia-like tissue when used in hernia repair, and that AlloDerm® is effective for use in complex ventral hernia repair.

The court finds that Dr. Badylak is qualified to testify, based on his extensive experience as a doctor, researcher, consultant, inventor, author, and professor in the field of tissue engineering, regarding the mechanical properties of biologic grafts and the processes of tissue remodeling and scar formation. The fifty-two page curriculum vitae of Dr. Badylak evidences his significant accomplishments as a tissue engineer with over twenty years of experience in the fields of tissue engineering and regenerative medicine. Evidence regarding such complex biological processes is undoubtedly beyond the ken of the average juror. As Plaintiffs apparently intend to offer Dr. Gregory Dumanian's testimony that AlloDerm® fails, in part, because it turns into scar tissue, not fascia,[33] Dr. Badylak's testimony regarding the processes of tissue remodeling, regeneration, and scar formation is relevant to the issue of causation and rebuttal of Plaintiffs' expert's testimony.

The court does not find Dr. Badylak's opinions on AlloDerm®'s remodeling properties to be inadmissible net opinion. That Plaintiffs believe Dr. Badylak's cited studies to be incomparable to the use of AlloDerm® in the human abdomen is not a basis for excluding testimony, but rather, may be addressed through cross-examination as it effects the weight of Dr. Badylak's testimony. See Hisenaj, supra, 194 N.J. at 24 (defense expert's testimony was admissible despite plaintiff's contention that the expert employed flawed methodology by relying on studies with patients dissimilar to plaintiff). Further, Dr. Badylak is not relying exclusively on the Glasberg and Eberli studies. Instead, Dr. Badylak uses those studies in conjunction with his extensive personal

[33] See Expert Report of Dr. Gregory Dumanian, dated February 25, 2015, Defendant's Brief in Support of the Motion for Summary Judgment on Patricia Julien's Failure to Warn Claim, Ex. C.

studies. Instead, Dr. Badylak uses those studies in conjunction with his extensive personal education and experience in tissue engineering for over twenty years. Although Plaintiffs argue that Dr. Badylak did not cite to any studies that confirmed AlloDerm® when implanted into humans for hernia repair remodels into fascia,[34] such a study is not necessary. The court finds that Dr. Badylak sufficiently provides a why and wherefore as to his extrapolation that AlloDerm® remodels into fascia like tissue when used in hernia repair based on his personal study of AlloDerm® in his laboratory research and the results of the Glasberg and Eberli studies.[35] Dr. Badylak is amply qualified to discuss basic principles of biologic scaffold properties and the processes of remodeling and scar formation.

As to the efficacy of AlloDerm® as a hernia repair product, the court finds that Dr. Badylak may offer testimony limited to the mechanics of graft failure and the factors that may lead to graft failure and/or strength and durability. At his deposition, Dr. Badylak stated that his opinion on the efficacy of AlloDerm® is based on "everything I know about the remodeling of AlloDerm versus other biologic scaffolds."[36] While Dr. Badylak has conducted laboratory research on the various mechanical properties of hernia repair products, he is not a surgeon, and concedes that he does not know any recurrence rates for AlloDerm® or other repair products.[37] Indeed, Dr. Badylak clarified at his deposition that, although he understands the factors that can lead to recurrence, he does not intend to testify about recurrence rates:

> Q: You've made it clear that you're familiar with the mechanisms that might lead to recurrence and that is your principal area of expertise, one of your principal areas of expertise that you bring to bear in this case.

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[34] Pls.' Reply Br. 18-19.

[35] See Badylak Dep., Pls.' Br. Ex. A at 181:5-182:24; Badylak Report, Pls.' Br. Ex. C, 21-22.

[36] Def.'s Opp. Br. 10 (citing Badylak Dep., Def.'s Opp. Br. Ex. B at 187:14-15). See footnote 28, supra. Again, the page cited by Defendant does not match the page included in Defendant's exhibit. Further, page 187 of Plaintiffs' version was not included, in whole or in part, with Plaintiffs' moving brief. Thus, the court relies on counsel for Defendant as to the accuracy of the cited quotation.

[37] Badylak Dep., Pls.' Br. Ex. A, 202:19-23.

A: Yes sir.

Q: Okay. My question to you ... is: In this case are you an expert intending to render opinions on the subject of hernia recurrence rates when Alloderm is used for ventral hernia repair?

...
A: I do not intend to talk about recurrence rates.[38]

As described above, Dr. Badylak is imminently qualified in the field of tissue engineering, and has extensive personal experience studying biologic hernia repair products, including AlloDerm®, in his laboratory. Thus, while he cannot opine as to the overall "efficacy" of AlloDerm® as it relates to recurrence rates (including statements that may be similarly construed, such as that AlloDerm® is "appropriate" for use in complex ventral hernia repair"), he may opine strictly on the mechanisms of biologic graft failure and the physical properties of AlloDerm® as observed by him in his personal experience and as relayed in published, peer-reviewed scientific studies upon which he relies (which studies Plaintiffs are free to address during cross-examination).

Although the question of whether the AlloDerm® proximately caused Plaintiffs' injuries is an issue that must be decided by the jury, the court finds that Dr. Badylak's "specialized knowledge" regarding ECMs, tissue engineering, regenerative medicine, and hernia repair products may assist the jury in understanding the evidence in these cases. See N.J.R.E. 702. To the extent Defendant intends to offer testimony from Dr. Badylak outside of the subjects addressed in this Memorandum, Defendant shall make a proffer as to the relevance and scope of such testimony to be submitted to the court and Plaintiffs' counsel no later than August 31, 2015.[39]

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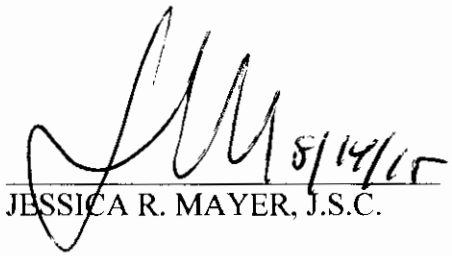
[38] Id. at 145:24-146:15.

[39] The court requests counsel to refrain from proffering cumulative testimony, as many experts appear to offer overlapping testimony.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Exclude the Testimony at Trial of Dr. Stephen Badylak is **GRANTED IN PART** and **DENIED IN PART**.



JESSICA R. MAYER, J.S.C.