#289
08-07-15

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LifeCell Corporation

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. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-6841-12 CM Civil Actions **ORDER**

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. Kristen L. Billiar 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 ~~stated on the record by the Court~~ in the attached memorandum of decision,

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

ORDERED that defendant's motion is ~~hereby granted~~ denied as moot *; and it is further

~~ORDERED that the testimony of Dr. Billiar is barred in the trials of each of the four bellwether cases;~~ and it is further

ORDERED that a copy of this Order be ~~served~~ posted online for 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

	Yes	No	Date
Notice of Motion	✓		
Movant's Affidavits	✓		
Movant's Brief	✓		
Answering Affidavits	✓		
Answering Brief	✓		
Cross Motion			
Movant's Reply	✓		
Other			

#0990
08-07-15

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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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Answering Affidavits	✓		
Answering Brief	✓		
Cross Motion			
Movant's Reply	✓		
Other			

#0791
08-07-15

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IN RE: ALLODERM® LITIGATION CASE CODE 295	
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Movant's Brief	✓		
Answering Affidavits	✓		
Answering Brief	✓		
Cross Motion	✓		
Movant's Reply	✓		
Other			

#022
08-07-15

DEBBIE FOSTER and DAVID FOSTER, w/h, Plaintiffs, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-6841-12 CM Civil Actions **ORDER**

FILED
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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. Kristen Billiar

In Re: AlloDerm® Litigation, Case Code 295

Thomas Dutcher v. LifeCell Corporation

Docket No. MID-L-1469-12 CM

Debbie Foster and David Foster v. LifeCell Corporation

Docket No. MID-L-6841-12 CM

Patricia Julien v. LifeCell Corporation

Docket No. MID-L-507-12 CM

Michael Simineri and Karen Simineri v. LifeCell Corporation

Docket No. MID-L-5972-11 CM

Dated August 14, 2015

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

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

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves to bar the testimony of Plaintiffs'[1] expert, Dr. Kristen Billiar ("Dr. Billiar"), as a biomechanical engineering expert in

[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").

the above matters. Counsel agreed to waive both oral argument on the motion and a hearing pursuant to N.J.R.E. 104 and consented to the court's disposition of this matter on the papers submitted. Upon considering the written arguments of counsel, all filed documents and exhibits (including Dr. Billiar's written report dated February 25, 2015 and deposition testimony of Dr. Billiar), and relevant case law,[2] the court determines that LifeCell's motion to exclude the testimony of Dr. Billiar is **DENIED AS MOOT**.

I. BACKGROUND

Dr. Kristen Billiar is a professor of biomedical engineering and mechanical engineering at the Worcester Polytechnic Institute (WPI).[3] He received a Bachelor of Science degree in Engineering from Cornell University in 1991, a Master of Science degree in Engineering and Bioengineering from the University of Pennsylvania in 1992, and a Doctorate of Philosophy (Ph.D.) in bioengineering from the University of Pennsylvania in 1998.[4] Dr. Billiar has over ten years' experience teaching various biomedical and mechanical engineering courses at the undergraduate and graduate level.[5] Prior to his teaching career, Dr. Billiar worked for four years as a staff engineer in the research and development arm of Organogenesis, Inc., working on tissue product design and testing.[6] He holds memberships and committee/board positions in approximately a dozen professional associations focused on biomechanics, tissue engineering, mechanical engineering, and education.[7] He also hold several medical-product related patents,

[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. Kristen Billiar, dated February 25, 2015 ("Billiar Report"), Defendant's Brief in Support of Motion to Bar the Testimony at Trial of Dr. Kristen Billiar ("Def.'s Br.) Ex. A, 1.
[4] Curriculum Vitae of Dr. Kristen Billiar ("Billiar C.V."), Plaintiffs' Brief in Opposition to Defendant's Corporation's Motion to Bar the Testimony at Trial of Dr. Kristen Billiar ("Pls.' Opp.") Ex. B, 1.
[5] Billiar C.V., Pls.' Opp. Ex. B, 1.
[6] Billiar C.V., Pls.' Opp. Ex. B, 1; Billiar Dep., Def.'s Br. Ex. B., 37:5-39:15.
[7] Billiar C.V., Pls.' Opp. Ex. B, 6-7.

including a patent for "Collagen and Fibrin Microthreads in a Discrete Thread Model of In Vitro ACL Scaffold Regeneration."[8]

Dr. Billiar states in his expert report that he intends "to serve as an expert and examine biomechanical and engineering design aspects of AlloDerm Regenerative Tissue Matrix (AlloDerm) as it pertains to use in abdominal wall reconstruction with a focus on ventral/incisional hernia repair . . . [and] to provide a scientific explanation for the failure of AlloDerm used in hernia repairs observed by surgeons." [9] Dr. Billiar explains a number of processes in his report by which biomaterials can generally be made stronger or customized to their intended use, such as chemical cross-linking, mechanical preconditioning, establishing pretension guidelines based on mechanical analyses, and optimizing graft thickness, density, and degradation rate.[10] Dr. Billiar opines that LifeCell's purported lack of analysis into the abdominal load pressures in the human abdomen and its failure to optimize AlloDerm® using the methods named above render AlloDerm® defectively designed and "unlikely to be reliably successful as a ventral/incisional hernia repair and abdominal wall reconstruction product."[11]

Defendant moves to bar Dr. Billiar's testimony as irrelevant, inadmissible net opinion, and unduly prejudicial pursuant to N.J.R.E. 702 and N.J.R.E. 403. Defendant argues that Dr. Billiar's report boils down to a critique of LifeCell's alleged failure to test and "optimize" the design of AlloDerm® for the specific purpose of hernia repair.[12] Defendant asserts that Dr. Billiar fails to identify any specific aspect of AlloDerm® that renders it defective, and instead simply opines that if LifeCell had conducted certain tests, it could have discovered the optimal design parameters for

[8] Billiar C.V., Pls.' Opp. Ex. B, 6.
[9] Billiar Report, Def.'s Br. Ex. A, 1.
[10] Billiar Report, Def.'s Br. Ex. A.
[11] Id. at 2.
[12] Def.'s Br. 1, 4-12.

its use in hernia repair. Defendant notes that defective design claims under the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. 2A:58C-1 et seq., are directed toward the product's characteristics as manufactured, not the *process* by which it was designed. See Green v. Gen. Motors Corp., 310 N.J. Super. 507, 529-30 (App. Div.), certif. denied, 156 N.J. 381 (1998) ("It is clear that a breach of any duty to test, insofar as it may exist, is [not] relevant to . . . a design defect claim. . . . [A] product that is not defective and has not been tested at all remains free of a defect. Similarly, a defective product that has been extensively tested is still defective.").

Defendant further argues that Dr. Billiar's report is inadmissible net opinion, because it is based on the pure speculation that if LifeCell had conducted certain tests, it may have discovered that AlloDerm® could have been designed more effectively. Defendant notes that Dr. Billiar admittedly has not conducted any of his proposed tests on AlloDerm®, and can draw no conclusions on what the findings of such tests would be – in fact, he concedes that the tests could reveal that no changes need to be made to AlloDerm®'s design.[13] Finally, in light of the two arguments above, Defendant argues that allowing testimony as to LifeCell's alleged lack of testing would be misleading and unduly prejudicial.

Plaintiffs, in their opposition papers, note that Defendant does not challenge Dr. Billiar's qualifications as an expert.[14] Indeed, the court finds that Dr. Billiar's extensive curriculum vitae leaves little question as to his expertise in the fields of biomedical and mechanical engineering. As to relevance, Plaintiffs argue that "evidence regarding LifeCell's lack of design, development, and testing of AlloDerm in ventral hernia repair is relevant to Plaintiffs' defective design claim," as Dr. Billiar's opinion "relates to the complexity of biologic materials and the various design criteria

[13] Def.'s Br. 15.
[14] Pls.' Opp. 16.

and alterations a manufacturer can consider and make to the biologic material for use in a specific application."[15] In opposition to Defendant's argument about net opinion testimony, Plaintiffs argue that because "Dr. Billiar relies upon peer-reviewed medical and scientific published literature, his personal experience working with biologic materials, including AlloDerm, and his extensive knowledge of these materials over the years from schooling, teaching, and lecturing on this topic[,]" he has sufficiently provided the "why and wherefore" of his opinions.[16] Lastly, Plaintiffs argue that while testimony as to LifeCell's lack of testing may be "unsavory," its "overwhelming probative value" is not outweighed by the potential for prejudice.[17]

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.][18]

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[15] Pls.' Opp. 19-20.
[16] Pls.' Opp. 19.
[17] Pls.' Opp. 19.
[18] 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

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)).]

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.

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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.

[State v. Buckley, 216 N.J. 249, 261 (2013) (internal citations and quotation marks 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.

III. ANALYSIS

Plaintiffs in this case each 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. In support of these claims, Plaintiffs have proffered various expert testimony as to general causation, specific causation, adequacy of warnings, and defective design. This court dismissed Plaintiffs' defective design claims for the reasons set forth in this court's Memorandum of Decision on Defendant's Motion for Summary Judgment on Plaintiffs' Design Defect Claims, dated August 14, 2015. Accordingly, any testimony that relates solely to Plaintiffs' defective design claims is irrelevant to the Plaintiffs' remaining claims.

The thrust of Dr. Billiar's expert report and deposition testimony is that LifeCell's failure to employ certain tests and clinical trials prior to marketing AlloDerm® for use in hernia repair and/or to specifically tailor the design of AlloDerm® for use in hernia repair, means that AlloDerm® is defectively designed, and there were numerous alternative methods by which AlloDerm® could have been made safer and more effective. The moving papers of both parties confirm that Dr. Billiar's testimony relates only to Plaintiffs' design defect claims.[19] While Dr. Billiar's expertise in biomedical and mechanical engineering has not been questioned, the court

[19] Def.'s Br. 1 ("The only 'opinion' he has articulated is his belief that a lack of development testing by itself constitutes a design defect."); Pls.' Opp. 20 ("[E]vidence regarding LifeCell's lack of design, development, and testing of AlloDerm in ventral hernia repair is relevant to Plaintiffs' defective design claim.").

notes that Dr. Billiar is not a medical doctor, has not reviewed Plaintiffs' medical records or the testimony of the implanting surgeons, and has never conducted any laboratory or clinical studies on hernia recurrence.[20]

Based upon Dr. Billiar's expert report and deposition testimony and the written arguments of counsel for the parties, the court finds that Dr. Billiar's testimony is limited to Plaintiffs' defective design claims, which were dismissed by the court's order granting summary judgment in favor of Defendant.[21] Because the court determines Dr. Billiar's testimony is barred on relevance grounds, the court need not analyze the parties' arguments on net opinion. To the extent Plaintiffs believe that Dr. Billiar's testimony is relevant to Plaintiffs' failure-to-warn claim, Plaintiffs shall make a proffer as to the relevance of such testimony to be submitted to the court and defense counsel no later than August 31, 2015.[22]

IV. CONCLUSION

For the reasons stated above, Defendant's motion to bar the testimony at trial of Dr. Kristen Billiar is **DENIED AS MOOT.**

8/14/15

JESSICA R. MAYER, J.S.C.

[20] Billiar Dep., Def.'s Br. Ex. B, 88:17-20.

[21] See court's Order and Memorandum of Decision on Design Defect dated August 14, 2015.

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