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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

Civil Action

ORDER

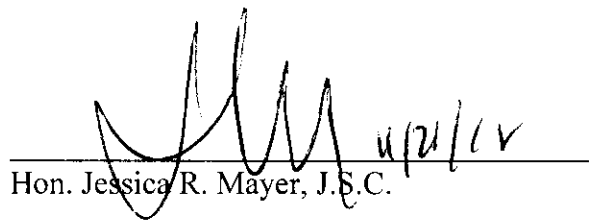
The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order barring plaintiff from introducing certain evidence or argument regarding LifeCell's testing of AlloDerm at the time of trial, and the Court having considered all papers submitted by the parties, and for good cause and the reasons ~~stated on the record by the Court~~ set forth in the attached memorandum of decision,

It is on this the 20th day of November, 2015,

ORDERED that defendant's motion is hereby granted; and it is further

ORDERED that plaintiffs are barred from introducing evidence or argument at trial that LifeCell tested AlloDerm on the patients who received it or other language ~~suggesting~~ that characterizes the implantation of AlloDerm as an experiment or study of the product's efficacy at the expense of the patients; and it is further

ORDERED that a copy of this Order be ~~served on~~ notify counsel of record all counsel of record within 7 days hereof.



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

OPPOSED

PAPERS CONSIDERED

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

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NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS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 Motions *In Limine* to Bar Plaintiffs from Introdueing Evidence or Argument at Trial Regarding LifeCell's Testing of AlloDerm® and the Absence of AlloDerm® Clinical Trials by LifeCell

In Re: AlloDerm® Litigation, Case Code 295

Michael Simineri and Karen Simineri v. LifeCell Corporation

Docket No. MID-L-5972-11 CM

For Plaintiffs: Lawrence R. Cohan, Esq., Joseph J. Fantini, Esq., and Sol H. Weiss, Esq., Anapol Weiss.

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

Dated November 20, 2015

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves to bar evidence and argument regarding LifeCell's testing of AlloDerm® on patients and the absence of AlloDerm® clinical trials by LifeCell.[1] Counsel for the parties presented oral argument regarding the absence of clinical trials during a case management conference held on November 17, 2015. Upon considering the arguments of the parties, legal memoranda, exhibits and relevant case law,[2] the

[1] Defendant submitted two separate motions on these issues: one motion to bar evidence and argument regarding LifeCell's testing of AlloDerm®, and one motion to bar evidence and argument regarding the lack of AlloDerm® clinical trials by LifeCell. Due to the overlapping issues in these two motions, and the overlapping arguments of the parties in their respective briefs on these motions, the court disposes of both motions in this memorandum.

[2] The parties signed a consent order stipulating that New Jersey law governs all issues in the AlloDerm® cases. See consent order dated January 15, 2015.

court determines that LifeCell's motions to bar evidence and testimony regarding LifeCell's testing of AlloDerm® and the absence of clinical trials by LifeCell are **GRANTED.**

The Parties' Arguments

Defendant moves to bar Plaintiffs from presenting evidence or argument that LifeCell tested AlloDerm® "on the backs of patients," and other such phrasing.[3] Defendant argues that such testimony will unduly prejudice the jury by implying that LifeCell was "unethically, if not illegally" testing AlloDerm® for use in hernia repair on patients.[4] In support of this argument, Defendant refers to the stipulation filed by the parties on October 22, 2015, wherein Plaintiffs agree not to make any argument at trial relating to LifeCell using patients as "guinea pigs."[5] Defendant asserts that the reason for precluding such argument as unduly prejudicial is not based on the specific phrase "guinea pig," but rather, is based on the overarching implication that LifeCell tested its product on unwitting consumers.

Defendant also moves to bar Plaintiffs from presenting evidence or argument that LifeCell failed to conduct clinical trials on AlloDerm®. Defendant argues that the alleged failure to test is not relevant in a failure-to-warn case. Defendant asserts that LifeCell had no legal obligation to conduct clinical trials on AlloDerm® for use in hernia repair prior to marketing it for such use,[6] and Plaintiffs have failed to submit any evidence that it is an industry standard to conduct such

[3] Defendant's Brief in Support of Motion *In Limine* to Preclude Plaintiffs from Introducing Certain References about LifeCell's Testing of AlloDerm ("Def.'s Testing Br."); Certification of David W. Field ("Field Testing Cert.") Ex. A, 264:3-8.

[4] Def.'s Testing Br. 4.

[5] Stipulations Governing the Conduct of Trial, filed October 22, 2015, ¶1.c.

[6] Defendant's Brief in Support of Motion *In Limine* to Preclude Plaintiffs from Introducing Argument and Evidence That LifeCell did not Sponsor a Clinical Trial ("Def.'s Clinical Trial Br.") 3.

tests.[7] Accordingly, Defendant argues that allowing Plaintiffs to raise lack of testing as an issue will "confuse and mislead the jury, inviting it to conclude that LifeCell violated some unspecified industry practice or the law by not undertaking such a study ... ."[8]

Defendant argues that a manufacturer must warn about risks of which it knew or should have known "on the basis of reasonably obtainable or available knowledge." Feldman v. Lederle Labs., 97 N.J. 429, 434 (1984). Defendant interprets "obtainable or available" to mean data or information which already exists in some accessible format; in other words, "is it in a published journal, or is it hidden in a file cabinet in some private company? The latter is not reasonably obtainable. ... 'reasonably obtainable' does not mean there's a duty to conduct expensive clinical trials."[9] Defendant argues in the alternative that even if a failure to test could theoretically bear on what LifeCell "should have known," Plaintiffs have failed to put forth the requisite proffer for such a claim. Citing a West Virginia case, Defendant presents the standard for such a proffer as: "(1) what results [a] study would have shown; (2) whether the results constituted information of a new risk or defect; and (3) whether the newly identified risk or defect is causally related to the injuries alleged." Cisson v. C.R. Bard, Inc., 2013 U.S. Dist. Lexis 102699, *5 (S.D. W.V. July 23, 2015).

Plaintiffs oppose both of Defendant's motions. As to Defendant's motion to bar testimony that LifeCell tested AlloDerm® on patients, Plaintiffs' opposition focuses on the issue of LifeCell's alleged failure to conduct clinical trials, and the centrality of this claim to Plaintiff's failure-to-warn case. While Plaintiffs do not specifically address the narrow issue of the motion,

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[7] Ibid; see also Certification of David W. Field ("Field Clinical Trial Cert.") Ex. C, 194 (Plaintiffs' expert, Dr. Roger Huckfeldt, cannot identify clinical studies conducted by any other hernia repair mesh manufacturer).

[8] Def.'s Clinical Trial Br. 1.

[9] Legal Argument of Defendant's counsel, Stephen R. Buckingham, on November 17, 2015, at 11:28AM per CourtSmart.

namely, the alleged undue prejudice flowing from testimony that LifeCell was testing its product on patients, it may be inferred that Plaintiffs believe the lack of clinical trials for AlloDerm® inherently means that the product was being tested on patients.

As to Defendant's motion to bar testimony regarding the lack of clinical trials, Plaintiffs argue that the failure to test is not only relevant to the failure-to-warn analysis, it is in fact so critical that if Plaintiffs are barred from offering testimony on the issue, they would be unable to prove their case.[10] Plaintiffs assert that "[a]bsent clinical testing, LifeCell empirically had no way of knowing whether or not AlloDerm® was safe in humans for this purpose, and further, had no way of knowing the inherent risks of when [sic] used in hernia repair and whether it would fail and require replacement."[11] Accordingly, Plaintiffs claim that "[LifeCell] could not adequately warn because it had no information on which to base such a warning."[12]

Plaintiffs argue that LifeCell's decision not to conduct a clinical trial on AlloDerm® cannot shield Defendant from liability for failing to warn of information that it would have learned through such a trial. According to Plaintiffs, such immunity would encourage manufacturers to avoid testing their products, in order to later assert a lack of knowledge about their products' dangerous propensities.[13] Plaintiffs additionally argue that Defendant will "open the door" for such testimony by putting forth its own evidence of AlloDerm® tests and studies purportedly showing the safety and/or efficacy of AlloDerm®.[14]

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[10] Plaintiffs' Response to Defendant's Motion *In Limine* to Preclude Plaintiffs from Introducing Argument and Evidence that LifeCell did not Sponsor an AlloDerm® Clinical Trial ("Pls.' Clinical Trial Opp.") 8.
[11] Plaintiffs' Response to Defendant's Motion *In Limine* to Bar Plaintiffs from Introducing Certain Evidence or Argument at Trial Regarding LifeCell's testing of AlloDerm® ("Pls.' Testing Opp.") 8.
[12] Id. at 2.
[13] Pls.' Clinical Trial Opp. 4.
[14] Id. at 11.

In response to the standard espoused by Defendant for proffering evidence regarding a failure to test, Plaintiffs note that this standard is not controlling in New Jersey, as it is based on a case from West Virginia. Plaintiffs further assert that if the court chooses to adopt this three-part standard, Plaintiffs have met the requirements by providing evidence that a clinical study would have revealed the alleged failures of AlloDerm®. According to Plaintiffs, thier evidence consists of (1) statements by their expert, Dr. Roger Huckfeldt, that LifeCell would havc discovered AlloDerm's dangerous cffects and high recurrence rate had it conducted proper testing,[15] and (2) a case study conducted by Grant V. Bochicchio et al. supporting a 100% recurrence rate at one year for patients with AlloDerm® hernia repairs.[16]

Legal Standards

Under New Jersey law, a manufacturer has a duty to warn of the adverse effects of a prescription medical product "of which they know or should have known on the basis of reasonably obtainable or available knowledge." Feldman v. Lederle Labs., 97 N.J. 429, 434 (1984). Unless subject to specific exclusions, "all relevant evidence is admissible." N.J.R.E. 402. Under the New Jersey Rules of Evidence, "'[r]elevant evidence' means evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. 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). 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.

[15] Certification of Joseph J. Fantini ("Fantini Clinical Testing Cert."), Ex. G, 158:18-24.
[16] Fantini Clinical Testing Cert. Ex. I.

Analysis

As to Defendant's motion to bar testimony that LifeCell tested AlloDerm® on patients, the court finds Defendant's argument persuasive. Plaintiffs agreed by stipulation not to offer testimony that LifeCell used patients as "guinea pigs." The prejudicial nature of this statement is not based on the specific words "guinea pigs," but rather the broader implication that Defendant conducted clandestine testing of a medical product on unwitting patients. Accordingly, any argument that LifeCell conducted testing of AlloDerm® "on the backs of patients" is precluded.

Next, the court addresses the issue of LifeCell's failure to conduct clinical trials for AlloDerm®. Plaintiffs argue that LifeCell was incapable of adequately warning about AlloDerm®'s use in hernia repair without first conducting a clinical trial to determine the risks of such a use. This court rejected a similar argument in its Memorandum of Decision granting summary judgment in favor of Defendant on Plaintiffs' defective design claim, noting that a failure to test alone does not render a product defective.[17] The Appellate Division, in Green v. General Motors Corp., 310 N.J. Super. 507, 529 (App. Div. 1998), reasoned:

> 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. Proof of a failure to test or of inadequate testing may be evidential as an explanation of why a design is defective, but it is not in itself proof of a separate basis for liability.
>
> [Green, supra, 310 N.J. Super. at 529]

[17] See Order and Memorandum of Decision on Defendant's Motions for Partial Summary Judgment as to Plaintiffs' Claims for Design Defect, dated August 14, 2015.

While Green dealt with a defective design claim, the same reasoning holds true for a failure-to-warn claim. A warning label that adequately warns of any danger of which a manufacturer knew or should have known will shield the manufacturer from liability, regardless of whether the warning was crafted as the result of testing or random chance. As in Green, the failure to test does not render product warnings inadequate per se.

As to the relevance of a failure to test to what a manufacturer knew or should have known, both parties cite Feldman, supra, as the controlling standard. The dispute among the parties can be distilled to their differing interpretations of the phrase "reasonably obtainable or available." Feldman, supra, 97 N.J. at 452. Defendant asserts that it means information already in existence; for example, an article published in a medical journal, which may be procured by the manufacturer. Plaintiffs believe that "obtainable" refers to data that may not exist in documented form at the time, but which could be discovered through testing that is technically feasible for the manufacturer. [18] Although Feldman holds prescription drug manufacturers to actual or constructive knowledge about the hazards of their products, the Feldman case itself did not deal with a failure to test claim. Neither party cited any New Jersey case addressing the failure to test as an element of what a manufacturer knew or should have known. Nor has the court found such a case. Nevertheless, the court need not resolve the issue to rule on Defendant's motion. Even by Plaintiffs' own standard, they have failed to make an adequate proffer.

Plaintiffs do not assert LifeCell failed to test AlloDerm® entirely; in fact, in Plaintiffs' brief in opposition to Defendant's motion to bar testimony regarding Strattice™, Plaintiffs note

[18] Plaintiffs also cite Feldman for the proposition that in a failure-to-warn case, a manufacturer's failure to test is relevant to whether it used appropriate foresight in light of subsequent medical literature. Feldman, supra, 97 N.J. at 452 (citing Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 141 (3d Cir. 1973)). However, Hoffman is a Third Circuit opinion on appeal from a Pennsylvania case, applying Pennsylvania law, where the plaintiff's cause of action relevant to the testing issue was negligent testing. As such, this particular case is inapposite.

that LifeCell conducted certain testing on AlloDerm®.[19] Rather, Plaintiffs claim that LifeCell failed to conduct a prospective, randomized clinical trial of AlloDerm®. Plaintiffs assert that the failure to conduct a randomized clinical trial is probative as to what LifeCell knew or should have known, in light of subsequent studies. The fatal flaw in Plaintiffs' argument is that Plaintiffs failed to produce evidence of a prospective randomized clinical trial for AlloDerm®. As such, Plaintiffs cannot put forth any evidence that such a study would have revealed the alleged risks about which Plaintiffs claim LifeCell failed to warn, including high recurrence rates, stretching, thinning, and bulging. To the contrary, Plaintiffs' own expert, Dr. Huckfeldt, testified that he is not aware of any prospective randomized clinical trial for any biologic graft or synthetic mesh product used for hernia repair.[20] Although Plaintiffs argue that the lack of a clinical trial may be probative as to what a reasonable manufacturer of hernia repair products should have known, Plaintiffs have not produced evidence indicating that any manufacturer of hernia repair products conducts such trials.

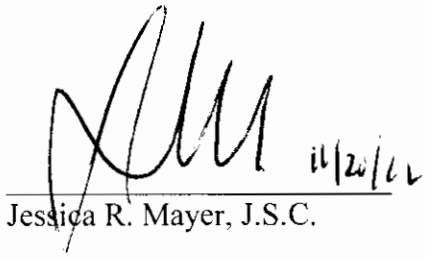
Plaintiffs have failed to proffer evidence that a prospective, randomized clinical study of AlloDerm® would more likely than not have resulted in a finding of high recurrence rates, stretching, thinning or bulging. Plaintiffs have similarly failed to submit evidence that conducting a prospective, randomized clinical trial is an industry standard such that it may be probative as to what a reasonable manufacturer of hernia repair products should have done. Accordingly, evidence regarding LifeCell's failure to conduct clinical trials is purely speculative, and has no probative value as to what LifeCell knew or should have known, regardless of whether the court adopts the Plaintiffs' or the Defendant's interpretation of Feldman. To allow testimony regarding LifeCell's failure to conduct a prospective, randomized clinical trial would confuse the jury as to Defendant's

[19] Plaintiffs' Response to Defendant's Motion *In Limine* to Bar Plaintiff from Introducing any Evidence or Argument Regarding Strattice™ ("Pls.' Strattice Opp.") 7.
[20] Field Clinical Trial Cert. Ex. C, 194, 259-60.

duty and create an impermissible inference of an independent duty to test. This court is not aware of any such duty, nor have the parties presented any New Jersey case supporting that proposition.

For the foregoing reasons, Defendant's motion to bar Plaintiffs from introducing evidence or argument at trial regarding LifeCell testing Alloderm® on patients is **GRANTED.**

Defendant's motion to bar Plaintiffs from introducing evidence or argument at trial regarding the lack of Alloderm® clinical trials by LifcCell is **GRANTED.**



Jessica R. Mayer, J.S.C.