

#0336  
05-07-15

David W. Field (00378-1984)  
**LOWENSTEIN SANDLER LLP**  
65 Livingston Avenue  
Roseland, New Jersey 07068  
973.597.2500  
Attorneys for Defendant  
LifeCell Corporation

**SUPERIOR COURT  
MIDDLESEX COUNTY  
RECEIVED & FILED**  
**JUL 10 2015**  
**GREGORY EDWARDS  
DEPUTY CLERK  
OF SUPERIOR COURT**

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

**FILED**  
**AUG 14 2015**

GREGORY EDWARDS MAYER

PATRICIA JULIEN,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

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

THOMAS DUTCHER,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

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

DEBBIE FOSTER and DAVID FOSTER, w/h,

Plaintiffs,

v.

LIFECCELL CORPORATION,

Defendant.

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

Civil Actions

ORDER

**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 granting summary judgment on all bellwether plaintiffs' punitive damages claims, and the Court having considered all papers submitted by the parties, and for good cause and the reasons <sup>in the attached memorandum</sup> ~~stated on the record~~ by <sup>of decision,</sup> ~~the Court,~~

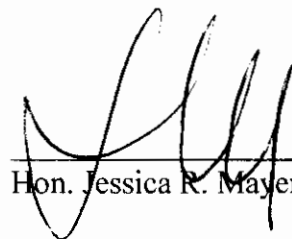
It is on this the 14th day of August, 2015, <sup>denied without prejudice;</sup>  
ORDERED that defendant's motion is ~~hereby granted;~~

~~ORDERED that the punitive damages for all bellwether plaintiffs' claims are hereby dismissed with prejudice and without costs;~~ and it is further

ORDERED that a copy of this Order be <sup>mailed online</sup> served on all counsel of record within

7 days hereof.

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

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

**PAPERS CONSIDERED**

**OPPOSED**

	<u>Yes</u>	<u>No</u>	<u>Date</u>
Notice of Motion	✓	_____	_____
Movant's Affidavits	✓	_____	_____
Movant's Brief	✓	_____	_____
Answering Affidavits	✓	_____	_____
Answering Brief	✓	_____	_____
Cross Motion	_____	_____	_____
Movant's Reply	✓	_____	_____
Other _____	_____	_____	_____

#0164  
08-07-15

David W. Field (00378-1984)  
**LOWENSTEIN SANDLER LLP**  
65 Livingston Avenue  
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973.597.2500  
Attorneys for Defendant  
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

**FILED**  
AUG 14 2015  
JUDGE JESSICA R. MAYER

PATRICIA JULIEN,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

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

THOMAS DUTCHIER,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

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

DEBBIE FOSTER and DAVID FOSTER, w/h,  
 Plaintiffs,  
 v.  
 LIFECCELL CORPORATION,  
 Defendant.

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

Civil Actions

**ORDER**

**FILED**  
 AUG 14 2015  
 JUDGE JESSICA R. MAYER

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It is on this the <sup>14<sup>th</sup></sup> day of <sup>August</sup>, 2015, \*

ORDERED that defendant's motion is <sup>denied without prejudice,</sup> ~~hereby granted, and it is further~~

~~ORDERED that the punitive damages for all bellwether plaintiffs' claims are hereby dismissed with prejudice and without costs; and it is further~~

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

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

#0237  
08-24-15

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

**FILED**  
AUG 14 2015  
JUDGE JESSICA R. MAYEE

~~SUPERIOR COURT  
MIDDLESEX COUNTY  
RECEIVED & FILED  
  
JUL 10 2015  
GREGORY EDWARDS  
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OF SUPERIOR COURT~~

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

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It is on this the 14<sup>th</sup> day of August, 2015,  
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\* For the reasons set forth in the court's memorandum of decision dated August 14, 2015.

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

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

# 0378  
05-27-15

DEBBIE FOSTER and DAVID FOSTER, w/h,

Plaintiffs,

v.

LIFECCELL CORPORATION,

Defendant.

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

Civil Actions

ORDER

**FILED**  
AUG 14 2015  
JUDGE JESSICA R. MAYER

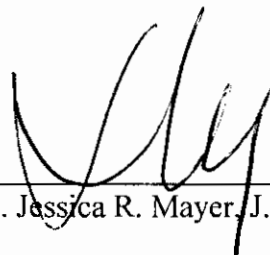
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It is on this the \_\_\_\_\_ day of \_\_\_\_\_, 2015,  
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\* For the reasons set forth in the court's memorandum of decision dated August 14, 2015.



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

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Other _____	_____	_____	_____

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

**SUPERIOR COURT  
MIDDLESEX COUNTY  
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**JUL 10 2015**  
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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

**FILED**  
**AUG 14 2015**  
JUDGE JESSICA R. WADSWORTH

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



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 for Partial Summary Judgment on Plaintiffs' Claim  
For Punitive Damages

**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., Adrienne W. Webb, Esq., and Sol H. Weiss, Esq., Anapol Schwartz.

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

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves for partial summary judgment as to punitive damages in the above cases. 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

**FILED**  
AUG 14 2015  
JUDGE JESSICA R. MAYER

Karen Simineri (collectively “Plaintiffs”). The court issues this opinion in response to LifeCell’s motion for partial summary judgment on Plaintiffs’ claim for punitive damages. Counsel agreed to waive oral argument on this motion and consented to the court’s disposition of the matter on the papers submitted. Upon considering the legal memoranda, exhibits and relevant case law,<sup>1</sup> the court determines that LifeCell’s motion for partial summary judgment on Plaintiffs’ claim for punitive damages is **DENIED WITHOUT PREJUDICE**.

LifeCell concedes that punitive damages are available, as the presumption of adequacy afforded to medical products approved by the United States Food and Drug Administration (“FDA”) is inapplicable in these cases. See Defendant’s Brief in Support of Motion *In Limine* To Bar Evidence or Argument about LifeCell’s Compliance or Lack Thereof with Regulations of the Food and Drug Administration, n. 3; see also N.J.S.A. 2A:58C-4. However, LifeCell argues that Plaintiffs are unable to meet the requisite statutory requirements for punitive damages in these cases. See N.J.S.A. 2A:15-5.9 et seq. (the “New Jersey Punitive Damages Act” or the “Act”)

Punitive damages “are awarded upon a theory of punishment to the offender for aggravated misconduct and to deter such conduct in the future.” Leimgruber v. Claridge Associates, Ltd., 73 N.J. 450, 454 (1977). In accordance with the Act, “punitive damages may be awarded to the plaintiff only if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant’s acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions.” Malice is not the sole requirement for an award of punitive damages. See Smith v. Whitaker, 160 N.J. 221, 240 (1999); see also N.J.S.A. 2A:15-5.13(c).

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<sup>1</sup> 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.

The New Jersey Punitive Damages Act defines both “actual malice” and “wanton and willful disregard” for recovery of punitive damages. Under N.J.S.A. 2A:15.10, “‘actual malice’ means an intentional wrongdoing in the sense of an evil-minded act.” In accordance with that same section of the Act, “‘wanton and willful disregard’ is defined as a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission. For an act to be considered wanton and willful, the conduct must be carried out with knowledge that harm is likely to result to another.” Ibid. As the Appellate Division held in Parks v. Pep Boys, 282 N.J. Super. 1, 17 (App. Div. 1995), “punitive damages may be granted if there is a deliberate act and the defendant has ‘knowledge of a high degree of probability of harm and reckless indifference to consequences’. The defendant, however, does not have to recognize that his conduct is ‘extremely dangerous’, but a reasonable person must know or should know that the actions are sufficiently dangerous.” Id. (quoting Berg v. Reaction Motors Div., 37 N.J. 396, 414 (1962) and McLaughlin v. Rova Farms, Inc., 56 N.J. 288, 306 (1970)). Additionally, the Act defines “clear and convincing evidence as “that standard of evidence which leaves no serious or substantial doubt about the correctness of the conclusions drawn from the evidence. It is a standard which requires more than a preponderance of the evidence but less than beyond a reasonable doubt, to draw a conclusion.” N.J.S.A. 2A:15-5.10. Thus, punitive damages premised upon proof of an act or omission with wanton and willful disregard may be awarded when a party presents clear and convincing evidence that the conduct is sufficiently dangerous to cause harm or injury to a person.

The factors to be considered by the trier of fact in determining whether to award punitive damages include, but are not limited to, the following:

- (1) The likelihood, at the relevant time, that serious harm would arise from the defendant's conduct;
- (2) The defendant's awareness of [sic] reckless disregard of the likelihood that the serious harm at issue would arise from the defendant's conduct;
- (3) The conduct of the defendant upon learning that its initial conduct would likely cause harm; and
- (4) The duration of the conduct or any concealment of it by the defendant.

[N.J.S.A. 2A:15-5.12.b.]

In this case, Plaintiffs allege that LifeCell withheld and/or misrepresented information that it knew or should have known regarding potential stretching, thinning, bulging and other issues allegedly associated with the use of AlloDerm® for hernia repair. Plaintiffs further argue that AlloDerm®'s Instructions For Use ("IFU") failed to inform the surgical community as to the requisite tension to be employed when implanting the tissue graft. See Plaintiffs' Brief in Opposition to LifeCell's Motion for Partial Summary Judgment on Punitive Damages ("Pls.' Opp."), 9-14. Plaintiffs also contend that LifeCell failed to impart information regarding the alleged high rate of hernia recurrence for AlloDerm®, the purported mechanism of hernia failure with use of AlloDerm® and other medical information that a surgeon performing a hernia repair would have wanted to know in conducting a risk-benefit analysis and rendering an informed medical decision before choosing to use AlloDerm® (as opposed to an alternate material) for a hernia repair. Pls.' Opp. 24.

In support of their theory for recovery of punitive damages, Plaintiffs rely on the testimony of their experts, specifically Drs. Dumanian, Gouge and Huckfeldt.<sup>2</sup> All three experts proffer opinions based upon their medical training, expertise and experience with respect to what LifeCell knew or should have known regarding AlloDerm® and its use in hernia repair surgery. The

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<sup>2</sup> The court addressed the testimony of Plaintiffs' experts in separate memoranda of decision issued on this date.

testimony of Plaintiffs' medical experts is based, in part, on the many peer reviewed medical journal articles regarding the use of various materials in hernia repair surgery<sup>3</sup>. These same experts also premised their opinions upon LifeCell's corporate e-mails addressing reported issues of thinning, stretching, laxity, bulging, as well as the deposition testimony of LifeCell's corporate representatives. Plaintiffs' experts believe that acts or omissions of LifeCell regarding the manufacturing, marketing and selling of AlloDerm® with the knowledge and information allegedly available to the company as of the dates of Plaintiffs' respective AlloDerm® surgeries constituted wanton and willful conduct that disregarded patient safety and health.

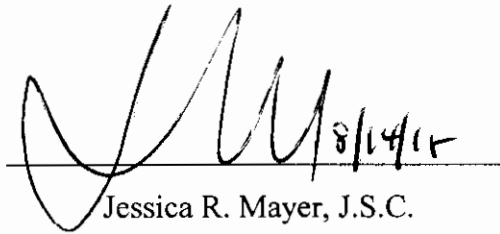
In reviewing a motion for partial summary judgment, Plaintiffs need only present evidence from which a jury *could* award punitive damages. Plaintiffs shall be given an opportunity to demonstrate to the jury, by clear and convincing evidence, that LifeCell's conduct was sufficiently dangerous to cause harm or injury to patients whose hernias were repaired with AlloDerm®. Plaintiffs have put forth evidence that suggests LifeCell knew or should have known of AlloDerm®'s purported stretching, thinning, etc. and deliberately failed to communicate that information to the surgical community with the knowledge that the use of AlloDerm® was certain to cause serious harm to patients' health and safety. To the extent that the evidence adduced at trial fails to support Plaintiffs' theories by way of clear and convincing evidence as to wanton,

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<sup>3</sup> Counsel for Plaintiffs and LifeCell submitted voluminous exhibits in support of the nearly two dozen motions filed in these cases on July 10, 2015. Contained within the many exhibits offered by the parties are peer reviewed medical journal articles authored since 2002 (when AlloDerm® was first marketed by LifeCell for hernia repair). The medical journal articles advance positions both in support of, and contrary to, the legal arguments made by the parties in this litigation regarding the suitability of AlloDerm® for hernia repair surgery. It is evident that the experts for Plaintiffs and LifeCell rely, in part, on these medical journal articles in forming the bases for their expert opinions regarding Plaintiffs' claims for compensatory damages and punitive damages. Counsel may cross-examine each other's expert witnesses as to the validity of the various medical journal articles and the validity of the opinions contained within those articles.

reckless or malicious conduct in support of punitive damages, LifeCell may renew its application at the close of the proofs.

For the foregoing reasons, LifeCell's motion for partial summary judgment on the issue of punitive damages is **DENIED WITHOUT PREJUDICE**.

 8/14/15  
\_\_\_\_\_  
Jessica R. Mayer, J.S.C.