#0116
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** **PR~~OPOSED~~ ORDER** FILED AUG 14 2015 JUDGE JESSICA R. MAYER

ORDER ~~GRANTING~~ ON PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT HOWARD LANGSTEIN, 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 Howard Langstein, M.D., ~~the parties having had an opportunity to be heard~~, and for good cause shown; ~~and~~ for the reasons ~~set forth~~ in the attached memorandum of decision,

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

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

~~conclusions that: 1) Mr. Simineri's hernia recurrence following his repair with AlloDerm was caused by his excessive lifting of heavy objects at work; 2) Mr. Simineri's significant coughing contributed to his hernia recurrence following his repair with AlloDerm; 3) Mr. Simineri's diabetes and/or obesity were contributing factors to his hernia recurrence; 4) incisional hernias have a significant recurrence rate, which can be greater than 50% in the case of a patient with Mr. Simineri's medical history; and 5) the IFU in the packaging of Mr. Simineri's AlloDerm graft provided adequate warnings of the risks of using the product.~~

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

*0132
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** ORDER

FILED
AUG 14 2015
JUDGE JESSICA R MAYER

ORDER ~~GRANTING~~ ON PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT HOWARD N. LANGSTEIN, 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 Howard N. Langstein M.D. ~~the parties having had an opportunity to be heard~~, and for good cause shown and for the reasons ~~set forth~~ in the attached memorandum of decision,

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. Langstein shall not testify about or offer conclusions:~~

~~(1) That AlloDerm is an effective repair material when properly used in complex hernia repairs where synthetic mesh is contraindicated or the surgeon believes there is a substantial risk of future infection;~~

~~(2) That AlloDerm is not defectively designed, but rather is a reasonably fit, safe and suitable hernia repair material for situations where surgical site occurrences, such as infection or adhesion, is a concern and/or synthetic mesh cannot otherwise be used;~~

~~(3) That the instructions and warnings in the AlloDerm Instructions for Use were adequate to inform surgeons of the risks of AlloDerm, including graft failure, and further warned surgeons that outcomes could be negatively impacted by poor patient health and compromised wound healing, and that such warnings warn of commonly-known risks of which a surgeon should be aware even without written warnings;~~

~~(4) That there was no practical and technically feasible alternative design that would have prevented AlloDerm from stretching/bulging under high intra-abdominal pressure without substantially impairing the intended function of AlloDerm to serve as a bioscaffold for the regeneration of host tissue;~~

(5) That the characteristics of AlloDerm are the same as human dermis, and are known to the hernia repair surgeon, and the capacity for stretching in response to stress is an inherent characteristic of implanted dermis that would be recognized by hernia repair surgeons;

(6) That any failure of AlloDerm due to compromised patient healing or stretching is an unavoidable aspect of human dermis, which was the subject of adequate warnings in the AlloDerm IFU;

(7) That a randomized clinical trial was not feasible in 2002 when LifeCell began promoting AlloDerm in complex ventral hernia repair and that a randomized clinical trial would not even be feasible now without great difficulty;

(8) That coughing and/or weight-lifting can cause a hernia recurrence; and

for

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

5/14/12

Jessica R. Mayer, J.S.C.

OPPOSED

#0113
080715

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** **PR~~OPOSED~~ ORDER**

ORDER GR~~ANTING~~ON PLAINTIFF'S MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT HOWARD LANGSTEIN, M.D.

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

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

Plaintiffs' Motion is ~~**GRANTED**. Dr. Langstein shall not testify about or offer~~ denied as moot for the reasons set forth in the * conclusions: 1) that Patricia Julien's surgeon (Joubin Khorsand, M.D.) committed medical malpractice during her January 2006 hernia repair by incorrectly implanting her AlloDerm graft; 2) that medical malpractice by Dr. Khorsand caused Ms. Julien's hernia recurrence; 3) that Ms. Julien's moderate obesity and eight pound weight gain over sixteen months caused her hernia recurrence; and 4) that the IFU in the packaging of Ms. Julien's AlloDerm graft provided ~~adequate warnings of the risks of using the product.~~

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

* Court's memoranda of decisions dated August 14, 2015

Jessica R. Mayer, J.S.C.

OPPOSED

#1034
08-07-15

IN RE: ALLODERM® LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY CASE CODE NO. 295 FILED AUG 14 2015 JUDGE JESSICA R. MAYER CIVIL ACTION
PATRICIA JULIEN, *Plaintiff,* v. LIFECELL CORPORATION *Defendant.*	DOCKET NO. L 507-12 CM ORDER

ORDER ~~GRANTING~~ ON PLAINTIFF'S MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT HOWARD N. LANGSTEIN, M.D.

This matter, having been opened to the Court by counsel for Plaintiff on her Motion to Exclude Testimony of Defendant, LifeCell Corporation's ("LifeCell") Expert Howard N. Langstein, M.D. ~~the parties having had an opportunity to be heard~~, and for good cause shown and for the reasons in the attached memorandum of decision dated August 14, 2015, and other decisions issued on August 14, 2015

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

Plaintiffs' Motion is ~~**GRANTED**. Dr. Langstein shall not testify about~~ denied as moot for the reasons set forth in the court's memoranda of decisions dated August 14, 2015 or offer ~~conclusions:~~

~~(1) That AlloDerm is an effective repair material when properly used in complex hernia~~ repairs where synthetic mesh is contraindicated or the surgeon believes there is a substantial risk of future infection;

(2) That AlloDerm is not defectively designed, but rather is a reasonably fit, safe and suitable hernia repair material for situations where surgical site occurrences, such as infection or adhesion, is a concern and/or synthetic mesh cannot otherwise be used;

(3) That the instructions and warnings in the AlloDerm Instructions for Use were adequate to inform surgeons of the risks of AlloDerm, including graft failure, and further warned surgeons that outcomes could be negatively impacted by poor patient health and compromised wound healing, and that such warnings warn of commonly-known risks of which a surgeon should be aware even without written warnings;

(4) That there was no practical and technically feasible alternative design that would have prevented AlloDerm from stretching/bulging under high intra-abdominal pressure without substantially impairing the intended function of AlloDerm to serve as a ~~bioscaffold for the regeneration of host tissue;~~

~~(5) That the characteristics of AlloDerm are the same as human dermis, and are known to~~ the hernia repair surgeon, and the capacity for stretching in response to stress is an inherent characteristic of implanted dermis that would be recognized by hernia repair surgeons;

(6) That any failure of AlloDerm due to compromised patient healing or stretching is an unavoidable aspect of human dermis, which was the subject of adequate warnings in the AlloDerm IFU;

(7) That a randomized clinical trial was not feasible in 2002 when LifeCell began promoting AlloDerm in complex ventral hernia repair and that a randomized clinical trial would not even be feasible now without great difficulty;

~~(8) That coughing and/or weight-lifting can cause a hernia recurrence; and~~

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

0112
8-7-15

IN RE: ALLODERM® LITIGATION	**SUPERIOR COURT OF NEW JERSEY** **LAW DIVISION: MIDDLESEX COUNTY** **CASE CODE NO. 295** **CIVIL ACTION**

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

THOMAS DUTCHER, *Plaintiff,* **v.** **LIFECELL CORPORATION,** *Defendant.*	**PROPOSED ORDER** **DOCKET NO. L-1469-12**

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

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

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

denied for the reasons set forth in the court's memorandum

Plaintiff's Motion is ~~**GRANTED**~~. ~~Dr. Langstein shall not testify about or offer the~~ of decision dated August 14, 2015.
~~following conclusions that: 1) Mr. Dutcher's recurrence following his repair with AlloDerm was caused by his excessive weight lifting; 2) weight lifting can cause hernia or hernia recurrence; 3) the lower right quadrant pain that Mr. Dutcher experienced months after his AlloDerm hernia repair surgery correlates to his hernia recurrence in his mid-abdomen; 4) Mr. Dutcher's hernia recurrence following his report with AlloDerm was caused by morbid obesity; 5) Mr. Dutcher's hernia recurrence was caused by delay wound healing; and 6) the instructions and warnings provided by LifeCell to Mr. Dutcher's surgeons, Drs. Hunter and Paige, adequately warned of any dangers of using AlloDerm in a hernia repair surgery and how to use AlloDerm safely.~~

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

Jessica R. Mayer, J.S.C.

OPPOSED

0135
05-07-15

IN RE: ALLODERM® LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY CASE CODE NO. 295 CIVIL ACTION FILED AUG 14 2015 JUDGE JESSICA R. MAYER
THOMAS DUTCHER, *Plaintiff*, v. LIFECELL CORPORATION *Defendant.*	DOCKET NO. L 1469-12 CM ORDER

ORDER ~~GRANTING~~ ON PLAINTIFF'S MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT HOWARD N. LANGSTEIN, M.D.

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

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. Langstein shall not testify about or offer conclusions:~~

~~(1) That AlloDerm is an effective repair material when properly used in complex~~ hernia repairs where synthetic mesh is contraindicated or the surgeon believes there is a substantial risk of future infection;

(2) That AlloDerm is not defectively designed, but rather is a reasonably fit, safe and suitable hernia repair material for situations where surgical site occurrences, such as infection or adhesion, is a concern and/or synthetic mesh cannot otherwise be used;

(3) That the instructions and warnings in the AlloDerm Instructions for Use were adequate to inform surgeons of the risks of AlloDerm, including graft failure, and further warned surgeons that outcomes could be negatively impacted by poor patient health and compromised wound healing, and that such warnings warn of commonly-known risks of which a surgeon should be aware even without written warnings;

(4) That there was no practical and technically feasible alternative design that would have prevented AlloDerm from stretching/bulging under high intra-abdominal pressure without substantially impairing the intended function of AlloDerm to serve as a ~~bioscaffold for the regeneration of host tissue;~~

(5) ~~That the characteristics of AlloDerm are the same as human dermis, and are known to~~ the hernia repair surgeon, and the capacity for stretching in response to stress is an inherent characteristic of implanted dermis that would be recognized by hernia repair surgeons;

(6) That any failure of AlloDerm due to compromised patient healing or stretching is an unavoidable aspect of human dermis, which was the subject of adequate warnings in the AlloDerm IFU;

(7) That a randomized clinical trial was not feasible in 2002 when LifeCell began promoting AlloDerm in complex ventral hernia repair and that a randomized clinical trial would not even be feasible now without great difficulty;

~~(8) That coughing and/or weight-lifting can cause a hernia recurrence; and~~

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

5/14/11

Jessica R. Mayer, J.S.C.

OPPOSED

#0115
08-07-15

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

ON

ORDER ~~GRANTING~~ PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT HOWARD N. LANGSTEIN, 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 Howard N. Langstein, M.D. ~~the parties having had an opportunity to be heard~~, and for good cause shown and for the reasons in the attached memoranda,

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

Plaintiffs' Motion is **~~GRANTED~~** denied as moot for the reasons set forth in the ~~Dr. Langstein shall not testify about or offer~~ conclusions: 1) ~~that~~ Mrs. Foster's hernia recurrence following her repair with AlloDerm was caused by coughing; 2) ~~that~~ Mrs. Foster's obesity was a contributing factor to her hernia recurrence following her repair with AlloDerm; 3) ~~that~~ Mrs. Foster hernia recurrence was caused by her December 2008 motor vehicle accident; 4) ~~that~~ incisional hernias have a significant recurrence rate, which can be greater than 50% in the case of a patient with Mrs. Foster's medical history; and 5) that the IFU in the packaging of Mrs. Foster's AlloDerm graft provided ~~adequate warnings of the risks of using the product~~.

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

* Court's memoranda of decisions dated August 14, 2015.

Jessica R. Mayer, J.S.C.

OPPOSED

#0134
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** ORDER

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

ORDER ~~GRANTING~~ PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DEFENDANT LIFECELL CORPORATION'S EXPERT HOWARD N. LANGSTEIN, 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 Howard N. Langstein, M.D. ~~the parties having had an opportunity to be heard~~, and for good cause shown; and for the reasons in the attached memorandum of decision,

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

Plaintiffs' Motion is ~~**GRANTED**. Dr. Langstein shall not testify about or offer conclusions:~~ denied as moot for the reasons set forth in the court's memoranda of decisions dated August 14, 2015.

~~(1) That AlloDerm is an effective repair material when properly used in complex hernia~~ repairs where synthetic mesh is contraindicated or the surgeon believes there is a substantial risk of future infection;

(2) That AlloDerm is not defectively designed, but rather is a reasonably fit, safe and suitable hernia repair material for situations where surgical site occurrences, such as infection or adhesion, is a concern and/or synthetic mesh cannot otherwise be used;

(3) That the instructions and warnings in the AlloDerm Instructions for Use were adequate to inform surgeons of the risks of AlloDerm, including graft failure, and further warned surgeons that outcomes could be negatively impacted by poor patient health and compromised wound healing, and that such warnings warn of commonly-known risks of which a surgeon should be aware even without written warnings;

(4) That there was no practical and technically feasible alternative design that would have prevented AlloDerm from stretching/bulging under high intra-abdominal pressure without substantially impairing the intended function of AlloDerm to serve as a ~~biosegfold for the regeneration of host tissue;~~

(5) ~~That the characteristics of AlloDerm are the same as human dermis, and are known to~~ the hernia repair surgeon, and the capacity for stretching in response to stress is an inherent characteristic of implanted dermis that would be recognized by hernia repair surgeons;

(6) That any failure of AlloDerm due to compromised patient healing or stretching is an unavoidable aspect of human dermis, which was the subject of adequate warnings in the AlloDerm IFU;

(7) That a randomized clinical trial was not feasible in 2002 when LifeCell began promoting AlloDerm in complex ventral hernia repair and that a randomized clinical trial would not even be feasible now without great difficulty;

(8) ~~That coughing and/or weight-lifting can cause a hernia recurrence; and~~

tN

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' Motions to Bar the Testimony of Dr. Howard Langstein

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.

In accordance with case management orders entered by the court, the above four (4) cases were selected by counsel for "bellwether" trials in the AlloDerm® litigation. The plaintiffs in the cases selected by counsel are as follows: Thomas Dutcher ("Dutcher"), Debbie and David Foster ("Foster"), Patricia Julien ("Julien") and Michael and Karen Simineri ("Simineri") (collectively

"Plaintiffs"). The court issues this opinion in response to Plaintiffs' motions to exclude the general and case specific causation testimony of Dr. Howard N. Langstein. 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 legal memoranda, exhibits (including Dr. Langstein's general causation reports dated May 7, 2015, and Dr. Langstein's reports issued for each Plaintiff dated May 7, 2015, and May 8, 2015,), deposition testimony of Dr. Langstein and relevant case law,[1] the court determines that Plaintiffs' motions to exclude the general and specific causation testimony of Dr. Langstein are **DENIED**.

I. Relevant Law

To establish liability in these cases, Plaintiffs must prove through expert testimony that implantation of AlloDerm® caused them to develop hernia recurrence, stretching and thinning of the graft used in the hernia repair, as well as other claimed injuries related to implantation of AlloDerm®. Kemp ex rel. Wright v. State, 174 N.J. 412, 417 (2002). The expert testimony of Dr. Langstein has been proffered by Defendant to rebut Plaintiffs' experts' testimony that Plaintiffs' injuries were caused by the use of AlloDerm®.

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.

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

[Ibid.][2]

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, supra, 174 N.J. at 424 (quoting Landrigan v. Celotex Corp., 127 N.J. 404, 413 (1992)).]

In certain contexts, an expert's testimony has to be "generally accepted within the relevant scientific community." State v. Chun, 194 N.J. 54, 91 (2008) (discussing New Jersey's continued use of the standard from Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), for evaluating scientific tests in criminal cases); see also State v. Harvey, 151 N.J. 117, 167-70 (1997). However, New Jersey applies a more relaxed standard for expert testimony in civil cases. Rather than requiring expert testimony to be generally accepted in the profession, "a scientific theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately-founded scientific methodology involving data and information

---

[2] 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.

of the type reasonably relied on by experts in the scientific field." Rubanick v. Witco Chem. Corp., 125 N.J. 421, 449 (1991); accord Kemp, supra, 174 N.J. at 430.[3]

Hence, even if an expert's opinion is not generally accepted in the scientific community, it may still be admitted as evidence, so long as the methodology and reasoning underlying that opinion is sound. See Clark v. Safety-Kleen Corp., 179 N.J. 318, 337-38 (2004). The Supreme Court of New Jersey has specifically noted that, in the case of pharmaceutical litigation "in which a medical cause-effect relationship has not been confirmed by the scientific community but compelling evidence nevertheless suggests that such a relationship exists," such evidence may be admissible. Kemp, supra, 174 N.J. at 430.

Under this standard, a trial judge must assess "the soundness of the proffered methodology and the qualifications of the expert." Id. at 426 (quoting Rubanick, supra, 125 N.J. at 454) (internal quotations omitted). The role of the trial court is to "determine whether the expert's opinion is derived from a sound and well-founded methodology that is supported by some expert consensus in the appropriate field." Id. at 427 (quoting Landrigan, supra, 127 N.J. at 417) (internal quotations omitted). 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.

Flaws in an expert's causation testimony are not fatal. 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 causation testimony may still be admitted, so long as the expert sufficiently

[3] This is particularly applicable to "tort cases involving novel theories of causation offered to connect a plaintiff's injuries to a drug or a toxic substance." Biunno, Current N.J. Rules of Evidence, comment 3 on N.J.R.E. 702 (2015); see Kemp, supra, 174 N.J. at 430-31 (involving defective vaccine); Landrigan, supra, 127 N.J. at 413 (involving exposure to asbestos); Rubanick, supra, 125 N.J. at 449 (involving exposure to a chemical).

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 v. Tavorath, 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.

II. Dr. Langstein's General Expert Opinions

A. Dr. Langstein's Opinons Regarding Design Defect, Alternative Designs, and the Characteristics of AlloDerm and Human Dermis

The court notes that several of Plaintiffs' arguments in support of barring the general expert testimony of Dr. Langstein relate to his opinions regarding Plaintiffs' design defect claims.[4] Plaintiffs argue that Dr. Langstein is not qualified to offer opinions on (1) defective design; and (2) practical and technically feasible alternative designs. This court dismissed Plaintiffs' design defect 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' design defect claims is irrelevant to the Plaintiffs' remaining claims. Plaintiffs contend that Dr. Langstein's opinions on AlloDerm®'s design defect and safer alternative designs are inadmissible because he is "not an expert in tissue biology" and "does not know how AlloDerm is designed."[5] To the extent that any of Dr. Langstein's opinions regarding the characteristics of AlloDerm® or human dermis are relevant to Plaintiffs' failure-to-warn claims, the court will address Plaintiffs' arguments.

Plaintiffs' primary argument is that Dr. Langstein is unqualified to render opinions on the characteristics of AlloDerm® and human dermis because Dr. Langstein is a surgeon, not a tissue biologist.[6] Defendant responds that Dr. Langstein is not being offered to provide "the perspective

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[4] Plaintiffs' Memorandum of Law in Support of Plaintiffs' Motion to Exclude the General Opinions of Defendant's Expert Howard N. Langstein, M.D. ("Pls.' Br.") at 9-10.
[5] Pls.' Br. 12.
[6] Pls.' Br. 12-15.

of a tissue engineer or biologist. Rather, he is being offered as an expert in hernia repair and abdominal wall surgery."[7]

Dr. Langstein is the Chief of Plastic Surgery at the University of Rochester School of Medicine and Dentistry, where he has held the position of Professor of Surgery since 2005.[8] Prior to joining the University of Rochester, Dr. Langstein held teaching positions at several medical schools.[9] He has been Board Certified in Plastic Surgery since 1998 and was Board Certified in General Surgery from 1993 to 2013.[10] Dr. Langstein currently teaches surgical resident students at the University of Rochester, where the treatment of complex abdominal wall patients is a "significant focus" of the program.[11] Dr. Langstein has been involved in hundreds of cases of abdominal wall repair and is familiar with the treatment of ventral hernia patients.[12] Dr. Langstein is currently the Medical Director of the Abdominal Wall Reconstruction Program at the University of Rochester School of Medicine and Dentistry.[13] Dr. Langstein's work has been published in peer-reviewed journals.[14] Dr. Langstein is also an ad hoc reviewer for the medical journal Plastic and Reconstructive Surgery and has reviewed scientific articles for several other journals.[15]

Dr. Langstein, in both his expert reports and deposition testimony, is careful to point out areas in which he lacks specific expertise to opine.[16] Dr. Langstein couches his opinions in the

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[7] Defendant's Brief in Opposition to Plaintiffs' Motion to Exclude or Limit Testimony of Dr. Howard N. Langstein, M.D. Based on His General Rebuttal Report ("Def.'s Opp.") at 4.
[8] Fantini Cert., Ex. A, Dr. Langstein Expert Report in Response to the Expert Report of Dr. Dumanian 1.
[9] Ibid.
[10] Ibid.
[11] Ibid.
[12] Id. at 2.
[13] Ibid.
[14] Fantini Cert., Ex. A, Dr. Langstein Curriculum Vitae 6-13.
[15] Fantini Cert., Ex. A, Dr. Langtein Expert Report in Response to the Expert Report of Dr. Dumanian ("Langstein Dumanian Report") 2.
[16] See, e.g., id. at 11; Fantini Cert., Ex. B, Dr. Langstein Report in Response to the Expert Report of Dr. Huckfeldt 11; Fantini Cert., Ex. D, Langstein Dep. at 97:6, 102:7-12.

context of his knowledge and experience as a surgeon who used AlloDerm® for hernia repairs.[17] Additionally, Dr. Langstein's opinions are based on his knowledge and expertise gained through his extensive experience as a surgeon, as well as his review of the available medical literature.[18] To the extent that Dr. Langstein offers opinions regarding the biomechanical characteristics of AlloDerm®, the court views those opinions as rebuttal opinions criticizing Plaintiffs' experts for lacking expertise for in certain areas.

The court agrees with Defendant that Dr. Langstein is qualified to testify regarding the characteristics of AlloDerm® and human dermis insofar as they are based on his own experience and expertise as a surgeon who has performed numerous hernia repair surgeries. Plaintiffs simply point to portions of Dr. Langstein's report wherein he candidly concedes that he does not have expertise in tissue engineering and is not being proffered for that purpose without Plaintiffs explaining how those admissions render Dr. Langstein's medical opinions inadmissible. Plaintiffs quote these sections and argue in conclusory fashion that "Dr. Langstein attempts provide [sic] a variety of 'expert opines [sic] which clearly fall under the umbrella of 'tissue engineering.'"[19] However, it is evident that Dr. Langstein is not being offered to opine on matters of tissue engineering but is being offered—based on his extensive abdominal surgery experience and his use of AlloDerm® and other hernia repair products—to provide opinions based on his perspective as a surgeon and his personal experiences handling and implanting AlloDerm®.

An expert is entitled to offer opinions based on his own personal experiences. Rosenberg, supra, 352 N.J. Super. at 403. Given Dr. Langstein's extensive experience as a surgeon performing hernia repairs and his familiarity with the use of AlloDerm® and other biologic products in hernia

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[17] See, e.g., Langstein Dumanian Report 12.
[18] Id. at 1-2, 19-22.
[19] Pls.' Br. 13.

repairs, he is more than qualified to discuss the characteristics of AlloDerm® and the appropriateness of using AlloDerm® in hernia repairs. If Plaintiffs believe that Dr. Langstein's lack of expertise in tissue engineering undermines his opinions on certain physical characteristics of AlloDerm®, Plaintiffs may challenge Dr. Langstein's opinions through cross-examination.

B. Plaintiffs' Arguments that Dr. Langstein's Rebuttal Opinions are Not Based on Reliable Scientific Methodology and Are Inadmissible Net Opinions

Plaintiffs also argue that portions of Dr. Langstein's expert testimony should be barred because his opinions are unreliable and inadmissible net opinions.[20] Plaintiffs' main arguments are focused on critiquing the various medical journal articles and other documents on which Dr. Langstein bases his opinions. The court will address the specific areas in which Plaintiffs argue Dr. Langstein should be barred from testifying.

1. Dr. Langstein's Opinions Regarding the Efficacy of AlloDerm®

Plaintiffs argue that in opining AlloDerm® is an effective repair material, "Dr. Langstein errantly relies on certain studies in forming his opinion that AlloDerm is effective."[21] Plaintiffs extensively criticize the numerous medical articles Dr. Langstein relied upon in forming his opinions. Plaintiffs critique the parameters of the studies underlying each of these articles and argue that "Dr. Langstein relied heavily upon research with, among other deficiencies, inadequate sample sizes and short term follow-up to conclude that AlloDerm was effective."[22]

For example, Plaintiffs criticize Dr. Langstein's reliance on Kim et al., Acellular dermal matrix in the management of high-risk abdominal wall defects (2006) ("Kim study") because it was observational, retrospective, not controlled, had a small sample size and a short-term follow-

[20] Pls.' Br. 16.
[21] Pls.' Br. 17
[22] Id. at 17-18.

up.[23] Plaintiffs criticize Dr. Langstein's reliance on Jin et al., Use of Acellular Dermal Matrix for Comlicated Ventral Hernia Repair: Does Technique Affect Outcomes? (2007) ("Jin study") because it purportedly revealed "significant safety concerns for repairs . . . ."[24] However, Plaintiffs fails to explain the safety concerns or how the study is scientifically unreliable.[25] Plaintiffs further argue that short-term follow-ups, small sample sizes, and reporting deficiencies in the eight additional published articles relied upon by Dr. Langstein render Dr. Langstein's opinions inadmissible.[26]

Dr. Langstein supports his opinions regarding the efficacy of AlloDerm® with several published and peer-reviewed articles.[27] Plaintiffs' statements as to the perceived flaws in the underlying medical studies do not render Dr. Langstein's opinion inadmissible.[28] If Plaintiffs believe the studies relied upon by Dr. Langstein are flawed in any way, Plaintiffs are free to challenge Dr. Langstein's reliance on those articles through cross-examination. However, Plaintiffs' criticisms of the specifics of those studies do not render Dr. Langstein's opinions inadmissible under N.J.R.E. 702. See Hisenaj, supra, 194 N.J. at 24. Plaintiffs' criticisms go to the weight of Dr. Langstein's opinion and it will ultimately be for a jury to decide the weight to be accorded his opinions.

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[23] Id. at 18; Fantini Cert., Ex. P.
[24] Pls.' Br. at 18; Fantini Cert., Ex. Q.
[25] The Jin study was a retrospective study that examined the results of thirty-seven hernia repairs using AlloDerm®. Jin et al., at 655. The study did note a high number of recurrences in the eleven repairs utilizing a "bridge" technique. However, the study recorded "acceptable" recurrence rates in the twenty-seven procedures for which AlloDerm® was used as reinforcement. The Jin study did not conclude that AlloDerm® is unsafe for all hernia repairs, only that AlloDerm® should be used as reinforcement rather than as a bridge. Jin, et al., 655-657.
[26] Pls.' Br. 18-20.
[27] See ibid.
[28] See supra, Point I of the court's Memorandum of Decision on Plaintiffs' Motion to Bar Dr. Langstein's Testimony.

2. Dr. Langstein's Opinions Regarding the Instructions for Use

Plaintiffs criticize Dr. Langstein's opinions that the Instructions for Use ("IFU") accompanying the AlloDerm® used in each of Plaintiffs' surgeries were adequate to apprise the implanting surgeons of the risks of using AlloDerm® in hernia repairs. Plaintiffs argue that Dr. Langstein's analysis of the IFUs was based on a methodology that was "questionable and unscientific."[29] Plaintiffs note there were many revisions to AlloDerm®'s IFUs and argue that Dr. Langstein was required to review every IFU in order to form a reliable opinion regarding the adequacy of the IFUs actually accompanying the AlloDerm® used in Plaintffs' suregeries.[30] Plaintiffs also note Dr. Langstein's failure to take into consideration the various marketing materials Defendant used in promoting AlloDerm®.[31] Plaintiffs also criticize Dr. Langstein's failure to address a number of factors that Plaintiffs believe are pertinent to the adequacy of the IFUs, including the risks of using certain surgical techniques, the risk of post-surgical stretching, the need to inform surgeons that AlloDerm® is only a temporary repair, and the need to instruct surgeons on the time it takes for AlloDerm to remodel into new tissue.[32]

In essence, Plaintiffs' argument is that Dr. Langstein failed to take into consideration certain evidence and alleged risks that Plaintiffs aver are pertinent to assessing their claims. However, "[t]he 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. Rather, such an omission merely becomes a proper

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[29] Pls.' Br. 24.
[30] Pls.' Br. 23-24.
[31] Id. at 25.
[32] Id. at 26-27.

subject of exploration and cross-examination at trial." Rosenberg, supra, 352 N.J. Super. at 402 (citations omitted) (quoting Rubanick, supra, 242 N.J. Super. at 36).

Plaintiffs bear the burden of proving that the alleged inadequacy of AlloDerm®'s IFUs used in each Plaintiff's surgery was a proximate cause of Plaintiffs' injuries. As Defendant notes, Dr. Langtein's opinions on AlloDerm®'s Instructions for Use are offered to rebut the opinions of Plaintiffs' experts on this issue.[33] Dr. Langstein is entitled to rely on his professional expertise as a surgeon with experience in hernia repairs to offer his opinions on AlloDerm®'s IFUs. Dr. Langstein may opine as to his experiences with AlloDerm® and the risks he believes are relevant to the use of AlloDerm® in hernia repairs. Similarly, Dr. Langstein is permitted to rely on his own review of IFUs and other warnings accompanying hernia repair products and provide an opinion regarding the information that needs to be conveyed to a surgeon in similar circumstances. Dr. Langstein's purported failure to give weight to factors and evidence that Plaintiffs believe are important to their cases does not render his opinions inadmissible. Although Plaintiffs may believe that the adequacy of the warnings can only be determined by reference to IFUs and marketing materials not packaged with each Plaintiff's specific AlloDerm® product, Plaintiffs fail to demonstrate how Dr. Langstein's failure to evaluate the information Plaintiffs believe to be relevant undermines his own professional opinion regarding the adequacy of the AlloDerm® IFUs. Dr. Langstein's purported failure to consider evidence that Plaintiffs believe to be relevant to the adequacy of AlloDerm®'s warnings and instructions goes to the weight to be accorded Dr. Langstein's opinions. Plaintiffs are free to pursue Dr. Langstein's purported deficiencies through cross-examination and the testimony of Plaintiffs' own experts.

[33] Def.'s Opp. 12.

3. Dr. Langstein's Opinions Regarding Randomized Clinical Trials

Plaintiffs argue that Dr. Langstein's opinions regarding the feasibility of randomized clinical trials for AlloDerm® in complex hernia repairs should also be barred.[34] Dr. Langstein opined that "a randomized clinical trial was not feasible in 2002 when LifeCell began promoting AlloDerm in complex ventral hernia repair" and that "[i]n fact, it would not even be feasible now without great difficulty."[35] Plaintiffs' argue Dr. Langstein's opinion on the issue of feasibility of clinical trials directly conflicts with his reference to a 2000 clinical trial in the Netherlands that examined the use of prosthetic meshes in small, ventral hernia repairs.[36] Dr. Langstein's opinion is specifically directed at the purported difficulties of performing such a study using biologic grafts in complex ventral hernia repairs. Plaintiffs' argument appears to be that the 2000 study involving synthetic meshes and small hernias undermines Dr. Langstein's opinion on the feasibility of clinical studies in a completely different context. Plaintiffs contend that Dr. Langstein failed "to adequately explain the methodology behind coming to his opinions . . . ."[37] Dr. Langstein is able to support his opinion regarding the difficulties of conducting such a study based on his own experience as a surgeon and his review of the relevant medical literature. That Plaintiffs disagree with Dr. Langstein's conclusion on the matter does not render his opinion inadmissible.

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[34] Pls.' Br. 28.
[35] Fantini Cert., Ex. A, Langstein Dumanian Report 22.
[36] Pls.' Br. 28.
[37] Ibid.

4. Dr. Langstein's Opinions Regarding Surgical Technique

Plaintiffs also seek to preclude Dr. Langstein's testimony that "combinations of component separation and reinforcement are now advised to reduce recurrence rates."[38] Plaintiffs claim that a 2013 article authored in part by Dr. Langstein contradicts his opinion in these cases because the article states that "[t]here is little consensus in the literature about the best approach for a midline ventral hernia repair with a dizzying collection of reports supporting contradictory strategies."[39] Plaintiffs also argue that Dr. Langstein's opinion on this point is irrelevant because Plaintiffs' surgeries predate the publication of Dr. Langstein's 2013 article.[40]

As a surgeon with many years of experience repairing ventral hernias, Dr. Langstein is qualified to provide an opinion regarding the development and acceptance of hernia repair techniques within the surgical community. Similarly, Dr. Langstein's own medical experiences and review of the relevant literature provide a reliable basis on which to form any opinions he has regarding hernia repair techniques. Furthermore, Plaintiffs' own medical experts testified that they have been using the component separation technique since well before Plaintiffs' surgeries.[41] To the extent that Plaintiffs feel the 2013 article authored by Dr. Langstein undermines his own current thinking on hernia repair surgeries, Plaintiffs are free to address that issue on cross-examination.

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[38] Pls.' Br. 30.

[39] Ibid.; Koltz et al., Evolution of Abdominal Wall Reconstruction (2013).

[40] Pls.' Br. 30.

[41] Plaintiffs' medical expert, Dr. Huckfeldt, testified that he has been performing component separations since the early 2000s. Field Cert., Ex. B, Huckfeldt Dep. at 70:1371:16. Plaintiffs' medical expert, Dr. Dumanian, testified that he first began performing component separations in the mid-1990s. Field Cert., Ex. K, Dumanian Dep. at 60:2-62:20.

5. Dr. Langstein's General Opinions Are Sufficiently Reliable and Admissible

Plaintiffs' arguments in support of their motion to bar portions of Dr. Langstein's general expert opinions go to the weight to be accorded to those opinions, not their admissibility. As a surgeon with extensive experience repairing ventral hernias, Dr. Langstein may provide opinions based on his own personal experiences and his review of the published medical literature regarding hernia repair. If Plaintiffs dispute Dr. Langstein's opinions and conclusions, Plaintiffs may challenge his opinions and conclusions by way of cross-examination and the introduction of Plaintiffs' own expert testimony.

III. Dr. Langstein's Case Specific Expert Opinions

In addition to dismissing all of Plaintiffs' design defect claims, this court dismissed the failure-to-warn claims of Plaintiffs Patricia Julien and Debbie and David Foster for the reasons set forth in this court's Memorandums of Decision on Defendant's Motions for Summary Judgment on Plaintiffs' Failure to Warn Claims, dated August 14, 2015.[42] The only remaining bellwether plaintiffs are Michael and Karen Simineri, and Thomas Dutcher. Therefore, the court will only address Dr. Langstein's case specific expert opinions for Mr. Simineri and Mr. Dutcher.

A. Dr. Langstein's Specific Causation Opinions Regarding Plaintiff Michael Simineri

Plaintiff Michael Simineri seeks to bar Dr. Langstein's opinion testimony regarding the cause of Mr. Simineri's hernia recurrence following his AlloDerm® implant in October 2007.[43] Mr. Simineri seeks to exclude Dr. Langstein's opinions that Mr. Simineri's recurrence was caused

[42] On August 14, 2015, the court issued separate Memoranda of Decision for each bellwether plaintiff on the issue of failure-to-warn.

[43] Plaintiff Michael Simineri's Memorandum of Law in Support of Plaintiff's Motion to Exclude Testimony of Defendant's Expert Howard Langstein, M.D. ("Simineri Br.") 2.

or exacerbated by: (1) lifting at work; (2) coughing; and (3) diabetes and/or obesity.[44] Mr. Simineri also seeks to bar Dr. Langstein from testifying that a patient with Mr. Simineri's health problems has a greater than 50% chance of developing a recurrence and that the IFUs in the packaging of Mr. Simineri's AlloDerm provided adequate warnings.[45] Mr. Simineri contends that Dr. Langstein's opinions are "unsubstantiated and unscientific personal opinions" and therefore are inadmissible net opinions.[46]

1. Dr. Langstein's Opinion that Excessive Lifting and Coughing Caused or Contributed to Mr. Simineri's Recurrence

In support of barring Dr. Langstein's opinions that excessive lifting and coughing caused or contributed to Mr. Simineri's recurrence, Mr. Simineri argues that (1) these opinions are contrary to the factual record; and (2) Dr. Langstein fails to provide scientific support for his opinion that lifting or coughing can cause or contribute to a hernia recurrence.[47]

According to Defendant, Mr. Simineri's medical records indicate that he first noticed a pain and bulge caused by his hernia recurrence "after doing some lifting at work."[48] At his deposition, Mr. Simineri testified that his business involves frequently lifting buckets of ice.[49] Mr. Simineri denies this lifting was "excessive" and argues that he waited a sufficient period of time post-surgery before he resumed lifting.[50] The record does not directly contradict Dr. Langstein's opinion on the issue of lifting weight so as to render it a net opinion. The court finds that Dr. Langstein drew a reasonable inference based on Mr. Simineri's medical records and deposition

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[44] Ibid.
[45] Id. at i-ii.
[46] Id. at 5-6.
[47] Simineri Br. at 9, 12.
[48] Field Simineri Langstein Cert., Ex. Q, Simineri Medical Record dated Apr. 13, 2010.
[49] Field Simineri Cert., Ex. T, Simineri Dep. 27:8-19.
[50] Simineri Reply 4.

testimony. At trial, Mr. Simineri is free to challenge Dr. Langstein's inference on the issue of lifting weight. Mr. Simineri repeatedly disputes Dr. Langstein's purported conclusion that Mr. Simineri's coughing "caused" his recurrence even though his coughing episode occurred five months after Mr. Simineri first began experiencing bulging and pain. Dr. Langstein's opinion is that the coughing episode "contributed" to Mr. Simineri's recurrence, not that the coughing retroactively caused it.[51]

Mr. Simineri is also critical of the studies and journal articles relied upon by Dr. Langstein in offering his opinion that a hernia recurrence may be caused by lifting and exacerbated by coughing.[52] The studies upon which Dr. Langstein relies examine how certain activities, including weight lifting and coughing, increase a person's intra-abdominal pressure.[53] Mr. Simineri argues that the studies relied upon by Dr. Langstein do not specifically state that weight lifting and coughing can contribute to hernia recurrence.[54] Mr. Simineri also disputes the conclusions reached by Dr. Langstein based on these studies.[55] Defendant notes that Dr. Langstein also cites two additional studies in his general causation report that both note coughing and weight lifting contribute to hernia recurrence.[56] Mr. and Mrs. Simineri are free to challenge Dr. Langstein's reliance on these studies and articles by way of cross-examination. Plaintiffs' criticisms of the studies and articles do not render Dr. Langstein's opinions inadmissible under N.J.R.E. 702.

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[51] Simineri Reply 6; Fantini Simineri Cert., Ex. B, Dr. Langstein's Simineri Report at 4.
[52] Simineri Br. 9.
[53] Fantini Simineri Cert., Ex. E, Cobb et al., Normal Intraabdominal Pressure in Healthy Adults (2005) ("Cobb et al."); Ex. G, Sanchez, et al., What is Normal Intra-Abdominal Pressure? (2001) ("Sanchez et al.").
[54] Simineri Br. 11.
[55] Mr. Simineri also disputes Dr. Langstein's reliance on Cobb et al. for his opinion that obesity contributes to hernia recurrence. Simineri Br. at 10. The Cobb article unambiguously states that "[o]besity has also been established as a risk factor for recurrence after incisional hernia repair." Cobb et al., at 234. Obesity will be addressed in Point III, A, 2 of the court's memorandum.
[56] Def.'s Simineri Opp. at 5; Fantini Cert., Ex. A, Langtein General Report at 4; Field Cert., Ex. J, Michael G. Franz, The biology of hernias and the abdominal wall (2006); Ex. I, Ziad T. Awad et al., Mechanisms of Ventral Hernia Recurrence after Mesh Repair and a New Proposed Classification (2005).

Hisenaj, supra, 194 N.J. at 24. Mr. Simineri actually concedes in his reply to Defendant's opposition that two of the articles relied upon by Dr. Langstein state that coughing and lifting "may" play a role in hernia recurrence.[56] In sum, Mr. Simineri's criticism of Dr. Langstein's reliance on these studies and articles goes to the weight, not the admissibility, of his expert opinions.

Furthermore, Dr. Langstein's opinion that weight lifting and coughing can contribute to hernia recurrence is based on his clinical experiences with his own patients.[57] As a surgeon who diagnoses and treats hernia recurrences, Dr. Langstein is permitted to rely on his professional training and experience in forming his medical opinion regarding Mr. Simineri's hernia recurrence. Mr. Simineri is free to rebut Dr. Langstein's medical opinions regarding the effects of lifting and coughing on hernia repairs with his own expert testimony.

2. Dr. Langstein's Opinion that Diabetes and Obesity Were Substantial Contributing Factors in Mr. Simineri's Recurrence and That a Patient With Mr. Simineri's Medical History Has a High Risk of Recurrence

Mr. Simineri challenges Dr. Langstein's opinion that Mr. Simineri's obesity and diabetes contributed to his hernia recurrence. As an experienced surgeon who is well-versed in diagnosing and treating hernia occurrences, Dr. Langstein may rely on his professional training and experience in offering such opinions. As Defendant notes, Mr. Simineri's own testifying experts and treating surgeon agree that diabetes and obesity are factors that increase a patient's risk of hernia recurrence.[58] Mr. Simineri may rebut Dr. Langstein's medical opinion with his own expert medical testimony.

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[56] Simineri Reply 5.
[57] Field Simineri Cert., Ex. A, Langstein Dep. at 184:1-19.
[58] Field Simineri Cert., Ex. K, Dumanian Dep. at 108:18-109:21; Field Simineri Cert., Ex. T, Garcia Dep. at 101:9-102:9, 115:24-116:6.

Mr. Simineri also criticizes Dr. Langstein's reliance on an article authored by Dr. Bahair Ghazi suggesting high blood pressure may cause hernia recurrence.[59] Mr. Simineri's criticism of the Ghazi article is misplaced. According to the article, the only statistically significant independent factor for hernia repair complications is high blood pressure.[60] However, the article notes that complication rates were higher in patients with two or more comorbidities.[61] The article specifically notes that obesity and diabetes were two prevalent comorbidities among the patients studied.[62] To the extent that Mr. Simineri disagrees with Dr. Langstein's reliance on a published, peer reviewed medical article, that disagreement may be addressed by cross-examination. Merely disagreeing does not render Dr. Langstein's opinion inadmissible. Dr. Langstein's extensive medical training and experience in treating hernia patients provides more than a sufficient basis for him to render opinions regarding the effects of a patient's comorbidities on the risk of hernia recurrence. See Rosenberg, supra, 353 N.J. Super. at 403 ("Evidential support for an expert opinion is not limited to treatises or any types of documentary support, but may include what the witness had learned from personal experience.").

3. Dr. Langstein's Opinion Regarding the Adequacy of the IFUs Accompanying the AlloDerm® used in Mr. Simineri's Surgery

Mr. Simineri's arguments regarding Dr. Langtein's opinions on the adequacy of AlloDerm®'s IFUs mirror the arguments made by Plaintiffs in their motion to exclude Dr. Langstein's general causation testimony. Mr. Simineri argues that Dr. Langstein was required to review multiple versions of the IFUs rather than just the IFU accompanying the AlloDerm® used

[59] Ghazi, et al., Current Options in the Management of Complex Abdominal Wall Defects (2011).
[60] Id. at 488, 491.
[61] Ibid.
[62] Id. at 491.

in his surgery.[64] Mr. Simineri also contends that Dr. Langstein needed to review "the entire AlloDerm message directed at surgeons to evaluate the adequacy of IFU warnings."[65] The court disagress. Dr. Langstein is entitled to offer his opinions regarding the IFUs based on his own professional medical training and expertise as well as his review of the IFUs accompanying the AlloDerm® used in Mr. Simineri's surgery. "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." Rosenberg, supra, 352 N.J. Super. at 402 (quoting Rubanick, supra, 242 N.J. Super. at 55). That Dr. Langstein may have failed to consider every aspect of each AlloDerm® IFU does not render Dr. Langstein's opinion inadmissible. At trial, Mr. Simineri is free to challenge Dr. Langstein's opinions as to the adequacy of the AlloDerm® IFU used in Mr. Simineri's surgery.

B. Dr. Langstein's Specific Causation Opinions Regarding Plaintiff Thomas Dutcher

Mr. Dutcher seeks to bar Dr. Langstein's specific causation expert testimony that his hernia recurrence was caused by excessive weight lifting, morbid obesity, and delayed wound healing, arguing that these opinions are "unsubstantiated personal opinions and therefore inadmissible."[66]

1. Dr. Langstein's Opinion that Mr. Dutcher's Hernia Recurrence Was Caused by Excessive Weight Lifting

Dr. Langstein's opinion that Mr. Dutcher's hernia recurrence was caused by excessive weight lifting is based on his own professional medical experience diagnosing and treating hernia

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[64] Simineri Br. 17-18.
[65] Id. at 19.
[66] Plaintiff Thomas Dutcher's Memorandum in Support of Plaintiff's Motion to Exclude Testimony of Defendant's Expert Howard Langstein, M.D. ("Dutcher Br.") 6.

recurrences and a review of Mr. Dutcher's medical records.[66] Additionally, Dr. Langstein relied upon several medical journal articles to support his opinion that a hernia recurrence can be caused by weight lifting. Mr. Dutcher challenges the bases for Dr. Langstein's opinion as unreliable.[67]

First, Mr. Dutcher challenges Dr. Langstein's reliance on two journal articles.[68] The articles examine the effect that lifting, among other activities, has on intra-abdominal pressure. Second, Mr. Dutcher argues that Dr. Langstein's opinion regarding Mr. Dutcher's weight lifting is unsupported by his medical record.[69]

Mr. Dutcher's criticisms of Dr. Langstein's reliance on two journal articles examining the effect of lifting on intra-abdominal pressure go to the weight to be accorded Dr. Langstein's opinion, not its admissibility. The articles generally examine the effects of certain activities, such as weight lifting, on intra-abdominal pressure.[70] Mr. Dutcher's criticism of Dr. Langstein's reliance on these articles is based on the fact that none of the articles specifically draws a connection between weight lifting and hernia recurrence. Defendant notes that Dr. Langstein also cites two additional studies in his general causation report that both note weight lifting can contribute to hernia recurrence.[71] Mr. Dutcher's criticisms of Dr. Langstein's reliance on these articles goes to the weight to be accorded Dr. Langstein's opinions and can be examined by Mr. Dutcher on cross-examination.

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[66] Fantini Cert., Ex. A, Dr. Langstein's Dutcher Report at 6-7; Field Dutcher Cert., Ex. A, Langstein Dep. at 184:3-19.

[67] Cobb et al., Normal Intraabdominal Pressure in Healthy Adults (2005) ("Cobb et al."); Sanchez, et al., What is Normal Intra-Abdominal Pressure? (2001) ("Sanchez et al.").

[68] Dutcher Br. 9.

[69] Id. at 12.

[70] Cobb, et al., at 231; Sanchez, et al., at 243.

[71] Def.'s Dutcher Opp. at 6-7; Fantini Cert., Ex. A, Langtein General Report at 4; Field Cert., Ex. J, Michael G. Franz, The biology of hernias and the abdominal wall (2006); Ex. I, Ziad T. Awad et al., Mechanisms of Ventral Hernia Recurrence after Mesh Repair and a New Proposed Classification (2005).

Disagreement with Dr. Langstein's medical opinion that weight lifting caused Mr. Dutcher's hernia recurrence is insufficient to render Dr. Langstein's opinion inadmissible. Dr. Langstein's opinion is based on his own clinical experiences, as well as his review of Mr. Dutcher's medical records.[72] Mr. Dutcher's medical records contain references to weight lifting.[73] Additionally, in Mr. Dutcher's medical records, one of Mr. Dutcher's care providers directly attributed his abdominal pain to his continued weight lifting.[74] Mr. Dutcher was advised repeatedly by medical professionals to limit or reduce the amount of weight he was lifting.[75] Mr. Dutcher's medical records offer support for Dr. Langstein's opinion that his hernia recurrence was caused by weight lifting. Mr. Dutcher is free to challenge Dr. Langstein's medical opinions with expert medical testimony of his own and by way of cross-examination at trial.

2. Dr. Langsteins' Opinion That Mr. Dutcher's Obesity and Delayed Wound Healing Contributed to His Hernia Recurrence

Mr. Dutcher also argues Dr. Langstein's conclusions that obesity and wound healing problems contributed to his hernia recurrence are "nothing more than a bald conclusion."[76] Dr. Langstein opined that these conditions were contributing factors in Mr. Dutcher's hernia recurrence. Mr. Dutcher disregards Dr. Langstein's extensive medical training and expertise in diagnosing and treating hernia recurrences and argues that Dr. Langstein has no basis on which to opine that Mr. Dutcher's obesity and poor wound healing contributed to his recurrence.[77] Notably, Mr. Dutcher's own medical experts and treating physicians concede that obesity increases a

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[72] Fantini Cert., Ex. A, Dr. Langstein's Dutcher Report at 6-7; Field Dutcher Cert., Ex. A, Langstein Dep. at 184:3-19.
[73] Field Dutcher Cert., Ex. BB, Outpatient Clinic Notes dated June 26, 2005, Sept. 21, 2005, May 22, 2006.
[74] Ibid. (Clinic Note dated May 22, 2006).
[75] Ibid.
[76] Dutcher Br. 15.
[77] Ibid.

patient's risk of hernia recurrence.[78] Mr. Dutcher also criticizes Dr. Langstein for ignoring purported evidence that Mr. Dutcher's recurrence was caused by AlloDerm®.[79] However, an expert's failure to address factors that an adverse party finds relevant does not make the expert's opinion an inadmissible net opinion. Rosenberg, supra, 352 N.J. Super. at 402.

3. Dr. Langstein's Opinion Regarding the Instructions for Use Accompanying the AlloDerm® Used in Mr. Dutcher's Surgery

In challenging Dr. Langstein's opinion as to the adequacy of the IFUs accompanying the AlloDerm® used in his surgery, Mr. Dutcher argues that by "failing to review all the IFU versions to see what changes were made over time . . . Dr. Langstein's methodology is flawed and unscientific."[80] Mr. Dutcher's arguments mirror the arguments made by the four bellwether plaintiffs in their motion to exclude Dr. Langstein's general causation opinions.

Dr. Langstein is entitled to base his opinion as to the adequacy of AlloDerm®'s IFUs on his own medical training and experience as well as his review of the actual AlloDerm® IFU used in Mr. Dutcher's surgery. Dr. Langstein need not refute every factor Mr. Dutcher believes to be relevant to his failure-to-warn claim.[81] To the extent Mr. Dutcher disagrees with Dr. Langstein's professional opinion regarding the AlloDerm® IFUs, Mr. Dutcher is free to challenge Dr. Langstein's conclusions at trial.

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[78] Field Dutcher Langstein Cert., Ex. K, Dumanian Dep. at 108:18-109:21; Ex. Z, Hunter Dep. at 17:22-18:12; 117:1-8).
[79] Dutcher Br. 16.
[80] Id. at 19.
[81] See supra, Point III, A, 3 of the court's Memorandum of Decision on Plaintiffs' Motions to Bar Dr. Langstein's Testimony

IV. Conclusion

For the foregoing reasons, Plaintiffs' motions to bar the general causation and case specific causation testimony of Defendant's expert, Dr. Howard Langstein, are **DENIED**.

8/14/11

JESSICA R. MAYER, J.S.C.