PREPARED BY THE COURT

IN RE STRATTICE HERNIA MESH LITIGATION **THERESA BLAKELY v. LIFECELL CORP., et al.**	SUPERIOR COURT OF NEW JERSEY LAW DIVISION ATLANTIC COUNTY MCL CASE NO. 636 MASTER DOCKET NO.: ATL-L-3857-21 CASE NO.: ATL-L-1214-22 ***ORDER***

THIS MATTER having been opened to the Court upon application of Defendant, LifeCell, for an Order granting Defendants' Motion for Summary Judgement, and the Court having considered the moving papers, opposition and arguments of counsel, and for good cause being shown as stated in the accompanying Memorandum of Decision;

IT IS, on this 23rd day of February, 2024, **ORDERED** that Defendants' Motion for Summary Judgement is **GRANTED** in part and **DENIED** in part, as follows:

1. Defendants' Motion for Summary Judgement is **GRANTED** as to Count 8 of Plaintiff's Complaint; Count 8 is **DISMISSED** with prejudice.

2. Defendants' Motion for Summary Judgement is **DENIED** as to Count 6 of Plaintiff's Complaint.

3. Defendants' Motion for Summary Judgement is **DENIED** as to Count 1 of Plaintiff's Complaint.

4. Defendants' Motion for Summary Judgement is **DENIED** as to Count 2 of Plaintiff's Complaint.

5. Defendants' Motion for Summary Judgement is **GRANTED** as to the application of New Jersey Law.

IT IS FURTHER ORDERED that service of this Order shall be deemed effectuated upon all parties upon its upload to eCourts. Pursuant to R. 1:5-1(a), movant shall serve a copy of this Order on all parties not served electronically within seven (7) days of the date of this Order.

(X) Opposed

( ) Unopposed

HON. JOHN C. PORTO, P.J.Cv.

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

JOHN C. PORTO, P.J.Cv.

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MEMORANDUM OF DECISION ON MOTION
Pursuant to Rule 1:6-2(f)

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All other Counsel of record listed on eCourts.

RE: In Re Strattice Hernia Mesh Litigation
Theresa Blakeley vs. LifeCell Corp., et al.

MASTER DOCKET NO. ATL-L-3857-21

Docket No. ATL-L-1214-22

NATURE OF MOTION: Defendant's Motion for Summary Judgment

HAVING CAREFULLY REVIEWED THE MOVING PAPERS, OPPOSITION FILED, AS WELL AS THE ARGUMENTS OF COUNSEL, I HAVE RULED ON THE ABOVE CAPTIONED MOTION AS FOLLOWS:

Nature of Motion and Procedural History

This case is one of a series of cases designated as Multicounty Litigation ("MCL") by the New Jersey Supreme Court and consolidated in this court for administrative purposes. As of February 10, 2024, there were ninety-three (93)

active cases originating from thirty-one states and the District of Columbia in this MCL.

Plaintiff's causes of action allegedly derive from a medical device manufactured by the Defendants, Strattice Reconstructive Tissue Matrix ("Strattice"). Strattice is a surgical mesh derived from porcine (pig) skin and used to reinforce soft tissue where weakness exists and surgically repair damaged or ruptured soft tissue membranes. Strattice is a Federal Food, Drug and Cosmetic ("FDA") cleared 510(k) product since June 2007 as a Class II medical device indicated for use for the repair of hernias and/or body wall defects. Plaintiff alleges she suffered personal injuries as a result of her surgeon's use of Strattice to repair a ventral incisional hernia.

The Plaintiff was diagnosed with a ventral incisional hernia and her surgeon performed a hernia repair surgery on August 17, 2020, and used a Strattice mesh for the surgery. Almost one year after the initial implant surgery, Plaintiff returned to the same surgeon complaining of abdominal pain; the surgeon diagnosed Plaintiff with a recurrent ventral hernia. The same surgeon performed another hernia repair surgery on June 3, 2021, and this time used a synthetic Parietex mesh to repair the recurrent hernia. Plaintiff's surgeon performed a component separation during this second surgery.

Following the second surgery, Plaintiff filed her Complaint against the following named Defendants: LifeCell Corporation, Allergan USA, Inc., and Allergan, Inc., (collectively, "Defendants") under the New Jersey Products Liability Act ("PLA"), N.J.S.A. 2A:58C-1 et seq. due to the use of the Defendants' Strattice mesh product in Plaintiff's first hernia surgery. Succinctly, Plaintiff alleges an injury caused by the use of Strattice caused an increased risk of recurrence and reoperation.

Plaintiff initially asserted nine causes of action against the Defendants: (1) design defect, (2) failure to warn, (3) negligence, (4) negligent misrepresentation,

(5) fraud, (6) breach of express warranty, (7) breach of implied warranties, (8) violation of consumer protection laws, and (9) punitive damages. The Plaintiff's counsel voluntarily dismissed the four common law causes of action on January 25, 2024. The remaining causes of action are: design defect, failure to warn, breach of express warranty and violation of consumer protection laws and are the subject of this motion.

Following the end of discovery, Defendants filed this motion for summary judgment seeking a dismissal of all of Plaintiff's remaining claims. Plaintiff filed opposition on December 5, 2023. Defendants filed their reply brief on December 15, 2023. Oral argument was conducted on January 18, 2024. Trial is scheduled for March 4, 2024.

Parties' Contentions[1]

Defendants

In support of their client's motion for summary judgment, counsel asserted and addressed the following arguments in their brief:

> I. Plaintiff's design defect claim fails because she has not identified a safer alternative design.
>
> A. Synthetic mesh is not an alternative design for Strattice.

Defendants disagree with the Plaintiff's experts' opinions that synthetic mesh is an alternative design for Strattice because synthetic mesh does not constitute an alternative design for Strattice which is a biologic mesh. Counsel contends identifying "an alternative product does not satisfy the requirements[2]" of New Jersey law to identify an alternative design. Specifically, synthetic mesh is a different

[1] The contentions are general summaries of the arguments addressed in counsel's briefs and raised during oral argument.
[2] Defs.' Br. at 8.

product from a biologic mesh[3] and cannot be identified as an alternative design in this litigation.

Defendants' counsel then refers to two unpublished out of state cases[4] that considered whether synthetic mesh and biologic mesh are alternative designs for the other and dismissed their claims for a design defect. Counsel argues the Plaintiff's proffered alternative design is an "attack [of] a fundamental characteristic of Strattice.[5]" Defendants also cite to the Plaintiff's expert, Dr. Panigrahy, to point out his recognition "that hernia mesh 'materials are divided into two groups: synthetic and biologic meshes.[6]'" Polypropylene is "an altogether different material that would result in an alternative different product[7]" and a different category of mesh. Counsel further argues the Plaintiff is advocating the elimination of a whole category of a "useful product from the market[8]." So, according to the Defendants, the Plaintiff did "not put forth an acceptable feasible alternative design for Strattice.[9]"

B. Plaintiff has not established that synthetic mesh was safer than Strattice at the time of its manufacture.

Alternatively, Defendants argue in the event the Plaintiff is permitted to proceed with their alternative design argument to Strattice, the Plaintiff did not

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[3] Faiella v. Sunbelt Rentals, Inc., No. 18-11383, 2021 WL 5980176 at *13 (D.N.J. Dec. 17, 2021), Hosford v. BRK Brands, Inc., 223 So. 3d 199, 208 (Ala. 2016); Torkie-Tork v. Wyeth, 739 F. Supp. 2d 895, 800 (E.D. Va. 2010); Brockert v. Wyeth Pharms., Inc., 287 S.W. 3d 760, 770-71 (Tex. Ct. App. 2009); Caterpillar, Inc. v. Shears, 911 S.W. 2d 379, 385 (Tex. 1995).

[4] Labiche v. Johnson & Johnson, No. H-20-4249, 2021 WL 3719554 (S.D. Tex. Aug 19, 2021); Barnes v. Medtronic, PLC, No. 2:17-cv-14194, 2019 WL 1353880 (E.D. Mich. Mar. 26 2019).

[5] Defs.' Br. at 10.

[6] Defs.' Br. at 10, quoting Panigrahy Report at 83, Ex. 14 to Lewis Cert.

[7] Defs.' Br. at 10.

[8] Caterpillar, 911 S.W. 2d at 385.

[9] Defs.' Br. at 11.

establish synthetic mesh "was safer than Strattice at the time of its manufacture[10]" because there is no expert testimony demonstrating synthetic mesh was safer than biologic mesh "in all cases." Defendants contend empirical data is lacking to show "synthetic mesh is actually 'safer' than a biologic mesh, particularly in instances of infection.[11]"

In support of that contention, the Defendants reference the Plaintiff's surgeon, Dr. Koelsch, when he chose Strattice for the Plaintiff and further asserts at the time of the surgery, the surgeon "viewed biologic mesh as more infection-resistant than synthetic mesh.[12]" Counsel also refutes the Plaintiff's reliance on medical literature[13] and argues "not one [referenced by Plaintiff] concludes that synthetic mesh is safer than biologic mesh.[14]" According to the Defendants, "[c]omparable results' and 'similar safety profiles' do not translate into evidence that synthetic meshes are safer than biologic meshes.[15]" Defendants' counsel also points out in a footnote, the Plaintiff's expert Dr. Liang found "synthetic mesh and biologic mesh 'had similar probability of major complications,' and reported a 'slight benefit with synthetic mesh as opposed to biologic mesh except for mesh infection[16].'" Defendants assert "for every article advanced by Dr. Panigrahy claiming to demonstrate that synthetic mesh is safer than biologic mesh, there is an article reaching the opposite conclusion.[17]"

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[10] Defs.' Br. at 11-12.
[11] Defs.' Br. at 12.
[12] Defs.' Br. at 13.
[13] PRICE Randomized Clinical Trial, the 2023 Makarainen article published in BMC Surgery, and the Rosen study published in 2022.
[14] Defs.' Br. at 13.
[15] Defs.' Br. at 14.
[16] Footnote #5, pg. 14 of the Defendants' brief dated October 30, 2023.
[17] Defs.' Br. at 14.

Counsel contends, based on the "competing literature and study results… there is no clear evidence that synthetic mesh is safer than biologic mesh", and that is "fatal to Plaintiff's design defect claim.[18]"

C. A synthetic mesh would not have prevented Plaintiff's injury.

On this point, the Defendants assert the state-of-the-art defense to "defeat" Plaintiff's claim[19]. The Defendants acknowledge they bear the burden to establish the defense and contend neither a biologic or synthetic hernia mesh, now or at the time of the operation, "would have prevented" Plaintiff's injuries. Defendants' attorneys argue Strattice is not "so egregiously dangerous and of so little use to rebut this defense.[20]"

II. Plaintiff's failure to warn claim fails because she cannot overcome the presumption of adequacy or, in the alternative, Dr. Koelsch knew of the risks associated with Strattice.

A. Plaintiff cannot overcome the presumption that the Strattice warnings were adequate.

Defendants argue since Strattice is subject to FDA oversight, "it is entitled to the presumption provided under N.J.S.A. 2A:58C-4[21]", and the Plaintiff lacks clear and convincing evidence to overcome the presumption, so, this claim must fail.

B. Dr. Koelsch was independently aware of the risks associated with Strattice, defeating plaintiff's failure to warn claim.

Here, the Defendants rely on the Plaintiff's surgeon's knowledge and associated deposition testimony to prevail on this point.

1. The learned intermediary doctrine applies.

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[18] Defs.' Br. at 15.
[19] Cavanaugh v. Skil Corp., 164 N.J. 1, 6 (2000).
[20] Defs.' Br. at 15.
[21] Defs.' Br. at 18.

According to the Defendants, Dr. Koelsch "had a prominent role in evaluating and selecting Strattice for the Plaintiff's hernia repair surgery.[22]" Accordingly, the doctor "considered many factors, including Plaintiff's comorbidities-specifically, her obesity." Under this doctrine, the Defendants contend they "discharged their duty to warn by providing an adequate warning that took into account the ordinary knowledge common to [Dr. Koelsch][23]."

2. Dr. Koelsch had independent knowledge of the risk of recurrence.

Counsel reasserts the Plaintiff's surgeon's deposition testimony that reveals his "independent" understanding of the risk of recurrence before the initial surgery and so this claim must also be dismissed.

III. Plaintiff's common law and Consumer Fraud Act claims should be dismissed as subsumed by the NJPLA.

As noted earlier, the Plaintiff's counsel voluntarily dismissed the common law claims, and the court does not need to consider this argument.

The Defendants' counsel argued the CFA claims are subsumed by the PLA because Plaintiff "cannot distinguish her product liability claims from her CFA claim."[24]

IV. Plaintiff has no evidence to support a breach of express warranty claim.

A. Plaintiff has no evidence of specific promises made by defendants.
B. Any alleged affirmations would not have been part of the basis of the bargain.

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[22] Defs.' Br. at 20.
[23] Niemiera by Niemiera v. Schneider, 114 N.J. 550, 559 (1989).
[24] Defs.' Br. at 25.

The essential argument presented by the Defendants is that the Plaintiff did not offer any evidence of any "specific affirmations", or "specific promises" made by Defendants" to the Plaintiff.

V. Plaintiff has no evidence to support her punitive damages claim.

The Defendants oppose any imposition of punitive damages arguing that "a reasonable juror" could not find the Defendants "acted with actual malice or with wanton and willful regard for others[25]" by clear and convincing evidence.

A. New Jersey law applies to Plaintiff's punitive damages claim.

1. New Jersey follows the most significant relationship test to determine choice of law.

2. New Jersey has the most significant relationship to punitive damages because all of the alleged wrongdoing occurred in New Jersey.

B. The punitive damages act governs Plaintiff's punitive damages claim.

C. No reasonable juror could conclude that LifeCell or Allergan acted with actual malice or a willful and wanton disregard of others.

In this part of their brief, the Defendants argue in support of the application of New Jersey law if there is any consideration for the imposition of punitive damages.

Counsel also addresses the court rule[26] and case law[27] regarding dispositions of summary judgment motions.

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[25] Defs.' Br. at 28.
[26] R. 4:46-2(c).
[27] Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 538 (1995) and Hoffman v. Pure Radiance, Inc., No. A-2765-20, 2022 WL 1739706, at *2 (N.J. Super. Ct. App. Div. May 31, 2022).

Plaintiff's Opposition

Plaintiff's counsel opposed the motion and also provided an introduction as well as case law[28] and court rules[29] in support of their client's position to the Defendants summary judgment motion. Counsel focuses their arguments in opposing the motion on their assertions regarding the Defendants' "rampant" off-label promotion, "significant" elevated risk of Strattice, regeneration, and the safer alternative mesh design.

A. Failure to Warn

1. LifeCell Engaged in Rampant Off-Label Promotion, Made False Statements, and Completely Failed to Warn About Strattice's True Risks, Benefits, and Clinical Performance.

i. LifeCell Failed to Warn Dr. Koelsch that Strattice Has a Significantly Elevated Risk of Recurrence over Cheaper Synthetic Mesh.

According to the Plaintiff, the Defendants' off label promotion, false statements and failure to warn the medical community included the following: (1) Strattice's recurrence rate relative to cheaper synthetic meshes available at the time Strattice hit the market, (2) Strattice's true mechanism of action when implanted in the body was resorption not regeneration; (3) the true scope and limitations of Strattice's cleared indications for use and the lack of supporting data in high risk patients, and (4) any adverse events, malfunctions, and failures associated with Strattice. Plaintiff supports these contentions with references to Dr. Koelsch's deposition testimony.

ii. LifeCell Made Off-Label, False Statements to Dr. Koelsch Regarding LifeCell's Mechanism of

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[28] Brill, 142 N.J. at 541 and C.V. by & through C.V. v. Waterford Twp. Bd. of Educ., 255 N.J. 289 (2023).

[29] R. 4:46-2(c).

Action: that Strattice Regenerates When It Really Resorbs.

Counsel also contends the evidence in this case confirms that LifeCell, at all times, claimed that when a surgeon puts Strattice in a patient, it will "support regeneration" and provide the ideal repair, namely one that is strong and durable. According to the Plaintiff, this claim was an "improper" off label promotion that was not cleared by the FDA. Plaintiff counters and asserts Defendants failed to warn that Strattice does not regenerate but "its mechanism of action was actually something entirely different: resorption.[30]"

iii. LifeCell Promoted Strattice Off-Label for Use to High-Risk Patients Like Blakeley Who Were Not Identified in the FDA-Cleared Indications for Use Without Supporting Data.

Plaintiff argues the Defendants claimed Strattice was the "ideal repair material" for the patients identified in the Defendants' "Hernia Grading System as Grade 2, 3, and 4 patients." Plaintiff argues the Defendants "never informed surgeons that high-risk patients like Grade 2, 3, and 4 patients were off-label or that risk stratifying patients with the hernia grading system or CeDAR app to position Strattice was off-label.[31]"

iv. LifeCell Failed to Warn About any Risks Associated with Strattice in Its Warning Label.

Plaintiff argues the Defendants also "failed to provide any warning about risks, adverse reactions or complication associated with Strattice, including the elevated risk of recurrence in the randomly controlled trials.[32]" The Plaintiff's injury,

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[30] Pls.' Opp. at 9.
[31] Pls.' Opp. at 10.
[32] Pls.' Opp. at 11.

a hernia recurrence, "[was] never mentioned in the warning label at all, let alone a discussion of the rate of recurrence associated with Strattice.[33]"

2. Defendants' Counter-Arguments Have No Merit.

i. Defendants Are not Entitled to the Presumption of Adequacy.

ii. As a Result of LifeCell's Conduct Dr. Koelsch Was Unaware of the True Risks, Benefits, Mechanism of Action, and Clinical Performance of Strattice.

The Plaintiff's counsel addressed and refuted the Defendants' arguments raised in their brief regarding the failure to warn.

B. Design Defect

1. Strattice Is Defectively Designed Because Its Risks Outweigh Its Utility and There Were Feasible Safer Alternatives Available.

i. Strattice's Risks Outweigh Its Utility.

Plaintiff identifies and addresses the seven "relevant factors" for the "risk-utility analysis" and referenced in Smith v. Keller Ladder Co., 275 N.J. Super. 280, 283 (App. Div. 1994) and argues none of those factors favor Strattice. According to Plaintiff's counsel, "these factors support the finding that Strattice is defectively designed, notwithstanding any alternative design, because its dangers outweigh its benefits.[34]"

ii. Plaintiffs Have Proffered Evidence of a Safer Alternative Design.

Plaintiff produced two expert witnesses who opined that "a middle weight, open-pore, monofilament synthetic polypropylene mesh presents a safer alternative design to Strattice." According to Plaintiff's attorneys their client's "proffered

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[33] Pls.' Opp. at 11.
[34] Pls.' Opp. at 19.

alternative design is not only backed up by expert testimony, but it is also scientifically validated at the highest levels by three different groups of surgeons who have published their results in peer-reviewed literature.[35]" Plaintiff argues there "is a sufficient basis for a jury to properly conclude that a mid-weight open pore polypropylene mesh is a safer alternative design… than Strattice" and cite to the proposed testimony of Dr. Liang.

2. Defendants' Counter-Arguments Have No Merit.

i. Defendants' Attempt to Discredit the RCTs Is not Appropriate at Summary Judgment.

Plaintiff addresses all of the Defendants' arguments on this point and states: the Defendants' arguments on the RCT's "are both meaningless and meritless at summary judgment.[36]" Plaintiff's counsel argues the Defendants "misstate the applicable law" and point out their client "need not establish that the alternative design carries no risk of injury, only that it minimizes or reduces the risk of injury.[37]" Plaintiff's counsel states one of their experts, Dr. Liang, "will testify…, more likely than not, Strattice increased [Plaintiff's] risk of recurrence and that she suffered a recurrence because of Strattice.[38]"

Plaintiff also contends the Defendants "cherry-picked" statements from medical articles arguing the "full studies and their actual conclusions speak for themselves.[39]" Plaintiff's counsel asserts the Defendants' citation to four articles are not "high-level, peer reviewed RCT studies" and only create an issue of fact to defeat summary judgment.

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[35] Pls.' Opp. at 21.
[36] Pls.' Opp. at 21.
[37] Pls.' Opp. at 21.
[38] Pls.' SAMF, at ¶¶ 380-382.
[39] Pls.' Opp. at 22.

ii. Defendants' Argument that Synthetic Hernia Mesh Cannot Legally Serve as an Alternative Design to Biologic Hernia Mesh Is Without Merit.

Plaintiff argues that the Defendants' contention that synthetic mesh cannot legally serve as a safer alternative "is without merit." Plaintiff's counsel argues "other products already available on the market [that] serve the same or very similar function at lower risk and at comparable cost . . . may serve as reasonable alternatives to the product in question[40]." Plaintiff argues their only burden is to come forward with an alternative design that is safer, feasible, and serves the same function as the challenged product and they have done so. According to Plaintiff's counsel, the Defendants "cherry-pick[ed] decisions from other courts largely applying the law of other states that suit their purpose.[41]"

iii. Defendants Failed to Meet Their Burden in Establishing the State-of-the-Art Defense.

Plaintiff's counsel argues the Defendants did not designate any expert testimony to support their proposition that "there was not a practical and technically

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[40] Green v. General Motors Corp., 310 N.J. Super. 507, 524 (App. Div. 1998) (citing Restatement (Third) of Torts: Products Liability § 2, cmt. f; Hrymoc, 467 N.J. Super. at 82-3 (upholding jury finding that a pelvic mesh could be safer if designed with a different type of mesh); Smith v. Covidien, LP, 2019 WL 7374793, at *4 (D.N.J. Dec. 31, 2019) (applying N.J. PLA to find that a non-polyester hernia mesh could be an alternative design to a polyester hernia mesh); O'Bryant v. Johnson & Johnson, 2022 WL 7670296, at *11-12 (D.N.J. Oct. 13, 2022); Dandy v. Ethicon Women's Health and Urology, No. 20-00431, 2022 WL 1284735, at *10-13 (D.N.J. Apr. 29, 2022) ("...but here again, neither Defendants nor Barnes explain why the use of different materials alone precludes a product from providing an alternative design.) (citing Barnes v. Medtronic, PLC, No. 217-cv-14194, 2019 WL 1353880 (E.D. Mich. Mar. 26, 2019)).

[41] Pls.' Opp. at 24.

feasible alternative design." Plaintiff's evidence "clearly puts this defense out of reach, or, at a minimum, creates an issue of fact.[42]"

iv. New Jersey's Law Does not Require Plaintiffs to Demonstrate that Defendants Knew of a Safer Alternative Design at the Time of Manufacture.

Plaintiff disagrees with the Defendants' use of unpublished court decisions on this point and assert, correctly, that they are not binding on this court[43]. Plaintiff's counsel reiterated the PLA requires the reasonable alternative design be "practical and feasible" and "Defendants knew or should have known at the time their products left their control that a safer alternative design existed.[44]" Plaintiff argues their alternative design, synthetic mesh, was both practical and feasible, and that two other products utilizing that design were on the market before Strattice. Plaintiff asserts synthetic mesh was the standard of care in 2008 when Defendant launched Strattice.

C. Punitive Damages

1. This Court Should Apply Kentucky or Illinois Punitive Damages Law to Plaintiffs' Punitive Damages Claim.

2. LifeCell Disregarded Patient Safety When It Engaged in Years-Long Misconduct Designed to Maximize Revenue, Including Off-Label Promotion, Making False and Misleading Statements, and Failing to Provide any Warnings About Strattice.

Plaintiff argues against the imposition of New Jersey law for any imposition of punitive damages and assert the Defendants' actions warrant the imposition of punitive damages, specifically, by disregarding patient safety by engaging in years-long misconduct designed to maximize revenue, including off-label promotion,

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[42] Pls.' Opp. at 28.
[43] The court notes both parties used unpublished decisions throughout their briefs.
[44] Pls.' Opp. at 30.

making false and misleading statements, and not providing any warnings about Strattice.

D. Plaintiffs' New Jersey Consumer Fraud Act Claim Is not Subsumed by the PLA.

Counsel presents arguments that their client's CFA claim is not subsumed by the PLA.

E. Plaintiffs' Breach of Express Warranty Claim Is Supported by the Law and the Facts.

Next, counsel addresses the breach of express warranty claim. Counsel argues "Plaintiffs' Breach of Express Warranty Claim Is Supported by the Law and the Facts."

F. Plaintiffs Stipulate to the Dismissal of Their Common Law Negligence, Negligent Misrepresentation, Fraud, and Breach of Implied Warranty Claims.

Defendants' Reply Brief

Defendants' attorneys filed their client's reply to the Plaintiff's opposition and refuted the arguments presented.

I. Plaintiff has failed to create a genuine issue of material fact to save her failure to warn claim.

A. Plaintiff has not overcome the presumption of adequacy.

Defendants argue the Plaintiff cannot overcome this presumption (through the three limited pathways) by clear and convincing evidence. First, the Defendants, FDA and surgeons knew of the risk of recurrence at the time Strattice was cleared by the FDA. Second, Plaintiff offers no proof that Defendants engaged in "economically-driven manipulation of the post-market regulatory process.[45]" Finally, the Plaintiff did not come forward with any evidence the Defendants acquired new information of risks associated with Strattice after bringing it to market

[45] Defs.' Reply at 2.

requiring an update of its label. Additionally, Counsel argues, this third pathway only applies to prescription drugs and is not applicable here.

B. LifeCell is not required to warn about rates of complications or alleged off-label promotion.

1. LifeCell is not required to warn about rates of complications.

Defendants contend New Jersey law does not require this type of warning. Defendants also argue despite Plaintiff's contention that the recurrence rate is "upwards of 20%," with supporting articles, the Plaintiff did not discuss "the dozens of other articles" demonstrating the "recurrence rates of less than 10% including those cited in the 'Don't Mesh Around Core Brochure.[46]'" The attorneys further note even Plaintiff's surgeon acknowledged "complications ... are impacted by many factors aside from the type of mesh, including the patient's comorbidities and surgical technique.[47]"

2. Plaintiff's arguments about off-label promotion are irrelevant.

According to the Defendants, "[r]egeneration" and "resorption" are "not risks of Strattice...these terms refer to two different mechanisms of action [i.e.] how Strattice works.[48]" New Jersey law does not require any manufacturer "to provide a surgeon with all information known to the manufacturer." Moreover, Defendants' counsel denies their client engaged in off-label promotion, but also argues "that has no impact on how physicians may ultimately choose to use products with their patients.[49]" Defendants contend Dr. Koelsch "already fully understood the risk of

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[46] Defs.' Reply at 5, citing generally Pl.'s SAMF.
[47] Defs.' Reply at 5, citing to Ex. 12 to Defs.' Opening Br., 69:10–70:25, 138:11-14.
[48] Defs.' Reply at 6.
[49] Defs.' Reply at 7.

recurrence, and there were no additional warnings that [Defendants] should have provided.[50]"

C. Plaintiff agrees that Dr. Koelsch understood the risk of recurrence.

Defendants emphasize the information possessed by Plaintiff's doctor prior to the Plaintiff's implant surgery.

II. Plaintiff's design defect claim fails because she has not identified a safer alternative design.

A. No New Jersey decision identifies synthetic mesh as a reasonable alternative design for Strattice.

B. Plaintiff has not established that synthetic mesh was safer than Strattice.

1. Plaintiff impermissibly narrows "injury" in arguing synthetic mesh is safer.

2. The time of manufacture is the correct time frame under New Jersey law to view evidence of an alternative safer design.

3. Dr. Liang does not offer opinions that synthetic mesh is a safer alternative design to Strattice.

Defendants contend Dr. Liang did not proffer any opinion in this regard in the deposition testimony, rather that testimony is "no more than his preferences when choosing a hernia repair product.[51]" Defendant contend the Plaintiff did not establish her design defect with expert testimony.

4. It is Plaintiff's burden, not defendants', to establish empirical evidence of a safer alternative design.

In reiterating their core argument, the Defendants emphasize that the Plaintiff did not cite any New Jersey decision permitting "a product to serve as a proposed

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[50] Defs.' Reply at 7.
[51] Defs.' Reply at 15.

reasonable alternative design where it would fundamentally alter the function and character of the product at issue.[52]" This argument focused on the biologic versus synthetic material composition and according to the Defendants they are "entirely different products." Defendants assert if the comparison was correct and Plaintiff was permitted to proceed with this contention, "Plaintiff did not establish[] that synthetic mesh was safer than Strattice at the time of its manufacture.[53]" Defendants also argue the Plaintiff's expert pointed out "biologic meshes were introduced as an alternative to synthetic mesh and were largely considered the 'mesh material of choice for contaminated hernias' because of the potential for 'chronic infection and further mesh-related complications and/or reoperation' with synthetic mesh.[54]" So, the Plaintiffs did not look at the "overall relative safety of synthetic mesh compared to Strattice" and simply looked at the recurrence rate as the measure of safety. Therefore, the Defendants argue the Plaintiff did not satisfy her burden that synthetic mesh was safer than Strattice at the time of the surgery.

C. Plaintiff ignores evidence that synthetic mesh would not have prevented plaintiff's injury to support the state-of-the-art defense.

The Defendants argue "the issue is not whether there was a practical or technically feasible alternative design because… both synthetic and biologic [meshes were] on the market at the time of the Plaintiff's [surgery]… [i]nstead the issue is whether there was an alternative design that would have prevented the harm.[55]" Defendants contend the Plaintiff overlooks her own expert, Dr. Liang's, testimony opining "there was no hernia mesh on the market that carries zero risk of

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[52] Defs.' Reply at 9.
[53] Defs.' Reply at 11.
[54] Defs.' Reply at 12.
[55] Defs.' Reply at 16.

recurrence."[56] Therefore, the state-of-the-art defense "is an absolute bar to Plaintiff's design defect claim, and Plaintiff offered no evidence to rebut the defense."

III. Plaintiff cannot proceed with her consumer fraud act claim.

Counsel reiterated their client's prior argument on this point.

IV. Plaintiff's breach of express warranty claim fails as a matter of law.

Counsel reiterates their client's prior argument on this point.

V. Plaintiff has not identified clear and convincing evidence to warrant Punitive damages.

A. New Jersey law applies.

B. Plaintiff has failed to establish malice.

Counsel reiterates their client's prior argument on this point.

Findings of Fact

Under R. 4:46-2(b), "[a] party opposing the motion [for summary judgment] shall file a responding statement [of material facts] either admitting or disputing each of the facts in the movant's statement. "Subject to R. 4:46-5, all material facts in the movant's statement which are sufficiently supported will be deemed admitted for purposes of the motion only, unless specifically disputed by citation conforming to requirements of [R. 4:46-2(a)] demonstrating the existence of a genuine issue of material fact." A judge does not act as the fact finder when deciding a motion for summary judgment. Judson v. Peoples Bank & Trust Co., 17 N.J. 67, 75 (1954).

[56] Liang Dep. 61:23-62-3, Ex. 16 to Lewis Cert.

This court examined and considered both fact statements submitted by both parties. However, this court finds, upon its review of the Plaintiff's submission of a "robust" statement of material facts, that the Plaintiff presented many additional facts that were determined by this court to be immaterial and of an insubstantial nature to the subject litigation and not applied in this memorandum of decision. This court made its determination of the material facts, based upon the submission of both parties, as it pertains to this record. In that regard the court's findings of material facts are viewed in the light most favorable to the Plaintiff. Due to their extended length, those material facts are set forth in a separate document that is attached and incorporated here[57].

Notwithstanding, to place this motion in context, this court sets forth the following abbreviated material facts:

On February 26, 2007, LifeCell submitted its 510(k) premarket notification for LRTM (LifeCell Regenerative Tissue Matrix) Surgical Mesh, aka Strattice.

Plaintiff was diagnosed with a ventral incisional hernia and her surgeon performed a hernia repair surgery on August 17, 2020. Plaintiff's surgeon used a Strattice mesh for the surgery. Almost a year after her initial implant surgery, Plaintiff returned to the same surgeon complaining of abdominal pain who diagnosed Plaintiff with a recurrent ventral hernia. The surgeon performed another hernia repair surgery on June 3, 2021, and in this instance used a synthetic Parietex mesh to repair the recurrent hernia. Plaintiff's surgeon performed a component separation during this surgery.

Following the second surgery, Plaintiff filed this Complaint against the named Defendants asserting the following causes of action: design defect, failure to warn, breach of express warranty, consumer fraud act violations, and punitive damages.

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[57] The material facts are on a separate thirteen (13) page exhibit.

Discussion[58]

The court first addresses the legal standard governing motions for summary judgement.

Summary judgment must be granted if "the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." R. 4:46-2(c).

This court must "consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill, 142 N.J. at 540. "[T]he court must accept as true all the evidence which supports the position of the party defending against the motion and must accord [that party] the benefit of all legitimate inferences which can be deduced therefrom[.]" Id. at 535 (citations omitted). A judge does not act as the fact-finder when deciding a motion for summary Judgment. Judson, 17 N.J. at 73.

This court must hew to that standard, and so based on this court's review of this record, the Defendants' motion for summary judgment is granted in part and denied in part, as discussed below: Count Eight of the Complaint is dismissed with

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[58] The court presents and addresses the arguments in the same order as they were presented by the Defendants' counsel at oral argument.

The court finds there is a heavy reliance by all counsel on unreported decisions from New Jersey courts (state and federal) and from other states and federal courts outside of New Jersey. This court will not and does not address or consider any unreported cases in the disposition of this motion. See R. 1:36-3. Additionally, this court is mindful of the New Jersey's Supreme Court's previous comment that the state law-based decisions of the federal courts are not binding on the state courts, at least respecting our New Jersey state law, and may be rejected if they are deemed to be incorrect. See Becker v. Baron Bros., 138 N.J. 145, 165 (1994).

prejudice. The Defendants' motion is denied as to Count One, Count Two, Count Six, and Count Nine. However, the court grants that part of the Defendants' motion and applies New Jersey law on Count Nine-punitive damages, if deemed necessary at trial.

Consumer Fraud Act – Count 8 of Complaint

In Count 8, Plaintiff alleges the Defendants engaged in wrongful and deceptive conduct and as a result suffered "ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws." Plaintiff also alleges "Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiff for [Strattice] that would not have been used had Defendants not engaged in unfair and deceptive conduct."

In paragraph 458 of the Complaint, Plaintiff alleges "Defendants knowingly and falsely represented that the Defendants' Hernia Mesh Products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials." In paragraph 461, Plaintiff further alleges, "Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices."

"By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages." See Plaintiff's Complaint at ¶.

Defendants argue this court should grant summary judgment on this CFA claim because the PLA subsumed this CFA cause of action because Plaintiff's claim is "based on harm caused by a product." Defendants assert "these allegations are, at their core, claims for design defect and failure to warn, the NJCFA claim should be

dismissed as subsumed by the NJPLA." Plaintiff disputes this argument and argues because the CFA claim is formed on the basis of Defendants' false statements, it is not subsumed by the PLA.

This court looks to "the essential nature of the claim" and Plaintiff's theory of liability. "New Jersey's Consumer Fraud Act (CFA), N.J.S.A. 56:8-1 to -224, and the PLA, N.J.S.A. 2A:58C-1 to -11, are remedial statutes that target different wrongs, address distinct types of harm, and provide for divergent remedies." Sun Chemical Corp. v. Fike Corp., 243 N.J. 319, 324 (2020)[59]. Sun Chemical involved a single count complaint under the CFA. The District Court granted defendants' motion determining the plaintiff's claims should governed by the PLA. Id. at 326. The Third Circuit certified its questions to the New Jersey Supreme Court. Id. at 327.

The facts in Sun Chemical are distinguishable but they provide insight on the disposition of the Plaintiff's CFA claim. Plaintiff purchased an explosion isolation and suppression system ("System") from the defendants. On the first day the System was operational, a fire occurred in the dust collection system and an alarm on the System's control panel activated but was not audible. Id. at 326. "Sun employees attempted to extinguish the fire, but an explosion sent a fireball through the ducts of the dust collection system, injuring seven Sun employees and causing damage to Sun's facility." Ibid. Sun then sued the defendants under the CFA "alleging

[59] The Third Circuit Court of Appeals certified the questions posed by this case to the New Jersey Supreme Court. Id. at 327. At the time of the Supreme Court's decision, the Court noted, "[t]here is no authority directly addressing the interplay between the CFA and PLA in this setting." Id. at 329. "Although we have thus rejected the idea that contract-based claims could be pled under the PLA, we have not yet considered the question at the center of this matter: whether tort-based claims that can be pled under the PLA can also -- or instead -- be pled under the CFA." Id. at 336.

[defendants] made material oral and written misrepresentations about four aspects of the... System: [the System] (1) would prevent explosions; (2) would have an audible alarm; (3) complied with industry standards; and (4) had never failed." Ibid. Following discovery, both parties filed summary judgment motions.

That Court reviewed and discussed "the pertinent provisions of the CFA and PLA, their purposes, and cases applying them." Id. at 329. Based on their review, the Court then stated, "the CFA and PLA are intended to govern different conduct and to provide different remedies for such conduct. There is thus no direct and unavoidable conflict between the CFA and PLA. The PLA governs the legal universe of products liability actions as defined in that Act and the CFA applies to fraud and misrepresentation and provides unique remedies intended to root out such conduct." Id. at 335-36. The Court determined that "it is the nature of the action giving rise to a claim that determines how a claim is characterized." Id. at 339. "The nature of the plaintiff's damages does not determine whether the cause of action falls under the CFA or PLA; rather, it is the theory of liability underlying the claim that determines the recoverable damages." Ibid. The Court held:

> a CFA claim alleging express misrepresentations -- deceptive, fraudulent, misleading, and other unconscionable commercial practices -- may be brought in the same action as a PLA claim premised upon product manufacturing, warning, or design defects. In other words, the PLA will not bar a CFA claim alleging express or affirmative misrepresentations.
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> [Ibid.]

Therefore, the Court concluded Sun's CFA claim was not subsumed by the PLA.

In Sun Chemical, the Court stressed "[i]f a claim is premised upon a product's manufacturing, warning, or design defect, that claim must be brought under the PLA with damages limited to those available under that statute; CFA claims for the same

conduct are precluded." Id. at 336. The Court further noted, however, "nothing about the PLA prohibits a claimant from seeking relief under the CFA for deceptive, fraudulent, misleading, and other unconscionable commercial practices in the sale of a product." Id. at 336-37. Therefore, "if a claim is based on deceptive, fraudulent, misleading, and other unconscionable commercial practices, it is not covered by the PLA and may be brought as a separate CFA claim." Id. at 337.

In New Jersey, the PLA encompasses virtually all possible causes of action relating to harms caused by consumer and other products. In re Lead Paint Litigation, 191 N.J. 405, 436-37 (2007). The PLA defines a "product liability action" as any claim or action brought by a claimant for harm caused by a product, except actions for harm caused by breach of an express warranty. N.J.S.A. 2A:58C-1(b)(3). The PLA also establishes the sole method to prosecute a product liability action:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.
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> [N.J.S.A 2A:58C-2; Tirrell v. Navistar Int'l, 248 N.J. Super. 390, 398 (App. Div. 1991).]

Accordingly, the PLA no longer recognizes negligence or breach of implied warranties as separate causes of action. Tirrell, 248 N.J. Super. at 398. Moreover, plaintiffs that claim harm from a product, pursuant to the PLA, may not, in addition, maintain a separate, but indistinguishable, count under the CFA. Sinclair v. Merck & Co., Inc., 195 N.J. 51, 66 (2008); see also McDarby v. Merck & Co., Inc., 401

N.J. Super. 10, 98 (App. Div. 2008) In both of those instances, the plaintiffs' CFA claims were subsumed by the PLA.

Relevant in this lawsuit, this Plaintiff attempts to bring both a CFA and PLA claim under separate counts, and this court notes that Sun Chemical also held "PLA and CFA claims may proceed in separate counts of the same suit, [so long as they] alleg[e] different theories of liability and seek[] dissimilar damages." Ibid.

Therefore, upon review of this Plaintiff's claims, this court finds, here, that the Plaintiff's CFA claim is not subsumed by the PLA. Following the decision in Sun Chemical, the Plaintiff's alleged claim arising from Defendants' manufacturing, warning, or design defect of Strattice. The court finds that claim must be brought under the PLA with damages limited to that statute; "CFA claims for the same conduct are precluded." See Sun Chemical, 243 N.J. at 336. Therefore, since the Plaintiff's cause of action allegedly arises due to "alleged deceptive, fraudulent, misleading, and other unconscionable commercial practices in the sale of the product" i.e., Strattice hernia mesh, this court finds this Plaintiff is not precluded from seeking relief under the CFA. See Id. at 337.

However, that does not end this court's analysis on this issue because the Defendants asserted an alternative argument directly under the CFA.

Alternatively, the Defendants argue even if this court were to allow Plaintiff to proceed with a separate claim under the CFA, Count 8 of Plaintiff's Complaint fails to state a viable claim under the CFA. This court agrees with the Defendants and finds the Plaintiff cannot prove a *prima facie* case under the CFA.

The legislature enacted the CFA to "provide[ ] relief to consumers from 'fraudulent practices in the marketplace.'" Dugan v. TGI Fridays, Inc., 231 N.J. 24, 50 (2017) (quoting Lee v. Carter-Reed Co., 203 N.J. 496, 521 (2010)). The three elements of a prima facie case for the CFA are: "1) unlawful conduct by defendants; 2) an ascertainable loss by plaintiff, and 3) a causal relationship between the

unlawful conduct and the ascertainable loss." Bosland v. Warnock Dodge, Inc., 197 N.J. 543, 557 (2009) (citing Int'l union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck and Co., Inc., 192 N.J. 372, 389 (2007). The CFA "created an efficient mechanism to: (1) compensate the victim for his or her actual loss; (2) punish the wrongdoer through the award of treble damages; and (3) attract competent counsel to counteract the 'community scourge' of fraud by providing an incentive for an attorney to take a case involving a minor loss to the individual." Lettenmaier v. Lube Connection, Inc., 162 N.J. 134, 139 (1999).

For purposes of this motion only, the court views the facts favorably to the Plaintiff and finds that a reasonable factfinder can find the Plaintiff established that the Defendants committed an unlawful conduct in the sale of Strattice. However, on this record and even when the facts are viewed in the light most favorable to the Plaintiff, this court finds the Plaintiff did not demonstrate or present any credible evidence regarding any an ascertainable loss as required by the CFA; the court finds the Plaintiff simply alleged, generically in the Complaint, that she sustained an "ascertainable loss." The Plaintiff did not present any credible evidence of an actual loss that is "quantifiable or measurable" to get to a fact finder. Perkins v. DaimlerChrysler Corp. 383 N.J. Super. 99, 106 (App. Div. 2006). The ascertainable loss cannot be "hypothetical or illusory." Ibid.

This court further finds the Plaintiff's bald allegation of a "loss" as found in the Complaint does not meet the necessary element under the CFA. Moreover, Plaintiff also failed to allege a causal relationship between the alleged unlawful conduct and the ascertainable loss. In order to survive summary judgment, a Plaintiff cannot simply allege "an ascertainable loss" or simply allege as was done here that the "Plaintiff and/or Plaintiff's physicians purchased and used the Defendants' product. Plaintiff thereby suffered ascertainable losses as a result of Defendants'

actions in violation of the consumer protection laws." See Plaintiff's Complaint pg. 65 paragraph 446.

Since this court finds since the Plaintiff failed to establish a bona fide claim of an ascertainable loss of an actual amount, the Plaintiff failed to raise a genuine issue of material fact as to the CFA claim. There is no genuine issue as to any material fact regarding Plaintiff's inability to prove a violation of the CFA. See Weinberg v. Sprint Corp., 173 N.J. 233, 254 (2002). Therefore, summary judgment is ordered in favor of the Defendants. Accordingly, Count 8 of the Complaint is dismissed with prejudice.

Breach of Express Warranty – Count 6 of Complaint

Defendants' counsel argues the Plaintiff did not offer any evidence of specific affirmations or promises made by their clients to support this claim and adds, "even if any did exist, they were not part of the basis of the bargain."

Plaintiff argues this particular claim is supported by the law and facts. The PLA does not subsume Plaintiff's express warranty claim, and privity is not required to maintain a breach of express warranty claim. See e.g., Alloway v. General Marine Industries, L.P., 149 N.J. 620, 642-43 (1997). "Whether a given statement constitutes an express warranty is normally a question of fact for the jury." Snyder v. Farnam Cos., Inc., 792 F. Supp. 2d 712, 722 (D.N.J. 2011). Plaintiff references: (1.) that the Defendants made affirmations of fact to Dr. Koelsch regarding Strattice that (2.) became part of the basis of the bargain and that (3.) Strattice did not conform to those affirmations.

This court finds this claim for breach of an express warranty is not subsumed by the PLA. See N.J. Stat. Ann. § 2A:58C-1(b)(3).

Under New Jersey law, "a *prima facie* case for breach of express warranty only requires evidence of non-performance by the warrantor." Ford Motor Credit Co., LLC v. Mendola, 427 N.J. Super. 226 (2012). The court in Mendola stated:

> 'Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.' N.J.S.A. 12A:2-313(1)(a). As opposed to a product liability or common law tort claim, 'the plaintiff in a warranty action need not establish the existence of a defect; the failure of the goods to perform as warranted is sufficient. Proof of causation must still be shown in a case based on breach of an express warranty, but 'mere failure of promised performance is enough without proof of any defect.'
>
> [Ibid. (internal citations omitted.)]

It is not enough to allege an express warranty through general representations about the product; rather, a plaintiff must show a specific express warranty was made by the defendant for the claim to survive. Mendez v. Shah, 28 F. Supp. 3d 282, 294 (D.N.J. 2014). With respect to the "basis of the bargain" element, a plaintiff must allege that they "read, heard, saw or knew of the advertisement containing the [express warranty]" when choosing to use the product. Cipollone v. Liggett Grp., Inc., 893 F.2d 541, 567 (3d Cir. 1990), overruled on other grounds, 505 U.S. 504 (1992). If the Plaintiff did not have access to said material produced by the Defendants, Plaintiff must plead her doctor saw Defendants' statement. Id. at n.29.

In this case, this court finds the Plaintiff provided sufficient material facts showing the Defendants' representative, Jaime Smith, made affirmations of facts including presenting marketing brochures regarding the appropriateness of Strattice to Dr. Koelsch such as its "durability" and its ability "hold up." The court also finds

through expert testimony the Plaintiff demonstrated sufficient material evidence whereby a jury could conclude Strattice did not perform as warranted to Dr. Koelsch.

Accordingly, the Defendants' motion for summary judgment on Count 6 is denied.

Design Defect – Count One of Complaint

In this Count of the Complaint, Plaintiff alleges a claim for a design defect. Plaintiff argues Strattice is defectively designed because its risks outweigh its utility and there were feasible safer alternatives to Strattice.

Defendants argue Plaintiff did not present a suitable alternative design. They argue synthetic mesh is an alternative product used in hernia repair procedures; synthetic mesh is not an alternative design for a biologic mesh like Strattice. According to the Defendants attorneys, Plaintiff's proposed alternative design is an "attack" on a "fundamental characteristic of Strattice" as it is "an altogether different material that would result in an altogether different product."

A design defect is defined by the PLA, N.J.S.A. 2A:58C-1 to -11, and the Plaintiff must establish by a preponderance of the evidence that a "product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it... was designed in a defective manner." N.J.S.A. 2A:58C-2(c). "The decision whether a product is 'not reasonably fit, suitable and safe' requires a risk-utility analysis to determine whether it creates a risk of harm that outweighs its usefulness." Hrymoc v. Ethicon, Inc., 467 N.J. Super. 42, 82 (App. Div 2021) revers. on other grounds 254 N.J. 446 (2023) (quoting Jurado v. W. Gear Works, 131 N.J. 375, 385 (1993)). "A plaintiff who asserts that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that was both practical and feasible at the time the product left the manufacturer's control." Ibid. (quoting Lewis v. Am. Cyanamid Co., 155 N.J. 544, 571, 574-75

(1998)). A design defect is further defined as a danger inherent in a product that was manufactured as intended when that danger, as a public policy matter, is greater than can be justified by the product's utility. See Jurado, 131 N.J. 375; see also Johansen v. Makita U.S.A., Inc., 128 N.J. 86, 95 (1992).

In Diluzio-Gulino v. Daimler Chrysler, 385 N.J. Super. 434, 435 (App. Div. 2006), the Appellate Division reversed the judgment against defendant because the plaintiff's expert failed to provide evidence of an alternative safer design. The plaintiff's expert failed to present an opinion, "substantiated by empirical evidence...." Id. at 438-39. The risk/utility analysis must focus on the specific product before the court, not on a category of products. Becker v. Baron Bros., 138 N.J. 145, 154 (1994).[60]

In a design defect claim, the plaintiff "only needs to prove the manufacturer's product was not 'reasonably' safe," see N.J.S.A. 2A:58C-2, "not that other design alternatives were completely safe." Hrymoc, 467 N.J. Super. at 84. "The phrase 'would have prevented the harm' within the state-of-the-art provision, N.J.S.A. 2A:58C-3, logically must be read to mean 'prevented the degree of harm' caused by the defendant's product, rather than total elimination of risk." Ibid. As stated in Hrymoc, "[v]irtually all products have some inherent risk of harm. If we were to read the state-of-the-art provision as defendants here suggest and require plaintiffs to posit risk-free alternatives, that could eviscerate strict liability in design defect cases." Ibid.

In Becker, the Supreme Court addressed categorical classification in a jury charge. The plaintiff was an auto mechanic and was diagnosed with and died of mesothelioma, a rare form of incurable cancer that affects the pleural membrane, the layer of cells surrounding the lungs and the chest cavity. See, 138 N.J. at 148. The

[60] The Supreme Court noted this case was filed before the enactment of the PLA.

products he used as a mechanic to perform brake repair jobs did not provide any warnings regarding asbestos exposure until sometime around 1975, when manufacturers apparently began putting warnings on some of their products. Ibid. Following trial, the jury returned a verdict of $250,000 for plaintiff's pain and suffering, $500,000 for his wrongful death, and $250,000 for his wife's loss of consortium and services. Id. at 150. The two remaining defendants then moved for, among other relief, a new trial. In denying the new-trial motions, the court stated that its basis for ruling that asbestos products without warnings are defective as a matter of law was "pretty much judicial gut reaction and instinct as well as Beshada."[61] Ibid. The Appellate Division affirmed and concluded "[t]he Beshada Court effectively concluded that asbestos products which are marketed without health warnings are defective as a matter of law." Ibid. The Appellate Division approved the trial court's charge to the jury, that all asbestos-containing products without warnings are defective as a matter of law.

The Supreme Court granted certification and reversed. Id. at 148. The Court explained "a ruling that all asbestos products are the same appears to confound reality. Our courts have acknowledged that asbestos-containing products are not uniformly dangerous and thus that courts should not treat them all alike." Id. at 160. Accordingly, the Court held the Appellate Division's determination "that all asbestos-containing products without warnings are defective as a matter of law was error." Id. at 166. The "error deprived the jury of the opportunity to determine whether the asbestos product was in fact dangerous, and rendered premature and unfounded the court's application of the risk-utility analysis and its conclusion that without a warning the asbestos product was defective as a matter of law." Ibid.

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[61] Beshada v. Johns-Manville Products Corp., 90 N.J. 191(1982).

In this case, Plaintiff identified two expert witnesses: first, Dr. Dipak Panigrahy, M.D., who offered an opinion on an alternative design, stated "biologic mesh is inferior to synthetic mesh, namely and particularly middle-weight, open pore, synthetic polypropylene. Put another way, middle-weight, open pore, synthetic polypropylene is a safer alternative design." (Panigrahy Report p. 42.). Plaintiff's second expert witness is Mike Liang, M.D., who also provided an opinion on a safer alternative design. Dr. Liang opined, "[s]ynthetic polypropylene mesh (synthetic "PP") is considered the 'gold standard' for hernia repair and is the most commonly-implanted hernia mesh." (Liang Report p. 4). He further opined, "the risk/benefit profile of biologic mesh, including Strattice, is unfavorable when compared to middle-weight, open-pore, monofilament polypropylene synthetic mesh." Id. at p. 10. Dr. Liang also noted the synthetic meshes were "commercially available years before Strattice was launched onto the market. The evidence indicates that it is safe and effective and 'inexpensive and… can be safely used to repair hernias in both clean and contaminated surgical wounds.'" Ibid.

On that issue, the Defendants filed a motion to exclude the testimony of Dr. Panigrahy and asserted that expert's opinions are not reliable or helpful.[62] Defendants also argued Dr. Panigrahy is not qualified to opine on a feasible alternative design and did not demonstrate a reliable methodology to support his opinion. Defendants also argued the Plaintiff did not identify a safer alternative design because synthetic mesh is not an alternative design for Strattice, a biologic mesh. According to the Defendants, "synthetic mesh may be an alternative product used in hernia repair procedures, it does not constitute an alternative design for a biologic mesh like Strattice and cannot support a design defect claim." (emphasis

[62] The court conducted a R. 104 hearing regarding the Defendants' motion on February 15, 2024. In the event the court barred this testimony, Plaintiff would rely on the testimony of Dr. Liang.

added.) As noted, this issue arose and was discussed in Becker as well as Hrymoc, albeit in a different context.

This court must view these facts in the light most favorable to the Plaintiff as to the alleged defective design. This court does not accept the out of state, unpublished opinions cited to and relied upon by the Defendants—i.e., Labiche[63] and Barnes[64]—as persuasive on this issue. In Labiche, the Texas Federal District Court addressed a different surgical procedure and also found an "Organic Sling" was not a change of design but a "different product." Id. at *5. Barnes originated from the Federal District Court of Michigan. In Barnes the plaintiff proposed "three feasible alternatives to Defendants' Parietex PCO mesh (1) the Shouldice surgical procedure, (2) biologic mesh, and (3) polypropylene mesh." Id. at *3. The Barnes court looked to an Alabama state court decision, a Texas and the Fifth Circuit Court of Appeals decision to conclude the Plaintiff was precluded from proposing an alternative product as an alternative design. Id. at *6. This court also considered the New Jersey Supreme Court's analysis in Becker.

In opposition, Plaintiff cited to Green. 310 N.J. Super. 507. In Green, the court addressed plaintiff's two alternative car roof designs: (1) a full sheet metal roof; and (2) installation of "two stabilizing bars, one connecting the left corners of the A (front) and B (rear) pillars, and the second connecting the right corners of these pillars." Id. at 523-524. The defendants argued the plaintiff's design "was different." Id. at 525. The appellate court found the "distinction unavailing." Ibid.

This court's research failed to uncover any reported New Jersey court decision that squarely addressed the issue presented, specifically whether a safer alternative

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[63] Labiche v. Johnson & Johnson, No. H-20-4249, 2021 WL 3719554 (S.D. Tex. Aug 19, 2021).
[64] Barnes v. Medtronic, PLC, No. 2:17-cv-14194, 2019 WL 1353880 (E.D. Mich. Mar. 26, 2019).

design to a biologic mesh can be a synthetic mesh or vice versa based on the material composition. So, in the absence of said published authority, this court finds it is entirely appropriate to look to the seven factors that comprise the risk-utility analysis:

> (1) The usefulness and desirability of the product - its utility to the user and to the public as a whole. (2) The safety aspects of the product - the likelihood that it will cause injury, and the probable seriousness of the injury. (3) The availability of a substitute product which would meet the same need and not be as unsafe. (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility. (5) The user's ability to avoid danger by the exercise of care in the use of the product. (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions. (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance. (emphasis added.)
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> [Cepeda v. Cumberland Engineering Co., 76 N.J. 152, 174 (1978).]

Based on that consideration as well as the aforementioned principles, this court finds New Jersey law does not have a categorical distinction regarding material composition as urged by the Defendants. As stated in factor three, above, New Jersey provides for and accepts the availability of a "substitute product which would meet the same need and not be as unsafe." (emphasis added.) So, New Jersey law looks to the "product" and whether there is a substitute product in this case for hernia mesh. According to the Plaintiff's experts, the product at issue is classified as "surgical mesh" and the material composition of the mesh is not a disqualifier. Therefore, this

court finds that, absent authority stating otherwise, a reasonable jury could and should consider synthetic mesh as an alternative hernia mesh design that was both practical and feasible in this litigation. As noted, the Plaintiff's position is supported by an expert's opinion.

Therefore, in viewing the facts favorably to the Plaintiff, a reasonable jury could find that a synthetic mesh is an alternative design hernia mesh that may be considered as an alternative and safer design to the biologic mesh, Strattice. The Plaintiff's experts opine the alternate design is "middle-weight, open pore synthetic polypropylene." This court finds there is no basis to preclude the Plaintiff from presenting this expert testimony as to this alternative design as proposed by the Plaintiff. Plaintiff does not need to show that synthetic mesh prevents all risks or was completely safe.

Moreover, synthetic mesh was in use and existed at the time of the manufacture of Strattice. Both parties also agree that all meshes have an inherent risk of harm, but, as the Plaintiff contends, synthetic mesh would have reduced the risk of harm—i.e., recurrence. A reasonable jury could find the Strattice mesh was not reasonably fit, suitable, or safe for its intended purpose because it was designed in a defective manner. The design defect was the use of the biologic material and, as noted, the Plaintiff provided the existence of an alternative design that was both practical and feasible at the time the product left the Defendants' control.

Accordingly, the Plaintiff established the existence of a material issue of fact as to the design defect claim. The Defendants' motion for summary judgment on Count 1 is denied.

Moreover, since this court finds that the facts reveal synthetic mesh existed at the time Strattice left the control manufacturer and was "a practical and technically feasible alternative design that would have prevented the harm [to the plaintiff] without substantially impairing the reasonably anticipated or intended function of

the product," see N.J.S.A. 2A:58C-3(a)(1), the Defendants are not entitled to have the jury instructed as to the state-of-the-art defense. This court finds the Defendants simply argued the categorical/material composition distinction of synthetic mesh versus biologic mesh. The court further finds the Plaintiff presented sufficient material evidence for a jury to find synthetic mesh would have prevented the degree of harm for a hernia recurrence.

Failure to Warn – Count Two of Complaint

In Count Two, Plaintiff alleges the Defendants failed to provide adequate and proper warnings and/or instructions regarding, among other things, the serious risk of bodily harm posed by the incompatibility of the material used to make the mesh and human blood and tissue or the serious risk of infection or serious scarring. See Plaintiff's Complaint at ¶ 280.

According to Plaintiff, the Defendants also allegedly failed to warn and instruct Plaintiff and Plaintiff's physicians as to the risks and benefits of the product, including adequately and properly the following:

> that the product is no more effective in repairing hernias than suture repair and carried a significantly higher risks for infection, scar tissue formation, recurrence, bowel obstruction and other serious risks leading to the need for revision and repair; b. that the product creates fluid collection, inflammation, which results in seroma formation, potentiating infections; c. that the biologic materials used in Strattice mesh created significant tissue ingrowth and adhesions leading to bowel complications, significant pain and the need for revision and repair; d. that the product may create significant scar tissue resulting in elastin creation which results in bulging and recurrence of hernias; e. that for patients who have more complicated comorbidities or higher risk surgeries, biologic mesh is inferior to synthetic mesh in hernia repair, as opposed to how they promoted it as more effective for that patient population; f. that Defendants did not adequately study

> and/or test the product and/or its labeling, including the lack of clinical trials concerning its safety; and g. that the product was ineffective at preventing adhesions; the biologic materials would create a greater risk for fluid collection and inflammation thus leading to infections.
>
> [Id. at ¶ 283.]

To support this allegation, Plaintiff principally contends the Defendants failed to warn Dr. Koelsch of Strattice's "significantly elevated risk of recurrence over cheaper synthetic mesh," Defendants made off-label, false statements to Dr. Koelsch regarding Defendants' mechanism of action i.e., Strattice regenerates when it really resorbs, Defendants promoted Strattice off-label for use to high-risk patients like Plaintiff who were not identified in the FDA-cleared Indications for Use without supporting data, and Defendants failed to warn about any risks associated with Strattice in its warning label. Plaintiff's attorneys also focused on the "high" rates of complications and a lack of "valid scientific studies" of Strattice and of the Defendants' marketing claims regarding regeneration, resorption, and the use of Strattice in comorbid patient populations that are off-label promotion.

Plaintiff specifically argues the Defendants never warned Plaintiff or Plaintiff's surgeon about this information and further argue "there are no specific risks identified at all in Strattice's Instructions for Use." Plaintiff's attorneys focus on their Exhibit 91—a 2019 marketing piece produced by the Defendants and entitled, "Don't Mesh Around."[65] Plaintiff proffered the opinion of their expert, Mike K. Liang, MD, FACS, to opine that the Strattice mesh failed and was the cause

[65] Plaintiff cited to Cornett v. Johnson & Johnson, 414 N.J. Super. 365, 402 (App. Div. 2010) aff'd in part and mod. in part, 211 N.J. 362 (2012) regarding off label use.

of Plaintiff's recurrence and necessitated further surgery. Notably, the Defendants did not challenge Dr. Liang's opinions.

In Count Three, Plaintiff seeks a judgment against the Defendants in excess of $15,000.00 together with costs expended and other relief as this court deems just and appropriate.

The Defendants disagreed and argued, the Plaintiff cannot overcome the presumption of adequacy or alternatively, that Dr. Koelsch knew and understood the risks associated with Strattice before the Plaintiff's August 17, 2020 hernia repair surgery. Defendants also argued the learned intermediary doctrine applies. Defendants referenced and cited specifically to Dr. Koelsch's deposition testimony to support his independent knowledge of the risk of recurrence and that he informed the Plaintiff of this risk before her Strattice implant surgery. According to Defendants, Dr. Koelsch understood the risk of recurrence before implanting Strattice in Plaintiff's hernia repair surgery, and that is an undisputed material fact that is fatal to this claim. Similarly, Defendants argue Dr. Koelsch also understood recurrence was a potential risk of any hernia repair surgery, regardless of the type of mesh used, and also knew recurrence was a risk associated with Parietex, a type of synthetic mesh he used in Plaintiff's second hernia repair surgery.

Defendants also argued since Strattice is subject to FDA oversight, it "is entitled to the presumption provided under N.J.S.A. 2A:58C-4." In addressing the Plaintiff's arguments that the Defendants did not disclose the "elevated risk of recurrence"; the Defendants contend that does not amount to "deliberate" nondisclosure "and the risk of recurrence is not 'after acquired knowledge.'" Defendants argue, "LifeCell, the FDA, and surgeons all knew about the risk of recurrence at the time Strattice was cleared by FDA."

As noted, the Plaintiff countered and stated the Defendants engaged in "rampant" off-label promotion, made false statements, and completely failed to warn

about Strattice's true risks, benefits, and clinical performance. That failure to warn also included the failure to warn the Plaintiff's doctor. The Plaintiff also argues the ability to overcome the presumption of adequacy.

Under N.J.S.A. 2A:58C-2,

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it . . . b. failed to contain adequate warnings or instructions....
>
> [(Emphasis added.)]

N.J.S.A. 2A:58C-4 defines an adequate warning as

> one that a reasonably prudent person in the same or similar circumstances would have provided with respect **to the danger** and that communicates adequate information on the **dangers** and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.
>
> [(Emphasis added.)]

In New Jersey, "[t]he PLA imposes strict liability if a product manufacturer or seller failed to provide adequate warnings concerning the dangers posed by a product's use." Hrymoc, 467 N.J. Super at 84 (citing Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 524 (2007)). In a failure-to-warn strict liability case, a manufacturer has a duty to warn foreseeable users of the dangers of using its product. Id. at 84-85 (citing Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 207 (1984)). "In essence, the adequacy of a warning is to be considered in the context of all communications by the product manufacturer or seller to the anticipated users of the

product." Koruba, 396 N.J. Super at 525. Ultimately, "the question of whether a warning is adequate is one for a jury to resolve." Levy v. Yamaha Motor Corp., U.S.A., 361 N.J. Super. 312, 318 (App. Div. 2003). Accordingly, this court finds the PLA requires an adequate warning or instruction from a manufacturer concerning "dangers" of the drug or devise; the PLA does not require a warning on the rates of risks.

Where, as in this case, the failure-to-warn involves something advised by a physician, such as a medical device, like Strattice, "the issue is whether the warning should have been given to the prescribing physician." London v. Lederle Labs., 290 N.J. Super. 318, 327 (App. Div. 1996), aff'd as modified sub nom, Batson v. Lederle Labs., 152 N.J. 14 (1997). The Defendants asserted the applicability of the learned intermediary doctrine. New Jersey's "learned intermediary" doctrine ("doctrine"), provides that "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Id. at 85 (quoting Perez v. Wyeth Labs. Inc., 161 N.J. 1, 10 (1999) (other citation omitted.)). The doctrine "recognizes that a prescribing doctor has the primary responsibility of advising the patient of the risks and benefits of taking a particular medication." Ibid. (quoting In re Accutane Litig., 235 N.J. 229, 239 (2018)). Thus, "it is the physician's responsibility to pass on to the parties the information that enables the patient to use the product safely." Ibid. (quoting Niemiera by Niemiera v. Schneider, 114 N.J. 550, 565-66 (1989)). However, when there is a failure to adequately warn the physician, the learned intermediary doctrine as a defense simply drops away. See Perez, 161 N.J. at 19. The focus is on the warning, if any, by the manufacturer. Accordingly, the court finds that unless the adequacy of the warning can be rebutted, the learned intermediary doctrine applies.

The court next examines whether a reasonable jury could find that the Plaintiff presented sufficient evidence to overcome the presumption of adequacy. N.J.S.A. 2A:58C-4 provides,

> [i]f the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration, . . . a rebuttable presumption shall arise that the warning or instruction is adequate . . . .
>
> [(Emphasis added.)]

Since Strattice was approved by the FDA, the Defendants are initially entitled to the presumption of adequacy.

However, there are three pathways to for the Plaintiff to overcome said presumption:

> The first pathway is if a plaintiff can establish "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." The second is if a plaintiff can demonstrate "economically-driven manipulation of the post-market regulatory process." The third is if a plaintiff can prove by clear and convincing evidence that a manufacturer knew or should have known in the post marketing phase that the drug warnings were inadequate based on the label warning updating requirements in 21 C.F.R. § 201.57(c), 21 C.F.R. § 314.70(c), or any other pertinent federal regulation.
>
> [Accutane, 235 N.J. at 277-78. (internal citations omitted.)]

As indicated, to overcome that presumption, a plaintiff must "present[] clear and convincing evidence that a manufacturer knew or should have known, based on newly acquired information, of a causal association between the use of the drug and 'a clinically significant hazard' and that the manufacturer failed to update the label

accordingly." Id. at 275. "Clear and convincing evidence" is evidence that produces "a firm belief or conviction" in the truth of the alleged facts sought to be established. N.J. Model Civil Jury Charges 1.19 Revised 2011); see also In re Perskie, 207 N.J. 275, 290 (2011).

Based on this record, the court finds that a reasonable jury can find the Plaintiff can overcome all of the three pathways by clear and convincing evidence. For the first pathway, Plaintiff asserted:

> 1. LifeCell was aware of and did not disclose the elevated risk of recurrence with Strattice relative to Plaintiffs' safer alternative design no later than December 2018 and well before Plaintiffs' surgery.
>
> 2. LifeCell knew in 2007 and did not disclose that it did not have any scientific support for the claim that Strattice could be used in high-risk patients like those in Grade 2 with obesity.
>
> 3. LifeCell knew but did not disclose that the RAM2P study, which compared Strattice to a synthetic mesh in patients with comorbidities resulted in over 90 adverse events in only 23 patients and was terminated early.
>
> 4. Despite consciously choosing to not conduct a resorption study for over a decade, LifeCell knew but did not disclose that Strattice resorbed long before Plaintiffs' surgery.
>
> 5. LifeCell chose not to disclose any of this risk information to Dr. Koelsch and Blakeley.
>
> 6. Quite the opposite. LifeCell falsely told Dr. Koelsch the opposite: that Strattice regenerate and did not resorb and that it was the ideal repair material in a Grade 2 patient like Blakeley.
>
> [Plaintiff's Opposition Br. at pp. 12-13.]

For the second pathway, the Plaintiff asserted:

> 1. LifeCell knew or should have known that Grade 2 patients were off-label but targeted them anyway because they presented a sizeable market opportunity of an additional $80-$100 million in annual revenue.
>
> 2. LifeCell knew that its regeneration claim, which FDA said was inappropriate, unsupported, and merely a hypothetical or theory, was critical to its ability to capture some or all of this market; so it made that off-label and unsupported claim anyway to differentiate Strattice and increase its market share.
>
> 3. As a result of LifeCell's aggressive and off-label promotion, it generated revenues of almost $1.5 billion through 2022.
>
> [Id. at p. 13.]

For the third pathway, the Plaintiff asserted LifeCell should have known that its warning label was inadequate because:

> 1. It does not warn of any specific risk of harm at all.
>
> 2. There is no adverse reaction section.
>
> 3. There are no warnings about its unsupported off-label regeneration claim, that higher risk Grade 2, 3, and 4 patients were off-label and that LifeCell had data supporting Strattice use in them, or that instead of providing a strong and durable repair, Strattice resorbs after 3 months.
>
> 4. The evidence also shows that LifeCell should have known of the risks of harm associated with Strattice in these patients—all LifeCell had to do was conduct a timely resorption study, study the use of Strattice specifically in Grade 2 patients it was targeting, and implement an adverse event reporting system designed

> to identify whether Strattice was failing or malfunctioning in these patients. LifeCell did none of these things.
>
> [Ibid.]

On this record and viewing the facts in the light most favorable to the Plaintiff, this court finds the Defendants also promoted positive attributes rather than a warning for Strattice in their referenced brochures. The record included the Defendants' "Don't Mesh Around" marketing brochure, which included affirmative remarks regarding Strattice including that Strattice, "[a] 100% Biologic Mesh, is a Durable Solution for abdominal wall reconstruction based on the long-term outcomes of low hernia recurrence rates across multiple published clinical studies." There was one "contraindication" in that document that stated "[t]hese products should not be used in patients with a known sensitivity to porcine material and/or Polysorbate 20." That information was clearly insufficient to constitute a warning under the PLA.

Accordingly, the court finds Plaintiff has rebutted the presumption of adequacy. Indeed, the record is silent as to any specific manufacturer warning on or about the Strattice mesh. The court considered all the communications issued by the Defendants that were addressed in this motion and did not find any warning. In fact, it appears there is no undisputed that the Defendants did not issue or provide any warning. Therefore, the Defendants are not entitled to the use of learned intermediary doctrine because a reasonable jury could conclude that Dr. Koelsch did not have full knowledge of the Strattice risks—i.e., the warning was not adequate. The jury could also find there was misinformation conveyed by the Defendants regarding Strattice in marketing material and as to the FDA clearance in the Plaintiff's claim of off label marketing.

Next, the court must also analyze causation. In order to succeed on a claim for failure-to-warn, a plaintiff must also prove that an adequate warning or instruction would have prevented their injuries. Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 209 (1984). "When the alleged defect is the failure to provide warnings, a plaintiff is required to prove that the absence of a warning was a proximate cause of his harm." James v. Bessemer Processing Co., 155 N.J. 279, 297 (1998) (quoting Coffman v. Keene Coro., 133 N.J. 581, 594 (1993)). In other words, a plaintiff must prove that an adequate warning, if provided, would have prevented the plaintiff from using the prescription drug or product in question. See Perez, 161 N.J. at 28.

However, "[d]ue to the individualized nature of the inquiry into what warning would have caused the plaintiff to alter her behavior . . . predicting how additional information would have affected any given individual may be well-nigh impossible." Ibid. (internal citations omitted). Thus, to counter this difficulty, New Jersey adopted the "heeding presumption." See Coffman, 133 N.J. at 597-98. The heeding presumption "provides the plaintiff with a rebuttable presumption on the issue of proximate cause [that], if a[n] [adequate] warning or instruction had been given, such warning or instruction would have been heeded by the plaintiff." Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 68 (App. Div. 1998), aff'd o.b., 158 N .J. 329 (1999). "The heeding presumption in failure-to-warn cases furthers the objectives of the strong public policy that undergirds our doctrine of strict products liability." Coffman, 133 N.J. at 602-03. Where the heeding presumption applies and the court finds it is appropriate here,

> the burden of production on the issue of proximate cause shifts to the defendant to come forward with rebuttal evidence. In essence, the defendant's burden of production requires evidence sufficient to demonstrate . . . that a warning would have made known to the plaintiff the danger of the product and, notwithstanding the knowledge imparted by the warning, the plaintiff would have

> proceeded voluntarily and unreasonably to subject him or herself to the dangerous product . . . . If the defendant fails to meet its burden of production to the trial court's satisfaction, the trial judge is required to direct a verdict in favor of the plaintiff on the issue of proximate causation. If, however, the defendant presents rebuttal evidence such that reasonable minds could differ as to whether the warning, if given, would have been heeded by the plaintiff, the defendant has satisfied its burden of production and the plaintiff loses the benefit of the presumption. The plaintiff must then carry the burden of persuasion as to proximate cause.
>
> [Sharpe, 314 N.J. Super. at 68-69 (internal citations and quotations omitted).]

In essence, Defendants' burden of production requires "evidence sufficient to demonstrate . . . that a warning would have made known to the plaintiff the danger of the product and, notwithstanding the knowledge imparted by the warning, the plaintiff would have proceeded voluntarily and unreasonably to subject him or herself to the dangerous product." Coffman, 133 N.J. at 604.

In an effort to rebut causation, the Defendants point out the surgical risks that were known by Dr. Koelsch, and that those risks were conveyed by him to the Plaintiff, such as: (a.) Recurrence; (b.) Infection; (c.) Bleeding; (d.) Damage to intra-abdominal structures; and (e.) Removal or explant of mesh. Dr. Koelsch also understood the following:

1. Dr. Koelsch also understood that a patient who is morbidly obese, like Plaintiff, has a higher risk of recurrence and infection than someone who is not morbidly obese.

2. Dr. Koelsch understood that recurrence and infection were potential risks regardless of the type of mesh used—i.e., regardless of whether he chose a biologic or synthetic mesh.

3. During his deposition, Dr. Koelsch testified that recurrence and infection are risks of using a Parietex mesh, a synthetic mesh manufactured by Covidien that he used regularly in his practice, and that he personally experienced both recurrence and infection in patients who had Parietex meshes implanted. Regarding infection, Dr. Koelsch testified that the infections with Parietex mesh are "horrible" because "it's hard to explant a synthetic mesh."

4. Dr. Koelsch understood these risks based on his education and experience as a general surgeon.

5. Dr. Koelsch testified that biologic mesh, like Strattice, is a safe product. He understood that many risks are inherent with any surgery, regardless of which mesh is used.

On this record, and viewing the facts favorably to the Plaintiff, this court reiterates its finding that the Defendants failed to provide any warning and that failure also extended to Plaintiff's doctor regarding Strattice. As to causation, the court finds Dr. Koelsch, as the surgeon, understood the general risks of hernia implant surgery; however, Dr. Koelsch did not receive any specific Strattice warning. This court finds the surgeon's knowledge of general risks is not a substitute for an adequate warning or instruction that should have been issued by the Defendants of any dangers, adverse reactions, or complications associated with Strattice. See Campos, 98 N.J. at 209. Accordingly, the court finds that a reasonable jury could find the Defendants did not present sufficient evidence to meet their burden of production.

However, for purposes of completeness, the court finds, even if the Defendants submitted sufficient evidence to rebut the burden of production and shifted the burden of persuasion, a reasonable jury could find the Plaintiff presented sufficient evidence to present the issue of causation to a jury. Indeed, Dr. Koelsch

testified, specifically, if he knew of the alleged Strattice recurrence rates, he would not have used it in Plaintiff's surgery. See In re Diet Drug Litigation, 384 N.J. Super. 525, 545 (Law Div. 2005) (citing Sharpe, 314 N.J. Super. at 63) (finding where the physician indicates they would have communicated the risk to the patient, there remains a factual question for the jury regarding proximate cause). This court agrees with those cases.

Accordingly, this court finds the Defendants are not entitled to summary judgment on this failure to warn cause of action. A reasonable jury could find the Defendants did not provide an adequate warning regarding Strattice and that the lack of an adequate warning was the proximate cause of Plaintiff's injury. The court also finds the presumption of adequacy and the learned intermediary doctrine do not apply at trial. The Defendants' motion for summary judgment on Count 2 is denied.

Punitive Damages – Count 9 of Complaint

The Defendants' attorney argues under New Jersey law, there is no evidence in this case that would permit a reasonable factfinder "to find, under the heightened standard of clear and convincing evidence, that Defendants have acted with actual malice or with a wanton and willful disregard for others." So, their clients are entitled to summary judgment on this claim. Defendants analyzed the law supporting their argument.

Plaintiff's attorney contends "[t]here are two disputes relative to punitive damages. The first is which state's law should apply under New Jersey's significant relationship test, and the second is whether Plaintiffs' designated evidence is sufficient to support a punitive damages claim." Plaintiff contends this court should apply Kentucky or Illinois punitive damages law to this claim and provided their analysis that supported their argument.

In this case, all parties agree that New Jersey law applies to all of the other claims asserted by the Plaintiff with the exception of the application of any punitive damages. To resolve this issue, this court looks to Accutane, 235 N.J. at 263. In that decision, the Supreme Court noted its authority under Rule 4:38A where it,

> may designate a case or category of cases as [MCL] to receive centralized management in accordance with [promulgated] criteria and procedures. MCL is a grouping of "mass tort" cases that typically involve substantial numbers of claims associated with a single product, a mass disaster, or a complex environmental event. MCL Resource Book 1. One of the criteria for MCL status is whether the cases "involve[ ] many claims with common, recurrent issues of law and fact." Other criteria include "whether centralized management is fair and convenient to the parties, witnesses and counsel" and "whether the cases require specialized expertise and case processing."
>
> [Ibid. (internal citations omitted).]

The Court also cited to Restatement § 146, Section 6 pertaining to "the factors relevant to the choice of the applicable rule of law:"

> (a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in the determination and application of the law to be applied.
>
> [Id. at 261-62 (citing Restatement § 6(2)).]

As in Accutane, this court also finds the two most significant Restatement factors in this MCL are also factors "f" and "g" in applying a single standard to govern the determination of any punitive damages in all of the ninety-three (93) individual cases

originating from thirty-one (31) states. Id. at 263. This court finds that the application of New Jersey law will ensure predictable and uniform results for all parties "rather than disparate outcomes among similarly situated plaintiffs" without the disparity of where the plaintiffs reside.

Therefore, as in Accutane, this court finds New Jersey law applies to the application of any punitive damages claims as "New Jersey has the most significant relationship to the occurrence and the parties, thus overcoming [Restatement] section 145's presumption that the law of the place of injury governs."

As provided in Hrymoc, 467 N.J. Super. at 76-77:

> Under the New Jersey Punitive Damages Act ("PDA"), punitive damages may be imposed if the jury finds a defendant behaved with "actual malice" or a "wanton and willful disregard of persons who foreseeably might be harmed" by that wrongful behavior. N.J.S.A. 2A:15-5.12(a). The PDA calls for the trier of fact to "consider all relevant evidence" on the subject, including such topics as the defendant's state of mind and the severity and duration of the conduct. Ibid.

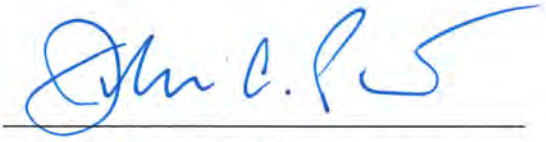
The PLA allows punitive damages only "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the [FDA]'s regulations, which information was material and relevant to the harm in question[.]" N.J.S.A. 2A:58C-5(c). Cornett v. Johnson & Johnson, 414 N.J. Super. at 405.

The court finds a reasonable jury could find on this record, the Defendants knowingly withheld or misrepresented information or acted with actual malice in their actions associated with Strattice. Accordingly, the Defendants' motion for summary judgment on the application of the choice of law in Count 9 of the Complaint-Punitive Damages is granted and New Jersey law applies.

Conclusion

Based upon the above analysis, the court finds summary judgment is ordered in favor of the Defendants on the CFA cause of action in Count Eight as well as to the application of the choice of law in Count 9 of the Complaint-Punitive Damages. Summary judgment is denied as to Count One-Design Defect, Count Two-Failure to Warn and Count Six-Breach of Express Warranty.

An appropriate Order is entered on eCourts. Conformed copies accompany this Memorandum of Decision.



HON. JOHN C. PORTO, P.J.Cv. Date: February 23, 2024

IN RE STRATTICE HERNIA MESH LITIGATION

Theresa Blakeley v. LifeCell Corp., et al.,
Case No. ATL-L-001214-22

Findings of Material Facts

A. Strattice

1. LifeCell Corporation ("LifeCell"), a medical device manufacturer, submitted a premarket notification for Strattice, pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, on February 26, 2007.
2. Strattice Reconstructive Tissue Matrix ("Strattice") is a surgical mesh derived from porcine dermal tissue that is LTM Surgical Mesh is intended for use as a soft tissue patch to reinforce soft tissue or weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing per bridging material to obtain the desired surgical outcome.
3. LifeCell's goal in developing Strattice was to create a "regenerative tissue matrix (RTM) produced from porcine dermal tissue."
4. At the time of Strattice's development, synthetic mesh was the "standard of care" for hernia repair and biologic mesh was "relatively new in the hernia marketplace."
5. LifeCell wanted to establish biologic mesh as the gold standard of care.
6. When LifeCell gauged the interest of a surgeon focus group early in the development process, the group—all users of synthetic hernia mesh—was "excited about the xenograft [biologic] opportunity" and the technology presented-LifeCell's suggestion that the xenograft would regenerate host tissue.

7. The FDA issued its clearance for Strattice, under Section 510(k), on June 11, 2007, as a Class II medical device and its indications for use include the repair of hernias and/or body wall defects.
8. LifeCell prepares quarterly and annual reports analyzing its post-market surveillance data, like its 2022 Periodic Safety Update Report that analyzed LifeCell's post-market surveillance activities for Strattice from January 1, 2022 through December 31, 2022.
9. The 2022 Periodic Safety Update Report includes worldwide complaint rates for various potential adverse events, with most rates under 1%, and 187 out of 240 reported complaints (77.9%) came from legal filings (one of which was Ms. Blakeley).
10. The 2022 Periodic Safety Update Report concluded that "there is sufficient data available from clinical use to demonstrate safety and performance."
11. Surgeons have used Strattice since 2008 and continue to do so today.
12. In May of 2020, AbbVie Inc. acquired Allergan plc and its subsidiaries, including LifeCell, Allergan USA, Inc., and Allergan, Inc. Following this acquisition, Defendants began the process of moving their corporate headquarters to North Chicago, Illinois, where AbbVie maintains its own corporate headquarters. This move took more than a year and was not completed and formalized until August 1, 2021.
13. LifeCell's development, manufacturing, and distribution facilities for Strattice have been located in New Jersey since its inception and remained in New Jersey even after the move of the corporate headquarters.

B. FDA Clearance, LifeCell Marketing, and Strattice Label

14. FDA's cleared indications for use for Bard Soft Mesh and Prolene Soft Mesh are virtually identical to that of Strattice.

a. Bard Soft Mesh: Bard Soft Mesh is indicated to reinforce soft tissue where weakness exists, e.g., repair of hernias and chest wall defects.

b. Prolene Soft Mesh: The PROLENE, Soft (Polypropylene) Mesh is indicated for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

c. Strattice: Strattice TM is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damages or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

15. Bard Soft Mesh and/or Prolene Soft Mesh "ha[ve] been commercially available years before Strattice was launched onto the market."

16. Bard Soft Mesh was FDA-cleared onto the market in 2004 and Ethicon's Prolene Soft Mesh was FDA-cleared onto the market in 2000.

17. Accordingly, both received FDA clearance and were on the market before Strattice, which was first cleared in June 2007 before launch in early 2008.

18. At no time did LifeCell publicly warn or inform surgeons that Strattice resorbs in its IFU or marketing and promotional materials.

19. Even current IFUs post-dating the resorption study fail to disclose that Strattice resorbs when implanted into the body. The IFU also fails to warn of strength problems associated with Strattice's resorbable profile and otherwise known by LifeCell and observed in studies.

20. LifeCell failed to warn about resorption even though it had claimed affirmatively that Strattice does not resorb and knew that resorption was a bad outcome.

21. LifeCell affirmatively represented to surgeons that Strattice regenerated, remained intact, provided a strong and durable repair, and did not resorb, which it identified as a bad outcome.
22. LifeCell did not warn about resorption even when concerns grew organically in the physician community about whether Strattice resorbs or goes away. Instead, LifeCell pushed back.
23. LifeCell's marketing team rolled out key messages through sales reps and marketing materials as late as 2015 that Strattice's mechanism of action was "Regeneration Not Resorption" and that Strattice "regenerates and continues to reinforce over time."
24. LifeCell's marketing department continued to take the position through 2018 when the regulatory department questioned the "regenerative" claim, that "we do not consider our mechanism of action to be resorption, we identify as reconstructive or regeneration."
25. The IFU does not warn surgeons that Strattice has not been studied in high-risk patients or that those patients were off-label.
26. LifeCell identified that by targeting Grade 2 patients with comorbidities, there was a "potential to add 80 to 100 million dollars to annual LifeCell revenue."
27. The IFU does not warn surgeons about the elevated risk of recurrence demonstrated by the three RCT(s) discussed herein or correct the claim made in marketing that Strattice has a single-digit recurrence rate.
28. The "Don't Mesh Around" brochure claims: "Procedures and patients can be complex," including those involving comorbidities like "obesity."
29. That brochure claims: Surgeons should not "mesh around in complex hernia repair. Choose Strattice RTM."

30. That brochure claims: "91.7% of patients were recurrence free at 7 years post-op" and that Strattice had a cumulative, single digit recurrence rate of approximately "8.3% at 7 years post-op."
31. That brochure claims: Strattice is "reliable," a "durable solution," and provides a "reinforced repair" for abdominal wall reconstruction.
32. That brochure claims: Strattice "demonstrate[s] remodeling". The brochure also claims that "not all biologic tissue matrices are the same: regeneration is key."
33. That brochure claims: LifeCell's "proprietary tissue processing allows for cell repopulation, rapid revascularization, and white blood cell migration," which LifeCell described as a "positive recognition" otherwise known as "regeneration."
34. That brochure claims: LifeCell "ha[s] a deep understanding of regenerative properties of acellular tissue matrices, solidifying [its] impact on the science behind abdominal wall reconstruction."

C. Expert Testimony

35. Plaintiff disclosed three experts in this case: a regulatory expert, a surgeon expert, and a pathology/biomedical expert.
36. Plaintiff's pathology/biomedical expert, Dr. Dipak Panigrahy, opined that "biologic mesh is inferior to synthetic mesh, namely and particularly middle-weight, open pore, synthetic polypropylene." He opined that "middle-weight, open pore, synthetic polypropylene is a safer alternative design."
37. Plaintiff's surgeon expert, Dr. Mike Liang, similarly opined that synthetic polypropylene mesh "is considered the 'gold standard' for hernia repair and is the most commonly implanted hernia mesh." He opined that the "'ideal' (i.e., safest and most effective) hernia mesh applicable to the vast majority of

hernia repairs is a middle-density (middle weight), open pore, monofilament synthetic polypropylene mesh" and that "[t]his design has proven itself to be the most ideal and biocompatible over the years."

D. Plaintiff's Medical Course

38. Plaintiff is a 52-year-old woman who resides in Kentucky.

39. Plaintiff presented to Dr. David Koelsch, a general surgeon, at West Kentucky Surgical on August 4, 2020, complaining of abdominal pain. Dr. Koelsch diagnosed Plaintiff with a ventral incisional hernia.

40. Prior to seeing Dr. Koelsch, Plaintiff presented to another surgeon in Hopkinsville, Kentucky; Plaintiff was instructed to lose 80 pounds before undergoing any hernia surgery.

41. Although Plaintiff was unable to lose weight, Dr. Koelsch decided it was best for Plaintiff to undergo surgery, and Dr. Koelsch performed a hernia repair surgery on August 17, 2020.

42. Dr. Koelsch used a Strattice mesh, during Plaintiff's August 17, 2020 hernia repair surgery.

43. The Strattice mesh Plaintiff received contained the lot number SP100172-075, and it was manufactured by LifeCell in New Jersey on October 28, 2019. LifeCell shipped the Strattice mesh to Murray-Calloway Hospital—where Plaintiff's implant surgery took place—on February 18, 2020.

44. Prior to recommending surgery on August 17, 2020, Dr. Koelsch understood the risks, benefits, and alternatives of surgery. Specifically, Dr. Koelsch understood the risks of:

    a. Recurrence;
    b. Infection;
    c. Bleeding;
    d. Damage to intra-abdominal structures, and
    e. Removal or explant of mesh.

45. Dr. Koelsch also understood that a patient who is morbidly obese, like Plaintiff, has a higher risk of recurrence and infection than someone who is not morbidly obese.

46. Dr. Koelsch understood that recurrence and infection were potential risks regardless of the type of mesh used—i.e., regardless of whether Dr. Koelsch chose a biologic or synthetic mesh.

47. Specifically, Dr. Koelsch testified that recurrence and infection are risks of using a Parietex mesh, a synthetic mesh manufactured by Covidien that Dr. Koelsch used regularly in his practice, and that he personally experienced both recurrence and infection in patients who had Parietex meshes implanted. Regarding infection, Dr. Koelsch testified that the infections with Parietex mesh are "horrible" because "it's hard to explant a synthetic mesh."

48. Dr. Koelsch understood these risks based on his education and experience as a general surgeon.

49. Dr. Koelsch testified that biologic mesh, like Strattice, is a safe product. He understood that many risks are inherent with any surgery, regardless of which mesh is used.

50. Dr. Koelsch testified that one of the main reasons for using a biologic mesh was to avoid the risk of an infection with a synthetic mesh.

51. Dr. Koelsch testified,

> "one of the major complications you can get from an open hernia repair is a wound infection or a wound healing problem. And with that, if you're using synthetic mesh, then you can potentially cause the mesh to become contaminated and infected, which is a really big problem, and it's a very difficult problem to treat. t's miserable for the patients. And so for that reason, . . . there was a lot of

> proponents at the time to use this biologic mesh because they had a propensity to not be infected."

52. Dr. Koelsch discussed with Plaintiff the risks, benefits, and alternatives to surgery. Plaintiff testified that Dr. Koelsch warned her of the following risks:

    a. Recurrence;
    b. Abdominal pain; and
    c. General surgical complications.

53. In addition, Plaintiff testified that she understood her obesity increased the risk of complications following surgery.

54. Dr. Koelsch testified that he would have explained the benefits of using biologic mesh over synthetic mesh to Plaintiff.

55. Plaintiff reviewed and signed a general surgical consent form before her August 17, 2020 surgery, which explicitly acknowledges that her surgeon "explained the potential benefits and risks associated with the [implant surgery]" and that her surgeon "has also explained to [her] the alternatives to this procedure which may be available and the major benefits and risks associated with those alternatives."

56. Plaintiff testified that she believes Dr. Koelsch adequately warned her of the risks associated with having her Strattice implant surgery on August 17, 2020.

57. Before her August 17, 2020 surgery, Plaintiff did not know what company manufactured the mesh she received.

58. Before her August 17, 2020 surgery, Plaintiff did not receive any written information from LifeCell, Allergan, or the companies' employees, nor did she talk to anyone from LifeCell or Allergan.

59. Plaintiff did not receive any information at all about LifeCell or Allergan before her August 17, 2020 surgery, and she did not think that Dr. Koelsch was an agent or employee of LifeCell or Allergan.

60. Following her Strattice surgery, Plaintiff presented back to Dr. Koelsch on May 4, 2021, complaining of abdominal pain. Dr. Koelsch diagnosed Plaintiff with a recurrent ventral hernia.

61. On June 3, 2021, Dr. Koelsch performed another hernia repair surgery on Plaintiff, where he used a synthetic Parietex mesh to repair Plaintiff's recurrent hernia. Dr. Koelsch performed a component separation during this surgery.

62. In June 2021, following Plaintiff's Parietex surgery, Plaintiff's husband heard an attorney advertisement on the radio related to hernia mesh. After hearing that advertisement, Plaintiff filed the present lawsuit.

E. Case Specific Facts

63. LifeCell sales representative Jaime Smith ("Smith") was responsible for a region that included Kentucky and he called on Dr. Koelsch from 2015 through the present.

64. Smith "frequently called on Dr. Koelsch . . ., including monthly lunches in Dr. Koelsch's office."

65. Smith also emailed with Dr. Koelsch April 2016 and May 2021.

66. Smith would provide Dr. Koelsch with information about LifeCell products, including Strattice.

67. LifeCell, via Smith, introduced Dr. Koelsch to two of LifeCell's risk stratification tools, the Ventral Hernia Work Group ("VHWG") Paper and Grading System and the CeDAR App.

68. Koelsch read the VHWG paper.

69. Dr. Koelsch relied on the VHWG publication to assist in identifying the patients he should use biologic vs. synthetic mesh in.

70. In the absence of this information, Dr. Koelsch downloaded CeDAR on his phone and used it before seeing patients to help him decide when "to use biologic mesh and when [to use synthetic mesh]."
71. LifeCell, via Smith, provided Dr. Koelsch with other LifeCell marketing materials for Strattice, including the "Don't Mesh Around" Strattice Core Brochure.
72. As a result of these promotional efforts, Dr. Koelsch believed Strattice was appropriate for obese patients like Blakeley.
73. Dr. Koelsch believed Strattice was associated with a single digit recurrence rate.
74. Dr. Koelsch believed Strattice's mechanism of action was regeneration, which he found appealing.
75. Dr. Koelsch believed Strattice was a "durable product" that would "hold up."
76. Dr. Koelsch did not believe that Strattice would "disappear," "go away," or resorb.
77. Dr. Koelsch relied on all this information.
78. Dr. Koelsch expected LifeCell and Smith to provide him with information important to the care of patients or his risk/benefit analysis, including a high recurrence rate.
79. Dr. Koelsch reads and reviews IFU(s) including the Indications for Use, Contraindications, Warnings and Precautions, and any adverse reactions sections.
80. The IFU that accompanied the Strattice mesh used in Plaintiff's surgery contained no warnings about any risk or benefit associated with Strattice at all.
81. The IFU did not warn Dr. Koelsch about the lack of data supporting LifeCell's regeneration and "ideal repair material" claims.

82. It did not warn Dr. Koelsch that Strattice resorbs.

83. It did not warn Dr. Koelsch about the rate of recurrence.

84. Nothing in the Strattice IFU indicated to Dr. Koelsch that Strattice would not perform as well as a synthetic mesh or that an obese patient like Blakely was not a suitable candidate for Strattice.

85. LifeCell never warned Dr. Koelsch of any risk of harm associated with Strattice let alone any specific rate of recurrence or other issue.

86. Prior to surgery, Plaintiff presented to Dr. Koelsch at his practice in Western Kentucky.

87. Dr. Koelsch noted Blakely's obesity was a risk factor he considered in terms of which mesh product to use.

88. As Dr. Koelsch testified, there are 300 different kinds of hernia mesh available on the market.

89. The VHWG publication impacted Dr. Koelsch's decision to use Strattice in Blakeley.

90. Dr. Koelsch determined Blakely was a Grade 2 patient under the VWHG grading system.

91. The VHWG recommended that Grade 2 patients should receive biologic mesh.

92. Dr. Koelsch also believes he used the CeDAR app before Blakeley's surgery to help him choose Strattice.

93. Finally, the "Don't Mesh Around" Core Brochure also influenced his decision to use Strattice in Blakeley's surgery:

> Q. And based on the information you had been given by LifeCell, including like the shark with all the different factors, did the information from LifeCell give you affirmation that Ms. Blakeley, being a Grade 2 patient, was an appropriate patient for biologic mesh over synthetic mesh?

A. Yes.

94. Before surgery, Koelsch discussed the standard risks and benefits of surgery in general.

95. Then Dr. Koelsch discussed the general risks of hernia repair.

96. He did not tell Blakeley that biologic mesh like Strattice carries a significant risk of recurrence as opposed to other types of meshes because it was not his belief at the time.

97. He believed, and told Blakeley, that Strattice was the superior choice over synthetic mesh based on his knowledge at the time.

98. There were no complications during surgery.

99. Ten months later, in June 2021, Blakeley returned to Dr. Koelsch with a hernia recurrence and Dr. Koelsch confirmed "her biologic repair failed."

100. Koelsch does not believe there were any flaws in his technique during the initial surgery that would have caused this failure.

101. Dr. Koelsch performed another hernia repair surgery on Plaintiff on June 3, 2021, where he placed a synthetic mesh to repair Plaintiff's recurrent hernia, which was much larger than the first hernia.

102. This was a much more significant, painful surgery than the first with a more significant recovery time.

103. The hernia recurrence occurred in the same location as the prior hernia where Strattice had been placed. However, during the revision surgery, Dr. Koelsch did not observe any Strattice mesh at all.

104. The Strattice mesh previously implanted into Blakeley was gone.

105. Since Blakeley's surgery, Dr. Koelsch stopped using Strattice.

106. At the time of Blakeley's surgery Dr. Koelsch believed that the recurrence rate for biologic meshes was lower than the rate of synthetic meshes.

107. If Dr. Koelsch was told that biologic meshes posed a higher recurrence rate than synthetics, but had similar adverse outcomes, it would have impacted his decision to recommend using Strattice in Plaintiff's surgery.

HON. JOHN C. PORTO, P.J.Cv.

Date: February 23, 2024