Theresa Blakeley, *Plaintiff-Appellant*, v. LifeCell Corporation, Allergan USA, Inc., and Allergan, Inc., *Defendants-Respondents*.	:	SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO. A-002807-23 ON APPEAL FROM THE SUPERIOR COURT OF NEW JERSEY, LAW DIVISION, ATLANTIC COUNTY Docket No. Below: DOCKET NO. ATL-L-001214-22 Sat Below: Honorable John C. Porto, J.S.C.

BRIEF OF PLAINTIFF-APPELLANT THERESA BLAKELEY

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PRELIMINARY STATEMENT

This appeal arises from the first bellwether trial in a Multi-County Litigation ("MCL") involving injuries caused by Defendants' (collectively "LifeCell") Strattice Reconstructive Tissue Matrix ("Strattice"), a medical device used in hernia repair surgery. Plaintiff Theresa Blakeley seeks a new trial based on three errors: (1) the entry of directed verdict on failure to warn, (2) the exclusion of a randomized controlled trial ("ROSEN") that defines Strattice's risks and that Ms. Blakeley's experts relied upon, and (3) the failure to prevent LifeCell's unqualified expert from offering a speculative "net opinion" bearing on specific causation and liability.

First, the trial court's directed verdict on failure to warn was based on its unsupported finding that Ms. Blakeley's surgeon, Dr. David Koelsch, had "independent knowledge of the risks [of Strattice] and there was an adequate warning." The record confirms LifeCell failed to warn Dr. Koelsch that Strattice resorbs or "goes away" after implant. Instead, LifeCell falsely told Dr. Koelsch that Strattice does not resorb. LifeCell also failed to warn Dr. Koelsch that Strattice fails, resulting in hernia recurrence, in 20-40% of patients after just one to two years. Instead, LifeCell misrepresented to Koelsch that Strattice had "low" recurrence rates equal to 8.3% after seven years. Dr. Koelsch testified that

if LifeCell had adequately warned him about Strattice's risks, he would not have used it in Ms. Blakeley's hernia repair and, in fact, he no longer uses it.

The directed verdict also conflicts with the trial court's denial of summary judgment, based on the same key evidence, where it found: (1) "Dr. Koelsch did not receive any specific Strattice warning," (2) "there was misinformation conveyed by [LifeCell]," (3) "Dr. Koelsch did not have full knowledge of the Strattice risks-i.e., the warning was not adequate," (4) Dr. Koelsch's "knowledge of general risks is not a substitute for an adequate warning," and (5) "Dr. Koelsch testified, specifically, if he knew of the alleged Strattice recurrence rates, he would not have used it in Plaintiff's surgery."

The trial court's about-face hinged on several legal errors. The trial court failed to properly apply the heeding presumption and improperly narrowed New Jersey's duty to warn, holding that (1) LifeCell had no duty to warn that Strattice has an elevated recurrence risk equal to 20-40% after one to two years, (2) LifeCell had no duty to warn that Strattice resorbs or "goes away," and (3) LifeCell cannot be liable because Dr. Koelsch should have done further research on Strattice.

Second, the trial court erred when it excluded ROSEN, a highly relevant randomized controlled trial with statistically significant results comparing outcomes with Strattice and synthetic mesh. The trial court erroneously

excluded ROSEN based on a "known or knowable" test advocated for by LifeCell even though the Product Liability Act, N.J.S.A. 2A:58C-1 to -11, (PLA) imputes knowledge of Strattice's dangers to LifeCell, making evidence of those dangers relevant. Moreover, whether the dangers articulated in ROSEN were "known or knowable" to LifeCell is not a bar to its admissibility; it is a defense that LifeCell had the burden of proving at trial. ROSEN's exclusion prejudiced Ms. Blakeley's expert testimony, her claims, and her ability to cross-examine LifeCell's experts, who were permitted to opine repeatedly that Strattice was "safe and effective."

Third, the trial court erred when it failed to prevent LifeCell's expert, Vedra Augenstein, M.D., from pointing to a line on a black and white CT scan and speculating that Strattice was present when Ms. Blakeley's hernia recurred and therefore did not resorb or "go away" (the "Anti-Resorption Opinion"). The trial court should have excluded this opinion because (1) Dr. Augenstein admitted that only "God or a pathologist" can differentiate between Strattice and human tissue on a CT scan, and (2) it was an unreliable and speculative "net opinion" that conflicted with Dr. Koelsch's undisputed, account that Strattice was not present in her abdomen at the time of the revision surgery.

These rulings deprived Ms. Blakeley of a fair trial. Accordingly, this Court should reverse and remand this case for a new trial on all claims.

STATEMENT OF PROCEDURAL HISTORY

In 2021, Strattice cases filed against the Defendants were coordinated into an MCL assigned to Judge John Porto in Atlantic County. Pa106.[1] Ms. Blakeley filed her Complaint on April 22, 2022, alleging several claims, including failure to warn, design defect, and breach of express warranty, and requesting punitive damages. Pa108. LifeCell answered on June 30, 2022. Pa182.

In 2023, Ms. Blakeley's case was selected for the first bellwether trial. On February 23, 2024, the trial court denied LifeCell's Motion for Summary Judgment on the issues relevant to this appeal: failure to warn, design defect, breach of express warranty, and punitive damages. Pa38. A jury trial commenced on March 7, 2024. 4T5. During trial, the court entered directed verdict on failure to warn only. Pa37; 10T60-82. On March 22, 2024, the jury returned a defense verdict on design defect and breach of express warranty. Pa1.

A. The Trial Court Denied LifeCell's Motion for Summary Judgment on Failure to Warn, Design Defect, Breach of Express Warranty, and Punitive Damages (Pa146).

LifeCell moved for summary judgment on all of Ms. Blakeley's claims. Pa42. On February 23, 2024, the trial court denied that motion as to all claims

[1] "Pa" means "Plaintiff's Appendix" per Rule 2:6-8. In accordance with Rule 2:6-8, the date and numbered designation of each transcript volume is listed in the Table of Contents for Transcripts. "T" denotes the various transcript volumes such that 1T8:3 refers to the first transcript volume, page 8, line 3.

relevant to this appeal: failure to warn, design defect, and breach of express warranty. Pa38. In support, the trial court issued a 67-page order with extensive findings, including:

> **Failure to Warn – Count Two of Complaint . . .**
>
> . . . 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 [(also known as the "Shark Brochure" – Pa253)], 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." . . . That information was clearly insufficient to constitute a warning under the PLA. . . . [Pa76, Pa84]
>
> ***
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> [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 Plaintiffs claim of off-label marketing. [Pa84.]
>
> ***
>
> 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 [v. Firestone Tire & Rubber Co.], 98 N.J. [198,] 209 [(1984)]. [Pa87.]
>
> ***
>
> [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. [Pa87-Pa88.]

> ***
> 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. [Pa88.]
> ***
> **Punitive Damages – Count 9 of Complaint . . . .**
>
> [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. [Pa88.]

Pa76, Pa84, Pa87-88, Pa90 (emphasis in original); see also Pa251 (Warning Label); Pa253 (Shark Brochure). The trial court also made extensive findings of fact relevant to the issues raised in this appeal. Pa94-Pa96, Pa101-Pa104.

B. Pretrial Motions

1. The Trial Court Denied Ms. Blakeley's Motion to Exclude Certain Opinions of LifeCell's Expert, Vedra A. Augenstein, M.D.

On October 25, 2023, LifeCell's expert, Vedra A. Augenstein, M.D. served her expert report and disclosed her opinion that Ms. Blakeley's hernia recurred, in part, due to the size of the Strattice Dr. Koelsch chose. E.g., Pa276. Meanwhile, Dr. Koelsch testified that when he reoperated on Ms. Blakeley, the Strattice he had implanted nine months earlier was not there. 5T289:1-5, 291:13-15, 293:5-6. Dr. Augenstein's report does not address this testimony or whether Strattice is a permanent mesh or temporary one that resorbs and "goes away."

See generally Pa260-Pa278.[2] Dr. Augenstein also did not address whether Ms. Blakeley's Strattice was still in her abdomen when her hernia recurred or whether it had resorbed. Id.

During her December 15, 2023, deposition, Dr. Augenstein opined for the first time that a line on a black and white CT scan revealed that Strattice was still in Ms. Blakeley's abdomen after her hernia recurred and therefore did not resorb or "go away." Pa366, at 129:5-13; Pa367-68, at 134:23-135:4. However, Dr. Augenstein is not a resorption expert. Pa403, at 277:9-17. She also cannot tell whether a line on a CT scan is human (Ms. Blakeley's) or porcine (Strattice) tissue. Pa368, at 134:9-17; Pa370, at 143:20-144:18. According to Augenstein, "only two people can tell what was [in Ms. Blakeley's abdomen], one is God and one is a pathologist . . . ." Pa370, at 143:20-144:18.

Ms. Blakeley moved to exclude Dr. Augenstein's Anti-Resorption Opinion, arguing it was not timely disclosed in compliance with Rule 4:17-4(e), that Dr. Augenstein was unqualified to offer it, that it was unreliable and based on cherry-picked evidence, and that it contradicted Dr. Koelsch's eyewitness account. E.g., 1T24:11-25:6; 26:24.

[2] Note that this report also disclosed a medical summary and opinions regarding another plaintiff that have been redacted. Pa278-284.

During a February 26, 2024, Rule 104 hearing, Dr. Augenstein admitted that that "nobody" can tell the difference between human tissue and Strattice on either a CT scan or even in the operating room. 2T193:10-22. When asked about Dr. Koelsch's testimony that the Strattice was not there, Dr. Augenstein speculated that he "probably doesn't know what Strattice looks like when you go back into the belly." 2T190:1-190:15. When asked whether the resorption of mesh can cause a hernia to recur, Dr. Augenstein answered, in relevant part: "Well, I mean we don't know. We don't know that. . . . So, it is possible that there are . . . meshes that can reabsorb and the patients somehow do well." 2T205:6-16.

On March 5, 2024, the trial court denied Ms. Blakeley's motion in its entirety without addressing the Anti-Resorption Opinion. Pa3.

2. The Trial Court Granted LifeCell's Motion to Exclude the ROSEN Randomized Controlled Trial (Pa851; 3T176-181; 4T7-18, 143-144).

LifeCell moved to exclude medical literature published after Ms. Blakeley's Strattice implant surgery. 3T176:17-181:20. In particular, this motion targeted a randomized controlled trial comparing outcomes with Strattice and synthetic mesh that Ms. Blakeley's experts reviewed and relied on ("ROSEN"). 3T180:23-25; Pa851. In testimony ultimately excluded by the trial court, Dr.

Koelsch testified at his deposition that he read ROSEN and it validated his decision to stop using Strattice. See Pa470-472; see infra at 18-19.

LifeCell argued ROSEN was not relevant and should be excluded under a "knowable standard" because there was no evidence LifeCell knew about it before Ms. Blakeley's 2020 surgery. 3T177:1-177:15. Ms. Blakeley argued this evidence was relevant to her claims. 3T177:18-180:16. The night before opening statements, the trial court granted LifeCell's motion without explanation. Pa34.

C. Trial

1. The Trial Court Clarified It Excluded ROSEN for all Purposes Because It Was not "Known or Knowable" to LifeCell.

Before opening statements, Ms. Blakeley sought clarification on ROSEN, arguing that there is no time-based limitation to the admissibility of this type of evidence and knowledge of ROSEN should be imputed to LifeCell. 4T7:3-20, 8:2-11, 10:1-11:20, 12:17-13:24.

Nevertheless, the trial court was concerned about imputing knowledge of ROSEN to LifeCell, 4T12:17-20, and confirmed it excluded ROSEN because it was not "known or knowable" to LifeCell and it would not reconsider that ruling. 4T18:3-17. The trial court also clarified that it had barred testimony from Dr. Koelsch about ROSEN. 4T18:10-13.[3]

[3] The key testimony from Dr. Koelsch's on ROSEN can be found at Pa470-472.

The trial court did, however, state it would permit Ms. Blakeley's experts to discuss ROSEN because they had relied on it. 4T18:7-10. However, later that same day, when Ms. Blakeley attempted to review ROSEN with Mike Liang, M.D., LifeCell objected and the trial court misstated its previous ruling as "eliminat[ing] everything" and barred any reference to ROSEN, even by Ms. Blakeley's experts. 4T176:8-177:13.

2. The Trial Court Entered Directed Verdict on Failure to Warn (Pa214; 8T60-82; 10T8-22).

On March 14, 2024, LifeCell moved for directed verdict on all of Ms. Blakeley's claims. 9T294:12-301:7. On March 18, 2024, the trial court granted LifeCell's motion on failure to warn based on essentially the same record as summary judgment.[4] At directed verdict, the trial court found that Dr. Koelsch "had independent knowledge of the risks and there was an adequate warning" and hence "independently understood the risk of recurrence for Plaintiff's Strattice surgery." 10T74:21, 75:14-17. The trial court held that LifeCell did not need to warn (1) that Strattice has an elevated recurrence risk, or (2) that Strattice resorbs or goes away. 10T77:7-17, 81:5-22, 75:25-76:3.

[4] The key evidence considered at summary judgment and directed verdict included: the Warning Label (Pa251), the Shark Brochure (Pa253), Dr. Koelsch's testimony (except that on ROSEN), LifeCell's sales representative's (Jamie Smith) testimony, two randomized controlled trials ("RCTs") referred to as LIANG and HARRIS (Pa499, Pa835, Pa525, Pa843), discussed further infra; Dr. Liang's expert opinions, and an Allergan/LifeCell Resorption Profile Study (Pa549), also discussed infra.

The trial court declined to enter directed verdict on breach of express warranty and punitive damages, finding there were disputed facts about representations LifeCell made to Dr. Koelsch regarding "Strattice's performance," including in the Shark Brochure. 10T67:17-68:10; see also Pa253. The trial court further found that "a reasonable jury could find defendants made affirmative misstatements regarding Strattice's benefits over synthetics and its mechanism of action as regeneration." 10T67:17-68:14, 79:6-80:5.

Ms. Blakeley moved for reconsideration, arguing that the court's ruling conflicted with New Jersey law and its summary judgment ruling. 11T129:5-141:7; compare Pa76-88, Pa90, with 10T68:15-78:9. The court denied Ms. Blakeley's motion, but added to its prior ruling that Dr. Koelsch could "not simply rely" on LifeCell's "perhaps self-serving" Shark Brochure "or studies" and should have conducted further research into Strattice:

> Under the doctrine, the doctor has the primary responsibility to analyze the medical device and not simply rely on marketing brochures or studies. I liken this to if a real estate agent gives you a brochure to buy a house. Do you buy the house based on the brochure or do you do some due diligence? In this case, it was incumbent on the physician to do due diligence to prescribe a medical device for this plaintiff and not simply rely on brochures -- marketing brochures, perhaps self-serving brochures, nonetheless.
>
> ***
>
> So after Dr. Koelsch was informed of the shark brochure and any other informational brochure that he may have looked at, he had the due diligence and the responsibility to perform the risk-benefit analysis and do further research.

12T14:25-15:10, 18:9-13; see also Pa253 (Shark Brochure).

3. The Trial Court's Rulings on Dr. Augenstein's Anti-Resorption Opinion.

During voir dire, Dr. Augenstein confirmed she was not an expert in resorption and that "nobody" can testify whether a line on a CT scan is Strattice or Ms. Blakeley's tissue. 12T126:14-16, 127:17-20. Subject to these limitations, the trial court certified Dr. Augenstein as an expert in "hernia repair and hernia repair research." 12T127:24-128:15.

Suspecting Dr. Augenstein would still try to offer her Anti-Resorption Opinion to the jury, Ms. Blakeley requested a sidebar. 12T218:21-219:2. At sidebar, the trial court agreed Dr. Augenstein should not "identify that something is there" via the CT scan because "no one can" and that would be "speculating." 12T222:15-224:14. The trial court then summoned Dr. Augenstein to the sidebar and gave a different instruction that she could "testify there's something there, but you can't name the product." 12T224:21-225:2.

Back on the stand and without a question pending, Dr. Augenstein pointed to the CT image and volunteered: "And I just need to say that this looks like mesh . . . ." 12T227:12-22; see also Pa833 (CT Scan). Ms. Blakeley objected and Dr. Augenstein responded, in front of the jury: "I'm not saying what kind." 12T227:24-228:1. Before Ms. Blakeley could weigh in, the trial court instructed the jury to "disregard that last part of the response that the doctor testified [that

she saw] something that measures 10 centimeters." 12T227:24-228:9. Nevertheless, several jurors could be seen pointing at the CT scan and glancing at each other.

Concerned that the jury had not fully appreciated the trial court's instruction, Ms. Blakeley requested an instruction that Dr. Augenstein was not permitted to speculate about the presence of mesh in Ms. Blakeley based solely on the CT scan because such testimony was outside of her expertise and no expert was qualified in this case to differentiate between human and porcine tissue on a CT scan. 12T248:17-20, 253:9-255:12. The trial court declined Ms. Blakeley's instruction but indicated that if Dr. Augenstein violated its instruction again, it would "address it then." 12T251:8-14, 252:1-10.

Shortly thereafter, during cross-examination, Dr. Augenstein offered unresponsive testimony that she believed Dr. Koelsch "was looking at Strattice" when he reoperated on Ms. Blakeley even though he had testified that it was gone. 12T347:15-349:1. Ms. Blakeley moved to strike this testimony as violating the trial court's instruction. 12T349:2-12. Instead, the trial court responded: "I'll let you continue . . . . Let's finish" without striking the testimony or instructing the jury to disregard it. 12T350:14-17.

STATEMENT OF MATERIAL FACTS

A. Dr. Koelsch Surgically Repaired Ms. Blakeley's Hernia with Strattice, Which Resorbed and Failed Months Later.

In August 2020, Dr. Koelsch diagnosed Ms. Blakeley with a hernia and recommended surgical repair with biologic mesh. 7T97:19-22, 98:11-14. Before surgery, Dr. Koelsch read and relied on the Strattice Warning Label and the Shark Brochure. 5T263:8-266:8, 267:3-268:5, 271:22-272:4. Dr. Koelsch also spoke with LifeCell's sales representative, Jamie Smith. 5T253:11-254:12. Based on that and other information, Dr. Koelsch believed Strattice was the superior choice for Ms. Blakeley's hernia repair. 5T265:23-266:8.

Dr. Koelsch repaired Ms. Blakeley's hernia on August 17, 2020. 5T236:16-22; Pa834. There were no complications during surgery. 5T276:6-8. Four to five months later, Ms. Blakeley began to experience pain. 7T109:4-110:18. Shortly thereafter, Dr. Koelsch determined her hernia had recurred. 7T111:1-112:5. During the revision surgery, Dr. Koelsch determined the Strattice was gone. See 5T289:1-23, 291:13-15, 291:24-25, 292:19-293:7. Dr. Liang opined at trial that Ms. Blakeley's hernia recurred because her Strattice resorbed. 4T198:7-17.

B. Strattice Resorbs 75-100% Within Three Months of Implant, Which LifeCell Admits Is a Bad Outcome.

Although not disclosed to surgeons, as set forth infra, Strattice is a temporary mesh that resorbs or "goes away" after implant. 6T87:4-12. LifeCell's own Resorption Profile Study confirms Strattice "is between 75 to 100%

resorbed at 3 months." Pa586. LifeCell admitted that resorption does not result in a strong repair and "is not a desired outcome." 7T182:20-183:1, 183:9-10.

1. LifeCell Did not Warn Dr. Koelsch that Strattice Resorbs.

Ms. Blakeley's regulatory expert, Laura Plunkett, Ph.D., testified that a responsible manufacturer would have warned surgeons that Strattice resorbs. 5T144:12-17. Dr. Plunkett explained that resorption information reveals "whether or not the product is durable, whether or not it provides a repair that is going to be able to be a long term repair for the patient . . . ." 5T79:6-19.

Dr. Koelsch testified that he wanted to know any information that could impact his risk-benefit analysis for patients. 5T254:21-255:25. However, LifeCell never warned Dr. Koelsch that Strattice is resorbable, has related durability issues, or disclosed the Resorption Profile Study's findings. See Pa251; Pa253; 4T187:20-189:13; 5T144:12-145:6, 266:15-19; see also Pa94-95, Pa101-102. Mr. Smith confirmed that he also never disclosed that Strattice resorbs. 7T228:13-229:1.

2. LifeCell Told Dr. Koelsch that Strattice Does not Resorb.

LifeCell spent years trying to dispel the notion that Strattice resorbs or "go[es] away" as a "myth." 9T180:9-14. Mr. Smith affirmatively told surgeons that Strattice does not resorb or "go away." 7T228:20-229:1. The Shark

Brochure claims Strattice is "reliable" and provides a "durable solution." Pa253, Pa255. The Warning Label claims Strattice is "strong." Pa251. Accordingly, Dr. Koelsch believed Strattice was "durable," would "hold up," and would not disappear or "go away." E.g., 5T259:3-8, 259:16-20; see also Pa101-102.

LifeCell also claimed Strattice's mechanism of action was "regeneration" not resorption. Pa255; 9T204:1-6. As Ms. Blakeley's expert, Dipak Panigrahy, M.D., testified, "regeneration" suggests Strattice stimulates new tissue growth. 6T154:15-155:12. LifeCell's Shark Brochure defined "regeneration" as consisting of "rapid revascularization, cell repopulation, reduced inflammatory response, transition into host tissue." Pa255. Mr. Smith used that term with Dr. Koelsch, who found it appealing. 5T260:16-19, 262:4-8.

However, LifeCell admitted that Strattice's mechanism of action is not "regeneration," and it never studied that concept. 6T82:8-83:4. LifeCell's own documents further confirm this claim was outside the FDA-cleared indications for use and thus constituted illegal "off-label promotion." E.g., Pa872-3; Pa903; see also 5T114:19-116:20.

C. Strattice Fails, Resulting in Hernia Recurrence, in 20-40% of Patients After Just One to Two Years.

Dr. Liang testified that Strattice fails, resulting in recurrence, in 20-40% of patients, at least double the rate of synthetic mesh. 4T114:9-14. This danger is confirmed by three randomized controlled trials ("RCTs"), known as

HARRIS, LIANG, and ROSEN, comparing outcomes with Strattice and synthetic mesh after just one to two years. E.g., Pa851, Pa843, Pa525, Pa835, Pa499.

HARRIS concluded that within two years of implant, recurrences occurred in 37% of Strattice patients versus 21% of synthetic mesh patients. Pa527. The numbers in the final published study, which the trial court excluded,[5] were 39.7% Strattice, 21.9% synthetic. Pa843. Based on these results, HARRIS concluded: "[t]he risk of hernia recurrence was significantly higher for patients undergoing ventral hernia repair with biologic mesh compared to synthetic mesh, with similar rates of postoperative complications." Pa527; see also Pa843.

The LIANG abstract did not contain a table with comparative recurrence rates but the final published version concluded that, within 13 months of implant, recurrences occurred in 30.3% of Strattice patients versus 13.5% of synthetic mesh patients. Pa499; Pa839. However, the LIANG abstract concluded: "Bayesian analysis demonstrated that, when compared to synthetic mesh, biologic mesh had a 75% probability of increased risk of major

[5] The court excluded the peer-review published versions of LIANG and HARRIS because they post-dated Ms. Blakeley's August 2020 surgery. 4T142:16-144:9; see also 4T17:24-18:17. However, LifeCell possessed abstracts of HARRIS and LIANG before the Ms. Blakeley's surgery (Pa498, Pa499, Pa524, Pa525; 4T15:1-3), which the court admitted. 4T144:1-9, 4T170:17-25.

complications at 1-year post-operative and a 78% probability of increased risk of [surgical site infections].” Pa499.

ROSEN, which the trial court excluded, concluded that within just one year of implant, recurrences occurred in 20.5% of Strattice patients versus just 5.6% of synthetic mesh patients. Pa853. ROSEN also concluded that “[c]ompared with biologic mesh, synthetic mesh significantly reduced the risk of hernia recurrence,” “Biologic mesh . . . is expensive and has been associated with high rates of long-term hernia recurrence,” and “[t]he primary [study] outcome was the superiority of synthetic mesh vs biologic mesh at reducing risk of hernia recurrence at 2 years . . . .” Pa853. ROSEN further concluded there were “comparable rates of surgical site infection; however, the biologic mesh group tended to have a higher risk of deep surgical site infection than the synthetic group (14 [11%] vs. 5 [4%]).” Pa858.

In testimony excluded by the trial court, Dr. Koelsch testified that “randomized controlled trials are something that, you know, you really pay attention to. They’re kind of the gold standard of medical research.” Pa470, at 93:19-22. For Dr. Koelsch, ROSEN “turn[ed] conventional wisdom on its head” and its inclusion in the prestigious Journal of the American Medical Association (JAMA) was “a pretty impressive thing.” Pa471, at 97:13-17. When Dr. Koelsch read ROSEN, it “made [his] eyebrow raise. [He] was like, gosh, why do you

even use biologic mesh at all at that point?" Pa470, at 95:2-4. Dr. Koelsch found compelling ROSEN's conclusions that (1) synthetic mesh reduces the risk of recurrence, Pa470, at 95:9-96:18, Pa471:97:18-98:2, and (2) that Strattice fares no better than synthetic mesh in patients with infections. Pa470, at 96:19-97:1.

1. LifeCell Did Not Warn Dr. Koelsch About Strattice's Elevated Risk of Recurrence.

Dr. Koelsch also expected LifeCell to tell him if Strattice had high recurrence rates or did not perform as marketed. 5T254:21-255:25. Dr. Liang testified that recurrence information is important because each time a hernia recurs, the risk of another increases as part of a "vicious cycle." 4T111:21-113:2. However, the Strattice Warning Label did not warn about recurrence. See Pa251-252; 8T67:11-17. LifeCell never warned Dr. Koelsch about Strattice's elevated recurrence risk or the RCTs, even though it possessed the LIANG and HARRIS abstracts before Ms. Blakeley's surgery. 5T263:19-264:5; 6T26:5-27:1, 5T134:135:3; Pa251-252, 498-99, 524-25.

2. LifeCell Told Dr. Koelsch that Strattice Has Low "Single-Digit" Recurrence Rates at Seven Years.

Instead, LifeCell told Dr. Koelsch that Strattice has "low" recurrence rates at seven years. Pa253, 255. The Shark Brochure claims Strattice has a recurrence rate of "8.3% at 7 years post-op[eration]" and that "91.7% of patients were recurrence free at 7 years post-op[eration]." Pa253, 255. Mr. Smith associated

this "low recurrence rate" with Strattice, 8T40:13-41:16, and told Dr. Koelsch that Strattice had "a single-digit recurrence rate." 5T263:19-264:5, 265:18-266:8. Dr. Koelsch believed this information reflected Strattice's recurrence risk. 5T265:23-266:14.

However, this claim is based on an observational cohort study ("GARVEY") that involved several porcine and bovine biologic meshes, not just Strattice. Pa922; 10T164:10-12, 166:1-167:11. GARVEY does not break out or separately analyze the Strattice results. 10T167:6-11. LifeCell's own expert agreed GARVEY was not reflective of Strattice's recurrence risk. E.g., 10T168:18-170:24. GARVEY also excluded 321/512 (62.7%) patients simply because they followed up for less than 36 months. Pa922, 925. Meanwhile, the recurrences identified in the RCTs, occurred in less than 24 months. See supra at 17-19.

LifeCell made this claim because it knew that recurrence rates, and specifically "low" recurrence rates, matter to surgeons. 8T308:16-309:4, 342:14-19. As Mr. Smith acknowledged, LifeCell made this claim because "extensive market research" showed that "the optimal positioning and messaging for Strattice should focus on risk mitigation and low recurrence data," 8T36:5-36:16, because a "surgeon's number one goal . . . is to prevent hernia

recurrence." 8T42:20-43:15, 40:4-12. Mr. Smith agreed "Strattice recurrence data" was "critical" for LifeCell's Strattice marketing campaign. 8T38:9-16.

D. Dr. Koelsch Testified That Had LifeCell Adequately Warned Him About Strattice's Dangers, He Would not Have Used It.

Dr. Koelsch testified that he wanted to know if Strattice recurred in 20-30% of patients versus the single-digit rate claimed in the Shark Brochure, 5T270:12-24, and that if LifeCell had warned him of this information, that would have impacted his decision to use it in Ms. Blakeley. 6T26:5-27:1. Dr. Koelsch no longer uses Strattice, 5T248:3-5; 6T26:3-4, and based on what he now knows, he would not use it in Ms. Blakeley's hernia repair if he could go back in time. 6T25:1-10. Ms. Blakeley testified that had she been told about the risks of Strattice, including that it resorbs and has an increased risk of hernia recurrence compared to synthetic mesh, she would not have agreed to its use in her surgery. 7T100:7-24; see also 5T243:22-244:19.

ARGUMENT

POINT I: This Court Should Reverse the Grant of Directed Verdict on Failure to Warn (9T294-301; 10T5-54; 11T129-143).

Directed verdict on failure to warn should be reversed and remanded for a new trial for several reasons. First, the record was sufficient to support a jury verdict regarding Strattice's resorption and recurrence dangers. Second, the trial

court misconstrued New Jersey law when it failed to properly apply the heeding presumption and improperly narrowed New Jersey's duty to warn in several ways.

A. Standard of Review

This Court reviews a directed verdict de novo. Lechler v. 303 Sunset Ave. Condo. Ass'n, Inc., 452 N.J. Super. 574, 582 (App. Div. 2017). "A motion for a directed verdict is granted only if, accepting the plaintiff's facts and considering the applicable law, 'no rational jury could draw from the evidence presented' that the plaintiff is entitled to relief." Prioleau v. Ky. Fried Chicken, Inc., 434 N.J. Super. 558, 569–70 (App. Div. 2014), aff'd as modified and rem., 223 N.J. 245 (2015); R. 4:37-2(b).

B. The Record Supported a Verdict that LifeCell Failed to Adequately Warn About Strattice's Resorption and Recurrence Dangers.

Under the PLA, "a manufacturer or seller of a product shall be liable . . . if the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it . . . failed to contain adequate warnings or instructions . . . ." N.J.S.A. 2A:58C-2. An adequate warning "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 prescribing physician." N.J.S.A. 2A:58C-4. Warnings are required regarding

"all hidden or latent dangers . . . ." Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 206–07 (1984) (emphasis added); N.J.S.A. 2A:58C-4.

"The adequacy of a warning is to be considered in the context of all communications by the product manufacturer . . . ." Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 525 (App. Div. 2007). A product "is not reasonably safe if the same product could have been made or marketed more safely." Michalko v. Cooke Color & Chem. Corp., 91 N.J. 386, 402 (1982). A manufacturer fails to adequately warn when it fails to provide "reliable medical information" or provides "misinformation" about its product. See Hrymoc v. Ethicon, Inc., 467 N.J. Super. 42, 86 (App. Div. 2021), aff'd as modified, 254 N.J. 446 (2023). "The question in strict liability . . . warning cases is whether, assuming that the manufacturer knew of the defect in the product, he acted in a reasonably prudent manner in marketing the product or in providing the warnings given." Feldman v. Lederle Labs., 97 N.J. 429, 451 (1984). "Generally, the adequacy of a warning is a jury question." Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 195 (2012).

Here, just weeks after denying summary judgment, the trial court held that "no rational jury could conclude from the evidence there was an [in]adequate warning." 8T78:6-9. This ruling was in error because the record was more than sufficient to support a verdict on failure to warn.

First, it is undisputed that Strattice resorbs or "goes away," Pa586; 6T87:4-12, which is "not a desired outcome." E.g., 7T182:23-183:1, 183:9-10. Dr. Plunkett testified a responsible manufacturer would disclose this information, but LifeCell did not. 5T144:12-17, 144:25-145:6; see also Pa251, 253. Instead, LifeCell misrepresented to Dr. Koelsch that Strattice does not resorb, which Dr. Koelsch believed. 7T228:20-229:1; 5T259:3-8, 259:16-20. LifeCell also told Dr. Koelsch that Strattice's mechanism of action was "regeneration" even though that was not true and LifeCell never studied it. 5T260:16-19, 262:4-8; 6T82:8-83:4. This evidence strongly supports a textbook failure to warn claim.

Second, regarding Strattice's recurrence danger, the evidence demonstrated that Strattice fails, resulting in recurrence, in 20-40% of patients after just one to two years, at least double the risk associated with synthetic mesh. 4T114:9-14, 179:11-18; see also Pa525. Dr. Koelsch expected LifeCell to provide information about elevated recurrence rates and Dr. Plunkett confirmed LifeCell should have warned about this information. 5T255:2-25, 121:20-123:17, 145:7-11. However, LifeCell did not warn Dr. Koelsch about Strattice's elevated recurrence risk or the RCTs even though it possessed the HARRIS and LIANG abstracts before Ms. Blakeley's surgery. See generally Pa251, 253; see also supra at 17-19.

Instead, it misled him with promises of "low" recurrence rates in the Shark Brochure. Pa253. The Shark Brochure claims Strattice has a recurrence rate equal to 8.3% over seven years, which annualizes to 1.19% per year, while the HARRIS abstract shows Strattice has a recurrence rate of 37% over 2 years, or 18.5% per year. In other words, the recurrence risk identified in HARRIS is almost 16 times higher than that claimed in the Shark Brochure.

As a result, the jury also could have concluded this claim was false and misleading, consistent with the trial court's findings at directed verdict that the Shark Brochure created disputed facts about Strattice's performance, contained "affirmative misstatements," and was so "self-serving" that Dr. Koelsch should not have relied upon it. 10T67:17-68:14, 79:6-9; 12T14:23-15:10, 18:9-13. As the trial court did at summary judgment, the jury also could have found this claim of "low" recurrence rates to be "clearly insufficient to constitute a warning under the PLA" and concluded "Dr. Koelsch did not receive any specific Strattice warning." Pa87. In fact, the evidence demonstrated that LifeCell put this claim on the front of the Shark Brochure because they knew it would be appealing to surgeons and would help it sell Strattice. 8T36:5-36:16, 38:9-16, 40:4-12, 42:20-43:15.

Dr. Koelsch himself confirmed the substantive difference between the Shark Brochure's claim and the RCT findings when he testified that he wanted

to know if Strattice had recurrence rates of 20-30% versus the single-digit rate in the Shark Brochure. 5T270:12-24; 6T26:5-27:1. Accordingly, this was a textbook failure to adequately warn case, and the evidence was more than sufficient to support that claim on at least two different theories: resorption and recurrence.

C. The Trial Court's Entry of Directed Verdict Was Based on Several Legal Errors.

1. The Trial Court Did Not Properly Apply the Heeding Presumption.

"Since the duty [to warn] is to place on the market a product free of defects, and this duty attaches at the time the product is introduced into the stream of commerce, a particular user's subjective knowledge of a danger does not and cannot modify the manufacturer's duty." Campos, 98 N.J. at 209; Coffman v. Keene Corp., 133 N.J. 581, 603 (1993) ("A plaintiff's mere knowledge of a product's inherent danger or risk will not absolve a manufacturer from its duty to warn.").

Regarding causation, New Jersey law gives a plaintiff a rebuttable presumption "that he or she would have followed an adequate warning had one been provided . . . ." Coffman, 133 N.J. at 603. To rebut the presumption, the defendant "must produce evidence that such a warning would not have been heeded." Id. at 603-04. In other words, evidence that "the plaintiff would have

proceeded voluntarily and unreasonably to subject him or herself to the dangerous product." Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 68-69 (App. Div. 1998), aff'd, 158 N.J. 329 (1999). If the defendant falls short, "the trial judge is required to direct a verdict in favor of the plaintiff on proximate causation." Id. at 69. If the defendant meets its burden "the plaintiff loses the benefit of the presumption" and "must then carry the burden of persuasion as to proximate cause." Id.

"[I]n order for dismissal of the lawsuit to be warranted on this basis," the prescribing physician must "unequivocally testify that they had full knowledge of the dangers associated with [the device] and that neither that knowledge nor anything in the enhanced post-injury warnings . . . would have altered their decision to prescribe it . . . ." Hrymoc, 467 N.J. Super. at 89 (internal citation omitted) (emphasis in original). "Where such a statement is not unequivocal the matter is properly for the jury." Id. at 90 (internal citations omitted); Michalko, 91 N.J. at 402 ("[W]hether the failure to warn proximately caused the plaintiff's injury is a factual dispute that the jury should decide.").

Here, the trial court based its entry of directed verdict on failure to warn, in part, on its finding that Dr. Koelsch had independent knowledge of the risk of hernia recurrence:

> Dr. Koelsch, the surgeon, had independent knowledge of the risks . . . . Dr. Koelsch testified he independently understood the risk of

> reoccurrence for plaintiff's Strattice surgery. . . . The reoccurrence risk is known by the surgeon . . . . Dr. Koelsch – in fact, with regard to hernia surgery in general, using any of these products is what this jury has heard.

10T74-76. This ruling was in error for several reasons.

First, as argued supra, the evidence simply does not support the trial court's finding (as a matter of law) that Dr. Koelsch "understood the risk of recurrence for Plaintiff's Strattice surgery." Second, the trial court failed to analyze whether LifeCell met its burden of production on the heeding presumption despite finding at summary judgment that it had failed. Compare 10T72:3-9, with Pa87 ("Defendants did not present sufficient evidence to meet their burden of production [on the heeding presumption]."). Indeed, Dr. Koelsch testified in his deposition that he would not have used Strattice had LifeCell adequately warned him of its dangers. See 6T25:1-10, 26:5-27:1. Because Dr. Koelsch testified at trial via his deposition, there was no new testimony that he would not have heeded an adequate warning necessary to support directed verdict on proximate causation. Coffman, 133 N.J. at 603-04; Hrymoc, 467 N.J. Super. at 89. Because LifeCell failed to produce evidence to rebut the heeding presumption, the trial court erred in entering directed verdict based on Dr. Koelsch's "independent knowledge."

Third, the trial court conflated Dr. Koelsch's knowledge of hernia recurrence generally with specific knowledge of Strattice's recurrence risk.

10T74-76. As Dr. Liang testified, hernia recurrence is an inherent risk in all hernia repair—any hernia mesh can fail and there is no hernia mesh that has a zero percent risk of recurrence. 4T215:22-25. Accordingly, Dr. Koelsch's mere knowledge that the implantation of hernia mesh can result in a recurrence does not mean he had sufficient knowledge about Strattice's recurrence risk, as he himself confirmed. See 5T270:12-24. The trial court correctly recognized this at summary judgment when it held Dr. Koelsch "did not have full knowledge of the Strattice risk," Pa84, and that his "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." Pa87 (citing Campos, 98 NJ. at 209); see also Coffman, 133 N.J. at 603. The trial court should have made these same findings at directed verdict.

2. The Trial Court Wrongly Narrowed LifeCell's Duty to Warn.

i. The Trial Court Improperly Held that LifeCell Had No Duty to Warn About Strattice's Elevated Recurrence Risk or the RCTs.

The PLA simply requires that a manufacturer "provide adequate information on the dangers and safe use of the product . . . ." N.J.S.A. 2A:58C-4. While the PLA is silent on whether it requires the disclosure of information bearing on the magnitude of a danger or the likelihood that it will occur, the duty to warn does require the disclosure of "material" and "reliable medical

information" about risks and benefits of a product. See Hrymoc, 467 N.J. Super. at 86; In re Diet Drug Litig., 384 N.J. Super. 525, 539 (L. Div. 2005).

Moreover, this Court has recognized that information bearing on the magnitude or likelihood of a risk is important to surgeons. Hrymoc, 467 N.J. Super. at 88-89 ("If Prolift put a patient at significant risk for problems, Dr. Mokrzycki did not know 'if he would even offer it to a patient.'"). The surgeon in Hrymoc also testified that he "need[ed] to know the number of people, you know, numerator and denominator that it happens in," when considering a medical device. Id. at 89; In re Diet Drug Litig., 384 N.J. Super. at 539 (noting that information regarding the remoteness of a risk can impact a surgeon's risk-benefit analysis).

While not addressed by a New Jersey court, other courts have held that a generic warning disclosing a danger without also disclosing the magnitude or likelihood of that danger cannot be "adequate as a matter of law." E.g., Keen v. C.R. Bard, Inc., 480 F. Supp. 3d 624, 641–42 (E.D. Pa. 2020) (Pennsylvania law); In re Bard IVC Filters Prod. Liab. Litig., 969 F.3d 1067, 1076–77 (9th Cir. 2020) (Georgia law); Dalbotten v. C.R. Bard, Inc., No. 1:20-CV-00034-SPW, 2023 WL 157735, at *5 (D. Mont. Jan. 11, 2023) (Montana law) (Pa1004); Johnson v. C.R. Bard Inc., No. 19-CV-760-WMC, 2021 WL 1784661, at *8 (W.D. Wis. May 5, 2021) (Wisconsin law) (Pa1012); Heinrich v. Ethicon, Inc.,

455 F. Supp. 3d 968, 975 (D. Nev. 2020) (Nevada law); McDowell v. Bos. Sci. Corp., No. 18-3007, 2018 WL 6182625, at *6 (C.D. Ill. Nov. 27, 2018) (Illinois law) (Pa1024); Davis v. C.R. Bard, Inc., No. 11-12556, 2012 WL 6082933, at *9 (E.D. Mich. Dec. 6, 2012) (Michigan law) (Pa1033).

In Johnson, the court rejected the manufacturer's argument that its warnings were adequate as a matter of law because the Warning Label "warned about the precise risks of complications" that occurred, holding:

> Here, although defendants did warn of the specific complications that happened to Johnson, a reasonable jury could conclude that those warnings were inadequate because they did not sufficiently communicate the degree and likelihood of the risk associated with placing a Meridian Filter in a patient's IVC, especially in light of purported, lower-risk options on the market and the seriousness of the potential complications. Accordingly, the court cannot conclude that the warning was adequate as a matter of law.

2021 WL 1784661, at *8 (emphasis added) (Pa1019).

Here, the trial court held that LifeCell had no duty to warn about the likelihood that Strattice would fail, resulting in recurrence. 10T76:1-3 ("I find that the rates of reoccurrence are not a factor here. It's the actual risk of reoccurrence."); 12T15:20-23 ("[T]he PLA requires the risk, not the rate of risk, as required under our PLA."). This ruling was in error.

First, while the PLA does not *expressly* require the disclosure of "rates of risks," it also does not preclude a jury from finding that a manufacturer failed to adequately warn regarding that type of information. Moreover, the PLA does

require the disclosure of "adequate" or "material" information about those dangers. But it leaves to a jury what that information is and whether LifeCell acted "in a reasonably prudent manner in marketing the product or in providing the warnings given." Feldman, 97 N.J. at 451. Accordingly, New Jersey entrusts its juries to decide whether a manufacturer has adequately disclosed the dangers of its products, and the trial court erred in taking that issue away from the jury.

Second, the evidence supported a finding that an adequate warning required the disclosure of more information about Strattice's recurrence risk. For example, LifeCell opened the door to a warning about recurrence rates when it made a claim about what Strattice's recurrence rates are in the Shark Brochure. Pa253. When compared apples to apples, the rate claimed in the Shark Brochure was almost 16 times lower than the actual risk identified in the HARRIS abstract. 8T38:9-16; see supra at 17-29, 25. LifeCell also knew recurrence rates, specifically "low" recurrence rates, mattered to surgeons. 8T308:16-309:4, 342:14-19; see also 8T36:5-17, 40:4-12, 42:20-43:15. Dr. Plunkett testified that "material information" about a danger includes information about its likelihood. 5T122:9-21. Dr. Koelsch wanted to know if Strattice recurred in 20-30% of patients versus the single-digit rate claimed in the Shark Brochure. 5T270:12-24.

Based on this evidence, the jury had several options; it was not necessarily required to decide that LifeCell should have disclosed Strattice's recurrence rates. It could have also found that LifeCell should have disclosed the RCTs it actually possessed before Ms. Blakeley's surgery or that Strattice has "elevated," "increased," or a "significant risk of recurrence." See Feldman, 97 N.J. at 451. The jury also could have concluded that the "low recurrence rate" claim in the Shark Brochure, based on GARVEY, and which the trial court itself described as "perhaps self-serving," was misleading and inadequate to warn of Strattice's true recurrence danger. Or the jury could have found LifeCell liable for failing to warn about recurrence in the Warning Label, which does not mention recurrence at all.

Finally, this ruling is inconsistent with New Jersey's policy that a "patient's interest in reliable information predominates over a policy interest that would insulate manufacturers." Perez v. Wyeth Labs. Inc., 161 N.J. 1, 29 (1999). If not reversed, this ruling will be used by LifeCell and, frankly, the manufacturer of any product, to argue the duty to warn requires the disclosure of only the danger and not additional information, including whether the danger is severe or mild, likely or unlikely, elevated or remote, permanent or temporary, or whether it occurs in 1%, 50%, or 100% of people. That will undoubtedly put patients at risk.

ii. The Trial Court Improperly Held that LifeCell Had No Duty to Warn About Strattice's Resorption Danger.

The duty to adequately warn extends to "all hidden or latent dangers . . . ." Campos, 98 N.J. at 206–07; N.J.S.A. 2A:58C-4 (requiring "adequate information on the dangers . . . ."); see also Hrymoc, 467 N.J. Super. at 88 (holding that a surgeon must be warned about "all the material risks of patient harm . . . ." (emphasis added)). Here, the trial court held that LifeCell's duty to warn extended to only one risk—hernia recurrence—which it described as the "ultimate risk." 10T75:1-5; 77:10-17. This was error.

First, this ruling directly conflicts with New Jersey precedent requiring a warning about "all dangers." E.g., Campos, 98 N.J. at 206-207 (emphasis added). In fact, the trial court cited Campos for this proposition at summary judgment:

> 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.

Pa87 (emphasis added).

Second, this ruling is unsupported by legal citation and there is no New Jersey authority limiting the duty to warn adequately warn to an "ultimate" risk as determined by a trial court as a matter of law. Moreover, it is undisputed that

resorption is a danger, as confirmed by LifeCell's admission that it does not result in a strong repair and is not a desired outcome. E.g., 7T182:23-183:1, 183:9-10. Dr. Plunkett also testified that LifeCell should have warned about Strattice's resorption danger. 5T144:12-17. Critically, LifeCell also falsely told surgeons, including Dr. Koelsch, that Strattice does not resorb. Accordingly, it was improper for the trial court to take this issue away from the jury under these circumstances.

Third, by holding that LifeCell needed only warn about recurrence, the so-called "ultimate risk," the trial court incorrectly assumed that resorption and recurrence are the same. But that is not true. Resorption is a mechanism of action that describes how Strattice reacts in the body over time, Pa586, and hernia recurrence is an outcome. Moreover, it is undisputed that hernia recurrence can happen with any hernia mesh, including permanent mesh that does not resorb. See 4T215:22-25. Similarly, resorption can occur without causing a hernia recurrence. For example, even though Strattice resorbs, it does not result in a recurrence in every patient as confirmed by the RCTs. See, e.g., Pa525.

iii. The Trial Court's Ruling Suggests that LifeCell Did Not Need to Disclose Accurate Information to Dr. Koelsch to Discharge Its Duty to Adequately Warn.

A manufacturer that misrepresents the risks and benefits of its product fails to provide an adequate warning. See Bailey v. Wyeth, Inc., 424 N.J. Super.

278, 332–33 (L. Div. 2008), aff'd sub nom. DeBoard v. Wyeth, Inc., 422 N.J. Super. 360 (App. Div. 2011) (noting that allegations that "defendants misrepresented the safety risks of their products" is a "classic articulation of tort law duties, that is, to warn of or to make safe," which is "squarely within the theories included in the PLA.").

A manufacturer "discharges its duty to warn the ultimate user of prescription [medical devices] by supplying physicians with information about the [device's] dangerous propensities." See Niemiera by Niemiera v. Schneider, 114 N.J. 550, 559 (1989) (emphasis added).

While it entered directed verdict on failure to warn, the trial court denied directed verdict on breach of express warranty and punitive damages, finding that there were "issues of fact regarding Defendants' representations to Dr. Koelsch regarding . . . Strattice's performance, including but not limited to, the presentation of marketing brochures, such as the shark brochure . . . ." 10T67:17-68:5. It found the same to be true about statements Jamie Smith made "to Dr. Koelsch relating to the performance of" Strattice. 10T68:6-10. Regarding punitive damages, the trial court held that LifeCell had made "affirmative misstatements [to Dr. Koelsch] regarding Strattice's benefits over synthetics and its mechanism of action was regeneration." 10T79:6-9 (emphasis added). The trial court also found the Shark Brochure was "self-serving" such that Dr.

Koelsch could "not simply rely" on it and "had the responsibility to . . . do further research." 12T14:23-15:12, 18:9-13. These rulings, which were well-reasoned and correct, further demonstrate how the trial court's entry of directed verdict on failure to warn was error.

For example, by claiming Strattice had a "low" recurrence risk over seven years when that risk is significantly higher at just one to two years, LifeCell failed to adequately warn about recurrence. By knowingly misrepresenting that Strattice does not resorb when in fact the opposite is true, LifeCell failed to adequately warn about resorption. By definition, a document misrepresenting a product's risks cannot also provide an adequate warning about those risks. See Bailey, 424 N.J. Super. at 332–33.

Nevertheless, the trial court set these misrepresentations aside when it held that Dr. Koelsch, a non-party, could not rely on information provided by LifeCell "or studies" and should have independently investigated Strattice's dangers. But the question at issue was whether LifeCell discharged its duty to warn by providing information to Dr. Koelsch. That duty does not ebb and flow based on whether it was reasonable for Dr. Koelsch to rely on the information provided. In fact, one who engages in fraud[6] "may not urge that his victim should

[6] "[P]artial disclosure [of information] may amount to fraud" and "silence, in the face of a duty to disclose, may be a fraudulent concealment." Berman v.

have been more circumspect or astute." Pioneer Nat. Title Ins. Co. v. Lucas, 155 N.J. Super. 332, 342 (App. Div. 1978), aff'd, 78 N.J. 320 (1978).

POINT II: The Trial Court Applied the Wrong Legal Test When It Excluded ROSEN and Dr. Koelsch's Proximate Cause Testimony. (3T176-181; 4T7-18.)

A. Standard of Review

"An appellate court reviews a trial court's evidentiary rulings . . . with substantial deference and will not overturn such a ruling unless it constituted a clear abuse of discretion." Hrymoc v. Ethicon, Inc., 254 N.J. 446, 463–64 (2023). However, "de novo review must be conducted if the trial court erred in its application of the law." State v. C.W., 449 N.J. Super. 231, 252 (App. Div. 2017). "A trial court's discretion is abused when relevant evidence offered by [a party] and necessary for a fair trial is kept from the jury." Id.

B. The PLA Imputes Knowledge of a Product's Dangers to the Manufacturer, Making Evidence of that Danger Relevant.

Failure to warn claims in New Jersey are based on strict liability. Freund v. Cellofilm Props., Inc., 87 N.J. 229, 238-39 (1981). Under "a strict liability analysis, the defendant is assumed to know of the dangerous propensity of the product, whereas in a negligence case, the plaintiff must prove that the defendant knew or should have known of the danger." Feldman, 97 N.J. at 450 (citing

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Gurwicz, 189 N.J. Super. 89, 93 (Ch. Div. 1981), aff'd, 189 N.J. Super. 49 (App. Div. 1983).

Freund, 87 N.J. at 238-239); Michalko, 91 N.J. at 394–95 ("Knowledge of a product's dangerous characteristics is imputed to the defendant."). Accordingly, "[t]he plaintiff [is] entitled to a strict liability charge that clearly and unmistakenly impute[s] knowledge of the dangers of the product to the defendant." Freund, 87 N.J. at 244; Model Jury Charges (Civil), 5.40C (app. Mar. 2000, rev. 11/2023) (the jury is to "assume the [Defendant Manufacturer/Seller] knew of the dangers of the [Product] at the time [Product] was sold/distributed.").

Whether information regarding a product's dangerous characteristics was "not reasonably available or obtainable and that [a defendant] therefore lacked actual or constructive knowledge of the defect" is a defense that the defendant bears the burden of proving. Feldman, 97 N.J. at 455–56, 458; Model Jury Charges (Civil), 5.40C ("In this case [*Defendant*] contends that [*describe danger*] was not knowable at the time the [*Product*] was manufactured/sold. . . . In evaluating this defense . . . .").

The trial court required Ms. Blakeley to prove that LifeCell knew about ROSEN as a prerequisite to using it at trial with her experts, who relied on it in forming their opinions. E.g., 4T18:3-17; see also supra at 8-9. This ruling was legally erroneous for several reasons and because ROSEN was excluded by a legal test that was not applicable, it should be reviewed de novo.

First, the trial court improperly used a legal defense to exclude key evidence defining the very danger the PLA imputed to LifeCell. The trial court further misapplied that defense by (1) limiting the analysis to what LifeCell knew, and (2) putting the burden of proof on Ms. Blakeley. There is no precedential case law supporting the proposition that a plaintiff and her experts can only rely on scientific literature known to the defendant prior to the plaintiff's exposure.

Second, the operative question was not whether LifeCell knew about ROSEN, but whether ROSEN was relevant to Ms. Blakeley's claims. The clear answer is yes. Relevant evidence is any evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action. N.J.R.E. 401.

ROSEN is relevant to each of Ms. Blakeley's claims and causation. For example, because the PLA imputes knowledge of Strattice's dangers to LifeCell on a failure to warn claim, evidence of those dangers is per se relevant. This is especially true of ROSEN, an RCT, which is "the gold standard for determining the relationship of an agent to a health outcome or adverse side effect." In re Accutane Litig., 234 N.J. 340, 353 (2018).

Because ROSEN also compares Strattice to synthetic mesh, a safer design already on the market at the time of Ms. Blakeley's surgery, it is also relevant to

her design defect claim. See Lewis v. Am. Cyanamid Co., 155 N.J. 544, 570 (1998) ("A plaintiff must prove . . . that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm."). In fact, ROSEN shows that synthetic mesh significantly reduces the risk of hernia recurrence over Strattice almost four-fold (20.5% vs. 5.6%). Pa853. ROSEN is also relevant to Ms. Blakeley's claim that Strattice did not live up to LifeCell's express warranties about durabilty and "low recurrence rates" and specifically that 91.7% of patients are recurrence free at seven years. Pa253, 255.

ROSEN is also relevant rebuttal and impeachment evidence. For example, ROSEN was a critical cross-examination weapon considering that LifeCell's experts were permitted to testify that Strattice was "safe and effective" at least 17 times. 10T107:21-108:1, 111:13-20, 122:6-9, 131:23-132:1, 147:2-6, 189:24-190:8, 198:25-199:4; 11T175:25-176:17, 218:20-23, 221:6-8, 223:4-11, 226:9-11, 228:11-13, 230:4-11, 235:24-236:6; 12T112:2-4, 151:1-6.

ROSEN also debunks several bold claims LifeCell made in opening statements shortly after ROSEN was excluded, including: "[t]he published literature showed that Strattice was the right choice for Dr. Koelsch. That's what it showed." 4T76:9-11. LifeCell also claimed in opening that synthetics are better than biologics because of the infection risk: "And so, you can get some nasty infections with synthetics. And so folks are at high risk of infection, you

got to be careful with synthetics. Here with Strattice, less so. The body has less foreign body reaction, with infections, less of them." 4T67:17-23. ROSEN debunks this claim by confirming that it has never been rigorously studied and finding that Strattice "tended to have a higher risk of deep surgical site infection than the synthetic group (14 [11%] vs 5 [4%])." Pa858.

POINT III: The Trial Court Erred When It Failed to Prevent Dr. Augenstein from Telling the Jury that Ms. Blakeley's Strattice Did Not Resorb Based on a CT Scan (1T24-26; 12T125-128, 218-225, 248, 251-255, 347-350).

Dr. Augenstein's Anti-Resorption Opinion was inadmissible for two primary reasons: (1) Dr. Augenstein was not qualified to offer it by her own admissions, and (2) it is a speculative "net opinion" that conflicts with undisputed eyewitness testimony. While the trial court eventually recognized both flaws at trial, it failed to effectively exclude it from reaching the jury at several junctures. Once given, the trial court failed to adequately strike this opinion and instruct the jury to disregard it on two separate occasions.

A. Standard of Review

This Court "appl[ies] an abuse of discretion standard to decisions made by trial courts relating to matters of discovery." Pomerantz Paper Corp. v. New Cmty. Corp., 207 N.J. 344, 371 (2011). That said, "appellate courts can digest expert testimony as well as review scientific literature, judicial decisions, and

other authorities." State v. Torres, 183 N.J. 554, 567 (2005) (internal quotation and citation omitted). Accordingly, "the appellate court need not be as deferential to the trial court's ruling on the admissibility of expert scientific evidence as it should be with the admissibility of other forms of evidence." Id.

B. Dr. Augenstein's Anti-Resorption Opinion Was Inadmissible for Several Reasons.

1. Dr. Augenstein Was Unqualified to Offer Her Anti-Resorption Opinion.

N.J.R.E. 702 requires that an expert "have sufficient expertise to offer the intended testimony." Anderson v. A.J. Friedman Supply Co., 416 N.J. Super. 46, 72 (App. Div. 2010) (citing N.J.R.E. 702). The expert must "possess a demonstrated professional capability to assess the scientific significance of the underlying data and information, to apply the scientific methodology, and to explain the bases for the opinion reached." Id. A medical degree does not guarantee the expert has the "sufficient expertise to offer the intended [medical] testimony." Id. at 74–75.

In Anderson, the defendant's expert, Gerald Kerby, M.D., sought to opine that the plaintiff's mesothelioma was not caused by asbestos. Id. at 73. Dr. Kerby was a specialist in internal medicine and pulmonary diseases. Id. He was not an oncologist, gynecologist, pathologist, or an epidemiologist. Id. at 73, 75. He had also never diagnosed a patient with mesothelioma and "deferred 'to the superior

knowledge of the pathologist to make the diagnosis.'" Id. at 73. Accordingly, the trial court precluded Dr. Kerby from testifying about the cause of the plaintiff's mesothelioma. Id. This Court affirmed, noting that "[e]ven if [Dr.] Kirby's license gave him some general competency to testify on all medical subjects, he did not have sufficient expertise to offer the intended testimony." Id. at 74-75.

Like the expert in Anderson, Dr. Augenstein is a medical doctor, but she was not qualified to give her Anti-Resorption Opinion. Dr. Augenstein is not a resorption expert, 12T126:14-16, and yet this opinion was intended to convey that Ms. Blakeley's Strattice did not resorb. Pa366, at 129:10-13 ("So . . . if you're trying to say that the Strattice went away, I don't think that's the case."). Dr. Augenstein was also not qualified to reliably determine whether "Strattice" or "mesh" was present in Ms. Blakeley's abdomen—and did not resorb—based on a CT scan. 12T127:17-20; see also 2T192:25-193:22; Pa368, at 134:9-17.

According to Dr. Augenstein, "only two people . . . can tell you what was [in Ms. Blakeley's abdomen], and one is God and one is a pathologist, and neither one of those I think were available for questioning in this case." Pa370, at 143:20-144:18; 2T193:10-22. Ironically, LifeCell's pathologist, Robert Padera, M.D., testified that even he could not determine whether Strattice was present based on a CT scan without speculating. Pa988, at 223:15-224-8; Pa990,

at 233:15-24. The trial court concurred when it limited her expert certification accordingly. See 12T127:17-128:15. Accordingly, there can be no doubt that Dr. Augenstein was unqualified to give her Anti-Resorption Opinion.

2. Dr. Augenstein's Anti-Resorption Opinion Was a Speculative Net Opinion.

New Jersey uses the methodology-based reliability test, which requires the court "to assess both the methodology used by the expert to arrive at an opinion and the underlying data used in the formation of the opinion" to "ensure that the expert is adhering to the norms accepted by fellow members of the pertinent scientific community." In re Accutane Litig., 234 N.J. at 396–97. "The courtroom is not the place for scientific guesswork, even of the inspired sort." Id. at 397 (internal citation omitted). Each opinion "must be based on facts or data of the type identified by and found acceptable under N.J.R.E. 703." Pomerantz Paper Corp., 207 N.J. at 372. "[A]n expert [must] 'give the why and wherefore' that supports the opinion, 'rather than a mere conclusion.'" Id.

A "net opinion" "is an expert's bare opinion that has no support in factual evidence or similar data" and "which is not admissible and may not be considered." Id. (citing Polzo v. County of Essex, 196 N.J. 569, 583 (2008)). "When an expert speculates, 'he ceases to be an aid to the trier of fact and becomes nothing more than an additional juror.'" Townsend v. Pierre, 221 N.J. 36, 55 (2015). "Given the weight that a jury may accord to expert testimony, a

trial court must ensure that an expert is not permitted to express speculative opinions or personal views that are unfounded in the record." Id.

In Townsend, a driver (Pierre) struck and killed a motorcyclist (Townsend). Id. at 45. Townsend sued Pierre and a property owner for failing to maintain shrubs adjacent to where the accident occurred. Id. at 44. Pierre offered undisputed testimony that while the shrubs initially obscured her view, she could see the intersection before entering it. Id. Nevertheless, Townsend's engineering expert opined that the shrubs were a proximate cause of the collision. Id. While acknowledging Pierre's testimony, Townsend's expert opined that Pierre's account was mistaken. Id. at 43. The trial court struck this as a "net opinion" lacking support in the record. Id. After a reversal in this Court, the Supreme Court held this opinion was a "net opinion that was not only unsupported by the factual evidence, but directly contradicted that evidence." Id.

Dr. Augenstein's Anti-Resorption Opinion is also a speculative, net opinion. For example, Dr. Augenstein admitted she cannot (nobody can) reliably tell whether the line on Ms. Blakeley's CT scan was Strattice. E.g., 12T127:17-20. Dr. Augenstein admitted it was hard to testify to "what was in the operating room" because she was not there. Pa370, at 143:20-144:18.

This opinion also conflicts with Dr. Koelsch's undisputed eyewitness testimony that Strattice was no longer in Ms. Blakeley's abdomen at the time of

her revision surgery. 5T289:1-5, 291:13-15, 293:5-6. When asked in her deposition if she knew what Dr. Koelsch had testified to on this issue, Dr. Augenstein responded: "I don't know." Pa369-70, at 141:5-144:11. Dr. Augenstein said his testimony did not matter to her opinion. Pa370, at 142:3-10. In her Rule 104 Hearing, Dr. Augenstein, like the expert in Townsend, claimed that Dr. Koelsch must have been mistaken: "Koelsch probably doesn't know what Strattice looks like when you go back into the belly." 2T190:1-193:14. At trial she speculated, in violation of the trial court's instruction, that Dr. Koelsch was looking at Strattice in the operating room. 12T349:1.

So not only does Dr. Augenstein's opinion conflict with the only eyewitness account, it turns on yet another layer of speculation about whether Dr. Koelsch, a surgeon she has never met, is capable of identifying the presence or absence of Strattice in a patient's abdomen.

Dr. Augenstein also failed to review LifeCell's Resorption Profile Study which confirms Strattice resorbs or consider the possibility that Ms. Blakeley's Strattice had resorbed. See Pa390, at 225:3-24. Like Dr. Koelsch, LifeCell never told Dr. Augenstein that Strattice resorbs. Pa391, at 227:15-20. She testified that in her view, Strattice does not resorb. Pa367, at 130:10-14. The only evidence on which Dr. Augenstein based this opinion was the CT scan, which does not objectively support her Anti-Resorption Opinion. In other words, there is no way

to reliably test or verify that the line on the CT scan is "Strattice" or "mesh" as opposed to Ms. Blakeley's own tissue.

Accordingly, because Dr. Augenstein's opinion was speculative and based on cherry-picked evidence, it was inherently unreliable.

C. The Trial Court Erred in Its Inconsistent Handling of Dr. Augenstein's Inadmissible Anti-Resorption Opinion.

The trial court made several errors regarding Dr. Augenstein's Anti-Resorption Opinion. The first error was its failure to exclude (or even address) this opinion on Ms. Blakeley's motion to exclude this opinion. Pa3. The second error occurred when, after recognizing at trial that Dr. Augenstein was not qualified to offer this opinion and that it would require her to speculate, the trial court failed to instruct Dr. Augenstein that she could not offer it at all. Instead, the court instructed Dr. Augenstein that she could "testify there's something there" but she could not "name the product." 12T224:23-225:2. This left the door wide open for Dr. Augenstein to deliver her Anti-Resorption Opinion by merely replacing the word "Strattice" with "mesh," which she immediately did. 12T227:12-22. But allowing Dr. Augenstein to call it "mesh" instead of "Strattice" did not magically qualify her to give her Anti-Resorption Opinion, render it reliable, or change the fact that it was mere speculation.

The third error occurred when the trial court, on its own, instructed the jury "disregard" Dr. Augenstein's testimony about "mesh" while Ms. Blakeley

was approaching the bench for a sidebar to discuss what should be done. See 12T227:24-228:10. The trial court should have consulted with the parties first and given a more appropriate instruction considering the circumstances and significance of the testimony, like the one proposed by Ms. Blakeley.

The final error occurred when Dr. Augenstein offered non-responsive testimony on cross-examination that Dr. Koelsch was "looking at Strattice" when he reoperated on Ms. Blakeley. 12T349:1. This testimony expressly violated the trial court's prior instruction that Dr. Augenstein could not "name the product" and was both unreliable and highly speculative. Despite the trial court's prior promise to address this type of testimony if given again, 12T252:8-10, when Ms. Blakeley moved to strike it, the trial court refused and did not instruct the jury to disregard it. 12T349:2-350:17.

These errors, which occurred during the testimony of the last trial witness and directly went to issues of general and specific causation and liability, prejudiced Ms. Blakeley's case and warrant a new trial on all claims.

CONCLUSION

For the reasons set forth herein, Ms. Blakeley respectfully requests that this Court reverse the rulings of the Law Division and remand this case for a new trial on all issues.

LITE DEPALMA GREENBERG & AFANADOR, LLC

Dated: November 8, 2024

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THERESA BLAKELEY, Plaintiff/Appellant, vs. LIFECELL CORPORATION, ALLERGAN, INC., and ALLERGAN USA, INC., Defendants/Respondents.	SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION Docket No. A-002807-23 On Appeal From Several Orders From The SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY Docket No. ATL-L-1214-22 Sat Below: Hon. John C. Porto, P.J.Cv.

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PRELIMINARY STATEMENT

No legal error infected the proceedings below in this case, which included a hard-fought and fair trial conducted over ten days resulting in a directed verdict on one claim at the close of plaintiff's evidence (failure to warn) and a total defense verdict after just two hours of deliberation on the two claims that went to the jury (design defect and breach of warranty). Plaintiff lost this case because her legal theories fell short and she could not produce evidence to support her claims. Those shortcomings flowed directly from the weakness of her case, not from any legal error committed below. This Court should affirm.

In 2020, Plaintiff Theresa Blakeley had surgery to repair a hernia, which included implanting a biologic mesh known as Strattice. Plaintiff's doctor chose Strattice after carefully considering her individual risk factors and the risks and benefits of this product and others. Plaintiff's doctor also understood—and warned her—that the hernia could come back, or "recur." Some months after her surgery, Plaintiff sustained a "recurrence. She then had a second operation.

Plaintiff initiated this lawsuit and claimed that Strattice caused her recurrence and that LifeCell (Strattice's manufacturer) and its parent companies were liable. She lost at trial and now asks for a second chance. She claims on appeal that the trial court erred in directing a verdict and in two evidentiary

decisions. None of her arguments should succeed on appeal.

First, the trial court correctly directed verdict on the failure-to-warn claim for three independent reasons. One, the New Jersey Product Liability Act gives Defendants' warning a presumption of adequacy, which Plaintiff does not even contest on appeal. Two, Defendants clearly and adequately warned of the only danger at issue—recurrence—in the brochure they gave to her doctor. The harms Plaintiff claims were omitted from the warning were not harms at all, and the studies she claims should have been included in the labeling each suffered serious problems that prevented their inclusion. Three, Plaintiff did not establish that any inadequacy in the warning proximately caused her injury. Each of these three reasons on their own—to say nothing of their combined force—supports the directed verdict.

Second, the trial court did not abuse its discretion when it excluded from evidence a study it concluded was not relevant and which was released *after* Plaintiff's surgery (the "ROSEN" study). As a matter of New Jersey law, a defendant is imputed with knowledge of a danger (and thus required to warn of that danger) only if plaintiff establishes the danger was "known or knowable" in the "relevant industry." The trial court concluded Plaintiff had not carried her burden to establish knowledge of the ROSEN study's findings. The trial court's

application of these basic evidentiary rules to exclude irrelevant evidence (1) was not an abuse of discretion and (2) did not prejudice Plaintiff.

Third, the trial court did not abuse its discretion when it limited testimony from *Defendants*' expert, Dr. Augenstein. Plaintiff contends that one of Dr. Augenstein's opinions—that Strattice remained in Plaintiff at the time of her second operation—was admitted improperly. Although Defendants contended such testimony was admissible, the trial court actually agreed *with Plaintiff* and struck testimony about that opinion when offered in response to defense questioning. When the opinion was offered a second time—in response to a question from Plaintiff's counsel—Plaintiff's counsel did not ask to strike the testimony. The trial court did not abuse its discretion in issuing an immediate curative instruction the first time Dr. Augenstein issued the opinion and in not *sua sponte* striking the same testimony when Plaintiff's counsel elicited it. Additionally, and a separate basis for affirmance, Dr. Augenstein's testimony was admissible, so its introduction was not error. Moreover, and a third reason to affirm, Plaintiff waived any argument about this testimony, including by failing to list it in her case information statement on appeal.

PROCEDURAL BACKGROUND

Plaintiff sued LifeCell in April 2022 for the damages she allegedly

sustained from her hernia recurrence. Pa108. The parties filed a variety of pretrial motions, including motions in limine and to exclude expert testimony. The court granted Defendants' motion to exclude Biologic vs Synthetic Mesh for Single-stage Repair of Contaminated Ventral Hernias, by Michael J. Rosen et al. (the "ROSEN" study) on the basis it was irrelevant. Pa34; 4T18:3-16. Plaintiff moved to exclude certain opinions of LifeCell's retained expert, Dr. Vedra Augenstein. See Pa3. Pre-trial, the court denied the motion and allowed Dr. Augenstein's opinion. Pa3–33.

At trial, Plaintiff presented her case and, after she rested, Defendants moved for directed verdict on all claims. Pa37. The court granted the motion as to only one claim, failure to warn. See id. With two claims remaining—breach of warranty and design defect—Defendants proceeded to introduce their case. Although the court had previously denied Plaintiff's pretrial motion to exclude Dr. Augenstein's opinion that Strattice remained in Plaintiff's body prior to her second hernia operation, see Pa3, the court subsequently agreed with Plaintiff at trial to exclude the opinion that a CT scan prior to Plaintiff's second operation displayed Strattice.[1] 12T224:23-225:1.

[1] Plaintiff took issue with this opinion because her theory was that Strattice was not sufficiently durable to support Plaintiff's healing. 13T179:20-180:2.

After the close of evidence, the jury deliberated for approximately two hours and found in favor of Defendants on both remaining claims. See Pa1.

COUNTER STATEMENT OF FACTS

I. LifeCell Developed Strattice To Meet A Critical Need For Low-Risk Mesh.

Hernias are a widespread and painful medical condition that require surgical repair. Pa922. A hernia occurs where "there is an area of weakness or a tear or a hole in the abdominal wall." 10T92:6-10. "The vast majority of [hernia] patients . . . need mesh reinforcement" of the soft tissue. 10T96:14-15; Pa251. Hernia mesh can be broadly sorted into either synthetic or biologic mesh. 10T96:18-23, 97:20-24; 4T113:17-21.

Synthetic mesh supports hernia repair by remaining in a patient's body and serving as a bridge for the damaged tissue. See 6T174:20-21; 11T188:1-7. Because synthetic mesh is constructed from artificial, non-biological material, the human body has a difficult time removing any bacteria that attaches to the synthetic materials. See 11T184:22-187:13. This can lead to dangerous infections (especially for patients with co-morbidities) and can require surgical removal, "a very dire consequence." See 6T47:10-19; 10T100:16-101:5, 101:20-24; 11T188:8-15; 12T71:17-25, 49:3-50:1.

Given the risks associated with synthetic hernia mesh, there was a need

for the development of alternatives. LifeCell developed a biologic mesh, Strattice, at the request of doctors who were not "completely satisfied with the current hernia repair products" on the market. 11T18:16-18, 20:4-7; see Da1. LifeCell spent multiple years designing and testing Strattice and, following FDA review, received clearance to market the device. See 11T21:12-22:2, 23:7-37:14, 47:1-8, 165:10-18; 5T113:9-10; Da4. Strattice has now been on the market for sixteen years. 11T47:1-8.

Unlike a synthetic mesh, Strattice, a biologic mesh, can be accepted by the body and serve as a scaffold for the body to heal itself. 11T39:16-21; 11T40:25-41:7. The "mechanism of action," ("in layman's term[s], . . . how the product works," 11T38:18-39:2), can be termed "regeneration" because it "[l]everages the body's regenerative process." 11T118:5-8, 206:2-8. Strattice causes cells to "com[e] in" and "lay[] down more and more collagen and tak[e] up more of the Strattice matrix" and, in the "final phase, Strattice is resorbed and the new tissue is now there." 11T45:3-23, 46:4-10; see 11T60:24-61:5. Resorption following implantation of Strattice is not a complication—it is part of the healing process. See 11T39:16-19, 58:11-16, 61:1-3.

Of course, Strattice—like all hernia meshes—comes with risks. For both biologic and synthetic mesh, it is well known among doctors that,

notwithstanding the mesh, a patient may sustain a hernia recurrence. See, e.g., 4T215:22-25 (Dr. Liang); 5T159:6-21, 268:12-20 (Dr. Koelsch); 10T100:16-18 (Dr. Bhanot). Obesity increases the risk of both a recurrence and a post-operative infection. 6T36:10-14; 10T100:10-101:5, 104:25-105:12.

Strattice's risks can be lower compared with other mesh options for certain patients. See 10T125:22-126:1, 108:16-25; 12T131:2-13; Da12; 10T127:23-128:1. Strattice has a lower risk of recurrence than other biologic mesh. 10T125:12-126:1; Da23. Strattice has a lower risk of post-operative infection when compared with synthetic mesh (thus lowering the risk the infection will need surgical cleaning and require a second repair surgery). See 6T49:2-50:10; 9T102:20-24; 10T100:19-101:5; 10T104:25-105:12; 11T37:4-5; see also 12T35:20-36:1, 37:18-38:12, 48:3-17 (testimony explaining that a study comparing synthetic mesh with Strattice in patients with comorbidities was cut short because not enough surgeons were comfortable with their comorbid patients using synthetic instead of Strattice).

Prior to Plaintiff's surgery, Defendants promoted Strattice through a brochure known as the "Shark Ad." See 9T138:25-139:3. On the front page of this brochure, Defendants warned of recurrence, noting that a recent study showed biologic mesh has "a cumulative hernia recurrence rate of 8.3% at 7

years post-op." Pa253. The brochure itself referenced four additional studies and the recurrence rates they found for biologic mesh. Pa255. Those studies reported recurrence rates of 6.0% (Golla), 7.5% (Liang), 8.3% (Garvey), 8.0% (Booth), and 13.2% (Richmond). Pa255.

II. Plaintiff's Doctor Evaluated The Risks Of Mesh, And Her History And Risk Factors, And Opted To Use Strattice To Treat Her Hernia.

When Plaintiff began experiencing hernia pain, she went to see a surgeon who declined to treat her until she lost weight. 7T94:3-8, 16-24. Plaintiff then presented to Dr. Koelsch, another surgeon, who recommended a hernia repair. 7T95:14-97:22. Dr. Koelsch testified that the first surgeon was likely worried about Plaintiff's obesity, a "risk factor[] for hernia recurrence." 6T35:9-22.

Dr. Koelsch recognized prior to prescribing Strattice that Plaintiff's obesity gave her "a higher risk for wound infection or wound healing complications" and accounted for this risk profile in selecting a mesh. 5T244:3-246:1. Dr. Koelsch was aware of the risk of hernia recurrence with Strattice (indeed, he was aware that all mesh posed a risk of recurrence). 5T244:3-13, 265:2-11, 268:12-20; 6T78:9-15. Dr. Koelsch also knew that Plaintiff's obesity increased her risk of both a recurrence and sustaining an infection. 6T36:2-14; 47:10-24. It was especially "important" to Dr. Koelsch that Plaintiff "avoid an infection." 6T46:18-24. He had experienced "infection in patients with

[synthetic mesh]" and testified that it's "horrible" because of the difficulty with "explant[ing] synthetic mesh." 6T46:2-8. "[I]t's just something you don't want, which is why we looked for an alternative to try to not have that complication." 6T46:7-12. Dr. Kolesch knew that, in addition to her obesity, the use of a synthetic mesh would increase her risk of infection. 5T245:1-8; 5T245:20-246:1. Dr. Koelsch thus concluded that the best course for Plaintiff was to use Strattice. 5T:244:3-246:1; 6T47:15-19, 59:13-18. He discussed his recommendation with Plaintiff and shared the risks, including the risk of recurrence, with her. See 6T45:7-11; 7T151:10-12.

Plaintiff's hernia defect was, at "its largest width," approximately 7.2 centimeters. 12T194:11-16. Dr. Koelsch testified that best practice for hernia mesh is to use a mesh that exceeds the hernia defect by at least 6 centimeters (which would afford 3 centimeters extra mesh on each end of the defect). 5T285:19-25. Dr. Augenstein testified that it is especially important for a mesh to substantially exceed the size of the hernia defect when the patient is "morbidly obese because there's more pressure." 12T202:5-25. Dr. Koelsch nonetheless selected a 10 centimeter mesh, which was 3 centimeters shorter than it should have been according to his own standard. 12T201:14-15; 5T285:1-22. Plaintiff did not develop any infection from the Strattice mesh. 6T59:10-12.

Approximately a year after Plaintiff's surgery, she returned to Dr. Koelsch, who diagnosed her with a recurrent ventral hernia and performed another surgery on June 3, 2021, this time using a synthetic mesh. 5T278:6-12.

LEGAL ARGUMENT

This Court should affirm. The trial court did not err in entering directed verdict on Plaintiff's failure-to-warn claim, it did not prejudicially abuse its discretion in excluding the ROSEN study, and it did not prejudicially abuse its discretion in *agreeing with Plaintiff* and limiting Dr. Augenstein's testimony.

I. The Trial Court Correctly Directed Verdict On The Failure To Warn Claim For Three Independent Reasons.

The trial court directed verdict for Defendants on the failure to warn claim. This Court reviews de novo the question whether a trial court properly grants a directed verdict. See Frugis v. Bracigliano, 177 N.J. 250, 269 (2003); Carbajal v. Patel, 468 N.J. Super. 139, 157 (App. Div. 2021). A directed verdict is proper "where no rational juror could conclude that the plaintiff marshaled sufficient evidence to satisfy each prima facie element of a cause of action." Smith v. Millville Rescue Squad, 225 N.J. 373, 397 (2016) (citation omitted).

This Court should affirm for three independent reasons: (1) Ms. Blakeley never overcame (and does not even argue on appeal that she could overcome) the statutory presumption in the New Jersey Product Liability Act (NJPLA) that

Defendants' FDA-compliant warning was adequate; (2) Plaintiff has not shown that Defendants' warning was inadequate; and (3) Plaintiff has not shown that any different warning would have prevented her recurrence.

A. Plaintiff Cannot Overcome the Statutory Presumption that Defendants' FDA-Compliant Warning Was Adequate.

The NJPLA was "intended to reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation." Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 194 (2012). One way the NJPLA accomplishes that goal is by entitling manufactures to a "super-presumption" that when a warning label complies with FDA requirements, that warning is adequate. See N.J.S.A. § 2A:58C-4; Kendall, 209 N.J. at 195. The Supreme Court has explained that "only in the 'rare case' will damages be assessed against a manufacturer issuing FDA-approved warnings." Kendall, 209 N.J. at 195 (citation omitted).

A decision by the FDA that a warning or instruction requires or does not require "certain information" entitles a manufacturer to a presumption of adequacy. That presumption is rebutted only by proof that the manufacturer deliberately concealed or did not disclose "after-acquired knowledge of harmful effects" or "manipulated the post-market regulatory process." Bailey v. Wyeth,

Inc., 424 N.J. Super. 278, 314 (Law. Div. 2008) (subsequent history omitted); see In re Accutane Litig., 235 N.J. 229, 277 (2018) ("In the absence of evidence . . . to rebut the presumption, as a matter of law, the warning[]" is adequate).

As part of its FDA market clearance application for Strattice, LifeCell submitted a draft "Instructions for Use," which is governed by FDA labeling regulations. 5T158:20-159:1, 180:24-181:2. Although the FDA could ask questions regarding the Instructions or decline to clear Strattice, the FDA cleared Strattice in 2007. See 8T203:14-21 (noting that the FDA had requested "clarification on some of the labeling"); Da4; 21 C.F.R. § 807.100(a)(2).

The trial court concluded that, "[s]ince Strattice was approved by the FDA, defendants are initially entitled to their presumption of adequacy." 12T11-6-9. The court further concluded that Plaintiff had not demonstrated one of the bases for rebutting that presumption, *viz.*, that "[t]he risk was [] concealed," 12T16:12-13; see Bailey, 424 N.J. Super. at 314.

Despite Defendants' entitlement to a presumption of adequacy, Plaintiff makes no attempt to overcome that presumption on appeal by arguing it is inapplicable or rebutted. Indeed, Plaintiff ignores the presumption entirely—the word "presumption" appears nowhere in this section of her brief. The presumption is an independent basis on which this Court can affirm the decision

below and Plaintiff's failure to challenge it in her opening brief dooms her request for reversal. See New Jersey Dep't of Env't Prot. v. Alloway Twp., 438 N.J. Super. 501, 505 n.2 (App. Div. 2015) ("An issue that is not briefed is deemed waived upon appeal."); accord L.J. Zucca, Inc. v. Allen Bros. Wholesale Distribs. Inc., 434 N.J. Super. 60, 87 (App. Div. 2014); see also Borough of Berlin v. Remington & Vernick Eng'rs, 337 N.J. Super. 590, 596 (App. Div. 2001) ("Raising an issue for the first time in a reply brief is improper.").

Even if this argument weren't waived, it fails. As explained above, the FDA cleared Strattice with full knowledge of its proposed label. See 5T158:20-159:1; Da4. The presumption of adequacy thus applies. And Plaintiff cannot rebut it. N.J.S.A. § 2A:58C-4; see, e.g., Greisberg v. Bos. Sci. Corp., No. 21-2364, 2022 WL 1261318, at *2 (3d Cir. Apr. 28, 2022); Da49. The principal danger that Plaintiff alleges in this litigation is recurrence, but the possibility of recurrence following mesh reinforcement was not "deliberate[ly] conceal[ed]"—it was both well known and disclosed in the labeling. Bailey, 424 N.J. Super. at 314; see, e.g., 5T159:6-21; 5T268:12-20 (Dr. Koelsch); 4T215:22-25 (Dr. Liang); 10T101:16-19 (Dr. Bhanot); Pa253, Pa255. Nor has Plaintiff provided "clear and convincing evidence" that Defendants manipulated the post-market regulatory process in any way. In re Accutane Litig., 235 N.J. at 275.

Because Plaintiff has not attempted to rebut the statutory presumption that Strattice's warning was adequate, this Court should affirm. See id. at 277 (an unrebutted presumption means the warning was adequate "as a matter of law").

B. This Court Should Also Affirm the Directed Verdict Because the Warnings Were Adequate.

Plaintiff asserts that Defendants' warnings were inadequate for failure to warn about resorption, regeneration, and recurrence. See Pb22–38. First, Plaintiff claims Defendants did not warn of resorption, when mesh "'goes away' after implant," which she claims is a problem because the mesh cannot adequately support healing after it resorbs. Pb14; 13T180:9-181:5. Second, Plaintiff claims that Defendants falsely promised Strattice would support the body's regenerative capabilities. Pb16, 24. Finally, although Plaintiff acknowledges that Defendants warned of the risk that a hernia could recur following implantation, Plaintiff claims that the warning should have included either different rates of recurrence or described the likelihood differently. Pb33.

Plaintiff's arguments fail. Regeneration (or lack thereof) and risk of resorption do not require a warning because they are not themselves "risks." As for recurrence, Defendants expressly warned of this risk and Defendants are not liable for failing to disclose Plaintiff's preferred (but flawed) specific recurrence

rates. As such, the trial court could rule "as a matter of law, the warnings provided physicians with adequate information to warn their patients." In re Accutane Litig., 235 N.J. at 236.

1. Defendants Had No Obligation to Warn of Resorption or Lack of Regeneration.

An adequate warning is one that "communicates adequate information on the dangers and safe use of the product." N.J.S.A. § 2A:58C-4. Plaintiff complains that Defendants should have warned that Strattice "resorbs" and that it does not "regenerat[e]." Pb24. But neither resorption nor lack of regeneration are "dangers" (nor are they related to "safe use of the product"). N.J.S.A. § 2A:58C-4. Even if Defendants did not include any information about resorption or regeneration in their warnings, that inaction could not support a failure-to-warn claim because that claim requires failing to warn of a *danger*.

Plaintiff cites no evidence that resorption or lack of regeneration is a "danger." Her sole evidence is testimony from an employee of Defendants that resorption is "not a desired outcome." Pb24 (quoting 7T183:9-10). The employee was clear, however, that resorption as he meant it was when Strattice resorbed prematurely, too fast to "allow[] . . . the product . . . the time to incorporate and infiltrate from host tissue" such that it could not "support the

regenerative effect." 7T182:15-17. And even in that case, resorption would not harm the patient—it would simply result in not "a strong repair" which of course could lead to an eventual recurrence. 7T182:23-183:10; see Pb35 ("hernia recurrence is an outcome [of resorption]"). Recurrence is the relevant risk—not resorption or lack of regeneration.

Moreover, what the overwhelming evidence actually shows is that resorption, when the product functions as testing shows it does and does not resorb prematurely, is a benefit of Strattice that generally indicates the product is working as intended. See 11T60:24-61:5 ("Strattice only resorbs when the cells come in and lay down new collagen."); 11T39:16-19, 45:3-23, 46:4-10. Strattice is designed to prompt the body to replace Strattice with its own cells and, as those cells arrive, Strattice resorbs. See id. This resorption leaves the patient with a successful repair consisting of their own tissue.[2]

Plaintiff next argues that Defendants falsely described that Strattice worked by allowing regeneration. Pb24. But multiple witnesses testified that

[2] Plaintiff attempts to portray the finding in LifeCell's "Resorption Profile Study" that Strattice resorbs "between 75 to 100% . . . at 3 months" as indicating the product is unsafe. Pb14, 15. But that was a *positive* finding that Strattice is operating as intended. On the very same page as the "75 to 100%" number, the Profile reports evidence of Strattice "remodeling into new host tissue by transitioning from a dense reticular dermal porcine collagen structure" (that is, the Strattice mesh) "to a loosely organized *host* collagen structure." Pa586.

Strattice supports regeneration. See 11T118:5-8 (explaining that the product is regenerative in the sense that it "[l]everages the body's regenerative process"); 11T206:2-8. For her part, Plaintiff cites no evidence that a lack of regeneration is a "danger." N.J.S.A. § 2A:58C-4. She argues that Defendants misled by promising regeneration. That argument may be relevant to Plaintiff's claim for breach of warranty (which the jury rejected), but it does not implicate whether Defendants failed to *warn* of a *danger*.[3]

To be adequate, a warning must warn of known dangers. See N.J.S.A. § 2A:58C-4. A product's *benefit* is not a *danger* and, thus, cannot serve as the basis for a failure to warn. As the trial court explained, the "ultimate risk" of Strattice was hernia recurrence—and Defendants warned of that. 10T16:12-15. Plaintiff's complaint that this "ultimate risk" language failed to warn of "all dangers" misses the point. The trial court did not ignore her claim of other dangers—it simply explained that resorption and lack of regeneration were not themselves harmful. Resorption or lack of regeneration might, under the trial

[3] The inapplicability of this argument is underscored by Plaintiff's failure to cite relevant authority. She cites language from Bailey v. Wyeth, Inc. indicating that a defendant cannot misrepresent the "safety *risks* of their products." See Pb36 (quoting 424 N.J. Super. at 332–33). That is true—but whether Strattice assists in regeneration is not a risk. It is a potential benefit.

court's view *lead to* a recurrence, which is why the recurrence can be colloquially referred to as the "ultimate risk."

2. The Trial Court Correctly Concluded that, as a Matter of Law, Defendants Adequately Warned of Recurrence.

Plaintiff next complains that Defendants' warning was inadequate because the risk of recurrence was (she claims) higher than disclosed. But Defendants are not required to warn of *any* risk rate. And even if they were, directed verdict was still appropriate because Defendants could not have relied on the studies with higher recurrence rates because they had damning flaws. Moreover, Defendants' warning was adequate because the law requires an *adequate* warning, not a *comprehensive* one, and here the warning was adequate because it excluded irrelevant studies and included five separate recurrence rates.

i. New Jersey Law Does Not Require Manufacturers to Warn of the Likelihood of a Potential Harm.

Defendants warned of the risk of recurrence. The face of the Shark Ad included this risk, and the brochure listed five rates of recurrence for biologic mesh found by various clinical studies. Pa253, Pa255. Plaintiff argues, however, that the warning is not adequate because it lacks what she views as the correct rates of recurrence or likelihood of complication. But she seeks more than the law requires. The NJPLA requires only that defendants warn of an

actual risk, not that they warn of any likelihood of that risk. Moreover, even when a manufacturer includes some studies cataloguing complication rates, that does not require they disclose *all* studies (regardless how unreliable they are).

An "adequate" warning is 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." N.J.S.A. § 2A:58C-4. Adequacy under the NJPLA also incorporates the "learned intermediary" doctrine, which relies on "the ordinary knowledge common to[] the prescribing physician." Id.; Hrymoc v. Ethicon, Inc., 467 N.J. Super. 42, 85 (App. Div. 2021), aff'd as modified by 254 N.J. 446 (2023).

A reasonable manufacturer, understanding that the prescribing physician "has the primary responsibility of advising the patient of the risks and benefits of taking a particular medication," In re Accutane Litig., 235 N.J. at 239 (citation omitted), gives a warning that empowers the physician to make the best medical decision for a patient. A cornerstone of our medical system is that the prescribing physician takes into account a specific patient's needs and risk factors when recommending a medical drug or device. See Bacardi v. Holzman, 182 N.J. Super. 422, 425 (App. Div. 1981) (quoting Davis v. Wyeth Lab'ys, Inc., 399 F.2d 121, 130 (9th Cir. 1968)).

A reasonable manufacturer thus warns of the risks involved in the use of a device because that empowers a physician to assess the potential risks for his patient. But it is not unreasonable for a manufacturer to omit from its warning complication rates that have been found only for a limited population (and Plaintiff cites no New Jersey case that requires such a disclosure).[4] Because any complication rate found in a study is intrinsically tied to the population studied and the various risk factors held by the individuals in that population, it cannot *actually* predict the likelihood that any given patient will sustain a complication. That likelihood is instead bound up with the unique medical history of the patient. Because manufacturers can reasonably expect that, when it is relevant to their medical judgment, physicians will assess the likelihood of a complication by taking into account the medical literature that is relevant in light of a patient's risk profile—and because a manufacturer cannot give a complication rate that accounts for a particular patient's risk profile, it is not

[4] Plaintiff cites Hrymoc v. Ethicon, Inc. for the proposition that "information bearing on the magnitude or likelihood of a risk is important to surgeons." Pb 30. That case is not about what constitutes an adequate warning. The discussion she quotes relates to proximate cause, not the adequacy of the warning. See Hrymoc, 467 N.J. Super. at 88–89. That discussion also arose from the desire of the particular physician in that specific case for understanding of the likelihood of the risk—the court does not opine that a warning is inadequate without a disclosure of likelihood. See id. at 85–91.

unreasonable for a manufacturer to omit complication rates from their warning.

Indeed, this case is a perfect illustration of the reality that manufacturers need warn only of the type (rather than quantum) of risk. Dr. Koelsch knew that recurrence was a risk of any hernia mesh he chose but was particularly concerned that Plaintiff not sustain an infection, particularly in light of her obesity. 5T244:3-13, 245:1-8; 245:20-246:1, 265:2-11, 268:12-20; 6T36:2-14, 46:18-24, 47:10-24, 78:9-15. He performed his role as the learned intermediary by weighing that risk and prescribing Strattice.

This reality explains why the NJPLA requires only an *adequate* and not a *comprehensive* warning. See N.J.S.A.§ 2A:58C-4. A comprehensive warning—including all potential complication likelihoods—would be both impractical and unhelpful. An adequate warning empowers physicians to know the types of risk their patient faces and then to assess the risks and benefits in light of the patient's medical history. Requiring the comprehensive warning Plaintiff seeks would expand the warning required beyond the plain text of the NJPLA and simultaneously undermine the balance it strikes between manufacturers and learned intermediaries in prescribing medical devices.

Plaintiff does not cite any New Jersey authority requiring that a manufacturer disclose the likelihood of a risk. Of the out of jurisdiction cases

she cites, several require only that a manufacturer disclose relative risk, namely, the risk of a product as compared with the risk posed by competitor products. See, e.g., In re Bard IVC Filters Prod. Liab. Litig., 969 F.3d 1067, 1076 (9th Cir. 2020) (allowing the jury to decide failure-to-warn because the applicable state law "has not adopted a categorical prohibition on basing a failure-to-warn claim on the absence of a comparative warning").[5] Plaintiff does not argue that Defendants failed to warn of the relative risk rate of Strattice with other biologic (or synthetic) mesh.

Plaintiff next argues that Defendants inclusion of some rates "opened the door" to a requirement that they include others. Pb32. This is not what the law requires. An adequate warning may include some studies (here, the most reliable) while excluding others (including those released in the future).[6]

In sum, Plaintiff has no authority for her novel argument that the NJPLA

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[5] See also Keen v. C.R. Bard, Inc., 480 F. Supp. 3d 624, 641 (E.D. Pa. 2020); Dalbotten v. C. R. Bard, Inc., No. 1:20-CV-00034-SPW, 2023 WL 157735, at *5 (D. Mont. Jan. 11, 2023); Pa1004.

[6] Plaintiff also offers a bare policy argument that she should win because a patient's interest in information "predominates over a policy interest that would insulate manufacturers." Pb33 (quoting Perez v. Wyeth Lab'ys Inc., 161 N.J. 1, 29 (1999)). But the trial court's directed verdict did not prioritize manufacturers over patients—it accepted that New Jersey does not impose the impractical and frequently impossible duty for a manufacturer to warn a patient's physician of the results of every study that has been performed on a product.

requires manufacturers disclose any—much less all—complication rates in a warning. This Court should hew to the statute as it is written, rather than expanding it as Plaintiff suggests. Because Defendants warned of the risk of recurrence—the harm that occurred here—their warning was adequate.

ii. Defendants Could Not Have Included Plaintiff's Preferred Recurrence Rates in Their Warning.

Even if New Jersey law required an adequate warning to include percentage risks of harm, this warning was still adequate because it included all reliable scientific data known to Defendants at the time. The three studies with higher recurrence rates that Plaintiff claims Defendants should have included all contained fatal flaws: they studied off-label use and were published after Plaintiff's surgery.

Here, the law is clear: Defendants' duty to warn attaches to "dangers of which they know or should have known on the basis of reasonably obtainable or available knowledge." In re Diet Drug Litig., 384 N.J. Super. 525, 534 (Law. Div. 2005) (citation omitted). It is Plaintiff's burden to establish "that knowledge of the defect existed within the relevant industry" before her surgery. Coffman v. Keene Corp., 133 N.J. 581, 599 (1993); see James v. Bessemer Processing Co., 155 N.J. 279, 304 (1998); Butler v. PPG Indus., Inc., 201 N.J. Super. 558, 563 (App. Div. 1985) ("The adequacy of a warning is to be evaluated

in terms of what the manufacturer actually knew and what it should have known based on information that was reasonably available or obtainable and that should have alerted a reasonably prudent person to act.").

The ROSEN, LIANG, and HARRIS studies with higher recurrence rates that Plaintiff points to (and that her expert witness relied on) is each fatally flawed.[7] First, these studies were unreliable (and unusable) because they focused on off-label use of the device. Including them would therefore conflict with (and be preempted by) federal law. See R.F. v. Abbott Lab'ys, 162 N.J. 596, 620 (2000); 5T129:5-18, 151:5-153:10. Second, even if not squarely preempted, including data about off-label use would make Strattice's warning less adequate. Third, these studies could not have been "known or knowable" because they were formally published only after Plaintiff's surgery. Fourth, the findings in HARRIS and LIANG, even if they were known or knowable (and they were not) were either statistically insignificant or underpowered (where the

[7] Hobart Harris et al., Preventing Recurrence in Clean and Contaminated Hernias Using Biologic Versus Synthetic Mesh in Ventral Hernia Repair: the PRICE Randomized Clinical Trial, Annals of Surgery (Vol. 273, No. 4, Apr. 2021), Pa843; Mike Liang et al., Synthetic Versus Biologic Mesh for Complex Open Ventral Hernia Repair: A Pilot Randomized Controlled Trial, Surgical Infections (2020), Pa835; Michael J. Rosen et al., Biologic vs Synthetic Mesh for Single-stage Repair of Contaminated Ventral Hernias, JAMA Surgery (Apr. 2022), Pa851.

number of "enrolled patients" are so few that "even a few patients may have changed the overall results," 10T190:22-5). In short, including the recurrence rates from any of these studies in the warning would have been unreasonable, impossible, or both.

First, HARRIS, LIANG, and ROSEN all substantially studied recurrence rates from off-label use of Strattice, see Pa835–36; Pa843; Pa846; Pa851, and federal law preempts the inclusion of off-label studies in a federally-regulated warning. Plaintiff's own regulatory expert confirmed in her testimony that "[i]t would be inconsistent with the regulations" for a "company who has been told [not to] market [its] product for this type of thing to then use a study for that type of thing and put it in [the manufacturer's] brochures." 5T153:3-10. In this case, FDA was clear that Strattice had not been cleared for use in contaminated or infected hernias. 5T129:5-18; Da28.

The federal statute, regulations, and FDA guidelines support that testimony. "[T]he FD&C Act and FDA's implementing regulations generally prohibit manufacturers of new drugs or medical devices from distributing products in interstate commerce for any intended use that FDA has not approved as safe and effective or cleared[.]" U.S. Dep't of Health and Human Services, Good Reprint Practices for the Distribution of Medical Journal Articles and

Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Jan. 2009) (hereinafter "Good Reprint Practices"),[8] Da32. Under FDA regulations, a cleared "use" is also tied to the approved population for that use. 5T65:22-66:4. Any "off-label" marketing—which would include all written communications by a manufacturer—would be considered "false or misleading" labeling. 21 U.S.C. §§ 331(a), 352(a)(1); see 5T26:15-20. The FDA was clear at the time of Plaintiff's surgery that communicating the results of clinical studies that analyze a non-cleared use of a medical device is, by default, impermissible off-label promotion. See Good Reprint Practices, Da36-39.[9]

Simply put, it was a "physical impossibility" for Defendants to comply with these rules and share data from these studies prior to Plaintiff's August 17, 2020 surgery. Gonzalez v. Ideal Tile Importing Co., 184 N.J. 415, 421 (2005). FDA has made clear that Strattice is not cleared for use in infected or

[8] Available at https://www.regulations.gov/document/FDA-2008-D-0053-0127. See Hollinger v. Shoppers Paradise of New Jersey, Inc., 134 N.J. Super. 328, 334 (Law. Div. 1975) (taking judicial notice of the contents of federal agency publications), aff'd, 142 N.J. Super. 356 (App. Div. 1976).

[9] One exception under those guidelines was to distribute the *entire* off-label study. See Good Reprint Practices, supra, Da36-39. This exception obviously did not permit Defendants to share these studies prior to Plaintiff's surgery because those studies were not actually published until after Plaintiff's surgery.

contaminated hernias. See 5T129:14-18; Da28. A principal objective of each of these three studies was to study the use of mesh in contaminated or infected hernias. See Pa835, 836; Pa843, 846; Pa851.[10] As such, if Defendants were to include these studies in their advertising, they would have been promoting studies analyzing a non-cleared use of Strattice and thus promoting off-label use of their product, a clear violation of FDA statutes, regulations, and guidance documents.

Any claim under New Jersey law that Defendants should have warned of these findings is preempted by federal law, including regulatory law, when it is "impossible for a private party to comply with both state and federal requirements." Merck Sharp & Dohme Corp. v. Albrecht, 587 U.S. 299, 303 (2019) (citation omitted). Defendants cannot be liable for failing to warn of findings that federal regulations prohibited them from including in their labeling.

Second, even if this Court does not hold that federal law preempted the inclusion of these studies, it still must decide whether their *exclusion* made

[10] For example, the tile of ROSEN study is "Biologic vs Synthetic Mesh for Single-Stage Repair of ***Contaminated*** Ventral Hernias." Pa851 (emphasis added). By contrast, although the studies included in Defendants' "Shark Ad" sometimes included patients with contaminated or infected hernias, the objective of those studies was to analyze biologic mesh across a broad patient population.

Strattice's warning inadequate. Their exclusion did not. The opposite is true: Including recurrence rates from off-label use would make the warning *less* reliable. Doctors know that the warnings they are given are warnings that attach to using the drug or device *as intended*. Cf. 5T65:11-15 (testimony from Plaintiff's regulatory expert that manufacturers must limit claims to on-label use). An adequate warning need not include—and as a matter of law should not include—data about uses for which the product is not intended.

Third, these studies were not "known or knowable" prior to Plaintiff's surgery. Plaintiff's surgery occurred on August 17, 2020. 6T51:15-22. The trial court excluded ROSEN because it was published online a year and a half *after* Plaintiff's surgery, Pa34; 4T18:3-17, on January 19, 2022, and in print in April 2022. Pa851. The findings in ROSEN were thus not "available knowledge" to Defendants that could have triggered any duty to warn. See Mays v. Gen. Binding Corp., 565 F. App'x 94, 98 (3d Cir. 2014) (applying New Jersey law and affirming summary judgment because the mere fact that a complication could occur "does not necessarily indicate that the industry was aware of the potential harm") Da66; see Toms v. J.C. Penney Co., No. 05-cv-2582 (PCS), 2007 WL 2893052, at *7 (D.N.J. Sept. 28, 2007), aff'd, 304 F. App'x 121 (3d Cir. 2008); Da51.

Although the trial court did not categorically exclude them for this reason, the same is true of the HARRIS and LIANG studies. Neither HARRIS nor LIANG had been published prior to Plaintiff's August 2020 surgery. Pb17 n.5; 4T142:16-144:9. Defendants had only the abstracts for the studies prior to the surgery, see id., and a reasonable manufacturer would not warn of findings in unpublished studies that it cannot verify are scientifically valid. See Hisenaj v. Kuehner, 194 N.J. 6, 22 (2008) ("Publication itself, although not necessarily dispositive of general acceptance in the scientific community, does provide additional evidence of acceptance."); Jones v. Constantino, 429 Pa. Super. 73, 89 (1993) (concluding that an "unpublished paper given at a medical conference" is not sufficiently authoritative to be admitted under an exception to hearsay); see also Good Reprint Practices, supra, Da36-39 (FDA allowing promotion of off-label studies only when a manufacturer distributes a full published study). Requiring such disclosure would hurt both manufacturers and patients by requiring manufacturers to disclose potentially faulty studies and increasing the risk patients do not receive needed care if a physician avoids a safe drug or device based on flawed studies.

Science is constantly evolving, and device manufacturers can and should ensure that they update warnings to include *reasonably known or knowable*

scientific data about a product's intended use. But that requirement does not mean that manufacturers can or should rush to include data that is not actually published—and therefore not reasonably knowable.

Fourth, even if the Court wanted to overlook that the HARRIS and LIANG studies were off-label and unpublished at the time of Plaintiff's surgery, these studies *still* should not have been included in Strattice's warning because they were either statistically insignificant or underpowered. The authors of HARRIS themselves acknowledged the "limitations of this trial," explaining that the results were "from a relatively small study size and thus the trial could be ***underpowered*** to answer some of [the authors'] secondary questions." Pa849 (emphasis added). And as for LIANG, one of the study authors admitted in deposition that the study was not statistically significant. See 4T276:11-13. Contrast this with one of the studies Defendants did disclose, GARVEY, which studied over two hundred patients using Strattice for its intended purpose and found a recurrence rate of 8.3% over five years. Pa922.

In sum, New Jersey law requires adequacy, and that requires manufacturers who include risk warnings to include only known or knowable and reliable studies. Including the recurrence rates in HARRIS, ROSEN, and LIANG would have made Strattice's warning *less* accurate. The Court should

affirm the adequacy of the warning because (1) federal law preempts the inclusion of these studies; (2) the studies were published after Plaintiff's surgery and thus were not known or knowable to Defendants; and (3) including off-label studies that are statistically insignificant or underpowered makes a label less accurate, not more adequate.

iii. Strattice's Warning Label Was Adequate and Included Five Different Studies' Complication Rates.

This Court could affirm by holding that Strattice's warning was adequate, full stop. The legal question whether a medical device warning is adequate is judged by what a reasonable doctor would know. This warning highlighted the risk of recurrence and included five different rates of recurrence from five separate studies. N.J.S.A. § 2A:58C-4; see Feldman v. Lederle Lab'ys, 97 N.J. 429, 451 (1984). Defendants acted reasonably, identifying the risk (recurrence) and offering five possible quantifications of it. Pa255. A reasonable prescribing physician would see this information, understand the inherent indefinite nature of complication rates, and know that the five included rates of recurrence were representative if not comprehensive. A reasonable physician would be on notice that a particular patient's risk of recurrence could be higher or lower based on their risk factors and that future studies about the device could uncover different

recurrence rates.

New Jersey law requires adequacy and this warning was adequate. Any contrary holding—requiring disclosure of off-label, statistically insignificant or underpowered studies—would make it impossible for any device manufacturer to ever legally warn of a device's risks. That would jeopardize the availability of life-saving (and life-improving) medical devices, which would harm patients and manufacturers alike. Medical device manufacturers in New Jersey should be entitled to the protections the law allows, which requires them to craft warnings that they are reasonably confident (based on reliable and material scientific findings) capture the real risks of their product. That is exactly why New Jersey requires only "adequate" and not "comprehensive" warnings. See, e.g., Rowe v. Hoffman-La Roche, Inc., 189 N.J. 615, 623 (2007) (explaining that the NJPLA's definition of adequacy "was enacted . . . to re-balance the law").

This Court should affirm that a warning is not inadequate when it discloses several (here: five) rates of complication and lacks only data found in small or statistically insignificant or underpowered studies that were not published at the time a patient alleges she was harmed.

C. Directed Verdict Was Further Warranted Because Plaintiff Failed to Prove that Any Failure to Warn Caused Her Harm.

This Court can alternatively affirm because Plaintiff failed to establish

that any defective warning proximately caused her injury. Dr. Koelsch testified that he was aware of the risk of recurrence (and shared that risk with Plaintiff) before prescribing Strattice. See 6T45:10-11; 7T151:10-12; 10T76:4-8, 77:14-17. That knowledge breaks the chain of causation and precludes any finding that additional warnings would have prevented Plaintiff's recurrence. Hrymoc, 467 N.J. Super. at 89.

Plaintiff argues that New Jersey law entitles her to a heeding presumption that Dr. Koelsch, if adequately warned of Strattice's risk, would have heeded that warning. Pb26–29. She argues that the trial court misapplied this heeding presumption. But under the NJPLA's "learned intermediary" rule, "the inadequacy of a warning cannot be the proximate cause of an injury where there is an intervening cause" such as the physician's "independent knowledge of the risks." Hrymoc, 467 N.J. Super. at 89. In other words, any heeding presumption is rebutted by testimony from the prescribing physician that they would have prescribed the device even if given the additional warning, such as testimony that they had independent knowledge of the risk. In re Diet Drug Litig., 384 N.J. Super. at 544–45; see Baker v. App Pharms. LLP, No. 09–05725 (JAP), 2012 WL 3598841, at *8 (D.N.J. Aug. 21, 2012) ("The heeding presumption is rebutted" by testimony that the physician was aware of the risk prior to

prescription); Da57.

In this case, Dr. Koelsch's pre-surgery awareness that recurrence was a risk is that "intervening cause." Hrymoc, 467 N.J. Super. at 89. Dr. Koelsch unequivocally testified that he understood the risk of recurrence before Plaintiff's surgery and shared that risk with Plaintiff. 5T268:12-20 ("[A]ll hernia mesh have recurrence rates"); 6T45:10-11.[11]

Plaintiff argues that the court erred because understanding recurrence risks "generally" is different from knowing of any one rate specifically. But she has no evidence that Strattice's risk of recurrence materially differed from whatever "general" risk of recurrence prevails across synthetic and biologic hernia mesh devices, particularly in the elevated context of a morbidly obese patient. Dr. Kolesch's pre-surgery knowledge of the recurrence risk is an "intervening cause" that precludes Plaintiff from establishing that any failure to warn proximately caused her harm. Hrymoc, 467 N.J. Super. at 89.

[11] Plaintiff argues that the court's order granting directed verdict conflicts with the trial court denying summary judgment. But a "denial of [a] defendant's motion for summary judgment" is an "interlocutory order" and the "denial [is] subject to the trial court's inherent power to review, revise, reconsider, and modify its order." Cineas v. Mammone, 270 N.J. Super. 200, 207 (App. Div. 1994). The court's caution in allowing this claim to proceed past summary judgment (to allow Plaintiff her day in court) is a virtue of what occurred below, and certainly not a reason for reversal.

II. The Trial Court Did Not Prejudicially Abuse Its Discretion In Excluding The ROSEN Study.

The trial court granted in part Defendants' motion in limine to exclude the ROSEN study, which was published years after Plaintiff's surgery, recognizing that its *post hoc* findings were not known or knowable prior to Plaintiff's surgery. Pa34; 4T18:3-16. Plaintiff contends that this exclusion was error entitling her to a new trial but she both fails (1) to show that it was an abuse of discretion and (2) to argue or establish prejudice. The Court should reject this invitation to require a new trial for a reasonable evidentiary decision entrusted to the trial court's discretion.

A. The Trial Court Did Not Abuse Its Discretion in Excluding ROSEN.

The trial court's exclusion of ROSEN was a routine application of the requirement that "any evidence presented at trial" be logically relevant to a disputed issue and that any probative value not be substantially outweighed by its risk of prejudice. Kuzian v. Tomaszewski, 457 N.J. Super. 458, 461 (Law. Div. 2018); see N.J.R.E. 402, 403.

Defendants moved in limine to exclude medical literature published after Plaintiff's surgery because such evidence is not relevant to whether Defendants failed to warn and because its probative value was substantially outweighed by

its risk of prejudice. Da42-43.[12] Because a manufacturer is imputed only with knowledge of defects that are "known or knowable" in the relevant industry, post-surgery studies were irrelevant to failure-to-warn if not known or knowable. Coffman, 133 N.J. at 599. The trial court decided that ROSEN was not known or knowable prior to Plaintiff's surgery (and was thus irrelevant for failure-to-warn) because it was "too far removed and . . . adds a little bit more speculation into the case." 4T18:3-7. The court then excluded ROSEN from all evidence, impliedly also accepting Defendants' argument that introduction of the Rosen article would confuse and mislead the jury. See Da42-43; N.J.R.E. 403.

"A trial judge has broad discretion in making relevance and admissibility determinations under N.J.R.E. 401, 402, and 403, which [this Court] will not disturb, absent a manifest denial of justice." Lancos v. Silverman, 400 N.J. Super. 258, 275 (App. Div. 2008). The law requires "a manifest injustice." E & H Steel Corp. v. PSEG Fossil, LLC, 455 N.J. Super. 12, 24 (App. Div. 2018). This exclusion was not an abuse of the trial court's "broad discretion" and Plaintiff does not meaningfully argue that it was. Lancos, 400 N.J. Super. at

[12] Defendants argued all post-surgery literature was irrelevant to design defect but the trial court's ruling focused on the literature's relevance to Defendants' warnings. Da42.

275. In a transparent attempt to attract a more favorable standard of review, Plaintiff instead claims that the trial court applied an incorrect "legal rule," namely that Plaintiff establish that LifeCell knew about the ROSEN article before she could introduce it. But the court did not require Plaintiff establish Defendants knew of the findings in ROSEN. The court instead acknowledged that Defendants could not be imputed with knowledge of ROSEN because Plaintiff failed to establish it was "known or knowable" in the relevant industry, which is indeed the rule under New Jersey law. 4T18:3-7; see Coffman, 133 N.J. at 599.

Nor did the court misplace the burden to establish whether ROSEN was "known or knowable." New Jersey law makes this Plaintiff's burden. Coffman, 133 N.J. at 600 (only "[o]nce the plaintiff comes forth with such evidence" does a court "impute[s] knowledge to the manufacturer). N.J.R.E. 104(b) requires a trial court to determine whether "proof [was] introduced sufficient to support a finding that the fact or condition"—here, the knowledge in the industry—"does exist." Here, Plaintiff failed to provide that evidence. 4T18:3-13.

Because it was irrelevant to Defendants' duty to warn and because any probative value would be outweighed by the risk of prejudice, the trial court did not abuse its "broad discretion" in excluding ROSEN. See, e.g., Lancos, 400

N.J. Super. at 275 (affirming exclusion); Bitsko v. Main Pharmacy, Inc., 289 N.J. Super. 267, 284 (App. Div. 1996) (same); DiNizio v. Burzynski, 81 N.J. Super. 267, 275 (App. Div. 1963) (same).

B. Excluding The ROSEN Study Did Not Prejudice Plaintiff.

New Jersey appellate courts apply a harmless error standard to evidentiary questions. See Willner v. Vertical Reality, Inc., 235 N.J. 65, 79 (2018); Cederlund v. Hub Loan Co., 88 N.J. Super. 238, 243 (App. Div. 1965). The appellant must show that the error raises "reasonable doubt as to whether the error led the jury to a verdict it otherwise might not have reached." Willner, 235 N.J. at 79 (citation omitted; alteration accepted); see Cherr v. Rubenstein, 22 N.J. Super. 212, 216 (App. Div. 1952).

Plaintiff does not argue (and thus waives any argument) that precluding Dr. Koelsch from discussing the ROSEN study caused the jury to issue a different verdict. See, e.g., L.J. Zucca, Inc., 434 N.J. Super. at 87. Nor would any such argument succeed in light of the fact that Plaintiff was able to introduce HARRIS and LIANG, which had more damning (from Plaintiff's perspective) recurrence rates. There is no "reasonable doubt as to whether" limiting one witness's discussion of one study where the jury heard of two other similar studies "led the jury to a [different] verdict." Willner, 235 N.J. at 79.

III. The Trial Court Did Not Abuse Its Discretion In Narrowing (But Not Excluding) Dr. Augenstein's Opinion That Plaintiff's Strattice Did Not Resorb.

Plaintiff alleged that a reason for her recurrence was that the Strattice that she received in her first surgery resorbed and thus failed to continue supporting her healing. One of Defendants' experts, Dr. Augenstein, opined that Strattice did not resorb and was, in fact, still present in Plaintiff at the time of her second surgery. 12T227:18-21. The trial court excluded this opinion and issued a curative instruction when Dr. Augenstein offered it at trial. 12T228:3-9. When Dr. Augenstein again later testified that Strattice was still in Plaintiff, Plaintiff did not ask for a targeted curative of the testimony and the court, in its discretion, did not give one. Plaintiff contends that the trial court abused its discretion in how it handled Dr. Augenstein's "anti-resorption" opinion.

There is no error here. To start, this Court need not address this alleged error because Plaintiff waived all issues regarding Dr. Augenstein's testimony by failing to include the issue in her initial appellate case information statement. Even if this Court overlooks that preservation problem and considers this issue on the merits, this Court should affirm because (1) the trial court did not abuse its discretion in how it limited Dr. Augenstein's opinion; (2) that limitation did not prejudice Plaintiff; and (3) the anti-resorption opinion was admissible.

This Court evaluates this evidentiary decision for abuse of discretion. New Jersey appellate courts apply that standard in "assessing whether a trial court has properly admitted or excluded expert scientific testimony in a civil case." In re Accutane Litig., 234 N.J. 340, 348 (2018). Plaintiff wants more searching review, but the Supreme Court has considered and rejected that: "this Court has continued to apply a pure abuse of discretion standard in civil matters concerning expert testimony." Id. at 391.

A. The Trial Court Instructed Dr. Augenstein Not to Testify that Strattice Remained in Plaintiff.

At trial in her voir dire, the court certified Dr. Augenstein to testify about "hernia repair and hernia repair research." 12T128:8-15. Following a later sidebar on whether Dr. Augenstein could opine on whether Strattice appeared on the CT scan taken prior to Plaintiff's second hernia operation, the trial court instructed Dr. Augenstein that she was "able to testify that there's something there [on the CT scan], but you *can't name the product*." 12T224:23-225:1. Soon thereafter, following a question about the CT scan taken prior to Plaintiff's second hernia operation, Dr. Augenstein noted that "this looks like mesh." 12T227:18-21. The court struck that testimony.[13] 12T227:5-228:9.

[13] She later testified out of the presence of the jury that she "understood [she]

On cross examination, Plaintiff's counsel asked Dr. Augenstein whether she agreed that Dr. Koelsch testified he did not see Strattice in Plaintiff during his second operation. 12T348:15-18. Dr. Augenstein explained her view that his opinion was suspect, noting "he has not re-operated on Strattice patients" and "Strattice, when you re-operate on it, may look like thickened hernia sac"—i.e., what Dr. Koelsch said he saw—"when it fails." Dr. Augenstein continued: "So I think he was looking at Strattice." 12T348:19-349:1. In response, Plaintiff's counsel asked that Dr. Augenstein's "*entire* testimony should be stricken." 12T349:4-5 (emphasis added). The court declined. 12T349:8-350:16.

B. The Court Should Strike Any Argument Relating to Dr. Augenstein's Testimony Because Plaintiff Failed to Include the Issue in Her Case Information Statement.

Rule 2:5-1 requires that, in commencing a civil appeal, an appellant file a Case Information Statement that conforms with Appendix VII of the Rules. See R. 2:5-1(h)(1). Appendix VII, for its part, requires the appellant, "[t]o the extent possible, list the proposed issues to be raised on the appeal." R. 2:5-1(h) also indicates that appellant has an ongoing obligation to update the Case Information Statement if it becomes inaccurate. The New Jersey rules

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wasn't allowed to identify it as Strattice" but "thought [she] was allowed to say it's mesh." 12T257:17-19.

themselves establish that "[a]ny deficiencies in the completion of the Case Information Statement" shall be "grounds for such action as the appellate court deems appropriate, including . . . dismissal of the appeal." R. 2:5-1(h)(3).

This requirement gives the appellee notice of what issues may be raised. The appellant receives substantial time to prepare her appeal. The clock on an appellant filing an opening brief does not even begin until the transcripts are filed. See R. 2:6-11(a). The Case Information Statement thus prevents the appellee from being deprived of the opportunity to prepare while waiting.

Here, Plaintiff included several issues in her Case Information Statement that she intended to raise. See, e.g., Da45 (listing as errors the directed verdict, the exclusion of certain "medical literature," and permitting Defendants to tell jury that Strattice is "safe and effective"). Problematically, she did not include her challenge to Dr. Augenstein's testimony in her appeal statement. Despite nearly six months passing between her notice of appeal and the filing of her amended opening brief, she never amended her Case Information Statement to include this issue. This doubly violates R. 2:5-1(h) by initially failing to include the issue in her Case Information Statement and by never amending her Case Information Statement to include the issue.

Defendants do not ask the Court for "dismissal of the appeal," as R. 2:5-

1 permits. A targeted remedy—dismissal of the specific waived argument—is appropriate. This Court routinely narrows the scope of an appeal for violations like this one. See Fusco v. Bd. of Educ. of Newark, 349 N.J. Super. 455, 461–62 (App. Div. 2002); Collas v. Raritan River Garage, Inc., 460 N.J. Super. 279, 280 n.1 (App. Div. 2019); United Hosps. Med. Ctr. v. State, 349 N.J. Super. 1, 8 (App. Div. 2002); see also Synnex Corp. v. ADT Sec. Servs., Inc., 394 N.J. Super. 577, 588 (App. Div. 2007) (reaching the merits of an issue although not listed in the notice of appeal because, *inter alia*, the "case information statement clearly indicates" that the appellant intended to raise the issue).

C. The Court Did Not Abuse Its Discretion in How It Limited Dr. Augenstein's Testimony.

Even if the Court exercised discretion to consider this issue on the merits, it fails because the trial court did not abuse its discretion. Plaintiff raises four "errors" that the trial court made in *how* it chose to limit Dr. Augenstein's "anti-resorption" testimony. Pb48–49. The trial court's decision on the admission of testimony is reviewed for abuse of discretion. See, e.g., State v. Garcia, 245 N.J. 412, 430 (2021); Rowe v. Bell & Gossett Co., 239 N.J. 531, 551 (2019); State v. Scott, 229 N.J. 469, 479 (2017); State v. Nantambu, 221 N.J. 390, 402 (2015); Townsend v. Pierre, 221 N.J. 36, 52–53 (2015). The court did not abuse that discretion in agreeing with Plaintiff to limit Dr. Augenstein's testimony. And

even if it had, Plaintiff has not shown prejudice.

The first "error" that Plaintiff raises is that the trial court failed "to exclude (or even address) this opinion on Plaintiff's motion to exclude." Pb48. But the court ultimately agreed with Plaintiff about the permissible scope of Dr. Augenstein's testimony before she testified. Plaintiff's counsel argued that Dr. Augenstein "can say there's something here . . . but she can't say . . . anything else." 12T223:3-8. The court agreed, 12T223:5 ("Right."), and then gave a version of that restriction: "[Y]ou're able to testify there's something there, but you can't name the product." 12T224:24-225:1. It is immaterial that the court initially rejected Plaintiff's motion in limine given that the Court later *agreed* to limit the testimony before it was offered. Moreover, Plaintiff has not even argued this decision prejudiced her (and it is hard to imagine that a pretrial ruling against Ms. Blakeley that the court changed in her favor before any testimony occurred somehow prejudiced her). See Willner, 235 N.J. at 79. And in any event, a litigant is not prejudiced by getting what they request.

The second "error" Plaintiff argues is the trial court's decision to tell Dr. Augenstein that she could testify that "there's something there" on the CT scan (but could not "name the product."). Plaintiff contends that the court should have instructed "Dr. Augenstein that she could not offer [this opinion] at all."

Pb48. But that is not what Plaintiff asked for below. See, e.g., 12T222:5-7 ("When I asked can you tell if this is human or porcine tissue, she said no."). The court did not abuse its discretion in limiting testimony in the way Plaintiff's counsel requested.

Plaintiff also complains that the court should have given the instruction "proposed by Ms. Blakeley." But, below, Plaintiff's counsel admitted the curative instruction was sufficient. 12T228:3-6 ("Yeah. . . . That's fine."). Moreover, even if the court should have used Plaintiff's specific phrasing for the instruction, Plaintiff has waived any argument as to prejudice. See Borough of Berlin, 337 N.J. Super. at 596 ("Raising an issue for the first time in a reply brief is improper.").

Another "error" Plaintiff raises is that, after Dr. Augenstein first testified she saw "mesh" on the CT scan, the court did not consult with the parties before sua sponte instructing the jury to "disregard" that testimony. Pb48–49. But the Supreme Court "has consistently stressed the importance of immediacy and specificity when trial judges provide curative instructions to alleviate potential prejudice to a [party] from inadmissible evidence." State v. Vallejo, 198 N.J. 122, 135 (2009). The court's immediate action is not grounds for a new trial.

Moreover, Plaintiff did not argue for (and thus waived any argument as

to) prejudice and cannot establish the court's quick action in issuing a curative instruction prejudiced Plaintiff. Because a hallmark of an effective curative is its immediacy, see Vallejo, 198 N.J. at 135, there is no reasonable basis to conclude that the court *increased* whatever prejudice Plaintiff sustained from the anti-resorption opinion by its quick action, see Willner, 235 N.J. at 79.

Plaintiff's fourth and final alleged error was that the court denied her motion to strike following Dr. Augenstein's testimony that Dr. Koelsch, when performing Plaintiff's second hernia operation, was looking at Strattice. But although Plaintiff asked for a remedy below, her request was that the court strike "this witness'[s] entire testimony." 12T349:4-5. In a later dispute, Defendants' counsel clarified that "the second time" Dr. Augenstein offered her anti-resorption opinion, "it was not stricken from the record" and Plaintiff has not "ask[ed] for it to be stricken from the record," "waiv[ing] that opportunity." 13T27:12-16. Plaintiff's counsel agreed that counsel did not ask for that specific testimony to be stricken and that the request was indeed for "all her testimony to be stricken." 13T27:18-28:5. Thus, Plaintiff waived any argument that this was error by not presenting it to the trial court.

Plaintiff does not now contend that the trial court should have stricken the entirety of Dr. Augenstein's testimony (her request below). She instead argues

the court should have done something narrower. She cannot complain that the court failed to take action that she did not timely request. Cf. Orlando v. Camden Cnty., 132 N.J.L. 173, 177 (Sup. Ct. 1944) (rejecting a claim for error because, "while there was objection to the admission of the testimony at the trial, there was no legal reason in support of the objection" below).

Any claim that the court erred in not striking the second anti-resorption opinion is thus reviewed for plain error. See R. 2:10-2; State v. Rose, 206 N.J. 141, 157 (2011). And the court did not plainly err. "It is axiomatic that trial errors which were induced, encouraged or acquiesced in or consented to by [opposing] counsel ordinarily are not a basis for reversal on appeal." Harris v. Peridot Chem. (New Jersey), Inc., 313 N.J. Super. 257, 296 (App. Div. 1998) (cleaned up). Plaintiff's counsel specifically asked Dr. Augenstein about Dr. Koelsch's testimony on the presence (or absence) of Strattice in Plaintiff. She cannot now complain that Dr. Augenstein answered that question and the Court did not sua sponte strike it. Id.; see D.G. ex rel. J.G. v. N. Plainfield Bd. of Educ., 400 N.J. Super. 1, 21 (App. Div. 2008).

D. Dr. Augenstein's "Anti-Resorption" Opinion Was Admissible.

In any event, there was no error below because Dr. Augenstein's anti-resorption opinion was admissible. Because Dr. Augenstein is qualified and the

opinion has a reliable basis, the trial court did not abuse its discretion in permitting (a limited version of) it. Under N.J.R.E. 702, "a witness qualified as an expert by knowledge, skill, experience, training, or education may testify" to an opinion based in "scientific, technical, or other specialized knowledge." "The admission or exclusion of expert testimony is committed to the sound discretion of the trial court." Townsend, 221 N.J. at 52.

First, Dr. Augenstein was qualified to offer the opinion that Strattice was in Plaintiff at the time of her second operation. Dr. Augenstein has "repaired over 3,000 hernias utilizing a variety of devices," including "implant[ing] Strattice over 600 times." Pa261; see 12T129:16-18. She is a Diplomate of the American Board of Surgery and Fellow of the American College of Surgeons with over 12 years of surgical practice and is currently in line to serve as the American Hernia Society president. See Pa260, Pa287, Pa289–90.

Plaintiff attempts to paint Dr. Augenstein as a doctor with no qualifications tailored to hernia mesh resorption. See Pb43–45. That is foolhardy. Dr. Augenstein has immense experience, training, and professional recognition in the field of hernia repair. Hernia mesh resorption is one of the competencies that come with such a robust experience.

Second, Dr. Augenstein's methodology for reaching her opinion was

reliable. She testified at her deposition that the basis of her opinion was her "[c]linical experience[and] CAT scan images of patients who have had Strattice in their body and you can see the Strattice there." Pa389. As she explained, she has looked at CAT scans constantly for "many, many years," including examining them to locate mesh. Pa367. Further: "[H]aving reviewed many, many CAT scans, similar appearance even, this is what a piece of Strattice would look like in the abdomen. And [she's] seen patients of [hers], so [she] certainly do[esn't] think that the mesh went away." Pa367. In some cases "'experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.'" State v. Olenowski, 255 N.J. 529, 602 (2023) (citation omitted). Dr. Augenstein's basis is sound.

Plaintiff's arguments are unpersuasive. She claims that Dr. Augenstein admitted "she cannot (nobody can) reliably tell whether the line on Ms. Blakeley's CT scan was Strattice." Pb46 (quoting 12T127:17-20). The cited testimony, however, reflects Dr. Augenstein's confirmation that she is not "an expert in discerning the difference between porcine and human tissue as it appears on a CT scan." 12T127:17-20. She later explains that her own experience enabled her to identify Strattice on the CT scan. Her testimony that she is not an expert in distinguishing porcine and human tissue on a CT scan

does not conflict with her ability to identify the Strattice.

Nor does Dr. Augenstein's disagreement with Dr. Koelsch that Strattice remained in Plaintiff render her opinion unreliable. Indeed, Dr. Augenstein gave legitimate reasons for discounting Dr. Koelsch's testimony—namely, that it is difficult for "somebody who maybe doesn't reoperate on a lot of recurrent hernias with Strattice and other types of biologic meshes" to identify Strattice when performing surgery. Pa370. "[I]t is for the jury to resolve any conflict that arises in" expert medical testimony. Wiggins v. Hackensack Meridian Health, 259 N.J. 562, 583 (2025).

Nor was Dr. Augenstein's opinion a "net opinion," where an expert issues a "bare conclusion[], unsupported by factual evidence." Nguyen v. Tama, 298 N.J. Super. 41, 48 (App. Div. 1997) (citation omitted). As explained above, Dr. Augenstein's basis included her own experience. See id. at 49.

To the extent the trial court admitted Dr. Augenstein's anti-resorption opinion, that opinion was admissible and the court did not abuse its discretion.

CONCLUSION

This Court should affirm the verdict and judgment.

Respectfully submitted,

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Theresa Blakeley, *Plaintiff-Appellant*, v. LifeCell Corporation, Allergan USA, Inc., and Allergan, Inc., *Defendants-Respondents*.	:	SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO. A-002807-23 ON APPEAL FROM THE SUPERIOR COURT OF NEW JERSEY, LAW DIVISION, ATLANTIC COUNTY Docket No. Below: ATL-L-001214-22 Sat Below: Honorable John C. Porto, J.S.C.

REPLY BRIEF OF PLAINTIFF-APPELLANT THERESA BLAKELEY

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POINT I: Directed Verdict on Failure to Warn.

A. Plaintiff Overcame the Presumption of Adequacy.

LifeCell argues the presumption of adequacy ("POA") bars Plaintiff's failure to warn claim. This Court should reject this argument. First, the trial court rejected it at summary judgment, Pa84, and LifeCell did not raise it at directed verdict. 9T298:8-299:11; 10T13:21-17:22. Despite LifeCell's contrary claim, the trial court did not base directed verdict on the POA. 10T74:21-25, 77:7-17.

Second, despite admitting Strattice "comes with risks," Db6, the Warning Label discloses no risks. Pa251-52. Finally, even if the Warning Label is presumed adequate, Plaintiff overcomes the POA under two pathways: (1) the "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects," and (2) "economically-driven manipulation of the post-market regulatory process." In re Accutane Litig., 235 N.J. 229, 277 (2018).

1. Pathway 1: Deliberate Concealment or Non-Disclosure of After-Acquired Knowledge of Harmful Effects.

A plaintiff overcomes the POA if the defendant was aware of post-market studies containing adverse events that demonstrate the warning label is inadequate. Cornett v. Johnson & Johnson, 414 N.J. Super. 365, 401 (App. Div. 2010), aff'd as modified, 211 N.J. 362 (2012).

LifeCell knew of, but did not disclose, two harmful effects of Strattice. E.g., Pa82-84. First, LifeCell knew about Strattice's elevated recurrence risk in December 2018, via HARRIS. Pa524-25. Plaintiff's expert, Dr. Plunkett, testified that manufacturers should warn about elevated recurrence risks. 5T122:9-21. Plaintiff's surgeon, Dr. Koelsch, wanted to know if Strattice recurred at 20-30% versus a single-digit rate. 5T270:12-24. LifeCell did not warn about recurrence in its warning label and did not disclose Strattice's elevated risk to Dr. Koelsch. 6T26:5-27:1.

Second, LifeCell knew Strattice resorbs within three months of implant. Pa549, 586. Resorption is a bad outcome. 7T183:6-10; 4T119:20-25; 9T59:25-60:24.[1] Dr. Plunkett testified LifeCell should have warned that Strattice resorbs. 5T:144:12-17. LifeCell told Dr. Koelsch the opposite—that Strattice does not resorb. 7T228:20-229:1; see also Pb15-16, 24.

2. Pathway 2: Economically-Driven Manipulation of the Post-Market Regulatory Process.

A plaintiff also overcomes the POA if the defendant opposed strengthening the warning or made misrepresentations about the product. McDarby v. Merck & Co., 401 N.J. Super. 10, 68–69 (App. Div. 2008).

[1] LifeCell complains Plaintiff's "sole evidence" that resorption is a bad is from a single LifeCell employee. Db15. However, that testimony was given by a corporate representative and is a party admission. 7T167:13-168:14. While that is enough, other witnesses gave consistent testimony (cited above).

In addition to not warning about Strattice's recurrence and resorption dangers, LifeCell made several misrepresentations about Strattice. LifeCell admits "regeneration" is not Strattice's mechanism of action. 6T82:12-83:4. The FDA told LifeCell this claim was inappropriate without more data, which LifeCell chose not to submit. 5T103:13-109:4. LifeCell admitted this claim was off-label. 9T68:7-69:7; Pa873. Yet LifeCell made this claim anyway, including in the Shark Brochure (Pa255) Dr. Koelsch received, to "differentiate" Strattice from the competition and to ensure Strattice's success. 8T319:7-320:15.

LifeCell also claimed Strattice does not resorb, despite knowing it does. 6T87:4-12; Pa586. LifeCell misled surgeons because it identified resorption as a threat to sales. 9T169:22-170:11. These marketing claims allowed LifeCell to generate $827 million in profits from 2008 through 2023. 13T174:1-15.

B. LifeCell Asks this Court to Re-Write the PLA, Weigh the Evidence, and Resolve Disputed Issues.

1. LifeCell Asks this Court to Re-Write the PLA to Provide Immunity in Two Ways.

LifeCell asks this Court to find its Strattice warnings adequate as a matter of law. E.g., Db27. To do that, this Court would have to narrow the PLA's duty to warn to (1) "ultimate risks" as determined by a court not a jury, and (2) "the type (rather than the quantum) of risk." Db21. Because the directed verdict was based on an interpretation of the PLA, not Plaintiff's evidence, affirmance would

immunize any manufacturer who fails to warn about "non-ultimate" dangers and who fail to disclose the frequency of danger.

As the movant, LifeCell had the burden at directed verdict to identify legal authority supporting its claimed immunity. It has never done so. Instead, LifeCell makes unsupported claims about what the PLA requires and does not require. E.g., Db17-18. LifeCell also fails to acknowledge the plain language of the PLA does not support immunity. The PLA simply requires "adequate warnings or instructions," N.J.S.A. 2A:58C-2, regarding "all hidden or latent dangers" as determined by a jury. Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 206–07 (1984). The jury instructions also make clear Plaintiff can advance any inadequate warning theory consistent with this plain language. Model Jury Charges (Civil), 5.40C, "Failure to Warn/Instruct," at 1 (rev. Nov. 2023).

Moreover, the FDA explicitly encourages the disclosure of frequency data,[2] which bears on New Jersey's duty to warn. See In re Accutane Litig., 235 N.J. at 274 ("[F]ederal regulations are of the utmost significance in determining whether 'a manufacturer satisfied its duty to warn . . . .'" (citation omitted)).

[2] The FDA's Device Labeling Guidance advises that frequency data be disclosed in the warning label. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/device-labeling-guidance-g91-1-blue-book-memo (last visited April 1, 2025).

As LifeCell acknowledges, this Court must "hew to the statute as written," Db23, and not "re-write a plainly-written enactment of the Legislature." DiProspero v. Penn, 183 N.J. 477, 492 (2005) (courts "cannot 'write in an additional qualification which the Legislature pointedly omitted . . . .'").

2. LifeCell Asks this Court to Resolve Disputed Facts and Ultimate Issues.

LifeCell does not claim the material facts were undisputed. Instead, LifeCell argues disputed material facts and ultimate issues without legal citations. E.g., Db2 (the only "danger at issue" is recurrence); Db15-16 (resorption "is a benefit of Strattice"); Db20-21 ("[I]t is not unreasonable for a manufacturer to omit from its warning complication rates."); Db21 (a warning "including all potential complication likelihoods—would be both impractical and unhelpful."); Db22 ("An adequate warning may include some studies (here, the most reliable) while excluding others . . . ."); Db30 ("recurrence rates . . . would have made Strattice's warning less accurate."); Db32 ("Defendants acted reasonably, identifying the risk (recurrence) and offering five possible quantifications of it.").

LifeCell then improperly asks this Court to decide the ultimate issue: whether Strattice's warnings were adequate. Db27-28. But it is the role of the jury, not the court, to decide whether Strattice's warnings were inadequate. Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 195 (2012) ("[T]he adequacy

of a warning is a jury question."); Michalko v. Cooke Color & Chem. Corp., 91 N.J. 386, 402 (1982) (holding that proximate causation is a jury question). These arguments were not raised or addressed at directed verdict. After finding LifeCell's mere disclosure of the type of risk (that is, recurrence) adequate, the trial court did not decide whether the "low" rates in the Shark Brochure adequately warned of Strattice's elevated risk. See 10T75:11-17.

Ultimately, the question is whether a jury could conclude that LifeCell's claim that Strattice's recurrence risk is 8.3% over seven years (1.19% annualized), Pa253, 255, was inadequate to warn of Strattice's actual risk of 37.1% after two years (18.6% annualized) per HARRIS. Because HARRIS, a higher-level study, identified Strattice's recurrence risk as 16 times greater than that disclosed in GARVEY, the answer to this question is: yes.

C. LifeCell's Preemption Argument Is Without Merit.

Conflict preemption occurs when "compliance with both federal and state regulations is a physical impossibility." Feldman v. Lederle Labs., 125 N.J. 117, 135 (1991). "The conflict, however, must be actual, not merely potential, speculative, or hypothetical." Id. There is no actual conflict here.

LifeCell argues it could not warn about Strattice's elevated recurrence[3] risk because the RCTs "focused on off-label use of the device" in

[3] Notably, LifeCell does not claim that a resorption warning was preempted.

"contaminated" patients. Db24, 27. LifeCell claims disclosing this defect would have been "a clear violation of FDA statutes, regulations, and guidance documents," but cite no authority. Db27. These arguments lack merit.

First, the real question is whether LifeCell should have warned Dr. Koelsch that Strattice has a particular defect—an elevated recurrence risk vis-à-vis synthetic mesh[4]—not whether LifeCell could have handed Dr. Koelsch the RCTs. 5T145:7-11, 122:22-123:12. LifeCell could simply have strengthened its Warning Label by disclosing that Strattice has an elevated recurrence risk, but chose not to. See McDarby, 401 N.J. Super. at 57 (noting that in the more stringent prescription drug context, "[a] manufacturer may, under FDA regulations, strengthen a labeling warning").

Second, LifeCell's citation to Dr. Plunkett's expert testimony is misleading. Dr. Plunkett said that LifeCell should have warned about Strattice's elevated recurrence risk based on the RCTs, 5T145:7-13, and about off-label uses LifeCell promoted, which included contaminated patients. 5T183:6-184:8. This Court recognized this principle in Cornett. 414 N.J. Super. at 402 ("[T]he manufacturer[s] promot[ion of] an off-label use . . . trigger[s] the duty to provide instructions or warnings about that off-label use."). LifeCell ignores that.

[4] LifeCell incorrectly claims Plaintiff does not argue relative risk. See Pb24.

Contradicting LifeCell's position, almost half the patients in GARVEY (shown in the Shark Brochure) had some contamination and thus were off-label. Pa926; see Db27 n.10 ("studies . . . in Defendants' 'Shark Ad' . . . included patients with contaminated or infected hernias"). In other words, if the RCTs were off-label, so was GARVEY. Once LifeCell shared GARVEY, it had to warn about Strattice's elevated recurrence risk and the RCTs. 5T183:6-184:8.

Third, the FDA's Good Reprint Practices, which LifeCell cites, undermines its argument. That document recognizes the "important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles . . . on unapproved uses." Da36. It further makes clear that "these publications are often distributed by manufacturers to healthcare professionals" and when done right, is appropriate. Da36, 39.

Ultimately, "the labeling changes sought by [P]laintiff at trial do not conflict with federal requirements, but are in fact consonant with them." McDarby, 401 N.J. Super. at 57.

D. LifeCell Failed to Overcome the Heeding Presumption

LifeCell argues Plaintiff failed to establish proximate causation. Db32-33. However, it is LifeCell who failed to rebut the heeding presumption. LifeCell does not address resorption at all, conceding the heeding presumption applies to that proposed warning. As for recurrence, LifeCell failed to identify

"unequivocal testimony" that Dr. Koelsch had full knowledge of Strattice's elevated recurrence risk as required by Hrymoc v. Ethicon, Inc., 467 N.J. Super. 42, 89 (App. Div. 2021), aff'd as modified, 254 N.J. 446 (2023). Instead, LifeCell cites Dr. Koelsch's testimony that "all hernia mesh have recurrence rates." Db34. That falls woefully short. LifeCell also cites no testimony from Dr. Koelsch that he would have used Strattice even had LifeCell warned of its elevated recurrence risk. Hrymoc, 467 N.J. Super. at 89-90. To the contrary, Dr. Koelsch said that if LifeCell had disclosed Strattice's elevated recurrence rates, he would not have used it. 6T26:5-27:1.

Accordingly, directed verdict on proximate causation was improper.

POINT II: The ROSEN RCT.

A. The Trial Court Abused Its Discretion When It Excluded ROSEN and Dr. Koelsch's Testimony for All Purposes.

LifeCell is silent about—and therefore concedes—that ROSEN and Dr. Koelsch's testimony about it were relevant to other issues, including design defect, medical and proximate causation, expert-witness credibility, and impeachment—and therefore admissible. Db35; Pb41-43.

Instead, LifeCell tries to belatedly expand the exclusion to include N.J.R.E. 403. Db36. However, 34 pages earlier, LifeCell admits ROSEN was excluded as not relevant. Db2 (the court "excluded . . . a study it concluded was not relevant"); see also 3T177:1-15; Da42. Regardless, LifeCell has never

identified anything about ROSEN—other than its publication date—that rendered it irrelevant or unfairly prejudicial. LifeCell also fails to explain why design defect, medical and proximate causation, and impeachment evidence must predate the harm to be admissible.[5]

Accordingly, as the trial court acknowledged before reversing course, Dr. Liang should have been permitted to discuss ROSEN with the jury. Compare 4T18:7-10 ("Dr. Liang can reference it. It's in his report, . . . because it's there."), with 4T176:8-177:13 (excluding ROSEN for all purposes).

Meanwhile, LifeCell insists, for her failure to warn claim, that Plaintiff needed to prove, before trial, ROSEN's results were known or knowable to be admissible. Db35-37. LifeCell cites no authority for that. Instead, LifeCell cites the following from Coffman v. Keene Corp.: only "[o]nce the plaintiff comes forth with such evidence" does a court "impute knowledge to the manufacturer." Db37 (citing 133 N.J. 581 (1993)). Coffman describes the evidentiary burden at trial, not a test of admissibility. The Model Jury Charges (Civil) are clear that whether the danger was knowable is determined by the jury. 5.40(C), at 3 ("In determining what [Defendant] should have known, ..."). Only when the jury

[5] Cf. Nicholson v. Biomet, Inc., 46 F.4th 757, 764 (8th Cir. 2022) ("But the post-2007 revision-rate data was admissible to prove causation—that is, the M2a Magnum's metal-on-metal design caused Nicholson's injury." (emphasis in original)).

finds the "[Defendant] prove[d] that the danger in question was not knowable" does failure-to-warn liability fall away. Ibid. (citing Feldman v. Lederle Labs., 97 N.J. 429 (1984)).

Coffman identifies the "very low threshold of proof" needed to impose the duty to warn: evidence "that knowledge of the defect existed within the relevant industry." 133 N.J. at 599. LifeCell contends Plaintiff did not meet this threshold. Db37. However, the evidence confirms that LifeCell had actual knowledge of Strattice's elevated recurrence risk years before Plaintiff's surgery. Pa524-25, Pa498-99. LifeCell's counsel conceded this before ROSEN was excluded. 4T15:1-3 ("Harris, totally fine, we knew about it. Liang . . . totally fine; we knew about it."); see also 4T7:14-16. Dr. Liang also testified (during an offer of proof) that Strattice's elevated recurrence risk and ROSEN's findings were knowable long before Plaintiff's surgery. 4T283:5-20. LifeCell's expert, Dr. Augenstein, agreed. Pa430, at 383:22-384:22.

B. The Exclusion of ROSEN and Dr. Koelsch's Testimony About ROSEN for All Purposes Was Unfairly Prejudicial.

LifeCell incorrectly claims Plaintiff did not argue ROSEN's exclusion was prejudicial. Db38. Plaintiff did argue that in detail. Pb3, 38-42. LifeCell next argues ROSEN's exclusion was not prejudicial because Plaintiff discussed the "similar" LIANG and HARRIS abstracts. Db38. Plaintiff explained how ROSEN is unique, Pb41-42, but adds that ROSEN was the most powerful (253

patients)[6] of the RCTs and its results were statistically significant. Pa852. ROSEN's admission would have blunted LifeCell's arguments at trial that HARRIS and LIANG were underpowered or not statistically significant, e.g., Db24, and that they were Plaintiff's "best evidence." 13T266:7-270:2.

LifeCell's claim that HARRIS and LIANG were more "damning" on recurrence is misleading. ROSEN, a statistically significant RCT, found Strattice's recurrence risk to be four times (20.5% vs. 5.6%) greater than synthetic mesh after two years, by far the largest differential of any RCT. Pa853.

The exclusion of Dr. Koelsch's testimony that ROSEN confirmed his decision to abandon Strattice entirely, see Pb18-19, was most prejudicial. The only unbiased surgeon to testify, Dr. Koelsch's testimony went to proximate causation on failure to warn, credibility, weight of the evidence, conflicts between the experts about the significance of the RCTs, and whether Strattice is "safe and effective." See Pb41. Exclusion of his testimony was prejudicial error.

POINT III: Dr. Augenstein's Anti-Resorption Opinion.

A. LifeCell Distorts the Events that Occurred.

LifeCell incorrectly claims Plaintiff dictated the initial instruction given to Dr. Augenstein. Db44-45. However, Plaintiff requested that Dr. Augenstein be precluded from testifying that Strattice was visible via CT scan and present

[6] More powerful than LifeCell's favored 191-patient study, GARVEY. Pa922.

in Ms. Blakeley's abdomen. 12T218:23-219:7. The trial court then gave a far narrower instruction that allowed Dr. Augenstein to say "mesh." 12T224:23-225:1. That the trial court struck this testimony immediately after it was given confirms that even it realized this instruction was error.

Next, LifeCell contends Plaintiff admitted the trial court's "curative instruction was sufficient" because her counsel stated: "yeah . . . that's fine." Db45. However, that statement was made before the instruction was given. 12T228:1-228:9. Despite requesting a sidebar, Plaintiff was not given a chance to weigh in on the instruction before it was given.

Finally, LifeCell contends the trial court did not err when it refused to strike Dr. Augenstein's speculative testimony that she "believed" Dr. Koelsch saw "Strattice" in Ms. Blakeley's abdomen. Db46. LifeCell incorrectly claims "Plaintiff's counsel did not ask to strike the testimony." Db3. However, Plaintiff requested a sidebar when this statement was made and then requested the testimony be stricken. 12T348:15-350:16.[7] As the gatekeeper, the trial court should have stricken this testimony and told the jury to disregard it. Instead, the trial court did not strike it, thus giving the jury the green light to consider it.

[7] LifeCell complains Plaintiff included the word "entire" in her request to strike, but that is semantics. The request immediately followed the testimony that the court had previously deemed inadmissible.

B. The Anti-Resorption Opinion Was Inadmissible.

LifeCell is silent on Dr. Augenstein's admission that she is "not an expert [in] resorption" or familiar with the "term." Pa403, at 277:9-17; Pa407, at 293:5-13; Pa366, at 128:21-129:4; Pa388, at 215:23-216:6. That is dispositive.

C. Dr. Augenstein's Testimony Prejudiced Plaintiff.

LifeCell says Plaintiff did not argue prejudice, Db44, but Plaintiff did. E.g., Pb49 ("These errors . . . prejudiced Ms. Blakeley . . . ."). The prejudice is clear. Due to the trial court's narrow initial instruction and subsequent failure to strike this opinion the second time it was given, the jury heard, and was then allowed to consider, inadmissible "expert" testimony that went to the heart of liability and causation. Dr. Augenstein's testimony that Strattice did not resorb simultaneously undermined Plaintiff's causation theory and Dr. Koelsch's testimony while bolstering LifeCell's causation theory that the Strattice was there, but "too small." Because Dr. Augenstein was the last witness, Plaintiff's rebuttal options were virtually non-existent. This likely caused the jury to render a verdict in LifeCell's favor on both design defect and express warranty.

D. LifeCell's CIS Argument Is Baseless.

LifeCell seeks dismissal of this issue because Plaintiff inadvertently did not update her CIS. Db39. However, LifeCell's cases involved omission from the notice of appeal of the order being appealed, which was problematic because "only the orders designated in the notice of appeal . . . are subject to the appeal

process and review." W.H. Indus., Inc. v. Fundicao Balancins, Ltd., 397 N.J. Super. 455, 458 (App. Div. 2008). There is no such principle regarding the CIS.

While Rule 2:5-1(h) allows "such action as [this C]ourt deems appropriate," no action is required because LifeCell fails to claim prejudice. See N.J. Highway Auth. v. Renner, 18 N.J. 485, 495 (1955) ("Justice is the polestar and our procedures must ever be moulded and applied with that in mind."). LifeCell cites the "opportunity to prepare," but never claims it lost that opportunity. In fact, LifeCell got an unusual 60-day extension of time to February 14, 2025, 92 days after Plaintiff's brief was filed. LifeCell's robust brief also shows it had ample chance to address this issue.

CONCLUSION

Accordingly, Ms. Blakeley respectfully requests that this Court reverse the rulings of the Law Division and remand this case for a new trial on all issues.

LITE DEPALMA GREENBERG & AFANADOR, LLC

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