IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004 4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
LIABILITY LITIGATION	*	Case No. 4:12-cv-176 (Taylor)

O R D E R

Trying twelve jury trials in the last ten months provides a fresh and unique perspective for evaluating post-trial motions that seek to overturn a jury verdict—a perspective that brings focus to the difference between a jury's job and a judge's job. A jury does not read selective portions of a sterile transcript to discern what happened. A jury sees evidence and hears evidence. They observe body language and interpret sighs, pauses, "uh ohs," and "uh huhs." They notice eye contact and furtive glances. They not only hear the "what" but also evaluate the "how" and the "why." What they do can only be done live and in person. And then they evaluate what they have seen and heard—not alone through their own selective lens, but through the community's lens as represented by twelve fellow members of the community. Then after thoroughly discussing and studying what they have seen and heard, they agree on what they heard and saw, sometimes compromising and sometimes realizing that what their single lens originally revealed may have been

clouded or just plain wrong. And after all of that, they render a verdict that speaks the truth—the truth of that case as they saw and heard it based on their collective wisdom and guided by the law as instructed by the judge.

After the jury is dismissed thinking that justice has been done, losing lawyers—well trained in dissecting every comma and spinning every word—mine the written transcript to weave a different story, one that suits their purposes but is often very different than what was actually experienced by that factfinding jury. The law has long recognized that only the jury can do this factfinding and that mischief can be created when judges are lulled into believing that due to their superior training and experience, they can actually second-guess that uniquely juror task of factfinding. Thus, we learn early in law school that these jury verdicts are entitled to great deference. But it is tempting to forget what we learned long ago and to inject ourselves into the factfinding inquiry, particularly when we may disagree with the facts found.

At the conclusion of a nine-day trial, the jury in this case found that Defendant Mentor Worldwide LLC sold a product that was defectively designed, that this defective product caused injuries to Plaintiff Teresa Taylor, that $400,000 was necessary to compensate Taylor fairly for her injuries, and that Mentor's conduct authorized an award of punitive damages in the

amount of $4 million. Disappointed with this outcome, Mentor has now mined the trial transcript and pieced together portions of it in support of its post-trial motion that seeks to overturn the jury's verdict (ECF No. 197). Because ample evidence was properly admitted to support the jury's verdict as to liability for compensatory and punitive damages and as to the amount of compensatory damages, that part of the jury's verdict cannot be disturbed. However, because no evidence was presented that Mentor had specific intent to cause harm to Taylor, punitive damages must be capped at $2 million under applicable law and that part of the verdict is accordingly modified.[1]

BACKGROUND

This case is one of more than 800 cases that were consolidated by the Panel on Multidistrict Litigation into the MDL proceeding known as *In Re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*. These cases arise from complications with a product called ObTape that was on the market for only a few years in the United States and was designed to treat women with stress urinary incontinence. ObTape, a mesh tape suburethral sling, was implanted into women to provide support in hopes of preventing such incontinence. Shortly after the introduction of the product, many women began

[1] The parties agree that Florida's substantive law applies in this case. The case was tried in this Court because the parties agreed to a waiver of venue under *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

experiencing complications that included erosion of the product. Due to poor tissue ingrowth of the tape, it would sometimes move through a woman's tissue and become exposed. This movement and lack of tissue ingrowth would often lead to infections and other symptoms. Mentor's scientists and doctors warned its executives of these issues, and yet Mentor continued to sell the product over their objections.

I. Factual Background

Taylor, the Plaintiff in this case, was implanted with ObTape in 2004. The implanting doctor was a true ObTape believer. He had been trained by Mentor, and he served as a surgical proctor who taught other physicians how to implant ObTape in patients. At trial, he defended the product as if he had manufactured it himself. And he testified that it had nothing to do with Taylor's problems, which included chronic cystitis and thinning of Taylor's urethral wall. Ideally, a patient in such a case would be able to rely on her treating physician to support her claim. But sometimes that evidence cannot be obtained. It may be because the treating physician genuinely does not believe his patient has a claim. But sometimes it may be for other reasons, such as loyalty to the manufacturer, a motive to divert attention away from the physician's treatment of his patient, or even a lack of confidence in the judicial medical tort system. A jury is best

suited to evaluate such testimony and assess the credibility of all witnesses, including a plaintiff's treating physician. In this case, they did just that—finding that other evidence supporting liability outweighed Taylor's physician's denials.

In this case, Taylor relied on evidence from Mentor's own files describing the defective nature of ObTape along with the testimony of well credentialed outside medical experts who explained how the defective product caused Taylor's problems. To fully understand that evidence requires a precise understanding of the problems that Taylor experienced after she was implanted with ObTape. Mentor focuses on the semantics of how those problems are labeled; the jury focused on evidence from which it could reasonably ascertain exactly what happened to Taylor and how ObTape played a role in her problems.[2]

Taylor presented evidence that she suffered two main injuries that were caused by ObTape. First, Taylor had significant thinning of her urethral wall, and her urethra had

[2] For example, Mentor places great weight on the fact that Taylor's treating physician never labeled Taylor's problem as an "erosion." The reason Mentor finds this issue significant is that erosion is one of the most common complications associated with ObTape, and it is one of the complications that its own employees warned Mentor management about. Erosion is simply the movement of the ObTape within a woman's tissues because of instability due to poor tissue in-growth which instability eventually can cause the tape to protrude through the tissue and become exposed to the naked eye. According to the medical testimony, Taylor's ObTape caused a "thinning" of the tissue around her urethra, but it never protruded through her urethral wall. The Court finds the significance of this to be one of degree and not a completely different mechanism of injury, as was explained by some of the medical experts.

to be repaired. Taylor presented evidence from several experts, including a biomaterials professor, a biomedical engineer, and a physician who studied the effects of ObTape in his patients. These experts all concluded that ObTape's small pore size does not allow adequate tissue ingrowth and that inadequate tissue ingrowth can lead to inflammation, infection, and erosion, which is the movement of ObTape through bodily tissues. In addition, Taylor introduced damning evidence from Mentor's former employees that the employees recommended removing ObTape from the market. Their recommendation was based on frequent reports of ObTape erosions, an analysis showing that the porosity of ObTape was similar to another sling that had a higher erosion rate than other slings, and reports from Mentor's sales force that physicians expressed concern that ObTape was not porous enough to allow tissue ingrowth.

In addition to presenting evidence that ObTape's physical properties *can* cause it to erode through a patient's bodily tissues, Taylor presented the testimony of a physician who opined that the thinning of Taylor's urethral wall *was* caused by an erosion of her ObTape. Though Taylor's ObTape did not become completely exposed through her urethral wall, her medical expert testified, to a reasonable degree of medical certainty, that the ObTape moved through Taylor's bodily tissues—the mechanism by

which a complete erosion occurs—and caused the thinning of Taylor's urethral wall.

Taylor also asserts that she suffered from chronic bladder inflammations, also called cystitis, caused by ObTape. In support of this assertion, Taylor presented the testimony of Dr. Ahmed El-Ghannam, a well credentialed biomaterials professor. Dr. El-Ghannam holds a PhD in biomaterials and bioengineering from the University of Pennsylvania. He currently serves as a tenured professor at the University of North Carolina – Charlotte, specializing in biomaterials and medical devices. His work includes testing medical devices for biocompatibility and functionality. Dr. El-Ghannam has published many articles on biomaterials in peer-reviewed journals. He holds several patents for implantable medical devices. And he is the associate editor of the Journal of Biomedical Research.

Dr. El-Ghannam explained that permanent implants like ObTape are supposed to be inert and should not degrade at all when implanted in a person. Dr. El-Ghannam conducted a battery of tests on ObTape, including an electron microscope examination, a Fourier Transform Infrared Spectroscopy test, an examination of an ObTape that had been immersed in a physiological solution, and a gas chromatography/mass spectrometry analysis of the physiological solution in which ObTape had been immersed. Dr. El-Ghannam explained to the jury

that because of the materials and methods used to make ObTape, ObTape has a propensity to degrade and shed polypropylene particles. Dr. El-Ghannam also explained the consequences of degradation, including erosion and infection. He expressed his view that ObTape's properties make these complications so prevalent that the design of ObTape (including the materials and methods used to make it) is defective and should not be used for a permanent medical device.

After establishing *general* causation on degradation through Dr. El-Ghannam, Taylor introduced the testimony of Dr. William Porter to establish that Taylor did in fact suffer from chronic infections, which is a complication that Dr. El-Ghannam opined could be caused by ObTape's defective design, and that those infections were likely caused by the ObTape as opposed to some other possible cause, which Dr. Porter ruled out. Dr. Porter is a board certified urogynecologist who has been licensed to practice medicine since 1999 and has been in private practice since 2003. He routinely treats patients with stress urinary incontinence. Dr. Porter has placed roughly 3,500 slings and has also removed slings from patients.

Dr. Porter testified that, assuming Dr. El-Ghannam's testimony about degradation is true, the degradation of ObTape more likely than not caused Taylor's inflammation, including her chronically inflamed bladder. Dr. Porter ruled out other

possible causes of these symptoms, stating that ObTape was higher on his list as the cause of Taylor's symptoms than any other possible causes.

Mentor, of course, had the opportunity to try to explain the damaging testimony of its former employees, and it called its own experts to refute Taylor's evidence. But the jury, as the factfinder, found Taylor's evidence more convincing. Mentor obviously disagrees with the jury's conclusion. But the existence of two plausible sides to the story is not the standard for review. Mentor must demonstrate that the evidence relied upon by the jury was not admissible and thus should not have even been considered by them or that Taylor's evidence was so lacking that no reasonable juror could have reached the conclusion that this jury reached.

II. The Jury's Verdict

With the concurrence of the parties, the Court submitted a special verdict form to the jury, which tracked the Court's instructions on the law. The jury made the following specific findings:

- The ObTape implanted in Taylor had a design defect, and the design defect was a legal cause of Taylor's injuries. Verdict Form ¶¶ 1-2, ECF No. 172.

- Mentor failed to provide Taylor's physician with an adequate warning about ObTape prior to her implant surgery, and the failure to provide an adequate pre-implant warning was a legal cause of Taylor's injuries. *Id.* ¶¶ 3-4.

- Mentor failed to provide Taylor's physician with an adequate warning about ObTape after her implant surgery, and the failure to provide an adequate post-implant warning was a legal cause of Taylor's injuries. *Id.* ¶¶ 5-6.

- Mentor was negligent with respect to the ObTape implanted in Taylor, and Mentor's negligence was a legal cause of Taylor's injuries. *Id.* ¶¶ 7-8.

- Taylor proved by clear and convincing evidence that punitive damages should be awarded against Mentor; that Mentor had a specific intent to harm Taylor and did in fact harm her; and that Mentor was motivated solely by financial gain, knew of the unreasonable danger of the conduct, and knew of the high likelihood of injury resulting from the conduct. *Id.* ¶¶ 10-12.

The jury awarded Taylor $400,000 in compensatory damages. *Id.* ¶ 9. The jury awarded $4,000,000 in punitive damages. *Id.* ¶ 13.

DISCUSSION

I. Motion for Judgment as a Matter of Law

A. Standard for Judgment as a Matter of Law

Under Federal Rule of Civil Procedure 50(a)(2), a party may move for judgment as a matter of law "before the case is submitted to the jury." For the party to prevail on such a motion, the Court must find that "a reasonable jury would not have a legally sufficient evidentiary basis to find for the [opposing] party on that issue." Fed. R. Civ. P. 50(a)(1). If the Court does not grant a Rule 50(a) motion, the movant may file a renewed motion under Rule 50(b) after trial. "The

standard for granting a renewed motion for judgment as a matter of law under Rule 50(b) is precisely the same as the standard for granting the pre-submission motion [under 50(a)]." *McGinnis v. Am. Home Mortg. Servicing, Inc.*, 817 F.3d 1241, 1254 (11th Cir. 2016) (alteration in original) (quoting *Chaney v. City of Orlando*, 483 F.3d 1221, 1227 (11th Cir. 2007)). Thus, the question for the Court "is whether the evidence is 'legally sufficient . . . to find for the party on that issue.'" *Id.* (alteration in original) (quoting Fed. R. Civ. P. 50(a)(1)). "In considering whether the verdict is supported by sufficient evidence, 'the court must evaluate all the evidence, together with any logical inferences, in the light most favorable to the non-moving party.'" *Id.* (quoting *Beckwith v. City of Daytona Beach Shores*, 58 F.3d 1554, 1560 (11th Cir. 1995)). The Court must also be mindful that it is the job of the jury, not the Court, to "weigh conflicting evidence and inferences, and determine the credibility of witnesses." *Id.* (quoting *Shannon v. Bellsouth Telecomms., Inc.*, 292 F.3d 712, 715 (11th Cir. 2002)).

B. Taylor's Design Defect Claims

Taylor contends that ObTape had design defects that caused her injuries. She also asserts that Mentor was negligent with regard to the design of ObTape and that the negligent design caused her injuries. To prove her claim under either theory,

Taylor must show that: (1) ObTape had a design defect (or defects), (2) the design defect was capable of causing injury, and (3) the design defect more likely than not contributed substantially to producing her injury. *See Gooding v. Univ. Hosp. Bldg., Inc.*, 445 So. 2d 1015, 1018 (Fla. 1984) (explaining standard of causation for negligence: that "negligence probably caused the plaintiff's injury"); *see also Cox v. St. Josephs Hosp.*, 71 So. 3d 795, 801–02 (Fla. 2011) (noting that directed verdict would be appropriate "where the plaintiff has failed to provide evidence that the negligent act more likely than not caused the injury" but "is not appropriate in cases where there is conflicting evidence as to the causation or the likelihood of causation").

Mentor does not appear to dispute that the evidence at trial was sufficient for a reasonable jury to conclude that ObTape had a design defect or that Mentor was negligent with regard to ObTape's design. But Mentor argues that Taylor failed to introduce sufficient evidence that a defective or negligent design caused Taylor's injuries. While causation was vigorously contested at trial, the Court finds that sufficient evidence was admitted from which a reasonable jury could reach the conclusion that it did.

1. ObTape Pore Size Defect

Taylor presented evidence that ObTape's small pore size contributed substantially to her injuries. Several experts testified that ObTape's small pore size does not adequately allow tissue ingrowth and that inadequate tissue ingrowth can lead to inflammation, erosion, and infection.

As previously mentioned, Taylor presented expert testimony form Dr. Ahmed El-Ghannam to establish general causation. With regard to pore size, he opined that ObTape had "very little pores," that some of the pores did not go all the way through the ObTape, and that tissue integration would be adversely impacted by such pores. Trial Tr. vol. III 189:20-21, 190:7-18, ECF No. 180. He also testified that if the pores are not large enough to allow for tissue ingrowth, then the body could have a severe foreign body response to the implant. *Id.* at 214:9-215:12.

Taylor also presented expert testimony from Dr. William Hyman to support her contention that the small pore size contributed to the defective design of ObTape. Dr. Hyman, like Dr. El-Ghannam, was certainly well qualified to give the opinions he gave. Dr. Hyman is professor emeritus of biomedical engineering at Texas A&M University. He taught biomedical engineering for thirty-nine years. During his years as a professor, Dr. Hyman conducted extensive research and published

many books, book chapters, and articles. He has consulted for a variety of clients on medical device design.

Dr. Hyman explained that for implantable mesh products, large pores are preferable to small pores. Large pores, unlike small pores, promote better tissue ingrowth, which is "an important component of meshes working or not working." Trial Tr. vol. II 44:19-45:12, ECF No. 186. Dr. Hyman also explained how proper tissue ingrowth helps control erosion and infection. *Id.* at 45:10-46:2.

Taylor also presented the testimony of Dr. Andrew Siegel, a urologist, on this issue. Dr. Siegel is a board certified urologist who has practiced urology since 1988. He is also board certified in female urology and pelvic reconstructive medicine. Dr. Siegel has authored a number of peer reviewed articles in medical and scientific journals, including articles on ObTape and other slings used to treat stress urinary incontinence. Dr. Siegel testified that based on his experience with his patients, the pore size of ObTape was not large enough to allow good tissue ingrowth. Trial Tr. vol. V 71:20-72:8, 77:24-78:13, 89:4-12, ECF No. 187. He also testified that ObTape is "[s]ignificantly more problematic" than other polypropylene sling products when it came to erosions and infections. *Id.* at 89:24-90:6.

In addition, according to a report by two Mentor employees, there were "frequent feedbacks on Obtape erosions," and ObTape's porosity was comparable to the porosity of another sling that was "known to generate an increased rate of erosion and infection." Pl.'s Trial Ex. 611, Obtape Erosion & Infections Report, ECF No. 176-6 at 33. Also, Mentor's regional sales manager, Ray Tantillo, testified that Mentor sales representatives reported to him that physicians were concerned that ObTape was not porous enough to allow tissue ingrowth; he reported these concerns to others in Mentor, including Dave Amerson and Delia Cook. Trial Tr. vol. V 214:17-215:6.

Taylor relied primarily on the testimony of Dr. William Porter, a urogynecologist who examined Taylor and reviewed her medical records, to testify about specific causation. As previously explained, Dr. Porter was well credentialed and qualified to provide expert testimony. He noted that Taylor's implanting physician, Dr. Vukovich, testified that he excised a portion of Taylor's ObTape in 2011 and found that her urethra was "really thin" and needed to be "bulked up." Trial Tr. vol. IV 22:13-22, ECF No. 181. Dr. Porter testified, to a reasonable degree of medical certainty, that "ObTape . . . was the cause of the thinning of the tissue damaging the urethra itself." *Id.* at 230:17-19. Dr. Porter further testified that it "would be erosion thinning the wall. It would be a thinning erosion,

exposure of the mesh." *Id.* at 230:23-24. Mentor emphasizes that Dr. Vukovich, Taylor's treating physician, did not diagnose Taylor with a urethral erosion of her ObTape. In other words, Taylor did not have an erosion where the ObTape became exposed through her urethral wall. Dr. Porter acknowledged that Taylor "did not have an erosion through the skin itself, *but it was right next to it*." Trial Tr. vol. V 15:10-13 (emphasis added). Dr. Porter went on to state that although there was no erosion inside the lumen of the urethra, "the skin has been worn thin in that area." *Id.* at 15:16-17. And it was his opinion that ObTape caused the thinning of Taylor's urethral wall. From this testimony, a reasonable juror could conclude that Taylor did have an erosion—type movement of the ObTape through her bodily tissue, even though it did not become completely exposed.[3]

[3] Mentor argues that the Court should have excluded Dr. Porter's testimony because Dr. Porter did not opine in his expert report that Taylor had suffered a urethral erosion of her ObTape or that degradation of ObTape likely caused her injuries, and he never updated his expert report to offer these opinions. Under Federal Rule of Civil Procedure 37(c)(1), "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." When Mentor moved to strike Dr. Porter's testimony at trial, the Court gave Mentor extra time to prepare for his cross examination so that any prejudice from the allegedly deficient disclosure would be minimized. And when Mentor renewed its motion to strike Dr. Porter's testimony, the Court observed that Mentor's counsel "did a fine job in that cross-examination," had "conducted a Clarence Darrow cross-examination," and that "[t]here could not be a possible finding of prejudice." Trial Tr. vol. VIII 175:15-20, ECF No. 183. Thus, any failure to disclose was harmless.

Mentor focuses on a tissue report on Taylor's ObTape (which was performed without a microscope), as well as the testimony of Dr. Vukovich, who stated that when he removed Taylor's ObTape, he observed good tissue ingrowth. But both Dr. El-Ghannam and Dr. Siegel offered testimony sufficient to cast doubt on the tissue report and Dr. Vukovich's testimony on this point. *See* Trial Tr. vol. III 214:2-215:2, 230:10-231:12 (Dr. El-Ghannam explaining what integration is and why it cannot be observed with the naked eye); Trial Tr. vol. V 151:11-23 (Dr. Siegel explaining that "the value of a gross look without a microscope is -- is minimal.").

In sum, Taylor presented evidence that ObTape's small pore size leads to poor tissue ingrowth, which can cause the sling to erode through a patient's bodily tissues. Taylor also presented evidence that her ObTape eroded through her bodily tissues, causing a thinning of her urethral wall that had to be repaired. After ruling out the other possible causes of this thinning, Taylor's expert opined that the poorly designed ObTape was the most likely cause. This evidence is enough to support the jury's finding that a negligent or defective design caused Taylor's injuries related to the thinning of her urethral wall.

2. ObTape Degradation Defect

Taylor also presented evidence that the degradation of ObTape contributed substantially to her injuries. In support of

this theory, Taylor also relied on the testimony of Dr. El-Ghannam and Dr. Porter. Mentor contends that the Court erred in permitting the jury to hear their testimony and that their testimony was not sufficient to establish causation.

a. DR. EL-GHANNAM'S TESTIMONY ON DEGRADATION

Mentor argues that the Court should have excluded Dr. El-Ghannam's testimony on degradation. First, Mentor argues that Dr. El-Ghannam's testimony should have been excluded because Dr. El-Ghannam (1) did not testify regarding the precise amount of degraded polypropylene necessary to cause an adverse reaction and (2) did not examine Taylor's explanted ObTape for evidence of degradation. Based on his testing, Dr. El-Ghannam opined that ObTape has a propensity to degrade. *E.g.*, Trial Tr. vol. III 145:17-22. Dr. El-Ghannam thoroughly explained his methodology and the rationale for his opinion that the heat-treated polypropylene used to make ObTape will degrade when implanted in a person. *Id.* at 146:24-148:22, 149:18-153:22, 158:24-162:15, 165:15-167:11, 173:8-175:14, 176:11-179:9 (explaining electron microscope examination; FTIR—Fourier Transform Infrared Spectroscopy—test; examination of an ObTape that had been immersed in a physiological solution; and gas chromatography/mass spectrometry analysis of the physiological solution that an ObTape had been immersed in). Due to the properties of the material and the manufacturing method, every

ObTape has the propensity to degrade inside the human body. While the complications caused by such degradation may vary from person to person, the fact of degradation does not. Dr. El-Ghannam further explained that ObTape is supposed to be inert and is not supposed to degrade at all when it is implanted in a person; he also explained the consequences of degradation—including erosion and infection. *Id.* at 156:15-16, 212:17-21. Mentor appears to argue that Taylor relied solely on Dr. El-Ghannam to establish that Taylor suffered complications due to this degradation. But Dr. El-Ghannam simply provided the scientific and biomaterials basis for general causation. Dr. Porter examined Taylor's specific complications, and after ruling out other possible causes, narrowed specific causation for her chronic inflammation to ObTape degradation.

Mentor relies on *McClain v. Metabolife International, Inc.*, 401 F.3d 1233 (11th Cir. 2005) and *Johnson & Johnson v. Batiste*, No. 05-14-00864-CV, 2015 WL 6751063 (Tex. App. Nov. 5, 2015) in support of its contention that Taylor did not present enough evidence for her degradation claim to go to the jury. In *McClain*, the plaintiffs alleged that they suffered injuries after taking the defendant's herbal weight loss supplement. 401 F.3d at 1236. The Eleventh Circuit noted that "to carry the burden in a toxic tort case, 'a plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally

as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover.'" *Id.* at 1241 (quoting *Mitchell v. Gencorp*, 165 F.3d 778, 781 (10th Cir. 1999)). In *McClain*, the plaintiffs' expert agreed that "a drug's effect is dose-driven" but did not offer any testimony on what dose of the defendant's supplement could cause harm. *Id.* In other words, he did not say "how much is too much." *Id.* And in *Batiste*, a case about a different brand of polypropylene mesh, the plaintiff's expert "admitted . . . there could be degradation from the polypropylene that would have no clinical significance in a patient, and there was no evidence as to how much the polypropylene would have to degrade before it caused injury to a patient." *Batiste*, 2015 WL 6751063, at *6.

In contrast, here, Dr. El-Ghannam testified that based on his tests, all ObTape will degrade when it is implanted in the human body even though ObTape is supposed to be inert. He further testified that ObTape will, after an incubation period, degrade at an "exponential" rate and cause problems like infections and erosions. Trial Tr. vol. III 212:22-213:9. He testified that this incubation period could be months or years, but once exponential degradation begins, the patient will experience complications. *Id.*; *accord id.* at 199:21-200:1, 201:15-23, 204:9-25. This testimony, combined with Taylor's expert testimony on specific causation from Dr. Porter (*see*

infra § I.B.2.b) was enough for the jury to consider whether degradation of the ObTape contributed to her injuries.

Mentor also argues that since Dr. El-Ghannam did not examine Taylor's explanted ObTape, he should not be permitted to offer an opinion on whether her ObTape did, in fact, degrade. But based on his tests—including the examination of ObTape after it had been immersed in a physiological solution and the analysis of the solution in which the ObTape had been immersed—Dr. El-Ghannam testified that "the implant in Ms. Taylor, as well as any patient who has taken this implant that was manufactured by these techniques that I describe -- applying pressure and heat at the same time -- will degrade." Trial Tr. vol. III at 199:21-24. According to Dr. El-Ghannam, the degradation of this product was not sample specific; it would occur in every sample due to the nature of the product materials, the manufacturing process, and the design. And thus it violated a fundamental principle of biocompatibility for implanted devices: it was not inert.

Mentor further contends that Dr. El-Ghannam's testimony on degradation should not have been admitted because the medical doctors who testified on Taylor's behalf had not personally seen evidence of Dr. El-Ghannam's degradation theory. These doctors are not biomedical engineers, and any doubts they may have about

Dr. El-Ghannam's opinions goes to the weight of Dr. El-Ghannam's testimony, not its admissibility.

Finally, Mentor argues that Dr. El-Ghannam's opinions on degradation are not reliable because he has not published any articles on his degradation theory and because he had not done any work on polypropylene before he began examining it for this MDL. The lack of publication does not demand exclusion of Dr. El-Ghannam's testimony. *See, e.g., Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593-94 (1993) (explaining that publication "is not a *sine qua non* of admissibility" and is not a dispositive "consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised"). Dr. El-Ghannam is a well-qualified biomaterials engineer, and he used widely accepted methods to test ObTape—such as electron microscope examination, FTIR test, and gas chromatography/mass spectrometry analysis.

With regard to Dr. El-Ghannam's lack of prior work on polypropylene, Mentor is correct that the courts may exclude an expert's testimony if the expert's opinion did not "grow[] naturally and directly out of research [he had] conducted independent of the litigation." *Lebron v. Sec'y of Fla. Dep't of Children & Families*, 772 F.3d 1352, 1369 (11th Cir. 2014) (second alteration in original) (quoting Fed. R. Evid. 702, Advisory Comm. Notes (2000 Amendments)). In *Lebron*, for

example, a clinical psychiatrist was not permitted to testify about drug use rates among certain demographic groups because he did not have any background in studying such rates. *Id.* But here, Dr. El-Ghannam is a biomaterials professor whose "research area is the characterization and design of medical devices and then testing them for their biological biocompatibility and functionality as medical devices." Trial Tr. vol. III 128:4-11. In other words, he studies medical devices like ObTape to determine their biocompatibility and functionality. Though he may not have examined polypropylene before he became an expert in this MDL, he is simply not like the psychiatrist in *Lebron* who sought to offer opinions in a completely different field. In fact, his area of expertise and experience fall exactly within the realm of someone who would be expected to analyze the issues on which he opined. Although Mentor may dispute his opinions, Dr. El-Ghannam is not a quack or expert-for-hire. He is a well credentialed, serious scientist with specific expertise regarding the issues on which he testified. Moreover, because of the number of cases in this MDL, he has probably studied ObTape from a biomaterials perspective more thoroughly than any other single person. The fact that this specific expertise regarding this particular product may have been obtained in part while he was retained as an expert in this litigation is something that the jury could certainly consider in evaluating

his bias and credibility, but it is preposterous to suggest that it disqualifies him. In the final analysis, Dr. El-Ghannam's conclusion was the same as Mentor's—this product should not be on the market. The jury properly considered Dr. El-Ghannam's testimony.

b. DR. PORTER'S TESTIMONY

Mentor also argues that the Court should have excluded Dr. Porter's causation testimony. Although Dr. Porter did not have any "personal evidence" that polypropylene slings degrade, Trial Tr. vol. V 42:10-15, Dr. Porter was asked to assume that Dr. El-Ghannam's testimony about degradation is true. He was then asked to opine whether the degradation of ObTape more likely than not caused Taylor's inflammation, including her chronically inflamed bladder (also called cystitis). Trial Tr. vol. IV 212:8-214:1. Contrary to Mentor's argument, Dr. Porter's testimony was not based on an assumption supplied by counsel. Dr. Porter testified in response to a hypothetical that simply asked him to assume that ObTape degrades as Dr. El-Ghannam testified it does. He then evaluated that hypothetical fact along with the other possible causes of Taylor's complications and concluded that it's more likely than not, to a reasonable degree of medical certainty, that those complications were caused by the degradation of ObTape. *Id.* at 213:17-214:1. If the jury accepted Dr. El-Ghannam's testimony, then it could also

accept Dr. Porter's testimony in response to the hypothetical question.

c. THE EVIDENCE ON DEGRADATION

Given the testimony of Dr. El-Ghannam and Dr. Porter, the evidence was clearly sufficient to support the jury verdict. As previously explained, Dr. El-Ghannam testified that because of the materials and methods used to make ObTape, ObTape has a propensity to degrade and shed polypropylene particles. Trial Tr. vol. III 161:24-162:15. Dr. El-Ghannam further testified that based on his testing, including tests that involved placing ObTape in a physiological solution and then examining both the ObTape and the solution, he is "sure that the implant in Ms. Taylor . . . will degrade." *Id.* at 199:21-24, 204:9-25. Dr. El-Ghannam also testified that degradation would cause complications such as inflammation and erosion. *Id.* at 187:20-188:9. Dr. Porter testified that, assuming Dr. El-Ghannam's testimony about degradation is true, the degradation of ObTape more likely than not caused Taylor's inflammation, including her chronically inflamed bladder (also called cystitis). Trial Tr. vol. IV 212:8-214:1. Dr. Porter further explained how he eliminated other possible causes and reached the conclusion that nothing else in Taylor's history or in Dr. Vukovich's notes

"could explain the inflammation."[4] *Id.* at 213:11-13. This evidence is sufficient to support the jury's verdict that a design defect or negligence with regard to ObTape's design caused Taylor's injuries related to her chronic bladder inflammation.

C. Taylor's Failure-to-Warn Claims

Taylor also claimed that ObTape was defective because Mentor did not provide adequate warnings about ObTape's risks, and this failure to warn caused her injuries. To prove her failure to warn claim, Taylor must show: (1) that Mentor did not provide an adequate warning regarding the risks of ObTape, (2) she suffered an injury caused by ObTape, and (3) the inadequate warning more likely than not contributed substantially to producing her injury. *Hoffmann-La Roche, Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009).

Mentor does not appear to dispute that Taylor submitted sufficient evidence for the jury to conclude that Mentor provided inadequate warnings regarding the risks of ObTape, including the true risks of erosion and infection. Mentor

[4] Mentor argues that Dr. Porter failed to rule out other potential causes of Taylor's bladder inflammation, such as menopause and the implantation of a different type of mesh sling. First, Taylor is required to prove that ObTape more likely than not contributed substantially to producing her injury—not that it was the sole cause of her injuries. Second, Dr. Porter did explain why, in his opinion, ObTape was "higher on [his] list" as a cause of Taylor's injuries than either Taylor's post-menopausal state or the Aris sling. Trial Tr. vol. V 34:7-13.

instead contends that Taylor failed to present enough evidence for the jury to conclude that she suffered injuries as a result of Mentor's failure to warn of increased risks of erosion and infection associated with ObTape. In support of this argument, Mentor repeats its contention that Taylor did not suffer a classic *erosion* of her ObTape. But, as discussed above, there was enough evidence for the jury to find that she did or that she suffered an "erosion-like" complication ("thinning").

Mentor also contends that Taylor did not present enough evidence for the jury to conclude that a failure to warn substantially contributed to her injuries. Under Florida law, a medical device company's duty to warn of the device's risks "is directed to physicians rather than patients under the 'learned intermediary' doctrine." *Mason*, 27 So. 3d at 77 (quoting *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989)). "[T]he duty of a [medical device] manufacturer to warn of the dangers involved in the use of a [device] is satisfied if it gives an adequate warning to the physician who prescribes the [device]." *Id.* "[T]he learned intermediary doctrine is based in part on a presumption that, once informed by the manufacturer, physicians will share the pertinent risks with his or her patient." *Guenther v. Novartis Pharm. Corp.*, No. 6:08-

CV-456-ORL-31-DAB, 2013 WL 1498162, at *2 (M.D. Fla. Apr. 9, 2013).[5]

Mentor argues that the only way Taylor can prove causation is to point to testimony that her treating physician, Dr. Vukovich, would have declined to implant Taylor with ObTape had he received a different pre-implant warning and that he would have employed a different course of treatment for Taylor had he received a different post-implant warning. Dr. Vukovich did not provide such testimony. Taylor contends that she does not need Dr. Vukovich's testimony to prove causation because some courts interpreting Florida law have concluded that a plaintiff may prove causation in other ways, such as by showing that a different warning would have prompted "the physician to pass along a more detailed warning" that would have prevented the plaintiff's injuries. *Guenther v. Novartis Pharm. Corp.*, 990 F. Supp. 2d 1299, 1304 (M.D. Fla. 2014); *accord Kirchman v. Novartis Pharm. Corp.*, No. 8:06-CV-1787-T-24-TBM, 2014 WL 2158519, at *5–6 (M.D. Fla. May 23, 2014) (finding genuine fact

[5] Taylor argues that Mentor has the burden of proof on this issue. If Mentor were trying to prevail under the learned intermediary doctrine by establishing that Dr. Vukovich knew as much as Mentor did about the risks of ObTape but recommended it for Taylor anyway, then Taylor would be correct. *See Walls v. Armour Pharm. Co.*, 832 F. Supp. 1467, 1482 (M.D. Fla. 1993) (finding that a manufacturer that raised the learned intermediary doctrine as an affirmative defense bears the burden of proof). But that is not Mentor's argument. Mentor's argument is that Taylor cannot prove an element of her claim because Dr. Vukovich never testified that if Mentor had given additional warnings about ObTape, he would have taken a different course with Taylor's treatment.

dispute on causation because there was evidence from which a juror could conclude that (1) the doctor would have passed along different warnings had the drug manufacturer provided them and (2) the patient would have declined the drug had he been given the different warnings); *Munroe v. Barr Labs., Inc.*, 670 F. Supp. 2d 1299, 1305 (N.D. Fla. 2009) ("A juror could reasonably infer that if a physician was told that generic Adderall, in combination with pseudoephedrine, could kill an otherwise healthy adult, the physician would so advise a patient . . . ."); *Barrow v. Bristol-Myers Squibb*, No. 96-689-CIV-ORL-19B, 1998 WL 812318, at *39 (M.D. Fla. Oct. 29, 1998) (finding that the plaintiff proved that she would not have gotten breast implants had her doctor received an adequate warning from the manufacturer and passed it to her).[6]

[6] The cases Mentor cited on this point are distinguishable. In each case, the doctor knew the risks that the plaintiff claimed the manufacturer should have warned about but prescribed the product anyway. *Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1367 (M.D. Fla. 2015) ("[T]he adequacy of the warning is irrelevant if the prescribing physician, as opposed to the patient, has knowledge of the risks and benefits of the drug and would have prescribed the drug anyway had the warnings been different." (quoting *Chase v. Novartis Pharm. Corp.*, 740 F. Supp. 2d 1295, 1297 (M.D. Fla. 2006))); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007) ("[T]he causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." (quoting *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995))); *Edgar v. Danek Med., Inc.*, No. 96-2451-CIV-T-24A, 1999 WL 1054864, at *6 (M.D. Fla. Mar. 31, 1999) ("A physician's independent awareness of those risks [that should have been warned about] disrupts probable cause and obviates any liability for a manufacturer's failure to warn.").

Mentor did not point to evidence that Dr. Vukovich knew of an increased risk of erosion and infection with ObTape but prescribed it anyway. Dr. Vukovich testified that he would expect a device manufacturer to keep him "up-to-date on products" and to provide truthful and accurate information about the product. Trial Tr. vol. IV 34:14-24. He also testified that Mentor did not inform him that ObTape had high rates of erosion and infection. *Id.* at 35:18-36:14. And he testified that he would have wanted that information. *Id.* at 36:15-37-9. Thus, there was sufficient evidence for the jury to conclude that Dr. Vukovich was not aware of the increased risks of erosion and infection that Taylor contends Mentor should have warned him about.

Taylor also introduced evidence from which a juror could conclude that the standard of care for a physician in Dr. Vukovich's position would have required him to inform Taylor of the risks associated with ObTape had Mentor informed Dr. Vukovich of them. *E.g.*, Trial Tr. vol. II 15:8-13 (Dr. Hyman testifying that informed consent includes a warning about potential complications). The jury had enough evidence to conclude that a reasonable physician who was aware of the increased risks of erosion and infection associated with ObTape, including Dr. Vukovich, would have passed those warnings along to his patients. And Taylor testified that if Dr. Vukovich had

told her that the ObTape may erode or that it was not suited to be a permanent implant, she never would have undergone the ObTape procedure. Trial Tr. vol. IV 95:13-25. Based on this evidence, the Court finds that sufficient evidence existed for the jury to find in favor of Taylor on her pre-implant warning claim.

Taylor also contends that Mentor did not provide adequate post-implant warnings. Mentor argues there was no legally sufficient evidentiary basis for the jury to find in Taylor's favor on her post-implant warning claim. To prevail on the claim, Taylor had to show that a different post-implant warning would have changed her course of treatment. Mentor is correct that Dr. Vukovich never testified that he would have altered his course of treatment had a different post-implant warning been given (he did not testify either way on this), but Taylor argues that Mentor should have warned her physician that if there was an erosion of her ObTape, the physician should remove as much of the sling as possible. *See* Trial Tr. vol. II 105:2-19 (Dr. Hyman testifying that Mentor decided against issuing such a warning). According to Dr. Porter, if Mentor had provided such a warning, then it would have been the standard of care for a doctor to remove as much of the sling as possible. Trial Tr. vol. V 55:3-12. And Taylor testified that if Dr. Vukovich had

passed this warning on to her, she would have "insisted" that Dr. Vukovich remove the ObTape. Trial Tr. vol. IV 120:6-121:17.

Mentor emphasizes that Taylor did not have a complete erosion of her urethral wall and argues that an additional warning would not have made a difference in her case. A jury could conclude otherwise. Dr. Vukovich performed a revision surgery on Taylor in 2011; at that time, he found that Taylor's urethra was "really thin" and needed to be "bulked up." *Id.* at 22:13-22. He excised only a portion of the ObTape at that time. For the reasons set forth above, a reasonable juror could conclude that the thinning of Taylor's urethra was related to the ObTape; that if Mentor provided an additional warning about how much ObTape should be excised, Dr. Vukovich would have excised as much as possible; and that if Dr. Vukovich had explained the additional warning to Taylor, she would have insisted that the sling be removed. For all of these reasons, the Court finds that there was sufficient evidence for a jury to find in Taylor's favor on her post-implant failure to warn claims.

D. Taylor's Punitive Damages Claim

1. Liability

Mentor contends that the evidence was not sufficient to support the jury's decision to award punitive damages. Under Florida law, "[a] defendant may be held liable for punitive

damages only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of intentional misconduct or gross negligence." Fla. Stat. Ann. § 768.72(2). "'Intentional misconduct' means that the defendant had actual knowledge of the wrongfulness of the conduct and the high probability that injury or damage to the claimant would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage." *Id.* § 768.72(2)(a). "'Gross negligence' means that the defendant's conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct." *Id.* § 768.72(2)(b).

Mentor again argues that the only alleged defect Taylor tied to her injuries was the degradation of ObTape and contends that Taylor did not establish that Mentor consciously disregarded the risk of degradation. But, as discussed above, Taylor also presented evidence that she had an erosion of her ObTape because of its small pore size. And she presented sufficient evidence for a jury to find, based on clear and convincing evidence, that Mentor was grossly negligent with regard to the risks of ObTape—both its porosity and its propensity to degrade. For example:

- Mentor employees ignored animal studies which demonstrated that ObTape caused inflammation to a greater extent than another type of sling. Trial Tr. vol. II 60:7-10, 61:18-62:25.

- Mentor did not conduct tests to determine if by-products would come off the ObTape even though, according to Dr. El-Ghannam, it was well known that heat and pressure cause polypropylene to degrade, and a reasonable manufacturer would have done such testing. Trial Tr. vol. III 158:17-159:8, 177:12-178:2. Dr. El-Ghannam testified that he did more testing on ObTape than Mentor did. *Id.* at 236:19-25.

- Mentor did not conduct clinical trials on ObTape before it went on the market. Trial Tr. vol. II 217:4-17. Taylor's witnesses testified that Mentor should have done so. Trial Tr. vol. II 48:1-52:14 (Dr. Hyman explaining the importance of testing); *id.* at 52:16-17 (Dr. Hyman testifying, "It turned out [ObTape] was bad. And [Mentor] didn't know that till after they sold it and put it in people."); Trial Tr. vol. VI 38:9-19, ECF No. 182 (Dr. Cosson testifying that Mentor was "not seeking enough for information" about ObTape complications).

- Before Taylor was implanted with ObTape, Mentor employees had begun to see "more and more ObTape erosions." Pl.'s Tr. Ex. 287, ECF No. 176-4 at 24. According to Dr. Hyman, Mentor "certainly knew" by May 2004 that ObTape had a higher rate of complications than other products and that the complications were worse. Trial Tr. vol. II 125:18-22.

- In 2004, the inventor of ObTape, Dr. Emmanuel Delorme, stopped using ObTape and began using a macroporous, woven mesh product instead. *Id.* at 116:15-119:14. Mentor did not disclose to anyone that Dr. Delorme had stopped using the product. *Id.* at 120:1-13.

- In 2004, Dr. Michel Cosson reported to Mentor employees that he had seen serious complications with ObTape, which he believed were caused by the material of the sling. Trial Tr. vol. VI 22:7-19. Dr. Cosson also made recommendations to Mentor about how to advise physicians on what to do in the event of a complication, but Mentor did not issue his suggested warnings. *Id.* at 24:14-25:22. Dr. Cosson then conducted a survey of his

colleagues, and he wrote an editorial in a French medical journal about the risks of ObTape. *Id.* at 25:23-26:13. Mentor decided not to respond to the editorial because "it might trigger off another article from Cosson, with more solid facts, and details of the Uratape and ObTape's serious cases." Pl.'s Trial Ex. 492, ECF No. 176-5 at 46.

- By early 2005, Mentor executives knew that the French health ministry had conducted a survey of mesh products on the French market and determined that ObTape had the highest complication rate. Trial Tr. vol. II 245:2-246:18.

- In April 2005, Mentor executives learned of an article regarding high rates of erosion with ObTape and its predecessor, Uratape. Pl.'s Trial Ex. 566, Mem. from Delia Cook on Journal of Urology Article: Erosions (Apr. 24, 2005), ECF No. 176-6 at 1-7. The article concluded that the complications were due to the tape itself, not the implantation method, and that complete removal of the tape is recommended in the event of an erosion. *Id.* at 4. Mentor, however, instructed its sales force to "keep in mind" that erosions may happen if improper technique is used. *Id.* at 2.

- In August 2005, Mentor senior executives received a report from two Mentor employees detailing problems with ObTape, including its small pore size and the fact that it was made of heat-welded polypropylene. Pl.'s Trial Ex. 611, Obtape Erosion and Infections Report, ECF No. 176-6 at 33-51. The employees recommended that ObTape be removed from the market. The report noted that a "key opinion leader" recommended against using heat-welded polypropylene. *Id.* at 33. The CEO of Mentor's French division knew about the report and ordered the authors to maintain "full radio silence." Pl.'s Trial Ex. 2863, Email from Adri Hoogwerf to Jean-Christophe Bizon, *et al.* (Sept. 22, 2005), ECF No. 176-8 at 58; *accord* Trial Tr. vol. II 234:7-16. Mentor executives tried to convince the report's authors that they were wrong, but the authors did not change their minds. *Id.* at 242:7-243:14.

- In August 2005, Mentor senior executives acknowledged that one of Mentor's ObTape sales representatives had not timely reported forty-eight ObTape erosions from twenty-two doctors; instead, he apparently held them for some

time. Pl.'s Trial Ex. 615, Email Chain (Aug. 24-25, 2005), ECF No. 176-6 at 53-55.

- ObTape's product insert data sheet stated that certain complications, such as erosions and infections, had been reported "very rarely" and did not disclose the risk of delayed infections, increased infections, or increased erosions. Trial Tr. vol. II 110:18-112:15. According to at least one of Taylor's experts, the warnings "simply misstate the facts" and are misleading. *Id.* at 112:16-113:22.

- Mentor suspended sales of ObTape in France pending an investigation, but the suspension was not announced to employees, to physicians who used ObTape, or to potential patients. *Id.* at 232:25-234:6.

Based on this evidence and the record as a whole, the Court finds that a reasonable juror could conclude that Mentor did not adequately test ObTape before putting it on the market, knew about risks of complications but understated those risks, concealed known risks of ObTape, and ignored warnings from physicians and Mentor's own employees. Thus, the evidence presented at trial was sufficient for the jury to find that Mentor acted with conscious disregard or indifference to the safety of the women who were implanted with ObTape. The evidence was sufficient to authorize punitive damages under Florida law.

2. Florida's Punitive Damages Cap

Mentor contends that the punitive damages award in this case must be capped under applicable Florida law. Under Florida law, punitive damages are generally capped at three times the

amount of compensatory damages or $500,000—whichever is greater. Fla. Stat. § 768.73(1)(a). If "the fact finder determines that the wrongful conduct . . . was motivated solely by unreasonable financial gain and . . . that the unreasonably dangerous nature of the conduct, together with the high likelihood of injury resulting from the conduct, was actually known by the managing agent, director, officer, or other person responsible for making policy decisions on behalf of the defendant," then punitive damages may not exceed the greater of $2 million or four times the amount of compensatory damages. *Id.* § 768.73(1)(b). There is no cap on punitive damages "if the fact finder determines that at the time of injury the defendant had a specific intent to harm the claimant and determines that the defendant's conduct did in fact harm the claimant." *Id.* § 768.73(1)(c). Mentor argues that the evidence does not support either exception to the cap and that the punitive damages award should be remitted to $1.2 million—three times the compensatory damages award.

a. UNREASONABLE FINANCIAL GAIN

Mentor contends that the record is devoid of evidence from which a reasonable factfinder could conclude that Mentor was "motivated solely by unreasonable financial gain and . . . that the unreasonably dangerous nature of the conduct, together with the high likelihood of injury resulting from the conduct, was actually known by the managing agent, director, officer, or

other person responsible for making policy decisions on behalf of the defendant." *Id.* § 768.73(1)(b). Mentor's argument on this point narrowly focuses on whether Mentor executives knew about the likelihood of injury due to the degradation of ObTape. But as discussed above, a reasonable juror could conclude that Taylor also suffered injuries caused by problems with ObTape's porosity. Based on the evidence discussed above, a jury could conclude that ObTape had a higher risk of erosion and infection than similar mesh products due to its physical characteristics, including its porosity. In other words, a jury could conclude that ObTape was significantly more likely to result in serious complications than other similar mesh sling products. And a jury could conclude that Mentor executives knew about the risks but decided not to disclose them to anyone so that Mentor could continue selling ObTape. The Court is thus satisfied that the evidence supported the jury's verdict on this issue.

b. SPECIFIC INTENT TO CAUSE HARM

Mentor also maintains that the evidence presented at trial does not support a conclusion that Mentor had a "specific intent to cause harm" to Taylor, and therefore, the punitive damages award must be capped at $2 million. Neither party pointed the Court to any Florida precedent explaining "specific intent to cause harm" under the Florida statute, but the Court finds

Georgia law interpreting this same language in Georgia's punitive damages statute instructive.

In *Viau v. Fred Dean, Inc.*, 418 S.E.2d 604, 608 (Ga. Ct. App. 1992), the Georgia Court of Appeals considered the "specific intent to cause harm" exception to the damages cap in the context of a drunk driver who caused a wreck.[7] The Georgia Court of Appeals noted that in the Restatement (Second) of Torts § 8A, the word intent is used "to denote that the actor desires to cause consequences of his act, or that he believes that the consequences are substantially certain to result from it." *Id.* (quoting Restatement (Second) of Torts § 8A (1965)). "On the other hand, the mere knowledge and appreciation of a risk, short of a substantial certainty, is not the equivalent of intent." *Id.* (quoting *Eubanks v. Nationwide Mut. Fire Ins. Co.*, 393 S.E.2d 452, 456 (Ga. Ct. App. 1990)). The *Viau* Court concluded that while the drunk driver's intent to drink and drive amounted to a "conscious indifference to the consequences of driving while intoxicated," it did not establish "a specific intent that his driving while intoxicated would cause harm." *Id.*

[7] The current version of O.C.G.A. § 51-12-5.1 provides that if it is found that a "defendant acted or failed to act while under the influence of alcohol . . . to that degree that his or her judgment is substantially impaired," the cap does not apply. *Id.* § 51-12-5.1(f). But the version in effect when *Viau* was decided only contained a "specific intent ot cause harm" exception to the cap. *See* O.C.G.A. § 51-12-5.1(f) (1991).

Here, the evidence discussed above is sufficient for a jury to conclude that Mentor acted with conscious disregard or indifference to the safety of the women who were implanted with ObTape. But Taylor did not point to evidence that Mentor acted with a specific intent that ObTape would cause harm to the women who were implanted with it. Accordingly, the punitive damages award must be reduced to the statutory cap of $2,000,000. Fla. Stat. § 768.73(1)(b).

II. Motion for a New Trial

"A losing party may . . . move for a new trial under Rule 59 on the grounds that 'the verdict is against the weight of the evidence, that the damages are excessive, or that, for other reasons, the trial was not fair . . . and may raise questions of law arising out of alleged substantial errors in admission or rejection of evidence or instructions to the jury.'" *McGinnis* 817 F.3d at 1254 (second alteration in original) (quoting *Montgomery Ward & Co. v. Duncan,* 311 U.S. 243, 251 (1940)). "Thus, under Rule 59(a), a district court may, in its discretion, grant a new trial 'if in [the court's] opinion, the verdict is against the clear weight of the evidence . . . or will result in a miscarriage of justice, even though there may be substantial evidence which would prevent the direction of a verdict.'" *Id.* (alterations in original) (quoting *Hewitt v. B.F. Goodrich Co.,* 732 F.2d 1554, 1556 (11th Cir. 1984)).

Mentor argues that it is entitled to a new trial for three reasons. First, Mentor contends that Taylor repeatedly violated the Court's rulings on Mentor's motions in limine. Second, Mentor asserts that the Court erred in admitting certain evidence and excluding other evidence. Third, Mentor argues that the jury's verdict was against the clear weight of the evidence. The Court addresses each issue in turn.

A. Violations of the Court's in Limine Rulings

Prior to trial, the Court ruled that "[e]vidence or argument regarding Mentor's withdrawal of ObTape or Mentor's decision to stop selling ObTape . . . may not be used to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction." *Taylor v. Mentor Corp.*, No. 4:12-cv-176, 2015 WL 7863032, at *3 (M.D. Ga. Dec. 3, 2015). In making this ruling, the Court followed its previous rulings that Mentor's decision to stop selling ObTape was a subsequent remedial measure under Federal Rule of Civil Procedure 407. *Stafford v. Mentor Corp.*, No. 3:07-cv-00101, 2010 WL 2015146, at *1-*2 (M.D. Ga. May 20, 2010); *accord* Order, *Morey v. Mentor Corp.*, ECF No. 179 in 4:11-cv-5065 (M.D. Ga. June 12, 2013).

Mentor contends that Taylor's counsel deliberately violated this order three times. First, Taylor's counsel elicited testimony from Dr. Hyman that ObTape was withdrawn from the

market in France. Trial Tr. vol. II 81:2-10. Mentor moved for a mistrial. Taylor's counsel explained that he believed that the Court had only excluded evidence of withdrawal from the American market. *Id.* at 81:21-82:2. The Court noted Mentor's motion and advised Taylor's counsel to "move on." *Id.* at 82:3-5. The next morning, the Court told Taylor's counsel not to "get into" "the final withdrawal." Trial Tr. vol. III 7:17-24. The Court did note that it had previously concluded that evidence of the French regulatory action regarding ObTape—including the regulator's decision to issue a recall if Mentor did not voluntarily withdraw the product—was relevant on the failure to warn claim. *Id.* at 8:23-9:14. But the Court did instruct Taylor's counsel not to ask witnesses about Mentor's withdrawal of ObTape "even in France." *Id.* at 11:23-25.

Second, Taylor's counsel asked Dr. Siegel if he knew "one single doctor anywhere" who was still using ObTape, and Dr. Siegel said no. Trial Tr. vol. V 99:24-25. Third, Taylor's counsel asked Dr. Michel Cosson if ObTape was withdrawn from the French market based on a survey regarding ObTape's risks. Trial Tr. vol. VI 52:24-53:2. At that point, Mentor again moved for a mistrial. After reviewing its prior orders, the Court concluded that the applicable order "makes it clear that the withdrawal of ObTape from the market shall not be admitted unless it's admitted for some purpose other than showing culpable conduct

affecting the product, affecting the design, need for a warning, or negligence." *Id.* at 64:10-15; *accord id.* at 70:2-72:1 (explaining contours of its order on Mentor's motions in limine). After seeking input from the parties, the Court issued a curative instruction, telling the jury to disregard Dr. Cosson's testimony that Mentor stopped selling ObTape in France. *Id.* at 79:4-80:18. The Court is satisfied that the curative instruction was sufficient to render harmless any violations of the Court's in limine rulings, and a new trial is not warranted on this basis.

B. Alleged Evidentiary Errors

1. Admission of Evidence of Erosions and Infections

Mentor argues that the Court improperly permitted Taylor to introduce evidence of erosions and infections in other women. As the Court previously noted, "[e]vidence of similar occurrences may be offered to show a defendant's notice of a particular defect or danger, the magnitude of the defect or danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, the strength of a product, the standard of care, and causation." *Taylor v. Mentor Corp.*, No. 4:12-cv-176, 2016 WL 393958, at *1 (M.D. Ga. Feb. 1, 2016) (quoting *Hessen v. Jaguar Cars, Inc.*, 915 F.2d 641, 650 (11th Cir. 1990)). "Evidence of similar occurrences 'is only admissible if conditions substantially similar to the

occurrence' also caused the plaintiff's injury." *Id.* (quoting *Hessen*, 915 F.2d at 649).

Prior to trial, the Court concluded that "for evidence of an ObTape complication to meet the 'substantially similar' requirement" and be admitted, "the complication must be (1) experienced by a woman who was implanted with ObTape (2) by the transobturator approach (3) to treat stress urinary incontinence and (4) caused by the physical characteristics of ObTape that Plaintiffs' experts opine make ObTape lack biocompatibility." *Id.* at *2. And before trial, the Court reviewed Taylor's proffered other similar incident evidence, along with Mentor's objections, and overruled several of Mentor's objections because the Court concluded that the other incidents—generally erosions and infections of ObTape—were sufficiently similar to be admitted. *Id.* Mentor contends that this ruling was error because Taylor did not suffer an erosion of her ObTape. Again, as discussed above, there was sufficient evidence for the jury to conclude that Taylor did have an erosion—type movement of the ObTape through her bodily tissues—although the sling did not become completely exposed as it did in other patients. The Court did not err in admitting this evidence, and a new trial is not warranted on this basis.

2. Admission of Foreign Regulatory Action Evidence

Before trial, the Court ruled that evidence of foreign regulatory actions would be admitted if Taylor established a genuine fact dispute on her post-implant failure-to-warn claim. Mentor does not seem to dispute that the evidence is relevant on a post-implant failure-to-warn claim, but Mentor argues that Taylor did not have a good faith basis for pursuing such a claim. As discussed above, there was enough evidence for a jury to find in favor of Taylor on her post-implant failure-to-warn claim. Even if Taylor had not prevailed on this claim, she had a good faith basis to believe that she would present sufficient evidence on her post-implant failure-to-warn claim, and a new trial is not warranted on this basis.

3. Exclusion of 510(k) Evidence

In a written order issued before trial, the Court excluded evidence that ObTape was approved by the FDA via the 510(k) clearance process. *Taylor*, 2015 WL 7863032, at *5-*6. The Court explained that the 510(k) evidence is irrelevant on the issue of whether ObTape was safe "because in approving the product for sale under the 510(k) process the FDA does not evaluate the product's safety or effectiveness." *Id.* at *5. The Court further found that even if the evidence had some probative value, "the probative value of the evidence is substantially outweighed by" the danger of unfair prejudice and

the danger of confusion such that it should "be excluded under Federal Rule of Evidence Rule 403." *Id.* at *6. The Court did not err in excluding this evidence, and a new trial is not warranted on this basis.

C. The Weight of the Evidence

Mentor also contends that the jury's verdict was against the weight of the evidence. For the same reasons the Court found that the jury's verdict was supported by the evidence, the Court finds that the verdict was not against the clear weight of the evidence. Mentor's motion for a new trial is denied.

CONCLUSION

For the reasons explained in this order, Mentor's motion for judgment as a matter of law, for a new trial, and to alter the judgment (ECF No. 197 in 4:12-cv-176) is denied, except the judgment shall be reduced to $2,400,000. The Court will enter a separate order on Taylor's motion for litigation expenses, including attorney's fees. With that order, the Court will direct the Clerk to enter an amended judgment to reflect its ruling in today's order and its ruling on the motion for litigation expenses.

IT IS SO ORDERED, this 20th day of October, 2016.

S/Clay D. Land
CLAY D. LAND
CHIEF U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA