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. 4:16-cv-300 (G. KAMPE)

O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Plaintiff Gayle Kampe was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Kampe brought this product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Kampe also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Mentor contends that Kampe's claims are barred by the applicable statute of limitations. For the reasons set forth below, Mentor's Motion for Summary Judgment (ECF No. 5 in 4:16-cv-300) is granted as to Kampe's breach of warranty claims but denied as to her other claims.

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the

movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether a *genuine* dispute of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

FACTUAL BACKGROUND

Viewed in the light most favorable to Kampe, the record reveals the following. Kampe sought treatment for stress urinary incontinence from Dr. Francisco Garcini. Dr. Garcini recommended ObTape, and he implanted Kampe with ObTape on December 29, 2004. After the procedure, Kampe could not urinate but was released from the hospital with a self-catheter. On January 4, 2005, Kampe presented to Dr. Garcini complaining of pelvic pain and difficulty moving her legs. Dr. Garcini did not find the source of these problems. A few days later, Kampe went to the emergency room with similar symptoms. And on January 9, 2005—less than two weeks after the implant surgery—Dr. Garcini found a vulvar induration consistent with infection. He removed Kampe's ObTape and drained an abscess. Although Dr. Garcini testified that he

told Kampe her ObTape was removed due to an infection, Kampe does not remember Dr. Garnici telling her that the ObTape had been removed. All of Kampe's ObTape-related treatment occurred in Illinois, and Kampe was a citizen of Illinois when she filed this action.

Kampe filed her Complaint on August 30, 2016. *See generally* Compl., ECF No. 1 in 4:16-cv-300. Kampe asserts claims for personal injury under the following theories: negligence, strict liability design defect, strict liability manufacturing defect, strict liability failure to warn, breach of express and implied warranties, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation. Kampe withdrew her warranty claims in response to Mentor's summary judgment motion, so Mentor's summary judgment motion is granted on those claims.

DISCUSSION

Kampe filed her action in this Court under the Court's direct filing order. The parties agree that for direct-filed cases, the "Court will apply the choice of law rules of the state where the plaintiff resides at the time of the filing of the complaint." Order Regarding Direct Filing § II(E), ECF No. 446 in 4:08-md-2004. The Illinois choice-of-law rules thus apply, and the parties agree that Illinois law applies to Kampe's claims because Kampe is an Illinois resident whose ObTape-related treatment took place in Illinois.

Kampe's tort claims "are governed by the two-year statute of limitations applicable to personal injury claims." *Curtis v. Mentor Worldwide, LLC*, 543 F. App'x 901, 903 (11th Cir. 2013) (per curiam) (citing 735 Ill. Comp. Stat. 5/13-202). "The 'discovery rule' in Illinois delays the commencement of the applicable statute of limitations until the plaintiff knows or reasonably should know that he has been injured and that his injury was wrongfully caused." *Id.* (citing *Hermitage Corp. v. Contractors Adjustment Co.*, 651 N.E.2d 1132, 1137 (Ill. 1995)). "The phrase 'wrongfully caused' does not mean knowledge of a specific defendant's negligent conduct or knowledge of the existence of a cause of action." *Id.* (quoting *Castello v. Kalis*, 816 N.E.2d 782, 789 (Ill. App. Ct. 2004)). Rather, the phrase means that the injured party "becomes possessed of sufficient information concerning his injury and its cause to put a reasonable person on inquiry to determine whether actionable conduct is involved." *Id.* (quoting *Castello*, 816 N.E.2d at 789).

Here, Mentor contends that Kampe knew her injury may have been wrongfully caused less than two weeks after her implant surgery because her doctor had to remove the ObTape due to an infection. But there is no evidence in the present record that the removal surgery was necessitated by an erosion or infection of the ObTape as opposed to some other surgical complication that caused Kampe to be unable to urinate after the implant surgery

and ultimately caused an abscess near the incision site. A genuine factual dispute exists as to whether ObTape was the mechanism that contributed to the complications Kampe suffered almost immediately after the implant surgery.

The Court's decision in *Curtis v. Mentor Worldwide, LLC*, which was affirmed by the Eleventh Circuit, is distinguishable. In that case, the plaintiff suffered a vaginal erosion several months after her implant surgery, and she underwent a partial excision of her sling. *Curtis*, 543 F. App'x at 902. Months later, the plaintiff developed a deep infection in her leg and had to have her entire ObTape removed. She knew at the time that "her infection and related problems had something to do with the ObTape sling, and she had the sling removed." *Id.* at 903-04. At that time, the plaintiff "was obligated to begin her inquiry as to who manufactured her sling and whether her complications were due to a problem with the surgery or a defective sling." *Id.*

Here, unlike in *Curtis*, there is a fact question as to whether Kampe's infection had something to do with her ObTape. If a reasonable jury could *only* conclude from the present record that the infection near the incision site shortly after Kampe's surgery was connected to ObTape, then the Court would likely find as a matter of law that Kampe's claim accrued on the date of the excision surgery. But that is not what the present record establishes. A reasonable jury could conclude that ObTape caused

the infection near the surgical site. But Mentor did not point to sufficient evidence for the Court to exclude the reasonable possibility that the infection was unrelated to the ObTape, or that the surgical procedure itself contributed to the problems Kampe suffered. For these reasons, a genuine factual dispute exists as to when Kampe suffered an ObTape-related physical injury that would commence the running of the statute of limitations under Illinois law. Thus, the Court cannot find as a matter of law that Kampe's claim accrued when Kampe had the excision surgery in 2005.[1] Mentor is therefore not entitled to summary judgment on statute of limitations grounds.

CONCLUSION

For the reasons set forth above, Mentor's Motion for Summary Judgment (ECF No. 5 in 4:16-cv-300) is granted as to Kampe's breach of warranty claims but denied as to her other claims.

TRANSFER OF ACTION

Kampe filed this action pursuant to the Court's Direct Filing Order in MDL No. 2004. *See* Order Regarding Direct Filing § II(A), ECF No. 446 in 4:08-md-2004 (permitting plaintiffs from outside the Middle District of Georgia whose cases "would be subject to transfer to MDL No. 2004" to file their cases "directly in the MDL proceedings in the Middle District of

[1] This ruling does not mean that Mentor may not eventually prevail on its statute of limitations defense, but it is not entitled to prevail *as a matter of law* based on the present record.

Georgia"). The action was "filed in MDL No. 2004 for pretrial proceedings only, consistent with the Judicial Panel on Multidistrict Litigation's December 3, 2008, Transfer Order." *Id.* § II(B). All discovery has been completed, and this case is ready for trial.

Given that Mentor has not elected to waive venue under *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998) since early 2016, the Court finds it appropriate to transfer this action to the court where venue is proper, the U.S. District Court for the Northern District of Illinois. *See* Compl. ¶ 1, ECF No. 1 ("Plaintiff is now and was at all times herein mentioned a citizen and resident of the State of Illinois, residing in Plainfield, Illinois."). For the convenience of that court, the appendix to this Order contains a brief chronicle of the coordinated proceedings, as well as a list of significant filings and orders in MDL No. 2004.

The Clerk of Court is directed to provide a copy of this Order to the Clerk of the Judicial Panel on Multidistrict Litigation.

IT IS SO ORDERED, this 20th day of October, 2017.

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

APPENDIX

I. Brief Background of the Mentor ObTape MDL

Mentor Worldwide LLC manufactured and sold a polypropylene mesh suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. The United States Food and Drug Administration cleared ObTape for sale in 2003 via its 510(k) regulatory process, and ObTape remained on the market in the United States until March 2006.

About ten years ago, women who had been surgically implanted with ObTape began filing lawsuits against Mentor, alleging that they had been injured by ObTape—primarily that they suffered infections caused by ObTape and that they were injured when ObTape eroded through their bodily tissues. In December 2008, the Judicial Panel on Multidistrict Litigation created MDL No. 2004 and transferred seventeen actions involving alleged injuries resulting from ObTape to this Court for consolidated and coordinated pretrial proceedings. *See In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 588 F. Supp. 2d 1374 (J.P.M.L. 2008). After pretrial proceedings and a bellwether trial that settled mid-trial, the original cases and approximately forty additional tag-along cases transferred to this Court were resolved through settlement. Since then, MDL No. 2004 has grown to include more than 800 additional tag-along cases, although only a few remain open. The litigation was

divided into phases, and cases from phase IV-10 are still pending. In 2013, the Court tried a Phase III bellwether case to verdict. In 2016, the Court tried a Phase IV-1 bellwether case to verdict.

II. Significant Filings in MDL No. 2004

These filings are, for the most part, evidentiary rulings that were made in the context of the bellwether cases that were tried in this Court; these issues may arise again.

1. Order Denying Motion to Disqualify Expert Witness Dr. Catherine Ortuno, Apr. 1, 2010. ECF No. 231 in 4:08-md-2004; 2010 WL 1416548.
   Summary: Mentor sought to exclude the testimony of Dr. Catherine Ortuno, who was an employee of a French Mentor subsidiary called Porges. While she was employed by Porges, Dr. Ortuno and a colleague developed concerns about the safety of ObTape and ultimately recommended that sales of ObTape be stopped. The Court concluded that Dr. Ortuno would be permitted to serve as an expert witness for Plaintiffs but that she would not be permitted to offer any testimony that would divulge privileged, attorney-client communications.

2. Order on Phase I Summary Judgment Motions and Admissibility of Plaintiffs' Experts, Apr. 22, 2010. ECF No. 241 in 4:08-md-2004; 711 F. Supp. 2d 1348.
   Summary: Mentor sought to exclude Plaintiffs' experts under Federal Rule of Evidence 702.
   Dr. Catherine Ortuno – motion denied; the Court found that Dr. Ortuno's methodology was sufficiently reliable.
   General Causation Witnesses (Dr. Linda Brubaker, Dr. Suzanne Bush, Dr. Michel Cosson, Dr. John Davis, Dr. James Hiller, Dr. Mickey Karram, Dr. Kenneth Mitchell, Dr. Donald Ostergard, Dr. William Porter, and Dr. Andrew Siegel) – motion denied; the Court found that these experts' methodology was sufficiently reliable.
   Specific Causation Witnesses (Dr. Linda Brubaker, Dr. Suzanne Bush, Dr. John Davis, Dr. James Hiller, Dr. Mickey Karram, Dr. Kenneth Mitchell, and Dr. Mark

Slack) – motion denied; the Court found that these experts' methodology was sufficiently reliable.
Dr. George Samaras – motion granted in part and denied in part; based on then-existing Rule 26 Report, the Court concluded that Dr. Samaras would be permitted to testify on general causation but not specific causation.
Dr. Ahmed El-Ghannam – motion denied; the Court found that Dr. El-Ghannam's opinions were sufficiently reliable.
Dr. Paul Ducheyne – motion granted in part and denied in part; based on then-existing Rule 26 Report, the Court concluded that Dr. Ducheyne could not testify regarding what caused degradation in ObTape but could testify that Mentor should have done more testing based on Mentor's awareness that ObTape could degrade.
Dr. Arnold Lentnek – motion deferred pending *Daubert* hearing. On May 12, 2010, the Court decided to permit Dr. Lentnek's testimony (ECF No. 301 in 4:08-md-2004).

3. Order re Evidence Related to FDA Regulatory Process, Apr. 23, 2010. ECF No. 242 in 4:08-md-2004; 2010 WL 1734638.
Summary: Plaintiffs sought to exclude evidence related to the FDA regulatory process. Discussed basic rules regarding evidence of FDA regulatory process. Deferred ruling until pretrial conference. At the pretrial conference on May 3, 2010, the Court granted the motion in limine but stated that if Plaintiffs opened the door to the FDA evidence, it could come in. (ECF No. 299 – Transcript 174:9-175:16).

Note: the Court admitted 510(k) evidence during the 2013 trial of *Morey v. Mentor*, 4:11-cv-5065 but gave a limiting instruction on this issue. *Morey*, Jury Instructions Charge No. 11, ECF No. 183 in 4:11-cv-5065. But the Court reconsidered its ruling on the admissibility of FDA 510(k) evidence in its order on Phase IV-1 motions in limine dated December 3, 2015.

4. Order re Phase I Plaintiffs' Experts, Apr. 27, 2010. ECF No. 246 in 4:08-md-2004; 2010 WL 1727828.
Summary: Mentor sought to exclude the testimony of Plaintiffs' experts under Federal Rule of Evidence 702 and based on relevance. The motion was granted in part and denied in part.
Dr. Ann Buchholtz – testimony not permitted.

Rabbit Study – testimony explaining rabbit study permitted, but not testimony that rabbit study establishes that ObTape is capable of causing similar conditions in humans.
Mentor's Warnings to Physicians and the FDA – testimony may be relevant to failure to warn claim, but Plaintiff must establish relevance before eliciting this testimony.

5. Order re Phase I Experts, Apr. 29, 2010. ECF No. 282 in 4:08-md-2004; 2010 WL 1782272.
Summary: The parties sought to exclude expert testimony of each other's experts under Federal Rule of Evidence 702. The motions were denied.
Dr. Michael Chernick (Plaintiffs' statistician) – testimony permitted.
Mentor's Specific Causation Rebuttal Witnesses (Dr. Marta Villarraga, Dr. Charles L. Secrest, Dr. A.W. Karchmer, Dr. James M. Anderson) – testimony permitted.
Dr. Marta Villarraga (Mentor's expert re Mentor's conduct in bringing ObTape to Market) – testimony permitted.
Mentor's Experts regarding Pore Distribution **(**Drs. Villarraga and Clevenger) – testimony permitted.

6. Phase I Bellwether Pretrial Conference Transcript (Day 1), May 3, 2010. ECF No. 299 in 4:08-md-2004. Ruled from the bench on several motions in limine.
Significant Issues:
- Cross Motions to Exclude Evidence re FDA Regulatory Process (ECF Nos. 249 & 259) – Granted. Hr'g Tr. 164:11-175:16. Written opinion on this issue December 3, 2015. *See infra* § III.18.i.
- Plaintiffs' Motion to Exclude "Complication Rates" (ECF Nos. 250 & 251) – Denied. Hr'g Tr. 175:20-178:19.

7. Phase I Bellwether Pretrial Conference Transcript (Day 2), May 4, 2010. ECF No. 300 in 4:08-md-2004. Ruled from the bench on several motions in limine.
Significant Issue:
Mentor's Motion to Exclude Evidence Adverse Event Reports (ECF No. 273) – Denied, but reports must be redacted. Hr'g Tr. 42:7-47:8.

8. Order re Dr. Arnold Lentnek, May 12, 2010. ECF No. 301 in 4:08-md-2004.

Summary: Denied Mentor's motion to exclude Dr. Lentnek, concluding that Dr. Lentnek's methodology was sufficiently reliable.

9. Order to "Tie Up Some Loose Ends" after Pretrial Conference, May 18, 2010. ECF No. 335 in 4:08-md-2004, 2010 WL 1998166.
Summary: addressed several issues. Significantly, the Court stated that it would permit recording of the testimony of European witnesses so the recordings could be used in later trials of MDL No. 2004 cases. Also addressed the trial structure and concluded that trial should be bifurcated (Phase 1: compensatory damages/punitive damages entitlement; Phase 2: punitive damages amount).

Note: part of this Order was later vacated (*see* ECF 350 re continuing duty to warn under Georgia law).

10. Order re Subsequent Remedial Measure, May 20, 2010. ECF No. 341 in 4:08-md-2004, 2010 WL 2015146.
Summary: Concluded that Mentor's decision to stop selling ObTape is a subsequent remedial measure under Federal Rule of Evidence 407, so evidence of this decision is not admissible "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" but may be admitted for another purpose. Also concluded that Mentor's introduction of a new sling product, Aris, was *not* a subsequent remedial measure under Federal Rule of Evidence 407.

11. Order re Similar Complications, May 28, 2010. ECF No. 351 in 4:08-md-2004, 2010 WL 2196632.
Summary: Explained rationale for concluding that other incidents of ObTape complications proffered by Plaintiffs were substantially similar to Plaintiffs' injuries.

12. Order Appointing Plaintiffs' Liaison Counsel and Co-Lead Counsel, Sept. 21, 2011. ECF No. 422 in 4:08-md-2004.

13. Order Establishing Plaintiffs' Litigation Expense Fund and Common Benefit, Aug. 9, 2012. ECF No. 493 in 4:08-md-2004. This agreement is between Plaintiffs' counsel and addresses the sharing among Plaintiffs of the cost

of special services performed and expenses performed for the common benefit of the Plaintiffs of MDL No. 2004.

14. Text Order re Dr. Ahmed El-Ghannam, June 4, 2013 in *Morey v. Mentor*, 4:11-cv-5065. Explained that general causation witness's must be tied to the Plaintiff: "To introduce [Dr. El-Ghannam'] testimony regarding ObTape degradation and/or the release of toxins, the witness must establish a causal connection between that degradation and/or release of toxins and Plaintiff's infection and extrusion/erosion."

15. Order re Post-Injury Evidence/Punitive Damages (in *Morey v. Mentor*), June 12, 2013. ECF No. 671 in 4:08-md-2004.
Summary: Concluded that, under Minnesota law, certain post-injury evidence is admissible on the issue of punitive damages.

16. Order re Withdrawal of ObTape from the Market (in *Morey v. Mentor*), June 12, 2013. ECF No. 673 in 4:08-md-2004.
Summary: Reiterated that the withdrawal of ObTape from the market was a subsequent remedial measure under Federal Rule of Evidence 407.

17. Jury Instructions and verdict form in *Morey v. Mentor*, June 13, 2013. ECF No. 183 in 4:11-cv-5065. **Notes:** Morey asserted a negligence claim under Minnesota law. The Court reconsidered its ruling on the admissibility of FDA 510(k) evidence in its order on Phase IV-1 motions in limine dated December 3, 2015.

18. Order on Motions in Limine, Dec. 3, 2015 (in *Taylor*, 4:12-cv-176; *Sanborn,* 4:13-cv-42; and *Mack*, 4:14-cv-117), ECF No. 92 in 4:12-cv-176, 2015 WL 7863032.

Significant issues:

i. **FDA 510(k) Evidence.** Ruled that evidence of 510(k) preclearance process would not be admitted because even if it is relevant, the probative value is substantially outweighed by the risk of unfair prejudice and potential to confuse and mislead the jury.

ii. **Dr. Lentnek.** Ruled that Plaintiffs would have to establish "fit" prior to admission of Dr. Lentnek's testimony.

iii. **Dr. El-Ghannam.** Ruled that Plaintiffs would have to make proffer of specific causation before Dr. El-Ghannam could testify on certain issues.

iv. **Post-Implant Evidence.** Ruled that evidence of Mentor's conduct and awareness after Plaintiffs' implant date is admissible.

19. Order re Similar Complications (in *Taylor*, 4:12-cv-176; *Sanborn*, 4:13-cv-42; and *Mack*, 4:14-cv-117), Feb. 1, 2016. ECF No. 115 in 4:12-cv-176, 2016 WL 393958.
Summary: Explained rationale for concluding that other incidents of ObTape complications proffered by Plaintiffs were substantially similar to Plaintiffs' injuries.

20. Jury Instructions and verdict form in *Taylor v. Mentor*, Feb. 18, 2016. ECF Nos. 172, 174 in 4:12-cv-176.
Note: Taylor's claims were under Florida law.