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 Nos. 3:07-cv-00088 (Parker *et al.*) 3:07-cv-00101 (Stafford *et al.*) 3:07-cv-00102 (Booth *et al.*) 3:07-cv-00130 (Dover *et al.*) 4:08-cv-05000 (Crews *et al.*) 4:08-cv-05003 (Cree *et al.*) 4:08-cv-05010 (Doria *et al.*)

O R D E R

Presently pending before the Court are three remaining motions to exclude expert testimony. For the reasons set forth below, the Court denies Mentor Worldwide LLC's ("Mentor") motion to exclude the expert testimony of Plaintiffs' statistician, Michael Chernick, Ph.D. (Doc. 164). The Court denies Plaintiffs' motion to exclude the testimony of Mentor's specific causation witnesses and denies Plaintiffs' motion to exclude certain testimony from Marta Villarraga, Ph.D. (Doc. 163). The Court also denies Plaintiffs' motion to exclude certain testimony regarding pore size distribution of the product at issue in this litigation (Doc. 165).

EXPERT WITNESS STANDARDS

Under Federal Rule of Evidence 702, "a witness qualified as an expert by knowledge, skill, experience, training, or education" may testify in the form of an opinion "if (1) the testimony is based upon

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sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." The trial court must act as a gatekeeper to ensure the reliability and relevancy of expert testimony; for an expert's testimony to be admitted, the proffered expert must be qualified to render a reliable opinion based on sufficient facts or data and the application of accepted methodologies. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-93 (1993). The purpose of this gatekeeping function is "to ensure that speculative, unreliable expert testimony does not reach the jury under the mantle of reliability that accompanies the appellation 'expert testimony.'" *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005) (internal quotation marks omitted).

> Scientific expert testimony is admissible when
>
> (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusion is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

Allison v. McGhan Med. Corp., 184 F.3d 1300, 1309 (11th Cir. 1999) (internal quotation marks omitted). "The party offering the expert has the burden of satisfying each of these three requirements by a

preponderance of the evidence." *Rink*, 400 F.3d at 1292. A district court "may not exclude an expert because it believes one expert is more persuasive than another expert." *Id.* at 1293 n.7.

Rule 702 further provides that a witness "may be qualified as an expert by virtue of his or her 'knowledge, skill, experience, training, or education.'" *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1342 (11th Cir. 2003) (quoting Fed. R. Evid. 702). Accordingly, in determining whether a proffered expert is "qualified" to offer an opinion, courts generally look to evidence of the witness's education and experience and ask whether the subject matter of the witness's proposed testimony is sufficiently within the expert's expertise. *E.g., Maiz v. Virani*, 253 F.3d 641, 665 (11th Cir. 2001). It is beyond dispute that experience in a field may provide a sufficient foundation for expert testimony. *United States v. Frazier*, 387 F.3d 1244, 1260-61 (11th Cir. 2004) (en banc).

To ascertain whether proposed expert testimony is "reliable," the courts consider several factors: "(1) whether the expert's methodology can be tested; (2) whether the expert's scientific technique has been subjected to peer review and publication; (3) whether the method has a known rate of error; (4) whether the technique is generally accepted by the scientific community." *Rink*, 400 F.3d at 1292 (citing *Quiet Tech.*, 326 F.3d at 1341). These four factors are not exhaustive, and the district court's primary focus

should be "'solely on principles and methodology, not on the conclusions that they generate.'" *Allison*, 184 F.3d at 1312 (quoting *Daubert*, 509 U.S. at 595).

For an expert's testimony to "assist" the trier of fact, "the evidence must have a valid scientific connection to the disputed facts in the case." *Id.* A court "may exclude expert testimony that is imprecise and unspecific, or whose factual basis is not adequately explained." *Cook ex rel. Tessier v. Sheriff of Monroe County, Fla.*, 402 F.3d 1092, 1111 (11th Cir. 2005) (internal quotation marks omitted). Also, expert testimony is generally only admissible "if it concerns matters that are beyond the understanding of the average lay person." *Id.* (internal quotation marks omitted). "Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments." *Id.* (internal quotation marks omitted).

RELEVANT BACKGROUND

Mentor developed a suburethral sling called ObTape Transobturator Tape ("ObTape"), which was used to treat women with stress urinary incontinence. ObTape was cleared for sale by the U.S. Food and Drug Administration ("FDA") via the FDA's 510(k) regulatory process. ObTape was a Class II medical device, available only through a prescription from a physician. It was sold to hospitals and physicians, not directly to patients. Every ObTape package

included an FDA-approved Product Insert Data Sheet ("PIDS") which listed vaginal erosion, urethral erosion, and infection as possible complications associated with ObTape. Plaintiffs were implanted with ObTape to treat stress urinary incontinence. Plaintiffs contend that the defective design and/or manufacture of ObTape caused complications that resulted in significant injuries, including serious infections and erosion of the tape through their bodily tissues. Plaintiffs also claim that Mentor did not provide adequate warnings to Plaintiffs' physicians regarding the risks of ObTape.

DISCUSSION

I. Mentor's Motion to Exclude Michael Chernick, Ph.D.

Plaintiffs intend to offer the testimony of statistician Michael Chernick, Ph.D. Though Dr. Chernick did not do a statistical analysis of ObTape complication rates, he did review Mentor's internal documents and the deposition testimony of various Mentor witnesses. Based on his review and his knowledge, training, skill and experience as a statistician who provides biostatistical consultation to medical device companies, Dr. Chernick opines, among other things, that Mentor's claimed complication rates for ObTape were statistically invalid for a variety of reasons. (Ex. 1 to Mentor's Mot. to Exclude Certain Test. from Dr. Chernick, Chernick Rule 26 Report 3-4.) Dr. Chernick also offers an opinion regarding what Mentor should have done if Mentor had grounds to be concerned

about ObTape's complication rate. (*Id.*; *see also* Chernick Dep. 112:11-113:12, Jan. 16, 2010 (explaining opinion and noting that Mentor employees "in a position to be concerned wrote that they were concerned").)

Mentor does not challenge the qualifications of Dr. Chernick, a Stanford-educated statistician who presently serves as Manager of Biostatistical Services at the Lankenau Institute for Medical Research. (Chernick Rule 26 Report 1.) Mentor also does not challenge the reliability of Dr. Chernick's opinions. Mentor does, however, contend that Dr. Chernick's opinion regarding the validity of Mentor's claimed complication rates for ObTape would be unhelpful to a jury because his testimony is nothing more than "common sense propositions that jurors either already know or will easily figure out for themselves." (Mentor's Mot. to Exclude Certain Test. from Dr. Chernick 6.) The Court disagrees and concludes that Dr. Chernick's testimony regarding statistical principles is not within the understanding and experience of the average juror. Accordingly, he shall be permitted to testify regarding the validity of Mentor's claimed complication rates for ObTape.

Mentor also contends that Dr. Chernick's opinion regarding what Mentor should have done if Mentor had grounds to be concerned about ObTape's complication rate should be excluded as unhelpful because it lacks a proper "fit" to the facts. (Mentor's Mot. to Exclude Certain

Test. from Dr. Chernick 7.) Specifically, Mentor contends that Dr. Chernick has no foundation for forming this opinion because he did not know whether Mentor had grounds for concern about ObTape. However, as the Court previously noted in its Order on Mentor's motions for summary judgment—and as Dr. Chernick noted in his deposition—at least one Mentor employee did raise concerns regarding ObTape's complication rate. *In re Mentor Corp. ObTape Transobturator Sling Products Liab. Litig.*, No. 4:08-MD-2004 (CDL), 2010 WL 1664965, at *2 (Apr. 22, 2010). Accordingly, the Court declines to exclude Dr. Chernick's testimony as lacking proper "fit." Mentor may certainly explore on cross-examination its argument that insufficient statistical evidence existed to give rise to a legitimate concern regarding ObTape's complication rate. For these reasons, Mentor's motion to exclude Dr. Chernick's testimony is denied.

II. Plaintiffs' Motion to Exclude Mentor's Certain Rebuttal Witnesses on Specific Causation

Mentor intends to offer the testimony of the following experts to rebut Plaintiffs' experts' opinions regarding specific causation: Marta Villarraga, Ph.D.; Charles L. Secrest, M.D.; A.W. Karchmer, M.D.; and James M. Anderson, Ph.D., M.D. These four experts criticize Plaintiffs' experts for failing to consider certain factors, including surgical technique, in reaching their conclusions that ObTape was the cause of Plaintiffs' injuries. It appears that

the role of these witnesses is to identify possible alternative causes of Plaintiffs' injuries, not to provide an affirmative specific causation opinion. Plaintiffs contend that the opinions of these four witnesses should be excluded as unreliable.

As discussed in more detail in the Court's Order on Mentor's motions for summary judgment, Plaintiffs' specific causation experts base their opinion that ObTape caused Plaintiffs' injuries on a differential diagnosis or differential etiology approach. *In re Mentor*, 2010 WL 1664965, at *20-*21. "Differential diagnosis involves the determination of which one of two or more diseases or conditions a patient is suffering from, by systemically comparing and contrasting their clinical findings." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1252 (11th Cir. 2005) (internal quotation marks omitted). A differential diagnosis leads to a "diagnosis of the patient's condition." *Id.* Differential etiology describes "the investigation and reasoning that leads to the determination of external causation, sometimes more specifically described by the witness or court as a process of identifying external causes by a process of elimination." *Id.* (internal quotation marks omitted).

A key component of a differential diagnosis or differential etiology analysis is "ruling out" alternative causes of the patient's condition. *Id.* Mentor's four rebuttal experts that are contested here opine that a competent differential etiology must identify and

properly account for alternative causes of Plaintiffs' injuries, such as surgical technique and physician error. The rebuttal experts further opine that Plaintiffs' experts did not adequately identify and rule out alternative causes for Plaintiffs' injuries, such as surgical technique. In reaching their conclusions, the four rebuttal experts did not consider the medical records of Plaintiffs themselves or the depositions of Plaintiffs and their physicians, and they did not conduct independent differential etiology analyses. Rather, they considered the reports of Mentor's experts and identified flaws in those reports. Accordingly, their testimony simply offers potential alternative causes and does not purport to offer an affirmative specific causation opinion.

Plaintiffs do not contend that Drs. Villarraga, Secrest, Karchmer, and Anderson are unqualified to offer an opinion regarding the components of a competent differential etiology analysis. They do argue that the four experts have not reviewed enough patient-specific information to reach an opinion on whether Plaintiffs' experts adequately considered alternative causes for Plaintiffs' injuries. Plaintiffs do not seriously dispute that the four experts, one biomedical engineer and three medical doctors, are familiar with the factors that are capable of causing the injuries Plaintiffs suffered. Therefore, the Court concludes that the four experts should be permitted to identify possible alternative causes of

Plaintiffs' injuries, and Plaintiffs' motion to exclude such testimony is denied. However, because the scope of their rebuttal appears to be limited to identifying possible alternative causes of Plaintiffs' injuries and not performing an independent differential etiology, these four witnesses shall not be permitted to testify that alternative causes, such as surgical technique or doctor error, actually caused Plaintiffs' injuries.

III. Plaintiffs' Motion to Exclude Certain Testimony from Marta Villarraga, Ph.D.

Mentor intends to offer the testimony of Dr. Villarraga to rebut Plaintiffs' experts' opinions that ObTape was defectively designed or manufactured, that Mentor did not act reasonably in bringing ObTape to market, that the ObTape warnings were inadequate, and that Mentor acted unreasonably in its post-market conduct. Dr. Villarraga has a B.S., M.S. and Ph.D. in Biomedical Engineering, and she has experience in the "design, research, development, and validation of new technologies and designs for various medical device companies." (Ex. 1 to Pls.' Mot. to Exclude Certain Testimony from Mentor's Proposed Experts (Doc. 163), Villarraga Rule 26 Report 2.) To reach her opinions, Dr. Villarraga reviewed thousands of pages of documents, most of them Mentor's corporate documents, and she intends to explain the basis for her opinions by referencing the documents and studies she reviewed.

According to Plaintiffs, however, Dr. Villarraga is being offered as a conduit for Mentor's fact evidence and to bolster the opinions of Mentor's experts by parroting their testimony. Plaintiffs also contend that Dr. Villarraga is only qualified as a biomedical engineering expert and that she is not qualified to opine regarding the reasonableness of Mentor's conduct. Though she is not a statistician or a medical ethicist, Dr. Villarraga has experience designing, researching, developing, and validating new medical device designs. Such experience provides a sufficient foundation for her to offer opinions regarding the Mentor's conduct in bringing ObTape to market and responding to complications. *See Frazier*, 387 F.3d at 1260-61 (noting that experience in a field may provide a sufficient foundation for expert testimony). In offering her opinions, Dr. Villarraga shall be permitted to explain the factual basis for those opinions, and Plaintiffs may challenge those opinions on cross-examination. Although the present record does not justify excluding Dr. Villarraga's testimony at this time, the Court may reconsider this ruling at trial, upon Plaintiffs' renewal of their objections, based upon the nature of her actual trial testimony.

IV. Plaintiffs' Motion to Exclude Certain Testimony Regarding Pore Size Distribution of ObTape

As discussed in more detail in the Court's Order on Mentor's motions for summary judgment, Plaintiffs' experts criticize the pore

size and pore structure of ObTape. *In re Mentor*, 2010 WL 1664965, at *3-*4. To rebut those criticisms, Mentor seeks to introduce the testimony of Drs. Villarraga and Clevenger, who offer certain opinions regarding the pore size distribution of ObTape. Plaintiffs contend that Drs. Villarraga and Clevenger made incorrect conclusions based on certain testing, mercury porosimetry, that was done on ObTape. In other words, though Plaintiffs agree that mercury porosimetry itself is a reliable and accepted scientific technique "used to characterize the porosity and pore structure of certain materials," Plaintiffs argue that Drs. Villarraga and Clevenger improperly extrapolated mercury porosimetry data to reach their conclusions regarding the pore size distribution of ObTape. (Pls.' Mot. to Exclude Certain Test. from Villarraga and Clevenger 3, 7.) However, based on the record before the Court, it does not appear that the disagreement between the experts regarding the limitations of mercury porosimetry and the conclusions that may be drawn from mercury porosimetry data renders either side's opinions unreliable such that they must be excluded; rather, these conflicts can best be explored through cross-examination, and the resolution of them is best left to the jury. Accordingly, the Court denies Plaintiffs' motion to exclude the testimony of Drs. Villarraga and Clevenger regarding pore size distribution of ObTape.

CONCLUSION

As discussed above, the Court denies Mentor's motion to exclude the expert testimony Dr. Chernick (Doc. 164). The Court denies Plaintiffs' motion to exclude the testimony of Mentor's specific causation witnesses and denies Plaintiffs' motion to exclude certain testimony from Dr. Villarraga (Doc. 163). The Court also denies Plaintiffs' motion to exclude certain testimony regarding pore size distribution of the product at issue in this litigation (Doc. 165).

IT IS SO ORDERED, this 29th day of April, 2010.

S/Clay D. Land
CLAY D. LAND
UNITED STATES DISTRICT JUDGE