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

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| IN RE MENTOR CORP. OBTAPE | * | MDL Docket No. 2004<br>4:08-MD-2004 (CDL) |
| TRANSOBTURATOR SLING PRODUCTS | * | |
| | | Case Nos. |
| LIABILITY LITIGATION | * | 3:07-cv-00088 (Parker *et al.*)<br>3:07-cv-00101 (Stafford *et al.*) |
| | * | 3:07-cv-00102 (Booth *et al.*)<br>3:07-cv-00130 (Dover *et al.*) |
| | * | 4:08-cv-05000 (Crews *et al.*)<br>4:08-cv-05003 (Cree *et al.*) |
| | * | 4:08-cv-05010 (Doria *et al.*) |

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O R D E R

The Court previously denied Defendant Mentor Worldwide LLC's ("Mentor") motions for summary judgment as to the Phase I Georgia Plaintiffs in this Multi-District Litigation ("MDL") proceeding. (Order, April 22, 2010.) In ruling on that motion, the Court also addressed Mentor's pending Motion to Exclude Certain Testimony from Plaintiffs' Proposed Experts (Doc. 156) ("*Daubert* motions"). Although the Court ruled on many of the *Daubert* motions in its ruling on Mentor's summary judgment motions, the Court did not rule on three categories of expert testimony. Those categories include testimony from Professor Ann Buchholtz in the area of business ethics; the testimony of various medical experts regarding a rabbit study done on ObTape, Mentor's product that is at issue in this litigation; and testimony from various experts that Mentor had a legal duty to make certain disclosures regarding ObTape.

For the reasons set forth below, Mentor's motion to exclude is granted in part and denied in part. First, Professor Buchholtz shall not be permitted to testify. Second, expert testimony shall be permitted explaining the results of the rabbit study, but no witnesses shall be allowed to testify that the study establishes that ObTape is capable of causing similar conditions in humans. Finally, the Court finds at this time that the proffered expert testimony as to what Mentor should have disclosed to the FDA and to physicians is not relevant to Plaintiffs' design defect claim; however, should that testimony be relevant to Plaintiffs' failure to warn claim, this expert testimony may be admitted. Plaintiffs shall notify the Court as to their intention to introduce such evidence, along with a persuasive explanation as to its relevance, prior to tendering or mentioning any such evidence before the jury.

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 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
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> > (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).

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. Professor Ann Buchholtz, Ph.D.**

Plaintiffs intend to offer Professor Ann Buchholtz, Ph.D., as an ethics expert. Prof. Buchholtz teaches in the management department of the University of Georgia's business school. She opines that Mentor "failed in its ethical duty to protect the safety of patients, as well as its ethical duty to provide the information to which physicians and patients are entitled." (Ex. 5 to Mentor's Mot. to Exclude Certain Testimony from Plaintiffs' Proposed Expert Witnesses [hereinafter Mentor's Mot. to Exclude], Rule 26 Expert Report of Ann K. Buchholtz 7.) Specifically, she asserts, based on a review of internal Mentor documents, that certain information about ObTape should have been reported to the FDA and to physicians and patients. (*Id.* at 3-7.) In reaching her conclusions, Prof. Buchholtz relied in part on a "Consumer Bill of Rights"[1] and the "Code of Ethics" of AdvaMed,[2] which is a trade association of medical device

[1]The Consumer Bill of Rights comes from a presentation by President John F. Kennedy regarding "the way that businesses should conduct themselves," and Prof. Buchholtz describes it as "just a moral minimum that these are rights to which consumers should be guaranteed." (Buchholtz Dep. 128:11-21, Dec. 11, 2009.)

[2]Dr. Buchholtz describes the AdvaMed Code of Ethics as "industry-agreed-upon norms that provide some indication of what is generally expected." (Buchholtz Dep. 151:13-14.)

manufacturers. (*Id.* at 13.) Mentor contends that Prof. Buchholtz's ethics opinions should not be permitted because (1) the opinions would not assist the jury, (2) the opinions are unreliable, and (3) Prof. Buchholtz is not qualified to render the opinions.

The key issues in the actions comprising this MDL are the obligations of a medical device manufacturer in testing, surveying, and developing warnings for its medical devices. Medical device manufacturers are subject to extensive governmental regulations regarding, among other things, testing of products and the drafting of warnings. Mentor contends that Prof. Buchholtz is not qualified to opine that Mentor should have reported certain information about ObTape to the FDA and physicians. Mentor points out that, among other things, Prof. Buchholtz has never authored a scholarly publication regarding a product manufacturer's duty to disclose information, and she has no expertise in FDA regulations or product design and labeling requirements. Plaintiffs counter that Prof. Buchholtz has taught management and business ethics courses at the University of Georgia for more than ten years; she provides ethics training and programs to executive groups; she was on the team that drafted the code of ethics for her professional association; and she authors a business ethics textbook.

The Court concludes that while Prof. Buchholtz is likely qualified to offer opinions in her field of "ethics . . . with an

emphasis on corporate governance and strategic leadership" (Ex. 2 to Mentor's Reply in Supp. of Mot. to Exclude, Buchholtz C.V. 1), she is not qualified to render an opinion regarding what information Mentor should have disclosed to the FDA or to physicians and patients. Prof. Buchholtz is not a physician, a medical researcher, or a medical ethicist. She has no expertise in the fields that would qualify a witness to testify about what scientific information should be reported to the FDA or to testify about medical device industry standards for warning physicians and patients about potential adverse effects of a medical device.[3] Therefore, she is not qualified to offer an opinion about the appropriateness of Mentor's conduct regarding its alleged failure to warn the FDA, physicians, and patients about certain risks associated with ObTape.[4] Consequently,

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[3]Even if the "Code of Ethics" that Prof. Buchholtz references is relevant to a medical device company's standard of care in the context of product development and marketing, it appears to the Court that anyone who reads and understands the English language can interpret and apply the principles underlying that "Code of Ethics," so Prof. Buchholtz's testimony on the subject is unnecessary. *Cook*, 402 F.3d at 1111 (noting that expert testimony is generally only admissible "if it concerns matters that are beyond the understanding of the average lay person" (internal quotation marks omitted)).

[4]Plaintiffs point the Court to *Wetherill v. University of Chicago*, a pre-*Daubert* case in which the court permitted a medical ethicist to offer an opinion as to whether medical ethical standards required disclosure of certain risks associated with an experimental drug. 565 F. Supp. 1553, 1564 (N.D. Ill. 1983). The expert was an ethics professor at a medical school, he was a member of an oversight body that regulated ethical aspects of medical experiments involving human participants, and he had written extensively in the field of medical ethics and experimentation. *Id.* The court concluded that, given this background, the expert was qualified to testify regarding the prevalent disclosure policies of hospitals that

Prof. Buchholtz shall not be permitted to testify as an expert in the actions comprising this MDL.

**II. 2003 Rabbit Study Witnesses**

Mentor seeks to preclude the following witnesses from testifying about the results of a 2003 rabbit implantation histopathology study: Dr. Linda Brubaker; Dr. Suzanne Bush; Dr. Michael Cosson; Dr. John Davis; Dr. Paul Ducheyne; Dr. James Hiller; Dr. Mickey Karram; Dr. Kenneth Mitchell; Dr. Anne Meddahi-Pelle; Dr. George Samaras; and Dr. Mark Slack.

In 2003, segments of the material of ObTape were implanted onto the back of a rabbit, and segments of the material of Gynecare TVT ("TVT"), another suburethral sling, were implanted onto the back of another rabbit.[5] (Mentor's Mot. to Exclude 36.) The rabbits were examined 10 days after implantation, 30 days after implantation, and 90 days after implantation. (Ex. 64 to Mentor's Mot. to Exclude.) Plaintiffs' experts offer several opinions regarding the rabbit

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conducted medical studies like the one at issue in the case. *Id.* In that case, it was the ethicist's extensive experience with medical ethics in the context of experimentation that qualified him to render an opinion on whether the patients were properly informed of the risks of an experimental drug. Here, Prof. Buchholtz has no comparable experience regarding a medical device manufacturer's legal duty to disclose information to the FDA or to physicians and patients.

[5]Based on the present record, it is not entirely clear to the Court how many rabbits were used in the study. According to Mentor, there were six—three implanted with ObTape and three with TVT. (Mentor's Mot. to Exclude 36.)

study. First, Dr. Anne Meddahi-Pelle opines that the rabbit study results show that ObTape did not exhibit the appropriate wound healing tissue response. Second, Dr. Meddahi-Pelle and others, including Drs. Brubaker, Bush, Davis, Hiller, Karram, Mitchell, Samaras, and Slack, assert that Mentor should have disclosed the rabbit study results to the FDA and/or to physicians. Third, Dr. Meddahi-Pelle and others, including Drs. Brubaker, Cosson, Ducheyne, and Slack, contend that the rabbit study results required additional inquiry by Mentor. Mentor contends that Plaintiffs' witnesses draw inappropriate comparisons between the rabbit study results and human ObTape patients.

"Extrapolations from animal studies to human beings generally are not considered reliable in the absence of a credible scientific explanation of why such extrapolation is warranted." *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1366 (N.D. Ga. 2001), *aff'd sub nom. Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002); *see also, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994) ("[A]nimal studies may be methodologically acceptable to show that chemical X increases the risk of cancer in animals, but they may not be methodologically acceptable to show that chemical X increases the risk of cancer in humans.") Plaintiffs appear to acknowledge that they may not draw comparisons between the rabbit study results and the human ObTape

patients. They contend that the experts are not "attempt[ing] to create a causal link between the rabbit study and Plaintiffs' injuries." (Pls.' Resp. to Mentor's Mot. to Exclude 48.) The Court finds that insufficient evidence has been presented to support any conclusion that the rabbit study establishes that ObTape caused problems in humans similar to those allegedly caused in the rabbits. Therefore, no testimony shall be permitted comparing the rabbit study results with complications in human ObTape patients. This does not, however, mean that other opinion testimony regarding the rabbit study is inadmissible.

Plaintiffs maintain that any reasonable, non-defective design for a medical device must take into account adverse events that occur in animal studies. While animal studies are not dispositive and a product can be non-defective even with the existence of adverse animal studies, Plaintiffs maintain that the issue of whether Mentor gave these studies any consideration is relevant to Mentor's reasonableness in going forward with the design in question. It appears indisputable that before medicines and implantable medical devices are tested on human patients, animal studies are often conducted to assess potential health risks in humans. *E.g., Villari v. Terminix Int'l, Inc.*, 692 F. Supp. 568, 571 (E.D. Pa. 1988). (*See also, e.g.,* Ex. 73 to Pls.' Resp. to Mentor's Mot. to Exclude, ObTape Master Verification and Validation Report, Aug. 13, 2003, at

MENTOR/OBTAPE CONFIDENTIAL_001203 (explaining biocompatibility testing for ObTape, which included animal testing under standards promulgated by International Organization for Standardization); Ex. 72 to Pls.' Resp. to Mentor's Mot. to Exclude, Mentor Brochure for Aris polypropylene support tape, Aug. 2004, at MENTOR/OBTAPE CONFIDENTIAL_063731 (summarizing rabbit study for Mentor product Aris conducted by Biomatech and stating, "Rabbits are considered to be an implantation model suitable for various international scientific publications for evaluating local tolerance to materials following intramuscular implantation.").) While animal studies may not necessarily be used to establish causation in human patients, that does not mean that all evidence of animal studies is inadmissible as unreliable. Although some of Plaintiffs' experts criticize the 2003 rabbit study for having too small a sample size and too short a study period, they nonetheless opine that the results, which they consider "preliminary," should have caused Mentor to investigate further. Mentor criticizes this opinion as unreliable, repeating its argument that "expert opinions based on animal studies [are] unreliable absent a good explanation for jumping from animals to humans." (Mentor's Mot. to Exclude 38.)

Expressing the opinion that a preliminary animal study warrants further investigation is different from opining that the animal study demonstrates that ObTape caused the same problems in Plaintiffs that

it caused in the animal study. The Court finds that Plaintiffs' experts may give a reliable opinion that the study warranted further investigation. They have adequately explained the basis for that opinion and are qualified to make it. In fact, Mentor points to no evidence that the proffered experts are not qualified to render such an opinion. Dr. Brubaker is a board-certified obstetrician and gynecologist ("OB/GYN"), specializing in urogynecologic surgery, who is also a medical researcher and teacher. (Ex. 1 to Mentor's Mot. to Exclude, Brubaker Rule 26 Report 1, 4.) Dr. Cosson is a professor of gynecology and obstetrics at the Medical University Lille. (Ex. 7 to Mentor's Mot. to Exclude, Cosson Rule 26 Report 1.) Dr. Ducheyne is a bioengineering professor at the University of Pennsylvania, where he has taught a course on medical device design, among other things. (Ex. 11 to Mentor's Mot. to Exclude, Ducheyne Rule 26 Report 15-16.) Dr. Meddahi-Pelle is a professor of medicine at Universite de Versailles Saint Quentin en Yvelines who is certified in animal experimentation and who conducts materials biocompatibility studies. (Ex. 69 to Pls.' Resp. to Mentor's Mot. to Exclude, Meddahi-Pelle C.V.) Dr. Slack is a professor of medicine at Cambridge University and a practicing urogynecologist who also conducts scientific research regarding "development of an animal model to compare a variety of synthetic and biological alloplastic materials," and he has conducted animal studies on ObTape. (Ex. 42 to Mentor's Mot. to

Exclude, Slack Rule 26 Report 1-2.) Based on the present record, including the evidence that animal studies of implantable medical devices are done as a precursor to human studies and the qualifications of Drs. Brubaker, Cosson, Ducheyne, Meddahi-Pelle and Slack, the Court concludes that these witnesses may offer opinions regarding whether the 2003 rabbit study warranted further investigation by Mentor during the design process. The Court will provide a limiting instruction to the jury that such evidence shall not be considered by them on the issue of whether the design caused the complications complained of by the Plaintiffs. They shall only consider it in determining whether the design of ObTape was defective.

Mentor also seeks to exclude any testimony that Mentor should have disclosed the rabbit study to regulatory authorities, such as the FDA, or to physicians. Mentor points to evidence that Dr. Meddahi-Pelle admitted that she is not qualified to provide such an opinion. (Meddahi-Pelle Dep. 65:3-23, 125:10-25, Oct. 20, 2009.) Therefore, Dr. Meddahi-Pelle shall not be permitted to provide opinion testimony on this point. Mentor apparently acknowledges that the failure to disclose the information to the FDA may be relevant to Plaintiffs' failure to warn claim because it does not challenge the testimony on this basis. Instead, Mentor challenges the remaining proposed experts because they did not conduct an independent review

of the specimens. Such a review, however, should not be necessary to offer an opinion regarding the significance of the rabbit study. Mentor offers no alternative reason why Plaintiffs' proposed experts are unqualified to testify on this issue. Mentor does point out that several of Plaintiffs' experts were critical of the rabbit study, especially its sample size. Mentor will certainly be allowed to put up evidence that the animal studies were too insignificant to warrant disclosure to the FDA or physicians. Such evidence, along with cross-examination of Plaintiffs' experts, will allow the jury to determine what weight to give the evidence, which under these circumstances is the appropriate way to handle this issue, rather than exclusion by the Court. The Court does find, however, that the question whether the rabbit study should have been disclosed to the FDA and/or physicians is only relevant to Plaintiffs' failure to warn claim and not Plaintiffs' design defect claim. Although the Court understands how the failure to consider the rabbit study during the design process may be relevant to whether the design was defective, the Court cannot see how the failure to disclose it to the FDA and/or physicians is likewise relevant on the design defect claim.

Mentor also argues that Plaintiffs' experts should not be permitted to offer any opinion about what the rabbit study shows because such an opinion would merely parrot the study results. While expert testimony regarding a scientific study might not be necessary

if a layperson would readily understand the meaning of the study and its results, where, as here, the meaning of the study is disputed, an expert "interpreter" may be needed to translate the study for the average juror. *E.g., Tishcon Corp. v. Soundview Commc'ns, Inc.*, Civil Action No. 1:04-CV-524-JEC, 2005 WL 6038743, at *11 (N.D. Ga. Feb. 15, 2005).[6] The Court has reviewed the English translations of the 2003 rabbit study results, and the Court concludes that interpretation of the specialized, scientific language in these reports is necessary. Therefore, Plaintiffs' experts shall not be precluded from explaining the rabbit study results and offering an opinion about what the results show.[7]

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[6]In support of its argument on this point, Mentor points out that expert testimony is not needed when the facts and issues are "well within common knowledge that would be obvious to the average juror." *McDowell v. Brown*, 392 F.3d 1283, 1299 (11th Cir. 2004). In *McDowell*, the court concluded that a doctor's opinion that earlier treatment of spinal epidural abscess is better than later treatment was "too vague" to assist the trier of fact since "the notion of early treatment is well within common knowledge that would be obvious to the average juror." *Id. See also Hibiscus Assocs. Ltd. v. Bd. of Trustees of Policemen & Firemen Retirement Sys. of Detroit*, 50 F.3d 908, 917 (11th Cir. 1995) ("Expert testimony is properly excluded when it is not needed to clarify facts and issues of common understanding which jurors are able to comprehend for themselves.").

[7]Plaintiffs appear to assert that Dr. Ducheyne, Dr. Meddahi-Pelle, and/or Dr. Samaras should be permitted to offer an explanation of the rabbit study. (Pls.' Resp. to Mentor's Mot. to Exclude 45-46, 47 n.39.) Based on the qualifications of Dr. Ducheyne and Dr. Meddahi-Pelle, discussed above, the Court concludes that these two witnesses are qualified to offer an expert interpretation of the rabbit study. The Court also finds that Dr. Samaras is qualified; he is a professional engineer who has a bachelor's degree in electrical engineering with biomedical emphasis, a master's degree in general physiology, a doctorate in physiology, pharmacology and biopsychology, and a doctorate in engineering management and industrial and organizational psychology. He who was also formerly

**III. "Legal Duty" Opinion Testimony**

Several of Plaintiffs' proposed experts opine that Mentor should have disclosed certain information to physicians, regulatory officials, or both. As discussed in more detail in a separate Order, evidence regarding Mentor's interactions with the FDA may or may not be relevant to Plaintiffs' claims, and the Court will decide that issue after hearing from the parties at the pretrial conference. (Order, Apr. 23, 2010.) The remaining issue is the scope of permissible testimony regarding what information Mentor should have disclosed to physicians. Plaintiffs rely upon this testimony in support of their failure to warn claims. Mentor contends that such testimony is impermissible and seeks to exclude testimony on this subject from: Dr. Linda Brubaker; Dr. Suzanne Bush; Dr. Michel Cosson; Dr. Francois Haab; Dr. James Hiller; Dr. Mickey Karram; Dr. Kenneth Mitchell; Dr. Anne-Meddahi-Pelle; Dr. George Samaras; and Dr. Andrew Siegel. Mentor contends that this type of testimony is a legal conclusion that usurps the Court's role to instruct the jurors on the law. Mentor's key argument is that this testimony would not be helpful to a jury; Mentor does not appear to argue that it is unreliable or that the experts are not qualified to testify on this issue.

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employed as associate director of the FDA in the Center for Devices and Radiologic Health.

In support of its argument, Mentor relies upon *Cook*, 402 F.3d at 1111-12. There, an inmate committed suicide while incarcerated. To establish a claim against the sheriff, the plaintiff sought to introduce expert testimony that the inmate should have been placed under close observation and that the deputy sheriff should have read the inmate's request for psychiatric help and sought help. *Id.* The Eleventh Circuit concluded that the district court was correct to exclude an expert's testimony that the inmate should have been placed under close observation because the testimony was "without a sufficient factual or medical foundation." *Id.* at 1112. The court also affirmed exclusion of the expert's testimony that the deputy should have read the inmate's request for psychiatric treatment and sought help because "[t]he notion that a correctional officer should read and respond to an inmate's medical request seems . . . to be well within the understanding of the average layperson." *Id.* In contrast, the issue here—whether Mentor's warnings regarding the risks of ObTape were adequate—is not well within the understanding of the average layperson. Again, Mentor does not appear to argue that the testimony of Plaitniffs' experts on this point is unreliable or that the experts are not qualified to testify on this issue. Under these circumstances, the Court declines to exclude testimony from Plaintiffs' experts regarding the adequacy of Mentor's warnings and instructions for ObTape. They shall not, of course, be permitted to

make legal conclusions that merely tell the jury what result to reach.[8]

CONCLUSION

As discussed above, Mentor's motion to exclude certain testimony of Plaintiffs' experts (Doc. 156) is granted in part and denied in part.

IT IS SO ORDERED, this 27th day of April, 2010.

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

[8]Under Federal Rule of Evidence 704(a), "testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact."