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	*	
		Case Nos.
LIABILITY LITIGATION	*	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.*)
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O R D E R

The Court previously denied Mentor Worldwide LLC's ("Mentor") motions for summary judgment, finding that genuine issues of material fact exist as to the design defect, manufacturing defect, and failure to warn claims asserted by all Phase I Georgia Plaintiffs in this Multi-District Litigation proceeding. (Order, April 22, 2010 (Doc. 223).) Mentor also moved for summary judgment as to any claims asserted by Plaintiffs based upon a fraud-on-the-U.S. Food and Drug Administration ("FDA") theory. Plaintiffs responded that they were not asserting any "fraud-on-the-FDA" claims, and the Court previously ruled that any such claims had been abandoned.

Nevertheless, it is apparent that the issue of whether evidence related to the FDA regulatory process shall be admissible in this action will recur. Therefore, the Court finds it appropriate to address in limine the admissibility of such evidence. Specifically, the issue remains as to whether the following evidence is admissible: (1) evidence that ObTape, the product at issue here, was

"adulterated" and "misbranded" in violation of the Federal Food and Drug Cosmetic Act ("FDCA") and FDA regulations; (2) evidence that Mentor engaged in a pattern of misrepresentation to the FDA before and after launching ObTape; and (3) evidence that Mentor falsely represented to the FDA that ObTape was substantially equivalent to another suburethral sling, Gynecare TVT.

DISCUSSION

I. Exclusion of FDA Evidence

Plaintiffs acknowledge that claims based solely on a company's alleged fraudulent representations to the FDA are preempted by federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). Therefore, evidence supporting any such claim would not be admissible unless it is relevant to Plaintiffs' remaining products liability claims. In some circumstances, courts have found regulatory compliance evidence probative of state law product liability claims. *See, e.g., In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 900 (D. Minn. 2006) (concluding that "plaintiffs may use evidence-if they are able to produce it-of [manufacturer's] efforts to manipulate the regulatory process in order to prove their negligence and strict liability claims, but they may not bring an independent claim for relief based on fraud-on-the-FDA"); *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396 JRTFLN, 2004 WL 45503, at *13

(D. Minn. Jan. 5, 2004) (finding that plaintiffs' claims were not fraud-on-the-FDA claims in disguise but were valid claims related to medical device manufacturer's inadequate warnings and labeling and concluding that genuine issues of material fact existed in part because of evidence that FDA was not aware of device's risks).[1] The Court must therefore determine whether such evidence is probative of Plaintiffs' state law claims.

Plaintiffs seek to introduce the following evidence in support of their state law claims: (1) ObTape was "adulterated" and "misbranded" in violation of the FDCA and FDA regulations; (2) Mentor engaged in a pattern of misrepresentation to the FDA before and after launching ObTape; and (3) Mentor falsely represented to the FDA that ObTape was substantially equivalent to another suburethral sling,

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[1] *See, e.g., In re Fossamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191 n.16 (S.D.N.Y. 2009) ("The cases in this MDL are not governed by federal regulations but by state law theories of negligence and strict liability. Expert testimony on regulatory compliance will assist the jury in determining whether Merck acted as a reasonably prudent pharmaceutical manufacturer. The Court will instruct the jury that it must take the law from the Court and not from any witness."); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, MDL No. 05-1708 (DWF/AJB), Civil No. 06-25 (DWF/AJB), 2007 WL 1725289, at *6-*9 (D. Minn. June 12, 2007) (concluding that plaintiff's negligence and fraud claims were not merely fraud-on-the-FDA claims in disguise because they were based not on any duty to the FDA but on duties to plaintiff); *Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA*, 145 F. Supp. 2d 565, 573 (D.N.J. 2001) (concluding that plaintiffs' claims were that manufacturer deceived the public, including the plaintiffs; unlike the claims in *Buckman*, a finding of a violation of FDA rules and regulations was not a necessary element of the plaintiffs' claims). *But see Swank v. Zimmer, Inc.*, No. 03-CV-60-B, 2004 WL 5254312, at *2 (D. Wyo. Apr. 20, 2004) ("[E]vidence of communications with the FDA, used to show that Defendants made misrepresentations, must be excluded.").

Gynecare TVT. Mentor contends that this evidence is not relevant to any of Plaintiffs' state law claims for design defect, manufacturing defect, or failure to warn. Accordingly, Mentor seeks to exclude the evidence.

The Court is skeptical as to the relevance of this evidence to Plaintiffs' claims. However, it will defer a final ruling on the admissibility of such evidence until it hears further from counsel at the pretrial hearing. The Court cannot presently conceive of how this evidence would be relevant to Plaintiffs' design and manufacturing defect claims. It is conceivable that Plaintiffs may be able to tie some of this evidence to their failure to warn claims, depending upon the nature of Mentor's defenses to those claims. At this time, the Court does not have sufficient information to rule in limine on this evidence and requires the parties to be prepared to address this issue at the pretrial hearing.

II. Mentor's Motion to Exclude Certain Witnesses

In a related *Daubert* motion, Mentor seeks to exclude testimony from proposed experts Dr. Linda Brubaker, Dr. Francois Haab, Dr. Anne Meddahi-Pelle, and Dr. Donald Ostergard because they are not qualified to express an expert opinion on FDA regulations and procedures. (Mentor's Mot. to Exclude Certain Testimony from Pls.' Proposed Expert Witnesses 44.) In their response, Plaintiffs represented that they would not tender Dr. Brubaker, Dr. Haab, Dr.

Meddahi-Pelle, or Dr. Ostergard regarding FDA regulatory matters. (Pls.' Resp. to Mentor's Mot. to Exclude 49 n.41.) Therefore, Mentor's *Daubert* motion is granted as to these four witnesses.

Mentor did not argue in either its opening *Daubert* brief or its reply *Daubert* brief that the remaining proposed experts—Dr. John Davis; Dr. Paul Ducheyne; Dr. Arnold Lentnek; Dr. Kenneth Mitchell; Dr. George Samaras; Dr. Andrew Siegel; and Dr. Mark Slack—are unqualified to render an opinion on the FDA's regulatory process or Mentor's compliance with that process. Rather, Mentor argues that such testimony by them should be excluded because it is not relevant to Plaintiffs' claims. As previously explained, the Court will make its relevancy determination after hearing from counsel at the pretrial hearing. The Court does find these experts qualified to provide testimony in the area of FDA regulatory compliance, and they will be permitted to do so if the Court rules that such testimony is otherwise relevant.

CONCLUSION

As explained, Plaintiffs are not asserting a "fraud-on-the-FDA" claim in this action. The Court defers ruling on whether evidence related to the FDA regulatory process is relevant to Plaintiffs' claims for design defect, manufacturing defect, and failure to warn. The parties shall be prepared to address the relevance issue at the pretrial hearing.

IT IS SO ORDERED, this 23rd day of April, 2010.

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