

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 No.
LIABILITY LITIGATION	*	4:11-cv-5065 (I. Morey)

O R D E R

At a final pretrial conference on May 31, 2013, the Court expressly found that Plaintiff could assert a continuing duty to warn claim under Minnesota law. Defendant has now filed a motion for reconsideration, or in the alternative, motion for summary judgment as to that claim (ECF No. 165 in 4:11-cv-5065). For the following reasons, that motion is denied. Plaintiff's continuing duty to warn claim is actionable under Minnesota law, and therefore, evidence of substantially similar complaints made to Mentor after Plaintiff was implanted with ObTape is admissible in support of such a claim to show that Mentor had notice of the alleged risk of harm associated with ObTape.

Defendant argues that Plaintiff has never asserted a continuing duty to warn claim in this case, and to allow her to do so now is inconsistent with the Federal Rules of Civil Procedure pleading requirements and just plain unfair. In the alternative, Defendant insists that a continuing duty to warn claim is not recognized in Minnesota under the circumstances

presented in this case. Notwithstanding Defendant's bold proclamation of reversible error, the Court finds that Defendant is simply wrong on both counts.

First, Defendant's attempt to manufacture an enumeration of error by feigning last minute surprise ignores the allegations in Plaintiff's Complaint which clearly put Defendant on notice of a continuing duty to warn claim. Those allegations include the following: "Defendant negligently failed to provide such warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Mentor ObTape vaginal sling, or those women who had been implanted with Mentor ObTape vaginal sling. . . ." Compl. ¶ 14, ECF No. 1 in 4:11-cv-5065. "Before Plaintiff suffered the injuries complained of herein, Defendant was on notice of numerous bodily injuries caused by ObTape, and based thereon, Defendant knew or should have known that ObTape caused an unreasonably high rate of vaginal erosion, [etc.], in women implanted with said device, but unreasonably failed to take action with respect to said adverse consequences." *Id.* ¶ 15. ". . . Defendant unreasonably failed to stop marketing the ObTape in the United States until in or around March of 2006." *Id.* ¶ 16. ". . . Defendant unreasonably failed to provide adequate warnings or information to physicians who implanted the device, or to women who were implanted with the device, informing them that ObTape caused an

unreasonably high rate of vaginal erosion, infection, extrusion, perforation and/or abscess." *Id.* ¶ 17. And perhaps the "clincher," "Defendant breached their duty of reasonable care to Plaintiff by failing to promptly and adequately notify Plaintiff, Plaintiff's doctors, the medical community, and the public at the earliest possible date of known defects in the Mentor ObTape vaginal sling." *Id.* ¶ 24. It is clear that Plaintiff's Complaint contained sufficient allegations to put Defendant on notice of Plaintiff's continuing duty to warn claim. The next question is whether such a duty exists under Minnesota law.

It is undisputed that a "continuing duty to warn claim" is recognized under Minnesota law, but it is not unlimited. The Minnesota Supreme Court has held that the "continuing duty to warn arises only in special cases." *Hodder v. Goodyear Tire & Rubber Co.*, 426 N.W.2d 826, 833 (Minn. 1988). The issue presented here is whether Plaintiff's case is a "special case." The Minnesota Supreme Court found the following factors relevant in determining whether a particular case is a "special case" such that a continuing duty to warn cause of action may be maintained: (1) whether the seller either knows or reasonably should know that the product poses a substantial risk of harm; (2) whether the product creates a serious risk of injury or death; (3) whether the seller remains in business, even if it no

longer sells the specific product in question; and (4) whether the seller undertook a duty to warn of the dangers presented by the product. *Id.* at 833. Defendant argues that the fourth factor not only weighs against a continuing duty to warn claim in this action, but that consideration of this factor alone mandates a finding that no such claim exists in this action as a matter of Minnesota law. The Court finds that this one factor is not, standing alone, dispositive of whether a continuing duty to warn claim may be asserted under Minnesota law.

Defendant reads *Hodder* to hold that a continuing duty to warn claim can only be asserted under Minnesota law if the seller affirmatively undertook a duty to warn of the dangers presented by the product after the product was sold. Under this interpretation, only the conscientious seller, who voluntarily undertook a duty to warn of product dangers after sale, would expose itself to liability for failing to provide an adequate post-sale warning. To escape any liability on a continuing duty to warn claim, the seller merely has to avoid even attempting to warn of a product's dangers after the sale. According to Defendant's argument, the manufacturer who reasonably appreciates a clear danger, attempts to warn about it, but does so negligently would be subjected to potential liability; but a manufacturer faced with the same evidence of product dangers and who likewise appreciates a serious danger that should be warned

about, but chooses to do nothing would be exposed to no liability. The Court finds nothing in *Hodder* that would sanction such an absurd result. *Hodder* does not emphasize this fourth factor, nor does it even suggest that it should be given a predominant place among the other factors. It certainly does not suggest that it is an essential element of a continuing duty to warn claim. The Court understands that it may be an essential element of a tort claim that is based on the general concept in tort law that while a person may have no legal duty to perform a particular act, when they do undertake to act, they must do so non-negligently. But that is not a cause of action for continuing duty to warn. The Court simply cannot find any indication that the Minnesota Supreme Court in *Hodder* intended to limit the continuing duty to warn to the narrow duty of providing a warning non-negligently once you have undertaken to warn. Although that may be an appropriate factor to consider, it is not dispositive.

At least one United States District Court judge sitting in Minnesota has rejected Defendant's interpretation of *Hodder* in a case remarkably similar to the present case. In *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517 (D. Minn. 1989), the district judge concluded that the manufacturer of an intrauterine device could have a continuing duty to warn of known dangers associated with the product even if the

manufacturer had not undertaken a duty to warn after the sale of the device. That court inferred that the Minnesota Supreme Court's reference to the manufacturer having undertaken a duty to warn referred to warnings that pre-dated the sale. *Id.* at 1528-29. While there was evidence in *Hodder* that the manufacturer had attempted to warn both pre-sale and post-sale, there is nothing in the holding to suggest that undertaking to warn post-sale had any more legal significance than attempting to warn pre-sale. The significance would appear to be that the manufacturer was arguably aware of dangers that should have been warned about before the sale of the product and the manufacturer continued to accumulate information, putting it on notice that it should issue warnings post-sale. If the manufacturer acted negligently in failing to warn, then it could be found liable. Although it is certainly not binding precedent, the Court observes that the Minnesota District Judges Association Committee on Civil Jury Instructions Guides apparently thought the approach taken in the *Restatement (Third) of Torts* should be considered when evaluating a continuing duty to warn claim. The elements for such a claim are quoted in the "Authorities" section of the pattern jury instructions, suggesting that this committee of Minnesota judges considered the *Restatement* to be consistent with the law of Minnesota. 4A *Minnesota Practice, Jury Instruction Guides - Civil* § 75.40.

The *Restatement* provides:

- (a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons . . . caused by the seller's failure to provide a warning after the time of sale or distribution of a product when a reasonable person in the seller's position would provide such a warning.
- (b) A reasonable person in the seller's position would provide a warning after the time of sale if:
 - (1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
 - (2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and
 - (3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
 - (4) the risk of harm is sufficiently great to justify the burden of providing a warning.

Restatement (Third) of Torts: Products Liability § 10 (1997).

In this case, Plaintiff contends that Mentor either knew or reasonably should have known that ObTape poses a substantial risk of harm to women who were implanted with it; that it creates a serious risk of injury; that Mentor is still in business; that Mentor undertook to warn women through their physicians prior to implantation of ObTape; that Plaintiff reasonably could have been identified as a woman who had been implanted with ObTape; that Plaintiff's physician who implanted

Plaintiff's ObTape reasonably could have been identified and located; that Plaintiff was otherwise unaware of the risk of harm associated with ObTape; that an effective warning reasonably could have been provided to Plaintiff's implanting physician and acted upon resulting in avoidance of the harm; and that the risk of harm is sufficiently great to justify the burden of providing the warning. The Court finds that the current record is adequate to support a finding that this is a "special case" under Minnesota law for the assertion of a continuing duty to warn claim.¹

¹ The Court finds that the cases cited by Defendant at the hearing either support the finding of the existence of a continuing duty to warn claim under the circumstances presented here, are distinguishable or are unpersuasive. See, e.g., *McDaniel v. Bieffe USA, Inc.*, 35 F. Supp. 2d 735, 742 (D. Minn. 1999) (holding continuing duty to warn of dangers associated with bicycle helmets existed even in the absence of manufacturer's attempt to warn post-sale and explaining that no one *Hodder* factor is determinative); see also *Sanny v. Trek Bicycle Corp.*, Civil No. 11-2936 ADM/SER, 2013 WL 1912467, at *11 (D. Minn. 2013) (holding that the plaintiff failed to plead sufficient facts to state a claim for continuing duty to warn and explaining that insufficient evidence existed regarding several of the *Hodder* factors); *Quist v. Sunbeam Products, Inc.*, Civil No. 08-5261 (DWF/AJB), 2010 WL 1665254, at *4-*5 (D. Minn. Apr. 22, 2010) (finding evidence insufficient to establish continuing duty to warn claim where, under the facts in the case, it would be unreasonable to expect manufacturer to trace every product that it sold and where there was no evidence that post-sale warnings would have prevented plaintiff's injuries); *Keller v. CNH America, LLC*, Civil No. 07-1648 ADM/AJB, 2009 WL 1766695, at *7 (D. Minn. June 22, 2009) (finding no continuing duty to warn where manufacturer had not undertaken such duty and the plaintiff presented evidence of only two previous substantially similar incidents); *Hammes v. Yamaha Motor Corp.*, Civil File No. 03-6456 (MJD/JSM), 2006 WL 1195907, at *13 (D. Minn. May 4, 2006) (dismissing post-sale duty to warn claim by noting that manufacturer never undertook a duty to warn of the risk in question but emphasizing that "[the] *Hodder* factors all turn on direct indifference to a known problem and to serious bodily injury," which the Court did not find in *Hammes*) (emphasis added); *Ramstad v. Lear Siegler Diversified Holdings Corp.*, 836 F. Supp. 1511,

The Court observes that Plaintiff must still present evidence at trial to support not only the basis for her continuing duty to warn claim but also the breach of that duty. If an adequate basis for the claim is shown, the Court will decide that a duty to warn exists and will submit the issue of whether it has been breached to the jury. To recover on the claim, Plaintiff must also prove that the breach caused her injuries. As to whether Defendant is entitled to judgment as a matter of law on Plaintiff's continuing duty to warn claim because of lack of evidence, Defendant will have an opportunity to raise that issue in a motion for judgment as a matter of law at the close of Plaintiff's case. The Court finds Defendant's request for summary judgment untimely.

Based on the Court's ruling regarding Plaintiff's continuing duty to warn claim, the Court finds that post-implant evidence of safety concerns associated with ObTape are admissible to show notice of the harm and need for additional post implant warnings. The Court also finds, however, that only evidence covering the period prior to the partial removal of Plaintiff's ObTape on June 29, 2005 would be admissible. As of the date her physician surgically removed part of her ObTape due to her complications allegedly caused by the ObTape, Plaintiff

1517 (D. Minn. 1993) (holding that no continuing duty to warn claim existed when *only* factor favoring imposition of such duty was the gravity of the resulting harm.).

was aware of risk of harm associated with ObTape, and thus, Mentor's duty to continue to warn would cease as of that date. Consequently, subsequent evidence of notice would be irrelevant.²

In conclusion, Defendant Mentor Worldwide LLC's Motion for Reconsideration Or, In the Alternative, Motion for Summary Judgment (ECF No. 165) is denied.

IT IS SO ORDERED, this 3rd day of June, 2013.

S/Clay D. Land

CLAY D. LAND
UNITED STATES DISTRICT JUDGE

² This does not mean that evidence subsequent to June 29, 2005 may not be admissible for some other purpose. For example, subsequent substantially similar incidents may be admissible to show causation, or subsequent evidence that ties directly to the period preceding June 29, 2005 may be admissible if the appropriate foundation is established.