IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION
LEAD CASE NO. 5:15CV57-RLV; 3:15CV211-RLV

MARTHA CARLSON,	)	
Plaintiff,	)	
	)	
v.	)	**O R D E R**
	)	
	)	
BOSTON SCIENTIFIC	)	
CORPORATION,	)	
Defendant.	)	

THIS MATTER is before the Court on Plaintiff Martha Carlson's Motion to Reconsider Summary Judgment in favor of Boston Scientific Corporation on her Failure to Warn Claim, N.C. Gen. Stat. §§ 99B-5, filed August 25, 2015. (Doc. 180). Defendant Boston Scientific Corporation opposes Plaintiff's motion. (Doc. 191). Plaintiff filed a Reply on September 21, 2015. (Doc. 207). Trial is scheduled for October 5, 2015.

I. Standard

Plaintiff brings her Motion to Reconsider pursuant to Rule 54 of the Federal Rules of Civil Procedure. Rule 54(b) of the Federal Rules of Civil Procedure provides that, in the absence of an express order directing final judgment as to certain claims or parties:

> [A]ny order or other decision, however designated, that adjudicates fewer than all of the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities.

Fed. R. Civ. P. 54(b). Pursuant to this rule, the Court "retains the power to reconsider and modify its interlocutory judgments, including partial summary judgments, at any time prior to final

judgment when such is warranted." *Am. Canoe Ass'n v. Murphy Farms, Inc*., 326 F.3d 505, 514–15 (4th Cir. 2003). The decision to grant or deny a Rule 54(b) motion is "committed to the discretion of the district court." *Id*. at 515. A prior dispositive order should be followed unless "(1) a subsequent trial produces substantially different evidence, (2) controlling authority has since made a contrary decision of law applicable to the issue, or (3) the prior decision was clearly erroneous and would work manifest injustice." *Id*. (internal quotations omitted).

In an attempt to further clarify when the rare motion for reconsideration might be warranted, this district court previously explained that this avenue of relief is well taken when "the Court has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension . . . ." *N. Carolina ex rel. Cooper v. Tennessee Valley Auth.*, No. 1:06CV20, 2008 WL 2115159, * 2 (W.D.N.C. May 16, 2008) (quoting *Wiseman v. First Citizens Bank & Trust Co.*, 215 F.R.D. 507, 509 (W.D.N.C. May 27, 2003) (motions for reconsideration only "allowed in certain, limited circumstances").

II. Inadequate Warning, N.C. Gen. Stat. § 99B-5

According to Plaintiff Carlson, the MDL Judge's analysis of her inadequate warning claim was skewed by a patent misunderstanding of the underlying facts surrounding Dr. Kennelly's awareness and purported lack of reliance on the Uphold DFU. Under North Carolina law:

> (a) No manufacturer or seller of a product shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant proves that the manufacturer or seller acted unreasonably in failing to provide such warning or instruction, that the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought, and also proves one of the following:

> (1) At the time the product left the control of the manufacturer or seller, the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.
>
> (2) After the product left the control of the manufacturer or seller, the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.
>
> (c) Notwithstanding subsection (a) of this section, no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product.

N. C. Gen. Stat. §§ 99B-5(a) and (c) (2015).[1] Most relevant here is that Plaintiff establish "the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought." § 99B-5(a).

Although the North Carolina Supreme Court has never expressly ruled on this issue, courts have presumed that the North Carolina Supreme Court would apply the learned intermediary doctrine in a case involving a medical device such as this. *See e.g., Baraukas v. Danek Medical, Inc*., 2000 WL 223508, at * 4 (M.D.N.C. January 13, 2000) (learned intermediary doctrine applied in context of action challenging surgical bone screw and observing, "There are indications that North Carolina courts would adhere to the learned intermediary doctrine.") (citing *Foyle By and Through McMillian v. Lederle Laboratories*, 674

[1] Subsection (c) of § 99B-5, which applies only to prescription drugs and is not applicable here, is a codification of the learned intermediary doctrine.

F.Supp. 530, 535−36 (E.D.N.C.1987), citing, *Holley v. Burroughs Welcome Co*., 330 S.E.2d 228 (N.C.App. 1985), *aff'd*, 348 S.E.2d 772 (N.C. 1986). "According to the learned intermediary doctrine, where a defendant manufactures a product which is dispensed to patients by doctors, rather than directly, the defendant has a duty to warn only the doctor, rather than the patients of any risks associated with the product's use. It is assumed that the doctors will pass along appropriate information to their patients." *Baraukas*, 2000 WL 223508, at * 4 (internal citations omitted).

Ms. Carlson cannot establish that an alleged inadequate warning for the Uphold was the proximate cause of her injuries without demonstrating Dr. Kennelly's reliance on the Uphold DFU (Directions For Use). The MDL Judge decided this issue on April 29, 2015, approximately four months prior to the filing of Plaintiff Carlson's Motion to Reconsider. (Doc. 101, 6−7). Applying the learned intermediary doctrine, the MDL Judge found that Dr. Kennelly, the implanting physician, did not rely on the Uphold DFU in prescribing the device. As a factual matter, the MDL Judge stated:

> "Here, the record is devoid of any evidence that would permit a reasonable juror to infer that Dr. Kennelly read or relied on the Uphold DFU in prescribing the device to Ms. Carlson."

(Doc. 101, 7). As a result, the MDL Judge held that "a reasonable juror could not infer that BSC's allegedly defective warnings proximately caused Ms. Carlson's injuries." Id. (citing *Lewis v. Ethicon*, No. 2:12CV4301, 2014 WL 186869, * 4 (S.D.W.Va. January 15, 2014; and *Jones v. C.R. Bard*, Inc., No. 2:11CV114, 2013 WL 5591948, * 6 (S.D.W.Va. June 4, 2013)).

In this case, the essence of Ms. Carlson's motion for reconsideration is that the MDL Judge analyzed this issue after "misapprehension of a key fact . . . ."[2] (Doc. 207, 4). In support

[2] Plaintiff Carlson apparently abandoned one aspect of her initial argument that would seem to undermine the MDL Judge's application of the learned intermediary doctrine. Plaintiff Carlson originally

of reconsideration, Plaintiff points to deposition testimony of Dr. Kennelly wherein Dr. Kennelly acknowledges that he, in fact, reviewed the Uphold DFU prior to Ms. Carlson's surgery and was familiar with its contents. (Kennelly Dep., 58:21−24; 67:13−16). Dr. Kennelly also testified that he considered the instructions for use in his decision making, and specifically when weighing the risks and benefits associated with the Uphold device, for Ms. Carlson's treatment. (Id. at 83:13−17).

In response, Defendant BSC contends that Ms. Carlson is unable to point to testimony that adequately counters Dr. Kennelly's testimony that *notwithstanding what he knew about the potential risks*, implantation of the Uphold device was the appropriate treatment for Ms. Carlson.[3] (Doc. 191, 2−3). In other words, BSC argues that Dr. Kennelly's firm opinion that the Uphold was the correct treatment plan forecloses Plaintiff's failure to warn claim. The Court's reading of the relevant portion of Dr. Kennelly's deposition testimony in context confirms this fact. After agreeing that he had adequate information to properly evaluate the risks and the

argued that had BSC published an adequate warning, her own reliance on the DFU as communicated to her by her physician would be sufficient to present this claim to a jury. Plaintiff does not mention this argument in her reply brief.

[3] Defendant BSC cites the *Frankum* case, which was also remanded from MDL 2326 to the Western District of North Carolina for trial. *See Frankum v. Boston Scientific Corporation*, No.: 1:15CV91-MOC. In *Frankum*, a similar motion for reconsideration was recently denied despite Frankum's assertion that the MDL Judge "improperly assessed the evidence" relevant to the failure to warn claim. (No.: 1:15CV91, Doc. 123). In *Frankum*, the MDL Judge found that the general statements of the treating physician about typically reviewing instructions for medical devices prior to use did not overcome the physician's testimony that he did not read the DFU for the device at issue. The pertinent deposition testimony in *Frankum* indicated unequivocally that the implanting surgeon did not read the DFU for the device at issue – a fact that distinguishes *Frankum* from the instant case, where Dr. Kennelly testified that he actually read the DFU for the Uphold. (Doc. 123, 4). The MDL Judge held in *Frankum* that no genuine issue of material fact existed as to causation. Consequently, the failure to warn claim was dismissed and summary judgment granted in favor of BSC on that issue. Judge Cogburn, who recognized that the MDL Judge reviewed all of the deposition testimony, declined to "re-think" the merits of the MDL Court's decision. (Doc. 123, 5).

benefits of the Uphold for Ms. Carlson, and aware of all of the risks (*e.g.*, erosion, recurrence, urgency symptoms, urinary incontinence, pain), Dr. Kennelly opined that Ms. Carlson was an appropriate candidate for the Uphold implant. (Kennelly Dep., 155−56). Dr. Kennelly specifically testified, "I believe that for what [Carlson] had that the Uphold device was the optimum therapy for her, given her clinical condition, her concerns, her desire for sparing the uterus." (Kennelly Dep., 189). Dr. Kennelly's professional opinion remains that the Uphold is "a safe and effective option for the treatment of pelvic organ prolapse" in certain cases. (Kennelly Dep., 55). In conclusion, while Dr. Kennelly's deposition testimony shows that Dr. Kennelly read the Uphold DFU, his testimony does not indicate that he relied on the DFU or that a different DFU content would have altered his treatment recommendation.

Plaintiff's Motion Reconsideration will be denied.

IT IS THEREFORE ORDERED that Plaintiff Martha Carlson's Motion For Reconsideration (Doc. 180) is hereby **DENIED**.

Signed: September 30, 2015

Richard L. Voorhees
United States District Judge