UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

MICHAEL B. BONANDER, Civil No. 09-2795 (JRT/JJK)

Plaintiff,

v. **MEMORANDUM OPINION AND ORDER**

BREG, INC.,

Defendant.

Steven B. Seal, Leslie W. O'Leary, Thomas B. Powers, and Michael L. Williams, **WILLIAMS LOVE O'LEARY & POWERS PC**, 9755 S.W. Barnes Road, Suite 450, Portland, OR 97225-6681; Matthew E. Munson, **BEASLEY ALLEN CROW METHVIN PORTIS & MILES, PC**, P.O. Box 4160, Montgomery, AL 36103-4160; Laura B. Kalur, **KALUR LAW OFFICE**, 9755 S.W. Barnes Road, Suite 450, Portland, OR 97225-6681; and Yvonne M. Flaherty, **LOCKRIDGE GRINDAL NAUEN PLLP**, 100 Washington Ave South, Suite 2200, Minneapolis, MN 55401-2179, for plaintiff.

John D. Sear, Molly J. Given, and William N.G. Barron, IV, **BOWMAN & BROOKE LLP**, 150 South Fifth Street, Suite 3000, Minneapolis, MN 55402, for defendant.

Plaintiff Michael B. Bonander brings negligence and strict products liability failure to warn claims against Breg, Inc. ("Breg") for injuries he alleges that he suffered from a pain pump that Breg manufactured. Bonander claims that the Breg pain pump used on his shoulder was unreasonably and dangerously defective because of Breg's failure to warn. The matter before the Court is Breg's motion for summary judgment. Breg argues that Bonander cannot show causation as a matter of law because an adequate

warning from Breg to Bonander's doctor would not have prevented Bonander's injuries. The Court will deny Breg's motion because Bonander has raised a genuine issue of material fact regarding whether an adequate warning might have prevented his injuries.[1]

Also before the Court is Breg's motion to exclude allegedly improper regulatory opinion testimony of Bonander's regulatory expert, Dr. Peggy Pence.[2] The Court will deny the majority of the motion to exclude testimony, without prejudice, because the issues it raises are best dealt with closer to or during trial. However, the Court will exclude testimony about the Neurontin criminal prosecution because it is irrelevant and prejudicial.

BACKGROUND

I. BONANDER'S SHOULDER SURGERY AND CHONDROLYSIS

Bonander underwent shoulder surgery on December 19, 2003, in Sioux Falls, South Dakota. (Second Am. Compl. ¶ 4, Dec. 22, 2010, Docket No. 110; Decl. of John D. Sear, Ex. 1 (Dep. of Dr. Peter A. Looby ("Looby Dep.") 23:16-20, May 1, 2012, Docket No. 126.) Bonander's orthopedic surgeon was Dr. Peter A. Looby. (Looby Dep. 22:19-25, 23:1-20.) During Bonander's surgery, Dr. Looby inserted a Breg PainCare

[1] Breg also seeks summary judgment on Bonander's design defect claim. Bonander has abandoned this claim; accordingly, the Court will grant this aspect of Breg's motion.

[2] Breg moved to exclude testimony from two of Bonander's experts, Dr. Peggy Pence and Dr. Suzanne Parisian. Bonander informed the Court at oral argument on August 6, 2012, that only Dr. Peggy Pence would testify in this case. Therefore, the Court only considers the motion to exclude the testimony of Dr. Pence.

3200 pain pump into Bonander's shoulder joint to infuse 200cc of Marcaine continuously into the inside of Bonander's shoulder joint (i.e., the intra-articular glenohumeral space). (Id. 26:22-27:8, 42:1-3.) Dr. Looby often used pain pumps to continuously inject pain relief drugs directly into patients' shoulders for the first forty-eight hours after surgery to increase patient comfort and facilitate rehabilitation. (Id. 9:11-16.)

Bonander claims that the pain pump caused a condition in his shoulder called chondrolysis. (Second Am. Compl. ¶ 1.) Chondrolysis is defined by one source as the "[d]isappearance of articular cartilage as the result of disintegration or dissolution of the cartilage matrix and cells." Stedman's Medical Dictionary 369 (28th ed. 2006).[3] Dr. Looby diagnosed Bonander with chondrolysis on or around April 19, 2004, the date when he performed a procedure to debride Bonander's shoulder. (Second Am. Compl. ¶ 4; Looby Dep. 28:3-12.) Bonander contends that he has suffered permanent impairment of the use and function of his affected upper extremity and that he may require future medical care as he ages, including possible future shoulder replacements, because of the insertion of the pain pump. (Second Am. Compl. ¶ 13.)

II. DR. LOOBY AND CAUSATION

The parties dispute whether Breg's alleged failure to warn caused Dr. Looby to insert the pain pump into Bonander's shoulder. The facts outlined below are relevant to this issue.

[3] Another source defines chondrolysis as "the degeneration of cartilage cells that occurs in the process of intracartilaginous ossification." Dorland's Illustrated Medical Dictionary 358 (31st ed. 2007).

A. Dr. Looby's Initial Use of Pain Pumps

Dr. Looby stated that he first used pain pumps intra-articularly in 2000 or 2001 after seeing a presentation by another doctor. (Looby Dep. 12:1-9.) In 2003, he began to use pain pumps to treat post-operative shoulder pain. (Id. 12:10-13.) He testified that he was not worried about injecting anesthetic directly into a shoulder, stating, "I've been injecting marcaine intra-articularly into shoulder joints since the first day of my training in orthopedics. . . . And I had been using [pain pumps] in the knee for years without a single problem." (Id. 20:18-25.)

B. Dr. Looby and Communications from Breg

Dr. Looby had limited communications with Breg about its pain pump. In his deposition, Dr. Looby testified that he had never read the instructions of the pain pump "until the night before the last time I was deposed[.]" (Id. 19:24-20:7.) Dr. Looby further testified that his decision to use pain pumps was the result of his "clinical experience and discussions with other orthopedic surgeons" and not "based upon any sales pitch by the Breg representative." (Id. 46:7-14.) He did not expect medical device companies and their sales representatives to inform him of the risks or benefits of their product. As he stated, "I don't expect those sales people to do anything except be sales people for their devices and their companies." (Id. 11:11-18.)

Dr. Looby further claimed that his knowledge of how to use the pumps and where to place the catheter did not come from a Breg sales representative. (Id. 47:7-15.) Breg's sales representative, Kyle Jellema, similarly testified that he "can't say" that he met with

Dr. Looby about pain pumps before 2003. (Powers Decl., Ex. AX at 4 (Dep. of Kyle Jellema 12:15-19), May 22, 2012, Docket No. 136.) When Dr. Looby was asked if he would have used the pain pumps intra-articularly if Breg or anyone else had told him that the device had not been tested for intra-articular use, he responded in the affirmative. (Looby Dep. 14:19-15:5.)

But on the issue of "Dear Doctor" letters from a medical device company, Dr. Looby was not as certain as to whether he had read them or would rely on them. When asked if he had ever received anything like a "Dear Doctor" letter from Breg about their pain pump, Dr. Looby responded, "I don't specifically recall, but I would be the first to admit that it could have come and I never – and I might have forgotten about it." (Id. 21:12-19.)[4] Bonander alleges – and Breg does not dispute – that Dr. Looby never received a "Dear Doctor" letter from Breg about the risks of chondrolysis associated with its pain pump.

C. Responsiveness to Warnings

Dr. Looby suggested that he would have been responsive to scientific evidence that suggested pain pumps were not safe. Specifically, when asked if he would have used pain pumps in shoulders if he thought there was a question about their safety for that use, he said, "Well, it would depend on how strong the evidence was that there was a problem

[4] In a deposition for two other pain pump cases, Dr. Looby testified that he "doesn't spend a lot of time" reading "Dear Doctor" letters. (Powers Decl., Ex. AZ (Suhn and Koch Dep. of Dr. Peter A. Looby 14:25, 15:1), May 22, 2012, Docket No. 136.)

with it, and how severe the implications of that problem would be for the patient." (Id. 14:8-18.)

In fact, Dr. Looby stopped using the pain pumps for shoulder surgeries once the medical evidence supported a link between pain pump use and chondrolysis. (Id. 7:20-8:13.) Prior to reading an article published in 2007, Dr. Looby did not believe there was a link between chondrolysis and pain pump use. (Id.) Later, as Dr. Looby tells it, "There was an article published in the American Journal of Sports Medicine which, through my reading, indicated that intra-articular placement of a marcaine pain pump was the leading risk factor for the development of post-arthroscopic glenohumeral chondrolysis." (Id. 7:25, 8:5.) Dr. Looby no longer uses pain pumps intra-articularly in shoulders because of this risk. (Id. 8:11-13.) In his testimony, Dr. Looby never foreclosed the possibility that he would have listened to a warning about pain pump use from a medical device company such as Breg.

ANALYSIS

I. STANDARD OF REVIEW

Summary judgment should be granted only when the defendant has shown that "there is no genuine dispute as to any material fact" and the defendant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A fact is material if it might affect the outcome of the suit, and a dispute is genuine if the evidence is such that it could "reasonably be resolved in favor of either party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). A court considering a motion for summary judgment must view

the facts in the light most favorable to the non-moving party and must give that party the benefit of all reasonable inferences that can be drawn from those facts. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

II. CHOICE OF LAW

Bonander and Breg agree that, for this motion, no choice of law analysis is necessary because both South Dakota and Minnesota apply the law of causation in the same way in a failure to warn claim. The Court likewise finds no conflict in the law at this stage.[5] The Court will therefore apply the law of the forum, Minnesota. See Best Buy Stores, L.P. v. Developers Diversified Realty Corp., 715 F. Supp. 2d 871, 875-76 (D. Minn. 2010).

III. CAUSATION

The Court analyzes strict liability and negligence in failure-to-warn cases under a single theory of products liability. Bilotta v. Kelley Co., 346 N.W.2d 616, 622 (Minn. 1984). In general, there is a duty to warn users of a dangerous product "if it is reasonably foreseeable that an injury could occur in its use." Gray v. Badger Mining Corp., 676 N.W.2d 268, 274 (Minn. 2004). The Minnesota Supreme Court has described the duty to

[5] In Minnesota, the Court can decide causation as a matter of law when "an adequate warning could not have prevented a plaintiff's injuries." Johnson v. Zimmer, Inc., No. 02-1328, 2004 WL 742038, at *9 (D. Minn. Mar. 31, 2004); see also Balder v. Haley, 399 N.W.2d 77, 81 (Minn. 1987) (where warnings are ignored, there is no causal relationship between the failure to warn and the injury). Similarly, in South Dakota, to survive summary judgment, the plaintiff must show a genuine issue of material fact regarding whether a failure to warn was the proximate cause of the injuries. See Burley v. Kytec Innovative Sports Equip., Inc., 737 N.W.2d 397, 410 (S.D. 2007) ("Causation is an essential element in a failure to warn claim.").

warn as twofold: "(1) [t]he duty to give adequate instructions for safe use; and (2) the duty to warn of dangers inherent in improper usage." Glorvigen v. Cirrus Design Corp., 816 N.W.2d 572, 582 (Minn. 2012) (quoting Frey v. Montgomery Ward & Co., 258 N.W.2d 782, 787 (Minn. 1977)).

The plaintiff must establish a causal link between the failure to warn and the injury. See Balder v. Haley, 399 N.W.2d 77, 81 (Minn. 1987). The Court can rule on causation as a matter of law at summary judgment when "an adequate warning could not have prevented a plaintiff's injuries." Johnson v. Zimmer, Inc., No. 02-1328, 2004 WL 742038, at *9 (D. Minn. Mar. 31, 2004); see also Balder, 399 N.W.2d at 81 (where warnings are ignored, there is no causal relationship between the failure to warn and the injury); see also 27 Minn. Prac., Prods. Liab. § 16.7 (2012) ("Even if a warning is inadequate, the manufacturer is not liable for a failure to warn . . . if the physician would have prescribed the drug or device regardless of any additional information or warnings the manufacturer could have supplied.").

In its summary judgment motion, Breg argues that causation does not exist as a matter of law because Dr. Looby admitted that he did not read the package insert with the pain pump.[6] Although Dr. Looby did not read the package insert, the Court finds that there remains a genuine issue of material fact regarding whether Dear Doctor letters, communications from sales representatives, or other warnings would have prevented

[6] Breg does not currently challenge whether Bonander has met the elements of duty, the adequacy of the warning, breach of duty, or injury, so the Court will not address these issues.

Bonander's injuries. Dr. Looby never said that he would not have listened to a warning from a medical device company through, for example, a sales representative or a Dear Doctor letter.[7] Indeed, he indicated that he **would have** responded to strong scientific information about a lack of safety in pumps. Although Dr. Looby did not **rely** on medical device companies to provide such information, he may still have responded to a warning – particularly a forceful one – they actually communicated to him.[8] There is a particularly significant question about whether Dr. Looby would have heeded warnings from Breg since he stopped using pain pumps intra-articularly in shoulders in 2007 when he became aware of the risk involved. Thus, the Court cannot say as a matter of law that a warning from Breg would not have had the same effect. See Schilf v. Eli Lilly & Co., 687 F.3d 947, 951 (8th Cir. 2012) (finding a genuine issue of material fact as to causation when a doctor's "deposition [was] unclear whether he would have" prescribed a drug if he had been given information about clinical trials or information about the "causal role" the drug played in inducing suicides). Therefore, whether Dr. Looby would have listened

[7] See Schedin v. Ortho-McNeil-Janssen Pharms., Inc., 808 F. Supp. 2d 1125, 1135 (D. Minn. Aug. 26, 2011) (considering that a doctor could have received a warning from other doctors who read a drug label) (distinguishing Zimmer, Inc., 2004 WL 742038, at *10); Wehner v. Linvatech Corp., No. 06-CV-1709, 2008 WL 495525, at *5 (D. Minn. Feb. 20, 2008) (considering methods of communication other than package inserts for failure to warn claim) (distinguishing Zimmer, Inc., 2004 WL 742038, at *10).

[8] Although Dr. Looby does not remember receiving any Dear Doctor letters, it appears that he did not receive any such letters from Breg – at least warning of the risk at issue – making his lack of memory of little import. Furthermore, Dr. Looby's statement that he did not remember reading Dear Doctor letters does not necessarily establish that he never read such letters or would not have been impacted by a strong warning in a letter from Breg. See In re Levaquin Prod. Liab. Litig., MDL No. 08-5742, 2011 WL 6826415, at *4 (D. Minn. Dec. 28, 2011) (declining to grant summary judgment where a doctor stated that she did not remember reading a package insert but never stated that she had not read the insert).

to a warning from Breg remains a genuine issue of material fact and the Court will deny Breg's motion for summary judgment.

IV. BREG'S MOTION TO EXCLUDE IMPROPER REGULATORY OPINION TESTIMONY

Breg moves to exclude improper testimony and evidence that Bonander's regulatory expert Dr. Peggy Pence might offer at trial. This motion to exclude testimony can be divided into two categories. The first category is the testimony that both parties agree should be excluded. These topics include: (1) opinions regarding Breg's or the FDA's motives or intent; (2) narrative testimony; and (3) testimony regarding causation. Because the parties appear to agree that this testimony should be excluded, the Court declines to address this issue further at this time but will entertain objections at or closer to trial if Bonander in fact attempts to enter such testimony.

The second category is testimony that Bonander seeks to enter over Breg's objections pursuant to Federal Rules of Evidence 401-403 and 702. The testimony includes (1) so-called "legal opinions" offered by Pence, (2) Pence's opinions about the "standard of care" applicable to Breg or Breg's "responsibility"; and (3) evidence about the Neurontin prosecution.

The Court will grant Breg's motion to exclude testimony regarding a Department of Justice criminal prosecution of Pfizer for off-label marketing of Neurontin. While Bonander claims that the prosecution is merely an example of the type of prosecution that the United States undertakes when investigating off-label use, the Court finds that the testimony is of minimal, if any, relevance to this action and is highly prejudicial because

it inappropriately links Breg's behavior to that of another company. See Fed. R. of Evid. 403. Accordingly, the Court will exclude it.

The Court will otherwise deny Breg's motion, however, because it is premature. This motion is almost entirely related to elements of Breg's claims that are undeveloped and not subject to the current summary judgment motion, namely Breg's alleged failure to warn. Accordingly, the Court is unable to determine the relevance and appropriateness of much of this testimony at this stage. Furthermore, the Court will deny the motion because it asks the Court to exclude broad categories of information such as "legal opinions." The parties, of course, must comply with the Federal Rules of Evidence. See In re Levaquin Prod. Liab. Litig., MDL No. 08-1943, 2010 WL 8399942, at *10 (D. Minn. Nov. 4, 2010) ("expert testimony on legal matters is not admissible") (quoting S. Pine Helicopters, Inc. v. Phoenix Aviation Managers, Inc., 320 F.3d 838, 841 (8th Cir. 2003)). However, the Court finds that excluding such broad categories of information as part of a pre-trial order is not appropriate in this case.[9] See In re Levaquin Prod. Liab. Litig., MDL No. 08-1943, 2010 WL 4676973, at *3 (D. Minn. Nov. 9, 2010) ("Motions that lack specificity and are 'essentially repetitive of well-established rules of evidence' are not generally granted."). Accordingly, the Court will deny Breg's motion to exclude expert testimony, except to the extent it requests exclusion of the Neurontin prosecution.

[9] Breg may bring motions to exclude **specific** testimony at or closer to trial. See United States v. Stuckey, 255 F.3d 528, 531 (8th Cir. 2001) ("Judges are not like pigs, hunting for truffles buried in briefs.") (quoting United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991)).

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendant's Motion for Summary Judgment [Docket No. 123] is **GRANTED in part** and **DENIED in part**, as follows:

   a. The motion is **GRANTED** as to the design defect claim. The claim for design defect is **DISMISSED**.

   b. The motion is **DENIED** in all other respects.

2. Defendant's Motion to Exclude Expert Testimony [Docket No. 128] is **GRANTED in part** and **DENIED in part**, as follows:

   a. The motion is **GRANTED** as to testimony regarding the Neurontin prosecution. Testimony regarding the Neurontin prosecution is **EXCLUDED**.

   b. The motion is **DENIED** without prejudice in all other respects.

DATED: September 18, 2012
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge