IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

- -

AMY MARIE STEVENS,

OPINION AND ORDER

Plaintiff,

12-cv-63-bbc

v.

STRYKER CORPORATION and
STRYKER SALES CORPORATION,

Defendants.

- -

In 2004, after plaintiff Amy Marie Stevens had surgery on her left shoulder, her doctor gave her a "pain pump" that was manufactured and sold by defendants Stryker Corporation and Stryker Sales Corporation. Plaintiff alleges that the pain pump caused "severe cartilage loss" in her left shoulder and defendants were negligent in failing to warn her about the risks associated with the pump. Plaintiff's is one of many cases filed around the country in recent years in which patients have sued pain pump manufacturers for damage to their cartilage. Jurisdiction is present under 28 U.S.C. § 1332.

Defendants have raised three issues in their motion for summary judgment: (1) whether they should have known at the time of plaintiff's surgery that the pump was dangerous; (2) whether their failure to warn plaintiff caused her injuries; and (3) whether plaintiff is entitled to punitive damages. Many courts have considered the first two issues in deciding motions for summary judgment. Although both sides argue that the

overwhelming weight of authority favors their position, my own review of the cases suggests that there is no clear trend. Huggins v. Stryker Corp., 2013 WL 1191058, *10 (D. Minn. 2013) ("Courts across the country have confronted this issue with inconsistent results."). See also Mack v. Stryker Corp., 893 F. Supp. 2d 976, 982-983 (D. Minn. 2012) (collecting cases in which courts granted and denied summary judgment on pain pump negligence claims). Only one federal appellate court has considered these issues, but that court came to opposite conclusions in two different cases. Compare Rodriguez v. Stryker Corp., 680 F.3d 568 (6th Cir. 2012) (finding no negligence or causation as matter of law) with Krumpelbeck v. Breg, Inc., 2012 WL 3242587 at *8 (6th Cir. Aug. 10, 2012) (unpublished) (leaving negligence and causation for jury to resolve).

After reviewing the evidence and arguments in this case, I can see why courts have come to different conclusions about defendants' alleged negligence. Although the question is a close one, I conclude that the evidence is sufficient to allow a jury to decide whether defendants should have known that the pain pumps could cause cartilage damage and whether defendants' alleged negligence caused plaintiff's injuries. However, the closeness of the question regarding negligence makes it clear that plaintiff cannot show that she is entitled to punitive damages. Accordingly, I am denying defendants' summary judgment motion as to their liability arguments, but granting it as to punitive damages.

From the parties' proposed findings of fact and the record, I find that the following facts are undisputed.

UNDISPUTED FACTS

Defendants Stryker Corporation and Stryker Sales Corporation manufacture and sell pain pumps, which are portable infusion devices used by physicians to deliver anesthetics to a patient's surgical site through a catheter. After a physician places the catheter, the pump delivers the prescribed dose of medication over the prescribed time period.

In 1999 defendants purchased the rights to the pain pump from McKinley Medical. At that time, the Food and Drug Administration had approved the pain pump for use under 21 U.S.C. § 360c(f), on the ground that it was substantially equivalent to devices available before 1976. (The parties refer to this method of approval as the "501(k) process." They do not identify what the equivalent product is.) However, the FDA had not approved the pump for use in the synovial cavity. (Perhaps because there have been so many cases involving pain pumps, the parties were a bit sloppy in defining some of the medical terms. Plaintiff defines "synovial cavity" as the "intra-articular space of a joint" without explaining what the "intra-articular space" is. Stedman's Medical Dictionary 993 (28th ed. 2006) defines "intraarticular" to mean "[w]ithin the cavity of a joint." In Mack, 893 F. Supp. 2d at 978 n.2, the court stated that the terms "synovial cavity," "intra-articular space" and "glenohumeral joint space" all refer to "the joint of the shoulder where the ball (humeral head) meets the socket (the glenoid)." See also Woodard v. Stryker Corp., 2012 WL 3475079, *2 (D. Wyo. 2012) ("'[I]ntra-articular' and 'synovial cavity' refer to the joint space.").

Before selling their pain pumps, defendants did not perform an assessment for

analyzing the risks of the product associated with intra-articular use, did not conduct any testing on intra-articular use and did not review the medical literature about continuous infusion of local anesthetics over multiple days. In June 2000, Dr. Lonnie Paulos became an orthopedic consultant for defendants. Paulos told defendants that they needed to conduct patient-controlled studies to establish the efficacy of a pain pump device and animal studies to establish the safety of using the device in orthopedic surgery. Defendants did not respond to these concerns.

In 2001 defendants submitted a request to the FDA for approval to market the pump for use in the synovial cavity. The FDA rejected this request on the ground that it had not previously approved a substantially equivalent device. The FDA did not require or recommend that defendants modify their product warnings or restrict a doctor's discretion to select intra-articular placement of the pump for postoperative pain management. (The parties dispute many facts about the extent to which defendants encouraged physicians to use the pain pumps in the intra-articular space, but none of these are material because defendants are not arguing for the purpose of summary judgment that it was not reasonably foreseeable that physicians would use the pain pumps that way. Wis.-JI Civil 3242 ("[A] manufacturer [ ] has the duty to warn of dangers inherent in a use not intended by the manufacturer [ ] if such unintended use is reasonably foreseeable by the manufacturer.")).

On July 23, 2004, in Rhinelander, Wisconsin, plaintiff Amy Marie Stevens had arthroscopic instability repair surgery on her left shoulder joint. Relying on the opinions of his peers and the scientific literature, plaintiff's doctor, James Dyreby, treated plaintiff's

post-surgery shoulder pain with a pump manufactured by defendants. Plaintiff later developed chondrolysis. (The parties do not explain what this is, but Stedman's Medical Dictionary 368 (28th ed. 2006), defines it as the "[d]isappearance of articular cartilage as the result of disintegration or dissolution of the cartilage matrix and cells.")

In November 2006 defendants decided to fund their own study into the causes of chondrolysis. In early 2007 defendants commissioned a study to "determine the effects of a continuous intraarticular infusion of bupivacaine in the rabbit shoulder." (Bupivacaine is an anesthetic commonly used in pain pumps.) The study concluded that a 48-hour bupivacaine infusion negatively affects shoulder cartilage in rabbits. Beginning in October 2007, other authors concluded that chondrolysis may be caused by continuous infusion of local anesthetic through a pain pump. In November 2009 the FDA issued an advisory to health care professionals not to use pain pumps for continuous intra-articular infusion of anesthetics after orthopedic surgery. (The parties dispute the extent to which the causal connection between pain pumps and chondrolysis has been established, but I need not consider these facts because defendants do not argue for the purpose of summary judgment that the pain pump did not cause plaintiff's injuries.)

OPINION

A. Subject Matter Jurisdiction

The parties failed to comply with this court's summary judgment procedures by not setting forth any proposed findings of fact about subject matter jurisdiction. Procedure to

Be Followed on Motions for Summary Judgment I.B.3, dkt. #18 ("The statement of proposed findings of fact shall include ALL factual propositions the moving party considers necessary for judgment in the party's favor. For example, the proposed findings shall include factual statements relating to jurisdiction."). Because federal courts "have an obligation at each stage of the proceedings to ensure that [they] have subject matter jurisdiction over the dispute," Northeastern Rural Electrical Membership Corp. v. Wabash Valley Power Association, Inc., 707 F.3d 883, 890 (7th Cir. 2013), I cannot treat this issue as waived. However, I need not require the parties to supplement their proposed findings of fact because I am satisfied that jurisdiction is present.

In her amended complaint, plaintiff cites 28 U.S.C. § 1332 as a basis for jurisdiction, which requires diversity of citizenship between plaintiff and defendants and an amount in controversy greater than $75,000. She does not request a specific amount of damages, but it is reasonable to infer from the nature of her injury that more than $75,000 is in controversy. Miller v. Herman, 600 F.3d 726, 730 (7th Cir. 2010) (court may infer amount in controversy from allegations in complaint). With respect to citizenship, plaintiff alleged in her amended complaint that she is a citizen of Virginia, dkt. #23 at ¶ 1, and defendants admitted that in their answer. Dkt. #24 at ¶ 1. That is sufficient to establish plaintiff's citizenship. Solon v. Gary Community School Corp., 180 F.3d 844, 858 (7th Cir. 1999) ("A judicial admission is conclusive, unless the court allows it to be withdrawn."). Defendants also admitted plaintiff's allegation that they are citizens of Michigan, dkt. #23 at ¶ 1; dkt. #24 at ¶ 1, but she did not identify their principal place of business or their state

of incorporation, both of which are relevant to a corporation's citizenship. Pastor v. State Farm Mutual Automobile Insurance Co., 487 F.3d 1042, 1047-48 (7th Cir. 2007). To the extent more specificity is required, defendants have acknowledged in other cases in this court that Michigan is their state of incorporation as well as their principal place of business. Bryant v. Stryker Corp., No. 12-cv-593-bbc, 2012 WL 5828749, *1 (W.D. Wis. Nov. 16, 2012). Accordingly, I conclude that jurisdiction is present under § 1332.

B. Merits

Both parties have assumed that Wisconsin law applies to plaintiff's claims, so I will do the same. RLI Insurance Company v. Conseco, Inc., 543 F.3d 384, 390 (7th Cir. 2008) ("When neither party raises a conflict of law issue in a diversity case, the applicable law is that of the state in which the federal court sits."). Under Wisconsin law, a negligence claim has four elements: (1) the existence of a duty of care on the part of the defendant; (2) a breach of that duty of care; (3) a causal connection between the defendant's breach of the duty of care and the plaintiff's injury; and (4) actual loss or damage resulting from the injury." Gritzner v. Michael R., 2000 WI 68, ¶ 19, 235 Wis. 2d 781, 611 N.W.2d 906. Defendants focus on the first and third elements, so I do not consider the others.

1. Duty to warn

With respect to the first element, the question of duty can be restated as a question of ordinary care, that is, *everyone* has a "duty" to use ordinary care if "it is foreseeable that

[his or her] act or failure to act might cause harm to some other person." Alvarado v. Sersch, 2003 WI 55, ¶ 13, 262 Wis. 2d 74, 662 N.W.2d 350. "Ordinary care is the care which a reasonable person would use in similar circumstances." Wis. JI-Civil 1005. This is the same standard that applies when the plaintiff is alleging a failure to warn. In that case, the question is whether the defendant knew or should have known of the danger that harmed the plaintiff. Mohr v. St. Paul Fire & Marine Insurance Co., 2004 WI App 5, ¶ 32, 269 Wis. 2d 302, 329, 674 N.W.2d 576, 589; Wis. JI-Civil 3242. This is a question of fact for the jury, unless the court determines that no reasonable jury could find in favor of the nonmoving party. Strasser v. Transtech Mobile Fleet Service, Inc., 2000 WI 87, ¶¶ 30-32, ¶ 60, 236 Wis. 2d 435, 450, 613 N.W.2d 142, 150. See also Trask-Morton v. Motel 6 Operating L.P., 534 F.3d 672, 677 (7th Cir. 2008); Lane v. Hardee's Food Systems, Inc., 184 F.3d 705, 708 (7th Cir. 1999).

Plaintiff does not argue that defendants knew that their pain pumps were dangerous. Instead, plaintiff argues that defendants *should have* known of the danger by reviewing the medical literature in existence in 2004 or by conducting their own research. In his report, plaintiff's expert, Stephen Trippel, M.D., cites 13 studies that he says made it foreseeable that defendants' pain pumps would cause cartilage damage. Dkt. #74, exh. 1. In most of these studies, the results showed that various solutions had a harmful effect on articular cartilage.

Defendants do not argue that Trippel is unqualified to give an opinion about the importance of these studies. In fact, it is not until their reply brief that defendants say

anything about the standard for admitting expert testimony, and even then they do little more than argue generally that courts have an obligation to scrutinize that testimony. Dfts.' Reply Br., dkt. #108, at 5. Nor do defendants cite any expert testimony undermining Trippel's conclusions. Instead, defendants focus on the decisions of other courts that have rejected similar opinions in other cases involving products liability claims against manufacturers of pain pumps.

Defendants rely primarily on Rodriguez v. Stryker Corp., 680 F.3d 568 (6th Cir. 2012). In that case, the court reviewed the same 13 articles that plaintiff cites in this case but did not find them persuasive because "none of the articles draws a connection between pain pumps and chondrolysis." Id. at 571. In particular, the court noted that many of the studies did not involve anesthetics and others had inconclusive results. Id.

Although the court raised a number of legitimate criticisms in Rodriguez, courts must be mindful not "to weigh the evidence and determine the truth of the matter" in deciding a motion for summary judgment because that is the province of the jury. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). Trippel has testified that the studies show generally that exposing articular cartilage to a variety of solutions can be harmful and the studies should have put defendants on notice that their product was dangerous. The evidence plaintiff cites is sufficient to allow a reasonable jury to find that defendants did not use ordinary care.

It is true that the studies left uncertainty about the specific effects of continuous infusion of anesthetics in the shoulder joint (the issue relevant to this case), but a reasonable

jury could find that the uncertainty was simply a red flag that more testing needed to be done to insure the safety of the product. Defendants repeatedly cite Adelman-Tremblay v. Jewel Companies, Inc., 859 F.2d 517 (7th Cir. 1988), for the proposition that they had no duty to conduct their own research, but that is inaccurate. The question in Adelman-Tremblay was whether a glue manufacturer had a "duty to warn of the possibility of a rare and unusual allergic reaction." Id. at 522. In this case, defendants are not arguing that plaintiff's injury is "rare and unusual," so Adelman-Trembly is not instructive. Further, it would make no sense to have a blanket rule that manufacturers never have a duty to test their own products. Under defendants' view, if there was no existing data about a new product, the manufacturer would be free to sell the product to the public without having any idea whether the product is safe.

That is not the law. The same standard that governs all other actions under negligence law governs testing as well, which is whether the defendant used ordinary care:

> Testing, of course, is often a duty; a manufacturer cannot escape liability by simply claiming not to know of various dangers. He is charged with a knowledge he would have had, had he made the effort to acquire it. Thus he cannot argue that he didn't know of a certain danger when he would have known of it if he had performed reasonable tests.

Delvaux v. Ford Motor Co., 764 F.2d 469, 475 (7th Cir. 1985) (applying Wisconsin law).

Defendants' alleged failure to determine for themselves whether their product is safe is related to plaintiff's argument regarding the FDA's refusal to approve the pain pump for intra-articular use. Defendants point out that the FDA did not reject their request because it concluded that the product was unsafe, but only because it had not previously approved

a substantially equivalent device. They argue that "Wisconsin law . . . imposes no duty to warn of a prescription medical device's regulatory history," Dfts.' Br., dkt. #58, at 15, but this argument misses the point. The FDA's refusal is relevant because it is further evidence that defendants were venturing into unchartered territory and that more information was needed before the pain pump could be used in joints.

Alternatively, defendants argue that plaintiff has failed to show what testing defendants should have done and what the results would be. This argument is puzzling because defendants conducted their *own* study in 2007 showing a connection between pain pumps and cartilage damage. Further, plaintiff's expert cites a number of other studies in his report showing a link between pain pumps and chondrolysis that he says defendants could have conducted before 2000. Dkt. #74, exh. 1, at 15-26.

Finally, defendants cite several studies from before 2004 that they say are evidence that it was reasonable to believe at the time that using pain pumps in shoulder joints was safe. Dkt. #60. However, Trippel states in his report that the studies available at the time focused on the efficacy of the pain pump, not its safety, and the studies lasted only a few days, so they would not be helpful in determining whether using the pumps had long term consequences. Dkt. #74, exh. 1, at 14. Accordingly, I cannot conclude that the studies show as a matter of law that defendants had no duty to warn, particularly in the absence of any expert testimony from defendants regarding the significance of the studies. This question will have to be resolved by the jury.

2. Causation

The next question is whether there is a genuine issue of material fact with respect to causation. In particular, defendants argue that plaintiff has not shown that a warning would have made any difference in this case because plaintiff's doctor testified that he did not rely on information he received from defendants when deciding whether to use a pain pump.

The parties debate whether this court should follow Tanner v. Shoupe, 228 Wis. 2d 357, 596 N.W.2d 805 (Ct. App. 1999), or Kurer v. Parke, Davis & Co., 2004 WI App 74, 272 Wis. 2d 390, 679 N.W.2d 867, in applying the standard for causation. Both of these cases involved causation in the context of an allegedly negligent failure to warn.

My review of the cases reveals two differences, one that seems to be semantic and one that is substantive. The first potential conflict is that, in Tanner, the court says that the failure to warn must be a "substantial factor" in causing the plaintiff's injury, but in Kurer the court uses the term "proximate cause." In my view, the most reasonable reading of Kurer on this issue is simply that the court used imprecise language.

It is well established in Wisconsin that legal causation has two components, cause-in-fact and "proximate cause." Fandrey v. American Family Mutual Insurance Co., 2004 WI 62, ¶¶ 11–13, 272 Wis. 2d 46, 680 N.W.2d 345. Like both Kurer and Tanner, the issue raised in this case is whether plaintiff can prove cause-in-fact. The test for cause-in-fact is also well established: whether the defendant's conduct is a "substantial factor" in producing the plaintiff's injury. Morgan v. Pennsylvania General Insurance Co., 87 Wis. 2d 723, 275 N.W.2d 660 (1979). "Proximate cause" is simply short hand for the public policies a court

may consider to deny recovery even if the plaintiff proves cause-in-fact. Fandrey, 2004 WI 62, at ¶ 12. Because the court in Kurer was discussing cause-in-fact, the reference to "proximate cause" likely was a misstatement. The court did not purport to be changing Wisconsin law, which it would not have the authority to do in any event. Accordingly, the relevant question is whether a reasonable jury could find that defendants' failure to warn was a substantial factor in causing plaintiff's physician to use the pain pump on plaintiff's shoulder.

The next question is whether plaintiff is entitled to a presumption that her doctor would have heeded any warning defendants provided. As the parties acknowledge, in Michaels v. Mr. Heater, Inc., 411 F. Supp. 2d 992, 1007 (W.D. Wis. 2006), I read Tanner as requiring a presumption and Kurer as rejecting that requirement and I concluded that I should follow the rule in Tanner. I see no reason to depart from that approach in this case. To the extent Tanner and Kurer conflict, I must follow Tanner because it is the earlier opinion and the court of appeals does not have the authority to overrule its own decisions. Cook v. Cook, 208 Wis. 2d 166, 190, 560 N.W.2d 246 (1997) (state court of appeals lacks power to overrule, modify or withdraw language from published opinion of court of appeals). Accordingly, I conclude that plaintiff is entitled to a presumption that defendants' failure to warn was a substantial factor in producing her injuries.

Even without a presumption, a reasonable jury could find in plaintiff's favor on this issue. Although plaintiff's physician testified that he did not rely on information he received from defendant when he decided to use the pain pump, it does not follow that he would have

ignored any warnings provided by defendants. Rather, the physician testified to the contrary that he *would have* considered warnings if defendants had provided them. Dkt. #89 at 55-56. In addition, he testified that he limited his use of the pain pumps as soon as he learned about potential problems. Id. at 24. From this, a reasonable jury could find that defendants' failure to warn was a substantial factor in the physician's decision to use the pain pump in plaintiff's shoulder joint.

3. Punitive damages

The parties agree on the standard for obtaining punitive damages under Wisconsin tort law, with both sides citing Strenke v. Hogner, 2005 WI 25, ¶ 38, 279 Wis.2d 52, 70, 694 N.W.2d 296, 304-05. Under Strenke the plaintiff must show by clear and convincing evidence that the defendant's conduct was deliberate; that its purpose was to "disregard the plaintiff's rights" or it was aware that it was substantially certain to have that result; and that the defendant's conduct was "sufficiently aggravated." Id. at ¶ 38. The supreme court instructed trial courts "to serve as gatekeepers before sending a question on punitive damages to the jury." Id. ¶ 40.

In attempting to meet this standard, plaintiff cites a 2000 statement by defendants' orthopedic consultant that they should conduct animal studies on their pain pump to establish safety. In addition, she cites two untitled documents that appear to be answers to a questionnaire. In one document the respondent writes that the "dosage" should be limited "due to toxicity." Dkt. #79-3. In the other the respondent writes that "toxicity is a big

problem = lawsuit waiting to happen." Dkt. #79-4.

From this evidence, no reasonable jury could find that defendants' conduct meets the standard articulated in Strenke. The statement by the orthopedic consultant might be further evidence that defendants were negligent, but it does not show that defendants were aware of a substantial certainty that plaintiff's rights would be disregarded, let alone that defendants intended to disregard plaintiff's rights. Although the consultant informed defendants of the need for tests, he did not identify any particular risk.

With respect to the other documents, defendants point out that plaintiff has not established a foundation to identify what the documents are, who prepared them and who reviewed them. However, even if I assume that defendants asked physicians to answer these questionnaires to evaluate the pain pumps, the answers provided are simply too vague to make the showing necessary to justify an award of punitive damages. Plaintiff has not shown that the respondents' concerns about "dosage" and "toxicity" have anything to do with the problems plaintiff experienced or, if they did, that the respondents provided defendants specific reasons to be concerned. Accordingly, I am granting defendants' motion for summary judgment as it relates to punitive damages.

ORDER

IT IS ORDERED that the motion for summary judgment filed by defendants Stryker Corporation and Stryker Sales Corporation, dkt. #56, is GRANTED with respect to plaintiff Amy Marie Stevens's request for punitive damages. The motion is DENIED in all other

respects.

Entered this 9th day of May, 2013.

BY THE COURT:
/s/
BARBARA B. CRABB
District Judge