UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

ROBERT L. HUGGINS, Civil No. 09-1250 (JRT/JJK)

Plaintiff,

v. **MEMORANDUM OPINION AND ORDER**

STRYKER CORPORATION and
STRYKER SALES CORPORATION,

Defendants.

Thomas B. Powers, **WILLIAMS LOVE O'LEARY & POWERS, PC**, 12725 S.W. Millikan Way, Suite 300, Beaverton, OR 97005; and Yvonne M. Flaherty, **LOCKRIDGE GRINDAL NAUEN PLLP**, 100 Washington Avenue South, Suite 2200, Minneapolis, MN 55401, for plaintiff.

Hall Marston, **SEDGWICK LLP**, 801 South Figueroa Street, Nineteenth Floor, Los Angeles, CA 90017; and Timothy P. Griffin, **LEONARD STREET AND DEINARD, PA**, 150 South Fifth Street, Suite 2300, Minneapolis, MN 55402, for defendants.

Plaintiff Robert L. Huggins brings claims against medical device companies Stryker Corporation and Stryker Sales Corporation (collectively, "Stryker"). Huggins alleges that pain pumps manufactured and distributed by Stryker, which a surgeon inserted into Huggins' shoulder following surgery in February 2002, caused chondrolysis (a condition involving rapid cartilage degeneration) in his shoulder. Huggins advances various product liability theories, sounding in both strict liability and negligence. This matter is currently before the Court on Huggins' motion to transfer, Stryker's motion for summary judgment, and Stryker's motion to exclude certain proposed expert testimony.

First, the Court will deny Huggins' motion to transfer. The balance of relevant factors does not sufficiently favor transferring the action to the District of Oregon. Second, the Court will deny Stryker's motion for summary judgment. A reasonable jury could find that Stryker should have known at the time of Huggins' surgery that continuous infusion of anesthetics into the shoulder joint using a pain pump could cause cartilage damage. The Court will also find that Stryker is not entitled to summary judgment on the basis of the statute of limitations. Finally, the Court will deny Stryker's motion to exclude expert testimony for the reasons described below.

BACKGROUND

I. HUGGINS' SURGERIES

Dr. A. Brooke Benz performed arthroscopic surgery on Huggins' shoulder on February 21, 2002. (Decl. of Tim Griffin, Ex. 16, June 28, 2012, Docket No. 175.) There is no dispute that Dr. Benz inserted a Stryker pain pump[1] into Huggins' shoulder joint following the operation. (*Id.*) Dr. Benz noted that the "articular surfaces . . . were in good condition." (*Id.*) On December 5, 2002, Dr. Benz performed a second shoulder surgery on Huggins and observed severe loss of cartilage on the humeral head and glenoid, which he described as "kind of global" and as "grade 3 degenerative changes." (Griffin Decl., Ex. 17.) Huggins' experts opine that the continuous infusion of

[1] A pain pump is a medical device that allows for continuous infusion of anesthetics into a specific part of the body during the days following an operation. (Decl. of Thomas B. Powers, Ex. 7 (Report of Dr. Stephen F. Badylak) at 2, July 19, 2012, Docket No. 180.)

anesthetics supplied by the pain pump after the first surgery caused chondrolysis, a painful and somewhat debilitating condition involving rapid cartilage degeneration. (*See* Decl. of Thomas B. Powers, Ex. 8 (Report of Dr. Robert Litchfield) at 11-12, July 19, 2012, Docket No. 180.)

II. REGULATORY HISTORY, DEVELOPMENT, AND MARKETING OF PAIN PUMPS

Stryker (and Stryker's predecessor, McKinley Medical) received 510(k) clearance[2] from the FDA to market pain pumps for certain uses. (Decl. of Jennifer Hoffman ¶ 3, June 28, 2012, Docket No. 176.) The pain pumps were cleared for "intraoperative" use. (*Id.*) However, the FDA denied McKinley Medical's attempt to modify the 510(k) clearance in 1998 by adding use in the "synovial cavity" – i.e., the intra-articular joint space – to the list of approved uses. (Powers Decl., Exs. 15-16.) The FDA reviewer explained that there was no predicate device that featured an indication for use in the synovial cavity and that the applicant needed to demonstrate that the different indication did not raise "new safety or effectiveness issues." (Powers Decl., Ex. 16.) Huggins alleges that the FDA rejected a similar attempt by Stryker in 2001 to obtain clearance for a specific indication for use in the synovial cavity. (*See* Powers Decl., Ex. 13 (Dep. of Nicole Petty and Robert F. Pomper) 98:19-99:3.)

[2] "Premarket notification," also referred to by its section number, 510(k), is a process that allows manufacturers to market new devices simply on the basis that a "substantially equivalent" device is already on the market. *See Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574-75 (6th Cir. 2012). The alternative is a more rigorous process called "premarket approval" that involves detailed analysis of a device's safety. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-78 (1996).

Huggins alleges that Stryker failed to conduct a review of the medical literature to assess the risks of continuous infusion of anesthetics into the intra-articular space prior to marketing pain pumps to orthopedic surgeons. (*See* Powers Decl., Ex. 4 (Dep. of Rodney D. Parker) 45:17-48:13.) Huggins also alleges that Stryker failed to conduct or commission safety tests that would identify whether intra-articular pain pump use posed a risk of cartilage damage. (*Id.* 43:5-46:9.)

Huggins has provided a variety of pieces of evidence regarding Stryker's marketing of pain pumps. For example, a surgeon who was a consultant to Stryker testified in a prior action that Stryker sales representatives communicated to surgeons that pain pumps could be used in the joint space. (Powers Decl., Ex. 30 (Dep. of Dr. Lonnie Paulos) 33:15-34:10.) Huggins' experts also summarize numerous internal documents from Stryker that discussed intra-articular pain pump use and discussed marketing pain pumps to orthopedic surgeons. (*See* Powers Decl., Ex. 12 (Report of Dr. Peggy Pence) at 54-58.) Further, in 2000, Stryker considered designing a pain pump that had two separate catheters, one of which was specifically intended for the joint space. (Powers Decl., Ex. 33 (filed under seal).)[3]

[3] As the Court will explain below, Stryker's interactions with the FDA and Stryker's alleged marketing of pain pumps for intra-articular use are relevant to whether Stryker should have known the risks associated with intra-articular pain pump use and whether it was foreseeable to Stryker that surgeons would pursue such use.

III. MEDICAL LITERATURE

The first peer reviewed article explicitly recognizing a potential causal link between pain pumps and chondrolysis appeared in July 2007. *See* Brent P. Hansen et al., *Postarthroscopic Glenohumeral Chondrolysis*, 35 Am. J. Sports Med. 1628 (2007). Stryker maintains that there is still uncertainty regarding the causes of chondrolysis. However, on the basis of a growing body of literature and case reports, the FDA issued a notice on November 13, 2009, that chondrolysis had been repeatedly reported in connection with intra-articular pain pump use and the FDA encouraged health care professionals to not use pain pumps "for continuous intra-articular infusion of local anesthetics after orthopedic surgery." (Powers Decl., Ex. 25.)

For purposes of the present case, the relevant question is not what is known about the risks of pain pumps today, but what was known about the risks of pain pumps at the time of Huggins' first surgery in February 2002. Huggins' primary evidence regarding the scope of scientific knowledge at the time of his surgery is provided by Drs. Stephen Badylak, Carl Basamania, and Peggy Pence. These experts review the scientific literature and opine that, prior to 2002, the literature was sufficient to put a medical device manufacturer on notice that continuous infusion of anesthetics over a period of multiple days into the intra-articular joint space could cause serious cartilage damage. (Badylak Report at 2-6; Powers Decl., Ex. 10 (Addendum to General Causation Report of Dr. Carl Basamania ("Basamania Addendum")) at 3-6; Pence Report at 59-61.)

Huggins' experts discuss the general anatomical and physiological properties of joint spaces and cartilage that were familiar to the scientific community prior to 2002.

(*See, e.g.*, Badylak Report at 2-4.) They explain that articular cartilage is fragile and that exposing it to any solution may damage it. (*See, e.g.*, Basamania Addendum at 5 ("[L]ong before the introduction of pain pumps to the market, the tenuous and delicate nature of cartilage and its intraarticular environment was well documented.").) The experts also discuss specific articles published between 1933 and 2002 that they contend demonstrated the risk of cartilage damage posed by continuous injection of anesthetics. (Badylak Report at 3-6; Basamania Addendum at 3-6; Pence Report at 59-61.) Many of the articles involved substances other than anesthetics, but the experts explain why each article is relevant to their conclusion. Generally speaking, the articles highlight the risks of exposing articular cartilage to foreign solutions and suggest that the risks increase as the length of exposure increases. The experts focus on the following articles[4]:

> (1) J. Albert Key, *The Production of Chronic Arthritis by the Injection of Weak Acids, Alkalies, Distilled Water, and Salt Solution in Joints*, 15 J. Bone & Joint Surgery 67 (1933). The Key study found that exposing rabbit joints to various water and saline solutions for an extended period of time, through multiple injections, damaged cartilage.
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> (2) Brian F. Reagan *et al.*, *Irrigation Solutions for Arthroscopy*, 65 J. Bone & Joint Surgery 629 (1983). The Reagan study analyzed different irrigating solutions for arthroscopic surgery and found that saline solutions harmed the metabolic process of cartilage cells. It also suggested that there "is probably little reason for concern" with respect to standard arthroscopy because "[t]he procedure takes fifteen to forty-five minutes" and "[s]upport of chondrocyte metabolism **during such a short exposure** . . . is probably not a crucial issue." *Id.* at 631 (emphasis added).

[4] Basamani relies on all eleven of the articles, Badylak discuss articles one through nine, and Pence discusses articles three, four, five, and seven.

(3) Roberta Nole *et al.*, *Bupivicaine and Saline Effects on Articular Cartilage*, 1 Arthroscopy 123 (1985) ("Nole"). The Nole study involved bupivacaine, the anesthetic that Dr. O'Connell used in Healey's pain pumps. The authors' state that "[b]upivacaine itself seems to be fairly well tolerated by articular cartilage." *Id.* at 126. However, the authors also note that "[c]onsidering the toxicity of bupivacaine to certain other cell types . . . , the possibility of long-term effects must be considered even though there is no clinical evidence of this as of yet" and also that "further studies should be made to find optimal ways of administering local anesthetics into human joints" because "adult human articular cartilage has no blood supply of its own and will be directly affected by whatever solution is injected into a joint." *Id.*

(4) John P. Fulkerson & Thomas F. Winters, Jr., *Articular Cartilage Response to Arthroscopic Surgery*, 2 Arthroscopy 184 (1986) ("Fulkerson"). The Fulkerson article is a literature review that found that bupivacaine had well documented toxic effects on a variety of tissues. However, the authors also stated that "[i]t appears that this effect on cartilage is transient."

(5) J. Neidel *et al.*, *Intra–Articular Injections and Articular Cartilage Metabolism*, 111 Archives of Orthopaedic and Trauma Surgery 237 (1992). The Neidel study found that repeated injections of a foreign solution into intra-articular cartilage "should be approached with caution," though single injections "probably do[] not cause permanent alterations." *Id.* at 240.

(6) J.S. Jurvelin *et al.*, *Effects of Different Irrigation Liquids and Times on Articular Cartilage*, 10 Arthroscopy 667 (1994). The Jurvelin study found that cartilage was softened after exposure to salt-based "Ringer's solution" for just a few hours.

(7) S.K. Bulstra *et al.*, *The Effect In Vitro of Irrigating Solutions on Intact Rat Articular Cartilage*, 76 J. Bone & Joint Surgery 468 (1994). The Bulstra study found that cartilage could be harmed by exposure to various irrigating solutions and stated that "we have clearly shown that all irrigating solutions inhibited the metabolism of healthy cartilage." *Id.* at 469.

(8) Kazuya Tamai *et al.*, *Chondrolysis of the Shoulder Following a "Color Test"-Assisted Rotator Cuff Repair—A Report of 2 Cases*, 68 Acta Orthopaedica Scandinavica 401 (1997). This case report identified a risk of chondrolysis when cartilage is exposed to a dye called "gentian violet."

(9) C.M. Douw *et al.*, *Clinical and Pathological Changes in the Knee After Accidental Chlorhexidine Irrigation During Arthroscopy*, 80 J. Bone & Joint Surgery 437 (1997). This case report identified a risk of chondrolysis when cartilage is exposed to chlorhexidine solution (an antiseptic).

(10) A.L. van Huyssteen & D.J. Bracey, *Chlorhexidine and Chondrolysis in the Knee*, 81 J. Bone & Joint Surgery 995 (1999). This case report documented the same risk as the Douw report.

(11) W. Leclair *et al.*, *Rapid Chondrolysis After an Intra-Articular Leak of Bone Cement in Treatment of a Benign Acetabular Subchondral Cyst: An Unusual Complication of Percutaneous Injection of Acrylic Cement*, 29 Skeletal Radiology 275 (May 2000). This case report identified a risk of chondrolysis when cartilage is exposed to methyl methacrylate (bone cement).

IV. RELATED CASES

The present case is one of many similar cases that have been filed across the country, including several in this district. *See Mack v. Stryker Corp.*, --- F. Supp. 2d ---, 2012 WL 3599458, at *6 (D. Minn. 2012) (compiling cases). While it is important to note that the specific evidence presented varies slightly from case-to-case and that the laws of each state are not identical, it is clear that results in both the district and circuit courts have been mixed. *See, e.g.*, *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 577 (6th Cir. 2012) (affirming grant of summary judgment); *Krumpelbeck v. Breg, Inc.*, No. 11-3762, 2012 WL 3241587, at *8 (6th Cir. Aug. 10, 2012) (reversing, in part, grant of summary judgment); *Phillippi v. Stryker Corp.*, 2:08-CV-02445, 2010 WL 2650596, at *3 (E.D. Cal. July 1, 2010) (granting summary judgment); *Hackett v. Breg, Inc.*, Civ. No. 10CV1437, 2011 WL 4550186, at *4 (D. Colo. Oct. 3, 2011) (denying summary judgment); *Kildow v. Breg, Inc.*, 796 F. Supp. 2d 1295, 1299-300 (D. Or. 2011) (denying

summary judgment). In this district's first case to reach summary judgment motions on the ground that the risks of intra-articular pain pump use were unforeseeable, the court granted summary judgment for the defendant. *See Mack*, 2012 WL 3599458, at *11.

ANALYSIS

I. MOTION TO TRANSFER

Before turning to Stryker's motion for summary judgment, the Court must address Huggins' motion to transfer the action to the District of Oregon. As the Court will explain, plaintiffs are not prohibited from bringing transfer motions despite having chosen the initial venue. *See Ferens v. John Deere Co.*, 494 U.S. 516, 529 (1990).

A. Standard of Review

Transfer under 28 U.S.C. § 1404(a)[5] is intended to "prevent the waste of time, energy and money and to protect litigants, witnesses and the public against unnecessary inconvenience and expense." *Van Dusen v. Barrack*, 376 U.S. 612, 616 (1964) (internal quotation marks omitted). "Section 1404(a) is intended to place discretion in the district court to adjudicate motions for transfer according to an individualized, case-by-case consideration of convenience and fairness." *Stewart Org., Inc. v. Ricoh Corp.*, 487 U.S. 22, 29 (1988). In determining whether to transfer an action pursuant to § 1404(a), courts must consider three general categories of factors: "(1) the convenience of the parties,

[5] Section 1404(a) provides that "[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought or to any district or division to which all parties have consented."

(2) the convenience of the witnesses, and (3) the interests of justice." *Terra Int'l, Inc. v. Miss. Chem. Corp.*, 119 F.3d 688, 691 (8th Cir. 1997). The analysis is not limited to these categories, however, and "courts have recognized that such determinations require a case-by-case evaluation of the particular circumstances at hand and a consideration of all relevant factors." *Id.*

"In general, federal courts give considerable deference to a plaintiff's choice of forum and thus the party seeking a transfer under section 1404(a) typically bears the burden of proving that a transfer is warranted." *Id.* at 695. Thus, courts in this district often require a movant to show that the balance of factors "strongly favors" transfer. *See, e.g., Brockman v. Sun Valley Resorts, Inc.*, 923 F. Supp. 1176, 1179 (D. Minn. 1996). On the other hand, the plaintiff's choice is entitled to less deference when the plaintiff is not a resident of the selected forum and when the underlying events giving rise to the action occurred outside the forum. *See Nelson v. Soo Line R. Co.*, 58 F. Supp. 2d 1023, 1026 (D. Minn. 1999). Based on that rule, Huggins' choice, Minnesota, would be entitled to significantly less deference because Huggins is an Oregon resident and the events occurred in Oregon.

Despite the rules outlined above, it is not entirely clear what burden Huggins should face on the instant motion to transfer. The rules above regarding deference to plaintiff's choice of forum developed in cases where the **defendant** sought to transfer the case. *See, e.g., Terra Int'l*, 119 F. 3d at 689-90; *see also Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir. 1995) ("[I]n ruling on defendants' motion the plaintiff's choice

of venue should not be lightly disturbed." (internal quotation marks omitted)). Those rules offer little guidance in the present case where the plaintiff moves to transfer.

Stryker suggests that Huggins is required to show changed circumstances in order to prevail on his motion to transfer because he chose the forum in the first instance.[6] Stryker is critical of Huggins for choosing the District of Minnesota in order to take advantage of Minnesota's statute of limitations and now moving to transfer the action back to Oregon while still enjoying Minnesota's statute of limitations.[7] However, in *Ferens*, the Supreme Court approved of these exact tactics. In *Ferens*, the plaintiffs brought certain claims in Pennsylvania (where the claims arose), but brought tort claims that would be time-barred by Pennsylvania's statute of limitations in Mississippi. 494 U.S. at 519-20. The plaintiffs then "took their forum shopping a step further" and moved to transfer the tort action to Pennsylvania on the basis of convenience. *Id.* at 520. The Supreme Court held that plaintiff's tactics were appropriate and that the law of the transferor court (*i.e.*, Mississippi's statute of limitations) would apply even though plaintiff brought the motion to transfer. The Court stated that:

> Some might think that a plaintiff should pay the price for choosing an inconvenient forum by being put to a choice of law versus forum. But this

[6] Some circuits require such a showing, but the Eighth Circuit has not adopted the rule. *See* 17 Moore's Fed. Prac. § 111.16[1] (Matthew Bender 3d ed.).

[7] *See Fleeger v. Wyeth*, 771 N.W.2d 524, 525 (Minn. 2009) (holding that even after the case is transferred, "[i]n a case commenced in Minnesota, . . . the Minnesota statute of limitations appl[ies] to the personal injury claims of a non-Minnesota resident against a defendant not a resident of Minnesota, where the events giving rise to the claims did not occur in Minnesota and took place before August 1, 2004").

> assumes that § 1404(a) is for the benefit only of the moving party. By the statute's own terms, it is not. Section 1404(a) also exists for the benefit of the witnesses and the interest of justice, which must include the convenience of the court. Litigation in an inconvenient forum does not harm the plaintiff alone.

Id. at 529. Under *Ferens*, it is clear that Plaintiffs are free to move to transfer even though they selected Minnesota to take advantage of its statute of limitations. The Eighth Circuit has not created a "changed circumstances" requirement for plaintiffs moving to transfer and it is not clear that a strict changed circumstances requirement would be consistent with *Ferens*.

That said, the Court recognizes that a plaintiff's motion to transfer raises concerns about forum shopping, judge shopping, and harassment of defendants. One commentator suggests that "to avoid harassment of defendants and to ensure the judicious use of Section 1404(a) transfers, it is appropriate that plaintiff be put to a higher burden of persuasion over defendant's objection." 17 Moore's Fed. Prac. § 111.16[1] (Matthew Bender 3d ed.); *see also Leiker v. Jarvis Prods. Corp.*, No. 90-1179-C, 1990 WL 112974, at *2 (D. Kan. July 10, 1990) ("If [plaintiff's subsequent choices for venue] were accorded the same favored status, a motion to transfer venue could become an unchecked tool for the plaintiff to shop among forums and between judges.").

In this case, the Court need not determine whether to apply a heightened burden to Huggins' motion to transfer. Based on the Court's weighing of the relevant factors below, the Court finds that the factors do not favor transferring the action and would deny Huggins' motion whether or not Huggins faced a heightened burden.

B. Weighing the Factors

1. Convenience of the Parties

The first factor to consider under § 1404(a) is the convenience of each venue for the parties. Huggins lives in Oregon and Stryker is based in Michigan. (Am. Compl. ¶¶ 4-5, 7, Dec. 22, 2010, Docket No. 103.) There is no doubt that Oregon would be more convenient for Huggins. On the other hand, Oregon would be somewhat less convenient for Stryker because Minnesota is closer to Michigan. The collective convenience of the parties weighs slightly in favor of transferring the present action, but granting the motion to transfer would also shift some inconvenience to the party resisting the motion, which counsels in favor of denying the motion. *See Nelson*, 58 F. Supp. 2d at 1027 ("Transfer should not be granted if the effect is simply to shift the inconvenience to the party resisting the transfer.") Thus, the Court finds that convenience of the parties is a neutral factor in the present case.

2. Convenience of the Witnesses

The second factor to consider under § 1404(a) is the convenience of each venue for witnesses. Huggins' surgery and subsequent health care all occurred in Oregon. Huggins asserts that he will call many witnesses who reside in Oregon, such as the surgeon, subsequent health care providers, and potentially Huggins' employer and a friend or family member. Stryker notes, however, that the surgeon, Dr. Benz, is the only Oregon-based witness Huggins identified in his Rule 26(a)(1)(A)(i) disclosures, *see* Fed. R. Civ. P. 26(a)(1)(A)(i), and in response to an interrogatory asking him to identify all

persons with knowledge of relevant facts. Huggins has also identified Dr. Frederick Matsen, who performed a later operation on Huggins, and is based in Seattle. Oregon would be substantially more convenient than Minnesota for witnesses based in Oregon and somewhat more convenient for witnesses based in Washington. On the other hand, relevant evidence and testimony will likely come from Michigan-based employees of Stryker, for whom Oregon will be slightly less convenient than Minnesota. The parties have not made arguments regarding the convenience of expert witnesses. On balance, the Court finds that the convenience of witnesses is a factor that weighs slightly in favor of transfer.

3. Interest of Justice

The final factor to consider under § 1404(a) is the interest of justice. In assessing the interest of justice, the Court considers "(1) judicial economy, (2) the plaintiff's choice of forum, (3) the comparative costs to the parties of litigating in each forum, (4) each party's ability to enforce a judgment, (5) obstacles to a fair trial, (6) conflict of law issues, and (7) the advantages of having a local court determine questions of local law." *Terra Int'l*, 119 F.3d at 696. Some courts treat the interest of justice as the most important factor in the analysis. *See, e.g.*, *Farm Boy Co-Op & Feed Co. v. Red River Clothing, Inc.*, Civ. No. 09-2936, 2010 WL 935747, at *3 (D. Minn. Mar. 12, 2010).

Several of these factors require little discussion here. The Court considered the relevance of Huggins' choice of forum above. Each party's ability to enforce a judgment, obstacles to a fair trial, and conflict of law issues appear to have no significance here.

The Court is also not strongly influenced by the comparative costs of litigating in either forum. Stryker contends that litigating in Oregon will be more costly because it and its witnesses will face additional travel expenses. However, the additional expenses would not be dramatic because Stryker and its employees will have to travel out of state whether or not the case is transferred. Huggins does not discuss costs in detail, but the Court has considered that litigating in Oregon would reduce travel expenses for Huggins and for any fact witnesses based in Oregon. On balance, the Court is not convinced that litigating in one forum would be dramatically costlier than the other.

The remaining considerations cut significantly in favor of denying the motion to transfer. As for judicial economy, the Court has already held a hearing on Stryker's motion for summary judgment and motion to exclude expert testimony. Although the District of Oregon is well-equipped to efficiently handle another pain pump case due to its familiarity with the issues, the Court is familiar with the specific facts of the present case. The Court finds that judicial economy is better served by the Court ruling on Stryker's dispositive motion and moving the action toward resolution than by transferring the action and perhaps forcing the parties to endure delays before receiving a ruling on their dispositive motions.

The final consideration is the advantages of having a local court decide questions of local law. The action will be governed by Minnesota's statute of limitations regardless of the Court's resolution of the motion to transfer, and the parties strongly disagree about

whether Huggins' claims are timely under Minnesota law.[8] Although the District of Oregon is capable of applying Minnesota's statute of limitations, the Eighth Circuit has suggested that it is preferable for local courts to determine issues of local law. *See Terra Int'l*, 119 F.3d at 696. Thus, this factor favors denying the motion to transfer.

Having considered the § 1404(a) factors as well as other relevant factors, the Court finds that Huggins has not demonstrated that transferring this action is warranted. Although Oregon would be more convenient for Huggins, it would be less convenient for Stryker. While convenience of the witnesses slightly favors transferring the action to Oregon, the interests of justice favor denying the motion to transfer because judicial economy will be better served and because it will allow this Court to decide unclear issues of local law.[9]

[8] Minnesota's "borrowing" statute, which provides that another state's statute of limitations applies if that state's substantive law governs, expressly does not apply to claims arising from incidents that occurred prior to August 1, 2004. *See* Minn. Stat. §§ 541.31 & .34. Therefore, Minnesota's statutes of limitations applies regardless of whether Minnesota substantive law will govern the action. *See Fleeger*, 771 N.W.2d at 528-29. Additionally, neither party argues that the action should be governed by Oregon substantive law.

[9] Huggins focuses on the fact that Stryker joined in a motion to transfer a separate pain pump case from Minnesota to Oregon. The Court recognizes that various strategic considerations may be behind Stryker's opposition to the motion to transfer in the present case and sees nothing inappropriate in Stryker apparently taking a different position about where it prefers to defend against pain pump actions.

II. MOTION FOR SUMMARY JUDGMENT

A. Standard of Review

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party can demonstrate that it 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 lead a reasonable jury to return a verdict for either party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A court considering a motion for summary judgment must view the facts in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences that can be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

B. Statute of Limitations

Before addressing the merits of the parties' dispute, the Court must determine whether Huggins' claims are barred by the applicable statute of limitations. Minnesota's statute of limitations for negligence actions is six years, Minn. Stat. § 541.05, subd. 1(5), and Huggins commenced the present action in May 2009, more than six years after his February 2002 surgery. However, Huggins contends that he had no evidence of the causal connection between Stryker's pain pump and his shoulder damage until several years after his surgery.[10] The parties dispute whether, under the applicable Minnesota

[10] As noted above, the first peer reviewed article recognizing a potential causal link between pain pumps and chondrolysis appeared in July 2007.

laws, Huggins' cause of action accrued at the time when his injury occurred or at the time when he had evidence of a causal connection between the injury and Stryker's conduct.

Federal courts applying Minnesota law have concluded that Minnesota applies a "discovery rule" in products liability actions, which mean that a cause of action does not accrue until two elements are satisfied: "(1) a cognizable physical manifestation of the disease or injury, and (2) evidence of a causal connection between the injury or disease and the defendant's product, act, or omission." *See Hildebrandt v. Allied Corp.*, 839 F.2d 396, 398 (8th Cir. 1987); *see also Mack v. Stryker Corp.*, Civ. No. 10-2993, 2010 WL 4386898, at *2 (D. Minn. Oct. 28, 2010). Were these the only relevant authorities, the issue would easily be resolved in Huggins' favor. But caselaw from Minnesota makes the issue less clear. Minnesota courts have not cited *Hildebrandt*, and there appears to be some tension in Minnesota law regarding the question at hand.

On the one hand, Minnesota courts have held on a number of occasions that "ignorance of a cause of action does not toll the running of the statutory limitations period," including in product liability cases. *See, e.g.*, *MacRae v. Grp. Health Plan, Inc.*, 753 N.W.2d 711, 719 (Minn. 2008); *Dalton v. Dow Chem. Co.*, 158 N.W.2d 580, 584 (Minn. 1968). And Minnesota courts have rejected a discovery rule in cases where the issue is whether the plaintiff must have knowledge of his or her injury before the cause of action accrues. In *MacRae*, the Minnesota Supreme Court explained:

> Amicus curiae . . . suggests that our rules governing the accrual of a cause of action 'require[ ] that plaintiff have a meaningful opportunity to have knowledge of the facts upon which the claim is based and that accrual cannot occur until all the elements of the cause of action can be established.' . . . This language implies a 'discovery' rule of accrual, which

> we have consistently declined to adopt. We again reject such a rule today and emphasize that the relevant inquiry is not when the plaintiff has knowledge of damage caused by the misdiagnosis of cancer, but rather when such damage occurs within the patient's body.

MacRae, 753 N.W.2d at 722 n.8 (internal citations and emphases omitted). *MacRae* dictates that the limitations period begins to run when a compensable injury exists, not when the plaintiff discovers, or has the opportunity to discover, the injury.

On the other hand, the Minnesota Supreme Court has suggested in a products liability action that a cause of action will not accrue until the plaintiff has some evidence of causation, though the evidence need not be definitive. In *Dalton*, the Court stated:

> The record indicates that plaintiff was totally disabled, surgery was performed, diagnosis was made, testing of chemicals was performed, **and a discussion of the possibility of the chemicals as causative agents in plaintiff's disability was accomplished**, all of this more than 6 years prior to the commencement of the common-law action. Plaintiff admitted in his deposition that he had discussed with his attorney the possibility of bringing a lawsuit against the manufacturers and distributors of the chemicals as early as the summer of 1958. **Plaintiff asserts . . . that he must positively know of, not suspect, the causal relationship before the action he commenced accrues.** The subjective determination of the accrual of his cause of action contended for by plaintiff is obviously without support in our decisions.

Dalton, 158 N.W.2d at 585 (emphases added). While it does not do so explicitly, *Dalton* appears to hold that the limitations period will not run if the plaintiff at least has evidence allowing him or her to suspect a causal relationship.[11]

[11] Yet, *Dalton* also held that "ignorance of a cause of action not involving continuing negligence or trespass, or fraud on the part of the defendant, does not toll the accrual of a cause of action[]," which is somewhat difficult to square with its discussion of a plaintiff's knowledge of causation. *See id.* at 584.

This district recently confronted the exact issue facing the Court today in another pain pump case. *See Mack*, 2010 WL 4386898, at *2. The *Mack* court analyzed Minnesota law and held that the rule from *Hildebrandt* would apply because it found no indication that Minnesota courts disagree with *Hildebrandt*'s explicit holding. *Id.* ("[I]t appears that, for products liability claims in Minnesota, the discovery rule applies."). Because *Hildebrandt* has not been repudiated by Minnesota courts and because *Dalton*, a product liability case, suggested that a plaintiff's knowledge of causation is relevant to the running of the limitations period, the Court will apply *Hildebrandt*'s rule in the present case. Thus, Huggins' cause of action did not accrue until there was some "evidence of a causal connection between the injury or disease and the defendant's product, act, or omission" such that Huggins "knew or should have known . . . the causal relationship." *See Hildebrandt*, 839 F.2d at 398-99. Because the first article recognizing a potential causal link between pain pumps and chondrolysis did not appear until 2007 and the FDA did not issue a notice on the topic until 2009, a jury could reasonably find that Huggins did not know, nor should he have known, of the causal connection between his injury and Stryker's conduct until well within six years of the time he filed.[12]

[12] Huggins argued, in the alternative, that the statute of limitations should be tolled due to Stryker's alleged fraudulent concealment of information essential to his cause of action. Having decided that Huggins' claim survives summary judgment on the statute of limitations issue for the reasons above, the Court need not reach this argument.

C. Stryker's Substantive Challenges to Huggins' Claims

Other than the statute of limitations argument, Stryker's sole challenge to Huggins' claim at this stage is that the risks associated with intra-articular pain pump use were unforeseeable and Stryker, therefore, cannot be liable for failing to warn of such risks. Huggins' response goes beyond the foreseeability issue and discusses other elements of his various claims. For the purposes of this motion only, the Court will limit its discussion to those grounds on which Stryker moved for summary judgment.

1. Duty to Warn

Broadly speaking, a failure to warn claim has three elements: "(1) whether there exists a duty to warn about the risk in question; (2) whether the warning given was inadequate; and (3) whether the lack of a warning was a cause of plaintiff's injuries." *Seefeld v. Crown, Cork & Seal Co.*, 779 F. Supp. 461, 464 (D. Minn. 1991) (citing *Balder v. Haley*, 399 N.W.2d 77, 81 (Minn. 1987)). As noted above, at this stage, Stryker focuses exclusively on the first element – duty.

i. Applicable Legal Standards

A manufacturer has a duty to provide warnings of foreseeable risks. *See Germann v. F.L. Smithe Mach. Co.*, 395 N.W.2d 922, 924 (Minn. 1986). That is, if a manufacturer "knew **or should have**" known of a risk, then there is a duty to warn. *Id.* (emphasis added). "[W]hether a legal duty to warn exists is a question of law for the Court – not one for jury resolution." *Id.* However, "[i]n close cases, the issue of foreseeability

should be submitted to the jury." *Domagala v. Rolland*, 805 N.W.2d 14, 27 (Minn. 2011).

The center of the parties' dispute in the present case is whether the risks associated with intra-articular pain pump use were foreseeable. Courts across the country have confronted this issue with inconsistent results. *See, e.g.*, *Rodriguez*, 680 F.3d at 577 (affirming grant of summary judgment); *Krumpelbeck*, 2012 WL 3241587, at *8 (reversing, in part, grant of summary judgment); *Phillippi*, 2010 WL 2650596, at *3 (granting summary judgment); *Hackett*, 2011 WL 4550186, at *4 (denying summary judgment); *Kildow*, 796 F. Supp. 2d at 1299-300 (denying summary judgment). In those cases that reached a jury, multiple juries have found that the risks were foreseeable. *See, e.g.*, Final Judgment, *Hackett v. Breg, Inc.*, Civ. No. 10-1437 (D. Colo. Nov. 22, 2011); *Beale v. I-Flow Corp.*, No. 0801-01554 (Ore. Cir. Ct., Multnomah Cnty. Dist. Jan. 22, 2010). Having considered these results and the evidence presented, the Court finds that this case is a "close case" where the jury should decide the issue of foreseeability. *See Domagala*, 805 N.W.2d at 27. As the Court will now explain, construing the evidence in the light most favorable to Huggins and drawing all reasonable inferences in Huggins' favor, the Court will find that a reasonable jury could find that Stryker should have known that intra-articular pain pump use could cause cartilage damage.

Under Minnesota law, manufacturers are subject to certain specific duties that bear on the issue of what risks are foreseeable and, therefore, bear on whether a manufacturer has a duty to warn of a particular risk. For example, "[a] manufacturer is held to the skill of an expert in its particular field of endeavor, and is obligated to keep informed of

scientific knowledge and discoveries concerning that field." *Karjala v. Johns-Manville Prods. Corp.*, 523 F.2d 155, 159 (8th Cir. 1975) (internal quotation marks omitted).[13] Additionally, Minnesota courts have recognized that manufacturers may have a duty to test the safety of their products that can bear on what warnings are required. *See Willmar Poultry*, 378 N.W.2d at 836.[14]

Failure to test is not an independent cause of action under Minnesota law, but manufacturers' "duty to test their products . . . to discover defects or dangers associated with use of the products . . . is a subpart of duties to design a product non-negligently, manufacture a product non-negligently, and provide adequate warnings of dangers associated with its use."[15] *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527-28 (Minn. Ct. App. 1989). Thus, if a manufacturer fails to provide a warning of a particular risk and reasonable testing would have made the manufacturer aware of that risk, the

[13] *See also Harmon Contract Glazing, Inc. v. Libby-Owens-Ford Co.*, 493 N.W.2d 146, 151 (Minn. Ct. App. 1992) ("A manufacturer's added responsibility of keeping informed of current scientific knowledge is relevant to whether a manufacturer knew or should have known of the risks in its product."); *Willmar Poultry Co. v. Carus Chem. Co.*, 378 N.W.2d 830, 837 (Minn. Ct. App. 1985) ("Both a manufacturer's duty to be informed of current scientific knowledge and a manufacturer's duty to exercise reasonable care and foresight to discover a danger in his product is relevant to whether a manufacturer knew or should have known of the risks in its product.").

[14] *See also O'Hare v. Merck & Co.*, 381 F.2d 286, 290-91 (8th Cir. 1967) ("[A] manufacturer's duty to additionally test and investigate the propensities of its product is dependent upon the foreseeable risk of harm to potential users in light of current scientific or medical knowledge and discoveries. A manufacturer is held to the skill of an expert in its particular field of endeavor, and is obligated to keep informed of scientific knowledge and discoveries concerning that field.").

[15] For this reason, paragraph 18(h) of the amended complaint overreaches. Stryker's alleged failure to test does not, in and of itself, give rise to a claim for negligence.

manufacturer may be liable for failure to warn. *See id.* at 1527 ("Once the manufacturer has discovered a defect or danger the manufacturer should . . . warn consumers of the danger."). The same is true of a manufacturer's duty to keep informed of scientific knowledge in its field. Failure to review scientific literature is not an independent cause of action. *Cf. id.* ("[U]nless the manufacturer's breach of its duty to test leads the manufacturer to produce a product that is defective in design, manufacture, or warning, no injury can result."). But if a manufacturer fails to provide a warning of a particular risk and a reasonable review of the scientific literature would have made the manufacturer aware of that risk, liability may follow. *See Karjala*, 523 F.2d at 159 (holding that a manufacturer may "be held liable for failing to warn if, while held to the 'knowledge and skill of an expert,' it did not disclose to the public those dangers inherent in its product 'that the application of reasonable foresight would reveal'").

ii. Application

Stryker acknowledges that Minnesota law imposes on manufacturers the duties outlined above, but nonetheless contends that the risk in question in the present case was unforeseeable. Stryker focuses on *O'Hare v. Merck & Co.*, in which the Eighth Circuit held that "[t]he manufacturer's duty to warn users of the potential danger inherent in its product is commensurate with its actual knowledge of the risk involved to those users or the knowledge constructively imparted to it by available scientific or other medical data."

381 F.2d 286, 291 (8th Cir. 1967).[16] Stryker reads *O'Hare* as holding that the duty to warn extends only to specific risks that were explicitly identified in the medical literature. Because the medical literature as of February 2002 did not explicitly articulate a connection between pain pumps and chondrolysis, Stryker contends that it had no duty to provide such a warning.

There are two problems with Stryker's argument. First, the question is not whether the specific risk of chondrolysis was foreseeable. Several courts have rejected the argument that the exact risk, chondrolysis, must have been foreseeable in order for pain pump manufacturers to face liability. *See, e.g.*, *Mack*, 2012 WL 3599458, at *8 n.6; *Schoenborn v. Stryker Corp.*, 801 F. Supp. 2d 1098, 1102 (D. Or. 2011). Under Minnesota law, "[a] manufacturer has a duty to warn of dangers where it knew or should have known of the risk or hazard involved." *Harmon*, 493 N.W.2d at 151. Crucially, "[t]he test is not whether the precise nature and manner of the plaintiff's injury was foreseeable, but whether the possibility of an accident was clear to the person of ordinary

[16] Stryker also points to Minnesota's civil jury instructions, which provide that "[a] manufacturer's duty to provide reasonably adequate (warnings) (instructions) must be judged according to the **scientific knowledge and advances that existed at the time** the product was designed." 4A Minn. Prac., Jury Instr. Guides – Civil 75.25 (5th ed. 2012) (emphasis added). As the instruction indicates, Stryker will be judged according to the scientific knowledge that existed at the time and not on the basis of later discoveries. It is Huggins' claim that the scientific knowledge that existed at the time, while not specifically indicating that intra-articular pain pump use could cause chondrolysis, was sufficient to put Stryker on notice that intra-articular pain pump use could cause cartilage damage.

prudence." *Domagala*, 805 N.W.2d at 27 (internal quotation marks omitted).[17] Here, as other courts have found, the Court finds that cartilage damage qualifies as a "danger" that could require a warning. Huggins need not establish that Stryker should have known that intra-articular pain pump use could cause chondrolysis because "[t]he test is not whether the **precise nature** . . . of the plaintiff's injury was foreseeable." *Id.* (emphasis added). Rather, if the evidence establishes that Stryker should have known intra-articular pain pump use posed a risk of cartilage damage, it is sufficient to give rise to a duty to warn.

Second, Stryker's attempt to limit its duty to warn to risks that are explicitly identified in the literature at the time is contrary to the flexible nature of the manufacturer's duty to warn of risks "which it could discover through the exercise of reasonable care." *See O'Hare*, 381 F.2d at 291. It also ignores the manufacturer's duty to test. In certain cases, "reasonable care" might require a manufacturer to extrapolate from existing medical literature or conduct tests to discover potential risks when the medical literature contains clues or red flags that the manufacturer's desired course of action is dangerous. *See Karjala*, 523 F.2d at 158 ("A manufacturer has a duty to test and inspect his products, and the extent of such research and experiment must be commensurate with the dangers involved."). The Court will not endorse a rule that

[17] Stryker focuses on the Minnesota Supreme Court's statement that "[i]n determining whether a danger is foreseeable, courts look at whether the specific danger was objectively reasonable to expect, not simply whether it was within the realm of any conceivable possibility." *See Whiteford by Whiteford v. Yamaha Motor Corp., U.S.A.*, 582 N.W.2d 916, 918 (Minn. 1998). The Court's decision – that the specific risk of **chondrolysis** need not have been foreseeable – is consistent with the Minnesota Supreme Court's holding because cartilage damage is a sufficiently specific danger to potentially require a warning.

"reasonable care" never requires manufacturers to identify a risk that has not already been explicitly identified in the medical literature.[18]

Turning to the evidence presented in this case, Huggins relies largely on his experts' opinions that the medical literature existing prior to Huggins' surgery was sufficient to put a manufacturer on notice that continuously injecting anesthetic into the intra-articular joint space for several days could cause serious cartilage damage. While no single article or study presented exactly this conclusion, Huggins' experts opine that a number of studies are relevant by analogy and would have presented clear red flags to Stryker. After considering the state of the literature and what was known generally about the anatomy of cartilage and joint spaces, Huggins' experts conclude that a manufacturer who conducted a thorough literature review prior to the time of Huggins' surgery would have known that intra-articular pain pump use could cause serious cartilage damage.

Additionally, Huggins has presented evidence that Stryker did not conduct or commission tests to determine the risks of post-operative continuous infusion of anesthetic into the intra-articular space. Huggins' experts opine that such testing was feasible prior to Huggins' surgeries and would likely have revealed that using a pain

[18] The Court notes that such a rule would be particularly unsatisfactory in the present case, where one reason the medical literature had not explicitly identified the risk at issue is that no one had contemplated using pain pumps for continuous, post-operative infusion of anesthetic into the intra-articular space until several medical device manufacturers began allegedly marketing pain pumps for such use. The extent to which a manufacturer must review scientific literature and conduct tests to discover potential risks that are not explicitly identified in the literature will vary from case to case. The novelty of the manufacturer's desired course of conduct is one of many factors that may bear on what amount of literature review and testing satisfies the "reasonable care" requirement.

pump to continuously infuse anesthetics into the intra-articular space could cause serious cartilage damage. (*See, e.g.*, Badylak Report at 4.)

The experts' conclusions regarding the scientific literature and the feasibility of safety testing are significant in light of the manufacturer's duties to keep abreast of scientific literature and conduct reasonable safety testing. The evidence could allow a jury to reasonably find that Stryker would have been aware of the risk of cartilage damage presented by intra-articular pain pump use if the company had exercised reasonable care in complying with those duties.

Huggins has also presented evidence that FDA reviewers repeatedly denied the efforts of Stryker (and Stryker's predecessor) to obtain 510(k) clearance to include use in the synovial space (i.e., the intra-articular space) on pain pump labels. During this process, an FDA reviewer informed Stryker that additional information would be needed to assess the safety of this use. Some courts have recognized that the simple denial of 510(k) clearance, without more, does not necessarily mean that a device is unsafe or that a manufacturer should know it poses certain risks.[19] But Huggins does not rely solely on the fact that the FDA denied Stryker's 510(k) applications. Huggins has presented evidence in this case that the FDA reviewer told Stryker as part of the denial that the safety of pain pumps for use in the synovial space was not established and Huggins has

[19] *See, e.g.*, *Rodriguez*, 680 F.3d at 574 ("The FDA's action means only that no other device on the market carried that indication for use. It does not mean that the pump was (or might potentially be) dangerous to use in the joint space."); *Forslund v. Stryker Corp.*, Civ. No. 09-2134, 2010 WL 3905854, at *4 n.5 (D. Minn. Sept. 30, 2010).

also presented evidence regarding Stryker's alleged marketing of pain pumps for intra-articular use following these denials.

Huggins' evidence regarding Stryker's interactions with the FDA and subsequent marketing is relevant as part of a body of evidence, including the available scientific literature and the feasibility of safety testing, that sheds light on what risks a jury could reasonably find that Stryker should have discovered. "The manufacturer is held accountable as an expert in its field only for those dangers of which it has knowledge or those which it could discover through the exercise of reasonable care." *O'Hare*, 381 F.2d at 291. What constitutes "reasonable care" depends on the surrounding circumstances. *See Bilotta v. Kelley Co.*, 346 N.W.2d 612, 621 (Minn. 1984). Here, those circumstances include Stryker's interactions with the FDA and its marketing strategies.

Considering all of the evidence in the light most favorable to Huggins, the Court finds that a genuine issue of material fact remains as to whether Stryker should have known the risks of intra-articular pain pump use. In light of a manufacturer's duties to keep abreast of scientific knowledge and conduct reasonable safety testing, and in light of the evidence Huggins' has presented regarding the scientific literature, the feasibility of safety testing, Stryker's interactions with the FDA, and Stryker's marketing, a jury could reasonably find by a preponderance of the evidence that Stryker should have known the risks of intra-articular pain pump use. If the jury finds that Stryker should have known

these risks, it follows that Stryker had a duty to provide a warning of these risks.[20] Therefore, the Court will deny Stryker's motion for summary judgment.

III. MOTIONS TO EXCLUDE EXPERT TESTIMONY

Having resolved Stryker's motion for summary judgment, the Court will now address Stryker's motion to exclude various aspects of the proposed testimony of Huggins' expert witnesses.

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[20] Huggins contends that Stryker also had a duty to warn surgeons that it had not determined the safety of intra-articular pain pump use and also that the FDA had denied clearance for intra-articular pain pump use. (*See* Am. Compl. ¶ 18(a) & (e); Pl.'s Memo. in Opp. at 32.) The Court concludes that the manufacturer's duty to warn does not extend this far. "A manufacturer has a duty to warn of dangers where it knew or should have known of the risk or hazard involved." *Harmon*, 493 N.W.2d at 151. The relevant danger in the present case is cartilage damage. Stryker's alleged failure to review literature and conduct safety testing is relevant to whether Stryker should have known this danger existed, but it is not, in and of itself, a "danger" that gives rise to a duty to warn. *See Kociemba*, 707 F. Supp. at 1527 ("[U]nless the manufacturer's breach of its duty to test leads the manufacturer to produce a product that is defective in . . . warning, no injury can result."). The same is true of the lack of FDA approval. While Stryker's interactions with the FDA may bear on whether Stryker should have known certain risks existed, the lack of FDA approval is not, in and of itself, a risk requiring a warning. *See Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1152-53 (D. Minn. 2011) (holding that the duty to warn does not encompass informing surgeons about a lack of FDA approval).

The Court also notes that none of Huggins' claims may hinge on the assertion that Stryker violated federal law. A claim that Stryker is liable in tort **because** it violated federal law is subject to implied preemption. *See Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 352-53 (2001). Huggins' amended complaint alleges that Stryker was negligent for "[p]romoting the pain pumps for use in the joint space after the FDA had considered and rejected such an indication." (Am. Compl. ¶ 18(I).) This allegation runs afoul of *Buckman* and will not be allowed. The conduct that Huggins alleges amounted to a breach of duties under state tort law may also happen to amount to a violation of federal law, but in order for Huggins to recover, he must rely on "traditional state tort law which . . . predated the federal enactments in question." *See id.* at 353.

A. Standard of Review

Under Federal Rule of Evidence 702, expert testimony must satisfy three prerequisites to be admitted:

> First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires . . . .

Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001) (citations and internal quotation marks omitted). The district court has a gate keeping obligation to make certain that all testimony admitted under Rule 702 satisfies these prerequisites and that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). The proponent of the expert testimony has the burden of establishing by a preponderance of the evidence that the expert is qualified, that his methodology is scientifically valid, and that "the reasoning or methodology in question is applied properly to the facts in issue." *Marmo v. Tyson Fresh Meats, Inc*., 457 F.3d 748, 758 (8th Cir. 2006).

The Supreme Court in *Daubert* outlined particular factors for courts to consider in assessing reliability, such as (1) whether the opinion is based on scientific knowledge, is susceptible to testing, and has been tested; (2) whether the opinion has been subjected to peer review; (3) whether there is a known or potential rate of error associated with the methodology; and (4) whether the theory has been generally accepted by the scientific community. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149-50 (1999)

(summarizing *Daubert* factors). However, in *Kumho Tire*, the Court explained that "the test of reliability is 'flexible,' and *Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts or in every case. Rather, the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." *Id.* at 141-42. The reliability inquiry is designed to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Marmo*, 457 F.3d at 757 (quoting *Kumho Tire*, 526 U.S. at 152).

"Courts should resolve doubts regarding the usefulness of an expert's testimony in favor of admissibility." *Id.* at 758; *see also Kumho Tire*, 526 U.S. at 152 ("[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable."). "Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001) (quoting *Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1996)).

B. Discussion

Stryker challenges the proposed testimony of three of Huggins' experts – Drs. Stephen Badylak, Carl Basamania, and Peggy Pence – on several grounds. Stryker claims that (1) Drs. Badylak and Basamania are not qualified to opine on what a reasonably prudent medical device manufacturer should have done or known; (2) the

experts' opinions about the medical literature prior to 2002 are unreliable because they misinterpret certain articles, ignore others, and draw a conclusion that is not present in the literature; (3) the experts' opinions about the medical literature prior to 2002 are irrelevant because the experts do not opine that the medical literature contained any indication that there was a risk of chondrolysis, specifically; and (4) testimony regarding the results that safety testing would have produced is too speculative to be admissible. For the reasons explained below, the Court will deny Stryker's motion.[21]

1. Qualifications of Drs. Badylak and Basamania

Dr. Badylak is a doctor and a professor who specializes in the study of musculoskeletal tissues. (Badylak Report at 1.) He specializes in tissue engineering and regenerative medicine. (*Id.*) He has conducted studies relating to cartilage, and he has experience with the FDA's investigation and approval process of medical devices. (*Id.*) Dr. Badylak opines that "[t]here existed in the literature, multiple peer reviewed medical articles during or prior to 2000, and any reasonably prudent search of the peer reviewed medical literature by a medical device manufacturer would have found multiple articles that at a minimum would have raised a red flag if not an alarm concerning the placement of foreign substances in contact with articular cartilage and the potential for a negative effect upon the health of articular cartilage." (*Id.* at 4.)

[21] As with Stryker's motion for summary judgment, the Court will address only the issues raised by Stryker and leave for later resolution other potential challenges to the testimony of Huggins' experts.

Dr. Basamania is an accomplished orthopedic surgeon. (*Id.*, Ex. 2.) Like Dr. Badylak, he opines that "[h]ad any prudent medical device manufacturer conducted even a basic search of the medical literature, they would have found multiple articles that would have suggested that any alteration, dilution or disruption of normal synovial fluid could be harmful to the health of articular cartilage." (*Id.*, Ex. 3 (Addendum to General Causation Report of Dr. Carl Basamania ("Basamania Addendum")) at 3.)

Stryker argues that Drs. Badylak and Basamania are not qualified to opine on what a reasonably prudent pain pump manufacturer should have done or known. At least one district court accepted a similar argument regarding the same two doctors and held that "[t]he proper duty of care exercised by a 'prudent, careful' pain pump manufacturer is beyond the scope of their expertise." *McClellan v I-Flow*, 710 F. Supp. 2d 1092, 1127 n.28 (D. Or. Apr. 29, 2010).

Huggins does not respond to Stryker's specific argument that Drs. Badylak and Basamania are unqualified to opine on what a reasonably prudent medical device manufacturer should have done or known. As was the *McClellan* court, the Court is somewhat skeptical that these doctors possess expertise on the customs and standards within the medical device manufacturing industry, but for the reasons explained below the Court will deny Stryker's motion at this stage.

The core opinion of Drs. Badylak and Basamania is their conclusion that the medical literature that existed prior to 2002 would have put a manufacturer on notice that intra-articular pain pump use could cause cartilage damage. Drs. Badylak and Basamania also opine on general causation. The Court finds that both doctors are qualified to review

medical literature within their field, opine on what red flags are contained within the literature, and opine on how those red flags relate to intra-articular pain pump use. The Court also finds that they are qualified to opine on general causation based on their knowledge of the literature and their experience in the field.

Although Dr. Badylak refers to a "reasonably prudent search of the peer reviewed medical literature" and Dr. Basamania refers to a "prudent medical device manufacturer," neither expert appears to actually opine on what standards of care apply to medical device manufacturers, what medical device manufacturers **should** do, or what medical device manufacturers **should** know. Rather, their opinion regarding the medical literature is simply that **if** a manufacturer had conducted a review of the literature at the time of Huggins' surgery, the manufacturer **would** have been put on notice that intra-articular pain pump use could cause cartilage damage. Because it does not appear that Drs. Badylak and Basamania actually intend to opine on the standards of care applicable to medical device manufacturers, the Court will deny this aspect of Stryker's motion.[22]

2. Reliability and Relevance of the Experts' Conclusions Regarding the Literature

As an initial matter, there does not seem to be a real dispute about the legitimacy of the experts' "methodology," which is to review the medical literature and draw a conclusion about what teachings or red flags were contained within the literature. *See*

[22] If, at a later stage, either expert does in fact attempt to offer opinions regarding the standards of care applicable to medical device manufacturers, the Court will entertain objections on the basis of their qualifications or other grounds at that time.

Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) ("Trained experts commonly extrapolate from existing data."). Stryker's arguments relate to the reliability of the experts' applications of their methodology and to the relevance of their conclusions. Stryker argues that Huggins' experts extrapolate a conclusion from the literature that is visible only with the benefit of hindsight, that some of the sources they cite contradict their conclusions, and that they ignore sources that undermine their conclusions.

With respect to the reliability, a difference of opinion regarding an expert's conclusions is usually a topic for cross-examination and competing testimony, not a reason to exclude testimony. *See Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."). However, there are limits to this principle. Expert opinions drawn from existing data are inadmissible if "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 552 U.S. at 146.

Taking into account what was known generally about the fragility of intra-articular cartilage at the time, Huggins' experts claim that the existing literature would have raised a red flag to a manufacturer considering marketing pain pumps to orthopedic surgeons for intra-articular use because the literature demonstrated that exposing intra-articular cartilage to any foreign substance could cause cartilage damage, and that the risks increased as the length of exposure increased.[23] The Court finds that the "analytical gap"

[23] As the Court explained above, if the evidence establishes that Stryker should have known that intra-articular pain pump use posed a risk of cartilage damage, it is sufficient to give

(Footnote continued on next page.)

between the articles on which the experts rely and the experts' conclusion is not so great that the opinions are inadmissible.[24] *See Joiner*, 552 U.S. at 146.

Stryker claims that the Nole article and the Fulkerson article both undermine rather than support the experts' conclusions. While the two articles are subject to various interpretations, the Court finds that the interpretation offered by Huggins' experts is sufficiently reliable. The Nole article provided that "[b]upivacaine itself seems to be fairly well tolerated by articular cartilage," (Nole at 126), but the authors noted that "[c]onsidering the toxicity of bupivacaine to certain other cell types . . . , the possibility of long-term effects must be considered even though there is no clinical evidence of this as of yet" and also that "further studies should be made to find optimal ways of administering local anesthetics into human joints" because "adult human articular cartilage has no blood supply of its own and will be directly affected by whatever solution is injected into a joint," (*id.*). The Fulkerson article explained that bupivacaine has an impact on cartilage that **appeared** to be transient. (Fulkerson at 186.) Although Stryker's experts may offer different interpretations of what clues the scientific literature presented regarding potential consequences of intra-articular pain pump use, the Court finds that Huggins' experts' conclusions regarding the scientific literature are not "so

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(Footnote continued.)

rise to a duty to warn. Therefore, the experts' opinions regarding the literature are relevant and satisfy *Daubert*'s "fit" requirement. *See Daubert*, 509 U.S. at 591.

[24] It is possible that the analytical gap might be too great if Huggins' experts had opined that the literature taught that intra-articular pain pump use could cause chondrolysis specifically, but they make a more general claim.

fundamentally unsupported that [they] can offer no assistance to the jury[.]" *See Bonner*, 259 F.3d at 929-30 (quoting *Hose*, 70 F.3d at 974).

Stryker also points to three publications that Stryker claims contradict the experts' conclusions, which the experts did not analyze. It is possible for an experts' omission of articles to render his or her opinion inadmissible on reliability grounds,[25] but "'[a]s a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination.'" *Bonner*, 259 F.3d at 929 (quoting *Hose*, 70 F.3d at 974). Having reviewed the publications Stryker contends were overlooked, the Court finds that Stryker's arguments go to the weight and credibility of the experts' opinions, but does not render their opinions inadmissible. Stryker will have ample opportunity to cross-examine Huggins' experts and also to present its own expert witnesses. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").[26] For these reasons, the

[25] *See Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 884 (10th Cir. 2005) ("Plaintiff's experts completely ignored or discounted without explanation the many epidemiological studies which found no medically reliable link between silicone breast implants and systemic disease. Therefore, the district court concluded that the methodology used by Plaintiff's experts was not medically or scientifically valid.").

[26] The Court recognizes that the experts' opinions were not developed independently from this litigation, which warrants careful scrutiny to ensure that they are sufficiently scientifically valid. *See Daubert v. Merrell Dow Pharms, Inc.*, 43 F.3d 1311, 1318-19 (9th Cir. 1995). The Court has reviewed the literature on which the experts rely and finds that the challenged opinions satisfy *Daubert*'s requirements. The Court's finding is not changed by the

(Footnote continued on next page.)

Court will deny Stryker's motion to exclude the testimony of Huggins' experts regarding the medical literature.

3. Opinions Regarding Feasibility of Safety Testing and Results of Hypothetical Safety Tests

Stryker's final challenge to the experts' testimony is that any evidence regarding the results that additional safety testing would have produced is "irrelevant and inherently speculative." As to relevance, Huggins' claim is that Stryker should have known the risks associated with intra-articular pain pump use. As described above, under Minnesota law, a manufacturer's duty to test bears on what risks are considered foreseeable to a manufacturer. *See Willmar Poultry*, 378 N.W.2d at 836. Therefore, testimony regarding what tests were feasible prior to Huggins' surgeries and what the results of such tests might have been is relevant to whether a jury could reasonably find that Stryker should have been aware of the risks of intra-articular pain pump use.

The Court also finds that evidence relating to what tests Stryker could have conducted and what the results of such tests would have been is not so speculative that it

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(Footnote continued.)

fact that a number of courts have reviewed similar evidence and found that it would be insufficient to support a verdict for a plaintiff. *See, e.g.*, *Rodriguez v. Stryker Corp.*, 680 F.3d 568 (6th Cir. 2012); *Mack v. Stryker Corp.*, Civ. No. 10-2993, 2012 WL 3599458 (D. Minn. Aug. 14, 2012). Not only is the Court not bound by these decisions, but also these decisions did not find that the expert opinions were inadmissible. Further, many other courts have found that similar expert opinions are admissible and denied motions for summary judgment in similar cases. *See, e.g.*, *Krumpelbeck v. Breg, Inc.*, No. 11-3726, 2012 WL 3241587 (6th Cir. Aug. 10, 2012); *Kildow v. Breg, Inc.*, 796 F. Supp. 2d 1295, 1299-300 (D. Or. 2011); *Creech v. Stryker Corp.*, No. 2:07CV22, 2012 WL 33360 (D. Utah Jan. 6, 2012).

is inadmissible. As an initial note, the manufacturer's duty to test, which Minnesota courts have recognized bears on the foreseeability of risks to a manufacturer, would be meaningless if defendants could successfully argue that it requires too much speculation to opine on what the results of tests that were not performed would have been. By recognizing that a duty to test may be relevant to what risks are treated as foreseeable to a manufacturer, Minnesota courts approved of plaintiffs arguing that a manufacturer **should** have conducted certain tests, and that **if** the manufacturer had conducted such tests, the manufacturer **would** have known of a risk. The exercise necessarily entails a degree of speculation, and rejecting the line of argument on the basis that it is speculative would undermine the duties Minnesota courts have assigned to manufacturers.

Here, Huggins' expert opines that "[t]est methods to address the toxic effects of [bupivacaine], including in vitro test methods and preclinical animal studies, have always been available and could have been used to address any questions regarding the safety of these compounds." (Badylak Report at 4.) As Huggins notes, such tests have now actually been conducted and revealed that intra-articular pain pump use poses a series risk of cartilage damage. The fact that the tests in question have occurred takes much of the speculation out of hypothesizing about what the results would have been had the tests been conducted prior to Huggins' surgery. The Court is not holding that arguments regarding hypothetical testing can never be rejected on the ground that they are too speculative, but the evidence Huggins seeks to present to the jury here is not "so fundamentally unsupported that it can offer no assistance to the jury[.]" *See Bonner*, 259

F.3d at 929 (quoting *Hose*, 70 F.3d at 974).[27] For these reasons, the Court will deny Stryker's motion to exclude testimony regarding safety testing.

This case will be placed on the Court's next available trial calendar.

ORDER

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

1. Plaintiff's Motion to Transfer [Docket No. 161] is **DENIED**.

2. Defendants' Motion for Summary Judgment [Docket No. 172] is **DENIED**.

3. Defendants' Motion to Exclude Expert Testimony [Docket No. 185] is **DENIED**.

DATED: March 25, 2013
at Minneapolis, Minnesota.

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

[27] While the decision that evidence is admissible is different from the decision that evidence is sufficient to allow a plaintiff to survive summary judgment, the Court respectfully disagrees with those courts that have found that evidence regarding testing is too speculative to support a verdict in favor of a plaintiff in a pain pump case. *See, e.g.*, *Mack*, 2012 WL 3599458, at *10; *Phillippi*, 2010 WL 2650596, at *2.