IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

AMANDA SMITH and JAMES SMITH,	)	
Plaintiffs,	)	
vs.	)	**Case No. 09 C 3908**
I-FLOW CORP.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Amanda Smith and James Smith have sued I-Flow Corporation alleging that Mrs. Smith suffered a disabling injury after using a pain pump manufactured by I-Flow. The Smiths allege that the pain pump injected an anesthetic drug, Marcaine, into her left shoulder joint and thereby caused a disabling injury known as chondrolysis.[1] Their claims against I-Flow are for negligence, negligent misrepresentation, fraud, strict tort liability, failure to warn, breach of implied warranty, and loss of consortium. I-Flow has filed a combined motion to exclude the opinions of the Smiths' expert witnesses and for summary judgment. For the reasons stated below, the Court grants in part and denies in part I-Flow's motion to exclude opinions and denies its motion for summary judgment.

Background

This opinion assumes familiarity with the factual background contained in the

[1] Chondrolysis is the "[d]isappearance of articular cartilage as the result of disintegration or dissolution of the cartilage matrix and cells." Stedman's Medical Dictionary 369 (28th ed. 2006).

Court's previous decision denying I-Flow's motion to strike the Smiths' request for punitive damages. *See Smith v. I-Flow Corp.*, — F. Supp. 2d —, No. 09 C 3908, 2010 WL 4872985, at *1 (N.D. Ill. Nov. 29, 2010) ("*Smith I*").

Discussion

I-Flow argues that the opinions and testimony of the Smiths' expert witnesses are inadmissible. It also contends that the Smiths have not shown that there is a genuine issue of fact regarding whether (1) continuous infusion of anesthetics via a pain pump causes chondrolysis or (2) I-Flow knew or should have known of a risk that continuous infusion could cause chondrolysis prior to Mrs. Smith's surgery in January 2006. The Court will consider the admissibility of the Smiths' expert testimony before turning to I-Flow's motion for summary judgment.

1. I-Flow's motion to bar the testimony of the Smiths' expert witnesses

The admission of expert witness testimony is governed by Federal Rule of Evidence 702 and the principles set forth by the Supreme Court in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Specifically, a court "must determine whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue." *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010) (internal quotation marks omitted). The court serves a "gatekeeping" function to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. As such, the court does not decide whether the expert's views are correct, but instead "is limited to determining whether

expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound." *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). In making this determination, the court may consider a number of factors, including (1) whether the scientific knowledge has been, or can be, tested; (2) whether the proffered theory or technique has been subjected to peer review or published; (3) the known or potential rate of error; and (4) whether the theory or technique has gained general acceptance in the relevant field. *Daubert*, 509 U.S. at 592-94.

I-Flow seeks to bar expert testimony from three witnesses. Two of them, Drs. Mark Hutchinson and Jon Sekiya, offer testimony on general causation (pain pumps can cause chondrolysis) and specific causation (I-Flow's pain pump caused Mrs. Smith's chondrolysis). The third witness, Dr. Peggy Pence, offers testimony on I-Flow's duties as a medical device manufacturer.

a. Dr. Mark Hutchinson

The Smiths offer Dr. Hutchinson's testimony as proof of both general and specific causation. I-Flow argues that Dr. Hutchinson's testimony must be excluded for two reasons: first, he is not qualified because his opinions were developed for the purpose of litigation; and second, his conclusions are not supported by the data upon which he relies, thus rendering his opinions unreliable.

The Court concludes that Dr. Hutchinson has the education, training, experience, and skills necessary to testify as an expert on whether continuous infusion of anesthetic via a pain pump can cause chondrolysis. He is a board-certified orthopedic surgeon and a tenured professor of orthopedics at the University of Illinois at Chicago. He has published numerous articles and presentations on subjects relating to various types of

shoulder injuries. Additionally, he serves as an editor or peer reviewer for professional journals in his area of expertise, including the Journal of Bone and Joint Surgery, the American Journal of Sports Medicine, the British Journal of Sports Medicine, Medicine and Science in Sport and Exercise, and the Physician and Sports Medicine. Dr. Hutchinson does not have particular expertise with regard to chondrolysis, but this does not categorically preclude him from testifying about chondrolysis and its causes given that "[d]ifferences in expertise bear chiefly on the weight to be assigned to the testimony by the trier of fact, not its admissibility." *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009); *see also 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").

Dr. Hutchinson is also not disqualified from testifying simply because he was retained to do so for the purpose of litigation. As his expert report makes clear, Dr. Hutchinson reached his opinion in reliance upon dozens of articles and studies that were "either published in peer reviewed journals, presented at national or international conferences, or [contained in] leading textbooks that orthopaedic surgeons regularly rely upon." Pls.' Resp., Ex. 15 at 6. In other words, his views are "based directly on legitimate, preexisting research *unrelated to the litigation*." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("*Daubert II*"). Such evidence "provides the most persuasive basis for concluding that the opinions he expresses were derived by the scientific method," and it is not the Court's role to assess the validity of the conclusions Dr. Hutchinson drew from this evidence. *Id.*; *Smith*, 215 F.3d at 718 ("The soundness of the factual underpinnings of the expert's analysis and the

correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact"). The fact that Dr. Hutchinson was not personally engaged in this research does not render his opinion inadmissible. *See Cummins v. Lyle Indus.*, 93 F.3d 362, 369 (7th Cir. 1996) (rejecting the argument that "hands-on testing is an absolute prerequisite to the admission of expert testimony.").

Finally, the Court rejects I-Flow's argument that "[t]he absence of reliable science concluding that chondrolysis is caused by continuous infusion therapy" renders Dr. Hutchinson's causation opinions unreliable. Def.'s Mem. at 16. As I-Flow concedes, Dr. Hutchinson relied upon several different categories of research and data in forming his opinion, including case reports and series, *in vitro* studies, and *in vivo* animal studies. *See, e.g.,* Andreas H. Gomoll et al., *Long-Term Effects of Bupivacaine on Cartilage in a Rabbit Shoulder Model*, 37 Am. J. Sports Med. 72 (Jan. 2009); Jason Dragoo et al., *The Effect of Local Anesthetics Administered Via Pain Pump on Chondrocyte Viability*, 36 Am. J. Sports Med. 1484 (Aug. 2008); B. Hansen & C. Beck, *Postarthroscopic Glenohumeral Chondrolysis*, 35 Am. J. Sports Med. 1628 (July 2007); Andres Gomoll et al., *Chondrolysis After Continuous Intra-Articular Bupivacaine Infusion: An Experimental Model Investigating Chondrotoxicity in the Rabbit Shoulder*, 22 Arthroscopy 813 (Aug. 2006).

I-Flow argues that because Dr. Hutchinson does not rely upon a controlled, epidemiological study, his opinion is unreliable. This argument lacks merit. There is no rule that requires an expert to base his causation opinion on an epidemiological study. To the contrary, "[n]on-epidemiological sources are frequently utilized by experts in

rendering scientific opinions and, under *Daubert*, should be considered by the court in assessing the reliability of those opinions." *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003); *see also In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 801 (N.D. Ohio 2004) (noting that "no court has held that epidemiological evidence is necessary to establish general causation when other methods of proof are available."). Dr. Hutchinson relied on a significant number of peer-reviewed studies that, taken as a whole, suggest an association between continuous delivery of anesthetic to a joint and chondrolysis in that joint. Whether Dr. Hutchinson reached a valid conclusion after considering this methodologically reliable evidence is a question for the trier of fact. *See United States v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir. 2007) ("[T]he fact that a study is associational—rather than an epidemiological study intended to show causation—does not bar it from being used to inform an expert's opinion").

More fundamentally, however, an expert's testimony is not rendered inadmissible simply because the evidence he or she relies upon does not conclusively establish causation. As the Supreme Court noted in *Daubert*, "[i]t would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science." *Daubert*, 509 U.S. at 590. Under *Daubert*, expert testimony must be relevant and reliable. An expert's testimony, however, need not satisfy the plaintiff's ultimate burden at trial as a prerequisite to admissibility. The Court agrees that it should "not exclude plaintiffs' expert testimony simply because the evidence supporting it does not establish causation to a scientific or

medical certainty." *McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1106 (D. Or. 2010) (reaching the same conclusion after considering the same medical studies); *see also W.R. Grace*, 504 F.3d at 765 (noting that a study's "failure to establish causation goes to the weight it should be accorded, *but does not mean that an expert could not rely on it in forming an opinion*") (emphasis added).

In sum, given Dr. Hutchinson's education, experience and familiarity with the medical literature relating to chondrolysis, his opinion on general causation is admissible under Rule 702 and *Daubert*. The studies cited by the Smiths and considered by Dr. Hutchinson constitute relevant and reliable evidence that will be helpful to the jury in determining the weight due to Dr. Hutchinson's opinion.

b. Dr. Jon Sekiya

I-Flow also challenges the testimony of Dr. Jon Sekiya, one of Mrs. Smith's treating physicians. Dr. Sekiya is an orthopedic surgeon and associate professor of orthopedic surgery at the University of Michigan. He specializes in pathologies of the shoulder. The Smiths offer Dr. Sekiya's testimony on the issue of specific causation only. I-Flow argues that his opinion must be excluded because (1) it was developed for the purpose of litigation and (2) is unsupported by the data upon which he relies.

The Court finds neither of these arguments persuasive. First, as with Dr. Hutchinson, Dr. Sekiya's opinion is not rendered inadmissible because he offers it as a retained expert. To the contrary, Dr. Sekiya's testimony is admissible because it is based upon a reliable scientific methodology. Specifically, Dr. Sekiya reached his diagnosis using "differential diagnosis," a process in which a doctor "systematically

compares and contrasts clinical findings from a patient's medical history to determine which of two or more diseases with similar symptoms is the one from which the patient is suffering." *Myers*, 629 F.3d at 644. This is "an accepted and valid methodology for an expert to render an opinion about the identity of a specific ailment." *Id.* Dr. Sekiya's report and deposition testimony indicate that he considered a number of different possible causes in assessing Mrs. Smith's injury, including surgical anchors used during the January 2006 procedure; chronic shoulder instability; overtightening of the joint; infection, use of thermal energy during the January 2006 procedure; and aging or overuse of the joint. After considering these possible causes, Dr. Sekiya rejected them based on his assessment of the nature of Mrs. Smith's injury, which was "far too advanced and diffuse for these to be reasonable causes." Pls.' Resp., Ex. 16 at 3.

Dr. Sekiya also considered the possibility that continuous infusion of anesthetic into Mrs. Smith's shoulder caused the chondrolysis. In deciding to "rule in" this potential cause, Dr. Sekiya considered his "review of Mrs. Smith's records, [her] clinical history, my own examination and the surgery I performed on her shoulder on November 9, 2009, my clinical experience and knowledge of the scientific literature regarding this potential cause, and a thorough analysis of other potential causes of chondrolysis." *Id.* Based on these factors, he opined that I-Flow's pain pump caused Mrs. Smith's injury.

I-Flow argues that Dr. Sekiya's opinion is not grounded in reliable science because he admits that there is no conclusive proof that continuous infusion causes chondrolysis. But as discussed earlier, absolute certainty is not the standard for the admissibility of expert evidence under Rule 702. The medical literature considered by Drs. Hutchinson and Sekiya is sufficiently relevant and reliable to support admission of

Dr. Hutchinson's general causation opinion. By the same token, this evidence also supports admission of Dr. Sekiya's opinion that continuous infusion caused Mrs. Smith's chondrolysis.

Though Dr. Sekiya admitted that "no one study has conclusively determined the cause" of chondrolysis, he also made clear that a randomized, epidemiological study of this nature would be impossible due to ethical concerns. Sekiya Dep. 210:17-18, Sept, 17, 2010; *see also id.* 193:20-24 ("[N]o one would be able to do [a controlled epidemiological] study because the general belief right now from experts and orthopedic surgeons is that [continuous infusion] does cause [chondrolysis] and they couldn't ethically randomize and have a control group because *it would be unethical to submit someone to a pain pump intra-articularly*") (emphasis added). In other words, Dr. Sekiya based his opinion on his own evaluation of the available evidence that suggests a link between continuous infusion and chondrolysis. *See id.* 209:5-12 ("We could never do a[n epidemiological] study on this answer. We could never do it. And as such we have to rely on what available evidence we have as well as correlative evidence from in vitro and biochemical and biologic studies. *And putting that all together as an expert shoulder surgeon I believe that the causation here is most likely due to pain pump chondrolysis*") (emphasis added); *see also Monroe v. Zimmer U.S. Inc.*, — F. Supp. 2d —, No. CIV. S-08-2944 FCD/EFB, 2011 WL 534037, at *18 (E.D. Cal. Feb. 14, 2011) (noting that a treating physician's "lack of certainty [regarding the link between continuous infusion and chondrolysis] does not mean that his analysis is not factually based or methodically sound"). It will be up to the jury to decide what

weight Dr. Sekiya's opinion deserves, in light of the evidence presented by both sides at trial.

To summarize, Dr. Sekiya—as an experienced orthopedic surgeon and Mrs. Smith's treating physician—is "qualified to render opinion testimony on causation, diagnosis, or other matters based on his treatment of plaintiff." *Monroe,* 2011 WL 534037, at *17. To the extent that his specific causation opinion depends upon evidence relating to general causation, the medical literature he considered in forming his opinions is sufficiently relevant and reliable to render his opinion admissible.

c. Dr. Peggy Pence

Finally, the Smiths offer Dr. Pence's testimony as evidence of I-Flow's duties as a medical device manufacturer and the extent to which I-Flow fulfilled those duties. I-Flow argues that Dr. Pence's testimony must be excluded because she goes beyond these issues and improperly offers conclusory testimony regarding I-Flow's compliance with various legal standards.

In the Seventh Circuit, "expert testimony as to legal conclusions that will determine the outcome of the case is inadmissible." *Good Shepherd Manor Found., Inc. v. City of Momence*, 323 F.3d 557, 564 (7th Cir. 2003) (upholding exclusion of testimony that defendant violated the applicable legal standard). In other words, an expert witness "cannot testify about legal issues on which the judge will instruct the jury." *United States v. Sinclair*, 74 F.3d 753, 758 n.1 (7th Cir. 1996). The Smiths' claims are based on state law doctrines such as negligence, failure to warn, strict products liability, and fraud. As such, whether I-Flow was negligent or acted with a

particular mental state are the ultimate issues that the jury will be required to decide. As I-Flow points out, however, Dr. Pence rendered opinions on these very issues at various points in her deposition testimony. *See, e.g.,* Pence Dep. 142:25-143:1, Oct. 6, 2009 (opining that I-Flow took "a passive approach" to promoting their pain pumps that was "reckless and negligent"); Pence Dep. 140:25-141:1, Dec. 1, 2009 (stating that "I-Flow was negligent" in failing to retrieve pain pumps shipped with outdated directions). Dr. Pence's testimony on these ultimate issues of law is inadmissible. She may not testify as to whether I-Flow acted negligently or with any other particular mental state.

Dr. Pence offers other testimony, however, that is relevant and reliable and does not consist of an ultimate legal conclusion. Specifically, she opines that I-Flow contravened federal regulations by marketing its pain pump for a use—continuous intra-articular infusion of anesthetic—that was not approved by the FDA. *See* Pls.' Resp., Ex. 5 at 5 (discussing a "continuum of I-Flow violations of FDA regulations" that "began with promotion of [I-Flow's pain pump] for continuous intra-articular infusion, a use that was not cleared or approved by FDA but purposely had been denied by FDA"). Whether I-Flow violated federal regulations is not an ultimate issue of law in this case, and therefore Dr. Pence can offer testimony on this question. *Cf. Schott v. I-Flow Corp.*, 696 F. Supp. 2d 898, 905 (S.D. Ohio 2010) (concluding in a similar case that "Plaintiffs do not offer [Dr. Pence's] testimony as an opinion on the ultimate issue of Ohio law, whether Defendant failed to adequately warn about its product, and therefore Defendant's objections are lacking in merit"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 164, 192 n.16 (S.D.N.Y. 2009) ("The cases in this [multi-district litigation] are not governed by federal regulations but by state law theories of negligence and strict

liability. Expert testimony on regulatory compliance will assist the jury in determining whether Merck acted as a reasonably prudent pharmaceutical manufacturer").

This testimony is relevant because it will aid the jury in understanding complex federal regulations and assessing, based on I-Flow's compliance or non-compliance with those regulations, whether I-Flow should have known of the risks posed by its pain pumps. The Smiths contend that after the FDA's rejection of I-Flow's request for approval of the pumps for intra-articular use, I-Flow "was on notice that it would have to conduct studies to determine the safety and effectiveness of orthopedic and intra-articular use" if it wished to permissibly market the pumps for this use. Pls.' Resp. at 7. Similarly, Dr. Pence opines that if I-Flow had complied with federal regulations, it would have been required to complete such studies, and thus would have likely found that—as the literature cited by Drs. Hutchinson and Sekiya suggests—continuous infusion is associated with the development of chondrolysis. *See* Pls.' Resp., Ex. 5 at 6. In short, Dr. Pence's testimony suggests that I-Flow should have known the risks allegedly posed by its pain pumps.

Dr. Pence has extensive experience in aiding medical device manufacturers to obtain FDA approval for various device applications. She has provided a detailed explanation of the regulations that are generally applicable to I-Flow, and her opinions are "based on [her] review and evaluation of the regulatory history of I-Flow's pain pumps." Pls.' Resp., Ex. 5 at 33; *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999) (noting that an expert may "draw a conclusion from a set of observations based on extensive and specialized experience"). The Court thus concludes that Dr. Pence's testimony regarding I-Flow's compliance with FDA

regulations is admissible. She may testify, and be cross-examined, on this subject. Dr. Pence may not, however, offer testimony on the ultimate issues to be decided in this case, including whether I-Flow acted negligently or violated any state law.

2. I-Flow's summary judgment motion

I-Flow also seeks summary judgment in its favor on the Smiths' claims. On a motion for summary judgment, the Court draws "all reasonable inferences from undisputed facts in favor of the nonmoving party and [views] the disputed evidence in the light most favorable to the nonmoving party." *Harney v. Speedway SuperAmerica, LLC*, 526 F.3d 1099, 1104 (7th Cir. 2009). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In other words, a court may grant summary judgment "where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

Though the parties' briefs do not address which states' substantive law applies to the issue of liability for compensatory damages on the Smiths' claims, the Court concludes that Michigan law governs that issue. When sitting in diversity, a federal court applies the choice-of-law rules of the state in which the court sits. *Malone v. Corr. Corp. Of Am.*, 553 F.3d 540, 543 (7th Cir. 2009). In Illinois, courts use the "most significant contacts" test in resolving conflicts of law. *Auto-Owners Ins. Co. v. Websolv Computing, Inc.*, 580 F.3d 543, 547 (7th Cir. 2009). In the personal injury context, "the law of the place of injury controls unless another state has a more significant

relationship with the occurrence and with the parties with respect to the particular issue." *Townsend v. Sears, Roebuck and Co.*, 227 Ill. 2d 147, 163, 879 N.E.2d 893, 903 (2007) (internal quotation marks omitted).

The Smiths are citizens of Michigan, and I-Flow is a citizen of California. The surgery that allegedly caused Mrs. Smith's injury, however, occurred in Michigan. As such, Michigan law is presumptively applicable. Though the Court concluded in its prior decision that California law governed the Smiths' request for punitive damages, it did so on the ground that "California has a significant[ly] greater interest than Michigan in deciding whether to *punish* a tortfeasor that operates, and engaged in the allegedly wrongful conduct, within California's boundaries[.]" *Smith I*, 2010 WL 4872985, at *4 (emphasis added). Outside of the context of punitive damages, this heightened interest does not exist. Because neither party has offered anything that overcomes the presumption in favor of applying the law of the place of injury, the Court will apply Michigan law in determining I-Flow's potential liability to the Smiths for compensatory damages.

I-Flow argues that the Smiths cannot show causation. In Michigan, causation consists of two separate elements, "cause in fact" and "legal cause." *Skinner v. Square D Co.*, 445 Mich. 153, 162-63, 516 N.W.2d 475, 479 (1994) (emphasis in original). The cause in fact element is satisfied by a "showing that, 'but for' the defendant's actions, the plaintiff's injury would not have occurred." *Id.* at 163, 516 N.W.2d at 479. By contrast, "legal cause or 'proximate cause' normally involves examining the foreseeability of consequences, and whether a defendant should be held legally

responsible for such consequences." *Id.*

As discussed above, the Smiths have offered admissible expert testimony indicating that continuous infusion of anesthetic into the shoulder joint can cause chondrolysis, and did cause it in Mrs. Smith's case. On this basis, the Court concludes that a reasonable jury could find that the Smiths have proven causation. The Court therefore denies summary judgment with respect to I-Flow's arguments regarding causation.

I-Flow also contends that the Smiths "cannot establish [I-Flow's] knowledge of any risk associated with continuous infusion therapy prior to or on the date of Plaintiff's January 20, 2006 surgery." Def.'s Mem. at 6. "In a product liability action brought against a manufacturer or seller for harm allegedly caused by a failure to provide adequate warnings or instructions," the plaintiff must prove that "the manufacturer *knew or should have known* about the risk of harm based on the scientific, technical, or medical information reasonably available at the time the specific unit of the product left the control of the manufacturer." Mich. Comp. Laws Ann. § 600.2948(3) (West 2000) (emphasis added). In other words, "[a] manufacturer has a duty to design its product to eliminate any unreasonable risk of foreseeable injury." *Ghrist v. Chrysler Corp.*, 451 Mich. 242, 248, 547 N.W.2d 272, 275 (1996).

The Smiths' causation experts have testified that a significant body of medical research suggests an association between continuous intra-articular infusion of anesthetics and chondrolysis. Moreover, as the Court concluded above, Dr. Pence's testimony is admissible under *Daubert* and Rule 702. She has testified that I-Flow would have been required to "submit evidence of safety through well-controlled

investigations" on its pumps in order to market them for intra-articular use without violating FDA regulations, but failed to do so. *See* Pls.' Resp., Ex. 5 at 36. The Court finds this evidence sufficient to raise a genuine issue of fact regarding whether I-Flow should have foreseen a risk of injury posed by the intra-articular use of its pain pump.

Conclusion

For the reasons stated above, the Court grants in part and denies in part defendant's Rule 702 motion to exclude expert opinions and denies its motion for summary judgment [docket no. 132]. The case remains set for trial on June 20, 2011 at 9:45 a.m. The case is set for a status hearing on May 19, 2011 at 9:30 a.m. to discuss the length of the trial as well as the possibility of settlement.

MATTHEW F. KENNELLY
United States District Judge

Date: May 3, 2011