UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

	:	NO. 1:08-CV-00323
	:	and related cases:
DIANNA SCHOTT, et al.,	:	
	:	1:08-CV-00700
Plaintiffs,	:	1:08-CV-00818
	:	1:09-CV-00098
vs.	:	1:09-CV-00155
	:	1:09-CV-00403
	:	
I-FLOW CORPORATION, et al.,	:	
	:	**OPINION AND ORDER**
Defendants.	:	

This matter is before the Court on Defendant I-Flow Corporation's motions in these related matters (the "I-Flow" cases). First, a set of motions premised on Daubert: Defendant's Motion to Exclude Plaintiffs' General Causation Experts (doc. 50)[1], Defendant's Motion to Exclude Testimony for Dr. Jason Louis Dragoo (doc. 51), Defendant's Motion to Exclude Testimony of Dr. Sander Greenland (doc. 52), Defendant's Motion to Exclude Testimony of Dr. Martin Wells (doc. 53), and Defendant's Motion to Exclude Testimony of Dr. Peggy Pence (doc. 54). Plaintiffs have responded to each respective motion (docs. 66, 68), Defendant has replied (docs. 72, 74), and the Court held a hearing on such motions on February 23, 2010, such that this matter is ripe for ruling. Also before the Court is Defendant's Motion for Summary Judgment (doc. 55), Plaintiffs' Response (doc. 67), and Defendant's Reply (doc. 73).

[1]All document citations in this Order will be to Case No. 1:08-CV-00323. The briefing is identical in the related cases.

Finally, before the Court is Plaintiffs' Joint Motion to Consolidate (doc. 58), Defendant's Response in Opposition (doc. 75), and Plaintiffs' Reply (doc. 88). For the reasons indicated herein, the Court DENIES all of Defendant's motions, and GRANTS IN PART Plaintiffs' Motion to Consolidate, on the question of general causation.

I. Background

In this and the related matters, Plaintiffs allege they have suffered severe and permanent damage in their shoulder joints, a condition called "chondrolysis," following the use of Defendants' infusion pump that administered continuous infusion of anesthetic into the joint following orthopedic surgery (doc. 1).[2] Plaintiffs allege that Defendant I-Flow Corporation ("I-Flow") failed to warn physicians to avoid using the pain pump in shoulder joints, even after Defendants became aware there were unreasonable risks and dangers of using the product in such manner (Id.). Plaintiffs bring causes of action for strict liability for defective labeling, negligence, breach of warranty, and loss of consortium, seeking past and future medical expenses, punitive damages, and other relief (Id.). I-Flow denies liability, contending that under the

[2]There are more than 200 pain pump cases in litigation around the country. The Judicial Panel on Multi-district Litigation will soon consider a motion pursuant to 28 U.S.C. § 1407(a) to transfer and coordinate some 150 pain pump actions. The instant cases were carved out from Plaintiffs' Section 1407 motion as they are further along procedurally than those at issue in the potential MDL.

current state of medical science, Plaintiffs cannot adduce evidence of medical causation (doc. 73). Defendant challenges the admissibility of Plaintiffs' expert opinions under the theory that such opinions are not scientifically reliable under Daubert v. Merrill Dow Pharms., Inc., 509 U.S. 579 (1993)(docs 50, 51, 52, 53, 54). Defendant further argues the Court should grant it summary judgment as to punitive damages because it did not cause Plaintiffs' injuries, Plaintiffs cannot prove misconduct, and Defendant did not manifest flagrant disregard for Plaintiffs' safety (doc. 73). Because the resolution of the summary judgment motions turn on whether Plaintiffs have enough admissible evidence to show a material issue as to whether I-Flow's pain pump caused Plaintiffs' injuries, the Court finds it appropriate to address Daubert motions first, then Defendant's motions for summary judgment, and finally, Plaintiff's motion.

II. Applicable Law

Defendants challenge the admissibility of each of Plaintiffs' experts under Rule 702 of the Federal Rules of Evidence and Daubert, 509 U.S. 579. Rule 702 governs the admissibility of expert testimony:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts

of the case.

Fed. R. Evid. 702. The trial judge must act as a gatekeeper, admitting only that expert testimony that is relevant and reliable. Daubert, 509 U.S. at 589. With regard to scientific knowledge, the trial court must initially determine whether the reasoning or methodology used is scientifically valid and is properly applied to the facts at issue in the trial. Id. To aid the trial court in this gatekeeping role, the Supreme Court has listed several key considerations: 1) whether the scientific knowledge can or has been tested; 2) whether the given theory or technique has been published or been the subject of peer review; 3) whether a known rate of error exists; and 4) whether the theory enjoys general acceptance in the particular field. Id. at 592-94. The Court's focus "must be solely on principles and methodology, not on the conclusions that they generate." Id. at 595. "[T]he test under Daubert is not the correctness of the expert's conclusions but the soundness of his methodology." Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995).

Although Daubert centered around the admissibility of scientific expert opinions, the trial court's gatekeeping function applies to all expert testimony, including that based on specialized or technical, as opposed to scientific, knowledge. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147-48 (1999). The trial court's objective "is 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." Kuhmo Tire, 526 U.S. at 152. The trial judge enjoys broad discretion in determining whether the factors listed in Daubert reasonably measure reliability in a given case. Id. at 153. The party proffering the expert testimony bears the burden of showing its admissibility under Rule 702 by a preponderance of the evidence. Daubert, 509 U.S. at 592 n.10. With this framework in mind, the Court will now address Defendant's motions.

III. The Arguments at the February 23, 2010 Hearing

Defendant brings two general sorts of motions under Daubert. First, Defendant brings four motions related to attacks on the general causation testimony of Plaintiffs' experts, and second, one motion attacking Plaintiffs' regulatory expert, Peggy Pence. The Court has reviewed all of the briefing in this matter, which is extensive, and finds it appropriate to focus its analysis on the parties' arguments at the February 23, 2010 hearing.

Defendant argued at the hearing that this is precisely the sort of case the Supreme Court envisioned when it issued its Daubert ruling. Defendant argued that the science in this case does not show that chondrolysis is caused by pain pumps administering anesthetics and Plaintiff's experts have to take a leap of faith to offer their opinions regarding causation. Defendant conceded there may be an association or strong suspicions

regarding cause and effect, but argued the experts must go beyond speculation to offer causation opinions.

At the hearing, and in its briefing, Defendant cited to Kilpatrick v. Breg, Inc., 2009 WL 2058384 (S.D. Fla. June 25, 2009), in which the Southern District of Florida excluded the opinion that pain pump causes chondrolysis after the expert stated that "the current state of medical literature is still unsettled about the cause of chondrolysis." Moreover, the expert in the Florida case relied on the same cohort study, the "Hansen study," of patients that underwent shoulder surgery, upon which Plaintiffs' experts in this case rely in part. The Kilpatrick court found that twelve shoulders developing chondrolysis out of nineteen shoulders in which pain pumps were placed was not a reliable indicator of causation because forty percent of the shoulders did not develop the condition. 2009 WL 2058384 at *5-6. The Court further noted that the expert's causation opinion was not supported by epidemiological studies, and questioned the expert's reliance on the Gomoll study, in which the authors reported statistically significant evidence of chondrolysis in rabbit shoulders exposed to anesthetic. Id. at 6. The Court found the Gomoll study failed to account for the possible dose-response relationship between humans and rabbits, such that it was unreliable to extrapolate conclusions about human disease from the animal-based study. Id.

Defendant emphasized at the hearing that it was not questioning the accomplishments of Plaintiffs' experts, but that it

believes they have taken steps in the context of litigation that they would not take in the laboratory. Defendant contended that Dr. Greenland, at his deposition, admitted that he did not submit his report in this case to peer review and would not unless he toned it down to reflect a more conservative approach. Defendant argued that in order for Plaintiffs' experts to testify, their opinions must be based on more than their credentials, but such opinions must be based on the medical and scientific data that is available and what conclusions can properly be drawn from such data.

As for Ms. Pence's regulatory opinion, Defendant argued that to the extent she will opine about a failure to warn, such testimony is irrelevant because the doctors for Plaintiffs Michener, Schoettmer, Schott, and West have all testified they did not look at any I-Flow materials or talk to any I-Flow representatives, but learned everything about using continuous infusion pain therapy during their residencies. Defendant argued its warnings were adequate under Food and Drug Administration requirements, but that Dr. Pence should not be permitted to testify otherwise, as the doctors did not refer to any of Defendant's warnings.

Second, Defendant argued that Pence's report neglects to mention the F.D.A's 2004 510(k) clearance, which gave permission to I-Flow to market its pain pump for orthopedic surgeries. Defendant argued that attached to the 510(k) clearance were clinical studies

showing surgeons were using the product for intra-articular placement. As such, Defendant argued, the F.D.A. knew what was going on. Ms. Pences' opinions, Defendant argued, are based on 510(k)'s and rejected 510(k)'s from 1999 and 1998, while ignoring the 2004 clearance allowing I-Flow to market its product as an orthopedic kit.

Next, Defendant argued that Pence's testimony is improperly premised on the theory that general causation has been established, and that she should not be permitted to testify about whether I-Flow's conduct comported with F.D.A. regulations, as such determination is a pure legal opinion that should not come from an expert on the stand. Finally, Defendant argued that Pence's testimony is essentially a long factual narrative arguing Plaintiffs' case, which amounts to mind reading as opposed to expert testimony.

Plaintiffs responded at the hearing that they agreed with Defendant that Daubert was intended to apply to just this sort of case. Plaintiffs argued Daubert seeks to keep out bad science, not new science or controversial science, but bad science where the methods are improper and cannot be relied upon. In Plaintiffs' view, their experts proffer testimony regarding new science, which can and should be weighed by the jury up against Defendant's experts, to arrive at a factual conclusion regarding causation. Plaintiffs argued their causation theory has been tested, as their expert Dr. Jason Dragoo of Stanford University conducted testing on

human cartilage with local anesthetic and concluded, in a dose and duration dependent manner, that continuous infusion with a pain pump would result in death of cartilage. Plaintiffs cited further to other studies, using both human and animal cartilage, which were all peer reviewed, and which show continuous infusion of anesthetic killed chondrocytes in the cartilage. Plaintiffs contended there is not a single peer-reviewed published article concluding that continuous infusion of local anesthetic does not cause chondrolysis.

Plaintiffs contend there are presently thirty studies relating to chondrolysis and anesthetic. Although such studies use terms like "strongly associated," "highly suspicious," or "most likely caused," Plaintiffs argue such language reflects how scientists talk, as they are not writing articles to be submitted for federal court. In Plaintiffs' view, the Daubert court recognized that scientists do not use the same sort of "reasonable degree of medical certainty" or "preponderance of evidence" language because that sort of language is not used in medical journals. However, Plaintiffs indicate, such language is in their expert reports because that is the sort of language experts use when opining for the court. For this reason, Plaintiffs stated, their experts testified in deposition that they would not submit their litigation reports to peer-reviewed journals, as the documents are created for different purposes.

In response, the Court queried Plaintiffs' counsel

whether the experts stand behind the opinions in the scientific community that they would give in court under oath. Plaintiffs' counsel replied, "Absolutely." Plaintiffs' counsel indicated that the topic of infusion pumps causing chondrolysis in human joints is the topic of conversation at every meeting of the American Association of Shoulder and Elbow surgeons, that this is what sports medicine doctors are talking about. Moreover, Plaintiffs indicate that experts are giving presentations saying not to use continuous infusion pumps in shoulders, and that the foremost textbook in the orthopedic community, the Fourth Edition of the Shoulder, volume two, edited by Rookwood, states that the anesthetic bupivacaine should not be placed intra-articularly after arthroscopic capsular procedures, and warns that there is a growing body of evidence that the intra-articular use of bupivacaine with or without epinephrine via pain is linked to post-operative chondrolysis. The fact that such conclusion is in the leading textbook, argue Plaintiffs, demonstrates general acceptance.

Plaintiffs further contend their general causation expert Dr. Dragoo published his 2008 article in the American Journal of Sports Medicine, which concluded, "All anesthetics containing epinephrine. . .were chondrotoxic and cannot be advocated for pain pump use. The use of 0.5% bupivacaine for greater than 48 hours is not recommended." Such a conclusion, contend Plaintiffs, has clearly been subjected to peer review and publication.

Finally, Plaintiffs argued that there have been no

epidemiological studies on groups of human patients because it would be unethical to subject human subjects to the certainty that a majority of them would get chondrolysis. Plaintiff argued that Defendant never completed such testing in the past, and now is trying to take advantage of the fact that such testing will never take place in the future.

As for Ms. Pence, Plaintiffs' regulatory expert, Plaintiffs argued that her testimony is relevant as it will show I-Flow had numerous opportunities to advise surgeons about what it knew, but that it did not take the opportunity to do so. Plaintiffs argued Pence is clearly qualified based on her thirty-five years working in the field of F.D.A. regulatory issues,her United States Regulatory certification ("RAC certification"), and her creditials as a Regulatory Affairs Professional Society fellow. Plaintiffs argued Defendants are free to cross-examine Pence regarding the May 2004 510(k) application, which they argue concerned labeling and not indication for use. Plaintiffs contended the F.D.A. has never said that you can put a catheter in the shoulder joint and continually infuse anesthetic, which is Pence's principal criticism. Plaintiffs argued that they intend to use Pence's testimony, not to testify as to causation, which the medical doctors in this case can do, but as to complex procedures of the F.D.A. regulatory framework and how Defendant either fulfilled or did not fulfill its obligations. Plaintiffs argued that Pence will not opine on the law of Ohio or otherwise usurp the

role of the jury, but that her testimony will simply assist the jury in doing its job. Specifically, Plaintiffs indicated they intend to offer Pence's testimony to show Defendant marketed its product to orthopedic surgeons with the knowledge the surgeons would put the pump in the shoulder joint without having an "indication" for such particular use, as required by the F.D.A.; that Defendants never had clearance to place the catheter in a joint; and that Defendants never completed required testing. In Plaintiffs view, all of such testimony can be evaluated by the jury in arriving at its conclusion whether Defendant's actions amounted to a failure to warn under Ohio law.

IV. Discussion

As the Court indicated at the hearing, in its view Daubert liberalized the admission of expert testimony beyond the previous Fry general acceptance test. As such, when expert testimony meets Daubert criteria, it can be admitted, and given whatever weight a jury might accord such testimony.

The Court sees more than adequate evidence that the expert opinions in this case have been published, subjected to peer review, and are generally accepted by the medical community. The combination of cohort studies, animal studies, and in vitro human cartilage studies demonstrates that the experts' causation opinions are supported by science. The Court respectfully disagrees with the Southern District of Florida's conclusion regarding the Hansen study, which showed 13 out of 19 patients treated with pain pumps

developed chondrolysis. The Court has found no authority for the proposition that because 40% of patients did not develop chondrolysis, such minority of patients constitutes an "error rate." The Court acknowledges difficulty with extrapolation from such a small sample. However, the Court believes that taken together with the body of medical evidence, which is greater than that before the Florida court, the Hansen study only affirms the admissibility of the expert opinions as to general causation.[3]

The Court further finds Plaintiffs' argument correct that Defendant's attacks on their experts' reports boils down to semantics. The Court finds the Plaintiffs' experts are clearly highly skilled in their respective fields and does not believe they would risk their professional reputations by offering bogus causation opinions before the Court. The Court is satisfied that the body of publications regarding the relation between

[3]In Kilpatrick v. Breg, Inc., 2009 WL 2058384 (S.D. Fla. June 25, 2009), the Court noted the expert's testimony relied on four sources: 1) the Hansen study, 2) the Gomoll rabbit cartilage study, 3) a study of two patients, and 4) the expert's opinions based on the previous three sources. Here, the experts rely not only on the Hansen study and the Gomoll study, but on statistical analysis of the Hansen study by Drs. Greenland and Wells, the 2008 study of human and bovine cartilage conducted by Dr. Constance Chu, Dr. Jason Dragoo's in vitro studies with human cartilage, and Busfield, Benjamin T., M.D., and Romero, Denise M., M.D., Pain Pump Use After Shoulder Arthroscopy As A Cause of Glenohumeral Chondrolysis, Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol. 25, No. 6 (June), 2009, pp. 647-652, (citing Levy JC, Virani NA, Frankle MA, Cuff D, Pupello DR, Hamelin JA. Young Patients with shoulder chondrolysis following arthroscopic shoulder surgery treated with total shoulder arthroplasty, J. Shoulder Elbow Surg 2008; 17:380-388).

chondrolysis and anesthetics provides a basis for the general causation testimony offered in this case. Finally, the Court finds Plaintiffs' argument persuasive that they are unable to obtain epidemiological studies, as conducting any such studies would be unethical. It therefore strikes the Court as unreasonable for Defendant to clamour for such studies.

The Court similarly finds the testimony of Peggy Pence could assist the jury in understanding the complex regulatory scheme applicable to medical devices. Plaintiffs do not offer her 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.

Defendant's summary judgment motion is premised on the theory that Plaintiffs have not adduced reliable expert opinions supporting general causation. Because the Court's instant ruling arrives at the opposite conclusion, Defendant's motion for summary judgment is denied. To the extent that Defendant's motion attacks Plaintiffs' specific causation, the Court finds Plaintiffs have proffered adequate evidence showing that Plaintiffs' experts have ruled out alternative causes as to each Plaintiff such that reasonable juries could find specific causation by a preponderance of the evidence. Defendant further argues that Plaintiffs' punitive damages claims should be dismissed (doc. 55). However, Plaintiffs proffer evidence showing Defendant knew in October 2006 that its pain pump could be causing chondrolysis, that an employee

proposed new warnings about chondrolysis, but that I-Flow's C.E.O Don Earhart nixed the warnings, which did not issue until ten months later (doc. 67). Every one of the Plaintiffs had their surgery during such ten month period. The Court finds that a reasonable fact-finder could conclude that an award of punitive damages is justified under Ohio law. Ohio Revised Code § 2307.80(A)(Plaintiff can recover punitive damages where he or she shows clear and convincing evidence that that harm for which he or she recovers compensatory damages was the result of misconduct of the Defendant that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question).

Finally, Plaintiffs move to consolidate these matters for trial, which have already been consolidated for purposes of pretrial scheduling and for summary jury trial. The Court finds, having discussed this matter with the parties at the summary jury charging conference, that consolidation of these matters on the question of general causation would foster judicial economy. After a trial on general causation, should the jury find general causation, such finding could apply to all the cases and serve to expedite the trials on specific causation as to each Plaintiff. As such, the parties only need to litigate the question of general causation in this above-captioned matter, set for trial to commence on April 6, 2010.

Accordingly, the Court DENIES Defendant's Motion to Exclude Plaintiffs' General Causation Experts (doc. 50), DENIES

Defendant's Motion to Exclude Testimony for Dr. Jason Louis Dragoo (doc. 51), DENIES Defendant's Motion to Exclude Testimony of Dr. Sander Greenland (doc. 52), DENIES Defendant's Motion to Exclude Testimony of Dr. Martin Wells (doc. 53), and DENIES Defendant's Motion to Exclude Testimony of Dr. Peggy Pence (doc. 54). The Court further DENIES Defendant's Motion for Summary Judgment (doc. 55), and GRANTS IN PART Plaintiffs' Joint Motion to Consolidate on the question of general causation (doc. 58). The Court further DIRECTS the Clerk to apply this ruling to the related cases as follows: (Case No. 1:08-CV-00700, the Court DENIES docs. 38, 39, 40, 41, 42, 43, and GRANTS IN PART doc. 46);(Case No. 1:08-CV-00818, the COURT DENIES docs. 39, 40, 41, 42, 43, 44, and GRANTS IN PART doc. 47); Case No. 1:09-CV-00098, the Court DENIES docs. 24, 25, 26, 27, 28, 29, and GRANTS IN PART doc. 33); (Case No. 1:09-CV-00155, the Court DENIES docs. 28, 29, 30, 31, 32, 33, and GRANTS IN PART doc. 36), (Case No. 1:09-CV-00403, the Court DENIES docs. 35, 36, 37, 38, 39, 40, and GRANTS IN PART doc. 29).

SO ORDERED.

Dated: March 16, 2010

/s/ S. Arthur Spiegel
S. Arthur Spiegel
United States Senior District Judge