UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

JENSEN MEHARG, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**CAUSE NO. 1:08-cv-184-WTL-TAB**
	)	
I-FLOW CORPORATION, et al.,	)	
	)	
Defendants.	)	

ENTRY ON MOTION FOR SUMMARY JUDGMENT

This cause is before the Court on a motion for summary judgment filed by Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, and Zeneca Holdings Inc. (hereinafter referred to collectively as "AstraZeneca").[1] The motion is fully briefed, and the Court, being duly advised, **GRANTS** the motion for the reasons set forth herein.

SUMMARY JUDGMENT STANDARD

Federal Rule of Civil Procedure 56(c)(1) provides that summary judgment is appropriate if "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to a judgment as a matter of law." In ruling on a motion for summary judgment, the admissible evidence presented by the non-moving party must be believed and all reasonable inferences must be drawn in the non-movant's favor. *Zerante v. DeLuca*, 555 F.3d 582, 584 (7th Cir. 2009). However, "[a] party

[1]AstraZeneca has also filed numerous motions to strike that are in various stages of briefing. It is unnecessary for the Court to resolve any of those motions in order to resolve the instant motion for summary judgment, inasmuch as even if the Court were to admit all of the disputed evidence AstraZeneca would still be entitled to summary judgment. To the extent that the Court has accepted as true or otherwise discussed any of the disputed evidence herein, it has done so only for purposes of resolving the instant motion, and any such discussion should not be viewed as an implicit denial of any motion to strike.

who bears the burden of proof on a particular issue may not rest on its pleadings, but must affirmatively demonstrate, by specific factual allegations, that there is a genuine issue of material fact that requires trial." *Hemsworth v. Quotesmith.com, Inc.*, 476 F.3d 487, 490 (7th Cir. 2007). Finally, the non-moving party bears the burden of specifically identifying the relevant evidence of record, and "the court is not required to scour the record in search of evidence to defeat a motion for summary judgment." *Ritchie v. Glidden Co.*, 242 F.3d 713, 723 (7th Cir. 2001).

BACKGROUND FACTS

In February 2006, Jensen Meharg, who was then a high school athlete, underwent surgery on her shoulder. The surgery was performed by orthopedic surgeon Scott Lintner. To help reduce the post-surgery pain experienced by Meharg, Dr. Lintner utilized a continuous infusion pain pump filled with a local anesthetic. The pain pump in question was manufactured and sold by I-Flow Corporation; the local anesthetic–bupivacaine Hcl, sold as a "branded generic" called Sensorcaine® (hereinafter referred to as "bupivacaine")[2]–was manufactured and sold by AstraZeneca. The pump was designed for continuous intra-articular administration of pain medication; that is, the continuous injection of pain medication directly into a joint. AstraZeneca did not in any way promote the use of bupivacaine with pain pumps, and that use was not mentioned in the instructions and warnings provided with the drug. Therefore it was an "off-

[2]AstraZeneca points out that the Plaintiffs allege in each of their complaints that the drug Meharg was given in the pain pump was "Marcaine and/or mepivacaine," neither of which is manufactured or sold by AstraZeneca. Meharg's medical records establish that she actually was given AstraZeneca's drug Sensorcaine®. AstraZeneca suggests that it is entitled to summary judgment solely because the Plaintiffs misidentified the drug at issue in their pleadings. This suggestion is without merit. *Cf.* Federal Rule of Civil Procedure 15(b)(1) (in the absence of prejudice, amendment of pleadings to conform to the evidence at trial should be freely permitted).

label" use of bupivacaine.[3] Dr. Lintner was trained to use the drug with the pain pump by a representative from I-Flow Corporation.

Dr. Lintner filled Meharg's pain pump with 300 mL of bupivacaine; the pump was designed to administer the drug at a rate of 5 cc/hour directly into Meharg's shoulder joint. Dr. Lintner sent Meharg home after surgery with the pump and instructed her to "keep it in for two or three days" and then remove it at home.

Meharg initially experienced dramatic improvement in her shoulder pain after the surgery and subsequent physical therapy. Several months later, however, she began to experience shoulder pain again. An MRI revealed that Meharg had develop chondrolysis in her shoulder; in laymen's terms, the cartilage in her shoulder had been destroyed. The Plaintiffs allege–and the Court accepts as true for purposes of this ruling–that Dr. Lintner's post-surgery administration of bupivacaine with the pain pump caused Meharg's chondrolysis.

DISCUSSION

The only claim remaining from the Plaintiffs' second amended complaint is their product liability claim against AstraZeneca.[4] Specifically, the Plaintiffs allege that AstraZeneca is liable to them for its "failure to warn of the risks created by continuous infusion of its drugs directly into the joint." This failure to warn claim is governed by the Indiana Product Liability Act, pursuant to which a plaintiff must prove the following in order to prevail:

1) the seller is engaged in the business of selling the product that caused the

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[3]The parties agree that the off-label use of prescription drugs by physicians is very common.

[4]The Plaintiffs have settled their claims against I-Flow Corporation and has voluntarily dismissed all of their other claims against AstraZeneca.

> injury; (2) the product was defective and unreasonably dangerous; (3) the defect existed at the time the product left the defendant's control; (4) the product was expected to and did reach the consumer without substantial change in its condition; and (5) the defective product was the proximate cause of plaintiff's injuries.

Ritchie v. Glidden Co., 242 F.3d 713, 720 (7th Cir. 2001). With regard to the second element, Ind. Code 34-20-4-2 provides that a product is "defective . . if the seller fails to . . . properly package or label the product to give reasonable warnings of danger about the product." In other words, the Plaintiffs must show that "there was a duty to warn that was not fulfilled" in order to prevail on her claim that bupivacaine was defective because of inadequate warning.[5] *See Ritchie*, 242 F.3d at 721 n.6. Whether a duty existed is a question of law for the Court to decide. *Id.* at 721.

In *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548 (Ind. App. 1979), the Indiana Court of Appeals held that in the context of a prescription drug manufacturer, "the duty to warn . . . does not arise until the manufacturer knows or should know of the risk" and that "the standard of constructive knowledge is that of an expert in that particular field." In cases such as this one that involve an off-label use of a prescription drug that is not endorsed or promoted by the manufacturer, the requisite knowledge of the risk is two-fold: the manufacturer must know (or be charged with knowledge of) both that the off-label use is occurring and that the off-label use carries with it the risk of the harm at issue–in this case, damage to cartilage.[6]

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[5]The parties (correctly) agree that any duty to warn in this case was a duty to warn Dr. Lintner, not Meharg (or her parents) directly. *See Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548 (Ind. App. 1979).

[6]AstraZeneca argues that "[t]here is no duty to warn of off-label use, least of all when the manufacturer is not aware of common and widespread off-label use coupled with no notice of serious harm." There is no Indiana case adopting the rule that a drug manufacturer has no duty

The Plaintiffs offer the following evidence in support of their argument that at the time of Meharg's surgery AstraZeneca knew or should have known of the risk "that the infusion of its drug directly into patients [sic.] joints could damage cartilage in those joints":[7]

- Scientific literature existed "dating back 60 years demonstrating a potential for certain intra-articular solutions to harm cartilage." Parisian Dec. at ¶ 88.
- A 1933 article indicated that "arthritic-like changes could be produced by injecting a small amount of a strong chemical irritant into a joint" and that "[r]epeated injections caused inflammation of the synovial tissue and [permanent]

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to warn with regard to off-label uses, and the Court declines to so rule in this case. Neither is there any Indiana case establishing that a drug manufacturer must be aware of both "common and widespread use" and "serious harm" in order to have a duty to warn against an off-label use. The Court declines to adopt this standard as well; that is best left up to the Indiana courts. Rather, the Court believes that this case is easily resolved by application of the general standard set forth in *Chapman* and other Indiana duty-to-warn cases, without adopting a specific test for cases involving the off-label use of a prescription drug.

[7]In addition to the evidence listed herein, the Plaintiffs assert that "In the fall of 2005, six months before [Meharg's] surgery, pain pump manufacturer Stryker, filed an FDA report indicating that a doctor suspected that the shoulder cartilage in seven of the doctor's patients had been destroyed by the use of a pain pump for infusion of bupivacaine following shoulder surgery." The Plaintiffs cite to the Declaration of Peggy Pence, PhD., RAC, as evidence supporting this factual allegation; however, while Dr. Pence's Declaration and accompanying exhibits do mention the Stryker report, they do not mention that bupivacaine was used on the patients at issue; rather, her summary of the Stryker report merely that "7 Patients developed chondrolysis approximately 6 months following shoulder surgery resulting in shoulder replacement surgery or micro fracture surgery." Therefore, the Plaintiffs have not submitted (or at least not directed the Court to) any evidence that supports their allegation that the Stryker report implicated bupivacaine. In addition, the report in question was submitted to the FDA's medical device adverse events reports database, MAUDE, not its pharmaceutical adverse event reports database, AERS. While Dr. Pence asserts in her Declaration that "a reasonably prudent pharmaceutical manufacturer should monitor the MAUDE database to discover if there are any adverse events associated with the use of its products in the medical device," Pence Dec. at ¶ 5, the FDA publication she cites for that proposition does not mention the MAUDE database at all and does not support the fact for which she cites it.

death of cartilage" Parisian Dec. at ¶ 89.

- A 1992 study of "the effects of repeated intra-articular injection of a sterile saline solution on articular cartilage" concluded that "the microtrauma produced by repeated injection into the joint with introduction of a saline solution over a short interval could produce damage to the articular cartilage." Parisian Dec. at ¶ 93.
- A 2004 study of "the effects of intra-articular injections of bupivacaine and neostigmine on articular cartilage and the synovial membrane of rabbit knee joints" showed that while "many studies had supported the safety of intra-articular injection of bupivacaine," "there is a potential for bupivacaine to cause inflammation in articular cartilage and synovial membranes." The authors of the study concluded:

> Our results showed that bupivacaine is an agent that can be used safely as an intra-articular injection. There have been a few case reports, however, indicating that bupivacaine can lead to a delayed hypersensitivity reaction and toxicity after intra-articular use. In this case, the histopathological changes in the joint brought about by bupivacaine might be important.

Parisian Dec. at ¶ 96.

- An article written in 2004, which AstraZeneca noted ed in its annual report to the FDA that year, "discussed glenohumeral chondrolysis following shoulder arthroscopy, in [sic.] implicated a pain pump in at least one of the cases." Plaintiffs' Brief at 14.[8]

[8]What the Plaintiffs fail to mention in their brief is that the study summarizes the case of a patient who suffered from glenohumeral chondrolysis after her surgeon used bupivacaine and epinephrine in a pain pump, yet the authors specifically state that there was "no indication that a

The Court finds as a matter of law that this information was insufficient to trigger AstraZeneca's duty to warn of the risk of cartilage damage from continuous infusion of bupivacaine into a patient's joint. Simply put, the Plaintiffs have failed to point to evidence that demonstrates that at the time of Meharg's surgery AstraZeneca knew of that risk or that it should have known of the risk because the experts in the relevant field had such knowledge. While undoubtedly the line between having and not having a duty to warn of a particular risk often is hard to draw, in this case the evidence of record makes it clear that wherever the line was, it had not been reached by the time of Meharg's surgery.

Indeed, the Plaintiffs' own expert's report supports the finding that AstraZeneca had no duty to warn of the risk of cartilage damage from bupivacaine at the time of Meharg's surgery. The Plaintiffs cite to the declaration of Dr. Suzanne Parisian at ¶ 119 for their claim that AstraZeneca

> should have voluntarily sent out a Dear Healthcare Provider letter to Hospital Risk Managers, Operating Room Managers, Surgeons, Pharmacists warning that neither bupivacaine nor ropivacaine are currently approved for continuous intraarticular infusion in postoperative pain pumps. That ASTRAZENECA considered this an unapproved use and ASTRAZENECA had received spontaneous reports of postoperative cartilage deterioration. In the letter briefly describe the medical literature that provides biologic plausibility that this adverse event could be associated with unapproved continuous infusion of bupivacaine and/or ropivacaine into a traumatized joint.

However, what the Plaintiffs fail to note is that Dr. Parisian stated that AstraZeneca should have taken these actions after it received "spontaneous reports from Sorenson Medical of patients with

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chondrotoxic chemical was introduced into the glenohumeral joints of the patients reported here." Petty et al., *Glenhumeral Chondrolysis After Shoulder Arthroscopy: Case Reports and Review of the Literature*, 32 AM. J. SPORTSMED. 509, 513 (2004). In other words, the authors of the article did not suspect at that time that bupivacaine was toxic to cartilage, and the article therefore did not provide notice of that risk to AstraZeneca.

cartilage deterioration"–something that occurred on June 9, 2006, ***after Meharg's surgery***. Therefore, like the Court, the Plaintiffs' own expert did not find that there was a known risk of harm at the time of Meharg's surgery.[9]

CONCLUSION

The Court has carefully examined the evidence cited to by the Plaintiffs and determined that that evidence is insufficient to establish that at the time of Meharg's surgery AstraZeneca had a duty to warn physicians regarding the risk of cartilage damage from using a pain pump to administer bupivacaine. In the absence of such a duty, AstraZeneca cannot be held liable for Meharg's injury. Accordingly, AstraZeneca is entitled to summary judgment.

SO ORDERED: 03/01/2010

William T Lawrence

Hon. William T. Lawrence, Judge
United States District Court
Southern District of Indiana

[9]Dr. Parisian opines that prior to Meharg's surgery AstraZeneca knew that bupivacaine was being used in pain pumps and that this knowledge triggered a duty to "investigate the nature of that use, determine whether the drug was being promoted in accordance with approved indications, conduct or sponsor those studies necessary to ensure that the promoted use was safe, and to warn physicians that long-term risks to the joint had not been scientifically established but the risks should be weighed serious given that the anticipated use was for elective post-operative pain therapy for which multiple alternatives existed." Parisian ¶ 112. This "duty" does not exist under Indiana law, however. Under Indiana law, "the duty to warn . . . does not arise until the manufacturer knows or should know *of the risk.*" *Chapman*, 388 N.E.2d at 548. Dr. Parisian urges a far broader duty–a duty to warn physicians that there *might be a risk, but we don't know yet because we (and the scientific community at large) haven't studied it yet.* Requiring such warnings regarding an off-label use in the absence of a known risk would be highly inefficient: it would drain the resources of drug companies; it would cause physicians to be inundated with such pseudo-warnings and risk distracting them from heeding warnings of actual risk; and it would add very little to the fact that physicians already know that if a use is omitted from a prescription drug's label that use has not been tested sufficiently to demonstrate that it is safe and effective. Further, the Court notes that Meharg expressly disavows the position that "simply saying that the use was not approved satisfies AstraZeneca's duty," and argues instead that AstraZeneca was required to provide "[a] clear cautionary statement setting forth the exact nature of the dangers involved." Meharg Brief at 29. The problem with that argument is the fact that the "exact nature of the dangers involved" simply was not known prior to Meharg's surgery.

Copies to all counsel of record via electronic notification