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

OSCAR N. CLIFTON and DARLENE N. CLIFTON,	)	
	)	
Plaintiffs,	)	
	)	11 C 627
vs.	)	
	)	Judge Feinerman
I-FLOW CORPORATION,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Oscar N. Clifton and Darlene N. Clifton brought this diversity suit against Defendant I-Flow Corporation, alleging that Oscar sustained injuries from a medical device manufactured and marketed by I-Flow and that Darlene suffered loss of consortium as a result. In response to I-Flow's motion to dismiss portions of the initial complaint under Federal Rule of Civil Procedure 12(b)(6), Plaintiffs filed an amended complaint. I-Flow now moves under Rule 12(b)(6) to dismiss the amended complaint's negligent misrepresentation, fraud, and implied warranty claims, as well as what the parties call a punitive damages "count." Plaintiffs have stood on the amended complaint and oppose the motion. I-Flow's motion is granted as to the implied warranty claim and otherwise is denied.

Background

The well-pleaded facts alleged in the complaint are assumed true on a Rule 12(b)(6) motion. *See Reger Dev., LLC v. Nat'l City Bank*, 592 F.3d 759, 763 (7th Cir. 2010); *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005). On March 5, 2004, Dr. James Hill performed shoulder surgery on Oscar. To help Oscar manage post-operative pain, Dr. Hill affixed an I-Flow ON-Q pain pump to Oscar's shoulder, which delivered

anesthetic via a catheter directly into the glenohumeral (shoulder) joint. In August 2004, during a second operation, abnormalities were discovered in the joint. The shoulder continued to worsen, and in April 2009 a different physician found that Oscar had "degenerative changes of the glenohumeral joint." According to the amended complaint, the delivery of anesthetic directly into Oscar's shoulder joint caused a condition called "chondrolysis," which is the nearly complete loss of cartilage in the joint. Oscar has undergone shoulder joint replacement and will require additional surgeries.

Pain pumps traditionally were used to deliver anesthetic to the muscle but not to the joint. In the 1990s, I-Flow and other pain pump manufacturers sought approval from the Food and Drug Administration ("FDA") to indicate pain pumps for intra-articular use—meaning with the catheter inserted directly into the joint—but the FDA rejected the applications due to insufficient data. Despite the FDA's decision, and despite knowing that intra-articular use was not safe, I-Flow promoted its pain pumps as safe and appropriate for such use. Oscar and Dr. Hill relied upon those false representations in deciding to use the pain pump inter-articularly after Oscar's March 2004 surgery.

Discussion

The amended complaint has eight counts: negligence, negligent misrepresentation, fraud, strict product liability (design defect), strict product liability (failure to warn), breach of implied warranty, punitive damages, and loss of consortium. I-Flow has moved to dismiss the negligent misrepresentation, fraud, implied warranty, and punitive damages counts.

A. Fraud

As a general rule, Federal Rule of Civil Procedure 9(b) requires a fraud plaintiff to allege "the identity of the person who made the misrepresentation, the time, place and content of the

misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff." *Vicom, Inc. v. Harbridge Merchant Servs., Inc.*, 20 F.3d 771, 777 (7th Cir. 1994). "This ordinarily requires describing the 'who, what, when, where, and how' of the fraud, although the exact level of particularity that is required will necessarily differ based on the facts of the case." *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 615 (7th Cir. 2011). Rule 9(b) recognizes that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); *see also Burks v. Raemisch*, 555 F.3d 592, 594 (7th Cir. 2009). Moreover, "[i]n alleging the time period during which the misrepresentations and omissions are alleged to have been made, the plaintiff may allege an approximate time frame." *Hernandez v. Childers*, 736 F. Supp. 903, 912 (N.D. Ill. 1990).

I-Flow contends that the amended complaint "fails to set forth the circumstances of I-Flow's alleged misrepresentations, their contents, or their speakers, and how Plaintiffs or Plaintiff Oscar Clifton's physician heard and relied upon them." Doc. 23 at 2. The contention is incorrect. The amended complaint identifies I-Flow as the speaker, which suffices where the defendant is a corporation and the corporation itself is alleged to have made fraudulent misrepresentations. *See Talavera v. Metabolife Int'l, Inc.*, 2004 WL 2260628, at *2 (N.D. Ill. Sept. 24, 2004); *AAR Int'l Inc. v. Vacances Heliades S.A.*, 202 F. Supp. 2d 788, 799 (N.D. Ill. 2002) (citing cases). The amended complaint also identifies the content and timing of I-Flow's alleged misrepresentations, including: (1) a press release on September 2, 1998, falsely claiming that I-Flow received FDA approval to market its pain pump for orthopedic surgery applications; (2) a PowerPoint presentation sent to physicians in May 2001 stating that pain pumps were particularly useful in shoulder and other joint surgery; (3) a PowerPoint presentation prepared in November 2001 stating that the catheter may be inserted into the joint; and (4) a guide developed

in July 2002 specifying that the pain pump's catheter may be used intra-articularly. Doc. 21 at ¶¶ 66, 74. Finally, the amended complaint alleges that Oscar and Dr. Hill justifiably relied on I-Flow's false representations in deciding to insert the catheter into Oscar's joint space after his March 2004 shoulder surgery. *Id*. at ¶ 72. The evidence may defeat these allegations—in particular, the allegation that Dr. Hill and Oscar were aware of and relied upon I-Flow's alleged misrepresentations—but at the pleading stage they are sufficient under Rules 9(b) and 12(b)(6).

I-Flow also contends that the fraud claim actually is a "fraud-on-the-FDA" claim and therefore is preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2000). Doc. 23 at 4-8. In *Buckman*, the Supreme Court held that the FDCA preempts state law claims alleging that the defendant made fraudulent representations to the FDA to obtain approval for a drug or medical device and that, had the defendant not made those misrepresentations, the FDA would not have approved the drug or device and the plaintiff would not have been injured. 531 U.S. at 343-45. The amended complaint makes no such claim—to the contrary, it alleges that the FDA *declined* to approve I-Flow's pain pumps for intra-articular use and that I-Flow, despite the FDA's (correct) decision, marketed its pain pumps for that use anyway. Because Plaintiffs allege not that I-Flow tricked the FDA into approving pain pumps for a use that would have been rejected had I-Flow told the truth, but rather that I-Flow made misrepresentations to the medical community and the public at large, *Buckman* does not apply. S*ee Lafaivre v. KV Pharm. Co.*, 636 F.3d 935, 944 (8th Cir. 2011) (rejecting *Buckman* preemption and explaining that "[t]he misrepresentation at issue in *Buckman* was not made to the plaintiff—or consumers at large—but to the FDA itself") (internal quotation marks omitted); *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 775 (5th Cir. 2011) (rejecting *Buckman* preemption where the plaintiff's "claim does not depend on speculation that

the FDA would have taken any particular regulatory action in response to violation of the regulations at issue"); *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1234 (9th Cir. 2011) (rejecting *Buckman* preemption where "[t]he question before us is not whether [the defendant] provided inaccurate or incomplete information to the FDA, but rather whether it complied with its post-marketing obligations to warn consumers and health care professionals about additional risks associated with its product"); *Smith v. I-Flow Corp.*, 753 F. Supp. 2d 744, 750 n.1 (N.D. Ill. 2010).

B. Negligent Misrepresentation

I-Flow seeks dismissal of the negligent misrepresentation claim on the ground that it does not satisfy Rule 9(b). Doc. 23 at 1-4. The contention is meritless, as "a negligent misrepresentation claim … is *not* governed by the heightened pleading standard of Rule 9(b)." *Tricontinental Indus., Ltd. v. PricewaterhouseCoopers, LLP*, 475 F.3d 824, 833 (7th Cir. 2007). I-Flow does not argue that the negligent misrepresentation claim fails to satisfy the ordinary pleading standards of Rule 8(a)(2), so any such argument is forfeited. The argument would have been rejected in any event; because the fraud claim satisfies Rule 9(b), the negligent misrepresentation claim—which is based on the same alleged misrepresentations as the fraud claim—surely satisfies the less stringent pleading requirements of Rule 8(a)(2). *See Proctor v. Metro. Money Store Corp.*, 645 F. Supp. 2d 464, 476 n.3 (D. Md. 2009) ("*A fortiori*, because Plaintiffs meet the heightened burden under Rule 9(b), they have undoubtedly met the lower threshold of 'notice pleading' under Rule 8(a)(2).").

C. Implied Warranty

I-Flow contends that the implied warranty claim is barred by the four-year statute of limitations established by 810 ILCS 5/2-725(1). Plaintiffs' claim accrued in March 2004, when

the pain pump was affixed to Oscar's shoulder. *See* 810 ILCS 5/2-725(2) ("A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made …."); *Lipinski v. Martin J. Kelly Oldsmobile, Inc.*, 759 N.E.2d 66, 75 (Ill. App. 2001) ("the cause of action for breach of an implied warranty accrues when tender of delivery was made"). Barring some tolling or extension of the statute of limitations, the limitations period expired in March 2008, and this suit was not filed until January 28, 2011, nearly three years later. In an effort to avoid dismissal, Plaintiffs invoke 735 ILCS 5/13-215, which extends the limitations period where the defendant has fraudulently concealed the plaintiff's cause of action. *See generally Horbach v. Kaczmarek*, 288 F.3d 969, 975-76 (7th Cir. 2002). This effort fails because the amended complaint does not adequately plead fraudulent concealment.

To prove fraudulent concealment, a plaintiff "must show affirmative acts or representations by defendants *which were designed to prevent* and, in fact, did prevent, plaintiff from discovering his claim." *Gredell v. Wyeth Labs., Inc.*, 803 N.E.2d 541, 548 (Ill. App. 2004) (emphasis added); *see also Clay v. Kuhl*, 727 N.E.2d 217, 223 (Ill. 2000) ("As a general matter, one alleging fraudulent concealment must show affirmative acts by the fiduciary designed to prevent the discovery of the action.") (internal quotation marks omitted). Plaintiffs devote a section of the amended complaint to fraudulent concealment. Doc. 21 at ¶¶ 43-46. There, Plaintiffs allege that their claims were concealed by I-Flow's fraudulent conduct, but they do not allege, as they must, that I-Flow *intended* to prevent them from discovering their claims or "to lull or induce" them "into delaying the filing" of their claims. *Rajcan v. Donald Garvey & Assocs., Ltd.*, 807 N.E.2d 725, 728 (Ill. App. 2004) (internal quotation marks omitted). Without such an allegation, Plaintiffs cannot adequately plead fraudulent concealment, and without

fraudulent concealment, the implied warranty claim is barred by the statute of limitations. Because this is a matter of pleading, the court will give Plaintiffs a chance to re-plead their fraudulent concealment allegations, although they are reminded that any allegation that I-Flow intended to prevent them from discovering their claims must comply with Rule 11(b)(3).

D. Punitive Damages

The amended complaint sets forth a separate "count" for punitive damages. The Illinois Supreme Court has explained, however, that "a prayer for punitive damages is not, itself, a cause of action," but rather is "a type of remedy." *Vincent v. Alden-Park Strathmoor, Inc.*, 948 N.E.2d 610, 615 (Ill. 2011); *see also Obi v. Chase Home Fin., LLC*, 2010 WL 4810609, at *6 (N.D. Ill. Nov. 19, 2010 ("Under Illinois law, punitive damages are a type of relief, not an independent cause of action."). Thus, I-Flow's Rule 12(b)(6) motion to dismiss the punitive damages "count" is really a Rule 12(f) motion to strike Plaintiffs' request for punitive damages. *See Taylor v. Wal-Mart Stores, Inc.*, 2010 WL 146003, at *2 (S.D. Ill. Jan. 12, 2010).

The parties dispute whether the law of California (I-Flow's principal place of business) or Illinois (where Oscar was injured) governs the availability of punitive damages. Illinois choice-of-law rules guide this inquiry. *See Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487 (1941); *Malone v. Corr. Corp. of Am.*, 553 F.3d 540, 542 (7th Cir. 2009). The first step in the analysis is determining whether there is an actual conflict between the two States' laws. *See Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 898 (Ill. 2007) ("A choice-of-law determination is required only when a difference in law will make a difference in the outcome."); *Barron v. Ford Motor Co. of Can., Ltd.*, 965 F.2d 195, 197 (7th Cir. 1992) ("before entangling itself in messy issues of conflict of laws a court ought to satisfy itself that there actually is a difference between the relevant laws of the different states"). The parties do not

address this issue, let alone demonstrate the presence of a conflict, so for purposes of this motion to strike, the court will assume that Illinois law applies. *See Jean v. Dugan*, 20 F.3d 255, 260 (7th Cir. 1994) ("Where there is no disagreement among the contact states, the law of the forum state applies."); *compare Smith*, 753 F. Supp. 2d at 747 (conducting choice-of-law analysis because California law, which the plaintiff favored, allows punitive damages in product liability cases while Michigan law, which the defendant favored, does not).

Illinois law holds that a plaintiff seeking punitive damages must show that the defendant's "tortious conduct evince[d] a high degree of moral culpability" and that the conduct was "committed with fraud, actual malice, deliberate violence or oppression, or [that] the defendant act[ed] willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others." *Slovinski v. Elliot*, 927 N.E.2d 1221, 1225 (Ill. 2010) (internal quotation marks omitted); *see also LM Ins. Corp. v. Spaulding Enters. Inc.*, 533 F.3d 542, 551 (7th Cir. 2008) (punitive damages "are permissible where a duty based on a relationship of trust is violated, the fraud is gross, or malice or willfulness are shown") (internal quotation marks omitted); *Roboserve, Inc. v. Kato Kagaku Co., Ltd.*, 78 F.3d 266, 275 (7th Cir. 1996) ("Illinois courts do not favor punitive damages and insist that plaintiffs must establish not only simple fraud but gross fraud, breach of trust, or other extraordinary or exceptional circumstances clearly showing malice or willfulness.") (internal quotation marks omitted). The amended complaint alleges that I-Flow "misled both the medical community and the public at large, including Plaintiffs herein, by making false representations about the safety of its products"; that I-Flow "downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects associated with the use of its products despite available information demonstrating these products were likely to cause serious side effects"; that I-Flow "actually and consciously

considered whether intra-articular use of its pumps would be safe," yet "did not notify physicians that the safety of [such] use … was unknown, had not been studied[,] and had not been tested by I-Flow"; that "[a]t the time of manufacture or distribution of its pain pumps, I-Flow had actual knowledge that its pain pumps were defective and that there was substantial likelihood that the defect would cause injury that is the basis of this action," but that it "willfully disregarded that knowledge in the manufacture or distribution of its pain pumps"; and that I-Flow knew before its 1999 promotional campaign expressly marketing its pain pumps for intra-articular use that the safety of such use had not been proven and was dubious. Doc. 21 at ¶¶ 28, 31, 37, 66, 71.

These allegations, which plausibly suggest that I-Flow acted willfully, with malice, and with conscious disregard of the right of others in representing that its pain pumps were safe for intra-articular use, are sufficient to plead an entitlement to punitive damages. *See LM Ins. Corp*, 533 F.3d at 551; *Roboserve*, 78 F.3d at 275; *Azimi v. Ford Motor Co.*, 977 F. Supp. 847, 854-55 (N.D. Ill. 1996). Whether the evidence adduced in discovery or at trial will support these allegations, of course, is a different matter entirely.

Conclusion

For the foregoing reasons, Plaintiffs' implied warranty claim is dismissed without prejudice. If Plaintiffs wish to replead their fraudulent concealment allegations, which as explained above are essential to the vitality of their implied warranty claim, they are allowed leave to do so by November 9, 2011. I-Flow's motion to dismiss otherwise is denied.

October 26, 2011

United States District Judge