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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Lynn K. Staub and John P. Staub, Plaintiffs, vs. Breg, Inc., Defendant.	No. CV 10-02038-PHX-FJM **ORDER**

We have before us defendant's motion to preclude certain testimony of Peggy Pence (doc. 122), plaintiffs' response (doc. 127), defendant's reply (doc. 130), defendant's motion for summary judgment (doc. 119), defendant's statement of facts in support of motion for summary judgment (doc. 120), defendant's declaration in support of motion for summary judgment (doc. 121), plaintiffs' response (doc. 131), plaintiffs' controverting statement of facts (doc. 132), plaintiffs' additional statement of facts (doc. 133), defendant's reply (doc. 136), errata to plaintiffs' additional statement of facts (doc. 139), and defendant's notice of supplemental authority (doc. 146). We also have before us plaintiffs' motion for leave to file a sur-reply (doc. 140) and defendant's response (doc. 144).

I

Plaintiff Lynn Staub underwent surgery on her right shoulder in April 2005. Her surgeon inserted a post-operative anesthetic infusion pump, commonly known as a pain pump, which continuously administered local anesthetic through a catheter in the shoulder

joint for more than 48 hours following surgery. The pump used by Staub's surgeon was a Pain Care 4200 manufactured by defendant Breg, Inc. ("Breg"). The anesthetic used was Marcaine, a brand name for bupivacaine. (Doc. 132, ex. 3 at 4). Mrs. Staub continued to have shoulder problems and underwent a second surgery in August 2005. This surgery did not relieve her pain and she began visiting her second orthopedic surgeon again in the summer of 2009. He diagnosed her with "grade 3-4 degenerative arthritis of the glenohumeral joint" in October 2009. Amended Complaint ¶ 20. A different orthopedic surgeon diagnosed her with "postarthroscopic glenohumeral chondrolysis" and advised Staub that the pain pump from her April 2005 surgery was "directly causative" of her chondrolysis. Amended Complaint ¶¶ 22-23. Glenohumeral chondrolysis is the complete or nearly complete loss of cartilage in the shoulder joint.

Plaintiffs Lynn Staub and her husband John Staub brought this action on September 22, 2010 against defendant Breg, alleging negligence, negligent misrepresentation, fraud, strict product liability, failure to warn, violation of the Arizona Consumer Fraud Act ("ACFA"), and loss of consortium.[1] Defendant moves for summary judgment and exclusion of certain testimony of Peggy Pence, Ph.D. Defendant also moves to strike two of plaintiffs' exhibits (doc. 136). Plaintiffs move for leave to file a sur-reply.

II

Rule 702, Fed. R. Evid., permits an expert to testify in the form of an opinion "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." The expert's testimony must be based upon sufficient facts or data, be the product of reliable principles and methods, and the principles and methods must be applied reliably to the facts of the case. The expert's testimony must go beyond "subjective belief or unsupported speculation." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 590, 113 S. Ct. 2786, 2795 (1993).

[1]Plaintiffs originally alleged breach of implied warranty but have voluntarily dismissed that count. (Doc. 131 at 16).

The trial court acts as a gatekeeper by ensuring that expert testimony is "both relevant and reliable." Avila v. Willits Envtl. Remediation Trust, 633 F.3d 828, 836 (9th Cir. 2011). This "entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592-93, 113 S. Ct. at 2796.

Defendant does not dispute Dr. Pence's qualification as an expert on the development of prescription medical device products and the federal regulatory scheme governing them. Rather, defendant seeks to prevent Dr. Pence from: (1) construing federal law and concluding Breg violated it; (2) offering narrative histories; (3) speculating as to Breg's motive and intent; (4) "effectively instructing the jury to find Breg liable by opining that Breg violated the experts' subjective definition of the 'standard of care'"; (5) opining about events that post-date Lynn Staub's surgery; and (6) opining that Breg's conduct was equivalent to an "illegal and fraudulent promotion scheme" described in a criminal prosecution of Pfizer regarding the drug Neurontin. (Doc. 122 at 2). Plaintiffs submit that they will not offer testimony concerning Pfizer or the Neurontin litigation. They also agree that Dr. Pence will not testify as to the FDA's or Breg's intent. These portions of defendant's motion (subparts 3 and 6) are therefore denied as moot.

The rules on expert testimony have a "liberal thrust" and a "general approach of relaxing the traditional barriers to 'opinion' testimony." Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 169, 109 S. Ct. 439, 450 (1988). Many courts facing pain pump litigation have permitted Dr. Pence to testify. See Musgrave v. Breg, Inc., No. 2:09-cv-01029, 2011 WL 4543872, at *4-5 (S.D. Ohio Sept. 29, 2011) (denying a motion to exclude almost identical to the one at hand); Smith v. I-Flow Corp., No. 09 C 3908, 2011 U.S. Dist. LEXIS 47197, at *15-19 (N.D. Ill. May 3, 2011) (permitting Pence to testify about manufacturer's compliance or non-compliance with federal regulations and whether it should have known of risks, but noting she could not testify on whether manufacturer acted with any particular mental state or violated state law); Schott v. I-Flow Corp., 696 F. Supp. 2d 898, 905 (S.D. Ohio 2010) (finding Pence's testimony admissible because it "could assist the jury in

understanding the complex regulatory scheme applicable to medical devices" and was not offered as an opinion on the ultimate issue of Ohio law); Paugh v. I-Flow Corp., No. 32D02-0802-CT-9, at *6 (Ind. Super. Ct. Apr. 19, 2010) (quoted in Musgrave, supra, at *5). We agree with these courts that Dr. Pence's testimony should not be precluded, subject to limits noted below.

First, we find much of Dr. Pence's testimony to be both relevant and reliable. Her opinions that defendant failed to comply with FDA regulations may assist jurors in understanding the specific FDA-approved applications of pain pumps. Plaintiffs contend that the FDA's rejection of defendant's description of its product should have made defendant aware of the need to conduct further testing. Dr. Pence's testimony is relevant to plaintiffs' testing theory. Her methodology includes reviewing FDA regulations and publications, medical literature, depositions, defendant's internal communications, and correspondence with the FDA. She lays a foundation for her opinions based on these documents and links her analysis to her opinions. "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." Daubert, 509 U.S. at 596, 113 S. Ct. at 2798.

An expert witness's otherwise admissible opinion is "not objectionable because it embraces an ultimate issue to be decided by the trier of fact." Rule 704(a), Fed. R. Evid. "However, an expert witness cannot give an opinion as to her *legal conclusion, i.e.*, an opinion on an ultimate issue of law." Elsayed Mukhtar v. Cal. State Univ., Hayward, 299 F.3d 1053, 1065 n.10 (9th Cir. 2002). Plaintiffs are not offering Dr. Pence as an expert on the ultimate issues of law in this case. Her testimony regarding FDA regulations could be helpful to the jury and will not usurp its role of deciding whether defendant violated Arizona law.

Breg objects that much of Dr. Pence's report involves narrative testimony summarizing Breg and FDA documents. Dr. Pence will generally not be allowed to simply read documents that jurors may read and interpret for themselves. See In re Fosamax Prods.

Liab. Litig., 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (court limited expert's commentary on documents and exhibits in evidence to "explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge."). She must provide some analysis, opinion, or expertise when testifying about the regulatory process and history of pain pumps. Objections to narrative testimony are best made at trial.

Defendant objects to Dr. Pence's proffered testimony that Breg violated the standard of care. As it notes in its reply, plaintiffs largely fail to address Breg's objection to Dr. Pence's testimony on this topic. (Doc. 130 at 6). Her report does not contain any description of industry standards other than governing FDA regulations. An expert is not permitted to give an opinion simply based on her "subjective belief or unsupported speculation." Daubert, 509 U.S. at 590, 113 S. Ct. at 2795. Dr. Pence may testify as to whether she believes defendant's actions were reasonable in light of objective standards, but any testimony that is grounded on nothing more than her personal views will be excluded.

Defendant further seeks to restrict Dr. Pence's testimony by excluding opinions based on events occurring after Lynn Staub's surgery. Defendant's motion on this topic is premature and overly broad. We cannot say at this time that all events and documents postdating the surgery are inadmissible on all potential grounds.

III

We grant summary judgment if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Rule 56(a), Fed. R. Civ. P. Summary judgment is not appropriate "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510 (1986). We view the facts and inferences in the light most favorable to the non-moving party. Adickes v. S. H. Kress & Co., 398 U.S. 144, 157, 90 S. Ct. 1598, 1608 (1970). "Questions involving a person's state of mind, e.g., whether a party knew or should have known of a particular condition, are generally factual issues inappropriate for resolution by summary judgment." Braxton-Secret v. A.H. Robins Co., 769 F.2d 528, 531 (9th Cir.

1985). Where there is disagreement over the legal effect of facts rather than the facts themselves, though, such a dispute can properly be decided on summary judgment. Fonda v. Gray, 707 F.2d 435, 438 (9th Cir. 1983).

IV

"A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings." Restatement (Third) of Torts: Products Liability § 2 (1998). Plaintiffs base their claims on design and warning defects. We address the design claim first and find that plaintiffs have failed to show the pain pump at issue was defectively designed.

A federal court sitting in diversity applies state law to product liability claims. See Adams v. Synthes Spine Co., 298 F.3d 1114, 1117 (9th Cir. 2002). Defendant urges us to apply the Restatement (Third) of Torts, while plaintiffs counter that this is not the law in Arizona. "Where the state's highest court has not decided an issue, the task of the federal courts is to predict how the state high court would resolve it." Ticknor v. Choice Hotels Int'l, Inc., 265 F.3d 931, 939 (9th Cir. 2001) (citation omitted). Although Arizona has not formally adopted the Restatement (Third) of Torts, it "has demonstrated a willingness to look to [it] as the current statement of the law." Gebhardt v. Mentor Corp., 191 F.R.D. 180, 185 (D. Ariz. 1999), aff'd 15 F. App'x 540 (9th Cir. 2001). Courts in this District apply the Restatement (Third) of Torts to medical device design defect claims. See Mills v. Bristol-Myers Squibb Co., No. CV 11-00968-PHX-FJM, 2011 WL 4708850, at *2 (D. Ariz. Oct. 7, 2011); Harrison v. Howmedica Osteonics Corp., No. CIV 06-0745 PHX RCB, 2008 WL 906585, at *21-22 (D. Ariz. Mar. 31, 2008); Gebhardt, 191 F.R.D. at 185. Section 6(c) provides that

> [a] prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Restatement (Third) of Torts: Products Liability § 6(c) (1998).

Under this standard, "a prescription drug or medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients." Id. cmt. b. The Food and Drug Administration ("FDA") has approved use of defendant's pain pump "to provide continuous infusion of a local anesthetic for the post-operative management of pain." (Doc. 121, ex. O). This approval suggests that the pain pump is useful to some patients and physicians would prescribe it for a class of patients. As a result, the pain pump is not defectively designed pursuant to § 6(c).

V

Defendant claims that insufficient evidence of a duty to warn warrants summary judgment on plaintiffs' claims for negligence, negligent misrepresentation, fraud, strict liability, failure to warn, violation of the ACFA, and punitive damages. We disagree because we find that plaintiffs have submitted evidence sufficient to create a genuine issue of material fact as to whether Breg should have known by April 2005 of the risk of chondrolysis following intra-articular infusion of anesthetics after shoulder surgery.

Failure-to-warn claims have survived summary judgment in numerous pain pump cases around the nation. See, e.g., Creech v. Stryker Corp., No. 2:07CV22 DAK, 2012 WL 33360 (D. Utah Jan. 6, 2012) (finding genuine issues of material fact regarding defective design and failure to warn, because jury could conclude manufacturer knew or reasonably should have known before surgeries dating from February 2003 to July 2004 that pain pump created a foreseeable risk of harm); Hackett v. Breg, Inc., No. 10CV1437, 2011 WL 4550186 (D. Colo. Oct. 3, 2011) (expert testimony established genuine dispute concerning what was knowable or foreseeable by April 2002 surgery); Slavenski v. Breg, Inc., No. 09-6241-AA, 2011 WL 2709108 (D. Or. July 11, 2011) (finding question of what was knowable or should have been anticipated by March 2006 appropriate for the trier of fact, based on medical literature and FDA regulatory history); Monroe v. Zimmer U.S. Inc., 766 F. Supp. 2d 1012, 1035-37 (E.D. Cal. 2011) (denying summary judgment in part on failure-to-warn claim based on testing theory because it was supported by Pence's expert testimony); Hamilton v. Breg, Inc., No. 2:09-CV-146, 2011 WL 780541, at *3 (S.D. Ohio Jan. 20, 2011) ("medical

evidence that pain pumps could cause chondrolysis was at best fragmentary at the time of plaintiffs' surgeries" in September 2005 and February 2006, but decades-old research showed that injecting foreign substances into a joint could harm or kill cells of cartilage tissue); Suhn v. Breg, Inc., No. CIV. 08-4190-KES, 2010 WL 5301043 (D. S.D. Dec. 20, 2010) (finding question of what was foreseeable by December 2005 appropriate for the trier of fact).

On the other hand, many courts have granted summary judgment to pain pump manufacturers. Rodriguez v. Stryker Corp., No. 2:08-0124, 2011 WL 31462, at *8 (M.D. Tenn. Jan. 5, 2011) ("[T]he risk of chondrolysis was not 'knowable' at the time of the plaintiff's surgery in November 2004. . . . no expert–at the relevant time–knew of the specific risk and, therefore, it is unreasonable to conclude that [defendant] should have had constructive knowledge of that risk."); Phillippi v. Stryker Corp., No. 2:08-CV-02445-JAM-KJN, 2010 WL 2650596 (E.D. Cal. July 1, 2010), aff'd, 2012 WL 759390 (9th Cir. Mar. 9, 2012) (medical knowledge available in July 2005 did not create a duty to warn or test); Meharg v. I-Flow Corp., No. 1:08-cv-184-WTL-TAB, 2010 WL 711317 (S.D. Ind. Mar. 1, 2010) (granting summary judgment to anesthetic manufacturer based on lack of duty to warn in February 2006). In many of these cases, the court based its decision on the plaintiff's failure to submit expert testimony. See, e.g., Pavelko v. Breg, Inc., No. 09-cv-01461-PAB-KMT, 2011 WL 782664, at *5 (D. Colo. Feb. 28, 2011) (granting summary judgment to manufacturer because literature without expert testimony explaining its significance did not suggest that defendant should have been on notice of potential dangers of intra-articular use, and no expert testimony supported claim of inadequate testing); Monroe, 766 F. Supp. 2d at 1034 (granting summary judgment in part because "[t]he court cannot accept *counsel's* interpretation of the medical literature"); Krumpelbeck v. Breg, Inc., 759 F. Supp. 2d 958, 968 (S.D. Ohio 2010) (pre-March 2005 articles "on their face" did not put defendant on notice of risk, and "the Court is not willing to rely on counsel's interpretation of the literature").

Arizona recognizes warning defects as one basis for a products liability action. "(A) product, although faultlessly made, may nevertheless be deemed 'defective' under the rule

and subject the supplier thereof to strict liability if it is unreasonably dangerous to place the product in the hands of a user without a suitable warning." Tucson Industries, Inc. v. Schwartz, 108 Ariz. 464, 468, 501 P.2d 936, 940 (1972) (quoting Canifax v. Hercules Powder Co., 46 Cal. Rptr. 552, 558 (Ct. App. 1965)). The foresight test of the Restatement (Third) of Torts applies to warning defects. Powers v. Taser Int'l, Inc., 217 Ariz. 398, 402-05, 174 P.3d 777, 781-84 (Ct. App. 2007).

Under the Restatement (Third), a medical device is defective if it is not reasonably safe due to inadequate instructions or warnings. Restatement (Third) of Torts: Products Liability § 6(b)(3) (1998).

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings . . . .

Id. § 6(d). A manufacturer is required to warn of risks that were known or should have been known to a reasonable manufacturer at the time of sale. See also id. § 6 cmt. g ("Duties concerning the design and marketing of prescription drugs and medical devices arise only with respect to risks of harm that are reasonably foreseeable at the time of sale.")

Plaintiffs contend that defendant had actual knowledge of an association between chondrolysis and pain pumps by February 2005, when two surgeons spoke to Breg at a meeting of the American Association of Orthopaedic Surgeons ("AAOS"). Manufacturers such as Breg set up booths at this meeting to display their products to doctors. According to plaintiffs, Dr. Charles Beck and Dr. Lonnie Paulos told Breg representatives that pain pumps were likely causing chondrolysis. But Dr. Beck's testimony from a 2009 trial does not indicate that he spoke with Breg, nor does it reflect that he actually warned manufacturers of anything at the AAOS meeting:

> I went and tried to tried say – to find out, like I mentioned earlier, what was going on. And I was met with a blank stare at most of them. When I asked them to call me, different manufacturers that I knew made these pain pumps, they just kind of nodded and gave me this little wry grin and took my name; and then that was it, never had any other response. And it wasn't just Stryker; it was all of them.

(Doc. 133, ex. 31 at 4). In addition, there is no evidence that Dr. Paulos expressed his concerns to Breg at this meeting. His affidavit merely states that he communicated his concerns about pain pumps to Stryker, another manufacturer, in 2005. (Doc. 133, ex. 26). At his deposition, he stated he met with Breg representatives at the AAOS meeting, but the quoted testimony provides no indication of what he purportedly told them and whether his information should have put Breg on notice of potential dangers. (Doc. 139, ex. 30). The evidence of conversations between these surgeons and Breg representatives does not support the contention that Breg knew or should have known of the potential causal link between pain pumps and chondrolysis.

Other evidence suggests Breg did not actually know of any danger until after plaintiff Lynn Staub's surgery in April 2005. For instance, the earliest adverse event reports which mentioned chondrolysis were submitted by a competitor in September 2005. (Doc. 132, ex. 19 at 45). Plaintiffs' expert, Dr. Pence, opines that Breg did not definitely have actual knowledge until December 2005. ("Breg internal correspondence demonstrates that Breg was on notice concerning chondrolysis reports no later than December 2005.") Id. at 44.

Plaintiffs have not demonstrated that Breg knew by April 2005 of the risk that intra-articular infusion of anesthetics could cause chondrolysis. As a result, their claims must rest upon what Breg should have known at that time. Plaintiffs submit evidence of presentations at medical conferences, adverse event reports, medical literature, and the FDA's rejection of orthopedic applications purporting to show that Breg should have known of the potential danger of continuous intra-articular infusion of anesthetics into a joint by April 2005.

Several presentations at medical conferences raised concerns about the growing trend of chondrolysis as early as 2003. A slide show prepared for an October 2003 closed meeting of the American Shoulder and Elbow Surgeons ("ASES") identified chondrolysis as a problem with an unknown cause. (Doc. 132, ex. 8 at 5). While intra-articular pain pumps were listed as a possible cause, only two of fifteen patients cited, who developed chondrolysis, had received a pain pump. A November 2003 ASES meeting identified the infusion of epinephrine as a concern. (Doc. 132, ex. 9). And at an undated 2003 ASES

meeting, another presenter concluded that surgeons should avoid only the use of intra-articular pain pumps with epinephrine. (Doc. 132, ex. 10). There is no indication epinephrine was used in plaintiff's pain pump. Without expert testimony, we decline to rely on counsel's interpretation that these presentations should have alerted defendant to a potential causal link between chondrolysis and intra-articular infusion of all anesthetics.

Plaintiffs submit adverse event reports. Pursuant to 21 C.F.R. part 803, medical device manufacturers must report certain device malfunctions and deaths and serious injuries that a device may have caused or contributed to. 21 C.F.R. § 803.1(a). The FDA compiles these adverse event reports and discloses some of the information to the public. The Manufacturer and User Facility Device Experience ("MAUDE") database contains reports of adverse events involving medical devices. In February 2002, a MAUDE adverse event report indicated that four patients developed wound necrosis after using a Breg pain pump following knee surgery. (Doc. 133, ex. 19). Plaintiffs claim that, like chondrolysis, necrosis is the death of cells, and this report should have put Breg on notice of a duty to test and warn. (Doc. 133 ¶ 27). Defendants counter that "to equate soft tissue necrosis with the cartilage damage characteristic of chondrolysis flies in the face of Plaintiffs' theme that it is one, specific use of pain pumps – intra-articular infusion of anesthetics directly into the shoulder cartilage – that is both unreasonably dangerous and (supposedly) off-label." (Doc. 136 at 8-9). Neither plaintiffs nor defendant have expert testimony to support their statements about soft tissue necrosis and cartilage damage.

Tissue necrosis occurred in these cases "as a result of leakage." (Doc. 133 ¶ 27). The pump failed to function as intended, and plaintiffs' own words show that it was this malfunction which caused necrosis. Other adverse events occurred in 2002 involving "secondary skin problems" developing after knee surgeries. (Doc. 133, ex. 20 at 4). At least one of these cases involved "off brand use" of part of a Breg pump kit with another infusion system. Id. at 3. It is unclear whether a manufacturing defect, design defect, failure to warn, operator error, or something else caused these problems. This evidence alone would not have established a duty to warn of dangers resulting from intra-articular infusion of anesthetics.

According to plaintiffs, medical literature pre-dating Staub's surgery in April 2005 should also have alerted Breg to the association between chondrolysis and continuous intra-articular infusion of anesthetics. Other courts have noted that the evidence that pain pumps could cause chondrolysis was "at best fragmentary" by February 2006 and "not so certain" as late as May 2010. Hamilton v. Breg, Inc., No. 2:09-CV-146, 2011 WL 780541, at *3 (S.D. Ohio Jan. 20, 2011); In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig., 709 F. Supp. 2d 1375, 1377 n.3 (J.P.M.L. 2010) (denying motion for centralized proceedings of more than 100 pain pump lawsuits). Articles published in the year before Staub's surgery provide mixed evidence on causation.

The American Journal of Sports Medicine published an article by Damon H. Petty et al. in 2004 describing three cases of glenohumeral chondrolysis. Only one of the patients reportedly used a pain pump, and the authors noted there was "no indication that a chondrotoxic chemical was introduced into the glenohumeral joints of the patients reported here." (Doc. 133, ex. 28 at 513). The authors concluded that the disease pathology is "currently not understood" but "thermal energy is suspected to play a role." Id. at 514.

The Journal of International Medical Research published an article in 2004 discussing chondrocyte changes after injecting rabbit knee joints with bupivacaine and neostigmine, two anesthetics commonly administered intra-articularly. The authors found that "bupivacaine is an agent that can be used safely as an intra-articular injection," but since the drugs caused histopathological changes in the joints, "physicians should be cautious when administering intra-articular bupivacaine and neostigmine." (Doc. 133, ex. 29 at 517-18).

In May 2004, an officer with the FDA published a two-page article in the journal Anesthesiology about adverse event reports involving infusion pumps. She wrote that "[t]he reports do not establish a causal link . . . . [I]t is not possible to definitively conclude that the reported necrosis or infections after surgery was due to infusion pump use . . . ." (Doc. 133, ex. 25 at 1306). Nevertheless, she believed the reports suggested "the need for further investigation," as it was unclear whether the injuries represented "sentinel events" or "isolated incidents." Id. at 1305-06. This brief report prompted a Breg employee to send a

memorandum to all sales representatives and distributors emphasizing that the article was "not a sanctioned FDA report" and "there is no conclusion on a cause and effect relationship between continuous infusion pumps and necrosis in this report." (Doc. 133, ex. 23). While these articles did not conclude that intra-articular infusion of anesthetics caused chondrolysis, a trier of fact could find that such a linkage was foreseeable based on the research.

Unforeseeable harms cannot be a basis of liability for failure to warn. "Drug and medical device manufacturers have the responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal." Restatement (Third) of Torts: Products Liability § 6 cmt. g. "If testing is not undertaken, or is performed in an inadequate manner, and this failure results in a defect that causes harm, the seller is subject to liability for harm caused by such defect." Id. § 2 cmt. m.

Plaintiffs present expert testimony establishing that defendant was marketing pain pumps for intra-articular use, the FDA approved the pumps for intra-operative use, and intra-operative use does not include intra-articular use. See Monroe v. Zimmer U.S. Inc., 766 F. Supp. 2d 1012, 1035-37 (E.D. Cal. 2011) (relying on Dr. Pence's testimony to deny summary judgment in regards to a duty to warn based on 'testing' theory); cf. Rodriguez v. Stryker Corp., No. 2:08-0124, 2011 WL 31462, at *7 (M.D. Tenn. Jan. 5, 2011) (There is "nothing to suggest that, if the 'intraoperative' site was at the synovial cavity, the pump was not indicated for use."); Krumpelbeck v. Breg, Inc., 759 F. Supp. 2d 958, 973 (S.D. Ohio 2010) (no evidence that pain pumps were not cleared for orthopedic applications or defendant was required to engage in pre-market approval process). Dr. Pence also testified that the FDA repeatedly refused to approve pain pump applications that included references to orthopedic use, which would include infusion into the intra-articular site. She opines that "there is no specific orthopedic application for which Breg could legally market any of its family of Pain Care infusion pumps and accessories." (Doc. 127, ex. 1 at 37). Even if this is true and defendant's off-label promotion violated the Federal Food, Drug, and Cosmetic Act ("FDCA"), plaintiffs do not have a private remedy under the FDCA. 21 U.S.C. § 337;

PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010). It is possible, however, that the FDA's rejection of defendant's descriptions and requests for data to support orthopedic use should have alerted defendant to the need to conduct safety testing and issue warnings specifically related to continuous infusion of anesthetics into an intra-articular site. (Doc. 127, ex. 1 at 31-36). It is a question of fact whether such testing should have been performed and whether the failure to test resulted in a warning defect that caused harm. There is sufficient evidence from which a jury could find that Breg should have known that continuous intra-articular infusion of local anesthetics could cause chondrolysis.

VI

Punitive damages may be awarded to punish defendant and deter defendant and others from future misconduct. Gurule v. Ill. Mut. Life & Cas. Co., 152 Ariz. 600, 601, 734 P.2d 85, 86 (1987). They are appropriate only if the defendant acted with an "evil mind," which may be found where "defendant consciously pursued a course of conduct knowing that it created a substantial risk of significant harm to others." Rawlings v. Apodaca, 151 Ariz. 149, 162, 726 P.2d 565, 578 (1986). As discussed above, there is no evidence that Breg had actual knowledge by the date of Staub's surgery. Accordingly, Breg could not have known that its conduct created a substantial risk of significant harm. There is insufficient evidence from which a jury could find by clear and convincing evidence that Breg acted with an "evil mind," and so a claim for punitive damages cannot be supported.

VII

Finally, we address plaintiffs' motion for leave to file a sur-reply (doc. 140). LRCiv 7.2 does not authorize a response to a reply. Plaintiffs contend they must be allowed to file a sur-reply because defendant's reply asked us to strike two exhibits as inadmissible hearsay. Defendant has not shown that the statements would be inadmissible at trial. In any event, LRCiv 7.2(m) does not permit motions to strike. No sur-reply is necessary.

VIII

IT IS HEREBY ORDERED GRANTING in part and **DENYING** in part defendant's motion for summary judgment (doc. 119). Summary judgment is granted as to

plaintiffs' implied warranty claim, all claims based on design defect, and the request for punitive damages. Summary judgment is denied as to plaintiffs' remaining claims.

IT IS FURTHER ORDERED DENYING defendant's motion to preclude testimony, without prejudice to make objections at trial. (Doc. 122).

IT IS FURTHER ORDERED DENYING defendant's motion to strike (doc. 136).

IT IS FURTHER ORDERED DENYING plaintiffs' motion for leave to file a sur-reply (doc. 140).

DATED this 29th day of March, 2012.

Frederick J. Martone

Frederick J. Martone
United States District Judge