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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Gilbert S. Placencia and Theresa Placencia, Plaintiffs, v. I-Flow Corporation, a Delaware corporation; Breg, Inc., a California corporation, Defendants.	No. CV10-2520 PHX DGC **ORDER**

Pending before the Court are the following motions: (1) Motion for Summary Judgment by Defendant I-Flow Corporation ("I-Flow") (Doc. 129); (2) Joint Motion to Strike Certain Opinions of Dr. Badylak by I-Flow and Defendant Breg Incorporated ("Breg") (Doc. 131); (3) Joint Motion to Strike Certain Opinions of Dr. Busfield by I-Flow and Breg (Doc. 132); (4) Joint Motion to Strike Dr. Pence by I-Flow and Breg (Doc. 136); (5) Motion for Partial Summary Judgment by Breg (Doc. 137); and (6) Motion to Strike Dr. Greenland by I-Flow (Doc. 140). The motions are fully briefed. For the reasons set forth below, the Court will grant in part and deny in part Defendants' motions. [1] [2]

[1] I-Flow's and Breg's requests for oral argument are denied. The parties' hundreds of pages of briefing and other submissions have amply addressed the issues raised by these motions, and the Court concludes that oral argument will not aid its decision. *See* Fed. R. Civ. P. 78(b); *Partridge v. Reich*, 141 F.3d 920, 926 (9th Cir. 1998).

[2] Throughout their briefing, Plaintiffs appear to use a font size not permitted by the Court's local rules. *See* LRCiv 7.1(b)(1). Plaintiffs' counsel shall comply fully with the Court's local rules in all future filings.

I. Background.

On April 13, 2005, Plaintiff Gilbert Placencia ("Gilbert") underwent arthroscopic surgery on his right shoulder. Doc. 1 at ¶ 2. Gilbert's surgeon, Dr. David Bailie, implanted an I-Flow ON-Q PainBuster continuous infusion therapy device into Gilbert's right shoulder joint space. *Id.* at ¶¶ 2, 9. A continuous infusion therapy device ("pain pump") delivers pain relief medication to a specific place in the body, usually a post-surgical site. *Id.* at ¶ 2. The pain pump contains a reservoir for the medication and a catheter that delivers the medication to the desired site continuously for 72 hours or more following surgery. *Id.* at ¶ 9. On November 21, 2005, Dr. Bailie performed a second arthroscopic surgery on Gilbert's right shoulder. *Id.* at ¶ 3. During this surgery, Dr. Bailie implanted a Breg PainCare 3200 pain pump in Gilbert's right shoulder joint space. *Id.* Dr. Bailie used the pain pumps according to the instructions provided by I-Flow and Breg. *Id.* at ¶ 11.

Gilbert experienced ongoing pain, immobility, and lack of function in his shoulder. *Id.* at ¶ 9. In late 2009, Gilbert was diagnosed with chondrolysis, a degenerative and permanent condition involving the complete or nearly complete loss of cartilage in the shoulder joint. *Id.* at ¶¶ 9-10. Plaintiffs Gilbert Placencia and his wife Theresa ("Plaintiffs") brought this action against I-Flow and Breg alleging (1) strict product liability: design defect, failure to warn, (2) negligence, (3) civil conspiracy between Defendants I-Flow and DJO (dismissed as to Defendant DJO, Doc. 48 at 6), (4) loss of consortium, (5) damages, and (6) punitive damages. Doc. 1.

In 1998, pursuant to I-Flow's 510(k) application, the FDA cleared I-Flow's pain pump for use in an intraoperative site. Doc. 161-1 at ¶¶ 29C-29D. I-Flow subsequently sought clearance for intra-articular and orthopedic indications, but the FDA denied such clearance. Doc. 161-1 at ¶¶ 29F-29J.

Breg filed a similar 510(k) application for its PainCare 3200 device and received clearance in 2001 for use in an intraoperative site. Doc. 138 at ¶ 6. Like I-Flow, Breg filed subsequent 510(k) applications that included references to orthopedic procedures,

but the FDA never cleared the device for orthopedic indications. Doc. 162-1 at ¶¶ 16-20.

Medical device companies' sales teams provide orthopedic physicians with information pertaining to the use of their product. Doc. 161-1 at ¶ 8A. In accordance with I-Flow's sales training materials, I-Flow's sales representatives marketed the pain pump for intra-articular use. *Id.* at ¶ 36. Breg's sales team similarly promoted its pain pump. Doc. 162-1 at ¶ 26. Although Defendants dispute these facts, the Court must construe the evidence in the light most favorable to the non-moving parties when ruling on motions for summary judgment.

The medical literature remains inconclusive as to the cause of chondrolysis (Doc. 130 at ¶ 27; Doc. 138 at ¶¶ 9-13), but reports indicating that articular cartilage cells are fragile and susceptible to damage when exposed to a variety of foreign substances began surfacing in the early 2000s (Doc. 161-1 at ¶ 22C; Doc. 162-1 at ¶ 22). Peer reviewed publications subsequently indicated a potential connection between intra-articular pain pump use and chondrolysis. Doc. 130 at ¶ 23; Doc. 138 at ¶¶ 4-5.

A party seeking summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the evidence, if viewed in the light most favorable to the nonmoving party, shows "that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

II. I-Flow's Motion for Summary Judgment.

A. Strict Product Liability.

To establish a claim for strict liability, a plaintiff must show that "the product is defective and unreasonably dangerous; the defective condition existed at the time it left

defendant's control; and the defective condition is the proximate cause of plaintiff's injuries or property loss." *Rocky Mountain Fire and Cas. Co. v. Biddulph Oldsmobile*, 640 P.2d 851, 854 (Ariz. 1992). Both design defects and informational defects encompassing instructions and warnings can result in an unreasonably dangerous product. *Gosewisch v. American Honda Motor Co.*, 737 P.2d 376, 379 (Ariz. 1987). Plaintiffs' strict liability cause of action alleges defective labeling and failure to warn (Doc. 1 at ¶¶ 13A-13F), and defective design (*id.* at ¶¶ 13G-13H). I-Flow argues it is entitled to summary judgment because the alleged risk of chondrolysis was unknown at the time of Gilbert's surgery (Doc. 129 at 2), and a medical device cannot be defective unless physicians would not prescribe the device for any class of patients (*Id.* at 3).

1. Failure to Warn.

In a strict liability failure to warn claim, a plaintiff must prove "that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Powers v. Taser Int'l, Inc.*, 174 P.3d 777, 783 (Ariz. Ct. App. 2007). A seller is charged, however, "'with knowledge of what reasonable testing would reveal.'" *Id.* at 784 (quoting *Restatement (Third) of Torts: Prod. Liab.* § 2 cmt. m (1998)); *see also Restatement* § 2 cmt. m ("[A] seller bears responsibility to perform reasonable testing prior to marketing a product. . . . 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.").

I-Flow argues that at the time of Gilbert's surgery, no one suspected a possible association between the use of pain pumps and chondrolysis and thus the risk was not known or knowable and testing was not required. Doc. 129 at 5. In response, Plaintiffs argue that I-Flow had reason to know there was a risk and would have discovered the risk through reasonable testing. Doc. 161 at 5-9.

Plaintiffs have not presented evidence that I-Flow knew that pain pumps would cause chondrolysis when Gilbert's surgery occurred in April of 2005, but they have

presented evidence that raises a genuine issue of material of fact as to whether I-Flow had sufficient information to prompt further testing before the pain pump was used for intra-articular purposes. For example, Plaintiffs have presented evidence that I-Flow's request that the FDA approve the pain pump for intra-articular uses was denied, in the words of an internal FDA memo, because "there was no accompanying data to demonstrate that this device may be used safely and effectively with this use." Doc. 163-48 at 4. Plaintiffs have also presented evidence that the FDA denied I-Flow's request for approval of intra-articular uses several times before 2005 (Doc. 161-1, ¶¶ 29A-29P), that a number of medical articles that predated Gilbert's surgeries, although not drawing a direct link between pain pumps and chondrolysis, suggested that various substances, including local anesthetics, can damage cartilage (*id.* at ¶¶ 22A-22F), and that I-Flow was told in 2004 about instances of chondrolysis related to pain pumps (*id*. at ¶ 22G). When this and other evidence produced by Plaintiffs is viewed in the light most favorable to Plaintiffs, with all reasonable inferences drawn in their favor, Plaintiffs have raised a genuine issue of fact as to whether I-Flow possessed sufficient information before 2005 to prompt testing of the pain pump for intra-articular uses.

2. Design Defect.

Courts in this District apply the Restatement (Third) of Torts to medical device design defect claims. *Staub v. Breg, Inc.*, 2012 WL 1078334, at *4 (D. Ariz. 2012). According to the Restatement, a medical device is defective if medical providers, knowing of its benefits and risks, would not prescribe the device "for *any* class of patients." *Restatement (Third) of Torts: Products Liability* § 6(c) (1998) (emphasis added). I-Flow contends that Plaintiffs' design defect claim fails because physicians prescribe its pain pump for use in a variety of operations. Doc. 129 at 8-9.

Plaintiffs fail to respond to I-Flow's argument (Doc. 161), and in responding to Breg's similar argument "concede that their claims are properly characterized as failure to warn, not design defect or manufacturing defect claims, whether couched in negligence or strict liability" (Doc. 162 at 2). The Court will grant I-Flow's summary judgment

motion as to Plaintiffs' design defect claim. To the extent Plaintiffs also assert a manufacturing defect claim, it too is undefended and will be eliminated by summary judgment.

B. Negligence.

"To establish a claim for negligence, a plaintiff must prove four elements: (1) a duty requiring the defendant to conform to a certain standard of care; (2) a breach by the defendant of that standard; (3) a causal connection between the defendant's conduct and the resulting injury; and (4) actual damages." *Gipson v. Kasey*, 150 P.3d 228, 230 (Ariz. 2007). A manufacturer owes a duty to the users of its products "to conform to the legal standard or reasonable conduct in light of the apparent risk." *Stanley v. McCarver*, 92 P.3d 849, 854 (Ariz. 2004).

Plaintiffs allege that I-Flow negligently (1) failed to instruct, warn and disclose information pertaining to the safety of using the pain pump in the shoulder joint space, (2) manufactured a product designed to inject dangerous medications into the shoulder joint, (3) failed to conduct studies or otherwise investigate the potential harm to articular cartilage when exposed to pain pumps and anesthetic medications for two or more days in the shoulder joint space, and (4) promoted pain pumps for use in the joint space after FDA consideration and rejection. Doc. 1 at ¶¶ 16-17. To the extent Plaintiffs' negligence claim includes negligent design or manufacture of the pain pump, the Court will grant summary judgment for reasons explained above.

1. Duty to Test.

In a negligent failure to warn case, a plaintiff must "prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." *Powers*, 174 P.3d at 783. I-Flow argues that Arizona law does not impose a duty to test or warn for unknown risks, and that the potential risks at issue in this case were unknown in 2005. Doc. 129 at 10. Even if I-Flow's statement of Arizona law is correct, Plaintiffs have presented sufficient evidence, as explained above, to raise a

genuine issue of fact as to whether I-Flow had reason to know that testing of intra-articular uses was reasonably required before the pain pump was put to those uses.

I-Flow's reply places considerable reliance on the Ninth Circuit's recent decision in *Rosa v. Taser International, Inc.*, 684 F.3d 941 (9th Cir. 2012). The Court finds *Rosa* distinguishable from this case. *Rosa* applied California law, and focused primarily on whether Taser International had a duty to warn that its product could cause death through metabolic acidosis. The Ninth Circuit found that the medical literature at the time of marketing created nothing more than a speculative connection between tasers and metabolic acidosis, and that the risk therefore was not sufficiently "knowable" to give rise to a duty to warn. *Id.* at 947. *Rosa* mentioned a duty to test only briefly, observing that "the Rosas have put forth no evidence creating an issue of fact regarding whether [Taser] conducted reasonable testing." *Id.* at 950. Plaintiffs in this case, by contrast, have presented evidence that I-Flow had reason to know that testing reasonably was required and yet did no testing of intra-articular uses of the pain pump before Gilbert's surgery.

I-Flow argues that Plaintiffs cannot offer evidence that additional testing would have shown an association between pain pumps and chondrolysis. Doc. 129 at 10-11. In support of this argument, I-Flow points to evidence that the medical community today cannot definitively state that intra-articular placement of pain pumps causes chondrolysis. Doc. 129 at 11. I-Flow further argues that Plaintiffs have failed to show that Gilbert's surgeon, Dr. Bailie, would have heeded a warning if it was given. *Id.*

In response, Plaintiffs cite the expert opinion of Dr. Badylak that I-Flow could have conducted tests before 2005 that would have produced the same kinds of results found in 2006 and later by Drs. Chu, Dragoo, and others. Doc. 163-30 at 1-7. I-Flow does not address this argument in its reply. Doc. 175. Plaintiffs also offer evidence that Dr. Bailie would not have used the pain pump if he had been informed that the FDA had denied 510(k) clearance for use in a joint cavity. Doc. 161-1 at ¶ 8D; Doc. 163-3, Ex. 2 at 155-57. This evidence creates a question of fact for the jury.

2. Preemption.

I-Flow contends the "duty to test" theory underlying Plaintiffs' negligence claim is preempted under 21 U.S.C. § 360k(a). Doc. 129 at 12. This statute provides that a federally-imposed medical device "requirement" preempts a state-imposed medical device "requirement." This is true even if the state requirement takes the form of a state tort cause of action. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323-24 (2008). I-Flow argues that Plaintiffs' "failure to test" claim would impose a testing requirement through state law that is not imposed through federal law, and therefore is preempted.

I-Flow's pain pump received FDA approval through the 510(k) process, which turns upon a relatively simple question – whether the device is equivalent to a device already on the market. If the answer is yes, the FDA approves the device for marketing in relatively short order and without imposing the substantial testing and safety requirements that are imposed in other forms of FDA approval. The Supreme Court held in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that the 510(k) process does not impose a federal "requirement" and does not preempt state law causes of action for negligence and strict liability. *Id.* at 493-94. *See Riegel*, 552 U.S. at 322 ("*Lohr* also rejected the . . . contention that § 510(k) approval imposed device-specific 'requirements.'"). This Court likewise concludes that the 510(k) approval process for the pain pump does not preempt the Arizona negligence and strict liability claims asserted by Plaintiffs.[3]

I-Flow additionally argues that Plaintiffs' "failure to warn of regulatory history" and "off-label" claims are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which held that a private litigant's state law "fraud on the FDA" claims were impliedly preempted. *Id.* at 348. An essential element of the plaintiff's

[3] I-Flow argues that *Degelmann v. Advanced Med. Optocs, Inc.*, 659 F.3d 835 (9th Cir. 2011), controls this case, but *Degelmann* recently was vacated by the Ninth Circuit. *See Degelmann v. Advanced Medical Optics Inc.*, --- F.3d ----, 2012 WL 5328277 (9th Cir. Oct. 30, 2012). The Court would not be persuaded even if *Degelmann* was still good law because *Degelmann* turned on a specific and detailed directive the FDA issued for contact lens solutions passing through the 510(k) approval process, and I-Flow has identified no comparable FDA directive for the pain pump 510(k) approval process.

claim in *Buckman* was that the FDA was defrauded. *Id*. at 347-48. The Supreme Court found that such a claim conflicted with federal law because "[t]he federal statutory scheme empowers the FDA to punish and deter fraud against it, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* Because the state claim conflicted with this FDA authority, it was preempted. *Id.*

In response to the *Buckman* preemption argument, Plaintiffs state that they make no claim for fraud on the FDA. Doc. 161 at 5. Instead, they assert a traditional negligence claim for breach of a duty I-Flow owed to Plaintiffs. The Court will accept this position as true, and will ensure at trial that no claim for fraud on the FDA is made. Because Arizona negligence law does not require a showing of fraud on the FDA, and because Plaintiffs will assert breach of a duty owed to them, not to the FDA, the claim asserted in this case does not conflict with the FDA's power to police fraud against it and is not impliedly preempted. *Buckman* itself distinguished between claims that arise "from the manufacturer's alleged failure to use reasonable care in the production of the product," which are not impliedly preempted, and claims that arise "solely from the violation of FDCA requirements," which are impliedly preempted. *Id.* at 352. Plaintiffs' strict liability and negligence claims are not grounded solely on allegations that I-Flow violated FDA rules or regulations.[4]

It is true that Plaintiffs seek to present evidence of FDA regulations and I-Flow's alleged violation of those regulations. But this evidence will be presented not to make

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[4] I-Flow also misreads this Court's prior order. Doc. 49. Civil conspiracy under Arizona law requires that the alleged conspirators agree to commit a tort. *Id*. at 4. The Court dismissed Plaintiffs' civil conspiracy claim against DJO because they had not alleged that Defendants conspired to commit a tort, but instead alleged that they conspired to violate the FDCA. The Court cited *Photomedix, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010), for the proposition that the FDCA bars private enforcement of the statute. *See* Doc. 49 at 6. The Court did not hold that Plaintiffs' claim against DJO was preempted, nor did it address when and to what extent evidence of FDCA violations may be admitted to establish the standard of care in a negligence claim. The Court merely held that Plaintiffs had not pled the elements necessary for a civil conspiracy claim under Arizona law.

out a claim for violation of the FDCA or fraud on the FDA, but as evidence that I-Flow breached the standard of care for purposes of the negligence claim and as evidence that I-Flow should have known that further testing was required for purposes of the strict liability claim. Arizona law permits Plaintiffs to present evidence of federal law violations as part of proving state-law tort claims. *See Wendland v. Adobeair, Inc.*, 221 P.3d 390, 395 (Ariz. Ct. App. 2009) ("evidence of administrative regulations" may be admitted "to inform the standard of care in negligence actions"); *cf. Robertson v. Burlington Northern R. Co.*, 32 F.3d 408, 410-11 (9th Cir. 1994) (evidence of OSHA regulations may be admitted as some indication of the applicable standard of care).

The Court recognizes that it will be required at trial to strike a careful balance between permitting Plaintiffs to prove standard of care in accordance with Arizona law on one hand, and preventing this case from becoming a claim for breach of FDA regulations or fraud on the FDA on the other hand. The jury will need to understand that any evidence of FDA regulations or their violation, if admitted, is relevant only for the limited purpose of determining the appropriate standard of care or for similar limited purposes. *See Wendland*, 221 P.3d at 397-98. The testimony of witnesses and arguments of counsel will also need to conform to the limited purpose of the evidence.

C. Civil Conspiracy.

"For a civil conspiracy to occur two or more people must agree to accomplish an unlawful purpose or to accomplish a lawful object by unlawful means, causing damages." *Wells Fargo Bank v. Arizona Laborers, et al.*, 38 P.3d 12, 36 (Ariz. 2002) (quoting *Baker v. Stewart Title & Trust of Phoenix*, 5 P.3d 249, 256 (Ariz. App. 2000)). More specifically, a civil conspiracy claim "requires an underlying tort which the alleged conspirators agreed to commit." *Baker*, 5 P.3d at 545. I-Flow contends that Plaintiffs' civil conspiracy claim fails as a matter of law because there is no underlying tort claim. Doc. 129 at 16.

Plaintiffs' civil conspiracy claim alleges that I-Flow and DJO "entered an agreement to promote the pain pumps for orthopedic use" and that "promoting pumps for

orthopedic use was contrary to federal law." Doc. 1 at 9. In dismissing the claim against DJO, the Court found that Plaintiffs' failed to plead an underlying state-law tort claim because, "[e]ven assuming *arguendo* that DJO Defendants' promotional acts violated the FDCA, the violation is not a tort for which a private plaintiff has a justiciable remedy." Doc. 49 at 6 (citing *Photomedex*, 601 F.3d at 924). The same reasoning applies here. I-Flow is entitled to judgment as a matter of law on this claim.

D. Loss of Consortium and Punitive Damages.

I-Flow contends that Plaintiffs' loss of consortium claim fails because all of Plaintiffs' other claims fail. Doc. 129 at 16. Because the Court has not granted I-Flow's motion for summary judgment on all of Plaintiffs' claims, this argument cannot succeed.

Punitive damages are recoverable only when the defendant's conduct was aggravated, outrageous, malicious or fraudulent. *Rawlings v. Apodaca*, 726 P.2d 565, 578, 151 Ariz. 149, 162 (1986). I-Flow argues punitive damages are unavailable because Plaintiffs can produce no evidence of such conduct. In response, Plaintiffs' "concede that their prayer for punitive damages may not withstand defendants' motion." Doc. 161 at 2 n.1. The Court will grant summary judgment to I-Flow on the punitive damages claim.

III. Breg's Motion for Partial Summary Judgment.

Breg moves for partial summary judgment on Plaintiffs' claims for (1) design defect, (2) failure to inform physicians of the FDA clearance status or regulatory history of PainCare 3200 or that its safety or efficacy was uncertain, (3) "off-label" promotion, and (4) punitive damages. Doc. 137 at 2. Breg does not seek summary judgment on Plaintiffs' claim that it should have warned about an association between intra-articular use of pain pumps and chondrolysis. Doc. 137 at 5.

A. Design Defect.

Plaintiffs "concede that their claims are properly characterized as failure to warn, not design defect or manufacturing defect claims, whether couched in negligence or strict liability." Doc. 162 at 2. The Court will grant Breg's summary judgment motion as to any design defect or manufacturing defect claims that might be found in the complaint.

B. Failure to Warn – FDA Regulatory History.

Breg argues that its duty under Arizona law is to warn about dangers of which it knows or reasonably should know, not to warn about whether a medical device has or has not been cleared by the FDA. Doc. 137 at 5-6. Breg asks the Court to grant summary judgment on Plaintiffs' claim that Breg should have warned about the regulatory status of its device. Plaintiffs' argue that this is really a motion in limine that seeks to limit the evidence Plaintiffs can present to prove their negligence and strict liability claims. Doc. 162 at 2, 4.

As noted above, Plaintiffs assert state-law negligence and strict liability claims. Plaintiffs are not asserting, and the Court will not permit, some kind of new "failure to warn of regulatory history" claim. The Court cannot say at this point, however, that the regulatory history of Breg's FDA approval process is irrelevant to Plaintiffs' state-law claims. As noted above, federal regulations and their violation may be relevant to the standard of care in Arizona negligence actions. *Wendand*, 221 P.3d at 395. Plaintiffs also contend that the regulatory history of Breg's pain pump gave it reason to know that it should have tested the pump for intra-articular use. Because the Court cannot conclude at this stage that the regulatory history of Breg's product is irrelevant to Plaintiff's tort claims, Breg's motion will be denied.

C. Off-Label Promotion.

Plaintiffs' negligence claim asserts that Breg "promot[ed] the pain pumps for use in the joint space after the FDA had considered and rejected such an indication." Doc. 1 at ¶17(I). Breg argues that this is not a cognizable claim under Arizona law and is preempted. Again, Plaintiffs' do not assert a new cause of action for off-label promotion, but state-law tort claims for which off-label promotion evidence may be relevant. Because the Court cannot say that off-label promotion of the pain pump is irrelevant to Plaintiffs' state-law claims, Breg's motion will be denied. The Court has also rejected Defendants' preemption arguments for reasons stated above.

D. Punitive Damages.

Plaintiffs "concede Arizona precedent suggests their prayer for punitive damages may not survive Breg's motion." Doc. 162 at 2. The Court will grant Breg's motion for summary judgment on punitive damages.

IV. Motions to Exclude Expert Testimony.

Under Federal Rule of Evidence 702, an expert may offer "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods" and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. The trial court acts as a "gatekeeper for expert testimony to assure that it is both relevant and reliable," *Avila v. Willits Envtl. Remediation Trust*, 633 F.3d 828, 836 (9th Cir. 2011), an exercise that "entails a preliminary assessment of whether the reasoning or methodology is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-93 (1993).

A. Dr. Badylak.

I-Flow and Breg do not dispute Dr. Badylak's knowledge and training as a medical doctor and pathologist, and do not challenge his opinions relating to the condition of chondrolysis. Doc. 131 at 3. Defendants challenge Dr. Badylak's expertise regarding FDA regulations, and seek to prevent him from offering any opinions relating to the FDA's regulation of pain pumps. Doc. 131 at 2.

Plaintiffs state that they "will not solicit any testimony from Dr. Badylak about FDA's regulation and oversight of drug or medical device manufacturers, the duties imposed by these regulations, or the adequacy of I-Flow's or Breg's pain pump labels." Doc. 172 at 2. The Court will grant Defendants' motion regarding any testimony Dr. Badylak might offer on these subjects.

B. Dr. Busfield.

Defendants acknowledge that Dr. Busfield is qualified to opine on medical issues,

but contend that his expertise does not encompass the FDA regulatory history of pain pumps, the warnings that accompanied pain pumps, and the nature of the pain pump marketing campaigns. Doc. 132 at 4. Plaintiffs respond by stating that they will not solicit any testimony from Dr. Busfield relating to FDA regulations, adequacy of warnings, and device promotion. Doc. 171 at 2. Plaintiffs point to Breg's allegation that Plaintiffs' injury was caused in whole or in part by the negligence or fault of others, and contend that if Defendants put at issue the propriety of Dr. Baillie's decision to use pain pumps in Gilbert's surgeries, they will seek to elicit Dr. Busfield's testimony that intra-articular use of pain pumps did not fall below the standard of care for orthopedic surgeons. Doc. 171 at 3. In reply, Defendants argue again that Dr. Busfield is "*unqualified to offer opinions as an expert* on what the FDA determined about the safety and efficacy of continuous infusion therapy devices," and should not be allowed "to testify on those exact same issues based on what he, *as a member of the orthopedic community 'understood' them to be*." Doc. 178 at 3 (emphasis in original).

The Court will grant Defendants' motion with respect to any testimony from Dr. Busfield about FDA regulations, adequacy of warnings, and device promotion. The Court must await trial to determine whether any other testimony of Dr. Busfield is inadmissible.

C. Dr. Pence.

Defendants ask the Court to exclude the testimony of Dr. Pence for various reasons. Defendants do not contend that Dr. Pence is unqualified, but they do argue that she does not use a reliable methodology. Doc. 136 at 7-10. Defendants are more specific in their reply, asserting that Dr. Pence fails to follow "the scientific method." Doc, 179 at 4. The Court does not agree that the scientific method applies to her opinions.

Dr. Pence is a Ph.D. toxicologist and a specialist in medical device product development, clinical studies, and regulatory affairs. She has nearly 40 years of experience in research and development of drug, biotech, and medical device products, has worked on regulatory and project development matters as an employee of Eli Lilly,

Serono Laboratories, Triton Biosciences, and Amgen, and has been responsible for preparing documents and clinical data for FDA review and for interfacing with the FDA. For fifteen years she has been President and CEO of Symbion Research International, a firm that offers research services for clinical studies and clinical trials, as well as regulatory and clinical development services for pharmaceuticals and medical devices. She has worked with more than 70 companies and more than 85 drugs and medical devices, including advising companies concerning applicable standards, preparing and submitting regulatory documents to the FDA such as 510(k) applications, and serving as the U.S. Agent or authorized representative for FDA matters. Doc. 164 at 3. According to Plaintiffs, "[s]he employed her education and related professional training and experience in forming her opinions in this case." *Id.*

The process of obtaining FDA approvals and applying FDA regulations is not subject to mathematical measurements or laboratory analyses. Dr. Pence does not purport to have applied scientific formulas or testing methods that are subject to laboratory verification or peer review. Her testimony is based on analysis of the facts she considers relevant in light of her years of experience and training. As the Ninth Circuit has noted, "[t]he *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable to this kind of testimony, whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000). Dr. Pence is qualified to opine on the issues addressed in her expert reports and she has reviewed relevant facts and data. The Court cannot conclude that the application of her expertise to these facts and data is so unreliable as to be inadmissible under Rule 702.

Defendants argue that Dr. Pence's opinions regarding off-label promotion of pain pumps are irrelevant, concern preempted claims, and will not aid the jury. For reasons explained above, the Court concludes that Plaintiffs' tort claims are not preempted and cannot conclude at this point that evidence of off-label promotions would be irrelevant to Plaintiffs negligence and strict liability claims. Nor can the Court conclude that Dr.

Pence's testimony would be unhelpful to the jury. The FDA regulatory process is complex and beyond the experience of the average juror. Her explanations and opinions might wells be helpful in understanding matters that are relevant to Plaintiffs' tort claims under Arizona law.

The Court hastens to note that it is not holding that Dr. Pence's opinions on these subjects are admissible. The Court instead holds only that it cannot find them to be inadmissible at this stage of the litigation. Relevancy and helpfulness decisions will be made more accurately during trial when the Court sees and more fully understands the parties' positions on the issues.

Defendants argue that Dr. Pence's opinions on Defendants' compliance with FDA regulations invades the Court's province of instructing the jury on the law. Certainly the Court, and not experts, will instruct the jury on the law in this case. But without understanding the context of particular questions, the Court cannot determine whether a particular opinion would or would not constitute an improper assertion of the law. As noted above, federal regulations may be admissible in state tort cases on the issue of standard of care. Just how those issues will be presented to the jury cannot be decided on the basis of the general arguments contained in Defendants' motion.

Defendants argue that Dr. Pence's opinion about Defendants' failure to review relevant medical literature is a medical opinion that Dr. Pence is not qualified to give. Plaintiffs respond that Dr. Pence will not be asked to provide medical opinions. The Court cannot at this point conclude that Dr. Pence's opinions on the diligence of Defendants is an inadmissible medical opinion. That too must be decided at trial.

Defendants object to Dr. Pence opining about Defendants' intent. Plaintiffs make clear, however, that she will opine only on the issue of intended use, an issue Plaintiffs characterize as "objective intent." The Court is not persuaded that this testimony will be permissible, but cannot at this point conclude with certainty that it would lack foundation or invade the province of the jury under all circumstances. The Court therefore will not exclude it at this stage. The same is true concerning Dr. Pence's testimony about

Defendants' internal policies and procedures.

Defendants ask the Court to preclude Dr. Pence from making any reference to events or information that occurred or arose after Gilbert's surgeries. This request is too broad. Although the Court has doubts about the relevancy of post-surgery facts in general, it cannot say that all such evidence will be inadmissible. It is possible that post-surgery events will shed relevant light on issues to be addressed by the jury. The Court must resolve these issues at trial.

Finally, Defendants ask the Court to preclude Dr. Pence from referring to the criminal investigation of another manufacturer for the drug Neurontin. The Court has serious concerns about the relevancy and prejudicial effect of this information and therefore instructs Plaintiffs not to mention it before the jury without first raising the issue with the Court and opposing counsel.

The Court will deny Defendants motion to exclude the testimony of Dr. Pence. The Court will rule on objections as they are made during trial.

D. Dr. Greenland.

I-Flow asks the Court to exclude the opinions of Dr. Greenland, an epidemiologist who analyzed several studies and opined that there is a strong association between the intra-articular use of pain pumps and chondrolysis. Doc. 140. I-Flow argues that Dr. Greenland cannot generalize from case studies to the general population and that his opinion therefore will not be helpful to the jury in determining whether the pain pumps in this case caused Gilbert's condition. I-Flow also argues that Dr. Greenland is not a medical doctor and therefore cannot give an opinion on causation. I-Flow further asserts that the case studies relied on by Dr. Greenland are flawed in various respects and are therefore insufficient to support his opinion. The Court is not persuaded by these arguments.

I-Flow does not contend that Dr. Greenland is unqualified as an epidemiologist, nor could it credibly do so. Dr. Greenland received a Master's Degree in mathematics from the University of California, Berkeley, and a doctorate in public health from

University of California, Los Angeles (UCLA). He is a full professor of Epidemiology and Statistics at UCLA, where he has taught since 1979. Dr. Greenland is the author and editor of the leading textbook for courses in advanced epidemiology and has published more than 300 papers in peer-reviewed literature.

I-Flow relies heavily on *McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092 (D. Or. 2010), and its conclusion that Dr. Greenland's testimony would not be helpful to the jury. As Plaintiffs note, however, other cases have found Dr. Greenland's testimony, or the testimony of a comparable expert, Dr. Wells, to be admissible. *See, e.g., Woodard v. Stryker Corp.*, No. 11-CV-36-F, 2012 WL 3475079, at *11-12 (D. Wyo. July 16, 2012); *Monroe v. Zimmer U.S. Inc.*, 166 F. Supp. 2d 1012, 1028 (E.D. Cal. 2011); *Hamilton v. Breg, Inc.*, No. 2:09-CV-146, 2011 WL 833614, at *12 (S.D. Ohio Jan. 24, 2011); *Schott v. I–Flow Corp.*, 696 F. Supp. 2d 898, 905 (S.D. Ohio 2010).

The Court concludes that Dr. Greenland's testimony could be helpful to the jury. He finds a high association between chondrolysis and the use of intra-articular pain pumps in the case studies he has reviewed – too high to be caused by chance. Doc. 170-3. In fact, he says that some of the association numbers are higher than any he has seen in his entire career. Doc. 170-18 at 9. On the basis of this high association, he opines that "causation of chondrolysis by some aspect of intra-articular use of pain pimps is far more credible and consistent with other findings than alternative explanations that have been offered for the dramatic association observed in these studies. Thus, with high scientific certainty, I would infer that the most likely explanation for the enormous associations seen in the literature . . . is that these pumps are a primary and essential contributing factor to the development of chondrolysis in cases with these pumps." Doc. 170-3 at 57. This case must be decided by a preponderance of the evidence, and the Court concludes that Dr. Greenland's opinion could help the jury decide whether the pain pumps most likely caused Gilbert's chondrolysis. The evidence satisfies the relevancy test of Federal Rule of Evidence 401; it has a tendency to make a fact in dispute – whether pain pumps cause chondrolysis – more probable.

I-Flow discusses several case studies reviewed by Dr. Greenland and points out shortcomings in each. Doc. 140 at 7-14. But Dr. Greenland does not appear to gloss over these shortcomings. He responds to them in his reports and deposition and explains why they do not change his opinion. For example, in responding to I-Flow's questions about the possibility of selection bias in one of the studies, Dr. Greenland explains: "I wouldn't say that I ruled out the possibility [of selection bias]. I would say that . . . the extremity of the association was so large that selection bias wouldn't be capable of accounting for it alone based on the materials I have seen." Doc. 170-18 at 4.

The Court concludes that the shortcomings identified by I-Flow go to the weight and not the admissibility of Dr. Greenland's opinion. I-Flow does not challenge Dr. Greenland's credentials or methodology, but instead argues that he relies on flawed data. I-Flow will be fully capable at trial of pointing out the flaws in this data so the jury can hear Dr. Greenland's response and decide what weight to accord his opinions. Other courts have reached the same conclusion. *See Hamilton*, 2011 WL 833614, at *12; *Woodard*, 2012 WL 3475079, at *12.

The Supreme Court explained in *Daubert* that "[v]igorous 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." 509 U.S. at 596. Dr. Greenland's opinions should be addressed through these traditional tools. "Neither *Daubert* nor Rule 702 demands absolute evidence of causation before an expert's testimony can be admitted." *Hamilton*, 2011 WL 833614, at *12.

IT IS ORDERED:

1. I-Flow's motion for summary judgment (Doc. 129) is **granted in part** and **denied in part** as set forth in this order.
2. Breg's motion for summary judgment (Doc. 137) is **granted in part** and **denied in part** as set forth in this order.
3. I-Flow and Breg's motion to strike certain opinions of Dr. Badylak (Doc. 131) is **granted**.

4. I-Flow and Breg's motion to strike certain opinions of Dr. Busfield (Doc. 132) is **granted**.

5. I-Flow and Breg's motion to strike Dr. Pence (Doc. 136) is **denied**.

6. I-Flow's motion to strike Dr. Greenland (Doc. 140) is **denied**.

7. The Court will set a final pretrial conference by separate order.

Dated this 20th day of November, 2012.

David G. Campbell
United States District Judge