UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

L. WAYNE ELLIOTT & NORMA ELLIOTT, husband and wife,

Plaintiffs,

v.

SMITH & NEPHEW, INC., an entity incorporated under the laws of Delaware, and ABC CORPORATIONS, 1 – 5,

Defendants.

Case No. 1:12-CV-0070-EJL-MHW

**AMENDED MEMORANDUM DECISION AND ORDER**

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As a preliminary matter, a factual error within this Court's Memorandum Decision and Order (Dkt. 36) has been brought to the Court's staff attorney's attention by Plaintiff's counsel. The Court issues this Amended Order to correct the factual error contained within the original Memorandum Decision and Order. The factual error (located on page 15 of the original Memorandum Decision and Order) noted that the specific recall notice Defendant sent to Plaintiff after recalling the device at issue in this case was attached to the Complaint. However, the recall notice attached to the Complaint (as Exhibit D) was the notice used in the United Kingdom, and was not sent to either Plaintiff or his physician.

The Court accordingly omits the portion of the sentence referencing Exhibit D from the Memorandum Decision. This correction does not alter either the Court's Order or the substantive analysis included within the Court's Memorandum Decision.

Plaintiffs L. Wayne and Norma Elliott, husband and wife, (the "Elliotts" or "Plaintiffs") bring this products liability action against Defendant Smith & Nephew ("Defendant"). Defendant is the manufacturer and seller of the PLUS Promos Shoulder Inclination Set ("Promos Inclination Set"). The Elliotts allege nine causes of action related to Defendant's allegedly defective and unsafe design and manufacture of the Promos Inclination Set. Pending before the Court is Defendant's Motion to Dismiss (Dkt. 16) for failure to state a claim.

Having fully reviewed the record, the Court finds that the facts and legal arguments are adequately presented in the briefs and record. Accordingly, in the interest of avoiding further delay, and because the Court conclusively finds that the decisional process would not be significantly aided by oral argument, this matter shall be decided on the record before this Court without oral argument.

## FACTUAL BACKGROUND

Plaintiff L. Wayne Elliott ("Mr. Elliott") underwent a total left shoulder replacement on January 21, 2009, wherein the Promos Inclination Set was implanted in his shoulder. (Dkt. 1-3, p. 3, ¶11.) The Promos Inclination Set implanted in Mr. Elliott's shoulder was manufactured by Defendant. (*Id*., ¶9.) On February 3, 2010, Defendant recalled the Promos Inclination Set, including that implanted in Mr. Elliott's shoulder.

(*Id*., ¶14, Exs. A, B and C.) The Promos Inclination Set was recalled due to eight complaints of set screws fracturing, both intra- and post-operatively. (*Id*., Ex. B.)

Mr. Elliott underwent a revision of his shoulder replacement on January 12, 2011 because the set screws within his implanted Promos Inclination Set had fractured. (Dkt. 1-3, p. 5, ¶16.) Mr. Elliott's revision surgery required removal of the Promos Inclination Set and replacement with a competitor's implant. (*Id*., ¶17.) Mr. Elliott claims he has suffered and will continue to suffer significant pain and disability as a result of the malfunction of the Promos Inclination Set. (*Id*. at p. 6, ¶24.)

The Elliotts filed a complaint in state court against Defendant, and unknown defendants ABC Corporations 1-5, alleging violation of Idaho's Products Liability Reform Act Idaho Code §6-1401 *et. seq*., as well as several other common law causes of action associated with Defendant's allegedly defective design and manufacture of the Promos Inclination Set. Defendant removed the case to federal court and, following denial of Plaintiffs' Motion to Remand, moved to dismiss each of Plaintiffs' claims under Federal Rule of Civil Procedure 12(b)(6). (Dkt. 16.)

Defendant argues in the Motion to Dismiss that all of the Elliotts' claims are preempted by the Medical Device Amendments ("MDA") to the federal Food, Drug and Cosmetics Act ("FDCA") 21 U.S.C. § 360c *et. seq*., which preempts certain product liability claims in the case of medical devices approved by the Food and Drug Administration's ("FDA") premarket approval process. Defendant also maintains that Plaintiffs have failed to meet their pleading obligations under the Federal Rules. The

Elliotts argue that, because the Promos Inclination Set was approved via the FDA's less rigorous § 510(k) process, rather than the extensive premarket approval process, their claims are not preempted.

The Elliotts also maintain that additional discovery is needed before the Court should dismiss their case for failure to state a claim. Although this matter is before the Court on Defendant's Motion to Dismiss, the Elliotts have sought to convert Defendant's motion into one for summary judgment, and have submitted a Motion for Permission to Conduct Limited Discovery under Rule Fed. R. Civ. P. 56(d) (Dkt. 21), in conjunction with their Opposition to Defendant's Motion to Dismiss. (Dkt. 22.)

## STANDARD OF REVIEW

A motion to dismiss for failure to state a claim challenges the legal sufficiency of the claims stated in the complaint. *Conservation Force v. Salazar*, 646 F.3d 1240, 1242 (9th Cir. 2011). Because a primary objective of the legal system "is to obtain a judgment on the merits, rather than a dismissal based on the pleadings," motions to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6) are generally viewed with disfavor. *Cabo Distrib. Co., Inc. v. Brady*, 821 F.Supp. 601, 608 (N.D.Cal. 1992).

To sufficiently state a claim to relief and survive a 12(b)(6) motion, the pleading "does not need detailed factual allegations," however, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Mere "labels and conclusions" or a "formulaic recitation of the

elements of a cause of action will not do." *Id*. Rather, there must be "enough facts to state a claim to relief that is plausible on its face." *Id*. at 570. In other words, the complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In light of *Twombly* and *Iqbal*, the Ninth Circuit summarized the governing standard as follows: "In sum, for a complaint to survive a motion to dismiss, the nonconclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." *Moss v. U.S. Secret Serv*., 572 F.3d 962, 969 (9th Cir. 2009). Apart from factual insufficiency, a complaint is also subject to dismissal under Rule 12(b)(6) where it lacks a cognizable legal theory, *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1990), or where the allegations on their face "show that relief is barred for some legal reason." *Jones v. Bock*, 549 U.S. 199, 215 (2007).

In deciding whether to grant a motion to dismiss, the court must accept as true all well-pleaded factual allegations in the pleading under attack. *Iqbal*, 556 U.S. at 663. A court is not, however, "required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001).

When ruling on a motion to dismiss, the court must normally convert a Rule 12(b)(6) motion into one for summary judgment under Rule 56 if the court considers evidence outside of the pleadings. *United States v. Ritchie*, 342 F.3d 903, 907 (9th Cir. 2003). However, a court may consider certain materials, such as documents attached to

the complaint, documents incorporated by reference in the complaint, or matters of judicial notice, without converting the motion to dismiss into a motion for summary judgment. *Id*. at 908.

## ANALYSIS

### 1. Preemption

Congress enacted the MDA in 1976 to regulate the safety and effectiveness of medical devices. *Riegel v. Medtronic, Inc*., 552 U.S. 312, 315 (2008). The MDA contains an express preemption clause which provides:

> …no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In 1996, the Supreme Court determined that lawsuits brought under state law against medical device manufacturers who undergo the FDA's § 510(k) "premarket notification" process are not preempted by 21 U.S.C. § 360k(a) when liability is premised on theories that the device was defective and unreasonably dangerous and that the manufacturer failed to use reasonable care in the device's design, manufacture, assembly, and sale. *Medtronic, Inc., v. Lohr*, 518 U.S. 470, 481, 494-95 (1996).

In 2008, the Supreme Court held in *Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008), that lawsuits brought under state law against medical device manufacturers who instead

undergo the FDA's rigorous "premarket approval" process are expressly preempted by §360k(a) of the MDA when liability is premised on violations of state law requirements that are "in addition to or different from" federal requirements regulating the device. *Id.* at 321-323.

To understand the holdings of *Lohr* and *Riegel*, an explanation of the difference between "premarket notification" to the FDA and the "premarket approval" process is necessary. The MDA delineates three classes for medical devices depending on the risks the device presents. Class I devices pose the least risk, and are subject to only "general" federal control such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A); *Riegel*, 552 U.S. at 316. Class II devices are potentially more harmful. Manufacturers of Class II devices must comply with federal performance regulations known as "special controls." 21 U.S.C. § 360c(a)(1)(B); *Riegel*, 552 U.S. at 317. However, Class I and Class II medical devices may be marketed without receiving premarket approval from the FDA. 21 U.S.C. § 360(a)(1)(A)-(B).

Finally, devices that either "presen[t] a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated as Class III. 21 U.S.C. § 360c(a)(1)(C)(ii). Class III devices are generally subject to the FDA's rigorous "premarket approval," or "PMA"

process.[1] *Lohr*, 518 U.S. at 477; *see also* 21 U.S.C. § 360e . If a product is approved via the PMA process, 21 U.S.C. § 360k(a) expressly preempts state law claims that are different from, or in addition to, the federal requirements because the medical devices have undergone a rigorous federal safety review.[2] *Riegel*, 522 U.S. at 323.

The Promos Inclination Set at issue in this case is a Class II device. As such, the Promos Inclination Set was not subject to the PMA process, but did undergo the § 510(k) premarket notification process. The § 510(k) review process is not "specific to the device in question" and instead reflects "entirely generic concerns about device regulation generally." *Id*. at 322, *citing Lohr*, 518 U.S. at 501. As the Supreme Court has explained, the § 510(k) process "is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." *Lohr*, 518 U.S. at 478-79.

Since the § 510(k) process does not impose specific federal requirements on a device, state law claims against devices subject only to premarket notification, rather than premarket approval, are not expressly preempted under the MDA. *Cornwell v. Stryker*

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1 Not all Class III devices are subject to premarket approval due to two important exceptions to the PMA requirement. First, the MDA allows for "grandfathering" of pre-1976 devices. Such devices are allowed to remain on the market without FDA approval until the FDA initiates and completes the requisite PMA. 21 U.S.C. § 360e(b)(1)(A). Second, "to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market, the Act also permits devices that are 'substantially equivalent' to pre-existing devices to avoid the PMA process." *Lohr*, 518 U.S. at 478 (*citing* 21 U.S.C. § 360e(b)(1)(B)).

2 However, "§ 360k(a) does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (*citing Lohr*, 518 U.S. at 495).

*Corp*., 2010 WL 4641112 (1:10-cv-00066-EJL), at *3; *see also Lohr* 518 U.S. at 502, *explaining*, "given the critical importance of device specificity in our (and the FDA's) construction of § 360k(a), it is apparent that few, if any, common law duties have been pre-empted by this statute."). Plaintiffs' state law claims are not expressly preempted under the MDA.

Defendant argues that Plaintiffs' claims are instead impliedly preempted. Before turning to Defendant's implied preemption theory, it is important to note that there is "a presumption against federal preemption of state laws that operate in traditional state domains." *Stengel v. Medtronic Incorp*., 704 F.3d 1224, 1227 (9th Cir. 2013) ("*Stengel II*"). The states have traditionally had "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons." *Lohr*, 518 U.S. at 475 (citation omitted). Regulation of public health and safety through protection from defective products is "primarily and historically" a matter of local concern. *Stengel II*, 704 F.3d at 1228 (*citing Lohr*, 518 U.S. at 475). Given the presumption against preemption, parties seeking to challenge state law claims based on preemption "bear the considerable burden of overcoming 'the starting presumption that Congress does not intend to supplant state law.'" *Stengel II*, 794 F.3d at 1227 (citation omitted).

The Supreme Court has determined state law claims are impliedly preempted by the MDA when such claims are based on a "fraud-on-the-FDA" theory. *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 348 (2001). Plaintiffs in *Buckman* brought a state-law negligence suit for damages resulting from orthopedic bone screws, a Class III

medical device. *Id*. at 343-44. Defendant in *Buckman* was not the manufacturer of the screws, but was instead a consulting company that plaintiffs alleged had made fraudulent misrepresentations to the FDA in the course of obtaining premarket approval for its client, the bone screw manufacturer. The Supreme Court determined such claims were impliedly preempted by the MDA. In so holding, the Court explained:

> The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

*Id*. at 348.

The *Buckman* Court distinguished plaintiffs' claims in *Lohr* because in *Lohr* plaintiffs' claims arose from the manufacturer's "alleged failure to use reasonable care in the production of the product," rather than from any wrongdoing during the FDA's premarket approval process. *Id*. at 352. The claims in *Lohr* escaped preemption, while those in *Buckman* were impliedly preempted. The Ninth Circuit initially extended the *Buckman* holding to plaintiffs' state law claims in *Stengal v. Medtronic Incorp*., 676 F.3d 1159 (9th Cir. 2012) ("*Stengel I*").

In *Stengel I*, a divided three-judge appeals panel held plaintiffs' negligence, breach of warranty and strict liability claims were expressly preempted under § 360k(a) because they "generally challenged the safety and effectiveness of [Medtronic's Class III pain pump] without any hint of an allegation that Medtronic's conduct violated FDA regulations." *Id*. at 1162. As such, plaintiffs' state law claims could not be considered

parallel to, rather than in addition to, FDA regulations. The panel also held that plaintiffs' proposed failure to warn claims were impliedly preempted because Medtronic's duty to warn was regulated by the FDA, and any further duty to warn under Arizona law would be in addition to, rather than parallel to, the federal requirements. *Id*. (*stating*, "[w]here a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and is thus preempted.") (citation omitted)

The *Stengal I* panel held there was no "meaningful distinction" between plaintiffs' failure to warn claim and the "fraud-on-the-FDA" claim held to be preempted in *Buckman*, as Medtronic's duty to warn was regulated by the FDA, and recognizing a state cause of action based on such conduct "would conflict with the statutory scheme established by Congress." *Id*. at 1164. In this case, Defendant argues the Elliotts' state law claims are impliedly preempted under *Buckman* and *Stengel I* because they clearly seek "to establish failure to comply with FDA regulations in failure-to-warn, failure-to-monitor, and other so-called 'fraud-on-the-FDA' claims." (Dkt. 32, p. 6.)

Defendant's argument regarding implied preemption may have succeeded were it not for a significant recent change in the law. After Defendant's Motion to Dismiss and Reply brief were filed, the Ninth Circuit decided to rehear *Stengel I en banc*. Upon rehearing, the appeals court reversed. In *Stengal II*, 704 F.3d 1224 (9th Cir. 2013), the Ninth Circuit held *Buckman* did not impliedly preempt plaintiffs' proposed state-law

failure to warn claim predicated on alleged regulatory violations. The *Stengel II* decision appears to limit implied preemption to the FDA's premarket approval process, noting:

> Our sister circuits have uniformly held that, in cases dealing with violations of the MDA outside the pre-market approval process, the MDA does not preempt state-law causes of action for damages in which the state-law duty 'parallels' the federal-law duty under the MDA.

*Id*. at 1231.

In deciding plaintiffs' proposed failure to warn claim was not preempted under the MDA, the *Stengel II* Court further explained:

> We do not decide whether plaintiffs can prevail on their state-law failure to warn claim. That question is not before us. But we do hold, under *Lohr*, *Buckman*, and *Riegel*, that this claim is not preempted, either expressly or impliedly, by the MDA. It is a state-law claim that is independent of the FDA's premarket approval process that was at issue in *Buckman*. The claim rests on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*. In holding that the Stengels' failure-to-warn claim is not preempted, we join the Fifth and Seventh Circuits, which reached the same conclusion with respect to comparable state-law claims…. (*citing Hughes v. Boston Scientific Corp*., 631 F.3d 762,765 (5th Cir. 2011) and *Bausch v. Stryker Corp*., 630 F.3d 546, 549 (7th Cir. 2010).

*Id*. at 1233.

In *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 765 (5th Cir. 2011), plaintiff suffered severe burns when hot liquid leaked from a Class III medical device manufactured by Boston Scientific. Plaintiff brought suit under Mississippi law, claiming violation of a state-law duty to warn. The Fifth Circuit held plaintiff's state-law duty to warn claim was not preempted, and specifically extended its holding to both express and implied preemption, "[w]e conclude that [plaintiff's] failure to warn claim is neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on Boston

Scientific's violation of FDA regulations with respect to reporting burns caused by the [device]." *Id*. at 776.

Similarly, in *Bausch v. Stryker Corp*., 630 F.3d 546, 549 (7th Cir. 2010), plaintiff brought suit under Illinois tort law, alleging violation of various state-law duties premised upon a violation of parallel federal-law duties, when she was injured by a Class III ceramic hip replacement device. The Seventh Circuit concluded plaintiff's state-law claims were neither expressly nor impliedly preempted, stating, "federal law does not preempt parallel claims under state law based on a medical device manufacturer's violation of federal law." *Id*. at 558. Like *Hughes* and *Bausch*, the *Stengel II* Court specifically held that state-law duties which parallel federal-law duties are not impliedly preempted under the MDA. Thus, to the extent the Elliotts can establish Defendant violated Idaho state-law requirements which parallel federal-law requirements, their claims are not impliedly preempted under the MDA.[3]

**2. Pleading Requirements**

Defendants also suggest the Elliotts' claims must be dismissed because they cannot satisfy the pleading requirements established under *Bell Atlantic Corp. v. Twombly*, 550

3 Although Defendant argues it is impossible to analyze whether the Elliotts' claims are based on state-law requirements that are parallel to federal-law requirements given the generality of the Complaint, the Court need not determine at this stage whether the Elliotts' claim that Defendant failed to comply "with applicable design, manufacturing and/or testing standards," refers to state standards that are different from or in addition to the federal regulatory standards (and which would thus be preempted under § 360k(a)). Complaints "that combine legally valid and invalid claims are common. When a complaint asserts claims that are legally valid and those that are not, the correct judicial response is not to dismiss the complaint… The case may proceed…with the understanding…as to the proper scope of claims that can survive the legal challenge." *Bausch*, 630 F.3d 546, 559.

U.S. 544, 555 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In *White v. Stryker Corp*., 818 F.Supp. 2d 1032, 1037 (E.D.Ky. 2011), a federal district court considered the pleading specificity required in the context of MDA preemption, explaining:

> In the context of MDA preemption, *Twombly* and *Iqbal* make a plaintiff's job more difficult than it would be in a typical products liability case. When facing MDA preemption, a plausible cause of action requires, among other things, a showing that the alleged violation of state law parallels a violation of federal law. This additional step requires some greater specificity in the pleadings.

*Id*. at 1037.

Although the Elliotts' Complaint is rather threadbare, the Seventh Circuit in *Bausch v. Stryker Corp*., 630 F.3d 546, 558 (7th Cir. 2010), an opinion specifically referenced with approval and applied by the *Stengel II en banc* Ninth Circuit panel, held there are no special pleading requirements for product liability claims in general, nor for claims involving preemption under the MDA in particular. As such, the "federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the new 'plausibility' standard applied in *Iqbal* and *Twombly*." *Id*. In applying this standard to claims for defective manufacture of a medical device in violation of federal law, the *Bausch* Court directed that district courts, "must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law." *Id*. As such, "formal discovery is necessary before a

plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." [4] *Id*.

Significantly, in *Bausch*, the Seventh Circuit determined plaintiff's original complaint satisfied *Twombly* and *Iqbal* where the complaint, like that here, failed to reference particular federal regulations violated by a medical device manufacturer. *Id*. Plaintiff in *Bausch* included several key factors in her original complaint, including: that the FDA investigated the medical device at issue prior to plaintiff's surgery and issued a letter warning to the defendant that the manufacturing methods were not in conformity with regulatory standards; that the FDA's warning was for a medical device model number bearing the same catalogue number as the one implanted in the plaintiff; and that the medical device implanted in the plaintiff was later recalled by defendant. The *Bausch* Court held that such facts made the plaintiff's claim for strict liability and negligence "plausible on its face as required by *Iqbal* and *Twombly*." *Id*. at 559.

Like plaintiff's original complaint in *Bausch*, the Elliotts' Complaint references Defendant's recall of the medical device implanted in Mr. Elliott, and includes documents identifying that the recall was for a medical device model number bearing the same catalogue number as the Promos Inclination Set implanted in Mr. Elliott's shoulder. The Complaint also attaches Defendant's recall notice to the FDA, stating the Promos Inclination Set was recalled due to reports of intra- and post-operative set screws

4 At this early stage of the proceedings, the Elliotts have not had any opportunity to conduct discovery.

fracturing, and alleges that Mr. Elliott required revision surgery when set screws, contained within the Promos Inclination Set implanted in his shoulder, fractured. The Complaint also includes the FDA letter agreeing with Defendant's decision to recall the Promos Inclination Set.

With respect to the Elliotts' claims for violation of the Idaho Products Liability Reform Act, strict liability, negligence and loss of consortium (Counts I, II, III and VIII) the Court determines the complaint satisfies the purposes of Federal Rule Civil Procedure 8 of giving Defendant fair notice of the nature of the claims against it and of stating claims for relief that are facially plausible as required by *Iqbal* and *Twombly*.[5] Under *Bausch*, the Elliotts need not "specify the precise defect or the specific federal regulatory requirements that were allegedly violated." *Id.* at 560. Although "the complaint would be stronger with such detail," the absence of such details does not show "a failure to comply with Rule 8 of the Federal Rules of Civil Procedure," nor can it "support a dismissal under Rule 12(b)(6)." *Id.*

Federal Rule of Civil Procedure 9(b) does not impose any special requirement that a products liability claim (even in the context of MDA preemption) be plead with particularity. *Id*. Moreover, victims of defective products, like Mr. Elliott, may not be able to determine without discovery and further investigation the specific source of the defect (such as whether it was caused by a design or manufacturing defect). *Id*. Indeed,

5 In so holding, the Court is not ruling on Plaintiffs' likelihood of success with respect to Counts I-III, and Count VIII. Indeed, to the extent such claims impose state requirements that are different from or in addition to federal regulatory standards, they will be preempted under 21 U.S.C. § 360k(a).

if a plaintiff were required to allege that defendant violated a particular FDA-approved specification before discovery, "then it is difficult to appreciate how any plaintiff [would] ever be able to defeat a Rule 12(b)(6) motion." *Id*. at 561 (*citing In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litig*., 592 F.Supp.2d 1147, 1212 (D.Minn. 2009) (Melloy, J., dissent)). The Court accordingly denies Defendant's Motion to Dismiss with respect to Counts I, II, III and VIII.

**3. Negligent Misrepresentation-Count IV**

Count IV of the Complaint alleges Defendant made representations to Mr. Elliott, his physician, other recipients and their healthcare providers that the Promos Inclination Set was safe for use in shoulder replacement surgery, and that Defendant knew or should have known that it did not have sufficient information to determine whether the Promos Inclination Set was, in fact, safe. (Dkt. 1-3, p. 8-9.) However, Idaho law does not recognize a tort claim for negligent misrepresentation outside of a professional relationship with an accountant. *Mannos v. Moss*, 155 P.3d 1166, 1174 (Idaho 2007); *Duffin v. Idaho Crop Imp. Ass'n*, 895 P.2d 1195, 1203 (Idaho 1995) (tort of negligent misrepresentation is strictly limited in Idaho to the "narrow confines of a professional relationship involving an

accountant.").[6] Accordingly, the Elliotts cannot state a claim for negligent misrepresentation against Defendant. Count IV is dismissed with prejudice.[7]

**4. Breach of Implied or Express Warranty-Counts V and VI**

Count V of the Complaint alleges Defendant impliedly warranted that the Promos Inclination Set was of merchantable quality and safe for the use for which it was intended. (Dkt. 1-3, pp. 9-10.) Count VI claims Defendant expressly warranted the Promos Inclination Set was "safe, fit, effective, and proper for Mr. Elliott and other Recipients undergoing shoulder replacement surgery." (*Id*. at p. 11.) Neither the implied nor the express warranty claim identifies any contract between Defendant and the Elliotts. As the Idaho Supreme Court determined in *Oats v. Nissan Motor Corp*., 879 P.2d 1095, 1105 (Idaho 1994), Idaho does not recognize a breach of warranty claim in personal injury products liability actions which do not involve a contractual relationship between the manufacturer and the injured person.[8] As the *Oats* Court explained:

> [W]hen a plaintiff brings a non-privity breach of warranty action against a manufacturer or seller to recover for personal injuries allegedly sustained as a result of a defective product, that action is one for strict liability in tort, governed by the provisions of [the Idaho Product Liability Reform Act "IPLRA"]. Such an action should not be governed by the buyer and seller concepts of the UCC…. While it follows from our holding that [plaintiff's] 'breach of warranty' claim survives under

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6 The Idaho Supreme Court has expressly declined to adopt the Restatement standard for negligent misrepresentation. *Idaho Bank & Trust Co. v. First Bancorp of Idaho*, 772 P.2d 720, 722 (Idaho 1989).

7 Dismissal with prejudice is appropriate where, as here, it appears clear that no amendment to the complaint can cure a legally deficient claim.

8 Many states have eliminated the privity requirement in order to maintain a products liability claim for breach of implied warranty. 3 MODERN TORT LAW: LIABILITY AND LITIGATION § 27:13 (2d ed. 2012). However, in Idaho, absent privity of contract, the adoption of strict liability in tort abolished a cause of action for breach of implied warranty. *Id*. (*citing Oats*, 879 P. 2d at 1105).

> the IPLRA's statute of limitations, we fail to see how, in a personal injury product liability action not involving a commercial relationship between the manufacturer and the injured person, [plaintiff's] warranty allegations add anything to his other allegations of strict liability and negligence.

*Id*. (citation omitted)

Without any allegations to establish existence of a contract between the Elliotts and Defendant, Counts V and VI fail to state a claim other than that for strict liability in tort. Plaintiffs' Opposition to Defendant's Motion to Dismiss states only that their warranty claims are "well plead," but does not provide any analysis or argument as to how their breach of warranty claims differ from their claim for strict liability. (Dkt. 22, p. 8.) Counts V and VI are accordingly dismissed without prejudice.

**5. Fraud-Count VII**

Count VII of the Complaint alleges Defendant falsely and fraudulently represented to Mr. Elliott, his physician, and to other recipients of the Promos Inclination Set that the device was safe for use in shoulder replacement surgery, that such representations were false, that Defendant knew or should have known such representations were false, and that Defendant made such representations with the intent to defraud and deceive Mr. Elliott, his physician, and other recipients. (Dkt. 1-3, p. 12.) Federal Rule of Civil Procedure 9(b) requires fraud claims to be plead with particularity. Federal rules of procedure apply in federal court irrespective of the source of subject-matter jurisdiction and irrespective of

whether the substantive law at issue is state or federal. 36 C.J.S. FEDCOURTS § 244 (2013).

Rule 9(b) ensures that allegations of fraud are specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge rather than simply deny that they have done anything wrong. *Ebeid ex. Rel. U.S. v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010). It also prevents the filing of a complaint as a pretext for the discovery of unknown wrongs. *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir. 1985). Under Rule 9(b), a fraud claim must state the time, place and specific content of false representations as well as the identities of the parties to the misrepresentation. *Miscellaneous Service Workers, Drivers & Helpers, Teamsters Local No. 427 v. Philco-Ford Corp*., 661 F.2d 776, 782 (9th Cir. 1981).

Here the Elliotts have done nothing more than recite the elements of fraud, punctuated with conclusory, non-specific allegations. The absence of any times, dates, specific representations (other than the general representation that the Promos Device "was safe for use in shoulder replacement surgery"), places or other details of Defendant's allegedly fraudulent conduct is contrary to the fundamental purposes of Rule 9(b). Because the Plaintiffs have not complied with the specificity requirement of Rule 9(b), Count VII is dismissed without prejudice.[9]

9 As with Rule 12(b)(6) dismissals, "dismissals for failure to comply with Rule 9(b) should ordinarily be without prejudice." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1108 (9th Cir. 2003); *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 701 (9th Cir.1988) ("[L]eave to amend should be granted if it appears at all possible that the plaintiff can correct the defect.").

6. **Punitive Damages-Count IX**

Defendant argues Count IX of the Complaint, regarding punitive damages, violates Idaho Code § 6-1604(2) and should be stricken. (Dkt. 16-1, pp. 12-13.) Claims for punitive damages are substantive and Idaho law is therefore controlling. *See Strong v. Unumprovident Corp*., 393 F.Supp.2d 1012, 1025 (D. Idaho 2005).

Idaho Code § 6-1604(2) provides that "no claim for damages shall be filed containing a prayer for relief seeking punitive damages." Idaho Code § 6-1604(2). Instead, punitive damages may be sought in a lawsuit only after the claimant proves "by clear and convincing evidence, oppressive, fraudulent, malicious or outrageous conduct by the party against whom the claim for punitive damages is asserted." *Id*. After presenting such proof at a hearing, the party seeking punitive damages may then amend the complaint to add a claim for punitive damages.

Count IX of the Complaint does not pray for punitive damages or allege a specific damage amount, but instead reserves the right of Plaintiffs "to seek leave of the Court to amend their Complaint to plead for the recovery of punitive damages against Smith & Nephew and ABC Corporations 1-5." (Dkt. 1-3, p. 13.) However, under Idaho Code § 6-1604(2), Plaintiffs would have to seek leave to amend their Complaint to add punitive

damages regardless of the inclusion of Count IX in the Complaint. Count IX is accordingly meaningless, and is stricken from the Complaint.[10]

**ORDER**

1. Defendant's Motion to Dismiss (Dkt. 16) is **GRANTED** in part and **DENIED** in part. Count IV of the Complaint for Negligent Misrepresentation is **DISMISSED WITH PREJUDICE**. Count V-Breach of Implied Warranty, Count VI-Breach of Express Warranty and Count VII-Fraud are **DISMISSED WITHOUT PREJUDICE**. Count IX-Punitive Damages is **STRICKE**N from the Complaint. Finally, Defendant's Motion to Dismiss with respect to Count I-Violation of Idaho Product Liability Reform Act, Count II-Strict Liability, Count III-Negligence, and Count VIII-Loss of Consortium is **DENIED**.

10 After the requisite pretrial hearing, Plaintiffs may later seek to amend their Complaint to add a claim for punitive damages.

2. Plaintiff's Motion for Permission to Conduct Limited Discover Under Rule 56(d) Federal Rules of Civil Procedure (Dkt. 21) is **MOOT**. The Court has not considered evidence outside of the pleadings in granting in part and denying in part Defendant's Motion to Dismiss, and has not converted Defendant's Motion to Dismiss into one for summary judgment pursuant to Rule 56(d).

DATED: April 15, 2013

Edward J. Lodge
United States District Judge