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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

JEFFREY POLL, Plaintiffs, vs. STRYKER SUSTAINABILITY SOLUTIONS, INC., et al., Defendants.	No. CIV 13-440-TUC-CKJ **ORDER**

Pending before the Court are the Motions to Dismiss (Docs. 7 and 12) filed by Defendants and the Motion for Rule 56(d) Relief (Doc. 10) filed by Plaintiff.

I. *Procedural Background*

On March 1, 2013, Plaintiff Jeffrey Poll ("Poll") filed a Complaint in the Pima County Superior Court alleging claims of strict liability, breach of express warranty, implied warranty, negligence, products liability failure to warn, and products liability defective design against Stryker Sustainability Solutions, Inc., Stryker Sales Corporation, Stryker Corporation and Howmedica Osteonics Corporation (collectively, "Howmedica" or "Defendants").[1] On June 6, 2013, Howmedica removed the action to this Court.

On June 13, 2013, Howmedica filed a Motion to Dismiss as to the original complaint.

[1]The claims are also alleged against John Does and Jane Does 1-5 and ABC-XYZ Corporations, Partnerships and Entities.

A response and a reply have been filed.

On July 8, 2013, Poll filed an Amended Complaint. The Amended Complaint alleges claims of strict liability, breach of express warranty, implied warranty, negligent failure to warn, products liability failure to warn, and products liability defective design against Defendants. Poll alleges he was damaged as a direct and proximate result of Howmedica's wrongful conduct in connection with the Cormet Cup and Cormet Head (collectively, the "Cormet System"), a Class III medical device under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). Howmedica is alleged to have entered into a marketing and distribution agreement to market and sell the Cormet System. Howmedica is alleged to have received approval from the Food & Drug Administration ("FDA") to market the Cormet System after completing a Pre-Market Approval ("PMA") process. As discussed *infra*, Poll alleges Howmedica's failure to advise the FDA of relevant adverse consequences of the Cormet System which has resulted in Poll's injuries/damages.

Poll also filed a Motion for Rule 56(d) Relief on July 8, 2013. A response and a reply have been filed.

On July 25, 2013, Howmedica filed a Motion to Dismiss as to the Amended Complaint. A response and a reply have been filed.

II. *June 13, 2013 Motion to Dismiss* (Doc. 7)

Poll asserts this motion is moot because an Amended Complaint has been filed. Howmedica does not dispute this assertion – in its Response to the Motion for Rule 56(d) Relief, Howmedica specifically acknowledges this motion is moot. The Court will deny this motion as moot.

III. *Motion for Rule 56(d) Relief* (Doc. 10)

Poll asserts Howmedica converted its June 13, 2013, Motion to Dismiss into a motion for summary judgment because it cited to and relied on materials and facts outside of the Complaint and not yet adduced in discovery. Howmedica asserts that, as Poll filed this

motion as to the original Motion to Dismiss, it is now mooted as is the original Motion to Dismiss. In his reply, Poll does not dispute this, but asserts that the July 25, 2013, Motion to Dismiss has similarly been converted into a summary judgment motion. Poll asserts, therefore, the procedures of Fed.R.Civ.P. 56 permit the Court discretion to permit discovery.

While the Court agrees with Howmedica that the motion is mooted by the filing of the Amended Complaint and the July 25, 2013, Motion to Dismiss, the Court finds it appropriate to consider whether the Motion to Dismiss has been converted into a summary judgment motion based on reliance of additional documents pursuant to Fed.R.Civ.P. 12(d) and whether relief pursuant to Fed.R.Civ.P. 56(d) is appropriate.

The applicable rule governing dismissal motions states:

> **Result of Presenting Matters Outside the Pleadings**. If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.

Fed.R.Civ.P. 12(d). However, a court "'may take judicial notice of matters of public record' and consider them without converting a Rule 12 motion into one for summary judgment." *United States v. 14.02 Acres of Land More or Less in Fresno Cnty.*, 547 F.3d 943, 955 (9th Cir. 2008) (*citing Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001)).

In its July 25, 2013, Motion to Dismiss, Howmedica has attached, cited to, and referred to a complaint filed in the Supreme Court of the State of New York, the Cormet System approval letter, the Cormet System Summary of Safety and Effectiveness, the Cormet System labeling and instructions for use, and the Cormet System supplemental PMA approvals. Judicial notice may be taken of documents on file in federal or state court. *Harris v. County of Orange*, 682 F.3d 1126, 1132 (9th Cir. 2012). The Court finds it is appropriate to take judicial notice of the complaint filed in the New York court.

Additionally, the Ninth Circuit has determined that, where the authenticity of a website or the accuracy of the information displayed on the website is not disputed, it is appropriate to take judicial notice of information displayed publicly on government websites. *See Daniels-Hall v. National Educ. Ass'n*, 629 F.3d 992, 998-99 (9th Cir. 2010) (taking

judicial notice of information on websites of school districts) (*citing* Fed.R.Evid. 201 (allowing a court to take judicial notice of a fact "not subject to reasonable dispute in that it is . . . capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned"); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (noting that courts ruling on 12(b)(6) motions to dismiss may take into consideration "matters of which a court may take judicial notice"); *In re Amgen Inc. Sec. Litig.*, 544 F.Supp.2d 1009, 1023–24 (C.D.Cal. 2008) (taking judicial notice of drug labels taken from the FDA's website); *County of Santa Clara v. Astra USA, Inc.*, 401 F.Supp.2d 1022, 1024 (N.D.Cal. 2005) (taking judicial notice of information posted on a Department of Health and Human Services web site)); *see also Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1089 (C.D. Cal. 2011) (taking judicial notice of PMA approval documents). The Cormet System approval letter, the Cormet System Summary of Safety and Effectiveness, the Cormet System labeling and instructions for use, and the Cormet System supplemental PMA approvals are available on the FDA's website. The Court finds it is appropriate to take judicial notice of these documents. The Court finds, therefore, the July 25, 2013, Motion to Dismiss has not been converted into a summary judgment motion.

Poll does not appear to be disputing that judicial notice of the documents is appropriate, but argues that the Supreme Court has interpreted Fed.R.Civ.P. 56(d) to require "discovery 'where the nonmoving party has not had the opportunity to discover information that is essential to its opposition.'" *Metabolife Int'l v. Wornick*, 264 F.3d 832, 846 (9th Cir. 2001) (*quoting Anderson v. Liberty Lobby*, 477 U.S. 242, 250 n.5 (1986)). However, as judicial notice of the documents is appropriate, the July 25, 2013, Motion to Dismiss is not a motion for summary judgment, Fed.R.Civ.P. 56(d), and the Supreme Court's interpretation of it, therefore, is not relevant to the pending motion.

Poll has not provided any other basis to permit discovery prior to resolution of the Motion to Dismiss. The Court finds it appropriate to deny the motion and to resolve the Motion to Dismiss at this time.

IV. *Motion to Dismiss* (Doc. 12)

Howmedica asserts that the claims as set forth in Poll's original Complaint are preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360k (the "MDA"), to the Federal Food, Drug and Cosmetics Act, as interpreted by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Further, Howmedica asserts that Poll has essentially conceded Howmedica's arguments by filing an Amended Complaint that includes additional claims in an attempt to evade preemption.

A. *Preemption under the MDA*

Under the Supremacy Clause, the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. Accordingly, "state laws that conflict with federal law are 'without effect.'" *Mut. Pharm. Co., Inc. v. Bartlett*, —— U.S. ——, 133 S.Ct. 2466, 2473, 186 L.Ed.2d 607 (2013) (*citations omitted*). "Federal preemption occurs when: (1) Congress enacts a statute that explicitly pre-empts state law; (2) state law actually conflicts with federal law; or (3) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field." *Chae v. SLM Corp.*, 593 F.3d 936, 941 (9th Cir. 2010) (*citations omitted*). The three categories of preemption are express, field and conflict. *Id.* Field and conflict preemption are subcategories of implied preemption. *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (*petition for certiorari pending*).

The framework for analyzing express preemption under the MDA was set forth by the Supreme Court in *Riegel*. Under this framework, a court must first determine whether the federal government has established requirements applicable to the device at issue. The court must then determine whether the plaintiff's claims are based on state requirements regarding the device that are "'different from, or in addition to' the federal [requirements], and that relate to safety and effectiveness." *Id*. at 321–22. If so, the plaintiff's claims are expressly preempted by the MDA.

However, the MDA does not prohibit states from providing damage remedies for claims premised on violations of FDA regulations. *Id*. at 330. In such a situation, the state duties are "parallel" to the federal duties, and claims based on the parallel state duties are not preempted. *Id*.; *Stengel v. Medtronic Inc.,* 704 F.3d at 1228 ("[T]he MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.").

Additionally, the Supreme Court in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001), interpreted 21 U.S.C. § 337(a) as impliedly preempting claims seeking to enforce an exclusively federal requirement not grounded in traditional state tort law. *Id*. at 352–53; *see Stengel*, 704 F.3d at 1235. "Together, express preemption and implied preemption provide only a 'narrow gap' through which the plaintiff's claims must fit in order to survive." *Kashani-Matts v. Medtronic, Inc.* No. SACV 13-01161-CJC (RNBx), 2013 WL 6147032 (C.D. Cal. 2013) (*citing Perez v. Nidek Co.,* 711 F.3d 1109, 1120 (9th Cir.2013)). As summarized by the Ninth Circuit, "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Perez*, 711 F.3d at 1120 (*citing In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1204 (8th Cir. 2010).

Furthermore, as the Ninth Circuit has explained, where a state law failure to warn claim is based on a defendant's failure to advise the FDA of relevant adverse consequences of a Class III device learned of after obtaining PMA, such a claim would not be preempted. *Stengel*, 704 F.3d at 1232-33; *see also* 21 C.F.R. § 803.50(a) (report required by FDA if manufacturer learns of information "reasonably suggest [ing]" that its device "[m]ay have caused or contributed to a death or serious injury[.,]"

B. *Preemption Standard as to the Cormet System*

As to the initial prong of *Riegel*, the Cormet System went through the rigorous PMA process of the FDA. The Cormet System received approval from the FDA after the PMA

process which involved a consideration of safety and effectiveness of the Cormet System. Motion to Dismiss, Ex. 3. The FDA imposed specific requirements regarding the Cormet System's labeling and marketing. *Id*. at Ex. 4. Further, subsequent changes or modifications of the Cormet System have undergone the supplemental PMA process. *Id*. at Ex. 5. Furthermore, the FDA retains strict oversight over the Cormet System as a Class III device. *Riegel*, 552 U.S. at 319 (*citing* 21 U.S.C. § 360e(d)(6)(A)(I)). The Court finds the federal government has established requirements applicable to the Cormet System.

As to *Riegel's* second prong, whether Poll's claims are based on any requirement of state law that is "different from, or in addition to" federal requirements and relate to safety and effectiveness, the Court will first address Poll's allegations of negligent failure to warn and products liability failure to warn. Poll alleges:

> 17. Upon information and belief, Defendants failed to issue warnings and to disclose problems with the Cormet System that are described more fully below. Upon information and belief, the failure to issue warnings and report problems and adverse events that occurred after the PMA process and/or after FDA approval. Upon information and belief, these failures constituted violations of federal law and regulations, including the terms of the FDA approval which required adequate and accurate reporting of adverse events.
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> 18. As a result of Defendants' wrongful conduct, Plaintiff has suffered, and continues to suffer, serious bodily injury and has incurred and continues to incur, medical expenses to treat his injuries and condition.
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> 19. Subsequent to the PMA process, Defendants became aware of European studies that revealed problems with the Cormet System, including the development of cobalt poisoning, the development of pseudo tumors around the devices and unacceptably high failure rates and revision surgeries being reported by patients and doctors in the United Kingdom and other European countries. Upon information and belief, Defendants failed to report these known risks to the FDA as required by the Medical Device Amendments to the Food, Drug and Cosmetic Act.
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> 20. Upon information and belief, the Defendants knew but did not report or disclose the known problems with certain manufacturing techniques such as double heat treatment that deteriorates the wear properties of the cobalt-chromium surfaces that were used in the Cormet system. The foreign manufacturer of the Cormet System had adopted double heat treating to help reduce factory scrap rates and to save money but the technique fundamentally changed the metal surfaces and their wear properties to the detriment of the patients. This was not disclosed to the FDA before or after approval, and doctors and patients in the United States were left in the dark about the propensity of the devices to shed debris and cause cobalt poisoning.
>
> 21. In July 2012, Defendants voluntarily withdrew the Cormet System from the United States market stating that the "distribution of a hip resurfacing device no longer fits within Stryker's long-term product strategy." Contrary to their public

> statements, Defendants' real concern with the Cormet System was the unreasonable risk of cobalt poisoning and other health problems.
>
> 22. Due to the Defendants' failure to issue post-PMA warnings regarding the Cormet System and to make appropriate disclosures to the FDA, patients, including Plaintiff Jeffrey Poll, have been forced to undergo surgeries to replace the failed hip implants.

Amended Complaint, Doc. 8, ¶¶ 17-22.

In other words, Poll has alleged Howmedica's failure to advise the FDA of relevant adverse consequences of the Cormet System has resulted in Poll's injuries/damages. The Court finds Poll has alleged a theory for liability as to the claims for negligent failure to warn and products liability failure to warn.

As to Poll's allegation of strict liability, in Arizona "sellers may be held strictly liable for harm caused by defective and unreasonably dangerous products they have sold[.]" *Grubb v. Do It Best Corp.*, 230 Ariz. 1, 2, 279 P.3d 626, 627 (App. 2012). A finding of Howmedica's liability on Poll's strict liability claim would constitute imposition of requirements on the Cormet system in addition to those mandated by the FDA through PMA approval and supplemental approval. Therefore, Poll's strict liability claim is preempted.

As to Poll's allegations of breach of express and implied warranties, Poll alleges Howmedica induced purchases of the Cormet System and its component parts by expressly warranting to Poll and/or his physician or hospital that the Cormet System was safe for implantation into the body and impliedly warranted that the Cormet System and its component parts were fit for use as an implantable hip and that they were in fact suitable for the use made by Poll. Here, Poll's claims are not based on statements made to the FDA, but alleged warranties/statements made to Poll and medical personnel. Other district court appear to have reached conflicting determinations of whether such a claim is preempted. In *Alton v. Medtronic, Inc.*, — F.Supp.2d — , 2013 WL 4786381 * 30 (D.Or. 2013), the court stated that "recognition of [plaintiff's] . . . warranty claim[s] presents no risk of interference with the federal medical device regulatory scheme, and the claim escapes express preemption[.]" However, the court in *Suckow v. Medtronic, Inc.*, — F.Supp.2d — , 2013 WL 5302223 (D.Nev. 2013), appears to have concluded that only warranties that

exceeded FDA conclusions would not be preempted. *See Riegel*, 552 U.S. at 318 (FDA only grants PMA if there is a reasonable assurance of the safety and effectiveness of the device). Because a state may not "establish or continue in effect with respect to a device . . . any requirement' relating to safety and effectiveness that is different from, or in addition to, federal requirements[,]" *Riegel*, 552 U.S. at 328 (*citing* 21 U.S.C. § 360k(a)), the Court finds that warranties that do not go beyond those conclusions made by the FDA are preempted. Therefore, Poll's claims for breach of warranties are preempted.

As to Poll's allegation of products liability defective design, a finding of Howmedica's liability on the defective design claim would constitute an imposition of additional requirements on the design of the device than those mandated by the FDA through PMA and supplemental approval. Therefore, the defective design claim is not a parallel claim and is preempted.

As to Poll's multiple claims of failure to warn, the Court has determined Poll has alleged claims that are not preempted. However, the Court must also consider whether Poll has adequately pleaded a factual basis for those claims.

C. *Pleading Requirements as Applied to Poll's Amended Complaint*

A complaint is to contain a "short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed.R.Civ.P. 8(a). Nonetheless, a complaint must set forth a set of facts that serves to put defendants on notice as to the nature and basis of the claim(s). The United States Supreme Court has found that a plaintiff must allege "enough facts to state a claim to relief that is plausible on its facts." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, (2007). A complaint will survive a motion to dismiss when it contains "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) (*citation omitted*); *see also Moss v. U.S. Secret Service*, 572 F.3d 962 (9th Cir. 2009) (for a complaint to survive a motion to dismiss, the non-conclusory "factual content," and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief); *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011)

("If there are two alternative explanations, one advanced by defendant and the other advanced by plaintiff, both of which are plausible, plaintiff's complaint survives a motion to dismiss[.]"). Indeed, Fed.R.Civ.P. 8(a)(2) requires a showing that a plaintiff is entitled to relief "rather than a blanket assertion" of entitlement to relief. *Bell Atlantic*, 554 U.S. at 555 n. 3.

This Court must take as true all allegations of material fact and construe them in the light most favorable to Poll. *See Cervantes v. United States*, 330 F.3d 1186, 1187 (9th Cir. 2003). In general, a complaint is construed favorably to the pleader. *See Scheuer v. Rhodes*, 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974), *overruled on other grounds*, 457 U.S. 800. "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement of relief." *Iqbal*, 556 U.S. at 679. Nonetheless, the Court does not accept as true unreasonable inferences or conclusory legal allegations cast in the form of factual allegations. *Western Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981).

Howmedica argues that Poll's inclusion in the Amended Complaint of allegations that Howmedica became aware of European studies that revealed problems with the Cormet System and that Howmedica knew but did not report or disclose known problems to the FDA are not supported with any factual specificity – i.e., Poll does not specify which studies he claims were unreported, despite the public nature of such studies, and does not point to any enforcement action by the FDA or other supporting fact.

In considering whether claims had been adequately pled, the Ninth Circuit recently dismissed claims, not because they were pled on information and belief, but because they were conclusory allegations unsupported by factual assertions. *Blantz v. Cal. Dept. Of Corr. And Rehab., Div. Of Corr. Health Care Srvs.*, 727 F.3d 917, 926-27 (9th Cir. 2013). Further, Howmedica argues that Poll's claims which sound in fraud have not been pleaded with specificity as required by Fed.R.Civ.P. 9(b).

Poll argues, however, that the Amended Complaint gives Howmedica fair notice of the claims and that the allegations contain sufficient facts to be plausible. *See Tellabs, Inc.*

v. Makor Issues & Rights, Ltd., 551 U.S. 308 (2007); *Bell Atlantic*. He further argues that the amount of particularity depends upon the amount of access a pleader has to specific facts. *See generally, Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010); *In re Rockefeller Ctr. Props., Inc. Secs. Litig.*, 311 F.3d 198, 216 (3rd Cir. 2002).

Poll's allegation regarding European studies that revealed problems with the Cormet System does not specify what studies and/or what problems are at issue. Further, it appears that Poll's allegations as to Howmedica's knowledge of but failure to report problems similarly does not specify what problems are at issue (e.g., if they are based on the European studies). Although the Court agrees with Poll that the amount of access may affect the level of specificity, the rule "still requires [Poll] to plead the fraud with some level of specificity." *Ebeid*, 616 F.3d at 999. Here, Poll has not disputed Howmedica's assertion that relevant reports are public; nonetheless, Poll did not provide any specificity about the reports discussing the problems. The Court finds Poll's allegations are conclusory and the non-conclusory "factual content," and reasonable inferences from that content, is not plausibly suggestive of a claim entitling Poll to relief. *See e.g., Williams v. Allergan USA, Inc.*, No. CV–09–1160–PHX–GMS, 2009 WL 3294873 ("Even construing the Complaint broadly, however, Plaintiffs alleged no facts regarding FDA requirements, the premarket approval process, *the study*, or [plaintiff's] consent.") (*emphasis added*).

D. *Conclusion*

The Court finds that dismissal is appropriate. The Court recognizes that when a dismissal is made, a party must be given at least one chance to amend a pleading when a more carefully drafted pleading *might* state a claim. *Bank v. Pitt*, 928 F.2d 1108, 1112 (11th Cir. 1991); *see also Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 969 (9th Cir. 2009). The Court finds it appropriate to afford Poll an opportunity to submit a Second Amended Complaint as to his multiple claims of failure to warn and breaches of warranties. However, as it is absolutely clear deficiencies as to the strict liability and products liability defective design claims cannot be cured by amendment, the Court will

dismiss those claims with prejudice. *See Noll v. Carlson*, 809 F.2d 1446, 1448 (9th Cir. 1987) (leave to amend is liberally granted unless absolutely clear deficiencies cannot be cured by amendment).

Accordingly, IT IS ORDERED:

1. The June 13, 2013, Motion to Dismiss (Doc. 7) is DENIED as moot.

2. The Motion for Rule 56(d) Relief (Doc. 10) is DENIED.

3. The July 25, 2013, Motion to Dismiss (Doc. 12) is GRANTED IN PART AND DENIED IN PART.

4 Poll's claims of strict liability and products liability defective design are DISMISSED WITH PREJUDICE.

5 Poll's claims of breach of express warranty, implied warranty, negligent failure to warn, and products liability failure to warn are DISMISSED WITH LEAVE TO AMEND.

6. Poll shall file a Second Amended Complaint within twenty (20) days of the date of this Order. The failure to timely file a Second Amended Complaint shall result in dismissal of this action without further notice to the parties.

DATED this 17th day of January, 2014.

Cindy K. Jorgenson
United States District Judge