IN THE UNITED STATES DISTRICT COURT

DISTRICT OF IDAHO

MABON CORNWELL,

Plaintiff,

vs.

STRYKER CORPORATION; STRYKER SALES CORPORATION; HOWMEDICA OSTEONICS CORP. d/b/a STRYKER ORTHOPAEDICS,

Defendants.

Case No. 1:10-cv-00066-EJL

MEMORANDUM ORDER

Pending before the Court in the above-entitled matter is Defendants' Motion to Dismiss (Docket No. 7). 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 Mabon Cornwell ("Plaintiff" or "Cornwell") underwent a left total hip replacement on May 23, 2003 wherein a Trident System with metal acetabular cup and femoral stem was implanted. The Trident Hemispherical Cup implanted in Plaintiff is

serial number 502-01-54E. It is undisputed that the Trident System implanted in Plaintiff was manufactured by Defendant Stryker Corporation. After surgery, Cornwell continued to experience pain and he underwent a revision of his total hip replacement on April 22, 2008, during which his Trident acetabular cup was revised. Plaintiff filed a Complaint in federal court against Stryker Corporation, Stryker Sales Corporation, Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics (collectively referred to as the "Defendants") alleging defects in the Trident acetabular shell prevented the bone in his hip from growing into the cup to secure it and led to the need for revision surgery.

It is undisputed that on January 22, 2009, Defendant Stryker Corporation initiated a recall of certain Trident PSL and Hemispherical Shells (the acetabular cups) manufactured in their Cork, Ireland facilities between January 2000 and the end of December 2007. Plaintiff alleged the Trident implanted in his body was manufactured at the Cork, Ireland facility. Discovery completed in this matter has now established the acetabular shell implanted in Plaintiff was *not* manufactured in Cork, Ireland and was not the subject of any recall or other regulatory action.

Defendants argue in the motion to dismiss for failure to state a claim that Plaintiff's claims are all preempted by the express preemption provision of the Medical Device Amendments ("MDA") to the federal Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 360c et seq., which preempts product liability claims in the case of medical devices approved by the Food and Drug Administration's ("FDA's") pre-market approval ("PMA") process. Plaintiff does not dispute that if a medical device was approved by the

FDA's PMA process, the alleged product liability claim would be preempted. Rather, Plaintiff alleges that the Trident metal acetablular cup was approved via a less rigorous § 510(k) process and his claims are not therefore preempted. Defendants argue the entire Trident System, including all components, was approved via the PMA process.

Alternatively, Plaintiff claims he has also plead manufacturing defects that are premised on alleged FDA regulation violations and these claims parallel the requirements of the MDA so they are not preempted. Defendants argue Cornwell has failed to state a parallel claim for violations of federal law since Cornwell's implant was not manufactured at the facility the subject to the FDA's warning letter and Defendant Stryker Corporation's voluntary recall.

STANDARD OF REVIEW

A motion to dismiss for failure to state a claim should not be granted "unless it appears beyond doubt that Plaintiff can prove no set of facts in support of his claim that would entitle him to relief." *Clegg v. Cult Awareness Network*, 18 F. 3d 752, 754 (9th Cir. 1994). All allegations of material fact in the complaint are taken as true and construed in the light most favorable to the non-moving party. *See Buckey v. County of Los Angeles*, 968 F.2d 791, 794 (9th Cir. 1992). The Ninth Circuit has held that "in dismissals for failure to state a claim, a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Cook, Perkiss and Liehe, Inc. v.*

Northern California Collection Service, Inc., 911 F.2d 242, 247 (9th Cir. 1990). While amendments are liberally permitted under Rule 15(a), the district court may deny leave to amend when there has been an undue delay in bringing the motion, and the opposing party would be unfairly prejudiced by the amendments. *See United States v. Pend Oreille Public Utility Dist. No. 1*, 28 F.3d 1544, 1552-53 (9th Cir. 1994).

Generally, the Court may not consider any material beyond the pleadings in ruling on a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *See Branch v. Tunnell*, 14 F.3d 449, 453 (9th Cir. 1994). If materials outside the pleadings are considered, the motion is converted to a motion for summary judgment governed by Fed. R. Civ. P. 56. *See Jacobsen v. AEG Capital Corp.*, 50 F.3d 1493, 1496 (9th Cir. 1995).

But as *Branch* makes clear, there are times when documents other than the pleadings can be considered without converting a motion to dismiss into a motion for summary judgment. "[D]ocuments whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleading, may be considered in ruling on a Rule 12(b)(6) motion to dismiss." *Branch*, 14 F.3d at 453.

ANALYSIS

1. Preemption under the MDA

The MDA authorizes the FDA to regulate the safety and effectiveness of medical devices. The MDA also contains an express preemption clause which provides:

> no State or political subdivision 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 held that lawsuits brought under state law against medical device manufacturers who submit 'premarket notification' to the Food and Drug Administration 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." *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 832 (S.D. Ind. 2009), *citing Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481, 494-95 (1996).

In 2008, in *Riegel v. Medtronic, Inc.*, 552 U.S. ___, 128 S. Ct. 999 (2008) ("*Riegel*"), the Supreme Court held that lawsuits brought under state law against medical device manufacturers who obtain federal "premarket approval" are 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 devices.

To understand the application of these two Supreme Court decisions, the Court needs to explain the difference between "notification" to the FDA and the PMA "approval" process. Under the MDA there are three classes for medical devices depending on the risks the device presents. Class I and Class II medical devices my be

marketed without receiving prior approval from the FDA. 21 U.S.C. § 360(a)(1)(A)-(B). The highest class of medical devices is Class III devices because they present a potentially unreasonable risk of injuring patients or they are used to sustain life. *See* 21 U.S.C. § 360c(a)(1)(C). There are two ways for a Class III device to be approved for market: the § 510(k) process or the PMA process.

The § 510(k) review process is not "specific to the device in question [instead reflecting] . . . entirely generic concerns about device regulation generally." *Riegel*, 128 S. Ct. at 1006 *citing Medtronic v. Lohr*, 518 U.S. at 510. Since no federal requirements are imposed on Class III medical devices approved under § 510(k), state law claims against such devices are not preempted under the MDA.

On the other hand, the PMA process is the most rigorous review process and only a small percentage of Class III medical devices have been subject to the PMA process. *See Riegel v. Medtronic, Inc.*, 451 F.3d 104, 11-12 (2nd Cir. 2006). If a product is approved via the PMA process, the MDA's preemption applies to 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. *Riegel*, 128 S.Ct. at 1007.

The Court finds the record in this case supports that the Trident System, including its component parts, received PMA approval under the PMA process. Plaintiff argues the Trident acetabular cup was initially approved via the § 510(k) process and even though it was later approved for use with the ceramic-on-ceramic Trident System which received PMA approval, claims regarding the acetabular cup are exempt based on its original

approval under § 510(k). This argument has been rejected by every other court determining whether the acetabular cup received approval via the PMA process. *See Phillips v. Stryker Cor*., 2010 WL 2270683 (E.D. Tenn June 3, 2010); *Funk v. Stryker Corp.*, 673 F.Supp. 2d 522, 530-31 (S.D.Tex. 2009); *Lewkut v. Stryker Corp.*, 2010 WL 1544275, *5 9S.D. Tex. April 16, 2010); and *Lemell v. Stryker Orthopaedics*, 2010 WL 996523, *7 (W.D. La. Mar. 15, 2010). Moreover, the information provided by Defendants from the FDA's website confirms that the Trident System, including all components, were approved via the PMA process.

Having found the medical device at issue in this case was approved via the PMA process, the Court finds Plaintiff's product liability claims are preempted by the MDA and must be dismissed.

2. Parallel Claims

Alternatively, Plaintiff argues that the Complaint should not be dismissed as he as also pled a "parallel claim" that the medical device violated federal regulations.

In Re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation, ___ F.3d ___, 2010 WL 4026802 (8th Cir. 2010) :

> In *Riegel*, the Court held that, for § 360k(a) preemption purposes, (i) FDA pre-market approval is "federal safety review" that results in federal "requirements" specific to the approved device, and (ii) common law product liability claims result in "state requirements" that are preempted to the extent they relate to the safety and effectiveness of the device and are "different from, or in addition to," the federal requirements established by PMA approval. 552 U.S. at

> 322-24. However, the Court noted, § 360k "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." *Id.* at 330.

In the present case, Plaintiff's Complaint alleges a violation of FDA regulations based on Plaintiff's belief (at the time the Complaint was filed) that the Trident component was manufactured at the facility where a FDA warning letter and voluntary recall applied. Discovery has established the component was not manufactured at the Cork, Ireland facility, so Plaintiff's basis for an alleged violation of FDA regulations fails.1

To the extent Plaintiff's parallel claim is based on a theory the medical device implanted in Plaintiff was "adulterated" such claim must also be dismissed as there is no private right of action for the enforcement of federal regulations relating to medical device provisions. *See Buckman Co. v. Plaintiffs' Legal Claims*, 531 U.S. 3341, 349 n.4 (2001). The United States government may prosecute a claim for adulterated devices, but there is no private right of action. 21 U.S.C. § 337(a); *In re Medtronic, Inc. Sprint fidelis Leads Products Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009).

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[1]Defendants argue Plaintiff's counsel should be subject to Fed. R. Civ. P. 11 sanctions for failing to dismiss this claim once documentation was provided the medical device at issue had not been manufactured at the Cork, Ireland facility. The Court agrees counsel for the Plaintiff should have acknowledged the undisputed facts and provided notice to the Court regarding Plaintiff's position due to changes to the factual basis for the parallel claim argument, but the Court declines to award Rule 11 sanctions in this matter.

3. Conclusion

The Plaintiff's Complaint fails to state a claim upon which relief can be granted and the Defendants are entitled to the dismissal of the Complaint in its entirety pursuant to Fed. R. Civ. P. 12(b)(6).

ORDER

IT IS ORDERED that Defendants' Motion to Dismiss (Docket No. 7) is GRANTED and the Complaint is DISMISSED IN ITS ENTIRETY.

DATED: **November 1, 2010**

Honorable Edward J. Lodge
U. S. District Judge