UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

MARTY PHILLIPS, Plaintiff, v. STRYKER CORPORATION, STRYKER SALES CORPORATION, and HOWMEDICA OSTEONICS CORP. d/b/a STRYKER ORTHOPEDICS, Defendants.	)	No.: 3:09-CV-488 (VARLAN/GUYTON)

MEMORANDUM OPINION AND ORDER

This civil action is before the Court on defendants' Motion to Dismiss [Doc. 8]. Plaintiff has filed a response in opposition to the motion to dismiss [Doc. 12]. Defendants have filed a reply to the response [Doc. 13]. The motion to dismiss is now ripe for this Court's consideration.

I. Background

Plaintiff filed the original complaint in this case on November 16, 2009 [Doc. 1]. Plaintiff filed his first amended complaint on January 7, 2010 [Doc. 4]. In the amended complaint, plaintiff alleges as follows: plaintiff is a resident of Oneida, Tennessee [*Id.*, ¶ 1]. Defendants Stryker Corporation ("Stryker") and Stryker Sales Corporation ("Stryker Sales") are Michigan corporations doing business in Tennessee [*Id.*, ¶¶ 2, 3]. Defendant Howmedica Osteonics Corporation d/b/a Stryker Orthopedics ("Stryker Orthopedics") is a New Jersey corporation doing business in Tennessee [*Id.*, ¶ 4].

Defendants were in the business of designing, manufacturing, marketing, and selling hip prostheses, including what is known as the "Trident System," on or about June 6, 2006 [*Id.*, ¶ 8]. The Trident System is an artificial hip replacement prosthesis consisting of two components of a ceramic-on-ceramic acetabular bearing couple: an alumina ceramic insert (socket liner) and an alumina ceramic femoral head (ball) [*Id.*, ¶ 10]. The Trident System is used with a metal acetabular shell (socket) and a metal femoral stem (hip stem), both of which were designed, manufactured, and marketed by Stryker prior to the approval of the Trident System by the United States Food and Drug Administration (the "FDA") [*Id.*]. Defendants sold the hip prosthesis that is the subject of this litigation to plaintiff, or to plaintiff's physicians on plaintiff's behalf [*Id.*, ¶ 9].

Stryker obtained approval from the FDA to market the Trident System under the pre-market approval, or "PMA," process [*Id.*, ¶ 11]. Prior to the submission of the ceramic bearing surfaces for PMA, some components of the Trident System were approved by the FDA pursuant to a separate § 510(k) approval process [*Id.*]. The components of the Trident System that received PMA on or about February 3, 2003 include the ceramic-on-ceramic acetabular bearing couple, which consists of the alumina ceramic insert with titanium sleeve and alumina ceramic femoral head [*Id.*]. These components were approved for use with the commercially available "Trident AD with Pure-Fix HA Acetabular Shell" and press-fit titanium alloy "Howmedica Osteonics Omnifit–HA Hip Stems" [*Id.*].

The metal Trident acetabular shells used with the PMA-approved ceramic-on-ceramic weight-bearing components are medical devices, and have been approved through the §

510(k) process [*Id.*, ¶ 12]. The Trident acetabular shells, formerly called Osteonics Secur-Fit AD, were commercially available and in use prior to the FDA's approval of the ceramic weight-bearing components [*Id.*]. These shells were approved by the FDA through the § 510(k) process on or about December 11, 1998 [*Id.*]. A second generation of shells, identified in FDA documents as Trident PS Acetabular Shells and Trident PS-HA, received FDA approval pursuant to the § 510(k) process on August 4, 2000 [*Id.*]. Trident hemispherical acetabular shells AD and AD-HA were approved through the § 510(k) process on or about December 5, 2001 [*Id.*].

The metal femoral stem used with the ceramic-on-ceramic Trident System was also approved through the § 510(k) process [*Id.*, ¶ 13]. According to FDA documents, the Trident System uses the Omnifit HA femoral stems, which were approved for commercial use through the § 510(k) process on or about July 9, 1998 [*Id.*, ¶ 13]. This component was also in use prior to the FDA's approval of the ceramic-on-ceramic components of the Trident System through the PMA process [*Id.*].

On or about March 15, 2007, the FDA issued a warning letter to Stryker arising from the FDA's inspections of Stryker's facilities in Cork, Ireland between October 31, 2006 and November 3, 2006 [*Id.*, ¶ 18]. Prior to the delivery of this warning letter, the FDA inspector issued to Stryker a list of inspectional observations, which identified the following violations of federal regulations at Stryker's Ireland facilities:

> (1) Failure to establish and maintain adequate procedures for implementing a corrective and preventative action . . . which included insufficient

dwell time, nonconforming temperature, pressure variation, and burst test method variability;

(2) Failure to establish and maintain adequate procedures to control product that fails to conform with specified requirements, including the evaluation of nonconforming products;

(3) Failure to timely make changes to procedures to lessen confusion and better assure that root causes of nonconforming products are identified;

(4) Failure to manufacture blister sealing used for sterilized products according to the federal requirements in that the blister sealing temperature, time, and pressure settings were outside of specified and validated operating parameters;

(5) Failure to establish and maintain adequate procedures to implement and record changes in methods and procedures needed to correct and prevent identified quality problems . . . including failing to verify and implement changes to reduce the final rinse tank bioburden; and

(6) Failure to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications.

[*Id.*, ¶ 19].

On January 22, 2008, Stryker initiated a recall of certain Trident PSL and hemispherical shells manufactured in its Ireland facilities [*Id.*, ¶ 20]. The recall applied to plaintiff's hip device [*Id.*]. The recall came after an investigation into deviations between specifications and processes for manufacturing required by the FDA, whereby viable microorganisms that were found in the final rinse tank contaminated the Trident devices [*Id.*]. Manufacturing residuals in excess of those permitted by the FDA were also found on the Trident devices pursuant to this investigation [*Id.*]. Plaintiff has been unable to determine

as of yet whether these residuals were foreign bodies or native material from the manufacturing process, as no public information is available other than a redacted FDA warning letter [*Id.*].

On or about June 6, 2006, Randall Robbins, M.D. performed a left hip arthroplasty on plaintiff at Methodist Medical Center in Oak Ridge, Tennessee [*Id.*, ¶ 2]. During surgery, a hip implant believed to be designed, manufactured, and marketed by Stryker was implanted in plaintiff's left hip [*Id.*]. Following surgery, and upon the instruction of Dr. Robbins, plaintiff performed rehabilitative exercises, and began to experience considerably less pain in his left hip than he had experienced before the surgery [*Id.*, ¶ 3].

In or about July 2008, plaintiff began to experience increased pain in his left hip, including popping sensations [*Id.*, ¶ 4]. Plaintiff reported his symptoms to Dr. Robbins on or about August 8, 2008 [*Id.*]. X-rays taken at that time showed that all of the components of the prosthesis were in their proper position [*Id.*]. These x-rays failed to show evidence of fracture, dislocation, or hardware loosening [*Id.*]. On or about September 19, 2008, plaintiff received a triphasic bone scan of his left hip; this scan also failed to show evidence of loosening or infection [*Id.*].

Plaintiff nevertheless continued to experience increasing pain in his left hip [*Id.*, ¶ 5]. On or about September 9, 2009, Dr. Robbins advised plaintiff that x-rays taken of his left hip revealed a failure of the prosthesis–specifically, circumferential radiolucency around the acetabular component, which was indicative of acetabular loosening [*Id.*]. Plaintiff alleges that loosening of the acetabular cup is caused by residues that remain on the cup following

manufacture and packaging, and which prevent bony ingrowth into the acetabular shell [*Id.*, ¶ 6]. Dr. Robbins recommended that plaintiff undergo revision surgery to correct the failure of the prosthesis, which Dr. Robbins attributes to the loosening of the Trident PSL acetabular shell [*Id.*, ¶ 5]. Plaintiff anticipates undergoing this surgery in the near future [*Id.*].

On the basis of these allegations, plaintiff brings state law claims against defendants under three theories of liability: strict liability, negligence, and breach of warranty [Doc. 4]. On March 8, 2010, defendants filed a motion to dismiss for failure to state a claim upon which relief can be granted [Doc. 8]. Defendants filed a supplement to the motion to dismiss [Doc. 11] on March 25, 2010. Plaintiff filed a response in opposition to the motion to dismiss [Doc. 12] on March 29, 2010. Defendants filed a reply to the response [Doc. 13] on April 5, 2010.

The Court has carefully considered the motion to dismiss, the supplement, the response, and the reply in light of the applicable law. For the reasons that follow, the motion to dismiss will be denied.

II. Standard of Review

Federal Rule of Civil Procedure 8(a)(2) sets out a liberal pleading standard. *Smith v. City of Salem*, 378 F.3d 566, 576 n.1 (6th Cir. 2004). Rule 8(a)(2) requires only "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the [opposing party] fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Detailed factual allegations are not required, but a party's

"obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions." *Twombly*, 550 U.S. at 555. A formulaic recitation of the elements of a cause of action will not do. *Id.* Nor will an "unadorned, the-defendant-unlawfully harmed-me accusation." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). A pleading must instead "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). "Determining whether a complaint states a plausible claim for relief will [ultimately] . . . be a context-specific task that requires th[is Court] to draw on its judicial experience and common sense." *Iqbal*, 129 S. Ct. at 1937.

III. Analysis

As noted, defendants argue that plaintiff's amended complaint should be dismissed for failure to state a claim upon which relief can be granted. Defendants contend that the Medical Device Amendments of 1976 (the "MDA") preempt plaintiff's state law claims [Doc. 9]. Plaintiff argues that the MDA does not preempt his state law claims [Doc. 12-1]. The Court considers the preemption question below.[1]

The Court first provides some necessary background on the law at issue in this case. In the period before Congress enacted the MDA, the "introduction of new medical devices was left largely for the States to supervise as they saw fit." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). "The regulatory landscape changed in the 1960s and 1970s," however, "as complex devices proliferated and some failed." *Id.* In the mid-1970s, "Congress stepped

[1] The Court notes that plaintiff brings only state law claims in this case.

in with passage of the [MDA], which swept back some state obligations and imposed a regime of detailed federal oversight." *Id.*

The MDA regime groups medical devices into one of three "classes," according to the risks these devices present. *Id.* at 315-16. Class I devices, like elastic bandages and examination gloves, pose little to no risk of injury, and are subject only to "general controls" applicable to all devices. 21 U.S.C. § 360c(a)(1)(A). Class II devices, like wheelchairs and surgical drapes, pose greater risks; manufacturers of this class of device must comply with federal performance regulations known as "special controls." *Id.* § 360c(a)(1)(B). Class III devices, like replacement heart valves, "receiv[e] the most federal oversight" because they are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or because they "present[] a potential unreasonable risk of illness or injury." *Riegel*, 552 U.S. at 317 (quoting 21 U.S.C. § 306c(a)(1)(c)(ii)).

Class III devices must undergo clinical trials and be approved by the FDA before they can be sold on the market. *Riegel*, 552 U.S. at 317. A small percentage of Class III devices is subject to a rigorous testing and approval process known as the premarket approval, or "PMA," process. *Id.* For a device to obtain approval through the PMA process, the FDA must find that there is a "'reasonable assurance' of the device's 'safety and effectiveness'" after "weig[hing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* at 318 (quoting 21 U.S.C. §§ 360c(a)(2)(C), e(d)). Most Class III devices are approved not through the PMA process, but

instead through a less rigorous process known as the § 510(k) premarket notification process. *Riegel*, 552 U.S. at 317.[2]

FDA approval for a device through the PMA process in turn triggers the MDA's preemption clause, which provides that:

> [N]o 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 . . . .

21 U.S.C. § 360k(a). In 2008, the Supreme Court construed this provision as generally preempting state common law claims challenging the safety and effectiveness of a Class III medical device approved pursuant to the PMA process. *Riegel*, 552 U.S. at 315, 322. No such preemption exists for Class III devices approved pursuant to the § 510(k) process. *Id.*

In *Riegel*, the Supreme Court laid out a two-step approach for determining whether a state common law claim challenges the safety and effectiveness of a Class III medical device approved pursuant to the PMA process, and is thus preempted. A court considering this question must first consider whether the federal government has established requirements applicable to the medical device at issue. *Id.* at 321. If so, the court must then determine whether a plaintiff's claim is "based upon [state] requirements with respect to the device that are 'different from, or in addition to' to the federal [requirements], and that relate to safety

[2] In 2005, for example, the FDA approved 3,148 devices through the § 510(k) process, but only 32 devices through the PMA process. *Riegel*, 552 U.S. at 317.

and effectiveness." *Id.* (quoting 21 U.S.C. § 360k(a)). The Court considers each step of this approach below.

A. Whether the Federal Government Has Established Requirements Applicable to the Medical Device at Issue

The Court first considers whether the federal government has established requirements applicable to the medical device at issue in this case. Here, the parties do not dispute that the "Trident System" was approved pursuant to the PMA process [*see* Docs. 9, 12-1]. Plaintiff contends, however, that the "component that failed, and which [p]laintiff alleges was defective, [is] the Trident acetabular cup" [Doc. 12-1]. Plaintiff argues that the acetabular cup "received approval through the § 510(k) process," rather than through the PMA process, but "was later approved for use with the components that received PMA approval" [*Id.*]. Plaintiff argues that the "mere coupling of a § 510(k) device with a PMA device [does not] somehow exempt[] the § 510(k) device from claims based upon state law" [*Id.*]. Plaintiff thus contends that the federal government has not established requirements applicable to the medical device at issue in this case [*Id.*].

Defendants disagree. Defendants argue that it is "undisputed" that the device plaintiff challenges in this case is the Trident System; that the Trident System includes the acetabular cup, of whose failure plaintiff complains; and that the Trident System, inclusive of its constituent parts, was approved through the PMA process [Doc. 9]. Defendants thus contend that the federal government has established requirements applicable to the medical device at issue in this case [*Id.*].

The Court agrees with defendants. In support of their motion to dismiss, defendants have provided FDA documentation demonstrating conclusively that the acetabular cup received FDA approval under the PMA process.[3] The FDA's publicly-available description of the Trident System identifies the "cup-shaped part of the [artificial] joint, called the acetabular cup" that is implanted into the patient's bone as part of the Trident System [Doc. 9-3]. This documentation further explains that a "battery of tests was completed to qualify the mechanical performance of the components of the . . . Trident System[]" [Doc. 9-4]. These tests included "fatigue testing of the acetabular cup system" and "fretting fatigue and corrosion testing of the Trident acetabular cup system" [*Id.*]. After performing these tests, the FDA found that it was "reasonable to conclude that the benefits of the use of the . . . Trident System . . . outweigh the risk of injury when used in accordance with the directions for use" [*Id.*]. The Court thus finds–as have a number of other courts that have considered the issue–that the federal government has established requirements applicable to the medical device at issue in this case. *See, e.g.*, *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 530-31 (S.D. Tex. 2009); *Lewkut v. Stryker Corp.*, No. 09-cv-3695, 2010 WL 1544275, at *5 (S.D.

[3] The Court notes and rejects plaintiff's argument that the Court must treat defendants' motion to dismiss as one for summary judgment if it considers as part of its analysis the FDA documentation defendants have provided [*see* Doc. 12-1]. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) ("[C]ourts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice."); *see also Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008) ("[T]he Court may take judicial notice of and consider the public record of the FDA . . . without transforming [a] motion [to dismiss] into a motion for summary judgment.").

Tex. Apr. 16, 2010); *Lemelle v. Stryker Orthopaedics*, Civ. Action No. 09–0987, 2010 WL 996523, at *7 (W.D. La. Mar. 15, 2010).[4]

The Court now turns to the second step in the analysis.

B. Whether Plaintiff's Claims are Based upon State Requirements with Respect to the Device that are Different from, or in Addition to, the Federal Requirements, and that Relate to Safety and Effectiveness

The Court next considers whether plaintiff's claims are based upon state requirements with respect to the device that are different from, or in addition to, the federal requirements, and that relate to safety and effectiveness. As noted, "State requirements are pre-empted under the MDA . . . to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting § 360k(a)(1)). Critically, however, "§ 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." *Riegel*, 552 U.S. at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

Prior to undertaking the second step in this analysis, the Court notes defendants' argument that plaintiff's claims are preempted under a separate strain of preemption: that set forth in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). *Buckman* addressed whether state tort law claims premised solely upon violations of the Federal Food, Drug, and

[4] The Court notes the serious practical difficulties associated with plaintiff's divisibility argument, even were the Court inclined to accept it. *See Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009) ("It makes no sense–indeed, it would probably be impossible–to pick apart the components of a medical device and apply different preemption analyses to different components.").

Cosmetic Act (the "FDCA"), as modified by the MDA, were preempted by the FDCA and the MDA. *Buckman*, 531 U.S. at 343-44. The Court in *Buckman* explained in a footnote that the "FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349 n.4; *see also* 21 U.S.C. § 337(a) ("All such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Finding that requiring applicants seeking FDA approval to "comply[] with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes" "would exert an extraneous pull on the scheme established by Congress," the Supreme Court held that the FDCA and the MDA impliedly preempted such state law claims. *Buckman*, 531 U.S. at 350, 353.

This Court notes the difficulty that lower courts, in the wake of the *Riegel* decision, have had in determining whether a particular plaintiff's state law claims survive express preemption under *Riegel* but not implied preemption under *Buckman*. Some district courts construing *Buckman* and *Riegel* have found these claims to be preempted, and dismissed them. *See, e.g., In re Medtronic, Inc.*, 592 F. Supp. 2d 1147, 1166 (D. Minn. 2009) ("[P]laintiffs' claims are predicated on a defect in the method of manufacture approved by the FDA when it granted the [device at issue] PMA . . . [S]uch claims are by their very nature preempted under Section 360k(a)."). Other courts have found similar claims not to be preempted, and denied motions to dismiss. *See, e.g., Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 832-33 (S.D. Ind. 2009) ("[T]he court . . . holds that plaintiff . . . may

pursue civil claims against [a replacement hip joint manufacturer] based on theories that [the manufacturer] failed to comply with federal requirements for manufacturing the replacement hip joint implanted in him.").

The Court further observes that lower court attempts to reconcile the language in *Buckman* with that in *Riegel* has spawned various frameworks for analyzing claims like those plaintiff brings in this case. *See, e.g., Riley*, 625 F. Supp. 2d at 777 ("*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA . . . but the plaintiff must not be suing *because* the conduct violates the FDCA . . . ."). This Court, however, notes that the Supreme Court's last word on the subject is that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Riegel*, 552 U.S. at 330. The Court thus analyzes this case under that holding.

Plaintiff in this case premises his state law claims on violations of 21 C.F.R. § 820.20(a) for defendants' alleged "fail[ure] to ensure the quality policy is understood, implemented and maintained at all levels of the organization";[5] on violations of 21 C.F.R. § 820.20(b)(2) for defendants' alleged "fail[ure] to provide adequate resources, including trained personnel, for management, performance of work and assessment activities, including

[5] 21 C.F.R. § 820.20(a) provides that "[m]anagement with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization."

internal quality audits . . .";[6] and on violations of 21 C.F.R. § 820.70(e) for defendants' alleged "fail[ure] to establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be anticipated to have an adverse effect on product quality" [*see* Doc. 4].[7] He links his state law claims to violations of these federal regulations by alleging, for example, that the "Trident acetabular cup contained a manufacturing defect in that it was adulterated as a result of being manufactured in violation of FDA regulations and requirements . . . such that manufacturing residuals remained on the prosthesis after its manufacture" which "proximately caused [p]laintiff's acetabular cup to become loose necessitating revision surgery" [Doc. 4].

Plaintiff, in other words, alleges that defendants failed to comply with FDA regulations in manufacturing the Trident System. Plaintiff advances several theories of state common law liability to link those compliance failures to the ultimate failure of the device implanted in his hip. These state law claims, which "parallel" federal requirements, thus survive preemption under the second step of the *Riegel* analysis. They also contain sufficient factual matter, accepted as true, to state a plausible claim for relief under *Iqbal*. *See Hofts*, 597 F. Supp. 2d at 840-41 (allegations that "the manufacturing process for the Trident [System] and certain of its components did not satisfy the FDA's PMA standards for the

[6] 21 C.F.R. § 820.20(b)(2) provides that "[e]ach manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part."

[7] 21 C.F.R. § 820.70(e) provides that "[e]ach manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality."

device[]" and thus "resulted in unreasonably dangerous manufacturing defects" satisfied pleading requirements for negligence claim). The Court thus finds plaintiff's claims not to be preempted. The Court will deny defendants' motion to dismiss accordingly.

IV. Conclusion

For the reasons above, the Motion to Dismiss [Doc. 8] is **DENIED**.

IT IS SO ORDERED.

s/ Thomas A. Varlan
UNITED STATES DISTRICT JUDGE