UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

PAUL ANTHONY, Plaintiff, v. STRYKER CORPORATION, et al., Defendants.	)	Case No. 1:09-cv-2343 JUDGE ANN ALDRICH MEMORANDUM OPINION AND ORDER

Before this court is the defendants' motion to dismiss this case pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. For the following reasons, this court grants the motion and dismisses the complaint with prejudice.

I. BACKGROUND

On September 21, 2009, plaintiff Paul Anthony ("Anthony") filed a complaint in the Cuyahoga County Court of Common Pleas against defendants Stryker Corporation, Howmedica Osteonics Corporation, and Stryker Orthopaedics (collectively, "Stryker"). Anthony claims that, on October 10, 2006, he underwent a total hip replacement utilizing the Trident Ceramic Acetabular hip prosthesis (the "Trident System"). Anthony claims that Stryker designed, tested, manufactured, and distributed the Trident System. On September 11, 2007, Anthony underwent surgery to have the Trident System removed because it caused him pain and disability. Nonetheless, Anthony alleges that the Trident System caused him permanent injuries. He claims that the Trident System was "defective in manufacture or construction in that . . . it deviated in a material way from its manufacturing performance standards and/or it differed from otherwise identical units manufactured to the same design formula." Anthony also alleges that the Trident System is "defective," is "dangerous," creates a "risk of harm to consumers," is not "safe," and is "unfit for use in the body."

On October 9, 2009, Stryker removed the case to this court. On October 26, 2009, Stryker filed a motion to dismiss the case pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Stryker claims that all of Anthony's claims are preempted by the Medical Device Amendments (the "MDA") of 1976 to the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.* Stryker also claims that Anthony's common law claims are abrogated by the Ohio Products Liability Act, Ohio Rev. Code § 2307.71(A)(1).

II. STANDARD

A defendant may move to dismiss a claim pursuant to Rule 12(b)(6) "for failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). Rule 8(a)(2) of the Federal Rules of Civil Procedure requires that a pleading contain a "short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). To survive a motion to dismiss, a complaint need not contain "detailed factual allegations," but it must contain more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "Factual allegations must be enough to raise a right to relief above the speculative level," *Twombly*, 550 U.S. at 545, and must create "a reasonable expectation that discovery will reveal evidence of illegal [conduct]." *Id.* at 556. This "plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 1949. "Where a complaint pleads facts that

are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* at 1949 (internal quotations omitted).

In deciding a motion to dismiss, a court must accept the factual allegations in the complaint as true. *Id.* A court must not, however, accept legal conclusions as true. *Id*. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555).

III. DISCUSSION

With the passage of the MDA, Congress established a detailed federal regime for the regulation of medical devices. 21 U.S.C. § 360c. The MDA categorizes medical devices into one of three classes, depending on the risk they pose to the public. *Id.* Class I devices are subject to "general controls," the lowest level of federal oversight, and include devices such as elastic bandages and examination gloves. 21 U.S.C. § 360c(a)(1)(A), *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Class II devices are subject to additional oversight called "special controls." 21 U.S.C. § 360c(a)(1)(B). Class II devices include devises such as powered wheelchairs and surgical drapes. *Riegel*, 552 U.S. at 316. Finally, Class III devices are subject to the highest level of federal oversight, or "premarket approval." 21 U.S.C. § 360c(a)(1)(C). Receiving premarket approval is a rigorous process wherein the Food and Drug Administration reviews an application and determines whether there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e; *Riegel*, 552 U.S. at 317-20 (describing the premarket approval process). Class III devices include devices such as replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators. *Riegel*, 552 U.S. at 317. Once a device has received premarket approval, the manufacturer of that device cannot change the design, manufacturing process, labeling, or other characteristic in a manner that would affect the device's "effectiveness or safety" without first applying for, and receiving, supplemental premarket approval.

21 U.S.C. § 260e(d)(6)(A)(I). After receiving premarket approval, the devices are subject to ongoing reporting requirements. 21 U.S.C. § 360i.

The MDA also contains a preemption clause, with certain exceptions, that "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 *Riegel*, the Supreme Court interpreted the MDA's preemption clause. The court held that common law claims relating to medical devices are expressly preempted by the MDA when (1) the federal government has established requirements applicable to the medical device; (2) the common law claims are based upon state requirements that relate to the safety and effectiveness of the medical device; and (3) the state requirements are different from, or in addition to, the federal requirements. 552 U.S. at 321-22.

Here, the parties do not dispute that the Trident System is a Class III medical device that is subject to federal regulation under the MDA. Furthermore, Anthony's claims all relate to the safety and effectiveness of the Trident System. In his complaint, Anthony stated claims for (1) strict liability; (2) negligence; (3) breach of implied warranty; (4) breach of express warranty; and (5) misrepresentation. In making these claims, Anthony alleged that the Trident System was defective, dangerous, harmful, unsafe, and unfit for use in the body. These statements that all relate to the safety and effectiveness of the Trident System.

The contested issue in this case is whether Anthony's claims are different from, or in addition to, the federal requirements. The court in *Riegel* noted an important exception to the express preemption clause for "parallel" claims, stating that the MDA "does not [expressly] prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Id.* at 330. Such "parallel"

claims are not different from, or in addition to, the federal requirements and are not, therefore, preempted by the MDA.

Anthony argues that his claims are not preempted by the MDA because they are parallel claims. In his complaint, Anthony states that the Trident System was defective because "it deviated in a material way from its manufacturing performance standards." In his response in opposition to Stryker's motion to dismiss, Anthony argues that the complaint alleges Stryker's noncompliance with FDA regulations. In his response, Anthony also elaborates upon the allegations contained within his complaint by stating that the FDA sent Styker two warning letters informing it of its noncompliance with FDA regulations. Anthony claims that the FDA issued the first warning letter on March 15, 2007, following an inspection of a Stryker facility located in Ireland. The letter claimed that the inspection revealed that the Trident Systems produced in the Ireland facility were "adulterated" and that the methods and/or facilities used in producing these Trident Systems were not in conformity with the Current Good Manufacturing Practice requirements of the FDA. The letter cited several general violations, including, (1) "Failure to establish and maintain adequate procedures for implementing a corrective and preventative action, as required by 21 CFR 820.100(a),"(2) "Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, including the evaluation of nonconforming product, as required by 21 CFR 820.90(a)," (3) "Failure to establish and maintain adequate procedures to implement and record changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR 820.100(a)(5)," and (4) "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, as required by 21 CFR 820.90(b)(2)."

Anthony also claims that the FDA issued a second warning letter on November 28, 2007, following an inspection of a Stryker facility in New Jersey. This letter also claimed that the Trident

Systems produced in the New Jersey facility were "adulterated" and that the methods and/or facilities used in producing these Trident Systems were not in conformity with the Current Good Manufacturing Practice requirements of the FDA. The letter went on to allege specific violations, including, (1) "Failure to establish and maintain procedures for identifying all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems, and verifying or validating the corrective and preventive action to ensure that such action is effective as required by 21 CFR § 820.100(a)(3) & (a)(4)," (2) "Failure to establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met as required by 21 CFR § 820.75(b)," (3) "Failure to establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality as required by 21 CFR § 820.70(c)."

Although Anthony did allege Stryker's deviation from "manufacturing performance standards" in the complaint, Anthony did not specifically mention either the FDA or its regulations. Furthermore, Anthony also did not plead any facts that would lead this court to plausibly infer that Stryker's noncompliance with FDA regulations led to his injury. Anthony's attempt to recast generalized deviations from "manufacturing performance standards" as specific violations of federal regulations is insufficient to state a claim. *See Bausch v. Stryker Corp.*, No. 08 C 4248, 2008 WL 5157940, at * 6 (N.D. Ill. Dec. 9, 2008) (dismissing plaintiff's claims as implausible, despite the fact that "[i]n Bausch's briefs opposing the motions to dismiss, Bausch attempts to recast her negligence claims as ones premised under violations of federal regulations despite the fact that the language in her complaint clearly indicates that her claim is based on common law theories of negligence and are, thus[,] preempted under the MDA."); *see also Funk v. Stryker Corp.*, No. H:09-00733, 2009 WL 4281389 (S.D. Texas Dec. 1, 2009) (granting motion to dismiss because plaintiff did "not cite a single FDA

requirement violated by [the defendant] or any fact indicating the presence of impurities on the device.").

In his opposition to Stryker's motion to dismiss, Anthony did allege that Stryker had received two warning letters from the FDA, but several courts have held that the mere mention of the 2007 warning letters is an insufficient factual basis upon which to state a plausible claim. Like other plaintiffs whose cases have been dismissed, Anthony did not allege that his Trident System originated from either the Ireland or the New Jersey facility or that his injuries were caused by any act of noncompliance specified in the 2007 warning letters. *See Horowitz v. Stryker Corp.*, 613 F. Supp.2d 271, 283 (2009) (granting motion to dismiss because "Plaintiff has failed to demonstrate that the injuries she sustained resulted form the federal violations spelled out in the warning letters."); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at * 15 (M.D.N.C. Aug. 5, 2009) (granting motion to dismiss because the plaintiff did "not allege that the Trident Ceramic System, which was implanted in him in 2005, was manufactured in either [the Ireland or New Jersey] facility, or that it was ever the subject of any FDA action or recall, or that it has ever been found by the FDA to be in violation of any particular regulation, or even that there is an independent reason to believe that *his particular system* violated a federal regulation in any way."). Without more detailed factual allegations, Anthony's complaint does not cross the critical threshold that distinguishes the speculative from the plausible.

Anthony urges this court to follow the analysis found in *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp.2d 830 (S.D. Ind. 2009). This court, however, declines to follow the *Hofts* analysis. As other courts have found, the cases relied upon in this court's opinion "are found to be more persuasive [than the *Hofts* analysis] with regard to the pleading standards of *Twombly*." *Covert*, 2009 WL 2424559, at *13.

Accordingly, this court finds that all of Anthony's claims are preempted by the MDA and grants Stryker's motions to dismiss Anthony's complaint with prejudice.

IT IS SO ORDERED.

/s/ *Ann Aldrich*
ANN ALDRICH
UNITED STATES DISTRICT JUDGE

Dated: March 18, 2010