UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
NORTHERN DIVISION
ASHLAND

Civil Action No. 13-18-HRW

GARNET ELIZABETH KITCHEN, **PLAINTIFF,**

v.

BIOMET, INC., *et al.,* **DEFENDANTS.**

MEMORANDUM OPINION AND ORDER

This matter is before the Court upon the Defendants' Motion to Dismiss Plaintiff's Amended Complaint [Docket No. 24]. The motion has been fully briefed by the parties [Docket Nos. 25 and 26]. For the reasons stated herein, the Court finds that Plaintiff has not stated a claim upon which relief can be granted and, thus, dismissal is warranted.

I. FACTUAL AND PROCEDURAL BACKGROUND

The relevant factual allegations are as follows:

> On October 25, 2010, Ms. Kitchen underwent an Oxford medial compartment replacement of the left knee at King's Daughters Medical Center in Ashland, Kentucky. Ms. Kitchen's implant consisted of a Biomet Oxford knee size small femur, size A tibial component and size 8 poly component. On February 9, 2012, Ms. Kitchen was sitting in a chair at work when she twisted her knee slightly, felt a pop, and experienced severe pain. She was taken to the emergency room of King's Daughters Medical Center in Ashland, Kentucky, where she was discovered to have a failure of the left knee implant with acute dislocation of the poly component and a partial tear of the MCL. On February 9, 2012, Ms. Kitchen underwent a total knee revision of the left knee at King's Daughters Medical Center in Ashland, Kentucky.

[Amended Complaint, Docket No. 23, ¶¶ 10-14].

Plaintiff claims:

> As a result of the failure of her Oxford partial knee implant, Ms. Kitchen experienced great pain and suffering and emotional distress, underwent replacement surgery, incurred expenses for medical care and treatment including physical therapy, missed work.

Id. at ¶ 15.

In her Complaint, Plaintiff asserted negligence, strict liability and breach of warranty claims. She contends that the Partial Knee System suffered from defects that caused her pain and ultimately required her to have the device removed. [Docket No. 1, Complaint, ¶¶12-15]. She claims that the Partial Knee System is "defective and unreasonably dangerous" because it (I) failed prematurely, (ii) failed with acute dislocation of poly component; and (iii) the component parts failed to remain properly aligned, affixed to each other, and/or affixed to Plaintiff's body. *Id.* at ¶¶ 17-18. She further alleges that Biomet "designed, manufactured, assembled, tested, inspected, provided with warnings and instructions, marketed, and distributed" the Partial Knee System "in an unreasonably dangerous and inherently defective condition" and "expressly and impliedly warranted" that the Partial Knee System was "of merchantable quality" and fit for its "usual and intended purpose." *Id.* at ¶¶ 20, 24)

Defendants sought dismissal of Plaintiff's Complaint, arguing that her claims were preempted by federal law [Docket No. 12]. In response to Defendants' motion, Plaintiff sought leave to file an Amended Complaint [Docket No. 19]. The parties agreed to permit the filing of the Amended Complaint [Docket No. 22] and it was entered on September 26, 2013 [Docket No. 23].

The Amended Complaint asserts no new factual allegations or causes of action. Indeed, the Amended Complaint is virtually identical to the original Complaint with the addition of three allegations:

> 18. The Oxford partial knee implant was defective in one or more of the following respects:
>
> ...
>
> (f) failure to comply with Quality System Regulations and Current Manufacturing Practices required by the FDA in 21 C.F.R. § 820.72 to 820.90. Among other things, these regulations require manufacturers to put in place suitable processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control non-conforming products;
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> 19. Because of these effects, the knee implant failed to comply and operate within the terms of its Pre-Market Approval from The Food and Drug Administration.
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> ...
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> 29. In the approval letter dated April 21, 2004 for the FDA Center for Devices and Radiological Health to Biomet, Inc., the FDA specifically states that: "CDRH doesnot evaluate information related to contract liability warranties, however, you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws".

[Docket No. 23, ¶¶ 18(f), 19 and 29].

Defendants again seek dismissal of all claims alleged herein, arguing that they are preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Acts, 21 U.S.C. §360k(a) ("MDA").

II. STANDARD OF REVIEW

Chief Judge Heyburn's opinion in *White v. Stryker* 818 F.Supp. 2d 1032 (W.D. Ky. 2011) is instructive in this case. With regard to this Court's standard of review of Defendants' motion, he wrote:

> To survive a motion to dismiss, a plaintiff "must plead 'enough factual matter' that, when taken as true, 'state[s] a claim to relief that is plausible on its face.' " *Fabian v. Fulmer Helmets, Inc.*, 628 F.3d 278, 280 (6th Cir.2010) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)).
>
> "Plausibility requires showing more than the 'sheer possibility' of relief but less than a 'probab[le]' entitlement to relief." *Id. (quoting Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009)).

White v. Stryker, 818 F.Supp.2d 1032, 1037 (W.D.Ky. 20111).

With regard to the standard of review in the context of MDA preemption, Judge Heyburn wrote:

> *Twombly* and *Iqbal* make a plaintiff's job more difficult than it would be in a typical product 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. However, our appellate courts have been unable to agree upon the precise level of that specificity. Nonetheless, in this Court's view, a plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955.

Id.

III. ANALYSIS

The MDA provides, in pertinent part:

> ... [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 ... which is different from, or in addition to, any requirement applicable under this chapter to the device, and ... which relates to the safety or effectiveness of the device or to any other matter included in the requirement applicable to the device under this chapter.

21 U.S.C. §360k(a).

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008), the Supreme Court established a two-part test to determine whether § 360k preempts a state common law claim. First, the Court "must determine whether the Federal Government has established requirements applicable to the" medical device at issue. *Id.* at 321, 128 S.Ct. 999. "If so, [the Court] must then determine whether the [plaintiffs'] common-law claims are based upon [state law] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* at 321–22, 128 S.Ct. 999 (*quoting* 21 U.S.C. § 360k(a)).

Writing for the majority, Justice Scalia explained that to preempt state law, the federal law violations must be somewhat specific to a particular medical device. For example, and germane to this case, the Supreme Court determined that premarket approval "imposes [federal] 'requirements' under the MDA," *Id.* at 322, 128 S.Ct. 999, because "devices that receive FDA premarket approval must be manufactured with 'almost no deviations from the specifications' in the approval application.... [A]ny changes to a device's design specifications, manufacturing process, labeling, or other attribute that would affect safety require FDA approval." *Cooley v.*

Medtronic, Inc., 2012 WL 1380265, at *3 (E.D.Ky. Apr. 20, 2012).

As for the state law analysis, Justice Scalia commented on each of the three elements that comprise the second step of the *Riegel* test, which are: (1) the existence of state law requirements applicable to the device, (2) that are different from or in addition to federal requirements, and (3) that relate to safety and effectiveness. Justice Scalia determined that plaintiffs' state law claims invariably deal with safety and effectiveness. *Riegel*, 552 U.S. at 323, 128 S.Ct. 999. Therefore, "the first critical issue is whether [the state's] tort duties constitute 'requirements' under the MDA." *Id.* He concluded that the plaintiffs' "common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be preempted by federal requirements specific to a medical device." *Id.* at 323–24, 128 S.Ct. 999.

Therefore, following *Riegel,* there are two inquiries for this Court's MDA preemption determination: (1) is the product at issue subject to federal requirements? (2) If so, would Plaintiff's state law claims impose requirements that are different from or in addition to federal requirements? If the answers to both inquiries is yes, the claims are preempted.

The FDA granted premarket approval for the Partial Knee System on April 21, 2004 [FDA's April 21, 2004 Letter, Docket No. 12-3]. That letter approved the "Oxford Meniscal Unicompartmental Knee System," which is the former name that Biomet used to market the Partial Knee System. On April 16, 2008, Biomet sent the FDA a letter indicating that it "is now marketing the [Oxford Meniscal Unicompartmental Knee System] under the name Oxford Partial Knee." [Docket No. 12-4]. The FDA acknowledged the name change and thereafter referred to the device as the Oxford Partial Knee System. [Docket No. 12-5]. the Partial Knee System falls squarely within the FDA's premarket approval of the device in 2004,

and at the time the Partial Knee System was implanted into Ms. Kitchen on October 25, 2010, the device had been approved by – and subject to the oversight of – the FDA for over six years.

As for the examination of Plaintiff's state law claims, Defendants argue that they do, in fact, impose additional requirements and are, thus, preempted. Given the copious case law in this regard, this Court in inclined to agree. *See, e.g., Rankin v. Boston Scientific Corp.*, No. 09-177-KSF, 2010 WL 672135, at *1, 3 (E.D. Ky. Feb. 19, 2010) (Forester, J.) (finding "common law tort claims of negligent design and negligent manufacture" preempted); *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997) (strict liability design defect claim based upon allegation that product was unreasonably and dangerously defective was preempted); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236-37 (6th Cir. 2000) ("[t]o allow a state cause of action for inadequate warnings would impose different requirements or requirements in addition to those required by federal regulations").

Moreover, rather than refute Defendants' argument, Plaintiff, instead, insists that her claims fall within the very narrow gap in preemption law, to-wit, the "parallel claim." The MDA does not preempt state claims premised upon a violation of FDA regulations. These claims are regarded as asserting state duties which are "parallel" to federal requirements, rather than additional to them. *See generally, Reigel*, 552 U.S. at 330, 128 S.Ct. at 999. Therefore, claims alleging a manufacturer failed to adhere to the specifications imposed by the FDA's premarket approval can survive preemption. Plaintiff's response to Defendants' dispositive motion is devoted to urging that her claims are "parallel claims", plead beyond the grasp of preemption.

However, in order to adequately plead a parallel claim, Plaintiff must allege the violation of a specific federal standard and allege how the device violated the regulation. *White*, 818

F.Supp. 2d at 1039. Plaintiff's Amended Complaint does not. Her specific allegations in this regard are:

> 18. The Oxford partial knee implant was defective in one or more of the following respects:
> ...
>
> (f) failure to comply with Quality System Regulations and Current Manufacturing Practices required by the FDA in 21 C.F.R. § 820.72 to 820.90. Among other things, these regulations require manufacturers to put in place suitable processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control non-conforming products;
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> 19. Because of these effects, the knee implant failed to comply and operate within the terms of its Pre-Market Approval from The Food and Drug Administration.

[Docket No. 23].

Plaintiff refers to a broad category of federal regulations and fails to allege how the device violated those regulations or how that deviation caused her injuries. This lack of specificity is fatal to her claim.

Judge Heyburn found a nearly identical allegation insufficient in *White v. Stryker*. In *White,* the plaintiff underwent a total hip arthroplasty in which a medical device known as the Trident System was implanted. More than five years after the surgery, the plaintiff had a second surgery during which the physician allegedly discovered that certain components of the Trident system had "failed." The plaintiff alleged that "defendants failed to manufacture [the Trident System] according to FDA approved standards and procedures for medical devices." *White*, 818 F.Supp.2d at 1033. The court found that the complaint did not contain sufficient specificity to

meet the requirements of *Iqbal* and *Twombly.* The court noted that the "Amended Complaint neither cites any particular federal standard or procedure, nor does it generally state how the alleged defect deviated from the federal standard or procedure." *Id.* Therefore, Judge Heyburn dismissed the Amended Complaint as insufficient to state a plausible claim for relief, noting that

> Plaintiff has not alleged any specific manufacturing failure, has not alleged the violation of any specific federal standard, including GMPs, and has already amended his complaint once in response to the motion to dismiss ... It does not identify any particular design flaw, manufacturing impropriety or product defect. It does not assert either a PMA-specific standard or a GMP regulation, the violation of which might form the basis for a state law action.

Id. at 1039.

Judge Heyburn's subsequent opinion in *Steiden v. Genzyme Biosurgery*, 2012 WL 2923225 (W.D. Ky. 2012) further reinforces the standards for pleading a parallel claim. In *Steiden*, Judge Heyburn reached the opposite result - finding that Plaintiff's proposed Amended Complaint sufficiently stated a parallel claim. Plaintiff William Steiden suffered from bilateral degenerative arthritis in his knees. He was treated by an orthopedic surgeon on July 22, 2010 for this condition. 2012 WL 2923225, *1 (W.D. Ky. 2012) The original complaint alleged that Genzyme's product, Synvisc–One, was injected into Steiden's knees and that he immediately suffered an adverse reaction in the right knee. Steiden allegedly suffered serious injury as a result of this occurrence. Genzyme argued that the claims alleged were preempted by federal law. *Id.* Steiden did not dispute that the product liability claim which forms the basis of his original complaint is preempted by the MDA. Instead, he sought leave to file an Amended Complaint purportedly alleging a parallel claim. The Amended Complaint would add the following

allegations:

> (1) Genzyme failed to comply with the FDA's premarket approval requirements in the continued manufacture, distribution and sale of Synvisc–One;
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> (2) Genzyme manufactured, held, sold, and delivered an adulterated dose of Synvisc–One;
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> (3) Genzyme did not meet the FDA's Current Good Manufacturing Practices ("CGMPs") in the manufacture, distribution and sale of Synvisc–One; and
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> (4) Genzyme violated KRS 217.175 by manufacturing, holding, selling and delivering an adulterated dose of Synvisc–One, the violation of which constitutes negligence *per se.*

Id. at *2.

Judge Heyburn found that the proposed Amended Complaint contained sufficient facts to support a plausible claim for relief which is not preempted by the MDA. He wrote, "the allegation of adulteration based on the occurrence of an immediate adverse reaction in one knee to the injection of Synvisc–One contains sufficient specificity to satisfy *Iqbal* and *Twombly.*" Judge Heyburn distinguished White by noting, "[i]n *White,* the plaintiff did not allege any specific manufacturing failure or violation of any federal standard. He alleged general claims of product liability, negligence and warranty. By contrast, Steiden has alleged that the means by which he was injured was the injection into his knee of an adulterated dose of Synvisc–One. He claims that CGMPs, the PMA and state law were violated thereby." *Id.* at *5.

In this case, as in *White* and in contrast to *Steiden,* Plaintiff fails to identify the federal regulation violated by Defendants, how the product deviated from the FDA approved process and how such deviation caused her injury. Simply incanting that a manufacturer violated federal

regulations does not pass *Iqbal/ Twombly* muster.

In a seemingly last ditch effort to resuscitate her case, Plaintiff maintains that her breach of warranty claims are not preempted because "the obligations imposed on the defendant arises from its own representations rather than state law." [Docket No. 25, p. 8]. Yet, the overwhelming majority of courts that have addressed this issue have held that such warranty claims are preempted by the MDA. In Kentucky, a seller of goods must conform its product to any "affirmations of fact or promise" or to any "description" made to the buyer. *See* KRS § 355.2-313(1).

Plaintiff alleges that Defendants breached an express warranty that the Partial Knee System was "of merchantable quality and further warranted the safety and fitness of those implants for their usual and intended purposes." [Amended Complaint, Docket. No. 23, ¶26]. Again, this Court finds an opinion from The Western District to be instructive. *Enlow v. St. Jude Med. Ct.*, 210 F. Supp.2d 853 (W.D. Ky. 2001). In *Enlow*, Judge Simpson held that "express representations" relating to a device are "limited to the labeling approved by the FDA." *Id.* at 861. Whether the claims "arise from the representations of the parties" matters not -- such an argument "minimizes the comprehensive FDA regulation of medical device labeling." *Id.* at 861-62. "The representations that can, cannot, and must be made about a [device] are all determined by the FDA." *Id.* (quoting *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1101 (6th Cir. 1997)). In other words, the representations a manufacturer may make with respect to a PMA device are limited to those approved by the FDA, and express warranty claims are therefore preempted. Plaintiff's suggestion that this Court's analysis somehow changes because the FDA stated in its approval letter that the FDA does not

evaluate information related to contract liability warranties is misguided. As Judge Thapar explained in *Cooley,* "[t]he MDA preempts … causes of action [alleging breach of implied and express warranties] because a jury would have to find that the devices were 'not safe and effective, a finding that would be contrary to the FDA's approval.'" 2012 WL 1380265, at *3 (quoting *Bryant v. Medtronic*, Inc., 623 F.3d 1200, 1208 (8th Cir. 2010)). Here, Plaintiff asks a jury to find that the Partial Knee System was "defective and unreasonably dangerous … unmerchantable, unfit for its ordinary and intended purpose" and as a result, Defendants "breached their express and implied warranties." (Doc. No. 23 at ¶28). "That claim is undoubtedly 'contrary to the FDA's approval' and therefore, preempted." *Cooley*, 2012 WL 1380265 at *3.

As for Plaintiff's breach of implied warranty claim, it, too, is preempted. The *Enlow* court aptly summarized as follows:

> An implied warranty claim is based on the accepted standards of design and manufacture of the products. In the case of a product that has gone through the PMA process, these criteria are set by the FDA. A state judgment for breach of implied warranty that rested on allegations about standards other than those permitted by the FDA would necessarily interfere with the PMA process and, indeed, supplant it. Accordingly, such a claim is preempted.

Enlow 210 F.Supp.2d at 862 (quoting *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997)).

IV. CONCLUSION

Case law makes clear that a jury is not permitted to second guess the FDA with respect to PMA devices. Plaintiff's claims fall squarely within the precedent holding that her state law claims are preempted, and she has not adequately pled a parallel claim.

Accordingly, **IT IS HEREBY ORDERED** that Defendants' Motion to Dismiss Plaintiff's Amended Complaint [Docket No. 24] be **SUSTAINED** and this matter be **DISMISSED WITH PREJUDICE**.

This 21st day of February, 2014.

Signed By:
Henry R. Wilhoit, Jr.
United States District Judge