UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

SARAH JAMES and GERRAD JAMES,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 1:10-cv-0527-TWP-TAB
	)	
DIVA INTERNATIONAL, INC.,	)	
	)	
Defendant.	)	

ORDER ON DEFENDANT'S MOTION TO DISMISS

This matter comes before the Court on Diva International Inc.'s ("Diva" or "Defendant"), Motion to Dismiss [Dkt. 15]. Plaintiff, Sarah James ("James" or "Plaintiff") and her husband Gerrad James (collectively, "Plaintiffs") filed suit in this Court alleging that a menstrual product manufactured by Defendant caused James to develop Toxic Shock Syndrome. Plaintiffs have alleged negligence and violations of two state statutes, Ind. Code §§ 34-20-4-1 and -2, for failure to warn and sale of a defective product. Diva filed the instant Motion to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), based upon failure to state a claim with specificity, and federal preemption as required by the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360c, *et seq*. For the reasons set forth below, Defendant's Motion to Dismiss [Dkt. 15] is **DENIED** in part and **GRANTED** in part.

I. BACKGROUND

For the following factual background, the Court accepts Plaintiff's well-pleaded allegations as true and draws all favorable inferences for Plaintiffs. *See Killingsworth v. HSBC Bank*, 507 F.3d 614, 618 (7th Cir. 2007). With this standard in mind, the Court will recite the pertinent facts of the case.

A. Factual Background

Diva is the manufacturer and upstream distributor of the DivaCup Menstrual Solution™ ("DivaCup®") model 1, which is the subject of this action. The DivaCup® is an alternative to traditional tampons and pads. The DivaCup® is manufactured in Ontario, Canada and sold in this instance, in Indiana. On or about March 26, 2008, James purchased and used the DivaCup® in accordance with its intended use and allegedly sustained injuries from Toxic Shock Syndrome. Through Plaintiffs' Amended Complaint ("Amended Complaint"), it is alleged that: (1) Diva failed to properly package or label the DivaCup® to give reasonable warnings of danger to James about the product even though Diva, by exercising reasonable diligence, could have made such warning available to James; and (2) at the time of purchase, the product was in a defective condition. [Dkt. 23 at 3]. The Amended Complaint alleges claims for "Negligence," "Product Liability; Strict Liability in Tort," and "Loss of Consortium" stemming from James' subsequent hospitalization after her use of the DivaCup®.

B. Medical Device Amendments to the Food, Drug and Cosmetic Act

As a medical device, the DivaCup® is governed in the United States by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360c, *et seq.* This means that the DivaCup® is subject to regulations and requirements as set out by the Food and Drug Administration ("FDA"). In 1976 Congress enacted the MDA as a system of regulation for all medical devices in which the FDA classifies each medical device intended for human use. 21 U.S.C. § 360c(a)(1). The three classifications the FDA utilizes establish an ascending order of control and oversight. *Dow v. Baxter Healthcare Corp.*, 899 F. Supp. 822, 824 (D. Mass. 1995).

Class I consists of devices which require only general control. *Id*. Class II includes devices which require compliance with both general controls and applicable performance standards promulgated by the FDA. *Id*. The FDA has classified the DivaCup® as a Class II medical device. *Id*. The performance standards of Class II devices include annual registration, labeling requirements, prohibitions against misbranding and adulteration, and good manufacturing practices. 21 U.S.C. § 360c; 21 U.S.C. § 360k; 21 C.F.R. § 860.3(c)(1)-(2). Finally, Class III includes devices which pose potential unreasonable risks of injury. The controls exercised over Class II devices are insufficient to determine safety or effectiveness of Class III devices; accordingly, Class III devices must be generally approved prior to being marketed through a premarket authorization procedure. *See* 21 U.S.C. § 360e and § 360c(a)(2)(C).

Some devices, however, enter the market through Section 510(k) of the MDA. This section applies to any device which the manufacturer submits as, and the FDA finds to be, *"substantially equivalent"* in design and function to a *"predicate device"* (i.e., a device which was on the market prior to the effective date of the MDA or was lawfully sold as a substantially equivalent device). 21 U.S.C. § 360c(f) and (i); 21 C.F.R. § 814.80. This is the process which allowed the DivaCup® to enter into the market. The "substantially equivalent" process has been described as follows:

> Under section 510(k), devices that are shown to be substantially equivalent to a device on the market before the MDA [was] passed (a "predicate" device) can gain approval without submitting to the type of premarket approval required for a new device. At least ninety days before marketing its device, a manufacturer must submit to the FDA information that the device has the same intended use as a pre-Amendment device and that it has the same technological characteristics. Alternatively, a device may satisfy the 510(k) process even if it has different technological characteristics, as long as these characteristics do not raise different questions of safety and effectiveness from the predicate device. If a device meets the equivalence requirement, it can enter the marketplace without further scrutiny.

Dow, 899 F. Supp. at 824-25. The FDA may also request additional information in an effort to determine whether the device is substantially equivalent to a predicate device. 21 C.F.R. § 807.100. Additionally, the FDA regulations govern the form and substance of the information required for a submission under Section 510(k), including proposed labeling. 21 C.F.R. §§ 807.87 and 807.92.

II. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must take the facts alleged in the complaint as true and draw all reasonable inferences in favor of the Plaintiff. *Mosley v. Klincar*, 947 F.2d 1338, 1339 (7th Cir. 1991). The complaint must contain only "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), and there is no need for detailed factual allegations. *Pisciotta v. Old Nat'l Bancorp*, 499 F.3d 629, 633 (7th Cir. 2007) (citation omitted). Nevertheless, the statement must "give the defendant fair notice of what the claim is and the grounds upon which it rests" and the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id*. (citations and quotations omitted). "Although this does 'not require heightened fact pleading of specifics,' it does require the complaint to contain 'enough facts to state a claim to relief that is plausible on its face.'" *Killingsworth,* 507 F.2d at 618 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

III. DISCUSSION

Defendant asserts that James' claims fail due to insufficient pleading, as well federal preemption by the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360c, et seq. The Court will address each allegation in turn.

A. Pleading Requirements

"While a complaint attacked by a *Rule 12(b)*(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly,* 127 S.Ct. 1955, 1964-65 (2007) (internal citations omitted).

The Seventh Circuit addressed the difficulty of pleading regarding a manufacturing issue on a medical device in *Bausch v. Stryker Corporation*, and determined that so long as the plaintiff alleges facts sufficient to meet the "plausibility" standard then pleading is sufficient. *Bausch v. Stryker Corp*., 630 F. 3d 546, 558 (7th Cir. 2010); *See Ashcroft v. Iqbal,* 129 S. Ct. 1937, 1949 (2009) (to survive a motion to dismiss, the complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face'.... 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."*) (emphasis added). *Ashcroft,* 129 S. Ct. at 1949 (citing *Twombly,* 550 U. S. at 570). We give the plaintiff "the benefit of imagination, so long as the *hypotheses are consistent with the complaint." Bausch*, 630 F. 3d at 559 (emphasis added) (quoting *Bissessur v. Indiana Univ. Bd. of Trs.,* 581 F. 3d 599, 603 (7th Cir. 2009)).

In deciding whether a complaint can survive a motion to dismiss, the Seventh Circuit has consistently said: "As a general rule...notice pleading remains the standard." *Id*. at 559 (quoting *Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Financing Services,* 536 F. 3d 663, 667 (7th Cir. 2008)). "Together, these rules ensure that claims are determined on their merits

rather than on pleading technicalities." *Christensen v. County of Boone,* 483 F. 3d 454, 458 (7th Cir. 2007).

According to James' Amended Complaint, the Defendant is identified as the manufacturer and seller of the Class II medical device DivaCup®. Plaintiff pled that on or about March 26, 2008, she purchased the DivaCup® and used it in accordance with its intended use. James' Amended Complaint further alleged that the DivaCup® product was unreasonably dangerous and caused her to suffer from Toxic Shock Syndrome. The Court does not find a fatal defect in the Amended Complaint that would justify dismissal of Count II. Additionally, objections to lack of specificity regarding identifications of precise defects were addressed in *Bausch*, where the court rejected defendants' objections that the complaint did not specify the precise defect of the product. *Bausch*, 630 F.3d at 560. Although faced with a different set of circumstances than those in *Bausch*, here, the *"plaintiff's pleading burden should commensurate with the amount of information available to them," Id*. at 561, and the Court finds that James has pled sufficiently based on the information available to her before discovery. The Court **DENIES** Defendant's Motion to Dismiss as to the product liability and strict liability claims in Count II of the Amended Complaint.

Count I however, warrants further analysis. The Court must now reiterate the conclusions of the Supreme Court in *Ashcroft*, "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949-50 (2009) (quoting *Twombly*, 550 U.S. at 555 (Although for the purposes of a motion to dismiss we must take all of the factual allegations in the complaint as true, we *"are not bound to accept as true a legal conclusion couched as a factual allegation"* (internal quotation marks omitted))). In Count I of James' Amended Complaint, the Court agrees with Defendant in that

Plaintiff has merely recited the elements of a cause of action in a conclusory manner and has not pled any facts that would establish plausibility of a negligence claim.

The Court therefore **GRANTS** Defendant's Motion to Dismiss - based upon insufficient pleadings - as to the negligence claim in Count I of the Complaint.

B. Federal Preemption

As the Court previously stated, the FDA utilizes three classifications of medical devices in ascending order of federal control and oversight. *Dow v. Baxter Healthcare Corp*., 899 F. Supp. 822, 824 (D. Mass. 1995). The issue before the Court is whether James' claims of injuries and damages allegedly caused by the DivaCup® - a Class II medical device which obtained 510(k) approval based on its substantial equivalence to a predicate medical device - are preempted by the MDA. The Court finds that total preemption of James' state law claims, as urged by Defendant is not warranted at this stage of the proceedings.

The MDA expressly prohibits a state from establishing *any requirement* relating to the device that *differs at all from* the federal requirements. 21 U.S.C. § 360k(a) states in full:

> [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 Act 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 Act.

21 U.S.C. § 360k(a). However, Congress narrowed the reach of Section 360k(a) by establishing that *"[s]tate or local requirements are preempted* ***only*** *when the [FDA] has established specific counterpart regulations or [when] there are other specific requirements applicable to a particular device under the act."* 21 C.F.R. § 808.1(d) (emphasis added). Further, Section 360k(a), does not preempt state rules that merely duplicate federal requirements. *Medtronic, Inc.*

v. Lohr, 518 U.S. 470, 494-95 (1996); *Bausch v. Stryker Corp*., 630 F.3d 546, 551 (7th Cir. 2010).

In analyzing whether a claim is preempted by the MDA, a court must make three determinations. First, it must find that federal requirements are imposed on the particular medical device. *Riegel v. Medtronic, Inc*., 552 U.S. 312, 321-22 (2008). If so, then the court must determine whether the plaintiff's claims are based on a state requirement that *"relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." Id.* at 322 (quoting § 360k(a)). Finally, such claims will be preempted where they impose requirements that are either different from, or in addition to, the federal regulations. *Id.*

1. Federal Requirements

Section 360k(a) provides protection from common law or statutory requirements by states where the federal government has established *applicable requirements relating to safety or effectiveness*. *See* 21 C.F.R. § 801.1(d); *Riegel v. Medtronic, Inc.,* 552 U.S. 312 (2008). Defendant argues that there are federal requirements that are particularly applicable to the DivaCup®. Specifically, Diva argues (1) the DivaCup® is subject to the FDA's quality system regulations ("QSR"); (2) the DivaCup® is subject to additional FDA's "foreign device" regulations; and (3) because the DivaCup® is manufactured in Canada, it is subject to Canadian regulations related to safety and effectiveness. The Court will address each argument in turn.

a. Regulatory Scheme

Defendant first argues that its menstrual cups are subject to the FDA's Quality System Regulations – Good Manufacturing Practice regulations and thus are subject to the requisite federal requirements. *See* 21 C.F.R. §§ 820.1(a)(1) and 820.20, *et seq*. Part 820 of Title 21 of the Code of Federal Regulations sets forth a regulatory scheme designed *"to ensure that finished*

[medical] devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act." 21 C.F.R. § 820.1(a)(1). Its provisions establish a minimum standard that manufacturers of certain medical devices are required to meet.

In *Riegel*, the United States Supreme Court discussed extensively the previous ruling of *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and the necessity of specific requirements to trigger preemption. The *Riegel* court stated the following:

> *Lohr,* a majority of this Court interpreted the MDA's pre-emption provision in a manner "substantially informed" by the FDA regulation set forth at 21 CFR § 808.1(d) … pre-empted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device...." 21 CFR § 808.1(d) … [*F*]*ederal manufacturing and labeling requirements applicable across the board to almost all medical devices did not pre-empt the common-law claims of negligence and strict liability* … the federal requirements were not requirements specific to the device in question-they reflected "entirely generic concerns about device regulation generally."

Riegel, 552 U.S. at 322 (citations omitted) (emphasis added).

Additionally, the FDA itself recognizes that these requirements *"are intended to serve only as 'an umbrella quality system,' providing 'general objectives' medical-device manufacturers must seek to achieve." Horowitz v. Stryker Corp*.**,** 613 F. Supp. 2d 271, 278-79 (E.D.N.Y. 2009) (citations omitted) (quoting FDA Device Advice, Good Manufacturing Practices/Quality System Regulation, available at http:// www. fda. gov/ cdrh/ devadvice/ 32. html# flexibility (last visited January 2, 2009)).

These regulations do not specifically address the design, production and marketing requirements for each and every type of medical device. *Id.* The Good Manufacturing Practice requirements leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective. *Id*. The Court

therefore finds the FDA's Quality System Regulations/Good Manufacturing Practice regulations referenced by Diva insufficient to warrant federal preemption.

b. Classification Process

Defendant further asserts that the menstrual cup's classification and categorization process trigger preemption. Defendants cite to DivaCup®'s three FDA reviews regarding its designation as a Class II device as evidence. Defendant argues that the DivaCup® is subject to the performance standards developed pursuant to 21 C.F.R. § 861.1, *et seq*. and that under 21 C.F.R. § 884.5400 these standards specifically regulate the DivaCup® within the meaning of regulation § 808.1(d).

The Court is not persuaded that preemption is triggered by these *identification or classification* regulations or the process to ascertain them. Defendant has not identified in any way that this process is not generally required of each type of medical device that falls under the purview of the MDA and that each device is classified and identified through the process identified by Defendant. Likewise, the Court is not persuaded that Regulation § 884.5400 and its panel recommendation process specifically regulate the DivaCup® as contemplated by §808.1(d). *See generally Ginochio v. Surgikos, Inc*., 864 F. Supp. 948, 953 (N.D.Cal. 1994). Therefore, the Court finds the proffered classification process insufficient to preempt Plaintiff's state law claims in a motion to dismiss.

The device at issue before the Court was approved by the "substantially equivalent" process. Defendant argues that this is of no consequence. However, it is worth noting that the Supreme Court has held that this process implements only generally applicable standards and does are not constitute sufficient "requirements" to trigger preemption under Section 360k(a). *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492-93 (1996) (finding that the section 510(k) process is

less rigorous than the pre-market authorization process); *Bausch v. Stryker Corp*., 630 F.3d 546, 551 (7th Cir. 2010).

c. Foreign Device

Defendant additionally argues in support of preemption that the DivaCup® is subject to specific requirements because it is a foreign device. Specifically, Defendant asserts that it is subject to heightened requirements regarding the appearance of either adulteration or misbranding. Compare 21 U.S.C. § 381(a) (requiring FDA to refuse admission of a device into the United States if it *appears* that the device is adulterated or misbranded), with 21 U.S.C. § 331(b) (requirement of prohibition for domestically manufactured devices only if the device *has in fact* been adulterated or misbranded). Defendant additionally asserts that the FDA has the authority to ban the DivaCup® if the product labeling is false, misleading, or inadequate. 21 U.S.C. § 360.

Plaintiff asserts that her claim insisting on a Toxic Shock Syndrome warning label would not constitute an additional or different requirement. Rather, Plaintiff argues that it would parallel the federal requirement by adding specificity. Whatever its merits, this argument is unnecessary because Defendant has not offered sufficient evidence to support the finding that the additional requirements placed upon it are specific to the DivaCup®.

Ultimately, because Defendant has failed to identify any special controls, performance standards, post-market surveillance, or guidelines to date, that are applicable to this *particular device*, Defendant's preemption argument fails. The Court therefore **DENIES** Defendant's Motion to Dismiss Plaintiff's state law claims based on federal preemption.[1]

[1] As Defendant was unable to cite to binding case law that would require consideration of foreign regulations, though novel, at this stage of litigation the Court declines to accept Defendant's preemption argument based on the proffered Canadian regulations.

2. State Requirements Related to Safety and Effectiveness

The Court need not address Plaintiff's claims relating *"to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device,"* making them subject to preemption. § 360k(a)(2). The salient inquiry was the first - whether the FDA had established specific counterpart regulations or specific requirements for this particular menstrual cup. *See Oliver v. Johnson & Johnson, Inc*., 863 F. Supp. 251, 253-54 (W.D.Pa. 1994).

IV. CONCLUSION

For the reasons stated herein, the Court **DENIES** Defendant's Motion to Dismiss Plaintiff's state law claims based on federal preemption and **DENIES** Defendant's Motion to Dismiss in regard to the product liability and strict liability claims in Count II of Plaintiff's Amended Complaint. The Court **GRANTS** Defendant's Motion to Dismiss in regard to the negligence claim in Count I of Plaintiff's Amended Complaint.

SO ORDERED.

Date: 03/18/2011

Hon. Tanya Walton Pratt, Judge
United States District Court
Southern District of Indiana

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