IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARGARET J. BAUSCH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 08 C 4248**
	)	
	)	
STRYKER CORPORATION, et al.	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

SAMUEL DER-YEGHIAYAN, District Judge

This matter is before the court on Defendant Howmedica Osteonics Corp.'s ("Howmedica") motion to dismiss. This matter is also before the court on Defendant Stryker Ireland, LTD.'s ("Stryker Ireland") motion to dismiss. For the reasons stated below, we grant Howmedica's motion to dismiss. We also grant Stryker Ireland's motion to dismiss.

BACKGROUND

Plaintiff Margaret J. Bausch ("Bausch") alleges that on March 21, 2007, she underwent a right total hip replacement surgery during which a surgeon implanted in

her a Trident Brand Ceramic on Ceramic Hip Replacement System ("Trident"). According to Bausch, the Trident was designed, manufactured, and sold by Defendants. Bausch alleges that the Trident used in her surgery was defective rendering it unreasonably dangerous. Specifically, Bausch alleges that the Trident contained a component known as the Trident Hemispherical Acetabular Shell, which was recalled by Defendants in January 2008. Bausch further alleges that Defendants had notice of defects in the Trident prior to her surgery and that the United States Food and Drug Administration ("FDA") had issued a letter to Defendants advising them that certain manufacturing methods relating to the Trident were not in conformity with industry, regulatory standards, and Defendants' specifications. Bausch claims that the defect in her Trident caused her to have an unstable right hip, pain, suffering, disability, loss of normal life, the need for revision surgery, delayed care for her other hip, and medical and other expenses.

Bausch brought the instant action and includes in her complaint strict liability in tort claims (Count I) and negligence claims (Count II). Howmedica and Stryker Ireland have moved separately to dismiss all claims pursuant to Federal Rule of Civil Procedure 12(b)(6).

LEGAL STANDARD

In ruling on a motion to dismiss brought pursuant to Rule 12(b)(6), the court must draw all reasonable inferences that favor the plaintiff, construe the allegations of the complaint in the light most favorable to the plaintiff, and accept as true all

well-pleaded facts and allegations in the complaint. *Thompson v. Ill. Dep't of Prof'l Regulation*, 300 F.3d 750, 753 (7th Cir. 2002); *Perkins v. Silverstein*, 939 F.2d 463, 466 (7th Cir. 1991). In order to withstand a motion to dismiss, a complaint must allege the "operative facts" upon which each claim is based. *Kyle v. Morton High Sch.*, 144 F.3d 448, 454-55 (7th Cir. 1998); *Lucien v. Preiner*, 967 F.2d 1166, 1168 (7th Cir. 1992). A plaintiff is required to include allegations in the complaint that "plausibly suggest that the plaintiff has a right to relief, raising that possibility above a 'speculative level' " and "if they do not, the plaintiff pleads itself out of court." *E.E. O.C. v. Concentra Health Services, Inc.*, 496 F.3d 773, 776 (7th Cir. 2007)(quoting in part *Bell Atl. Corp. v. Twombly*, 127 S.Ct. 1955, 1965 (2007)). Under the current notice pleading standard in federal courts a plaintiff need not "plead facts that, if true, establish each element of a 'cause of action. . . .'" *See Sanjuan v. Amer. Bd. of Psychiatry & Neurology, Inc.*, 40 F.3d 247, 251 (7th Cir. 1994)(stating that "[a]t this stage the plaintiff receives the benefit of imagination, so long as the hypotheses are consistent with the complaint" and that "[m]atching facts against legal elements comes later"). The plaintiff need not allege all of the facts involved in the claim and can plead conclusions. *Higgs v. Carver*, 286 F.3d 437, 439 (7th Cir. 2002); *Kyle*, 144 F.3d at 455. However, any conclusions pled must "'provide the defendant with at least minimal notice of the claim,'" Kyle, 144 F.3d at 455 (quoting *Jackson v. Marion County*, 66 F.3d 151, 153-54 (7th Cir. 1995)), and the plaintiff cannot satisfy federal pleading requirements merely "by attaching bare legal conclusions to narrated facts which fail to outline the bases of [his] claims."

Perkins, 939 F.2d at 466-67. The Seventh Circuit has explained that "[o]ne pleads a 'claim for relief' by briefly describing the events." *Sanjuan*, 40 F.3d at 251; *Nance v. Vieregge*, 147 F.3d 589, 590 (7th Cir. 1998)(stating that "[p]laintiffs need not plead facts or legal theories; it is enough to set out a claim for relief").

DISCUSSION

Howmedica and Stryker Ireland separately move to dismiss the instant action arguing that, based on the allegations in Bausch's complaint, Bausch can prove no set of facts that would support her claims for relief. Howmedica and Stryker Ireland argue that both of Bausch's state common law claims are preempted by the Medical Device Amendments ("MDA") of 1976, 21 U.S.C. § 360k, to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* The enactment of the MDA in 1976, established a new "regulatory regime" whereby the preapproval of medical devices into the market would be almost exclusively monitored by the FDA. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1003 (2008). The MDA contains a preemption clause that provides, 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). Howmedica and Stryker Ireland argue in their motions to dismiss that Bausch's

claims are predicated upon state common law theories of strict liability and negligence which are considered to be regulations that are "different from, or in addition to" established federal regulations and are, therefore, preempted under the MDA. 21 U.S.C. § 360k(a).

Under the Supremacy Clause of the Constitution, "the Laws of the United States . . . shall be the supreme Law of the Land . . . the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI. The doctrine of preemption arises out of the Supremacy Clause. *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1246 (7th Cir. 1997)(stating that "[p]ursuant to this authority [in the Supremacy Clause], Congress may preempt state law"). Courts have recognized three different forms of preemption: express preemption, field preemption, and conflict preemption. *Aux Sable Liquid Products v. Murphy*, 526 F.3d 1028, (7th Cir. 2008). The instant case presents a situation where "a statutory provision [] expressly preempts state law." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (7th Cir. 1996).

I. Supreme Court Decision in *Riegel*

The United States Supreme Court recently addressed the issue of preemption under the MDA in *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008), and found that common law claims relating to medical devices are expressly preempted by the MDA when "the Federal Government has established requirements applicable to" the device, and when the claims "are based upon [state] 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 1006 (quoting in part 21 U.S.C. § 360k(a)). In *Riegel*, the plaintiffs brought strict liability, negligence, and other product liability-related claims under New York state common law against the manufacturer of a medical device used in one of the plaintiffs' heart surgery. *Id.* at 1005-06.

In addressing whether the federal government had established a requirement with respect to the device at issue in *Riegel*, the Supreme Court found in *Riegel* that devices that are required to undergo the "rigorous process" of "premarket approval," *Id.* at 1004, are considered to be subject to established federal government requirements for the purposes of preemption. *Id.* at 1007. The Supreme Court reasoned that the premarket approval process, which is specific to certain devices is sufficient to govern the production of the devices that obtain premarket approval. *Id.* In addressing whether the plaintiffs' claims in *Riegel* were considered to be based upon a state requirement that was "different from, or in addition to" requirements by the federal government, the Supreme Court found that a state's common law "tort duties" do qualify as "requirements" for the purposes of preemption under the MDA. *Id.* at 1007. The Supreme Court stated, for example, that a "[s]tate tort law that requires a [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Id.* at 1008. The Supreme Court further pointed out that even if a state does impose a requirement on a device, such a requirement may not necessarily be preempted if the requirement is not "different from, or in addition to" the federal requirement. *Id.* at 1011. The Supreme Court stated, for example, that state

provisions providing damages remedies for violations of FDA regulations would be considered "parallel" to federal regulations and would not be preempted. *Id.*

II, Application of *Riegel* Preemption Analysis

Applying the framework set out in *Riegel* for analyzing preemption under the MDA, the court must address, based on the allegations in the complaint, (1) the Trident was subject to federal government requirements, and (2) whether Bausch's strict liability and negligence claims qualify as state regulations that are "'different from, or in addition to'" such federal government requirements. *Id.* at 1006 (quoting 21 U.S.C. § 360k(a)).

A. Subject to Federal Government Requirements

With respect to the first issue of whether the Trident is subject to federal government requirements, there is little dispute. The parties agree that the Trident is a Class III medical device which, like the device in *Riegel*, was subjected to the process of premarket approval by the FDA. (S.I. Mot. Dis. 2); (H. Mot. Dis. 2); (Ans. H. Mot. Dis. 9); *see Heisner v. Genzyme Corp.*, 2008 WL 2940811 at *1 (N.D. Ill. 2008)(J. Coar)(taking judicial notice of the fact that the device at issue in the case was a Class III medical device despite the fact that such was not pled in the complaint). The Supreme Court in *Riegel* unequivocally held that devices which are subject to premarket approval by the FDA are considered to be subject to federal government regulation for the purposes of preemption under the MDA. *Riegel*, 128

S.Ct. at 1007. Bausch argues that the instant case is distinguishable from the holding in *Riegel* by pointing out that in this case after the premarket approval the FDA sent Defendants a letter advising them of certain deficiencies. However, Bausch has not alleged that the FDA withdrew the premarket approval of the Trident. On the sole issue of whether the Trident was subject to regulations by the federal government it is clear that, based on the precedent of *Riegel*, that devices that have received premarket approval by the FDA are considered to be regulated by the federal government for the purposes of preemption. *Id.* at 1004; *see also McMullen v. Medtronic*, 421 F.3d 482, 487-88 (7th Cir. 2005)(holding that a device that obtained premarket approval and was subject to post-premarket approval requirements by the FDA was considered to be subject to federal requirements even though the plaintiff alleged that the defendant failed to comply with such federal requirements after obtaining premarket approval). Therefore, we find that Trident was subject to federal government regulations for the purposes of preemption.

B. The Nature of Bausch's Claims

With respect to the second issue in the analysis of preemption under the MDA, it is also clear that Bausch's claims are premised on "tort duties" that are capable of being preempted under the MDA. *Id.* at 1007-08. The issue that is at the heart of the parties' dispute in the instant motions is whether the tort duties that form the basis for Bausch's claims are "different from, or in addition to" regulation of the Trident by the federal government. 21 U.S.C. § 360k. Howmedica and Stryker Ireland argue

that Bausch's claims are "different from, or in addition to" FDA regulations of the Trident. Howmedica and Stryker Ireland argue that Bausch's claims do not fall into the narrow universe of tort claims against medical device manufacturers that survive the Supreme Court's ruling in *Riegel*. (Reply H. Mot. Dis. 4). Bausch, in contrast, argues that both of her claims should be considered as "parallel" to the federal regulation of the Trident. (Ans. H. Mot. Dis. 6).

The issue of what constitutes a parallel claim that would survive preemption under the analysis in *Riegel* is an issue that the Supreme Court did not address since the plaintiffs in *Riegel* did not argue at the Circuit level that their claims were parallel to a federal government regulation. *Riegel*, 128 S.Ct. at 1011. The Supreme Court did state, prior to *Riegel*, that claims could survive preemption when they are "'substantially identical'" to FDA requirements. *Lohr*, 518 U.S. at 496-97(quoting 21 C.F.R. § 808.1(d)(2)); *see also McMullen*, 421 F.3d at 489 (indicating that common law actions must "'mirror[]'" federal regulations in order to survive preemption)(quoting *Mitchell v. Collagen Corp.*, 126 F.3d 902, 909 (7th Cir. 1997)). The only example provided by the Supreme Court in *Riegel* of a claim that would certainly be substantially identical to federal government regulations, and therefore would not be preempted, is a claim that is based on a state statutory enactment providing a damages remedy for violations of FDA regulations. *Id.* In the instant action, Bausch's claims are not based on any specific state law damages provisions for violations of the FDA or claims that are substantially identical to FDA requirements, but rather the claims are based on generalized common law theories of

strict liability and negligence and are "different from, or in addition to" the FDA regulations. (Compl. 2-4); 21 C.F.R. § 808.1(d)(2).

1. Strict Liability Claim (Count I)

With respect to Bausch's strict liability claim, Howmedica and Stryker Ireland argue that such a claim, by its very nature, imposes a standard on manufacturers that is different from the standard provided by FDA regulation of the Trident. As the Seventh Circuit has noted, "Illinois follows the Restatement (2d) of Torts § 402A (1965), and imposes strict liability on sellers of unreasonably dangerous products where the dangerous condition existed when it left the manufacturer's control." *Apperson v. E.I. du Pont de Nemours & Co.*, 41 F.3d 1103, 1106 (7th Cir. 1994). The very nature of a strict liability claim under the Illinois standard conflicts with the regulatory scheme for Class III medical devices as enacted under the MDA. *See Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1247 (7th Cir. 1997)(pointing out that the strict liability standard imposed by Indiana law could impose liability on any experimental device "that meets all FDA standards and requirements but is still somehow adjudged unreasonably dangerous"). A Class III medical device includes devices that, by definition, "'present[] a potential for unreasonable risk of illness or injury.'" *Riegel*, 128 S.Ct. at 1003 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)). The premarket approval process is designed to screen such dangerous devices, which also provide "'substantial importance in preventing impairment of human health.'" *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)). Any strict liability claim raised by a

plaintiff under Illinois law would, by necessity, require a trier of fact to assess whether a product is unreasonably dangerous. Such a claim could potentially implicate every single Class III medical device without regard for whether that device received premarket approval by the FDA. Even in a case such as this, where the plaintiff has also separately alleged that the device did violate certain FDA regulations, such a violation would not be the actual predicate for the strict liability claim, but would rather be a matter collateral to the claim. Thus, we find that Bausch's strict liability claims by their very nature are incompatible with federal regulations relating to Class III medical devices, such as the Trident. In the instant action, Bausch's inclusion of separate allegations in her complaint that Defendants violated regulations of the FDA does not make her strict liability claim premised in any way on those violations and, thus, parallel to the regulatory scheme of the federal government. We agree with Howmedica and Stryker Ireland that Bausch's strict liability claim in Count I is preempted by the MDA. Therefore, we grant the motions to dismiss Count I.

2. Negligence Claim (Count II)

With respect to the negligence claim, Bausch argues that such a claim should be considered parallel to FDA regulations since Bausch has set forth an allegation in her complaint that Defendants violated regulations of the FDA and that such an allegation must be accepted by the court to be true at this stage in the litigation. As discussed above, the Supreme Court in *Riegel* stopped short of deciding what kinds

of claims would be "parallel" to federal regulations and, as such, would survive preemption. *Riegel*, 128 S.Ct. at 1011. We do know that any claim under state law must be "different from, or in addition to" a federal regulation, or, to put it a different way, the claim must be "'substantially identical'" to federal regulations. *Lohr*, 518 U.S. at 496-97 (quoting 21 C.F.R. § 808.1(d)(2)).

Based on the language of the MDA and the holding in *Riegel*, Howmedica and Stryker Ireland make a strong argument to support their contention that all state common law negligence claims are preempted under the MDA. Bausch argues that negligence claims are not mutually inconsistent with FDA regulations so long as the plaintiff alleges that the same conduct that violated the FDA also caused the plaintiff's alleged injuries. However, such a conclusion ignores the fact that the preemption clause in the MDA bars all claims "*different from*, or in addition to" federal regulations. 21 U.S.C. § 360k(a)(emphasis added). The fact that Congress did not merely bar regulations that were "in addition to" federal regulations implies that Congress anticipated that state regulations including state common law claims, would be preempted even when they are based on the same conduct by the defendant as conduct that violates federal regulations, so long as the standard applied is "different." *Id.* Negligence claims, by their very nature, would require the application of common law principles that are entirely distinct from the enactments of the FDA. Thus, even if a negligence claim was premised on conduct that also violated the FDA, and thus would not impose a requirement on manufacturers that would be "in addition to" federal regulations, such a requirement would still be

"different" and preempted under the clear language of the MDA. *Id*. Under such a reading of the statute, the only claim that would survive MDA preemption after *Riegel* would be the one example given in *Riegel* of a parallel claim, namely, an action that is premised on a state regulatory enactment that provides damages remedies for violations of FDA regulations, or a similar claim. *Riegel*, 128 S.Ct. at 1011.

We note that other district courts have addressed the issue of properly pleading non-preempted claims since *Riegel*. *See Parker v. Stryker Corp.*, 2008 WL 4716879 at *5 (D. Colo. 2008)(addressing a plaintiff's common law claims based on injuries allegedly caused by the Trident and finding that, to the extent that it was possible to plead common law claims not preempted by the MDA, the plaintiff had not pled such a claim); *Heisner*, 2008 WL 2940811 at *5 (implying that it might be possible for a plaintiff to plead a common law claim that is not preempted by the MDA, but finding that the plaintiff had not pled such a claim). The above courts have focused on whether the plaintiffs in those cases pled their claims in such a manner as to state a claim that would be considered parallel to federal regulations. *Parker*, 2008 WL 4716879 at *5; *Heisner*, 2008 WL 2940811 at *5. Thus, to the extent that it is possible for Bausch to plead a negligence claim that is not preempted by the MDA, we will examine Bausch's complaint to see whether she has pled such a claim.

Bausch's complaint states "[i]t was a duty of the defendants to exercise reasonable care to protect the safety of the plaintiffs and others yet, notwithstanding this duty, defendants negligently manufactured and sold a Trident brand ceramic on

ceramic hip replacement system that was out of compliance with defendants' specifications, industry standards, and regulatory standards. . . ." (Compl. Par. 25). This language illustrates that Bausch seeks to impose a standard of liability that is not in line with FDA regulations. Although Bausch references the fact that the Trident was not made within "regulatory standards" she also lists "industry standards" and Defendants' own specifications as standards to which Defendants are to be held accountable under her negligence claim. (Compl. Par. 25).

Bausch argues that the court should construe the complaint in a manner that is most favorable to her and find that her negligence claim is premised entirely on violations of federal regulations. However, while the court must construe the complaint in a light most favorable to Bausch, a plaintiff must allege facts that plausibly suggests a viable claim. *See Pugh v. Tribune Co.*, 521 F.3d 686, 699 (7th Cir. 2008)(stating that "a plaintiff can plead himself out of court by alleging facts that show there is no viable claim"). In 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. We are cognizant of the fact that a plaintiff can survive a motion to dismiss even if the plaintiff has not attached the correct label to a certain claim so long as the allegations in the complaint plausibly suggest a right to relief. *Bartholet v. Reishauser A.G.*, 953 F.3d 1073, 1075 (7th Cir. 1992). However, in this case Bausch has not plausibly suggested a right to relief on any claim.

Based on the language in Bausch's complaint, we find that, although Bausch has alleged that Defendants violated the FDA, Bausch's negligence claim is not based on a duty that is "substantially identical" to the duty that is imposed on the Trident by FDA regulations. *Lohr*, 518 U.S. at 496-97. Even if there exists a narrow means whereby Bausch could bring a common law claim for negligence solely on the basis of a defendant's violations of FDA regulations, Bausch has not pled such a claim in this case. As other courts in this district have pointed out, such a claim could only be considered "substantially identical" to federal regulations "to the extent that [a] [p]laintiff's allegations are concerned not with the nature of [the product] as approved by the FDA, but rather with [the] [d]efendant's action or inaction in its efforts to take part in the [premarket approval] process or implement its results. . . ." *Heisner*, 2008 WL 2940811 at *5. There are no allegations in the complaint that might put Defendants on notice of a claim that is based entirely on a specific defect in the Trident that existed outside of the knowledge and regulations of the FDA. Thus, even if Bausch's claims were not preempted, Bausch has failed to state a cognizable claim. We find that Bausch's negligence claim is also preempted under the FDA and fails to state a claim upon which relief can be granted. Therefore, we grant the motions to dismiss Count II.

III. Claims Against Stryker Corporation

We note that, while Howmedica and Stryker Ireland have moved to dismiss the complaint, Defendant Stryker Corporation, has not moved to dismiss. However,

since our ruling on Bausch's claims applies equally to all Defendants, we dismiss the entire action against all Defendants, including Stryker Corporation, as a matter of law.

CONCLUSION

Based on the foregoing analysis, we grant the motions to dismiss brought by Howmedica and Stryker Ireland, and we also dismiss the claims against Stryker Corporation. All pending motions are denied as moot.

Samuel Der-Yeghiayan
United States District Court Judge

Dated: December 9, 2008