UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

INGRID ANDERSON, et al.,	:	
	:	NO. 1:12-CV-00762
Plaintiffs,	:	
	:	
	:	
v.	:	**OPINION & ORDER**
	:	
	:	
BOSTON SCIENTIFIC CORPORATION, et al.,	:	
	:	
	:	
Defendants.		

This matter is before the Court on Defendants' Motion to Dismiss (doc. 4), Plaintiff's response in opposition (doc. 8), and Defendants' reply in support thereof (doc. 9). For the following reasons, the Court GRANTS Defendant's motion.

I. Background

This case is here on diversity of citizenship and arose out of the insertion of a spinal cord stimulator, which was manufactured by Defendant Boston Scientific Corporation. Plaintiff Ingrid Anderson had the stimulator implanted on September 7, 2010, and on September 11, 2010 she began experiencing serious and increasing pain (doc. 2). At the time the device was implanted, Plaintiff was introduced to Defendant Jenny, who told her that she was an employee of Defendant Boston

Scientific and that she was to be Plaintiff's liaison between Plaintiff and the doctor doing the insertion (Id.).

When Plaintiff began experiencing the pain in her back, she attempted to contact Defendant Jenny six times but did not hear back from Jenny for two days (Id.). When they did speak on September 13, 2010, Jenny informed Plaintiff that she should keep her regularly scheduled appointment with the doctor on September 14, 2010 (Id.). Plaintiff arrived at that appointment in extreme pain, nearly unable to walk (Id.). Upon examining the insertion site, the doctor immediately called an ambulance and sent Plaintiff for emergency surgery for an abscess and infection that had developed in her spinal column (Id.). In addition to that infection, Plaintiff also suffered damage to her bladder, nerve damage, pain, and mental and emotional anguish.

Plaintiffs' complaint contains three counts: Count One is a negligence claim under Ohio common law, where Plaintiffs allege that Defendant Jenny negligently mishandled information, failed to inform the physician who implanted the stimulator of Plaintiff's condition, and negligently advised Plaintiff to simply keep her regularly scheduled appointment. In Count Two, Plaintiffs allege that Defendant Boston Scientific negligently manufactured, inspected, maintained and/or designed the

stimulator in violation of Ohio Revised Code Sections 2307.71 et seq. and/or that Defendant Boston Scientific breached implied warranties of fitness with respect to the stimulator. Count Three is a loss of consortium claim under Ohio common law, where Plaintiffs Chloe and Isabelle Anderson allege that as a result of Defendants' negligence and/or defective product, they have suffered a loss of consortium with their mother, Plaintiff Ingrid Anderson (doc. 2).

Defendants move to dismiss on the bases that the complaint fails to set forth a plausible cause of action and that Plaintiffs' claims are preempted.

II. Applicable Standard

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) requires the Court to determine whether a cognizable claim has been pled in the complaint. The basic federal pleading requirement is contained in Fed. R. Civ. P. 8(a), which requires that a pleading "contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Westlake v. Lucas, 537 F.2d 857, 858 (6th Cir. 1976); Erickson v. Pardus, 551 U.S. 89 (2007). In its scrutiny of the complaint, the Court must construe all well-pleaded facts liberally in favor of the party opposing the motion. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). A

complaint survives a motion to dismiss if it "contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Courie v. Alcoa Wheel & Forged Products, 577 F.3d 625, 629-30 (6th Cir. 2009), quoting Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009), citing Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007).

A motion to dismiss is therefore a vehicle to screen out those cases that are impossible as well as those that are implausible. Courie, 577 F.3d at 629-30, citing Robert G. Bone, *Twombly*, Pleading Rules, and the Regulation of Court Access, 94 IOWA L. REV. 873, 887-90 (2009). A claim is facially plausible when the plaintiff pleads facts that allow the court to draw the reasonable inference that the defendant is liable for the conduct alleged. Iqbal, 129 S.Ct. at 1949. Plausibility falls somewhere between probability and possibility. Id., citing Twombly, 550 U.S. at 557. As the Supreme Court explained,

> In keeping with these principles a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief. Id. at 1950.

The admonishment to construe the plaintiff's claim

liberally when evaluating a motion to dismiss does not relieve a plaintiff of his obligation to satisfy federal notice pleading requirements and allege more than bare assertions of legal conclusions. Wright, Miller & Cooper, Federal Practice and Procedure: § 1357 at 596 (1969). "In practice, a complaint…must contain either direct or inferential allegations respecting all of the material elements [in order] to sustain a recovery under some viable legal theory." Car Carriers, Inc. v. Ford Motor Co., 745 F.2d 1101, 1106 (7th Cir. 1984), quoting In Re: Plywood Antitrust Litigation, 655 F.2d 627, 641 (5th Cir. 1981); Wright, Miller & Cooper, Federal Practice and Procedure, § 1216 at 121-23 (1969). The United States Court of Appeals for the Sixth Circuit clarified the threshold set for a Rule 12(b)(6) dismissal:

> [W]e are not holding the pleader to an impossibly high standard; we recognize the policies behind Rule 8 and the concept of notice pleading. A plaintiff will not be thrown out of court for failing to plead facts in support of every arcane element of his claim. But when a complaint omits facts that, if they existed, would clearly dominate the case, it seems fair to assume that those facts do not exist.

Scheid v. Fanny Farmer Candy Shops, Inc., 859 F.2d 434, 437 (6th Cir. 1988).

III. Discussion

Plaintiffs' complaint must be dismissed for the

following reasons: Count One fails to set forth sufficient facts from which the Court can plausibly infer liability; Count Three, which is wholly derivative of Count One, necessarily fails as a result; and Count Two fails because the claims contained within are entirely preempted.

With respect to Count One, Plaintiffs have failed to set forth factual allegations sufficient to allow the Court to plausibly infer a negligence cause of action. A very generous reading of the complaint does allow for a plausible inference that Defendant Jenny owed a duty to Plaintiff Ingrid Anderson, because Plaintiffs allege that Jenny held herself out to Plaintiff Ingrid Anderson as Defendant Boston Scientific's representative and as Plaintiff's liaison to the doctor who implanted the device. Similarly, the complaint can liberally be read to include facts sufficient to support an inference that Defendant Jenny breached that duty when she failed to make herself available to Plaintiff and when she failed to communicate information about Plaintiff's condition to the doctor who implanted the device. However, as Defendants correctly note, the complaint contains no factual allegations that can support a plausible inference of causation. Instead, Plaintiffs simply assert in the complaint that Plaintiff's injuries were "a proximate result of the negligent misconduct of

the defendants and/or the defective spinal cord stimulator" (doc. 2). Later in the complaint, Plaintiffs assert that "Defendant's defective product and/or defendant's [sic] conduct directly and proximately caused or contributed to" Plaintiff's injuries (Id.). These are legal conclusions, not factual allegations, and "[w]hile legal conclusions can provide the framework for a complaint, they must be supported by factual allegations." Iqbal, 556 U.S. at 679.

Plaintiffs seem to contend that their complaint should be allowed to proceed because they can't get to the facts that would support their causes of action without discovery (doc. 8, "it is impossible for Plaintiff to be certain how the [stimulator] injured her because there has not yet been discovery"). Unfortunately for Plaintiffs, discovery cannot be used as a fishing expedition to uncover the facts necessary to support the causes of action presented in the complaint, "even when the information needed to establish a claim…is solely within the purview of the defendant or a third party." New Albany Tractor, Inc., v. Louisville Tractor, Inc., 650 F.3d 1046, 1051 (6th Cir. 2011). Plaintiffs "may not use the discovery process to obtain facts after filing suit." Id. Absent factual support from which the Court may plausibly infer negligence, Count One fails to meet the pleading standard set

forth by the Supreme Court in Iqbal and Twombly and must therefore be dismissed.

With respect to Count Two, the spinal cord stimulator at issue here is subject to the Medical Device Amendments (the "MDA"), 21 U.S.C. §360k(a), which amended the Federal Food Drug, and Cosmetic Act. The MDA expressly preempts states from imposing requirements "different from, or in addition to" federal requirements. 21 U.S.C. § 360k(a)(1)-(2). In 2008, the Supreme Court determined that once a medical device receives premarket approval from the Food and Drug Administration (the "FDA"), the MDA's preemption clause bars common law claims challenging the safety and effectiveness of that medical device. Riegel v. Medtronic, Inc., 552 U.S. 312, 321-24 (2008). Using a two-step analysis, the court determined that the FDA's premarket approval process imposes federal "requirements" as understood by the MDA. Id. at 322. Next, the court determined that allowing the plaintiffs' state claims to proceed would impose state requirements "different from, or in addition to" premarket approval requirements. Id. at 324.

Pursuant to Riegel, the Court must first determine whether the spinal cord stimulator is subject to federal requirements and, if so, whether Plaintiffs' state-law claims impose requirements that are different from or in addition to

the federal requirements. The first inquiry is easily answered: the spinal cord stimulator is subject to federal requirements because it received premarket approval from the FDA. See Riegel, 552 U.S. at 322-3 ("Premarket approval…imposes 'requirements' under the MDA…."). The second question is just as easily answered. Plaintiffs' state-law claims assert negligent manufacture, inspection, maintenance and design, as well as breach of implied warranties of fitness (doc. 2). However, Plaintiffs did not allege a single specific manufacturing or design defect in the stimulator or provide any factual basis from which the Court could plausibly infer that Defendant Boston Scientific violated FDA manufacturing, inspection or maintenance standards. The MDA preempts Count Two because Plaintiffs would have to show that the stimulator should have been manufactured, designed, inspected and/or maintained in a manner different from that approved by the FDA. See, e.g., Kemp v. Medtronic, Inc., 231 F.3d 216, 220 (6th Cir. 2000) ("To permit a jury to find Medtronic negligent for failing to manufacture [an approved medical device] with [a component different than what the FDA approved] would be to impose a requirement different from and in addition to those established by the FDA.").

Plaintiffs argue in response to Defendants' motion

that their product liability claim should not be dismissed because it is a parallel claim and because Congress did not intend to foreclose all recourse to plaintiffs. Unfortunately for Plaintiffs, they are wrong on both points. First, their claim is not a parallel claim. State claims that are "premised on a violation of FDA regulations" are not preempted by the MDA because such state duties would be "parallel" to federal requirements rather than additional to them. Riegel, 552 U.S. at 330. Plaintiffs have not, however, alleged a parallel claim because there is nothing in the complaint that even approximates an allegation, let alone anything providing factual support for that allegation, that the spinal cord stimulator deviated from FDA requirements.[1] Instead, Plaintiffs' claims assert that Defendant Boston Scientific either breached duties owed to Plaintiff Ingrid Anderson or did not comply with Ohio's product

[1] In their response, Plaintiffs cite Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010) for the proposition that they need not specify the precise defect or regulatory requirement that was violated (doc. 8). That case cites a Sixth Circuit case where the court reversed a grant of summary judgment on a medical device on the basis that the plaintiff's negligence per se claim for violations of the Good Manufacturing Practices, which were incorporated into the premarket approval process of the device at issue, was not preempted. Howard v. Sulzer Orthopedics, Inc., 382 Fed.Appx. 436 (6th Cir. 2010). Neither case can save Plaintiffs' complaint here because, unlike those two cases, Plaintiffs simply do not allege—or provide any factual support for an allegation of—violations of federal law. Plaintiffs' complaint is expressly premised on violations of state law. As such, neither Bausch nor Howard is availing.

liability law, and those claims are entirely dependent on state law. In essence, the complaint alleges that Defendant Boston Scientific violated state law notwithstanding its compliance with the FDA premarket approval process. This is not a parallel claim.

Second, as the Supreme Court discussed in Riegel, Congress did indeed foreclose the very avenue Plaintiffs seek to take. This point was raised by the dissent in Riegel and dispensed with by the majority:

> The dissent would narrow the pre-emptive scope of the term "requirement" on the grounds that it is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for consumers injured by FDA-approved devices…. But, as we have explained, this is exactly what a pre-emption clause for medical devices does by its terms. The operation of a law enacted by Congress need not be seconded by a committee report on pain of judicial nullification….It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available—the text of the statute—suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.
> Riegel, 552 U.S. at 326 (internal citations omitted).

Plaintiffs' policy argument cannot stand in the face of the Supreme Court's decision in Riegel.

IV. Conclusion

Because Plaintiffs' complaint fails to set forth

sufficient factual allegations from which the Court can infer a plausible claim for relief and because Plaintiffs' product liability cause of action as pled is preempted, Defendants' motion is GRANTED and Plaintiffs' complaint is dismissed without prejudice to filing an amended complaint within thirty days of the filing of this order, should Plaintiffs be in a position to cure the defects identified herein.

SO ORDERED.

Dated: February 19, 2013 s/S. Arthur Spiegel
S. Arthur Spiegel
United States Senior District Judge