UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

ALLIE LANE and FLORENCE LANE,	)	
	)	
Plaintiffs	)	
	)	
v.	)	**3:14 CV 1982**
	)	
BOSTON SCIENTIFIC CORPORATION,	)	
	)	
Defendant	)	

ORDER and OPINION

This matter is before the court on defendant Boston Scientific Corporation's (hereinafter, "Boston Scientific") motion to dismiss plaintiffs Allie and Florence Lane's ("the Lanes") complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). The well-known legal standard applicable is that, with the complaint's factual allegations accepted as true, dismissal for failure to state a claim pursuant to Rule 12(b)(6) is appropriate when those facts are not enough to make a right to relief plausible, meaning more than speculative. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007); *Vinson v. Vermilion Cty., Illinois*, 776 F.3d 924, 928 (7th Cir. 2015). To avoid dismissal. the well-pleaded factual content must allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 678.

The Lanes' amended complaint (DE # 11) pleads that plaintiff Allie Lane ("Allie") had a medical device surgically implanted into his back called a Precision Plus ™ Implantable Pulse model #SC-1110-02, with serial #235086. The device was designed

and manufactured by Boston Scientific, and intended to relieve back pain by providing electrical pulses. The device is what is known as a Class III Medical Device under the federal Food, Drug, and Cosmetic Act, about which a bit more will be said shortly.

Not long after the operation Allie began experiencing severe shocks, which he understandably believed were being caused by some problem with the device, and he informed Boston Scientific of the issue. Approximately five months after the device was implanted, representatives of Boston Scientific determined that the battery in the device was discharging and depleting at a faster rate than expected, and that Boston Scientific would replace it under warranty. The surgeon who implanted the device indicated that it had malfunctioned and should be removed.[1]

The essence of Boston Scientific's argument is that the Lanes' claims are preempted by federal law because plaintiffs have failed to plead enough facts to show that a plausible non-preempted claim exists. Because the heart of the parties' disagreement is limited to one issue, the court need not engage in a lengthy reiteration of Boston Scientific's entire argument or of the issue of federal preemption. It will suffice to say that Class III Medical Devices, because they are extremely important to human health but also have a high potential risk for causing illness or injury, are subject to extensive federal regulation including a premarket approval process. Once a device is

[1] It apparently was later removed, but this is not alleged in the complaint. (DE # 16, Exhibit A at ¶ 14.)

approved, its manufacturer gains the benefit of an express preemption of liability claims:

> [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 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).

This provision does not, however, preempt a so-called "parallel" claim, which is a state common-law claim based on a violation of the federal laws and regulations applicable to the medical device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *Bausch v. Stryker Corp.*, 630 F.3d 546, 552-53 (7th Cir. 2010). In *Bausch*, which involved a hip-replacement device, the plaintiff pleaded that the defendant had violated federal regulatory standards applicable to the device causing an unreasonably dangerous device to be implanted in plaintiff, and that prior to plaintiff's surgery the defendant knew or should have known the device was defective. *Bausch*, 630 F.3d at 558-59. The Seventh Circuit reversed the district court's dismissal of plaintiff's complaint, finding no "fatal defect in the original complaint that would have justified its dismissal." *Id.* at 559.

The Lanes argue that, just as in *Bausch*, they have adequately pleaded a parallel state claim. Their amended complaint alleges at paragraph 20 that the device implanted

in Allie was "manufactured and distributed in violation of Federal law," more specifically:

> 17. That the actions of the defendant are violative of . . . Federal law particularly 21 U.S.C. §360 et. seq. as amended and the regulations set forth by the Federal Food and Drug Administration including but not limited to the Quality System Regulation and Current Good Manufacturing practices 21 C.F.R. §820.1(a)(1), and other mandates as set forth under Federal law;
> 18. That the defendant's failure to comply with the applicable provisions set forth above render the spinal cord stimulator adulterated as set forth under Section 501 (h) of the Act;
> 19. That the aforementioned product failed to comply with Section 820.90 and 21 C.F.R. Sections 820.72 – 820.90, and the product which had been implanted into Plaintiff Allie Lane failed to comply with product specifications as approved by the FDA through the pre-market approval process.

(DE # 11 at 3-4.)

Boston Scientific argues that these allegations are nothing more than legal conclusions and fall short of establishing a plausible claim:

> Plaintiffs' reliance on *Bausch* is misplaced because the *Bausch* plaintiff pled several key **facts** linked to specific regulatory violations that plausibly supported a parallel claim that would survive preemption. In contrast, Plaintiffs here have pled nothing more than legal conclusions of unspecified federal regulations with no underlying supporting facts to connect them to Plaintiffs' alleged injuries.

(DE # 17 at 1.) The key facts Boston Scientific is talking about that were available to the *Bausch* plaintiffs were that complaints had been received almost two years prior to the implantation of the hip-replacement device; that defendant had previously recalled components of the device; and that prior to its implantation in plaintiff, and the FDA

had warned the defendant about deficiencies in the manufacturing process. *Bausch*, 630 F.3d at 559.

The Lanes have alleged no such facts,[2] and Boston Scientific argues that without them the Lanes "cannot unlock the doors to discovery." (DE # 17 at 2.) Boston Scientific has cited a number of cases stating that the sole fact that a Class III Medical Device malfunctions is not indicative that it was manufactured in violation of federal law because of the numerous other reasons why such a device could fail, for example, poor surgical technique. *See, e.g.*, *Clark v. Medtronic*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008); *Cafferty v. Cayuga Med. Ctr.*, No. 5:08-CV-0179 NPM/ATB, 2011 WL 541809 (N.D.N.Y. Feb. 8, 2011); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 531-32 (S.D. Tex. 2009); *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 308 (E.D. Pa. 2009); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 438 (E.D. Pa. 2004); *Enlow v. St. Jude Med., Inc.*, 327 F. Supp. 2d 738, 743 (W.D. Ky. 2003) (listed in same order as cited by Boston Scientific, DE # 17 at 7-8).

However, the fact that a device can fail for many reasons does not by itself make failure because of a defect violating a regulation applicable to the device implausible. Manufacturing processes "are not perfect" and were a patient harmed because a "production worker's blood or mucus . . . caused an infection after implantation, that

[2] According to Boston Scientific, this is because no such facts exist. That does not necessarily rule out the possibility that this case could be the first example of problems to come, or of an isolated manufacturing defect that would nevertheless violate federal law applicable to the device.

contamination would present a substantial claim for violating [federal] requirements." *Bausch*, 630 F.3d at 555. More to the point, none of this precedent Boston Scientific cites is from the Seventh Circuit, and its argument echoes one the Seventh Circuit considered and rejected in *Bausch*. Discussing *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir.2010), where the court had affirmed dismissal of a complaint that "failed to identify specific violations of federal law," *Bausch*, 630 F.3d at 554, the Seventh Circuit stated that it "essentially agree[d]" with the dissenting opinion in *Medtronic* that plaintiffs can "not be expected to plead their claims with greater specificity without discovery to obtain access to confidential government and company documents." *Id*.

In short, the court believes that under the applicable precedent in this circuit, the Lanes' amended complaint is sufficient to state a plausible claim. As the Seventh Circuit stated in *Bausch*, in applying the *Twombly/Iqbal* plausibility standard to complaints involving Class III Medical Devices, district judges:

> [M]ust keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.

Id. at 558. In *Bausch* the Seventh Circuit went on to explain that while the defendants therein, like here, "object[ed] that the original complaint does not specify the precise defect or the specific federal regulatory requirements that were allegedly violated,"the Court of Appeals did "not believe the absence of those details shows a failure to comply

with Rule 8 of the Federal Rules of Civil Procedure or can support a dismissal under Rule 12(b)(6)." *Id*. at 560. The reasons for this were fourfold.

First, "Rule 9(b) does not impose any special requirement that such a claim be pled with particularity, as it does for fraud claims, for example." *Id*. Second, "the victim of a genuinely defective product—for example, . . . an implantable cardiac defibrillator that delivers powerful electric shocks to a heart that is functioning normally—may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem." *Id.*

> Third, in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law. The specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public access to complete versions of these documents. An injured patient cannot gain access to that information without discovery.

Id. Fourth and last:

> It is also unreasonable to expect . . . [a complaint to be] pled more specifically without access to the failed Trident [medical device] itself, but accessing the Trident outside of a discovery process would risk charges of spoliation of evidence[.] . . . As Judge Melloy noted in *Medtronic Leads*: "If plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion." *Id*. [623 F.3d] at 1212 (Melloy, J., dissenting).

Id. at 561.

The Lanes have pleaded that Allie Lane received powerful and painful shocks from Boston Scientific's Precision Plus medical device, that the device's battery was discharging too quickly, and that both Boston Scientific and the surgeon who implanted

the device indicated that it should be replaced. That is enough to plead a plausible parallel state claim based on possible violation(s) of federal standards. Accordingly, Boston Scientific's motion to dismiss (DE # 13) is **DENIED**. The Lanes' motion for a pretrial conference (DE # 18) is **GRANTED**, and Magistrate Judge Gotsch will hold a conference at his and the parties' earliest convenience.

SO ORDERED.

Date: September 26, 2016

s/James T. Moody
JUDGE JAMES T. MOODY
UNITED STATES DISTRICT COURT