UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

ERIKA CHIASSON, ET AL	*	**CIVIL ACTION**
	*	
versus	*	**Nos. 16-789;**
	*	**16-3552; 16-3721**
	*	
MEDTRONIC INC, ET AL	*	**SECTION "L" (4)**

ORDER & REASONS

Before the Court are three Motions to Dismiss filed by Defendants Medtronic Inc., Medtronic Puerto Rico Operations, and Medtronic Logistics, LLC (collectively, "Medtronic") in three separate cases which have been consolidated for purposes of discovery and pretrial motions. Because the three Motions to Dismiss raise substantially similar questions of law, the cases were also consolidated for oral argument, which took place on August 3, 2016. Having reviewed the briefs and the applicable law and having considered the parties' oral arguments, the Court now issues this Order & Reasons.

I. BACKGROUND

This products liability case concerns the SynchroMed® II Implantable Infusion System, which is comprised of an implantable pump, specifically the 8637 SymchroMed® II Infusion Pump (the "Pump"), and a Model 8709SC catheter (the "Catheter") (together, the "Device"). All three Plaintiffs suffered lower back pain and, in an attempt to mollify that pain, chose to have the Device surgically implanted. All the plaintiffs allege post-surgery complications with the device spanning a period of years, including that the Device did not relieve their pain. Chiasson and Taylor both had the pumps explanted.

The Device has a history of malfunctioning, as documented by the FDA. On August 29, 2011, the FDA issued a Class I Recall of the Device due to the "potential for reduced battery performance that can lead to sudden loss of therapy." *See, e.g.*, 16-789 R. Doc. 37 at 5. All three devices fell within the scope of this recall. In May 2013, Medtronic issued an "URGENT: Medical Device Removal" letter to customers who had devices such as Plaintiffs'. *See, e.g., id.* at 5-6. Plaintiffs claim that they never received this letter. On April 27, 2015, United States District Court Judge Joan Erickson signed a Consent Decree of Permanent Injunction against Medtronic, prohibiting the manufacture and sale of the Device outside the terms of the decree. *See, e.g., id.* at 30. Within a year from the date of the Consent Decree, each Plaintiff filed a claim against Medtronic.

Plaintiffs allege that Medtronic is responsible for medical expenses and their lost quality of life during the years they battled the effects of the defective Device, and accordingly seek compensation under the Louisiana Products Liability Act ("LPLA"), specifically, as was elucidated in oral argument on August 3, 2016, defective manufacturing.

II. PRESENT MOTION

Medtronic filed three separate motions to dismiss. The Motion to Dismiss in *Erika Chiasson v. Medtronic Inc., et al* was filed on June 8, 2016 (R. Doc. 40), Plaintiff's response was filed on July 26, 2016 (R. Doc. 46), and Defendants' reply was filed on August 2, 2016 (R. Doc. 49). The Motion to Dismiss in *Janet Taylor v. Medtronic Inc., et al* was filed on June 29, 2016 (R. Doc. 14), Plaintiff's response was filed on July 26, 2016 (R. Doc. 25), and Defendants' reply was filed on August 2, 2016 (R. Doc. 30). The Motion to Dismiss in *Musser et al v. Medtronic Inc., et al* was filed on July 1, 2016 (R. Doc. 13), Plaintiff's response was filed on July 26, 2016 (R. Doc. 23), and Defendants' reply was filed on August 2, 2016 (R. Doc. 27).

Relying largely on the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq* ("FDCA"), Medtronic contends that Plaintiffs' claims are expressly and impliedly preempted by the FDCA's regulatory regime. *See, e.g.*, 16-789 R. Doc. 40-1 at 8-19. Medtronic also argues that the Plaintiffs' claims are untimely and that they fail to state a claim. *See, e.g., Id.* at 20-25.

III. Discussion

The Federal Rules of Civil Procedure permit a defendant to seek a dismissal of a complaint based on the "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In considering a motion to dismiss under Rule 12(b)(6), the Court accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007). But the Court "do[es] not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005). A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corporation et al v. William Twombly*, 550 U.S. 544, 545 (2007)). Dismissal is appropriate only if the complaint fails to plead "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft*, 556 U.S. at 678.

A. Preemption

"The Supremacy Clause of the Constitution prohibits state laws from conflicting with federal law." *Gomez v. St. Jude Medical Daig Div. Inc.*, 442 F.3d 919, 928-29 (5th. Cir. 2006)

(citing U.S. CONST. art. VI, cl. 2). Therefore, "[a] 'state law that conflicts with federal law'" is federally preempted and "'without effect.'" *Id*. at 929 (quoting *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 516 (1992)).

Federal preemption "may be either expressed or implied." *Gade v. National Solid Wastes Management Association*, 505 U.S. 88, 98 (1992). Inevitably, "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 106 (1963)). Congressional intent is primarily "discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." *Id*. at 486 (quoting *Gade*, 505 U.S. at 111, 112). However, the Court should also review the "'structure and purpose of the statute as a whole'" in order to determine "the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id*. (quoting *Gade*, 505 U.S. at 98).

In 1976, Congress passed the MDA, which established a regulatory regime to approve and monitor the manufacture and sale of medical devices. The regulatory regime created by the MDA established three levels of "oversight for medical devices, depending on the risks they present." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Class I devices are "subject to the lowest level of oversight" such as "labeling requirements." *Id*. (citing 21 U.S.C. § 360c(a)(1)(A)). Class II devices are subject to all of the Class I requirements and additional "'special controls' such as performance standards and postmarket surveillance measures." *Id*. at 316-17 (quoting 21 U.S.C. § 360c(a)(1)(B)). Class III devices are subject to the "most federal oversight." *Id*. These devices either support or sustain human life, substantially prevent impairment of human health, or present a potentially unreasonable risk of injury or illness. *Id*.

(citing 21 U.S.C. § 360c(a)(1)(C)(ii)). The Medtronic device at issue in the present case is a Class III device.

The Food and Drug Administration ("FDA") subjects all new Class III devices to premarket approval ("PMA"), at which time the "manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective." *Lohr*, 518 U.S. at 477 (quoting 21 U.S.C. § 360e(d)(2)). "Premarket approval is a 'rigorous process,'" and the FDA spends "an average of 1,200 hours reviewing each application." *Riegel*, 552 U.S. at 317-18 (quoting *Lohr*, 518 U.S. at 477).

The doctrine of preemption, especially as it relates to the FDA and products liability, varies among and within the circuits. Interpreting the MDA,[1] the Supreme Court has held that state law tort claims asserted in federal court can be either expressly or impliedly preempted by the MDA. *See Riegel* 552 U.S. 312 (2008); *Lohr* 518 U.S. 470 (1996). "The Supreme Court has twice addressed the preemption of state-law claims regarding medical-device liability pursuant to 360(k), most recently in Riegel. . . . Riegel, like the Court's earlier decision in [*Medtronic v. Lohr*], makes clear that a medical device manufacturer is protected from liability under state-law tort claims related to a defective or dangerous device to the extent that the manufacturer has complied with federal statutes and regulations." *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 767 (2011).

[1] 1976 (MDA), 21 U.S.C. § 360c et seq. "Except as provided in subsection (b) of this section, 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)

1. *Express Preemption*

State law tort claims are expressly preempted if they rest on state law that imposes requirements different from or in addition to the FDA requirement. *Riegel* lays out a two-part test to determine preemption: (1) has the FDA established applicable requirements for this device, and (2) does the state law create requirements "different from, or in addition to" the relevant FDA requirements. *Riegel* 552 U.S. at 316. If a device complies with FDA regulations, there is no state law cause of action available to a Plaintiff.

Section 360(k) of the MDA does not prevent a state from providing state law damage remedies for FDA violations. In certain instances, "a manufacturer is not protected from state tort liability when the claim is based on the manufacturer's violation of applicable federal requirements." *Hughes* 631 F.3d at 767. *See also Riegel* 552 U.S. 312; *Lohr* 518 U.S. 470. To properly assert such a claim, however, Plaintiffs must plead a state law cause of action that is parallel to the allegedly-contravened federal regulation. *Riegel* 552 U.S. at 330; *Hughes* 631 F.3d at 774. For a state claim to be parallel to a federal violation, the state remedy must not create requirements that are different from or greater than the FDA requirements. *See Hughes* 631 F.3d at 767. *See also Riegel* 552 U.S. 312; *Lohr* 518 U.S. 470

The Fifth Circuit has, particularly in recent years, opened the door to such parallel claims. *See, e.g., Rodriguez v. Am. Med. Sys.*, 597 F. App'x 226, 228 (5th Cir. 2014) ("Section 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.")(quoting *Riegel*, 552 U.S. at 330); *Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012) ("Bass has sufficiently pleaded parallel claims in his first amended complaint, to the extent that the claims are based upon manufacturing defects resulting from violations of federal

regulations."); *Hughes* 631 F.3d 762 ("*Riegel*, *Lohr*, and *Gomez* are consistent in holding that claims for negligent failure to warn or negligent manufacturing of a device are not preempted, provided that such claims are premised entirely on violation of the applicable federal requirements."); *Gomez* 442 F.3d at 932 ("[A] lawsuit that simply parallels or enforces the federal regulatory requirements without 'threatening' or interfering with them is not preempted.")

2. *Implied Preemption*

In asserting a parallel claim, a Plaintiff cannot merely allege a Defendant's failure to comply with the FDA and, in so doing, seek to employ the FDA's exclusive enforcement power over certain medical devices. "The Supreme Court found that … Congress granted the FDA sole authority to enforce violations of the FDCA and MDA. Allowing state-law claims [such as] fraud on the FDA would have interfered with the delicate federal statutory scheme empowering the FDA to punish and deter fraud against it." *Bush v. Thoratec Corp.*, 837 F.Supp.2d 603, 609 (2011) (citing *Buckman Co. v. Plaintiffs' Legal Committee*, 5341 U.S. 341, 347-49 (2011)). A cognizable parallel claim must primarily assert the state law claims that are parallel to (i.e., not expressly preempted by) the FDA regulations. "We therefore hold that if a plaintiff pleads [in a state law claim] that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the CGMPs themselves and that this failure caused the injury, the plaintiff will have pleaded a parallel claim." *Bass v. Stryker Corp.*, 669 F.3d 501, 512-13 (5th Cir. 2012).

Essentially, in a parallel claim, relief is sought under state law alleging that certain conduct of the defendant resulted in a breach of a state duty, that this conduct also resulted in a breach of an FDA-imposed federal regulation, and that certain damages resulted from this

breach. If the Plaintiff fails to properly plead her parallel claim, that is, she pleads a violation of a state law that imposes different or additional regulations *or* she merely seeks to use the court as a runaround to enforce FDA regulations, her claim will be preempted.

Because of the potential for preemption, courts have required greater specificity in pleading parallel claims. *See, e.g.*, *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (finding Plaintiff's claim "impermissibly conclusory and vague" because it does not "specify the manufacturing defect; nor does it specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury. Nor does the complaint tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process."). *See also* Bass v. Stryker Corp., 669 F.3d 501, 511-12 (5th Cir. 2012) ("The key distinction between complaints [alleging state law causes of action] that are sufficient to withstand a motion to dismiss and those that are not is … the existence of a manufacturing defect caused by a violation of federal regulations and allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury.")

In this case, Plaintiffs have asserted some of the skeletal requirements for a cognizable parallel claim under the LPLA. They have not, however, plead with sufficient specificity for this Court to accurately determine whether a successfully parallel claim may exist. Plaintiffs initially plead 4 causes of action: (1) design defect under the LPLA (LA. R.S. 9:2800.56); (2) inadequate warning under the LPLA (LA. R.S. 9:2800.57); (3) Breach of Express Warranty under the LPLA (LA. R.S. 9:2800.56); and 4) Redhibition (La. C.C. art. 2520). During the oral argument for this matter, the Plaintiffs clarified that their claim was primarily for manufacturing defect: a claim mentioned but not plead with sufficient clarity in their amended complaints.

Because of the complex nature of this area of law and in the interest of justice, this Court has given plaintiffs in similar cases an opportunity to amend their complaints to clarify the parallel claim, specifically to plead a violation of state law, a parallel violation of a federal regulation, and the connection between that violation and the Plaintiff's injury. *See, e.g.*, *Cenac v. Hubbell*, No. 09-3686, 2010 U.S. Dist. LEXIS 114733, at *3 (E.D. La. Oct. 21, 2010) (granting plaintiff two opportunities to amend and clarify her parallel claim); *Bush v. Thoratec Corp.*, 837 F.Supp.2d 603, 609 (2011) (granting plaintiff leave to amend the complaint to attempt to "thread the needle" and state a cognizable parallel claim).

"[T]he issue is whether [Plaintiff] sufficiently pleaded that his … claims are causally related to [Defendant's] alleged violations of the FDA's requirements." *Bass* 669 F.3d at 519 (holding that because the Plaintiff incorporated all his factual allegations into his claim, the claims survive even though they are not particularly clear). So too here, the Plaintiff incorporates all of her factual allegations into each claim. While under *Bush*, this broad pleading does preserve Plaintiffs' claims, the lack of specificity in their allegations makes it difficult for the Court, and, likely, for the Defendant, to determine exactly what Plaintiffs' claims are and whether or not they are parallel. This Court therefore grants Plaintiffs leave to amend their complaints to plead their parallel claims with greater specificity, particularly the federal regulation that Defendant breached, the parallel state claim, and its causal nexus to Plaintiffs' injuries.

B. Prescription

It is premature at this time to consider prescription. First, if the amended complaints fail to correct the deficiencies in the pleadings, the claims will be preempted and the issue of

prescription will be moot. Second, even if not mooted, a prescription claim is often pregnant with facts and may require some discovery to determine whether or not the claims are prescribed.

Each Plaintiff filed their Complaint more than one year after both the Device was implanted and they began experiencing complications with the Device. Because Louisiana has a one-year prescriptive period for tort claims, the timing of the Plaintiffs' filings, raises questions of prescription. "[The prescription of delictual actions] commences to run from the day injury or damage is sustained." La. Civ. Code art. 3492 (2016). In Louisiana, damages are considered sustained "only when [the damage] has manifested itself with sufficient certainty to support accrual of a cause of action." *Cole v. Celotex Corp.*, 620 So.2d 1154, 1156 (La. 1993) (citing *McCray v. New England Ins. Co.*, 579, So.2d 1156 (La. App. 2 Cir. 1991)).

If a cause of action has accrued, Louisiana's prescriptive period may be tolled through the equitable doctrine of *contra non valentem*. *See Grenier v. Med. Eng'r Corp.*, 243 F.3d 200, 203-04 n.2 (5th Cir. 2001) (explaining the distinction between the accrual of an LPLA cause of action and *contra non valentem*). "The doctrine of *contra non valentem agere nulla curit praescriptio* prevents the running of liberative prescription where the cause of action is not known or reasonably knowable by the plaintiff." *Cole*, 620 So.2d at 1156-57. In other words, "Louisiana's one-year prescriptive period does not begin to run until the plaintiff has actual or constructive knowledge of the tortious act, the damage, and the causal relationship between the tortious act and the damage." *Knaps v. B & B Chem. Co.*, 828 F.2d 1138, 1139 (5th Cir. 1987) (citing *Duhon v. Saloom*, 323 So.2d 202, 204 (La. App. 3 Cir. 1975); *see also Aucoin v. Amneal Pharm., LLC*, No. 11-1275, 2012 WL 2990697, at *4 (E.D. La. July 20, 2012) (citing *Ducre v. Mine Safety Appliances, Inc.*, 963 F.2d 757, 760 (5th Cir. 1992). Courts have summarized the *contra non valentem* doctrine as an inquiry into the "reasonableness" of the

victim's behavior in light of his perceived injuries. *See Carter v. Matrixx Initiatives, Inc.*, 392 Fed. App'x 343, 345 (5th Cir. 2010) (citations omitted) ("When prescription begins to run depends on the *reasonableness* of a plaintiff's action or inaction."); *see also Chevron USA, Inc. v. Aker Mar., Inc.*, 604 F.3d 888, 893-94 (5th Cir. 2010) ("When a plaintiff acts reasonably to discover the cause of a problem, the prescriptive period does not begin to run until he has a reasonable basis to pursue a claim against a specific defendant."); *Griffin v. Kinberger*, 507 So.2d 821, 823-24 (La. 1987) ("Prescription will not run as long as it was *reasonable* for the victim not to recognize that the condition might be treatment related.").

Upon review of the facts and the statements made at oral argument, the Court finds it inappropriate to dismiss the present cases at this stage of the litigation. In cases of medical products liability, the accrual of a cause of action and the reasonableness of delay in filing suit often hinge on the testimony of the plaintiff and his or her doctor. For example, in *Guidry v. Aventis Pharmaceuticals, Inc.*, 418 F.Supp. 2d 835 (M.D. La. 2006), the plaintiff "began experiencing symptoms of nausea, vomiting, diarrhea, loss of weight and problems with her sense of smell" after taking the drug Arava. *Id.* at 841. The *Guidry* plaintiff subsequently contacted her doctor, who reported that Arava could be responsible for her symptoms, and she advised that the plaintiff should stop taking the drug. *Id.* The district court granted summary judgment on the grounds that the plaintiff's prescriptive period began to run following her discussion with her doctor. *Id.* at 841. In contrast, the Louisiana Supreme Court held in *Guitreau v. Kucharchuk* that two consultations with a doctor were insufficient to trigger prescription. 1999-2570 (La. 5/16/00), 763 So. 2d 575, 576. In *Guitreau*, the plaintiff underwent a knee surgery, and afterwards experienced swelling and a worsening of his condition. The plaintiff's employer became concerned, and referred the plaintiff to the company physician. The plaintiff met with the company doctor three times: once for an

examination of his knee, once for a discussion of the results of the examination, and once to "talk[] with [plaintiff] about his alternatives." *Id.* at 577. After the discussion regarding the results of the examination but before the discussion of medical alternatives, the plaintiff consulted with an attorney "just to be safe." *Id.* at 580. The Louisiana Supreme Court held that the prescriptive period was triggered by the visit to an attorney, and not by the initial medical examination or the discussion of the results of the examination. *Id.* In so holding, the Louisiana Supreme Court found it relevant that "the medical records do not reflect when or if [the company doctor] suggested to plaintiff that his condition was the result of negligent treatment," and that the discussion of the need for additional surgeries occurred after the meeting with the attorney. *Id.*

So too here. The Plaintiffs' claims may be prescribed, but the facts presented on the face of the Complaint are sufficient to entitle the parties to discovery. Each of the Plaintiffs had post-operative discussions with a medical professional about the medical device at issue. Without discovering the content of these interactions, the Defendants cannot present sufficient evidence to foreclose the Plaintiffs' claims as a matter of law.

C. Failure to State a Claim

Medtronic lastly contends that Plaintiffs' Amended Complaints should be dismissed for failure to satisfy federal pleading standards, asserting that the Plaintiffs allege no facts linking their injuries to a defect in the Device caused by a violation against the FDA, and that they fail to sufficiently address the elements of their LPLA claims. *See, e.g.*, 16-789 R. Doc. 40-1 at 22-25. Medtronic also avers that the Amended Complaints' allegations of an express or implied warranty are merely conclusory and do not survive Medtronic's Rule 12(b)(6) challenge. *See, e.g., id.* at 23. Because this claim is necessarily related to the question of preemption, the Court

finds that the preemption issue must be addressed prior to deciding whether Plaintiffs fail to state a claim.

IV. CONCLUSION

Accordingly, this Court grants Plaintiffs leave to amend their complaints to further elucidate their parallel claims, specifically the allegedly violated federal regulations, the parallel state claims, and the connection between that violation and Plaintiffs' injuries. IT IS SO ORDERED.

New Orleans, Louisiana, this 9th day of August, 2016.

UNITED STATES DISTRICT JUDGE