UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

GARY WAYNE SKINNER, ET AL	*	**CIVIL ACTION NO. 2:16-cv-107**
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	*	
v.	*	**JUDGE MINALDI**
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	*	
ST. JUDE MEDICAL, INC.	*	**MAGISTRATE JUDGE KAY**

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MEMORANDUM RULING

Before the court is a Motion to Dismiss (Rec. Doc. 14) filed by defendant St. Jude Medical, Inc. Plaintiffs Gary Wayne Skinner and Cherlyn Skinner did not file a response. For the following reasons, the Motion to Dismiss (Rec. Doc. 14) will be **GRANTED**.

FACTS & PROCEDURAL HISTORY

On February 11, 2013, Gary Skinner underwent surgery to receive a Trifecta Valve, a heart valve manufactured by St. Jude Medical.[1] The Food and Drug Administration ("FDA") classifies the Trifecta Valve as a Class III medical device and has granted it premarket approval (PMA).[2] Several months after the surgery, Gary Skinner began having difficulty breathing along with other health issues that caused him to make several emergency room and physician visits.[3] On November 17, 2014, Gary Skinner was admitted to the hospital to determine the basis of his health problems.[4] Diagnostic tests revealed that his Trifecta Valve needed to be replaced.[5] The Skinners allege that the Trifecta Valve was defective and forced Gary Skinner to undergo another surgery to replace the valve on December 13, 2014.[6]

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[1] Am. Compl (Rec. Doc. 11), ¶¶ 1, 3.
[2] *See* Order Granting Judicial Not. (Rec. Doc. 18).
[3] Am. Compl (Rec. Doc. 11), ¶ 3.
[4] *Id.* at ¶ 5.
[5] *Id.*
[6] *Id.* at ¶¶ 6-7.

The Skinners originally filed suit in the Fourteenth Judicial District Court for Calcasieu Parish, Louisiana.[7] On January 22, 2016, St. Jude Medical removed the case.[8] Subsequently, St. Jude Medical filed a Motion to Dismiss, Or, Alternatively, a Motion for a More Definite Statement, arguing that the Skinners' complaint was insufficiently pleaded.[9] The Skinners filed an amended complaint in response, and St. Jude Medical withdrew its original motion to dismiss.[10] On March 28, 2016, St. Jude Medical filed the present motion to dismiss.[11]

LAW AND ANALYSIS

Motions to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure seek the dismissal of an action for failure to state a claim and challenge the sufficiency of a plaintiff's allegations. *See* FED. R. CIV. PRO. 12(b)(6). In the Fifth Circuit, Rule 12(b)(6) motions to dismiss are generally viewed with disfavor and should rarely be granted. *Harrington v. State Farm Fire & Cas. Co.*, 563 F.3d 141, 147 (5th Cir. 2009) (quoting *Gregson v. Zurich Am. Ins. Co.*, 322 F.3d 883, 885 (5th Cir. 2003)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "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." *Id.* (quoting *Twombly*, 550 U.S. at 556). "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 679. When deciding a 12(b)(6) motion to dismiss, the Court "must consider the complaint in its entirety as well as other sources . . . in particular,

[7] Pet. for Damages (Rec. Doc. 1-1).
[8] Notice of Removal (Rec. Doc. 1).
[9] Mot. to Dismiss (Rec. Doc. 9).
[10] *See* Am. Compl. (Rec. Doc. 11).
[11] Mot. to Dismiss (Rec. Doc. 14).

documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights Ltd.*, 551 U.S. 308, 322 (2007).

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, was amended by the Medical Device Amendments ("MDAs") of 1976, 21 U.S.C. § 360c *et seq.*, "which swept back some state obligations and imposed a regime of detailed federal oversight" into the realm of medical device production and sales in the United States in the wake of what had come to be perceived as the "inability of the common-law tort system to manage the risks associated with dangerous [medical] devices." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008). The MDAs also contain an express preemption provision, *see* 21 U.S.C. 360k(a), the disputed applicability of which forms the basis of St. Jude Medical's main argument.

The MDAs group medical devices into various classes, with the degree of required federal oversight depending on into which class a given device falls. *See Riegel*, 552 U.S. at 316-17 (citations omitted). Class III devices are those which receive the most federal oversight, such as "replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators." *Id.* at 317 (citation omitted). Such devices are subject to a "rigorous regime" of premarket approval. *Id.* Although the PMA process is rigorous and very involved,[12] a device's passing through the PMA process does not imbue that device with a no-harm guarantee. As the Supreme Court noted in *Riegel*, the current statutory scheme requires the FDA to "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Riegel*, 552 U.S. at 318 (*quoting* 21 U.S.C. § 360c(a)(2)(C)). As a result, the agency "may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.*

[12] *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (citations omitted) (noting that "[m]anufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission").

In *Riegel*, a case strongly relied upon by St. Jude Medical, the plaintiffs sued the manufacturer of a balloon catheter—a Class III device—after the catheter ruptured within the plaintiff's heart. *Id.* at 320. The Supreme Court, noting that "the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law," stated that it must first be determined whether federal requirements applicable to the device in question were in place. *Id.* at 321 (*citing* 21 U.S.C. § 360k(a)(1)). If so, it then must be determined whether the common law claims "are based upon [state law] 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 321-22 (*citing* 21 U.S.C. § 360k(a)). The Court was careful to leave room for so-called "parallel" proceedings, wherein the state requirements upon which the state claims are predicated are *not* "different from, or in addition to" the applicable federal requirements, permitting such claims to survive an attack on preemption grounds. *Riegel*, 552 U.S. at 330.

Furthermore, claims predicated on state law that seek only to enforce federal law are impliedly preempted. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 344 (2001). The federal statutory scheme imbues the FDA with the power and authority to deter fraud against the administration, and dole out punishment, when necessary. *Id.* at 348. The enforcement of the various provisions of the FDCA is thus entrusted to the federal government, not to private plaintiffs. *See, e.g., Ramirez v. Medtronic, Inc.*, No. cv-13-00512-PHX-GMS, 2013 U.S. Dist. LEXIS 118822, at *18 (D. Ariz. Aug. 21, 2013). This concept is clearly set forth in the statutory language of 21 U.S.C. § 337(a), which states that, "[e]xcept as provide in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States." However, courts have distinguished between claims which seek to assert

FDCA enforcement actions against a medical device manufacturer and those claims which seek to assert a state law tort claim. *See, e.g., Bass v. Stryker Corporation*, 669 F.3d 501, 513-14 (5th Cir. 2012) (citations omitted).

The Fifth Circuit's recent opinion in *Bass v. Stryker Corporation*, 669 F.3d 501 (5th Cir. 2012), expounded upon *Riegel*. In *Bass*, the plaintiff sued Stryker under a variety of state law theories based upon the alleged malfunction of his hip replacement, which had been manufactured by Stryker. *Bass*, 669 F.3d at 505. In determining whether the *Bass* plaintiff's claims were preempted, the Fifth Circuit, applying *Riegel*, stated that "[d]evices that are approved through PMA procedures *automatically* satisfy the 'federal requirements' prong" of the preemption inquiry. *Id.* at 507 (*citing Riegel*, 552 U.S. at 322) (emphasis added).

Turning to the second prong of the preemption inquiry—whether the state law requirements impose different or additional requirements to those set forth by federal law—the *Bass* court stated that,

> [a]lthough "common-law causes of action for negligence and strict liability do impose 'requirement[s],'" *Riegel*, 552 U.S. at 323-24; *see also id.* at 324 ("Absent other indication, reference to a State's 'requirements' includes its common-law duties."), that is not the end of our inquiry. "[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." *Id.* at 330.

Bass, 669 F.3d at 508-09 (emphasis added). The pleading requirements of a "parallel" claim, as set forth in *Funk v. Stryker Corporation*, 631 F.3d 777 (5th Cir. 2011), were relied upon by the *Bass* court.

The *Funk* court dismissed the plaintiff's complaint therein because the complaint did not identify the specific manufacturing defect, "nor d[id] 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 d[id] the complaint [explain] how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process." *Bass*, 669 F.3d at 509 (*quoting Funk*, 631 F.3d at 782). In contrast, the *Bass* court found that the plaintiff therein had "sufficiently pleaded parallel claims . . . to the extent that the claims [were] based upon manufacturing defects resulting from violations of federal regulations."[13] *Id.* at 510.

The Trifecta Valve was granted premarket approval, and thus the federal requirements prong of the preemption inquiry is automatically satisfied. As for the second prong, it is difficult to discern whether any of the Skinners' claims are parallel claims because the amended complaint contains little more than a laundry list of bare, conclusory allegations. *See Funk*, 631 F.3d at 782. Normally, leave would be granted to cure such defects. However, the court notes that the Skinners have already amended their complaint once in response to a motion to dismiss with little discernable benefit, and have also entirely failed to oppose the present motion to dismiss. This leads the court to conclude that the Skinners are unable to remedy the deficiencies in their amended complaint. Because any claims that could have potentially survived the preemption inquiry are insufficiently pleaded, the motion to dismiss will be **GRANTED**.

Lake Charles, Louisiana, this 24 day of July, 2016.

PATRICIA MINALDI
UNITED STATES DISTRICT JUDGE

[13] *See also Bass*, 669 F.3d at 510 (stating that "[u]nlike the *Funk* complaint, Bass 'specifies with particularity what went wrong in the manufacturing process and cites the relevant FDA manufacturing standards Stryker allegedly violated'").