UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

Sons

versus

Medtronic Inc.

Civil Action No. 6:12-2579

Judge Richard T. Haik, Sr.

Magistrate Judge C. Michael Hill

MEMORANDUM RULING

Before the Court is a Motion To Dismiss filed by defendant, Medtronic, Inc. ("Medtronic"), plaintiff's Opposition to the Motion To Dismiss [Rec. Doc. 22], plaintiff's Amended Complaint [Rec. Doc. 24], Medtronic's Motion To Dismiss Supplemental Complaint [Rec. Doc. 25], Plaintiff's Opposition to Medtronic's Supplemental Motion To Dismiss [Rec. Doc. 31] and Medtronic's Reply Memorandum thereto [Rec. Doc. 33]. While the foregoing motions were set by the Clerk of Court for hearing on oral argument, the Court finds that this matter is appropriate for determination on the written briefs. For the reasons which follow, the Court will grant Medtronic's Motion To Dismiss Supplemental Complaint.

Background

This matter arises out of the September 11, 2002 surgery performed on plaintiff, Kenneth Sons, during which his treating physician, Dr. Patrick J. Welch, implanted a pacemaker in his chest. Plaintiff alleges that he has suffered with medical issues as a result of Dr. Welch failing to appropriately wire the pacemaker and defendant, Medtronic, Inc., failing to "adequately monitor the "emplacement, benefits, and function of the implanted pacemaker." *R. 1; Exh. A.* Plaintiff's Amended Complaint alleges that he was implanted with a Medtronic pacemaker system comprised of the following devices: (1) Medtronic Model 8040 InSync Pacemaker, serial Number

PIN631876S; (2) Medtronic Model 40068-58 CapSure Fix Lead, Serial Number LCE260376V; (3) Medtronic Model 419388 Attain OTW Lead, Serial Number BAA016412V; and (4) Medtronic Model 5076-45 CapSure Fix Novus Lead, Serial Number PJN231232V (collectively referred to as "the Medtronic Devices"). *R. 24,* ¶*3.* Plaintiff also alleges that "[a]ll defects in the function and emplacement of the pacemaker were unbeknownst to [him] until he failed his Coast Guard mandated employment physical." *Id. at* ¶ *4.* He further alleges that he underwent surgery to replace the pacemaker on March 29, 2012 and that after the surgery he was informed "that the previous pacemaker had been wired incorrectly and provided no benefit to his health whatsoever during the time it was implanted in his body." *Id.* Finally, plaintiff alleges he continued to suffer with medical issues such as shortness of breath and fatigue as a result of the incorrectly wired pacemaker. *Id.* Medtronic filed its original Motion To Dismiss on October 12, 2012. *R. 8.* On November 15, 2012, plaintiff filed an Amended Complaint addressing Medtronic's motion. *R. 24.* On December 6, 2012, Medtronic filed a Supplemental Motion to Dismiss Plaintiff Kenneth Sons' Amended Complaint which Medtronic indicates "supersedes" its original Motion To Dismiss. *R. 25.* In light of Medtronic's representation, the Court will dismiss the original Motion To Dismiss as moot and consider only Medtronic's Supplemental Motion To Dismiss in which Medtronic argues that plaintiff's claims are all preempted by federal law.

Legal Standard

"The ultimate question in a Rule 12(b)(6) motion is whether the complaint states a valid claim when all well-pleaded facts are assumed true and are viewed in the light

most favorable to the plaintiff." *Lone Star Fund V (U.S.), L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir.2010) (citing *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir.2007)). "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." *Reyna v. Donley,* 479 Fed.Appx. 609, 611 (5th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotations omitted)). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Robinson v. Coca–Cola Co.*, 477 Fed.Appx. 232, 235 (5th Cir. 2012) (citing *In re Katrina Canal Breaches Litig.*, 495 F.3d at 205). The court must not evaluate the likelihood of the claim's success, but instead ascertain whether the plaintiff has stated a legally cognizable claim that is plausible. *Lone Star Fund*, 594 F.3d at 387 (citing *Iqbal*, 556 U.S. 662).

"The pleading standards for a Rule 12(b)(6) motion to dismiss are derived from Rule 8 of the Federal Rules of Civil Procedure, which provides, in relevant part, that a pleading stating a claim for relief must contain 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *In re McCoy*, 666 F.3d 924, 926 (5th Cir.2012) (quoting Fed.R.Civ.P. 8(a)(2)). Although the court must accept all allegations in a complaint as true, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. 662 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). "Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law." *Neitzke*

v. Williams, 490 U.S. 319, 326 (1989) (citing *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984).

Law and Analysis

The Medical Device Amendments

In response to a bevy of state laws regulating medical devices largely enacted due to the failure of the Dalkon Shield contraceptive in the 1970s, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") in 1976. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 336 (2008). The MDA authorizes the U. S. Food and Drug Administration ("FDA") to regulate the safety and effectiveness of medical devices.

Under the MDA there are three classes for medical devices depending on the risks the device presents. Class III devices are subject to the greatest level of FDA scrutiny and "must complete a thorough review process with the FDA before they may be marketed." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001).

Pre-market approval ("PMA") of Class III medical devices is a rigorous process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). "Once a device has received pre-market approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel* at 319 (citing 21 U.S.C. § 360e (d)(6)(A)(I)). Further, "[i]f the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental pre-market approval, to be evaluated under largely the same criteria as an initial application." *Id.* (citing 21 U.S.C. 360e(d)(6); 21 C.F.R. § 814.39(c)).

To preserve federal regulatory authority over medical devices, § 360k of the MDA sets forth an express preemption clause that prohibits states from imposing "any requirement which is different from, or in addition to, any requirement ... which relates to the safety or effectiveness of [a Class III PMA medical device intended for human use]...." 21 U.S.C. § 360k(a). The preemption clause establishes a two-step procedure for determining if state law claims are preempted. *Riegel* at 321. First, a court must determine whether "the Federal Government has established requirements applicable to the particular medical device." *Id.* Second, the court must determine whether the state law claims raised by the plaintiff would impose requirements that are "different from or in addition to" the federal requirements. *Id.* If both of these conditions are satisfied, then the claim is preempted. *Id.*

Claims involving a Class III PMA medical device satisfy the first condition of the test for preemption because the PMA process establishes specific "requirements applicable to [particular devices.]" *Id.* Similarly, state duties underlying negligence and strict-liability claims impose "requirements" with respect to medical devices. *Id.* at 322–323. Accordingly, state tort claims are necessarily preempted to the extent that they impose duties on Class III PMA medical devices that are "different from or in addition to" the requirements set forth by the FDA. *Id.* at 329; *Gomez v. St. Jude Medical Daig Division, Inc.*, 442 F.3d 919, 929 (5th Cir.2006).

State tort claims against manufacturers of Class III PMA medical devices that are not premised on violations of federal requirements impose duties that are "different from or in addition to" the requirements set forth by the FDA. "These claims cannot be presented to a jury because, if successful, they would be inconsistent with the

federal regulatory requirements." *Gomez* at 933. To the extent that state tort claims against manufacturers of Class III PMA medical devices are premised on violations of federal law, however, such claims do not impose duties that are "different from or in addition to" the requirements set forth by the FDA. *Riegel* at 312. "[T]he state duties in such a case "parallel," rather than add to, federal requirements." *Id.*

A plaintiff must, therefore, set forth a parallel claim to recover state tort damages for injuries suffered from a defective Class III PMA medical device. *Id.* at 330. In his Amended Complaint, plaintiff alleges that his "claims are parallel, State and Federal." *R. 24, ¶ 7.*

Whether Plaintiff's Claims Are Preempted Under The MDA

While it is not evident from the face of the Complaint and Amended Complaint that the devices at issue are Class III, Medtronic has provided to the Court a number of FDA Websites which indicate that the FDA considered the Medtronic Devices and each has received pre-market approval. Plaintiff offers no argument or evidence to rebut Medtronic's evidence on this point. In deciding a motion to dismiss the court may consider documents attached to or incorporated in the complaint and matters of which judicial notice may be taken pursuant to Federal Rule of Evidence 201(b). *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011). A court "may take judicial notice of and consider the public records of the FDA ... without transforming a [motion to dismiss] into a motion for summary judgment." *Rollins v. St. Jude Medical*, 583 F.Supp.2d 790, 805 (W.D.La.2008) (citation omitted). The Court takes judicial notice of the FDA Websites stating that the Medtronic Devices are Class III PMA medical

devices, and accordingly, finds that the first prong of the *Riegel* preemption analysis is met in this case.

Plaintiff's Amended Complaint asserts claims against Medtronic under the Louisiana Products Liability Act ("LPLA") for defects in the products' design, manufacture, inspection, and marketing and failure to provide adequate warnings, as §well as claims for negligence, strict liability and failure to train/instruct the medical community. *R. 24, ¶ 6(a)-(x).* Thus, the Court must next determine whether the second *Riegel* prong is also met.

As provided in the foregoing, plaintiff cannot plead a parallel claim under state law if his complaint seeks to impose duties that are "different from or in addition to" the requirements established by federal law. *See Riegel*, 552 U.S. at 328. The Court must therefore determine whether any of these theories seek to impose a requirement to use a design, manufacturing process or warnings "different from, or in addition to" those approved by the FDA.[1]

Initially, Medtronic argues that plaintiff does not allege the manner in which his Medtronic Devices were defective, nor that they malfunctioned. Instead, Medtronic argues, plaintiff "makes vague assertions about 'defects in the function' of his pacemaker and that his 'pacemaker had been wired incorrectly ....'" The Court agrees that plaintiff's counts are pleaded abstractly, lacking any specifics to back them, and

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[1] In his Opposition Memorandum, plaintiff cites *Medtronic v. Lohr*, 518 U.S. 491 (1996) in support of his "parallel claims" position. Plaintiff's reliance is misplaced as *Lohr* is not applicable in this case. The devices in *Lohr* did not receive PMA approval, but instead received clearance through a much less rigorous process, § 510(k) clearance, requiring only that the manufacturer demonstrate that the device is a "substantial equivalent" of a Class III medical device that was already on the market prior to the MDA's enactment in 1976. *See Riegel*, 552 U.S. at 317-19.

that most of these counts contain overlapping allegations. However, because the Court finds that plaintiff's claims are preempted, it is not necessary to address the plausibility of plaintiff's claims under *Twombly*.

1. Design and Manufacturing Defect

Plaintiff alleges that Medtronic "design[ed] and manufactur[ed] a defective and unreasonably dangerous product" "in such a way that there was a high probability that injury would occur." *R. 24, ¶ 6(f)-(g).* Plaintiff further alleges that Medtronic "design[ed] a pacemaker not fit for its intended use" and that Medtronic "fail[ed] to use a better designed pacemaker," "fail[ed] to color code wiring" and "fail[ed] to provide some sort of indicator to ensure that the pacemaker is in an operational condition." *Id. At ¶ 6(o), (u) - (w).* In essence, plaintiff challenges the FDA's findings concerning the safety of Medtronic's devices which necessarily imposes requirements that are different from, or in addition to federal regulations. As such, plaintiff's defective design claims are expressly preempted. *See, Riegel* at 327-28; *Funk*, 631 F.3d 779 (upholding grant of dismissal because design-defect claims against PMA-approved device were preempted). *See, e.g.,Bass v. Stryker Corp.*, 669 F.3d 501, 518 (5th Cir. 2012) (upholding dismissal on Rule 12 grounds of strict liability and negligence claims premised on failure to warn and marketing defect claims).

2. Failure To Warn

Plaintiff also alleges that Medtronic "fail[ed] to warn of the existence of an unreasonably dangerous defect in the product" and "fail[ed] to take proper corrective action upon notice of dangerous defects, including recall, redesign and/or replacement of any defective part." *R. 24, ¶ 6(h)-(l).* Plaintiff further alleges that Medtronic

"fail[ed] to design some sort of warning or safety if pacemaker was implanted incorrectly." *Id. at ¶ 6(s).* "To permit a jury to decide [a plaintiff's] claims that the information, warning, and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations." *Cenac v. Hubbell*, 2010 WL 4174573, at *6 (E.D.La., 2010) (quoting *Gomez v. St. Judge Med. Diagnosis Div. Inc.*, 442 F.3d 919, 932 (5th Cir.2006). Because plaintiff's failure to warn claims would require a finding that Medtronic should have provided different or additional warning than those approved and required by the FDA as part of the PMA process, these claims are preempted.

3. Negligence and Strict Liability

Plaintiff alleges that Medtronic: was "the seller and/or custodian of the pacemaker in question," fail[ed] to keep an accurate accounting of the location and number of defective products," fail[ed] to use accurate measures to confiscate the defective products," and "fail[ed] to properly monitor the benefits and function of the pacemaker." *R. 24 ¶ 6(b)-(e).* Plaintiff further alleges that he "wouldn't have had surgery if it was known that the pacemaker did not operate properly." *Id at ¶ 6(a).* Ultimately, plaintiff alleges, "[o]ther acts of negligence and/or manifestations of fault will be proven at trail[sic]..." *Id at ¶ 6(x).* The Court interprets these allegations as claims of negligence against Medtronic. In order for plaintiff to succeed on a negligence claim, he must demonstrate that, notwithstanding the FDA's regulation of medical devices and specific PMA requirements for its manufacture, Medtronic failed to exercise reasonable care. Such negligence claims are preempted because they

impose requirements that are different from or in addition to the federal requirement of pre-market approval.[2] *See Riegel*, 552 U.S. at 320 ("the MDA pre-empted ... claims of ... negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the [device]."); *Bass*, 669 F.3d at 514.

Plaintiff alleges that Medtronic "design[ed] an unreasonable dangerous product which included conditions which made the product more dangerous than it was designed to be and which caused damages from a reasonably anticipated use of the product" and "fail[ed] to design a pacemaker with proper safeguards to prevent mis-wiring during surgical emplacement." *R. 25, ¶ 6(l)-(m), (r).* As this Court has observed, "in the ten months following *Riegel*, courts across the country have applied Section 360k broadly, preempting all manner of claims from strict products liability and negligence ... to failure to warn and manufacturing-and-design defect." *Lemelle v. Stryker Orthopaedics*, 698 F.Supp.2d 668, 682–83 (W.D.La., 2010) (noting that state law product liability claims are preempted by the MDA). Thus, any claim that Medtronic defectively designed the Medtronic Devices is expressly preempted. *Riegel*, 552 U.S. at 327-28; *see also Funk*, 631 F.3d at 779.

Even if plaintiff could rely on the theories of negligence and strict liability to prove his case, it is well-established that the LPLA "establishes the exclusive theories of liability for manufacturers for damages caused by their products" and state law claims are therefore barred under Louisiana law, La. R.S. § 9:2800.52. "Louisiana does not recognize any claim for violations of FDA regulations. The only remedies

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[2] Plaintiff has not pleaded specific facts as to how the marketing/accounting of the Medtronic Devices violated FDA regulations. *See. Bass*, 669 F.3d at 515.

available to plaintiffs in this case are provided in the LPLA." *Doucet, et al v. Danek Medical, Inc., et* al, 1999 WL 1129648 (W.D. La., 1999). Accordingly, pursuant to the LPLA, plaintiff's claims against Medtronic for negligence and strict liability are not viable as independent theories of recovery outside of the LPLA framework. *See King v. Bayer Pharmaceuticals Corp.,* 2009 WL 2135223, 4 (W.D.La., 2009) (citing *Jefferson v. Lead,* 106 F.3d 1245, 1251 (5th Cir.1997).

5. Failure to Instruct

Plaintiff alleges that Medtronic "fail[ed] to properly train, supervise, and/or equip the doctors and/or surgical techs responsible for emplacement of their product," "fail[ed] to ensure that the pacemaker was properly installed," fail[ed] to provide a representative of Medtronic at Plaintiff's surgery," and fail[ed] to provide a representative of Medtronic to educate the physician implanting the Medtronic pacemaker." *Id.,* ¶ *6(n), (p),(q),(t).* In *Riegel,* the Supreme Court held that any attempt to impose a requirement relating to the safety or effectiveness of the device that is different from, or in addition to, federal requirements is preempted. *Riegel* at 327-28; *see also Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919, 926 (5th Cir. 2006)(failure to train medical personnel claim was preempted as a matter of law).

Nevertheless, even assuming *arguendo* that plaintiff's failure to train/instruct claims are not preempted, plaintiff has failed to state a claim for which relief can be granted. It is well established that a medical device manufacturer is not responsible for the practice of medicine. In *Swayze v. McNeil Laboratories, Inc.*, 807 F.2d 464, 468 (5th Cir. 1987), the Fifth Circuit refused to impose on a manufacturer a "duty to intrude into the hospital operation as well as the doctor-patient relationship." In affirming the trial court's grant of directed verdict in favor of a drug manufacturer on plaintiff's

negligence claims, the court stated, "[i]t is both impractical and unrealistic to expect drug manufacturers to police individual operating rooms to determine which doctors adequately supervise their surgical teams;" *see also Hall v. Horn Medical, LLC*, 2012 WL 1752546, at *3 (E.D. La. 2012) (finding it "patently unreasonable" for a "seasoned neurosurgeon .... to rely on a sales representative's opinion about the type of procedure that should be employed in operating on a patient's spine."

Conclusion

As provided in the foregoing, the Court finds that: (1) plaintiff's claims against Medtronic regarding the Medtronic InSync Pacemaker, CapSure Fix Lead, Attain OTW Lead, and CapSure Fix Novus Lead are preempted by the FDA's pre-market approval of these Medtronic Devices; (2) plaintiff's negligence, strict liability and failure to instruct/train claims are prohibited by the exclusivity provisions of the LPLA and therefore fail to state a claim; and (3) plaintiff's failure to instruct claim must fail because Medtronic is not responsible for the manner in which these devices were implanted. The Court will therefore grant Medtronic, Inc.'s Motion To Dismiss Supplemental Complaint.

Signed in Lafayette, La on Jan 14, 2013.

RICHARD T. HAIK, SR.
UNITED STATES DISTRICT JUDGE