UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

DEBORAH PARDO, ET AL.	*	**CIVIL ACTION**
	*	
VERSUS	*	**NO. 10-1562**
	*	
MEDTRONIC INC., ET AL.	*	**SECTION "B"(5)**

ORDER AND REASONS

Before the Court is Defendant Medtronic's Motion to Dismiss (Rec. Doc. No. 4), Medtronic's Motion for Request for Judicial Notice in Support of its Motion to Dismiss (Rec. Doc. No. 8) Plaintiffs' Memorandum in Opposition (Rec. Doc. No. 10), and Defendant's Reply Memorandum(Rec. Doc. No. 18).

This case is a product liability action arising from the implantation of a medical device manufactured by Defendant Medtronics; the Medtronic RestoreULTRA Rechargeable Neurostimulation System "Restore System" is a system which transmits electrical sitmuatilion to the spine which relives pain by interrupting pain signals to the brain. (Rec. Doc. 4-1 at 3) The Restore System consists of several pieces including the Neurostuimulator, a pain simulator lead, and a lead extension kit which all act to deliver electrical stimulation to the spine. *Id.* When prescribed by a physician, the system is implanted in a patient's body. *Id.* Plaintiff Mrs. Pardo had the Restore System implanted to relieve pain in her right occipital nerve by Defendant Dr. Elkersh. (Rec. Doc. 1-8 at 1) The complaint alleges that

defendants are liable for injuries and damages resulting from the "defective neurosimulator" which Mrs. Pardo agreed to have implanted because "Dr. Elkersh and representatives of Medtronics assured her that the neurostimulator would significantly reduce the pain . . . and reduce her reliance on pain medications." *Id.* The complaint further alleges that, after realizing that the device was not relieving her pain, Mrs. Pardo returned to the pain clinic where Medtronics Representatives attempted to adjust the device but to no avail; thereafter, Dr. Elkersh told her to find another physician. *Id.* at 2. Following a December 18, 2009 visit to the pain clinic, Mrs. Pardo left, allegedly after "no one would see her" and on her way home blacked out from severe pain and crashed her vehicle.

The case was removed from the 21st Judicial District Court on May 25, 2010.

Defendant Medtronics contends that each of the subject devices received premarket approval ("PMA") from the Food and Drug Administration ("FDA") and, in accordance with Supreme Court and Fifth Circuit jurisprudence interpreting the Medical Device Amendments of 1976 ("MDA"), the Pardos' claims are preempted by federal law. (Rec. Doc. No. 4) Additionally, Medtronics submits that, were the Pardos' claims not preempted, their complaint would still be subject to dismissal under FRCP 12(b)(6) pursuant to the Supreme Court's decisions in *Ashcroft v. Iqbal*, 129 S.Ct. 1937

(2009) and ***Bell Atlantic Corp v. Twombly***, 127 S.Ct. 1955 (2007). ***Id.***

Plaintiffs respond by asserting that there exists insufficient evidence to show the nerurostiumlator was in fact "approved pursuant to the Premarket Approval process." (Rec. Doc. 10 at 2) Plaintiff lists the parts of the device including two items not mentioned in Defendant's motion; the neurostimultor's battery recharger and the programer which "allows the user to set the strength/velocity of the electrical impulses." ***Id.*** Although plaintiff admits that these additional items were never implanted in Mrs. Pardo, Plaintiff does state that the PMA documentation listed by Defendant as "Exhibit B" does not identify the neurostimulator by model number, but the entire system as the "RestoreUltra Rechargeable Implantable Neurostimulation System." As such, Plaintiff argues that one cannot discern whether the neurostimulator underwent the Premarket Approval process. ***Id.*** at 3. By implication therefore, Plaintiff seems to acquiesce in Defendant's contention that, if a medical device receives Premarket Approval by the FDA, then claims against the manufacturer will be preempted under the MDA and Supreme Court precedent.

Plaintiff further argues that "[t]he most important issue in this matter is w hether the subject device was being used in a manner consistent with FDA's approval." ***Id.*** at 3. Plaintiff cites to the PMA documentation for the system and submits that ***assuming***

arguendo that the neurostimulator was covered by that PMA, that PMA approved the device for certain uses (almost all of which involve back or spinal pain) none of which involve the manner in which it was implanted in Mrs. Pardo. (Rec. Doc. No. 10 at 4) Plaintiff explains that the device was implanted in her right forehead, the leads funneled across the back of her neck into her right shoulder, all to relieve Mrs. Pardo's facial pain. Because plaintiff submits that the device was implanted in a manner inconsistent with the applicable PMA, Plaintiff observes that "[i]n all of the other cases cited by the defendant, the Class III medical devices were being used in a manner consistent with their approval." *Id.* at 5. Plaintiffs conclude this argument by stating, without citing to any supporting authority, that "[p]reemption was not intended to provide blanket protection from all liability, just liability consistent with the device's approved use." (Rec. Doc. No. 10 at 5).

Plaintiff next argues that Defendant breached an express warranty but fails to allege whether Mrs. Pardo relied on that warranty; additionally, Plaintiff defeats her own argument in the reply to Defendant's motion to dismiss.*Id.* at 6. Plaintiff quotes a portion of the warranty in the reply stating "[s]hould the Components fail to function within normal tolerances *due to a*

[1]"Class III" devices are those "receiving the most federal oversight." *Riegel v. Medtronic*, 552 U.S. 312, 317 (2008).

defect in the materials or workmanship within a period of . . . ." *Id.* Plaintiff then goes on to conclude that "[a]dmittedly, [Mrs. Pardo] has no idea why [the device] does not work - she only knows that it does not work, at all." *Id.* at 8. Thus, Plaintiff fails to allege that the warranty was ever in fact applicable.

For the reasons set forth below, the instant Motion to Dismiss pursuant to FRCP 12(b)(6) is hereby converted to a Motion for Summary Judgment under FRCP 56 as matters outside the pleadings are presented and is hereby **GRANTED**.

Law and Analysis

A. Summary Judgment Standard

Summary judgment is proper if the pleadings, depositions, interrogatory answers, and admissions, together with any affidavits, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986). A genuine issue exists if the evidence would allow a reasonable jury to return a verdict for the nonmovant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, (1986). Although the Court must consider the evidence with all reasonable inferences in the light most favorable to the nonmoving party, the nonmovant must produce specific facts to demonstrate that a genuine issue exists for trial. *Webb v. Cardiothoracic*

Surgery Assocs. of N. Texas, 139 F.3d 532, 536 (5th Cir. 1998). The nonmovant must go beyond the pleadings and use affidavits, depositions, interrogatory responses, admissions, or other evidence to establish a genuine issue. *Id.* Accordingly, conclusory rebuttals of the pleadings are insufficient to avoid summary judgment. *Travelers Ins. Co. v. Liljeberg Enter., Inc.* 7 F.3d 1203, 1207 (5th Cir. 1993). Finally "[w]hen matters outside the pleadings are considered, a motion for dismissal based on failure to state a claim is converted into a motion for summary judgment . . . ." *Roque v. Jazz Casino Co. LLC*, 2010 WL 2930876, at *2 (5th Cir. Jul. 22, 2010) (quoting *Fernandez-Montes v. Allied Pilots Ass'n*, 987 F.2d 278, 283 n.7 (5th Cir.1993).

B. Preemption Under The MDA

The MDA's preemption clause, 21 U.S.C. § 360k states:

> (a) General Rule: 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.
>
> (b) Exempt Requirements: Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--
>
> (1) the requirement is more stringent than a

> requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection . . . .

In ***Riegel v. Medtronic, Inc.*** 552 U.S. 312, the Supreme Court held that the MDA's preemption clause bars common-law claims challenging the safety or effectiveness of medical devices marketed in a form that received premarket approval from the FDA. Plaintiff, individually and as administrator of her husband's estate, sued Medtronic who manufactured the balloon catheter which burst when it was over inflated during the patient's angioplasty.[2] ***Id.*** The District Court's grant of summary judgment in favor of Medtronic on Plaintiff's breach of express warranty and negligent manufacturing claims were affirmed by the Second Circuit and thus, were not before the Supreme Court. ***Id.*** at 321 n.2.

Before the Court were plaintiff's common law claims of negligence, strict liability, and implied warranty. The Court explained at length the PMA process, calling it "rigorous", explaining that "[t]he FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety

[2] The balloon catheter at issue in ***Riegel*** was a Class III device that received premarket approval by the FDA; changes in its label received supplemental approval from the FDA as well. ***Id.*** at 320.

and effectiveness.'"[3] *Id.* at 318 (citing § 360e(d)). The Court articulated the FDA's power to withdraw PMA after it is granted as well as the reporting requirements to which devices having received PMA are subject. *Id.*

The Court then focused on the language of 21 U.S.C. § 360k(a)(1), specifically the "different from or in addition to" clause in light of the Second Circuit's finding that, the Plaintiff's claims "would, if successful, impose state requirements that differed from, or added to" the device-specific federal requirements." *Id.* at 321. The Court adhered to and broadened the view taken by the Court in *Medtronic, Inc. V. Lohr*, 518 U.S. 116 (1996) that "common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device.' *Id. at* 323-24. In broadening the holding of *Lohr*, finding that the statute does not require the preempted state requirements to apply only to a specific device, the Court stated "[a]bsent other indication, reference to a State's 'requirements' includes its common-law

[3] The Court also stated that "Premarket approval, in contrast, imposes 'requirements' under the MDA as we interpreted it in *Lohr*. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review-it *is* federal safety review." *Id.* at 322-23.

duties."[4]

In dismissing the last of the Riegels' contentions, the Court examined the text of § 808.1(b) of the MDA which "sets forth a 'general rule' pre-empting state duties 'having the force and effect of law (whether established by statute, ordinance, regulation, ***or court decision***).'" The Court added "[w]e are aware of no duties established by court decision other than common-law duties . . . ." ***Id.*** at 329. In addition to ***Riegel***, other cases reach substantially the same holding.[5]

CONCLUSION

Accordingly, Defendant's Motion for Request for Judicial Notice in Support of its Motion to Dismiss (Rec. Doc. No. 8) is hereby **GRANTED.** Defendant Medtronic's Motion to Dismiss pursuant to FRCP 12(b)(6) (Rec. Doc. No. 4) is hereby converted to a Motion for Summary Judgment as matters outside the pleadings are presented. ***See Roque v. Jazz Casino Co. LLC***, 2010 WL 2930876, at *2 (5th Cir. Jul. 22, 2010) (quoting ***Fernandez-Montes v. Allied***

[4] The Court further stated, citing the plurality opinion in ***Cipollone v. Liggett Group, Inc.***, 505 U.S. 504 (1992), "common-law liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation." ***Id.*** at 324.

[5] ***See Gomez v. St. Jude Medical Daig Div. Inc.***, 442 F.3d 919 (5th Cir.2006); ***Lemelle v. Stryker Orthopaedics***, 698 F. Supp.2d 668, 680 (W.D.La. 2010) (stating "that the PMA process preempts state tort causes of action to the extent that they relate to safety, effectiveness, or other MDA requirements if the state-law claims impose substantive requirements different from, or inconsistent with, the federal law.") (***citing Gomez***) (internal quotations omitted).

Pilots Ass'n, 987 F.2d 278, 283 n.7 (5th Cir.1993)(stating that "[w]hen matters outside the pleadings are considered, a motion for dismissal based on failure to state a claim is converted into a motion for summary judgment . . . .").

Further, Defendant Medtronic's Motion for Summary Judgment (Rec. Doc. No. 4) is hereby **GRANTED**. Finally, the portion of this Court's Order of October 26, 2010 administratively closing the above captioned matter and preserving the parties' right to file a motion to reopen the case within 30 days of receipt of a decision of the Medical Review Panel (Rec. Doc. No. 23) is hereby **VACATED**.

New Orleans, LA this 15th day of December, 2010.