UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

CIVIL ACTION

No. 09-3686

SECTION I/4

LINDSEY CENAC, ET AL

VERSUS

DR. PAUL J. HUBBELL, III, ET AL

ORDER AND REASONS

Before the Court is a motion to dismiss pursuant to Rule 12(b)(6) filed by defendant, Medtronic, Inc. ("Medtronic").[1] Plaintiffs, Lindsey and Cami Cenac oppose this motion.[2] For the following reasons, the motion is **GRANTED** and plaintiffs' claims against Medtronic are **DISMISSED WITH PREJUDICE**.

BACKGROUND

On April 24, 2009, plaintiffs filed this lawsuit on behalf of their deceased father, Ovide Cenac ("Mr. Cenac"). Plaintiffs allege that in March, 2008, defendant, Dr. Paul J. Hubbell ("Dr. Hubbell"), implanted a medication pump,[3] designed and manufactured by Medtronic, into Mr. Cenac. The pump was designed to dispense a controlled amount of medication directly into the area around the spine. Plaintiffs allege that on April 29, 2008, the pump malfunctioned and administered a lethal dose of medication, which caused Mr. Cenac's death.

In June 2009, Medtronic filed a motion to dismiss arguing that plaintiffs' claims were

preempted by federal law.[4] The Court denied the motion to dismiss, but ordered that plaintiffs could amend their complaint to plead a violation of federal law. Plaintiffs subsequently amended

[1] R. Doc. No. 54. [2] R. Doc. No. 57. [3] Plaintiffs' second amended complaint identifies this pump as a model 8637 SynchroMed pump serial number NGP315822H. R. Doc. No. 48, para H(i). Plaintiff alleges that the pump was programmed using a model 8840 SynchroMed II B programmer. R. Doc. No. 48. [4] R. Doc. No. 6.

their complaint. In September 2009, Medtronic once again moved to dismiss the amended complaint for failure to adequately plead a violation of federal law. Concluding that the amended complaint also failed to plead a sufficiently specific violation of federal law, the Court nevertheless denied Medtronic's motion, giving plaintiffs one more opportunity to amend their complaint.

After plaintiffs filed a second amended complaint asserting eleven causes of action, Medtronic filed the motion to dismiss that is currently under consideration. Medtronic argues that each of plaintiffs' claims is preempted by federal law.

STANDARD OF LAW

I. 12(b)(6)

A district court can dismiss a complaint, or any part of it, for failure to state a claim upon which relief can be granted if the plaintiff has not set forth a factual allegation in support of his claim that would entitle him to relief. *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65, 167 L. Ed. 2d 929, 940 (2007) (AFactual 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).@ (citations and footnote omitted)); *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th

Cir. 2007). Generally, the Court will not look beyond the factual allegations in the pleadings to determine whether relief should be granted. *See Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999); *Baker v. Putnal*, 75 F.3d 190, 196 (5th Cir. 1996).[5] In assessing the complaint, a court must accept all well-pleaded facts as true and liberally construe all factual allegations in the light most favorable to the plaintiff. *Spivey,* 197 F.3d at 774; *Lowrey v. Tex. A&M Univ. Sys.*, 117 F.3d 242, 247 (5th Cir. 1997).

[5] See, however, footnote 5 of this Order and Reasons.

> ATo survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead >enough facts to

state a claim to relief that is plausible on its face.=@ *In re Katrina Canal Breaches Litig.*, 495

F.3d 191, 205 (5th Cir. 2007) (*quoting Twombly*, 127 S. Ct. at 1974, 167 L. Ed. 2d at 949).

A>[C]onclusory allegations and unwarranted deductions of fact are not admitted as true= by a

motion to dismiss.@ *Id.* (*quoting Associated Builders, Inc. v. Ala. Power Co.*, 505 F.2d 97, 100

(5th Cir. 1974)). "[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to

relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal citations omitted).

II. THE FOOD, DRUG, AND COSMETIC ACT

In 1976, Congress enacted the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c et seq., to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq. The MDA established a "regime of detailed federal oversight," *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1003 (2008), with respect to the regulation of medical devices in order "to provide for the safety and effectiveness of medical devices intended for human use." Medical Device Amendments of 1976, Pub L. No. 94-295, 90 Stat. 539. Three levels of oversight for medical devices are provided by the MDA. Class III medical devices[6] receive the most stringent oversight and are "subject . . . to pre-market approval to provide reasonable assurance of its safety and efficacy." 21 U.S.C. § 360c(a)(1)(c).

> 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

[6] The Court notes that the pump's status as a Class III PMA medical device is not evident from the face of the complaint. "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." *Lovelace v. Software spectrum, Inc.*, 78 F.3d 1015, 1017-18 (5th Cir. 1996). 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 (E.D. La. 2008) (citation omitted). Further, no party disputes that the pump in question is a

Class III PMA medical device.

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*, 128 S. Ct. at 1005 (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." *Riegel*, 128 S. Ct. at 1005 (*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*, 128 S. Ct. at 1006. 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 1007-08. 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 1011; *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, 442 F.3d 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*, 128 S. Ct. at 1011. "[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. *Riegel*, 128 S. Ct. at 1011. As stated, the parties agree that the pump at issue is a Class III PMA medical device. Accordingly, to the extent that plaintiffs' claims are not premised on violations of FDA regulations, the claims are preempted by § 360k of the MDA as interpreted by the Supreme Court in *Riegel*.

DISCUSSION

Rule 8(a) of the Federal Rules of Civil Procedure provides the governing standard by

which the adequacy of the pleadings is tested. It requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "The function of a complaint is to give the defendant fair notice of the plaintiff's claim and the grounds upon which the plaintiff relies." *St. Paul Mercury Ins. Co. v. Williamson*, 224 F.3d 425, 434 (5th Cir. 2000).

The pleader is required to do more than merely incant labels, conclusions, and the formulaic elements of a cause of action. *Twombly*, 550 U.S. at 555.

I. Plaintiffs' allegations in the amended complaint

Plaintiffs' second amended complaint states that Medtronic is negligent:

> a) By failing to comply with 21 C.F.R. sec. 820.1 and failing to follow current good manufacturing practice (CGMP) requirements for the manufacturing, installation and servicing of [the devices] which malfunctioned in the programming and administration of the medication given to Ovide J. Cenac which resulted in his death when it knew that the manufacturing of the pump at its Minneapolis plant was causing missing propellant in the pump's reservoir which results in a drug overdose which could cause a serial increase in the concentration of a drug in the reservoir and cause an eventual drug overdose; b) By failing to comply with 21 C.F.R. sec. 820.70(a) by: (i) failing to properly follow the prescribed manufacturing process and ensure the proper controls were in place for [the devices]; (ii) failing to monitor the component characteristics during production; (iii) failing to comply with the specified reference standards or

codes; and, (iv) failing to follow the proper criteria for ensuring proper workmanship during the manufacturing process when it knew that the manufacturing of the pump at its Minneapolis plant was causing missing propellant in the pump's reservoir which results in a drug overdose which could cause a serial increase in the concentration of a drug in the reservoir and cause an eventual drug overdose. c) By failing to comply with 21 C.F.R. sec. 820.72 by: (i) failing to make sure the proper equipment was used to calibrate [the devices]; (ii) failing to follow the proper calibration procedures for [the devices]; and, (iii) failing to make sure the equipment used to calibrate [the devices] [was] properly calibrated, all failures which resulted in pump not having sufficient propellant in the pump's reservoir which results in a drug overdose which could cause a serial increase in the concentration of a drug in the reservoir and cause an eventual drug overdose; d) By failing to comply with 21 C.F.R. sec. 820.75 by failing to properly monitor the control methods and keeping the appropriate data regarding the process and use of the manufacturing equipment or maintaining validation of the equipment used in the manufacturing of [the devices] which malfunctioned in the programming and administration of the medication given to [Mr. Cenac] which resulted in his death as evidenced by the fact that Medtronic intentionally failed to submit 37 adverse event reports to the FDA;

II. The federal regulations cited by plaintiff are not specific enough to state parallel claims

A. CGMPs

As noted above, plaintiffs cannot plead a parallel claim under state law if plaintiffs' complaint seeks to impose duties that are "different from or in addition to" the requirements established by federal law. *See Riegel*, 128 S. Ct. at 1011. Defendant argues that plaintiffs'

complaint should be dismissed because the regulations relied upon by plaintiffs are not specific

enough to ever support a parallel claim. Defendant contends that the regulations cited by

plaintiffs are so vague that any requirements imposed by state tort law would necessarily be

"different from or in addition to" requirements imposed by federal law.

Paragraphs (a) – (d) of plaintiffs' second amended complaint base their parallel claims on

four provisions of the federally prescribed Current Good Manufacturing Practices ("CGMPs").

As stated in this Court's April 2010 order, several courts have found that given the "intentionally

vague and open-ended nature of the [CGMPs] . . . they cannot serve as the basis for a parallel

claim." *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009); *see also In re*

Fidelis Leads, 592 F. Supp. 2d, 1147, 1157 ("[The CGMPs] are simply too generic, standing

alone, to serve as the basis for Plaintiffs' manufacturing-defect claims.").

As previously determined by this Court,[7] an examination of the regulations cited by

plaintiffs in their second amended complaint reveals that they are, in fact, too vague to support a

parallel claim. 21 C.F.R. § 820.1[8] simply governs the applicability of the other regulations and

imposes no specific requirements on manufacturers of medical devices. § 820.70[9] requires

manufacturers to develop quality control processes, but leaves the specific provisions of such

processes to the discretion of the manufacturer. § 870.72[10] requires manufacturers to ensure that

[7] R. Doc. No. 47. [8] Cited by plaintiffs at R. Doc. No. 48, para. 8(a). [9] Cited by plaintiffs at R. Doc. No. 48, para. 8(b). [10] Cited by plaintiffs at R. Doc. No. 48, para. 8(c).

their measuring, calibration, and test equipment is "suitable for its intended purpose and []

capable of producing valid results." § 870.75[11] requires only that the manufacturer establish, maintain, and document procedures for monitoring the production process.

> None of the CGMF regulations cited by plaintiffs impose any specific requirements

related to Medtronic's manufacturing process or the Medtronic pump at issue. Accordingly, any tort liability based on those regulations would necessarily impose requirements that are "different from or in addition to" federal requirements and are preempted by federal law.[12]

B. 21 C.F.R. § 814.80

Plaintiffs' reliance on 21 C.F.R. § 814.80 in paragraphs (e) – (g) of the second amended complaint, fails for similar reasons.[13] Plaintiffs claim that Medtronic was negligent:

> e) By failing to comply with 21 C.F.R. sec. 814.80 and 21 C.F.R. Sec. 814.3a(d) which requires [sic] the manufacturer to meet ongoing reporting

> and other obligations to report experience with [the device] when Medtronic failed to report at least 37 adverse events, and failed to update and correct the Instructions For Use information previously approved by the FDA;[14] f) By failing to warn [Dr. Hubbell] pursuant to the requirements of 21 C.F.R. 814 et seq., sec. 814.80 and 21 C.F.R. sec. 814.3a(d) of the problems it knew of in the manufacturing of the pump at its Minneapolis plant which was causing the missing propellant in the pump's reservoir which results in a drug overdose which could cause a serial increase in the concentration of a drug in the reservoir and cause an eventual drug overdose;[15] g) By failing to warn and violating the express and implied warranty of the fitness of the product to [Mr. Cenac] pursuant to the requirements of 21 C.F.R. 814 et seq., sec. 814.80 and 21 C.F.R. sec. 814.3a(d) of the problems it knew of in the manufacturing of the pump at its Minneapolis plant which was causing the missing propellant in the pump's reservoir which results in a drug overdose which could cause a serial increase in

[11] Cited by plaintiffs at R. Doc. No. 48, para. 8(d). [12] This Court considers only those regulations specifically identified by plaintiffs in their second amended complaint. [13] Again, this Court considers only those regulations specifically identified by plaintiffs in their second amended complaint. Additionally, as defendant observes, 21 C.F.R. § 814.3a(d) does not currently appear in the Code of Federal Regulations. Accordingly, such regulation cannot provide the basis for a parallel claim. [14] Cited by plaintiffs at R. Doc. No. 48, para. 8(e). [15] Cited by plaintiffs at R. Doc. No. 48, para. 8(f).

> the concentration of a drug in the reservoir and cause an eventual drug overdose;[16]

21 C.F.R.§ 814.80 provides that "[a] device may not be manufactured, packaged, stored, labeled distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." By only generally asserting that defendant

is negligent in failing to adhere to such section's requirements, plaintiffs fail to allege the manner in which any action of defendant was inconsistent with the PMA. Such failure necessarily precludes plaintiffs from asserting a parallel claim. *See Riegel*, 128 S.Ct. at 1007 ("[P]remarket approval is specific to individual devices. . . . [T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness."). Accordingly, the regulations cited by plaintiffs are not specific enough to support parallel claims.

The claims asserted in paragraphs (e) – (g) of the second amended complaint fail for other reasons. First, the claims asserted in paragraph (e) fails because the Fifth Circuit has determined that "state-law claims relat[ing] to [a defendant's] alleged failure to provide information obtained after the FDA approved the [device] risk [interfering] with the federal regulatory scheme . . . and are preempted." *Gomez v. St. Judge Med. Diagnosis Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006). Paragraph (e) claims that Medtronic failed to provide and update information with respect to the device after FDA approved the device. Accordingly, such claims are preempted.

Second, the failure to warn claims asserted in paragraphs (f) and (g) fail because the

Fifth

Circuit has determined that, "[t]o permit a jury to decide [a plaintiff's] claims that the

[16] Cited by plaintiffs at R. Doc. No. 48, para. 8(g).

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 on [medical device manufacturers.]" *Id.* at 931. Because plaintiffs have identified no specific federal requirement mandating[17] that Medtronic warn Mr. Cenac and Dr. Hubbell of the alleged problems in the device's manufacturing process, permitting plaintiffs to go forward with the failure to warn claims asserted in paragraphs (f) and (g) would risk imposing obligations on Medtronic that are inconsistent from those imposed by the FDA in the PMA. *See also McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) ("Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted.") Accordingly, such claims are preempted.

Third, in *Riegel*, the United States Supreme Court determined that breach of implied

warranty claims relative to Class III devices are preempted. *Riegel*, 128 S.Ct. 1009-10. Accordingly, paragraph (g)'s breach of the "implied warranty of the fitness of the product" claim fails. Finally, although *Riegel* did not address express warranty claims, the Fifth Circuit has determined that applying Louisiana's law[18] governing claims of breach of express warranty claims to FDA-approved Class III devices would risk imposing inconsistent obligations on medical device manufacturers. *Gomez*, 442 F.3d at 932. Accordingly, plaintiffs' breach of express warranty claim is preempted.

III. The Louisiana statutes cited by plaintiffs are insufficient to support parallel claims

Paragraphs (h) – (k) of plaintiffs' second amended complaint assert that defendant was

[17] In fact, plaintiffs have failed to identify any specific federal reporting requirement.

[18] La. R.S. § 9:28000.58.

negligent in failing to adhere to the requirements of certain provisions of the Louisiana Products Liability Act ("LPLA").[19] Plaintiffs claim that Medtronic was negligent:

> h.) By violating LSA-R.S. 9:2800.52, as limited by 21 C.F.R. sec. 820, 21 C.F.R. sec. 820.70(a), 21 C.F.R. Sec. 820.72, and 21 C.F.R. Sec. 820.75, by permitting a product manufactured by Medtronic to be used in Louisiana

> when it knew that the product was improperly manufactured, said manufacturing defect rendering the product dangerous to use as reasonably intended, and which caused the death of [Mr. Cenac];[20] i.) By violating LSA-R.S.[]9:2800.54(a), as limited by 21 C.F.R. sec. 820, 21 C.F.R. sec. 820.70(a), 21 C.F.R. sec. 820.72, and 21 C.F.R. sec. 820.75, which states that a manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity, as reflected in the fact that Medtronic was supposed to have sent an urgent medical device correction letter to all physicians and healthcare professionals containing a warning about an increased rate of inflammatory masses in patients using various types of Synchromed Pumps, including the [device] that was implanted in [Mr. Cenac]. Medtronic failed to send this letter to [Dr. Hubble], as well as failing to advise [Mr. Cenac and/or Dr. Hubble], that the FDA issued a Class 1 recall for the dangerous and defective product that predictably could cause serious health problems or death;[21] j.) By violating LSA-R.S.[]9:2800.54(B), as limited by 21 C.F.R. sec. 820, 21 C.F.R. sec. 820.70(a), 21 C.F.R. sec. 820.72, 21 C.F.R. Sec. 820.75, 21 C.F.R. Sec. 814.80 and 21 C.F.R. Sec. 814.3a(d), by putting into the market and failing to warn healthcare professionals and patients that the [devices were] unreasonably dangerous in construction and design and that if [sic] failed to conform to the warranties of the product;[22] k.) By violating LSA-R.S. 9:2800.54(c), as limited by 21 C.F.R. sec. 820, 21 C.F.R. sec. 820.70(a), 21 C.F.R. sec. 820.72, and 21 C.F.R. sec. 820.75, in that at the time the pump left the manufacturing facility, the characteristic in the pump product rendered it unreasonably dangerous.[23]
>
> Nevertheless, plaintiffs fail to demonstrate the way in which the cited LPLA provisions

parallel a specific federal requirement. Such omission is unsurprising because, as another section of this Court has concluded, "there is no need for speculation as to whether the LPLA is a

[19] To the extent plaintiffs assert claims based on violations of CGMPs, such claims, as stated, are preempted for failure to sufficiently plead specific violations of federal law. [20] Cited by plaintiffs at R. Doc. No. 48, para.

8(h). [21] Cited by plaintiffs at R. Doc. No. 48, para. 8(i). [22] Cited by plaintiffs at R. Doc. No. 48, para. 8(j). [23] Cited by plaintiffs at R. Doc. No. 48, para. 8(k).

state requirement that is 'different from or in addition to' the federal requirements." *Bencomo v. Guidant Corp.*, Civil Action No. 06-2473, 2009 WL 1951821, at *5 (E.D. La. June 30, 2009) (Barbier, J.). "The state law [LPLA] that forms the basis for the plaintiff's claim creates [] state requirement[s] that [are] 'different from or in addition to' the federal requirement[s]." Id.

Accordingly, plaintiffs claims based on defendant's alleged violations of the LPLA are preempted.

CONCLUSION

IT IS ORDERED that the motion is **GRANTED** and that all of plaintiffs' claims against defendant are **DISMISSED WITH PREJUDICE**.

New Orleans, Louisiana, October ____, 21st 2010.

LANCE M. AFRICK UNITED STATES DISTRICT JUDGE