UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

MELINDA S. HINKEL, ET AL.	CIVIL ACTION
VERSUS	NO: 11-1608
ST. JUDE MEDICAL, S.C., INC.	SECTION: J(5)

ORDER AND REASONS

Before the Court are Defendant's Motion for Summary Judgment and Memorandum in Support **(Rec. Doc. 22),** Plaintiffs' Memorandum in Opposition **(Rec. Doc. 27)**, and Defendant's Reply Memorandum in Support of its Motion **(Rec. Doc. 31).** The motion is before the court on supporting memoranda and without oral argument.

PROCEDURAL HISTORY AND BACKGROUND FACTS

In June 2009, Plaintiff Melinda Hinkel underwent surgery to have a medical device called an Eon Mini Implantable Pulse Generator("IPG") implanted in her spine. The device was designed to relieve chronic back pain by sending low-intensity electrical impulses to selectively trigger nerve fibers along her spinal cord. Although the surgery was considered successful, Plaintiff's back pain reportedly persisted until June 16, 2010, when she had the IPG device removed and replaced with another similar spinal chord stimulator.

Approximately one year later, on June 14, 2011, Plaintiff, along with her husband Brett Hinkel (collectively, "Plaintiffs"), commenced this action against Defendant St. Jude Medical, S.C., Inc. ("St. Jude") in the 22nd Judicial District Court in St. Tammany Parish, Louisiana. In their petition, Plaintiffs alleged that the Eon Mini IPG System was manufactured by St. Jude, that it was defective at the time it was purchased, and that it had continuously malfunctioned during the year it was implanted in her spine, causing her bodily injury and pain. Based on these allegations, Plaintiffs sought damages for past and future medical expenses, pain and suffering, emotional damages, and loss of consortium.

On July 8, 2011, St. Jude removed the case to this Court on the basis of federal diversity jurisdiction. It answered shortly thereafter, denying any liability for Plaintiffs' claimed injuries and asserting various affirmative defenses. After completing discovery, St. Jude filed the instant motion.

PARTIES' ARGUMENTS

In its motion, St. Jude argues that it cannot be liable for Plaintiffs' injuries as a matter of law for principally two reasons. First, it argues the record conclusively demonstrates that it was not the "manufacturer" of the Eon Mini IPG System alleged to have caused Ms. Hinkel's injuries, as that term is

defined under the Louisiana Product Liability Act ("LPLA"). Instead, it maintains that it merely sold the device to the surgery center that had implanted it in Ms. Hinkel's spine. As St. Jude explains, the Eon Mini IPG system was manufactured by a company called Advanced Neuromodulation Systems, Inc. ("ANS"). While St. Jude Medical, S.C., Inc., and ANS are both wholly-owned subsidiaries of the same parent company, St. Jude Medical, Inc., they are distinct legal entities. Accordingly, because it was only a "mere seller" of the allegedly defective product, St. Jude submits that it cannot be liable for Plaintiffs' injuries under the LPLA.

Second, even if it is determined to be a manufacturer of the device under the LPLA, St. Jude argues that summary judgment is still proper because each of Plaintiffs' claims are completely preempted by federal law. It explains that the Eon Mini IPG System is a Class III medical device, as that term is defined by the Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1976, and was approved through the Federal Drug Administration ("FDA")'s rigorous pre-market approval process. The Medical Device Amendments include a preemption provision that expressly preempts any state law imposing requirements different from, or in addition to, the federal requirements for such devices. St. Jude contends that this provision, as interpreted by the United States Supreme Court's decision in Riegel v.

Medtronic, Inc., 552 U.S. 312 (2008), preempts Plaintiffs' claims.

In opposition, Plaintiffs argue that summary judgment is improper based on the evidence they have produced. They cite a voluntary recall letter dated December 19, 2011, in which St. Jude purportedly acknowledges complaints about the spinal cord stimulator at issue, and goes on to state that the company has "improved [its] manufacturing instructions."[1] Plaintiffs maintain that this is sufficient to demonstrate that there is at least a factual issue as to whether St. Jude is actually the manufacturer of the device at issue, or at least, that it held itself out as the manufacturer of the device, which is sufficient to make them a "manufacturer" under the terms of the LPLA.

With respect to St. Jude's preemption arguments, Plaintiffs do not appear to dispute that the Eon Mini IPG System is a Class III medical device under the MDA, or that the device has received FDA approval. Instead, under the Supreme Court's holding in Riegel, they argue that their claims are not preempted if they demonstrate a "violation of FDA regulations." See id. at 330 (noting that state-law claims are not preempted where they are "premised on a violation of FDA regulations"). Plaintiffs argue that if they can establish any one of the four bases under which a product is deemed "unreasonably dangerous" under the LPLA, this

[1] See Rec. Doc. 27-1.

would essentially be "no different from proving that St. Jude had deviated from FDA requirements," which is sufficient to escape preemption.[2]

In reply, St. Jude argues that Plaintiffs' arguments miss the mark. First, they argue that the voluntary recall letter attached to their opposition has not been authenticated and is thus not proper summary judgment evidence. They also note that the letter is not from St. Jude Medical, S.C., Inc., but rather *St. Jude Medical, Inc.*, which is its parent company. Regardless, however, St. Jude argues that Plaintiffs cannot avoid summary judgment, because they have failed to submit any evidence to establish that their claims are not preempted by the MDA.

LEGAL STANDARD

Summary judgment is appropriate when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c)(2); Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986); Little v. Liquid Air Corp., 37 F.3d 1069, 1075 (5th Cir. 1994). A material fact is a fact which, under applicable law, may alter the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Ameristar Jet

[2] Plaintiffs' Memorandum in Opposition, Rec. Doc. 27, p. 6.

Charter, Inc. v. Signal Composites, Inc., 271 F.3d 624, 626 (5th Cir. 2001). A dispute is genuine when a reasonable finder of fact could resolve the issue in favor of either party, based on the evidence before it. Anderson, 477 U.S. at 250; TIG Ins. Co. v. Sedgwick James of Wash., 276 F.3d 754, 759 (5th Cir. 2002).

When assessing whether a dispute as to any disputed issue of material fact exists, the Court considers "all of the evidence in the record but refrains from making credibility determinations or weighing the evidence." Delta & Pine Land Co. v. Nationwide Agribusiness Ins. Co., 530 F.3d 395, 398 (5th Cir. 2008). All reasonable inferences are drawn in favor of the nonmoving party, but a party cannot defeat summary judgment with conclusory allegations or unsubstantiated assertions. Little, 37 F.3d at 1075. A court ultimately must be satisfied that "a reasonable jury could not return a verdict for the nonmoving party." Delta, 530 F.3d 399.

If the dispositive issue is one on which the nonmoving party will bear the burden of proof at trial, the moving party may satisfy its burden by merely pointing out that the evidence in the record is insufficient with respect to an essential element of the nonmoving party's claim. See Celotex, 477 U.S. at 325. The burden then shifts to the nonmoving party, who must, by submitting or referring to evidence, set out specific facts showing that a genuine issue exists. Id. at 324. The non-movant may not rest upon the pleadings, but must identify specific facts

that establish a genuine issue for trial. See, e.g., id. at 325; Little, 37 F.3d at 1075; Isquith for and on Behalf of Isquith v. Middle South Utils., Inc., 847 F.2d 186, 198 (5th Cir. 1988).

DISCUSSION

As explained above, St. Jude has advanced two alternative arguments why summary judgment is proper as to each of Plaintiffs' claims: first, because it is not a "manufacturer" under the LPLA; and second, because all of Plaintiffs' claims are preempted by federal law, even if it is deemed to be a "manufacturer." Because the Court agrees with St. Jude's second argument, it need not address the first.

A. The Medical Device Amendments

Before turning to substance of St. Jude's preemption argument, a brief overview of the federal regulatory scheme applicable to medical devices may be helpful. Initially, the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301, et seq., only required FDA approval for the introduction of new drugs into the market. Medtronic, Inc. v. Lohr, 518 U.S. 470, 475-76 (1996). The "introduction of new medical devices was left largely for the States to supervise as they saw fit." Riegel, 552 U.S. at 315. "The regulatory landscape changed in the 1960s and 1970s," however, as the nation witnessed the failure of several complex medical devices, most notably the Dalkon Shield,

resulting in large numbers of injuries and even deaths. In 1976, responding to rising concerns that state regulatory regimes were demonstrably inadequate, Congress stepped in and passed the Medical Device Amendments ("MDA"), 21 U.S.C. § 360c, et seq., giving the FDA authority to regulate medical devices and expressly preempting certain state-law regulations. Id.

The MDA employs a three-part classification scheme for medical devices, according to the degree of risk the device presents. See Lohr, 518 U.S. at 476. Class I devices, such as elastic bandages and examination gloves, pose little to no risk of injury, and are subject only to "general controls" that are applicable to all devices. 21 U.S.C. § 360c(a)(1)(A). Devices receiving the "Class II" designation, such as wheelchairs and surgical drapes, pose somewhat greater risks. Manufacturers of Class II devices must therefore comply with federal performance regulations known as "special controls." Id. § 360c(a)(1)(B). Both Class I and Class II medical devices can generally be marketed without prior approval of the FDA.

The Class III designation is reserved for devices designed to support or sustain human life, or to prevent the impairment of human health. Riegel, 552 U.S. at 317. Because these devices present "a potential unreasonable risk of illness or injury," they are subject to the heaviest federal regulation. Id. (quoting 21 U.S.C. § 306c(a)(1)(c)(ii)). Generally, before a

Class III device may be marketed and sold, it must undergo clinical trials and a detailed and rigorous pre-market approval process ("PMA"), through which the manufacturer must provide the FDA with "reasonable assurance of its safety and effectiveness." Lohr, 518 U.S. at 477.[3] The PMA process requires a manufacturer to submit detailed information regarding the safety and efficacy of the device, including full reports of all safety and efficacy studies or investigations; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples of both the device and its component parts; and the proposed labeling. Riegel, 552 U.S. at 318 (citing 21 U.S.C. § 360e(c)(1)).

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[3] It should be noted that not all Class III devices are required to undergo the extensive PMA process. The MDA provides two important exceptions, although neither is pertinent to the instant case. First, the MDA includes a "grandfather clause" permitting manufacturers to continue to sell medical devices that were in existence and being marketed prior to 1976 "to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite" pre-market approval. See Lohr, 518 U.S. at 477-78 (citing 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1)). Second, where the device is "substantially equivalent" to a pre-existing device exempt from the PMA process, the MDA permits the FDA to approve the device through a substantially less rigorous approval process referred to as a § 510(k) approval. Id. (citing 21 U.S.C. § 360e(b)(1)(B)).

The FDA conducts an extensive review of the above information and may also require the manufacturer to submit additional data before approving the device. Id. (citing 21 U.S.C. § 360e(c)(1)(G); 21 C.F.R. § 814.44(a)). The FDA must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use" and may "thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." Riegel, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)).

B. Federal Preemption

The Supremacy Clause of the United States Constitution provides that the "Laws of the United States . . . Shall be the supreme Law of the Land." U.S. CONST. Art. VI, cl. 2. When state law conflicts with federal law, the state law is without effect under the Supremacy Clause. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992). However, because of the important principles of federalism in areas of public health and safety, the states' police power will not be preempted by federal law unless congressional intent to the contrary is clearly expressed. Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985).

In the MDA, Congress clearly indicated its intention to preempt at least some state laws by including an express

preemption clause, which provides:

> 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).[4]

In Riegel, the Supreme Court established a two-prong test for determining whether a plaintiff's state-law claims are preempted by MDA § 360k(a). Under the first prong, the court must determine the threshold issue of whether the federal government has "established requirements" applicable to the device at issue in the plaintiff's lawsuit. Riegel, 552 U.S. at 321-22. If it has, the court must then determine whether the plaintiff's state-law claims are based upon state-law requirements that are "different from, or in addition to" the federal ones, and that relate to safety and effectiveness." Id.

[4] Subsection (b) of the statute authorizes the FDA to grant certain exemptions to state requirements that would otherwise be pre-empted by subsection (a).

If the state requirement is different from or in addition to the federal requirements, then it is preempted.

The Riegel Court recognized that any device approved under the PMA process will satisfy the first prong, because through the process, the FDA establishes detailed and device-specific requirements that must be satisfied before it will grant approval. Id. at 322; see also Bass v. Stryker Corp., 669 F.3d 501, 507 (5th Cir. 2012) ("Devices that are approved through PMA procedures automatically satisfy the 'federal requirements' prong.").

With respect to the second prong, the Riegel Court confirmed its earlier holding in Lohr that state-law tort actions are considered "requirements" that relate to safety and effectiveness under Section 360k(a) when applied to a medical device that has undergone the PMA process. Riegel, 553 U.S. at 323-24 (citing Lohr, 518 U.S. at 512). Accordingly, if a state-law tort claim seeks to impose different or additional requirements than those established by the FDA, a plaintiff's claims will necessarily be preempted. Id. at 324-25 (holding that state-law claims for negligence, strict liability, and breach of warranty imposed requirements that were preempted by the MDA).

C. Are Plaintiffs' Claims Preempted under the MDA?

There appears to be little dispute that the Eon Mini IPG System, a Class III medical device, was granted FDA approval by

the FDA on November 21, 2001, and that it has consistently maintained that approval until the present time.[5] Plaintiffs offer no argument or evidence to rebut St. Jude's evidence on this point, and accordingly, the Court finds that the first prong of the Riegel preemption analysis is clearly met in this case.

As a result, the Court must next determine whether the second Riegel prong is also met. Although Plaintiffs do not specifically enumerate their causes of action in their state-court, they do appear to acknowledge in their opposition memorandum that their only claims against St. Jude arise under the LPLA.[6] The LPLA provides "the exclusive theories of liability for manufacturers for damage caused by their products." See La. Rev. Stat. § 9:2800.52. The LPLA sets forth four theories under which a device may be deemed "unreasonably dangerous," and thus defective: (1) a defect in construction or composition; (2) a defect in design; (3) an inadequate warning; or (4) the failure to comply with an express warranty. See La. R.S. 9:2800.54(B)(l-4). The Court must therefore determine

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[5] See FDA Approval Order re: P010032, Nov. 21, 2001, Rec. Doc. 22-3, Exh. A; available at http://www.accessdata.fda.gov/cdrh_docs/pdf/P010032A.pdf; see also Affidavit of Andrew Johnson, Rec. Doc. 22-3, Exh. 2.

[6] The petition states only that "[t]he defendant, St. Jude Medical, as the manufacturer and distributor of the 'ANS Stimulator' must stand responsible for the damages and injuries complained of herein." See State Court Petition, Rec. Doc. 1-2, p. 2, ¶ 5.

whether any of these theories seek to impose requirements "different from, or in addition to" the applicable federal standards.

This issue was squarely addressed in a recent decision by a sister court from the Western District of Louisiana. In Poole v. Hologic, Inc., No. 10-314, 2010 WL 3021528 (W.D. La. Jul. 29, 2010), the plaintiff filed suit under the LPLA against the manufacturer of a Class III medical device called the "NovaSure machine" after suffering a perforated uterus when the machine allegedly malfunctioned during a surgical procedure. Id. at *1-2. The plaintiff alleged that the NovaSure machine was unreasonably dangerous in design; in its construction and composition; because it did not provide an adequate warning; because it failed to conform to both an express warranty of fitness and an implied warranty of fitness; and finally because the manufacturer's employees or agents failed to properly and adequately train the physicians involved on the proper use of the NovaSure machine. Id. at *5. The manufacturer moved for judgment on the pleadings, and the court granted the motion, finding that each of the plaintiff's claims would necessarily impose requirements that are "different from, or in addition to" the requirements approved by the FDA and would directly contravene the FDA's determination that the device was both "safe and effective." Id.; see also McQuiston v. Boston Scientific

Corp., No. 07-1723, 2009 WL 4016120 (W.D. La. Nov. 19, 2009) (plaintiff's LPLA claims were preempted under the MDA); Rollins v. St. Jude Med., 583 F. Supp. 2d 790 (W.D. La. 2008) (granting manufacturer's motion to dismiss plaintiff's LPLA claims as preempted).

Furthermore, even before the Supreme Court's decision in Riegel, the Fifth Circuit had generally found LPLA claims to be preempted by the MDA. In Gomez v. St. Jude Medical Daig Div. Inc., 442 F.3d 919 (5th Cir. 2006), the plaintiff sued the manufacturer of a Class III medical device called the Angio-Seal, asserting that the product was defective under the LPLA due to its unreasonably dangerous design, for its failure to include an adequate warning, and for its failure to conform to an express warranty.[7] Employing essentially the same two-prong test that the Supreme Court subsequently adopted in Riegel, the Fifth Circuit reasoned that the plaintiff's LPLA claims amounted to a "state-law challenge" to the federally countenanced requirements for the device, and thus found them completely preempted by Section 360k(a). Id. at 930-32.

Here, just as in Gomez and Poole, Plaintiffs' LPLA claims seek to impose liability on St. Jude, notwithstanding the Eon Mini IPG System's compliance with the design and manufacturing

[7] The Plaintiff also asserted various other non-LPLA claims, which are not relevant to the instant case.

specifications and labeling requirements approved by the FDA during the PMA process. Because these claims necessarily impose requirements that are different from or in addition to those required by the federal regulatory scheme, they are clearly preempted by the MDA.

Plaintiffs seek to escape this result by recasting their claims as what have often been referred to as "parallel" claims. The Gomez court recognized that a "lawsuit that simply parallels or enforces the federal regulatory requirements without 'threatening' or interfering with them is not preempted" under Section 360k. Id. at 932; see also Riegel, 552 U.S. at 330 (noting that a state-law claim would not be preempted if it was "premised on a violation of FDA regulations"). Accordingly, courts have permitted state-law actions to proceed when they allege that a defendant failed to comply with the FDA-approved specifications for the device. See, e.g., Martin v. Medtronic, Inc., 254 F.3d 573, 585 (5th Cir. 2001) (affirming district court's refusal to dismiss claims asserting failure to comply with the FDA's PMA-approved requirements).

Here, however, Plaintiffs' petition includes no allegation that directly or impliedly asserts that St. Jude failed to manufacture or sell the Eon Mini IPG device in compliance with the specifications approved by the FDA during the PMA process. Instead, Plaintiffs' argument, as the Court appreciates it, is

that the LPLA's standards for liability are somehow the same as the federal requirements established by the PMA process. Proceeding on this assumption, they assert that if they can establish any one of the four bases under which a product is deemed "unreasonably dangerous" under the LPLA, this would essentially be "no different from proving that St. Jude had deviated from FDA requirements."[8]

Plaintiffs have cited no authority for this bold contention, however, and as noted above, the cases that have addressed the issue have quite clearly found the opposite to be true. It is clear that any claim based on the Eon Mini IPG System's construction or composition, design, warnings, or express warranties would each specifically impose requirements different from or in addition to the FDA-approved requirements for the device.

For instance, were Plaintiffs to prove that the Eon Mini IPG System was defective due to the construction or composition of the system, they would essentially be challenging the construction, composition, and manufacturing process that the FDA approved for the device. As the Supreme Court noted in Riegel, a PMA application must include a complete statement of the device's "components, ingredients, and properties and of the principle or principles of operation," as well as "a full description of the

[8] Plaintiffs' Memorandum in Opposition, Rec. Doc. 27, p. 6.

methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device." 552 U.S. at 318. Allowing Plaintiffs to proceed on this theory would enforce standards distinct from the federally approved requirements, rather than merely enforcing the same construction or composition specifications approved by the FDA.

The same is also true for any claim asserting that the Eon Mini System was defective due to inadequate warnings or its failure to comply with an express warranty. As the Fifth Circuit has noted, in order to establish that the device was defective due to breach of an express warranty under the LPLA, a plaintiff must prove that the representations made regarding the device were untrue. Gomez, 442 F.3d at 932 (citing LA. REV. STAT. § 9:2800.58). A jury hearing a breach of express warranty claim would thus be required to determine whether St. Jude's representations regarding the Eon Mini System – including the FDA-approved label, warnings, and instructions for use – were false. Such a determination would clearly undermine the federal regulatory scheme. The same is true should Plaintiffs wish to proceed on a failure to warn theory. The FDA approved the product's warnings based on its evaluation of the results of the extensive clinical trials and safety studies required during the PMA process. To permit a jury to decide that these warnings are

inadequate under Louisiana law would effectively "displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations" on manufacturers of PMA-approved devices. Id. at 930. As such, neither of these theories simply enforce federal requirements, as Plaintiffs suggest.

Finally, were Plaintiffs to maintain a claim that the Eon Mini IPG System was "unreasonably dangerous" because of a defective design, they would have to prove that an alternative design existed and that St. Jude's choice not to adopt this alternative design was unreasonable under the circumstances. See LA. REV. STAT. § 9:2800.56. Rather than mirroring federal requirements, this would allow the state to directly contradict the FDA's determination that the approved design of the Eon Mini IPG System was both "safe and effective." Poole, 2010 WL 3021528, at *5; see also Gomez, 442 F.3d at 930 ("The FDA studied the Angio-Seal design through the PMA process and approved it. To permit a jury to second-guess the Angio-Seal design by applying the Louisiana statutory standard for unreasonably dangerous design would risk interference with the federally-approved design standards and criteria.").

Based on the foregoing analysis, the Court finds that each of Plaintiffs' LPLA claims would at least potentially place St. Jude in the precarious position of choosing whether it should comply with federal or state requirements, but without the option

of satisfying both, which is a result the Supremacy Clause does not permit. The Court therefore finds that Plaintiffs' claims are entirely preempted under Section 360k of the MDA.[9]

Perhaps anticipating this conclusion, Plaintiffs alternatively request leave to amend their petition to allege that "St. Jude deviated from FDA requirements in connection with the manufacture and sale" of the Eon Mini IPG System.[10] Plaintiffs have been well aware that St. Jude intended to assert a preemption defense since at least July 27, 2011, when it was raised in its Answer.[11] Nevertheless, not once did they ever move to amend their Complaint to include the allegation that St. Jude deviated from FDA requirements in manufacturing this device, opting instead to make the request in the final line of their opposition to St. Jude's motion for summary judgment.[12] Absent any such allegation in their Complaint, and finding no competent evidence supporting the notion that such a deviation ever occurred, the Court will not entertain Plaintiffs' last-minute

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[9] Under Louisiana law, "a loss of consortium action is a derivative claim of the primary victim's injuries." Ferrell v. Fireman's Fund Ins. Co., 696 So. 2d 569, 575 (La. 1974). Thus, because the Court finds that Mrs. Hinkel's claims are preempted, Mr. Hinkel's loss of consortium claims are barred, as well.

[10] Plaintiffs' Memorandum in Opposition, Rec. Doc. 27, p. 7.

[11] See Defendant's Answer, Rec. Doc. 11.

[12] Plaintiffs' Memorandum in Opposition, Rec. Doc. 27, p. 7.

request to recast their suit as a "parallel claim" in order to avoid preemption. See McQuiston, 2009 WL 4016120 at *7 (denying plaintiff's request for leave to amend in same procedural posture). St. Jude's motion will therefore be granted.

CONCLUSION

Accordingly, for the reasons expressed above, **IT IS ORDERED** that St. Jude's **Motion for Summary Judgment (Rec. Doc. 22)** is hereby **GRANTED**.

New Orleans, Louisiana, this 23rd day of April, 2012.

CARL J. BARBIER
UNITED STATES DISTRICT COURT