UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

CALVIN WILLIAMSTON & GLADYS DRISKER WILLIAMSTON	*	**CIVIL ACTION NO. 2:13-CV-02433**
Plaintiffs	*	
V.	*	**JUDGE MINALDI**
MEDTRONIC, INC., & MEDTRONIC U.S.A., INC.	*	
Defendants	*	**MAGISTRATE JUDGE KAY**

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MEMORANDUM RULING

Before the court is a Motion to Dismiss [Doc. 5] pursuant to Federal Rule of Civil Procedure 12(b)(6), filed by the defendants, Medtronic, Inc., and Medtronic USA, Inc. (defendants), to which the plaintiffs have filed an Opposition [Doc. 16], and the defendants have filed a Reply [Doc. 18]. For the following reasons, the Motion [Doc. 5] be and hereby is **DENIED** at this time, and the plaintiffs are hereby granted leave to amend their complaint within twenty-one (21) days of the filing of this Memorandum Ruling into the record.

Also before the court is the defendants' Request for Judicial Notice [Doc. 7], requesting that the court take judicial notice of several Premarket Approval Database Listings that are directly pertinent to the matters herein. For the following reasons, the Motion [Doc. 7] be and hereby is **GRANTED**.

FACTS & PROCEDURAL HISTORY

On January 19, 2012, Mr. Williamston underwent a procedure that involved the surgical implantation of an implantable cardioverter-defibrillator (ICD)[1] that was manufactured by the

[1] *See* Pet. [Doc. 1-2], at ¶ 3 (identifying the ICD as a Medtronic Virtuoso II VR Defibrillator, Model #D274VRC, Serial #PZR207070H, and an accompanying lead, Medtronic Model #694765, Serial #TDG529247V).

defendants.[2] The plaintiffs allege that, on June 27, 2012, the ICD system underwent a malfunction that resulted in Mr. Williamston's receiving approximately thirty-two electrical shocks causing "significant physical and emotional pain, suffering, injury and distress."[3] Mr. Williamston received treatment and a brief hospitalization as a result.[4]

Following the incident, his ICD device was "reprogrammed" in an effort to remedy the problem.[5] There is no allegation that the shocks have continued; however, Mr. Williamston states that he "has continued to suffer, incur and sustain damages, including but not limited to ongoing physical, mental and emotional pain, suffering and distress related to the ICD system that remains implanted in his chest and medical expenses for the ongoing monitoring and management of the ICD system."[6]

The ICD system in question has received Pre-Market Approval (PMA) from the Food and Drug Administration, and, as a Class III medical device, is subject to regulation under the applicable provisions of the Food, Drug and Cosmetic Act (FDCA), as well as the Medical Device Amendments (MDAs).[7] Specifically, the plaintiffs' Petition [Doc. 1-2] notes that the defendants, as the manufacturers of a Class III device, were required to abide by the following regulations: Reliability Assurance Testing [under 21 C.F.R. § 820.20], Purchasing Controls [under 21 C.F.R. § 820.50], Production and Process Controls [under 21 C.F.R. § 820.70],

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[2] Pet. [Doc. 1-2], at ¶¶ 3, 13. The plaintiffs' state court Petition [Doc. 1-2] also notes that a Medical Review Panel proceeding against the attending surgeon, Dr. Robin Yue, the Cardiology Clinic of DeRidder, L.L.C., and West Louisiana Health Services, Inc., d/b/a Beauregard Memorial Hospital, has been commenced. *Id.* at ¶ 10.

[3] *Id.* at ¶ 4.

[4] *Id.* at ¶ 5.

[5] *See id.* at ¶¶ 5-7.

[6] Pet. [Doc. 1-2], at ¶ 9.

[7] *See id.* at ¶ 16. *See also* 21 U.S.C. § 360k(a), (stating as follows:

> (a) General rule. Except as provided in subsection (b), 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 Act [21 USCS §§ 301 et seq.] 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 Act [21 USCS §§ 301 et seq.].).

Inspection, Measuring and Test Equipment [under 21 C.F.R. § 820.72], Process Validation [under 21 C.F.R. § 820.75], Receiving, In-Process and Finished Device Acceptance [under 21 C.F.R. § 820.80], Acceptance Status [under 21 C.F.R. § 820.86], Nonconforming Product [under 21 C.F.R. § 820.90], and Corrective and Preventive Action [under 21 C.F.R. § 820.100].[8]

Calvin and Gladys Williamston, husband and wife, plaintiffs herein, filed suit against the defendants in the Thirty-Six Judicial District Court for the Parish of Beauregard on June 26, 2013.[9] Mr. Williamston seeks recovery of monetary damages under theories of product liability "and applicable state and/or federal law," and Mrs. Williamston seeks monetary damages for loss of consortium.[10]

LAW & 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). The Fifth Circuit has stated that Rule 12(b)(6) motions to dismiss are generally viewed with disfavor and should be rarely granted. *Harrington v. State Farm Fire & Cas. Co.*, 563 F.3d 141, 147 (5th Cir. 2009) (*citing Gregson v. Zurich Am. Ins. Co.*, 322 F.3d 883, 885 (5th Cir. 2003) (additional citations omitted)).

In ruling on motions to dismiss under Rule 12(b)(6), courts "must consider the complaint in its entirety, as well as other sources courts ordinarily examine . . . in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Jackson v. NAACP*, No. 12-20399, 2013 U.S. App. LEXIS 20493, at *9 (5th Cir. Oct. 8, 2013) (*citing Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (additional citation omitted)). "The court must accept all well-pleaded facts as true, and it must view them in the

[8] Pet. [Doc. 1-2], at ¶ 16.
[9] Pet. [Doc. 1-2], at 1.
[10] *Id.* at ¶¶ 40, 42.

light most favorable to the plaintiff." *Hebert v. Delta Airlines, Inc.*, No. 11-cv-1574, 2012 U.S. Dist. LEXIS 93848, at *6 (W.D. La. Jun. 5, 2012) (*citing In re Katrina Canal Breaches Litigation*, 495 F.3d 191, 205 (5th Cir. 2007) (citations omitted)). However, conclusory allegations are not to be accepted as true, and courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* (*citing Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted)).

A plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. The allegations must "raise the right to relief above the speculative level." *Id.* at 555. "Determining whether a complaint states a plausible claim for relief . . . [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009).

The FDCA, 21 U.S.C. § 301 *et seq.*, was amended by the 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 the defendants' argument herein.

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,[11] 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.*

In *Riegel*, a case strongly relied upon by the defendants, 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).

[11] *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").

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."[12] *Id.* at 510.

Here, the defendants' primary argument is that the plaintiffs' suit is preempted by 21 U.S.C. § 360k(a).[13] The defendants state that "*Riegel* stands unequivocally for the proposition that state law causes of action such as the ones asserted here do impose requirements 'different from' or 'in addition to' those imposed by the FDA . . . and are therefore expressly preempted by Section 360k(a)."[14] Neither the court, however, nor the Fifth Circuit (as indicated above) can concur with the defendants' sweeping position that *Riegel* insulates medical device manufacturers from liability absolutely via preemption as a matter of course. Indeed, the Supreme Court previously rejected this total preemption interpretation in *Medtronic, Inc., v.*

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[12] *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'").
[13] Memo. in Supp. [Doc. 5-1], at 15-21.
[14] *Id.* at 16.

Lohr, 518 U.S. 470 (1996), wherein the Court noted that such a construction would have the "perverse effect of granting complete immunity" to an industry that Congress had determined was in need of more stringent regulation, not less. *Lohr*, 518 U.S. at 487. The Court continued by stating that it is "'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,' and it would take language much plainer than the text of § 360k to convince [the Court] that Congress intended that result." *Id.* (*quoting Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

The defendants next argue that, "as pled, these claims would require a jury to find that the Medtronic ICD devices should have been different in some way and/or were not safe and effective despite Premarket Approval."[15] This argument was also addressed by the *Bass* court. In *Bass*, the defendants argued that a pleading predicated on the standards set forth in the Current Good Manufacturing Practices (CGMPs), 21 C.F.R. § 820 *et seq.*, could not stand because the regulations themselves were not specific enough to support a claim and permitting the case to proceed would "allow a jury to set bioburden or residual standards that are not in the regulations." *Bass*, 669 F.3d at 511-12. In rejecting this argument, the court stated that

> [t]he key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMPs, but rather the existence of a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury.

Id. at 511-12 (*citing Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011) (additional citations omitted)) (emphasis in original).

Indeed, it is the very identification of the defendants' violation of federal requirements that is necessary to produce a pleading that sets forth a claim that is not preempted, for it is in doing so that a plaintiff pleads a state law claim that is neither "different from" nor "in addition

[15] *Id.* at 18.

to" federal requirements. Put simply, "if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the CGMPs themselves *and* that this failure caused the injury, the plaintiff will have pleaded a parallel claim." *Id.* at 512.

"[A] plaintiff may avoid express preemption of their claim by alleging a valid parallel claim based on violations of FDA regulations to recover state tort damages for injuries suffered from the use of a Class III medical device that has received premarket approval." *Gavin v. Medtronic, Inc.*, No. 12-0851, 2013 U.S. Dist. LEXIS 101216, at *12 (E.D. La. Jul. 19, 2013) (*citing Riegel*, 552 U.S. at 330). The plaintiffs' initial state court Petition [Doc. 1-2] provides a list of federal regulations applicable to the device in question, but does not articulate the existence of a specific manufacturing defect as required by this circuit's post-*Riegel* decisions. *See, e.g.*, *Bass*, 669 F.3d at 510.[16] The petition also does not allege a connection between a specific defect in the device in violation of federal regulations and Mr. Williamston's specific injury. *See id.* at 511-12 (citation omitted).

The plaintiffs argue that discovery is required to "identify and evaluate all of the specifications, standards, procedures, protocols, testing, analysis and evaluation required of Medtronic pursuant to applicable FDA and/or other applicable guidelines."[17] The Fifth Circuit has noted that "reliance on CGMPs may be appropriate where . . . 'a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit.'" *Bass*, 669 F.3d at 512 (*citing In re*

[16] *See also* Pet. [Doc. 1-2], at ¶ 16. The Petition [Doc. 1-2] also states that "the ICD system . . . [was] defective because [it] deviated in a material way from the specifications and/or performance standards applicable to such devices/products, including but not limited to specifications and/or performance standards required and/or and [sic] approved by the FDA." Pet. [Doc. 1-2], at ¶ 27. Again, however, such allegations lack sufficient specificity to survive a motion to dismiss.

[17] Pet. [Doc. 1-2], at ¶ 30.

Medtronic, 623 F.3d at 1206). The *Bass* court rejected the defendants' argument that "the regulations [were] too vague to be enforced by a jury, because by the time the case is tried, the jury will have before it the PMA application that was approved by the FDA." *Id.* at 512. However, the plaintiffs' petition differs from the *Bass* plaintiff's allegations in several important respects.

The plaintiffs essentially state that discovery is necessary in order to determine what federal regulations the defendants have violated.[18] The *Bass* plaintiff, on the other hand, alleged that the device in question was "adulterated" due to violations of three specific regulations. *Bass*, 669 F.3d at 510 (*citing* 21 C.F.R. § 820.20(a), 820.20(b)(2), and 820.70(e)). There are no similar allegations herein. Likewise, the *Bass* plaintiff relied on the fact that the specific device in question had previously been voluntarily recalled by Stryker in response to a warning letter from the FDA which cited a specific violation of federal law. *Bass*, 669 F.3d at 510. However, although the plaintiffs herein reference previous recalls of defibrillator leads manufactured by the defendants, they also concede that the lead in question here was never included within a recall.[19]

Before ruling on the merits of the Motion to Dismiss [Doc. 5], it would be appropriate to discuss the defendants' Request for Judicial Notice [Doc. 7], seeking that the court take judicial notice of several Premarket Approval Database Listings which relate to the various components of the ICD device that is the subject of this litigation. Federal Rule of Evidence 201(b)(2) permits a court to take judicial notice of facts that are not reasonably subject to dispute because they "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FED. R. EVID. 201(b)(2). A court may take judicial notice of the FDA's public records without transforming a motion to dismiss under Rule 12(b)(6) into a motion for summary

[18] *Id.*
[19] *See* Pet. [Doc. 1-2], at ¶¶ 30-34.

judgment. *Sons v. Medtronic, Inc.*, 915 F. Supp. 2d 776, 781 (W.D. La. 2013) (*citing Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790, 805 (W.D. La. 2008) (*citing Lovelace v. Software Spectrum, Inc.*, 78 F.3d 1015, 1017-18 (5th Cir. 1996); *see also Horne v. Novartis Pharmaceuticals Corp.*, 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008))). Courts in this circuit have previously taken judicial notice of similar records under similar circumstances. *See Sons*, 915 F. Supp. 2d at 781; *Funk*, 631 F.3d at 783. Additionally, the plaintiffs have in no way challenged the ICD in question as to its status as a Class III device that has undergone the PMA process. Accordingly,

IT IS ORDERED that the defendants' Request for Judicial Notice [Doc. 7] be and hereby is **GRANTED**.

The court is not unsympathetic to the plaintiffs' somewhat paradoxical position insofar as the difficulty of successfully pleading a parallel state law claim is concerned. The plaintiffs contend in their Opposition [Doc. 16] that

> [a]lleging facts more specific than those set forth in Plaintiff's Petition for Damages . . . would require Plaintiffs to: (a) obtain confidential, proprietary and non-public product-related information (including but not limited to the FDA-approved specifications and standards for the subject devices); and (b) perform forensic testing . . . of the devices which remain implanted in [the plaintiff's] chest.[20]

Other courts have acknowledged the difficulty of successfully pleading a parallel claim that is not preempted by the MDA, noting "'how difficult it is to plead such a claim sufficiently to survive a motion to dismiss for failure to state a claim' and that '[f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.'" *Gray v. Stryker Corp.*, No. 1:12-cv-437-TWP-DKL, 2013 U.S. Dist. LEXIS 22848, at *12 (S.D. Ind. Feb. 20, 2013) (*citing Bausch v. Stryker Corp.*, 630 F.3d 546,

[20] Memo. in Opp. [Doc. 16], at 9.

558 (7th Cir. 2010)). In response to this difficulty, at least one court has held that plaintiffs pleading parallel claims in MDA cases are "not expected to plead violations of specific federal laws or product specific information . . . because plaintiffs often do not have access to product-specific information about the manufacturing of these devices, which are kept confidential by federal law, until they are able to obtain this information through discovery." *Id.* at *13 (citation omitted). Similarly, the law of this circuit dictates that

> "courts must keep in mind that much of the product-specific information about manufacturing needed to investigate [a medical device claim] fully is kept confidential by federal law." *Bausch*, 630 F.3d at 558. Therefore, asking [a] plaintiff to make more specific allegations than those found in [the *Bass* plaintiff's] complaint may make pleading a parallel claim regarding defective manufacturing nearly impossible. *See In re Medtronic*, 623 F.3d at 1209 (Melloy, J., dissenting) (stating that *Twombly* only requires a degree of specificity that may be achieved without the use of confidential documents).

Bass, 669 F.3d at 511.[21]

Despite the foregoing, the plaintiffs' complaint herein differs from the *Bass* plaintiff's complaint in that the latter went a step beyond the instant plaintiffs' pleading in claiming that his injury was caused by the violation of several specific regulations. *See id.* at 510. The plaintiffs in this case have failed to set forth the specific federal violations upon which their parallel claims are predicated. As a result, the court finds that the plaintiffs have failed to successfully state a parallel claim. The simple listing of various federal regulations[22] is insufficient to successfully plead a state law claim predicated on the violation of federal requirements. As previously stated, "[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,

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[21] On the other hand, it should be noted that other district courts have embraced the view that, "[w]hen facing MDA preemption, a plausible cause of action requires, among other things, a showing that the alleged violation of state law parallels a violation of federal law. This additional step *requires some greater specificity in the pleadings*." *Elliot v. Smith & Nephew*, No. 1:12-cv-70-EJL-MHW, 2013 U.S. Dist. LEXIS 59072, at *20 (D. Idaho Apr. 15, 2013) (*quoting White v. Stryker Corp.*, 818 F. Supp. 2d 1032, 1037 (E.D. Ky. 2011)) (emphasis added).

[22] *See* Pet. [Doc. 1-2], at ¶ 16.

federal requirements." *Bass*, 669 F.3d at 508-09. The plaintiffs have also not been clear as to which state law causes of action correspond to, or "parallel," which specific violations of federal regulations. Mere assertions that a defendant is liable because a given product deviated from federal specifications and regulations without any more specificity are precisely the types of legal conclusions of which Rule 12(b)(6) motions are designed to dispose.

The plaintiffs' Opposition [Doc. 16] requests an opportunity to amend the complaint in lieu of dismissal in the event that the court finds the initial state court petition to be inadequate.[23] District courts should generally grant leave to amend freely "when justice so requires." FED. R. CIV. PRO. 15(a)(2). The decision whether to grant or deny such leave, however, is at the discretion of the court. *Moore v. Manns*, 732 F.3d 454, 456 (5th Cir. 2013) (citations omitted). A district court is empowered to deny a party leave to amend when the proposed amendment would be futile in that any amendment to the complaint would nevertheless fail to state a claim upon which relief could be granted. *Stripling v. Jordan Production Co., L.L.C.*, 234 F.3d 863, 872-73 (5th Cir. 2000) (citation omitted).

It cannot be said with certainty that the granting of leave to amend would necessarily be futile. The case law suggests that pleading a parallel claim with sufficient particularity to avoid preemption can be a challenging task, indeed. Still, the plaintiffs' complaint does not appear to satisfy the Fifth Circuit's particularity requirements as set forth in *Bass*. However, "unless there is a 'substantial reason to deny leave to amend, the discretion of the district court is not broad enough to permit denial.'" *Id.* at 873 (*quoting Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 598 (5th Cir. 1981) (additional citation omitted)). Accordingly,

IT IS ORDERED that the plaintiffs' request to amend their complaint be and hereby is **GRANTED**, and the plaintiffs are hereby granted leave to submit an amended complaint within

[23] Memo. in Opp. [Doc. 16].

twenty-one (21) days of the filing of this Memorandum Ruling into the record. If no amended complaint is filed, the court will have no choice but to dismiss the plaintiffs' claims pursuant to Federal Rule of Civil Procedure 12(b)(6).

IT IS FURTHER ORDERED that, in accordance with the foregoing, the defendants' Motion to Dismiss [Doc. 5] be and hereby is **DENIED** at this time. The defendants are, however, granted leave to move for dismissal again following the submission of the plaintiffs' amended complaint, should one be forthcoming.

Lake Charles, Louisiana, this 12 day of May, 2014.

PATRICIA MINALDI
UNITED STATES DISTRICT JUDGE