IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
EASTERN DIVISION

BRYANT, et al. **PLAINTIFFS**

v. **CIVIL ACTION NO. 2:17-CV-169-KS-MTP**

THORATEC CORP., et al. **DEFENDANTS**

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Defendants' Motion to Dismiss [10] and Plaintiffs' Motion for Leave to File Second Amended Complaint [35]. Both parties have filed motions requesting that the Court judicially notice certain facts in ruling on these motions [13] [28]. After considering the submissions of the parties and the applicable law, the Court finds that:

- Defendants' Motion to Dismiss [10] should be granted, as Plaintiffs' claims are either preempted or not adequately pled.
- Defendants' Motion for Judicial Notice [13] should be granted in part and denied in part.
- Plaintiffs' Motion for Judicial Notice [28] should be granted in part and denied in part.
- Plaintiffs' Motion to Amend [35] should be denied, as the proposed amendments would be futile.

I. BACKGROUND

A. Factual Background

This is a products liability suit. Plaintiff Melody Bryant had a HeartMate II heart pump implanted at the University of Alabama Birmingham ("UAB") in 2015. The device, the HeartMate II Left Ventricular Assist System ("LVAS"), consists of a left ventricular assist device ("LVAD"), which is the actual heart pump, along with other parts, including a system controller, drive or percutaneous lead, and batteries or power source. The controller checks the pump and sends alarms

and messages to the patient and medical personnel at UAB. The driveline connects the pump and the controller, and is located both internally and externally. The driveline is made up of several wires or cable, and it is intended to have a material to insulate the cables from contact with the metal sheath.

After implantation, Melody received training about the use of the LVAS and received a Patient Handbook developed by Defendant Thoratec. The Handbook and training did not provide warnings that the insulation on the driveline could wear out over time.

On September 24, 2016, Ms. Bryant presented at UAB with a controller connection issue. Plaintiff alleges that she was off the pump for two minutes while trying to change to her back-up controller when she had an acute and subacute stroke. The personnel at UAB switched out her controller. On October 15, 2016, the LVAS experienced "several slow-speed events and pump stoppages," and "a short-to-shield phenomenon." First Am. Compl. ¶ 16, ECF No. 9 (hereinafter "FAC"). Plaintiffs allege that "insulation of one or more of the driveline wires was either missing, had worn off, or was otherwise damaged, thereby allowing a wire or wires to contact the metallic shield enveloping them," resulting in an ischemic stroke. *Id.* Plaintiffs also submit that the controller did not notify Ms. Bryant of any issues with the driveline.

B. Procedural History

Plaintiffs filed suit on October 13, 2017, alleging products liability, negligence per se and a loss of consortium claim for Ms. Bryant's husband. On November 3 and November 10, 2017 Defendants' counsel Jenny Covington and Plaintiffs' counsel, Robin E. Blackledge Blair spoke on the phone. Covington Aff. ¶¶ 1-2, ECF No. 40. Ms. Covington informed Ms. Blair that her clients' claims were likely preempted because the HeartMate II LVAS had received pre-market approval from the FDA. Blair Aff ¶ 1, ECF No. 42-1. Because Ms. Blair was unaware of the federal law,

the two agreed that Plaintiffs could file an amended complaint. *Id.* They also agreed to extend the deadline for Defendants to file responsive pleadings and "otherwise defend the operative Complaint filed against them." Agreed Stip. Extens. Time 1, ECF No. 8. Plaintiffs filed their First Amended Complaint on December 29, 2017 and Defendants filed their Motion to Dismiss [10] on January 23, 2018, raising preemption. Plaintiffs then requested a month extension to their filing deadline, citing the complexity of the case and scheduling issues. Mot. Extension Time to File Resp., ECF No. 16. Defendants agreed to a two-week extension. Covington Aff. ¶ 4, ECF No. 40. The Court granted a two-week extension. Order, ECF No. 22. Each party filed a motion for judicial notice in connection with the motion to dismiss.

A week after briefing on the Motion to Dismiss was completed, Plaintiffs filed their Motion for Leave to File Second Amended Complaint [35] in attempt to address Defendants' preemption arguments. Defendants have opposed this request arguing that Plaintiffs have been dilatory and acting in bad faith, that granting leave to amend would be unduly prejudicial to Defendants, and that such amendments would be futile.

II. LEGAL STANDARD

A. Motion to Amend

"Rule 15(a) requires a trial court to grant leave to amend freely, and the language of this rule evinces a bias in favor of granting leave to amend." *Jones v. Robinson Prop. Grp., LP*, 427 F.3d 987, 994 (5th Cir. 2005) (citation and internal quotations omitted). "[U]nless there is a substantial reason, such as undue delay, bad faith, dilatory motive, or undue prejudice to the opposing party, the discretion of the district court is not broad enough to permit denial [of a motion to amend]." *Martin's Herend Imports, Inc. v. Diamond & Gem Trading U.S.A. Co.*, 195 F.3d 765, 770 (5th Cir. 1999) (quoting *Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 597 (5th Cir. 1981))

(internal quotations omitted). However, "[i]t is within the district court's discretion to deny a motion to amend if it is futile." *Stripling v. Jordan Prod. Co., LLC*, 234 F.3d 863, 872-73 (5th Cir. 2000) (citing *Martin's Herend Imps. Inc. v. Diamond & Gem Trading United States of Am. Co.*, 195 F.3d 765, 771 (5th Cir. 1999); and then citing *Leffall v. Dallas Indep. Sch. Dist.*, 28 F.3d 521, 524 (5th Cir. 1994)).

B. Motion to Dismiss

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Great Lakes Dredge & Dock Co. LLC v. La. State*, 624 F.3d 201, 210 (5th Cir. 2010) (punctuation omitted). "To be plausible, the complaint's factual allegations must be enough to raise a right to relief above the speculative level." *Id.* (punctuation omitted). The Court must "accept all well-pleaded facts as true and construe the complaint in the light most favorable to the plaintiff." *Id.* But the Court will not accept as true "conclusory allegations, unwarranted factual inferences, or legal conclusions." *Id.* Likewise, "a formulaic recitation of the elements of a cause of action will not do." *PSKS, Inc. v. Leegin Creative Leather Prods., Inc.*, 615 F.3d 412, 417 (5th Cir. 2010) (punctuation omitted). "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

C. Preemption

Defendants primarily argue that Plaintiffs' claims should be dismissed as they are preempted under the Medical Device Amendments ("MDA") to the Food Drug, and Cosmetics Act, codified at 21 U.S.C. § 360k(a). Under *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), courts must follow a two-part test to determine whether § 360k preempts the state law causes of actions

alleged by Plaintiffs. *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011). "First, we ask if the FDA has established requirements applicable to the particular device at issue. Second, we ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is 'different from or in addition to' the federal requirement." *Id.* at 767-68 (quoting *Riegel*, 552 U.S. at 322).

When a Class III medical device has received pre-market approval, the first prong is established. *Riegel*, 552 U.S. at 322; *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012).[1] Under the second prong of the *Riegel* test, state law claims are preempted under the MDA if they seek to impose requirements that are different from, or are in addition to, those imposed by the FDA. It is well established that holding a manufacturer liable for tort damages can amount to a "requirement" that is different from or in addition to those imposed by the FDA. *Bass*, 669 F.3d at 508-09 (quoting *Riegel*, 552 U.S. at 323-24). The MDA does not, however, preempt state law claims that seek to hold medical device manufacturers liable for failing to comply with applicable federal requirements. *Id.* at 509. Such cases, often referred to as "parallel claims," may proceed if they are adequately pled. *Id.*

Implied preemption may also bar a plaintiff's claim, if such claims are based only on a violation of federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Under 21 U.S.C. § 337(a), only the federal government may file suit for noncompliance with the medical device provisions. *Id.* Thus, "to avoid implied preemption, Plaintiff[s'] claims must be premised upon 'state-tort claims rather than any duties independently created' by the FDCA or the FDA regulations." *Williams v. Ciba Vision Corp.*, 100 F. Supp. 3d 585, 590 (S.D. Miss. 2015) (quoting *Bass*, 669 F.3d at 513-14); *Smith v. St. Jude Medical*, No. 1:15-cv-263-KS-RHW, 2015

[1] As discussed *infra*, the Court takes judicial notice of the fact that the HeartMate II LVAS is a Class III medical device that received pre-market approval by the FDA. Therefore, the first prong of the *Riegel* test is satisfied.

WL 9094383, at *5 (S.D. Miss. Dec. 16, 2015) (citing *Hughes*, 631 F.3d at 775) ("[T]here is no preemption of Mississippi tort claims premised on violations of federal law.").

III. ANALYSIS

A. Motions for Judicial Notice

When ruling on a motion to dismiss, a district court may consider well pleaded allegations in the complaint and "matters of which a court may take judicial notice." *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011). Both parties have filed motions requesting that the Court take judicial notice of certain documents under Federal Rule of Evidence 201. Federal Rule of Evidence 201(b) provides that a court may take judicial notice of a fact "that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b).

Defendants have asked that the Court take judicial notice of the following documents:

1. Exhibit A, FDA Premarket Approval Database Listing for HeartMate II
2. Exhibit B, April 21, 2008 FDA Premarket Approval for the HeartMate II
3. Exhibit C, October 12, 2017 FDA Premarket Approval Supplement No. 69 for the HeartMate II
4. Exhibit D, August 5, 2014 FDA Premarket Approval Supplement No. 31 for the HeartMate II
5. Exhibit E, January 20, 2010 FDA Premarket Approval Supplement No. 5 for the HeartMate II
6. Exhibit F, January 4, 2017 Form 8-K, Abbott Laboratories
7. Exhibit G, January 4, 2017 Form 8-K, St. Jude Medical
8. Exhibit J, March 30, 2017 Medical Device Safety Recall—Abbot-Thoratec Recalls HeartMate LVAS Pocket System Controller Due to Risk of Patient Injury and/or Death During Backup Controller Exchange

Plaintiffs did not respond to Defendants' motion; therefore, the Court assumes that they do not oppose Defendants' request to judicially notice such documents. Instead, Plaintiffs filed their own Motion for Judicial Notice [28] in support of their response to Defendants' Motion to Dismiss. They request that the Court take judicial notice of the following documents:

1. Exhibit B, Jay D. Pal et al., *Outcomes of External Repair of HeartMate II LVAD Percutaneous Leads*, The VAD J. (2016).

2. Exhibit C, FDA MAUDE Adverse Event Report for the HeartMate II LVAS LVAD

3. Exhibit D, Class 2 Device Recall for the Thoratec HeartMate II LVAS from December 22, 2008

4. Exhibit E, October 24, 2008 press release *Thoratec Corp. Issues Worldwide Medical Device Correction of HeartMate II LVAS*

5. Exhibit F, January 8, 2009 PMA Supplement for the HeartMate II LVAS

6. Exhibit G, Third Supplemental Complaint in Bush v. Thoratec Corp, 2:11-cv-1654-EEF-DEK

7. Exhibit H, Class 1 Device Recall for the HeartMate LVAS with Pocket Controller from May 24, 2017

8. Exhibit I, May 23, 2017 Med Watch Safety Alert entitled *HeartMate II LVAS Packet System Controller by Abbott-Thoratec: Class I Recall – Due to Risk of Patient Injury and/or Death During Backup Controller Exchange*

9. Exhibit J, Urgent Medical Device Correction from March 4, 2014

10. Exhibit K, Class 2 Device Recall for the HeartMate II System Controller from October 13, 2010

11. Exhibit L, Omar Wever-Pinzon et al., *Repetitive HeartMate II Pump Stoppage Induced by Transitioning from Batter to Main Power Source*, J. Heart & Lung Transplantation (2015)

12. Exhibit M, Robert L. Kormos et al., *Left Ventricular Assist Device Malfunctions: It Is More Than Just the Pump*, Am. Heart Ass'n J. (2017).

13. Exhibit N, Document 00513198245 in Bush v. United States, No. 14-30896 (5th Cir. Sept. 17 2015)

14. Exhibit O, Screenshot of Abbott's website

Neither party disputes that documents produced by the FDA are proper for judicial notice. *Funk*, 631 F.3d at 783. Defendants' Exhibits A through E and Exhibit J include actions taken by the FDA, including that the HeartMate II LVAS is a Class III medical device that received pre-market approval, and other information disseminated by the FDA. Plaintiffs' Exhibits D through F, and Exhibits H through K show various recalls and safety alerts sent out by the FDA. Defendants have not contested that these are proper for judicial notice. Therefore, the Court will **grant** both of the parties' motions to the extent that they request these documents be judicially noticed.

Defendants contest the remaining documents that Plaintiffs have submitted. The Court finds that such documents are not proper to be judicially noticed or are not relevant to the Court's analysis. Two of Plaintiffs' proposed documents are scholarly articles regarding key issues in dispute in this action: the potential outcomes after a repair of HeartMate II leads (Ex. B), the potential for malfunction when transitioning the device's power source (Ex. L), and the potential for malfunction in the HeartMate II (Ex. M). Plaintiffs simply cite *Scales v. George Washington Univ.*, No. 89-0796-LFO, 1993 WL 304016, at *10 n.18 (D.D.C. July 27, 1993) where the court took judicial notice of some scholarly publications, but Plaintiff has not shown that factual substance in these articles can be "accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Therefore, Plaintiffs' motion is **denied** as to these motions.

Next, Defendants take issue with Plaintiffs' request that the Court take the facts listed in the FDA's MAUDE database to establish that Defendants did not report Ms. Bryant's stroke to the FDA. The Court finds that it is not proper to judicially notice such, as these facts cannot be "accurately and readily determined from sources whose accuracy cannot reasonably be questioned" as the FDA cautions that the "incidence or prevalence of an event cannot be

determined from this reporting system alone."[2] "herefore, Plaintiffs' motion is denied to this extent. The Court will however, take Plaintiff's allegations as true when ruling on the motion to dismiss, *infra*.

Several of the documents presented by both parties had no bearing on the Court's analysis in ruling on these motions. Plaintiffs submit several documents from *Bush v. Thoratec Corporation* and asks that the Court take judicial notice of the facts stated in these documents, not the documents' existence. The Court finds that the facts of this case are not relevant to the dispute at hand, as the underlying alleged facts took place seven (7) years ago. Furthermore, the documents regarding the relationship between Abbott and Thoratec are not relevant to the Court's analysis, so the Court will deny both parties' motions to the extent that it asks that those documents be judicially noticed.

B. Motion to Amend: Bad Faith, Delay, and/or Unfair Prejudice

Defendants cite the above procedural history and assert that Plaintiffs' actions are dilatory, as they had notice that Defendants were asserting preemption as a defense to their claims as of early November 2017. Both parties have submitted affidavits regarding the conversation between Ms. Covington and Ms. Blair.[3] Defendants assert that Plaintiffs are acting in bad faith in attempting to "move the goal posts" by filing their motion to amend after briefing was completed on the motion to dismiss and that the First Amendment Complaint "was merely a placeholder to buy time for a Second Amended Complaint and to draw out all legal theories challenging their claims." Thoratec's Resp. Opp Pls.' Mot. Leave File Second Am. Compl. 4, ECF No 39. They further

[2] MAUDE—Manufacturer and User Facility Device Experience, FDA (June 30, 2018), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#disclaimer.

[3] Defendants filed a Motion for Leave to File a Supplemental Affidavit [43] in support of their opposition to Plaintiffs' Motion for Leave to File a Second Amended Complaint "to address certain inaccurate characterizations" regarding the conversation between Ms. Covington and Ms. Blair. As the Court reviewed such affidavit when considering whether Plaintiffs' have acted in bad faith in requesting leave to amend, this motion is **granted**.

suggest that to permit Plaintiffs another chance to amend their complaint would unduly prejudice them, since they have already briefed a motion to dismiss. In response, Plaintiffs suggest that Defendants acted in bad faith by suggesting that Plaintiffs file an amended complaint and that Ms. Covington misled Ms. Blair into thinking Defendants would answer an amended complaint, not file a motion to dismiss.

A review of the affidavits does not show bad faith on the part of either party. The fact that Plaintiffs requested a month-long extension to respond to Defendants' Motion to Dismiss and that they waited until briefing was complete to file their motion to amend does not suggest to the Court that they have intentionally tried to delay this case, especially given the complexity of the law surrounding FDA preemption of Class III medical devices. Furthermore, the Court finds that there was no bad faith on the part of Defendants in earlier giving Plaintiffs the opportunity to amend their complaint.

Nor is there any prejudice to Defendants in permitting the amendments, as this case is in the very early stages. No case management order has been entered. As Defendants have argued that such amendments are futile, the Court will consider Plaintiffs' proposed amendments in their Second Amended Complaint in conjunction with their allegations in the First Amended Complaint to determine whether Plaintiffs have stated a claim.

C. Sufficiency of Pleading and Futility of Amendments

1. Design Defect

Defendants argue that any of Plaintiffs' claims that arise out of an alleged design defect must be dismissed as they are preempted. "[D]esign-related defect claims whether sounding in strict liability or negligence, are preempted because the FDA has already assessed and approved the risks and utility of the existing design of the [medical device]." *Carlson v. Medtronic Inc.*, No.

3:13-cv-687-WHB-RHW, 2014 WL 11514911, at *4 (S.D. Miss. Aug. 28, 2014) (citing *Riegel*, 552 U.S. 312; then citing *Hughes*, 631, F.3d at 768; and then citing *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 930 (5th Cir. 2006)).

Defendants suggest that Plaintiffs have conceded that their design defect claims are preempted and should be dismissed, pointing the twenty-third footnote in Plaintiff's response to their motion to dismiss, which states: "Plaintiffs hereby dismiss all claims based upon allegations of failure to abide by requirements pursuant to 21 U.S.C. §§ 360e(d)(2), 360e(c)(1) and 360d, preserving the claims based on the remaining failures as alleged in the First Amended Complaint." Pls.' Mem Opp. Defs.' Mot Dismiss 21 n.23, ECF No. 26.

A review of Plaintiffs' response to Defendants' Motion to Dismiss shows that Plaintiffs are still attempting to assert some design defect claims. Pl.'s Mem. Opp. Defs.' Mot. Dismiss 21, ECF No. 26 ("The claims are based upon allegations of inadequate warnings, manufacturing defects and *design* defects . . . . Medical device claims based on all these theories can survive motions to dismiss." (emphasis added)); Second Am. Compl. ¶ 57(p), ECF No. 35-1 (alleging "other defects to be discovered, including but not limited to design and manufacturing defects") (hereinafter "SAC"). To the extent that Plaintiffs attempt to assert a claim that Defendants should be liable for a design defect despite the FDA's approval of the HeartMate II's design, their claims are preempted and should be dismissed.

2. Claims Relating to Recalls

A claim related to a recall is preempted to the extent it attempts to add additional or different requirements from what the FDA required in a recall. A claim related to a recall is not preempted, however, if it alleges that the manufacturer failed to comply with the FDA's requirements and regulations related to that recall.

In a few different sections, Plaintiffs allege that Defendants should have issued additional recalls for the HeartMate II's driveline, that healthcare professionals should have been instructed not to use the driveline after the recall, and that Defendants should have sooner issued a recall on the controller for its failure to signal a hazard when the driveline is damaged. FAC ¶ 33(k), (n); SAC ¶ 57 (h), (o). Plaintiffs submit that manufacturers may self-police and initiate their own recalls; thus, the claim is parallel. Plaintiffs state no facts that support their arguments that Defendants failed to comply the FDA's regulations, as they conceded that the FDA has overseen all of the recalls of the HeartMate II. SAC ¶¶ 33-41. Furthermore, the fact that the FDA permits voluntary recalls does not make Plaintiffs' claim parallel. The Court finds that this claim is expressly preempted as requiring Defendants to issue another or different type of recall would be an "additional or different" requirement from what the FDA required.

3. Failure to Report and Failure to Warn

Plaintiffs have also asserted claims that fall under the Mississippi Products Liability Act's failure to warn provisions. Their claims may be divided into two categories: a failure to report serious injuries or malfunctions of the device to the FDA and a more traditional failure to warn Ms. Bryant of the risks related to use of the HeartMate II. A state law claim for failure to warn is preempted if it "challenge[s] the sufficiency of FDA-approved warnings and labels." *Carlson*, 2014 WL 11514911, at *5. However, such claims are not preempted when they allege "the manufacturer failed to comply with federal regulation regarding reporting and warning, or failed to label the device as required by the FDA when it granted pre-market approval." *Id.*

a. *Failure to Report*

Plaintiffs' failure to warn claim primarily stems from her allegations that Defendants did not report Ms. Bryant's strokes to the FDA; therefore, Plaintiffs argue, Defendants have violated

FDA regulations and they have stated a parallel claim. Plaintiffs compare their case to *Hughes v. Boston Scientific Corp*. The plaintiff in *Hughes* alleged that the manufacturer "developed an 'algorithm' regarding reportable events caused by the [the medical device] according to which Boston Scientific[, the manufacturer,] reported some, but not all burns." 631 F.3d at 766. The Fifth Circuit held that a manufacturer's "failure to report 'serious injuries' and 'malfunctions' of the device as required by the applicable FDA regulation" could state a parallel claim for failure to warn. *Id.* at 769. The Court noted that Hughes's causation theory was that if the manufacturer had reported the true number of device malfunctions and injuries caused by the medical device, such "would have appeared on the FDA's MAUDE internet database[4] and in medical journals, and with this information [Hughes's doctor] would not have recommended the [medical device] to Hughes for treatment, nor would Hughes have chosen the [medical device] as a treatment option." *Id.* at 776.

Turning to Plaintiffs' FAC, Plaintiffs allege that Defendants' actions constitute a failure to comply with the Medical Device Reporting requirements of 21 U.S.C. § 360i(a)(1) and 21 C.F.R. § 803.50(a), and a failure to report serious injuries and malfunctions of the device as defined in the Medical Device Reporting regulations. FAC ¶ 33(e), (h). Plaintiffs' proposed amendment adds: "On information and belief, Defendants did not report either of Ms. Bryant's events. If they were not reported, there are [sic] no doubt that others were not reported, thereby preventing the FDA from effectively monitoring the efficacy of the device." SAC ¶ 57(b).

Plaintiffs' allegations do not state a claim and their proposed amendment would be futile. This case is distinguishable from *Hughes* in several regards. First, the plaintiffs in *Hughes* alleged

[4] Defendants argue that it is inappropriate for Plaintiffs to rely on the FDA's MAUDE database as a basis for a parallel claim. Defs.' Reply Mem. Supp. Mot. Dismiss 3, ECF No. 31. The Court will assume that such reliance is permissible for the purposes of this motion, resolve all inferences in Plaintiffs' favor.

that the manufacturer had, in a widespread manner, failed to report numerous serious incidents, as a part of a flawed algorithm the manufacturer used to decide which events were "reportable." *Hughes*, 631 F.3d at 766. The Plaintiffs here have only alleged that Defendants did not report her own incident. As Defendants have pointed out, such cannot give rise to a failure to warn claim, as there is no causation between the alleged violation of FDA regulations and Plaintiffs' purported injury. Furthermore, Plaintiffs' only allegation as to a more widespread failure to report, that since Defendants purportedly did not report her injury so other events were likely not reported, is speculative. The Court need not take unwarranted inferences or speculation as true when ruling on a motion to dismiss. *Great Lake Dredge & Dock Co., LLC*, 624 F.3d at 210.

b. *Failure to Warn*

Plaintiffs' other allegations arise out of Defendants' alleged failure to inform her of the risks of wear and tear on the driveline in her HeartMate II. Plaintiffs' FAC alleges that Defendants failed "to adequately label and/or warn of the inherent risk of the device as contemplated by 21 U.S.C. § 360f." FAC ¶ 33(p). Plaintiffs' proposed amendment adds: "Defendants did not change the labeling,[5] nor adequately warn the Plaintiffs of the inherent risks concerning the driveline, which is subject to become damaged due to wear and fatigue overtime." SAC ¶ 57(k). Plaintiffs also allege that the device was "misbranded" under 21 U.S.C. § 352, as she did not receive warnings regarding driveline's potential to wear out over time and that the Patient Handbook only suggests that driveline damage could occur when the wires are twisted or bent. FAC ¶ 33(s); SAC ¶ 57(m). They also submit that Defendants were negligent in their communication in the 2008 recall under 21 C.F.R. ¶¶ 7.46, 7.49, and/or 7.53, and that Ms. Bryant "received a HeartMate II

[5] Plaintiffs allege that after a 2008 recall, the FDA approved revised labeling for the HeartMate II LVAS to include a warning "regarding the potential damage to the percutaneous lead resulting from wear and fatigue." SAC ¶ 35.

that was not accompanied by the appropriate warnings and/or that had not been properly corrected or destroyed."[6] FAC ¶ 33(l); SAC ¶ 57(i).

As Defendants point out, the fact that Ms. Bryant herself did not receive warnings regarding the driveline is not sufficient to state a parallel claim for failure to warn. Under Mississippi law,[7] "a manufacturer's duty to warn only extends to physicians and not to laymen." *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So. 2d 31, 57 (Miss. 2004) (quoting *Swayze v. McNeil Labs.*, Inc., 807 F.2d 464, 470 (5th Cir. 1987)). Plaintiffs have not alleged that UAB did not receive any such warnings; in fact, Plaintiffs aver that they are not aware of what information Defendants gave to UAB regarding the HeartMate II. *See* Pls.' Mem Opp. Defs.' Mot. Dismiss 9, ECF No. 26.[8] Therefore, Plaintiffs' claims that Defendants failed to provide FDA-approved materials to UAB are clearly speculative.

In the alternative, Plaintiffs' claims for failure to warn, such as their claims that the HeartMate II LVAS was "misbranded," are preempted, as they seek to impose different or additional warnings from those required by the FDA. FAC ¶ 33(s). Plaintiff's proposed amendments are futile as they do not change this, as they simply allege that Defendants should have given additional or different warnings to Plaintiff. SAC ¶ 57(m). Once a device receives PMA approval, a manufacturer may not make any changes to the labeling of the device that would affect

[6] As noted, any claims that the HeartMate II should have been designed differently after the recall are expressly preempted. Thus, the Court considers this to be attempting to allege a failure to warn claim.

[7] Plaintiffs have heavily relied on *Bush v. Thoratec Corp.*, No. 11-1654, 2012 WL 2513669 (E.D. La. June 28, 2012) to show that they have adequately stated a claim for failure to warn, as the plaintiff in that case allegedly died when the percutaneous lead in his LVAS wore out. *Id.* at *1. This case is distinguishable, mainly in the fact that it applies Louisiana failure to warn law, which requires manufacturers to give post-sale adequate warnings. *Id.* at *6. Plaintiffs have not argued that Mississippi law contains such requirements.

[8] Plaintiffs state:

"[T]he Plaintiffs have no knowledge of whether UAB received [Instructions for Use, which Defendants submit was provided to healthcare providers,] or was otherwise instructed that 'over time' the percutaneous lead can become damaged due to wear and fatigue. Nor are Plaintiffs aware of whether UAB knew that such damage could cause serious injury or death if the pump was not replaced."

safety or effectiveness. *Riegel*, 552 U.S. at 319. Any changes must be approved by the FDA. Id. As the Fifth Circuit noted in *Hughes*, Plaintiffs "cannot ask the jury to second-guess the [medical device's] label or user manuals, which were specifically approved by the FDA" *Hughes*, 631 F.3d at 776 n.12 (citing *Gomez*, 442 F.3d at 931). Plaintiffs have not submitted any facts that support their allegations that Defendants failed to comply with the FDA's mandated warnings or labels. Therefore, Plaintiffs claims that fall under a failure to warn should be dismissed and their motion to amend should be denied as futile in this respect.

4. Manufacturing Defect

Finally, Plaintiffs have asserted that the HeartMate II had a manufacturing defect. Such claims are preempted when "they challenge the federal-approved manner in which, or the process by which, a Class III medical device is manufactured. State law manufacturing defect claims are not, however, preempted to the extent they are predicated on allegations that the manufacturer failed to follow the FDA-approved manufacturing process." *Carlson*, 2014 WL 11514911, at *4 (internal citations omitted). Defendants have argued that Plaintiffs' allegations are conclusory and without factual support.

The Fifth Circuit has recently twice addressed the sufficiency of allegations to state a parallel claim for a manufacturing defect. First, in *Funk v. Stryker Corp.*, the Fifth Circuit affirmed the district court's decision to dismiss a complaint based on inadequate pleading. For his manufacturing defect claim, the plaintiff alleged:

> [3.] The hip prostheses contained a manufacturing defect in that it was manufactured in such a manner that impurities, residues and bacteria remained on the prosthesis in violation of the FDA standards and requirements and in violation of the manufacturing processes and design approved by the FDA.
>
> [4.] The hip prosthesis deviated, in its construction or quality, from the specifications or planned output.

631 F.3d at 782. Plaintiff then invoked *res ipsa loquitur*. *Id.* The Fifth Circuit, affirming dismissal of the complaint stated:

> This complaint is impermissibly conclusory and vague, it does not specify the manufacturing defect, nor does 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 does the complaint tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process. It instead relies on *res ipsa loquitur* to suggest only that the "that the thing speaks for itself."

Id. The Fifth Circuit contrasted to the second amended complaint which "specifies with particularity what went wrong in the manufacturing process and cites the relevant FDA manufacturing standards Stryker allegedly violated" *Id.*

The next year, the Fifth Circuit reversed a district court's dismissal of a complaint, finding that the plaintiff's complaint was sufficient. *Bass v. Stryker Corp.*, 669 F.3d 501 (5th Cir. 2012). The Fifth Circuit stated that a plaintiff must plead "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. The Fifth Circuit described the plaintiff's specific, non-conclusory allegations as follows:

> In summary, Bass pleaded; (1) he received a Shell implant; (2) the FDA had previously warned Stryker of bioburden in excess of FDA regulations in its final rinse of the Shells; (3) after Bass's surgery, Stryker ultimately voluntarily recalled those Shells, including the Shell specifically used in Bass's implant; (4) Bass suffered from a loose Shell due to a lack of bony ingrowth; and (5) the lack of bony ingrowth is a known effect of an excess of bioburden and manufacturing residuals on Shells. Bass has thus pleaded sufficient facts to find that his injury plausibly resulted from a violation of FDA standards in connection with his manufacturing defect claims . . ., and, therefore, has pleaded a non-conclusory parallel claim under our precedents in *Funk* and *Hughes*.

Id. at 510.[9]

[9] Plaintiffs characterize *Bass* as holding that "all that needs to be alleged is reliance on the CGMP and causation of the injury when a 'plaintiff [does] not have access to the specific federal requirements in the [pre-market approval]

In *Williams v. Ciba Vision Corp.*, this court considered the sufficiency of allegations required to support a parallel claim for a manufacturing defect. 100 F. Supp. 3d 585 (S.D. Miss. 2015). This court noted that more than the legal elements were required:

> Plaintiff does assert the basic legal elements of a parallel claim, that Defendant deviated from the pre-approved manufacturing process which in turn caused a defect in the lens which in turn caused her injury. However, Plaintiff has not stated any fact to support the conclusory allegation that the alleged 'buffered tumbling process' violated the pre-approved manufacturing process or any requirement specific to the MemoryLens IOL.

Id. at 591. The Court then compared that complaint to the one in *Funk*, noting that the allegations were "unsupported by any fact specific to the [device at issue]," and found that the complaint should be dismissed. *Id.* The Court concluded: "Unlike *Bass*, because all of Plaintiff's claims in this case are premised upon the unadorned conclusory allegation that Defendant failed to follow the FDA's pre-approved manufacturing process, Plaintiff has not articulated a parallel state law claim." *Id.* at 592.

Plaintiffs allege that "after having received pre-market approval, [Defendants made] changes to one or more features of the device without obtaining FDA permission, as required by 21 U.S.C. § 360e(d)(6). FAC ¶ 33(d). Plaintiffs' proposed amendment adds that "upon information and belief, inadvertent changes were made to the driveline and controller, including but not limited to, changes in material utilized and safety control processes that allowed the insulation to wear and the controller not to alert the user or her caregivers of the problem." SAC ¶ 57(a), ECF No. 35-1.

Plaintiffs also allege that Defendants failed to comply with post approval conditions or that they manufactured the device inconsistently with the PMA application. FAC ¶ 33(f), (g). Their proposed amendment adds that such changes concern the driveline and that "[t]hese conditions are

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prior to commencing the lawsuit." Pls.' Resp. Opp. Mot. Dismiss 25, ECF No. 26 (quoting *Bass*, 669 F.3d at 512). A review of *Bass* shows that much more is required to state a parallel claim.

privileged and confidential and will be identified when discovery ensues and appropriate protective orders are in place." SAC ¶ 57(c), (d).

Plaintiffs further allege that Defendants did not "adhere to the quality system regulation requirements or good manufacturing practice as set for the 21 C.F.R. § 820.1." SAC ¶ 33(m). Their proposed amendment specifies these regulations and states that "the controls and requirements reference [sic] herein are privileged and confidential and will be identified when discovery ensues and appropriate protective orders are in place." SAC ¶ 57(j).

The Court finds that Plaintiffs' claims are insufficient under *Bass* and *Funk* and that Plaintiffs' proposed amendments are futile. Plaintiff's original claims are wholly devoid of the specifics required by *Funk*, as they simply assert in a conclusory manner that Defendants violated some federal regulations in the manufacturing process. Plaintiffs' proposed amendments add no factual allegations. They simply assert that discovery is required to uncover which manufacturing defects existed. Such allegations are not sufficient.

Plaintiffs point out that the Fifth Circuit has stated that:

> "[C]ourts 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 the plaintiff to make more specific allegations than those found in Bass's complaint may make pleading a parallel claim regarding defective manufacturing nearly impossible.

Bass, 669 F.3d at 511 (alterations in original). But Plaintiffs have not plead any facts that come near to those in *Bass*, where the plaintiffs alleged that the FDA warned the defendants about a manufacturing defect, the device was ultimately recalled[10] because of such defect, and plaintiff's injuries were consistent with such defect. In contrast, Plaintiffs have not "specifie[d] with particularity what went wrong in the manufacturing process and cite[d] the relevant FDA

[10] It is undisputed that the 2008 recall regarding issues with the driveline was related to the design of the HeartMate II LVAS, not a manufacturing issue. SAC ¶ 33.

manufacturing standards [Defendants] allegedly violated." *Funk*, 631 F.3d at 782.[11] Instead, they cite a list of regulations and assert that discovery will determine which regulations were violated.

In so holding, the Court briefly notes that it is not suggesting that Plaintiffs are required to plead product-specific requirements that Defendants allegedly violated. In their response to Defendants' motion to dismiss, Plaintiffs argued at length as to this issue. It is clear that in this circuit that such specificity is not required. *Bass*, 669 F.3d at 511-12 (noting a circuit split on the issue of specificity of regulations required to state a parallel claim). Nevertheless, the factual allegations must be sufficient to raise the right to relief above a speculative level. The Fifth Circuit has stated:

> The key distinction between the 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 regulation *and* allegations connecting a defect in the manufacture of the specific device to the plaintiff's specific injury.

Id. Plaintiffs have alleged no facts that connect the alleged manufacturing defect to their specific injury. Therefore, the Court finds that Defendants' motion should be granted to this extent.

5. Other Pending Claims

For the reasons stated above, Plaintiffs' claim for negligence and loss of consortium are also dismissed.

IV. CONCLUSION

IT IS THEREFORE ORDERED AND ADJUDGED that the Motion to Dismiss [10] is **granted**, as all of Plaintiffs' claims are either preempted or inadequately pled.

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[11] Plaintiff has attempted to distinguish *Funk* by citing *Winslow v. W.L. Gore & Assocs.*, No. 10-00116, 2011 WL 873562 (W.D. La. Mar. 11, 2011), arguing that *Funk* does not apply when a plaintiff does not invoke *res ipsa loquitur*. Plaintiffs fail to mention in their brief that the *Winslow* court distinguished *Funk* as inapplicable, as *Funk* involved both res ipsa *and preemption*. *Id.*, at *1 n.1. Clearly, that is not the case here, as preemption is at the heart of Defendants' motion to dismiss. Thus, the Court finds *Winslow* to be inapplicable to the facts at hand.

Plaintiffs' Motion to Amend is **denied**, as their proposed Amendments are futile.

SO ORDERED AND ADJUDGED, on this, the 30th day of July, 2018.

s/Keith Starrett
KEITH STARRETT
UNITED STATES DISTRICT JUDGE