UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

DINA M. ROBLES BUSH	*	**CIVIL ACTION**
	*	
VERSUS	*	**NO. 11-1654**
	*	
THORATEC CORPORATION, ET AL.	*	**SECTION "L"(3)**

ORDER & REASONS

The Court has pending before it Defendant Thoratec Corporation's Motion to Dismiss (Rec. Doc. 5). The Court has reviewed the briefs and the applicable law and heard oral argument, and now issues this Order and Reasons.

I. BACKGROUND

This case arises out of the death of Pete Bush, a recipient of the Thoratec HeartMate II Left Ventricular Assist System, a surgically-implanted heart pump manufactured by Defendant Thoratec Corporation. According to the allegations in the petition, Mr. Bush had the LVAS implanted on September 26, 2008, at the VA Hospital in Richmond, Virginia. On or about October 24, 2008, the Food and Drug Administration issued a notice regarding the LVAS due to issues with "wear and fatigue of the percutaneous lead connecting the [device] to the system controller [which] may result in damage that could interrupt pump function, require re-operation to replace the pump and potentially result in serious injury and death."

Mr. Bush later returned to New Orleans with his wife, Plaintiff Linda Robles Bush. He visited the Heart Failure Department at Tulane University Medical Center ("Tulane") from early 2009 through May, 2010 to check the LVAS. Plaintiff alleges that Tulane did not inform Mr. Bush of the notice issued regarding his implanted LVAS. On May 4, 2010, Mr. Bush's LVAS

ceased functioning, allegedly resulting in his cardiac arrest and death. Plaintiff alleges that Tulane arranged for an autopsy and that the LVAS was removed and sent to Thoratec for evaluation. Thoratec has not disclosed the findings of that evaluation, but Plaintiff alleges that the evaluation demonstrates that the pump stopped due to the defect described in the FDA notice.

Plaintiff Linda Robles Bush, the decedent's widow, filed suit in Civil District Court for the Parish of Orleans against Defendants Thoratec, a California citizen, and University Healthcare System, LLC, d/b/a Tulane University Medical Center and Clinic, a Louisiana citizen. As to Thoratec, Plaintiff alleges that Thoratec misrepresented the safety of the LVAS and knew of the risk of failure that caused the decedent's death but failed to notify Plaintiff or decedent of the dangerous defects. As to Tulane, Plaintiff alleges that Tulane failed to test the LVAS to detect damage as set forth in the FDA recall notice and intentionally failed in a duty to inform him of the known defect. As to both, Plaintiff alleges that Thoratec and Tulane knowingly concealed defects from the FDA and concealed the results of an autopsy analysis from Plaintiff. On July 14, 2011, Thoratec removed to this Court. On October 24, 2011, the Court denied Plaintiff's motion to remand and granted Tulane's motion to dismiss. (Rec. Doc. 40).

II. PRESENT MOTION

Thoratec moves to dismiss on the grounds that all of Plaintiff's claims are either preempted by the Medical Devices Amendment to the Food, Drug, and Cosmetics Act, or too vague to state a claim under Rule 12(b)(6). In response, Plaintiff attempts to articulate claims that survive preemption.

III. LAW AND ANALYSIS

A. Standard on Motions to Dismiss

When a court considers a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), "all well-pleaded facts are viewed in the light most favorable to the plaintiff, but plaintiffs must allege facts that support the elements of the cause of action in order to make out a valid claim." *City of Clinton v. Pilgrim's Pride Corp.*, 632 F.3d 148, 152-53 (5th Cir. 2010). "To avoid dismissal, a plaintiff must plead sufficient facts to 'state a claim to relief that is plausible on its face.'" *Gentilello v. Rege*, 627 F.3d 540, 544 (5th Cir. 2010) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)). The court "do[es] not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005).

B. Analysis

Thoratec argues that all of Plaintiff's claims fail as a matter of law. Thoratec relies in large part on the express preemption clause in the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act, and the Supreme Court's decision in *Riegel v. Medtronic, Inc.* 552 U.S. 312 (2007) interpreting that clause. Thoratec also argues that to the extent that Plaintiff has attempted to allege a non-preempted parallel claim, she has failed to do so with the requisite factual specificity.

1. Preempted Claims

Congress included an express preemption clause in the MDA:

> (a) General Rule
> Except as provided in subsection (b) of this section, no State or political

> subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement 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).[1] The Supreme Court in *Riegel* has interpreted § 360k and held that it preempts state tort law with respect to medical devices if (1) "the FDA has established requirements applicable to the device at issue" and (2) if "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.'" *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 768 (5th Cir. 2011) (quoting *Riegel*, 552 U.S. at 322). Thoratec submits (and Plaintiff does not dispute) that the LVAS device is a Class III medical device that went through premarket approval (PMA) before the FDA, which imposes safety "requirements" and prohibits "any changes to the design, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Accordingly, the first prong of *Riegel* is satisfied. *See* 552 U.S. at 319, 322-23; *Hughes*, 631 F.3d at 768.

The issue is therefore whether Plaintiff's state-law claims would impose different or additional requirements on Thoratec with respect to the LVAS. Clearly, state tort law cannot "question the sufficiency of the FDA-approved labeling, warnings, and instructions for the [LVAS] or require [Thoratec] to have included different warnings, labels, or instructions with the device." *Hughes*, 631 F.3d at 769. Likewise, a claim that the device, as approved, was

[1]Subsection (b) relates to exceptions granted by the Secretary of Health and Human Services upon application by a State and does not apply to the present case.

unsafe is also preempted. *See Riegel*, 552 U.S. at 325 ("State tort law that requires a manufacturer's [devices] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.").

On the other hand, § 360k does not preempt a state-law tort claim that relates to the device's safety or effectiveness but does not impose requirements different or in addition to the federal requirements. Thus, the statute "does not prevent a State from providing a damage remedy for claims ***premised on a violation of FDA regulations***; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (emphasis added). Thus, "to the extent that [a plaintiff] asserts a failure to warn claim based only on [defendant's] failure to comply with FDA regulations ... such a claim is not expressly preempted." *Hughes*, 631 F.3d at 769. The Court must consider the elements of purported state-law tort claims "to determine whether these claims impose requirements that differ from or are in addition to federal requirements." *Id.* at 768.

In her petition, Plaintiff makes the following allegations with respect to Thoratec and the LVAS:

> At all relevant times, Thoratec **misrepresented the safety of the LVAS and negligently manufactured, marketed, advertised, promoted, sold and distributed the leads** as safe and effective devices for implantation with HeartMate II heart pumps for heart failure patients.
> At all times relevant, Thoratec knew, and had reasons to know, that **the LVAS leads were not safe for patients because of damage** and, therefore, may cause serious medical problems in some patients, and catastrophic injuries and death in others.
> Despite Thoratec's knowledge of the defects in the LVAS, **it sold, distributed and marketed the device without notifying or advising Mr. Bush or petitioner of the need for re-operation and replacement in direct contravention of notice requirements of the U.S. Food and Drug Administration for recalled devices.**
> ....

> Additionally, both **Thoratec** and Tulane have **knowingly concealed known defects from the FDA** and the results of the analysis of the LVAS in Mr. Bush, **which constitutes fraudulent concealment.**

(Rec. Doc. 1-2 at ¶¶ 11-13, 15) (emphasis added).

Thoratec contends that these allegations are preempted. With respect to the allegations that Thoratec negligently manufactured, marketed, advertised, promoted, and sold the LVAS, or that the LVAS was not safe, Thoratec argues that those claims impose different or additional requirements than those approved by the FDA regarding with respect to design, labels, or manufacturing, and are therefore preempted. With respect to the allegations that Thoratec failed to notify Plaintiff or the decedent, Thoratec contends that the FDA regulations required no direct notice to patients, *see* 21 C.F.R. §§ 7.45-7.50, and thus state tort law cannot impose additional disclosure requirements.

In response, Plaintiff first requests leave to amend to state her causes of action with greater specificity. With respect to preemption, Plaintiff argues that Thoratec failed to notify her or the decedent of issues with the LVAS and that claim is not preempted by federal regulations. She offers two bases for non-preemption: (1) that her claims are preserved by 21 U.S.C. § 360h(d), which permits state court remedies for claims relating to compliance with recall notifications issued by the Secretary of Health and Human Services; and (2) that Thoratec in fact violated applicable FDA reporting guidelines, which can be remedied through a non-preempted parallel state-law claim.

(a) 21 U.S.C. § 360h(d) Argument

Plaintiff argues that Thoratec violated 21 U.S.C. § 360h, which governs recall orders issued by the Secretary of Health and Human Services. Pursuant to § 360h(d), "compliance with

an order issued under this section shall not relieve any person from liability under Federal or State law." She argues that § 360h(d) is a savings clause that preserves state tort law remedies for failure to comply with FDA recall orders. Plaintiff submits an affidavit from a purported legal expert, James P. Walters, attesting that the regulation should be interpreted in that fashion. The Court does not find that the expert affidavit is an appropriate or relevant method for arguing for a particular interpretation of this statutory provision.

Thoratec responds that § 360h(d) is not implicated at all in this case because the medical device correction and recall were voluntarily issued by Thoratec and not issued by the Secretary; without "an ordered issued under this section" by the Secretary, § 360h simply does not apply. Plaintiff responds that § 360h applies because by regulating, the FDA "ordered" the disclosure that occurred in this case. Thoratec also points out that Plaintiff has not cited any cases finding the express preemption provision of § 360k is affected in any way by § 360h.

Plaintiff has not cited any authority for the proposition that § 360h(d) giveth back what § 360k taketh away. Section 360h(d) governs "[c]ompliance with an order issued ***under this section***," and the section is concerned with orders issued by the Secretary of Health and Human Services, *see id.* at § 360h(a) (emphasis added).[2] Plaintiff has not alleged that any such order was issued. Moreover, the Supreme Court has commented that§ 360h(d) at most "indicates that some state-law claims are not pre-empted .... [b]ut it could not possibly mean that *all* state-law claims are not pre-empted, since that would deprive the MDA pre-emption clause of all content." *Riegel*, 552 U.S. at 325 n.4. Accordingly, § 360h(d) has no applicability to Plaintiff's claims and

[2]In her opposition brief, Plaintiff incorrectly quotes § 360h(d) as applying to "an order issued under [the MDA]." (Rec. Doc. 25 at 6) (alteration in Plaintiff's memorandum). That alteration misstates the scope of subsection (d).

does not avert preemption.

(b) Thoratec's Breach of FDA Reporting Regulations

Second, Plaintiff also argues that she has asserted viable parallel state-law claims predicated on violation of FDA regulations. In the Complaint Plaintiff alleges that Thoratec "sold the device without notifying or advising Mr. Bush or petitioner of the need for re-operation and replacement in direct contravention of notice requirements of the U.S. Food and Drug Administration for recalled devices," and "knowingly concealed known defects from the FDA ... which constitutes fraudulent concealment." Thoratec also argues that Louisiana law does not provide a cause of action for "fraudulent concealment" against a manufacturer. *See* La. Rev. Stat. § 9:2800.52 ("[The Louisiana Products Liability Act] establishes the exclusive theories of liability for manufacturers for damage caused by their products.").

In her opposition, Plaintiff does not cite any FDA requirements which explicitly require Thoratec to directly notify patients who received the LVAS, rather than the health care providers who purchased the device. Plaintiff also does not specify the authority for a Louisiana cause of action for "fraudulent concealment" against a product manufacturer. Rather, she proceeds on the theory that Thoratec did not completely notify the FDA of the nature of LVAS malfunctions, pursuant to FDA regulations, which possibly affected how the FDA categorized the recall notice. According to Plaintiff, there are discrepancies between Thoratec's October 24, 2008 voluntary medical device notice and December 22, 2008 voluntary recall. Plaintiff theorizes that if Thoratec had fully informed the FDA, the FDA would have issued a Class I recall rather than a Class II recall and "had the FDA classified Thoratec's recall as Class 1, it would have likely imposed more stringent notice requirements, and expanded the class of recipients of the notice,

including end users like [decedent]." Plaintiff again cites the affidavit from her legal expert to argue that the information contained in the initial October 24, 2008 notice, but omitted from the December 22, 2008 recall notice, would have changed how the FDA categorized the recall, and therefore "there is a serious question as to whether Thoratec provided the necessary information to FDA."

Thoratec replies first that Plaintiff's argument is factually baseless because Thoratec provided both the October 24 and December 22 notices to the FDA and thus fully informed the FDA of the relevant facts. It also argues that the claim is impliedly preempted pursuant to the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee*. 531 U.S. 341 (2001). In *Buckman*, the Supreme Court examined a "fraud-on-the-FDA" claim based on misrepresentations made during the PMA process without which the product allegedly would not have been approved and would not have injured the plaintiffs. *See id.* at 347-49. The Supreme Court found that such claims were impliedly preempted because Congress granted the FDA sole authority to enforce violations of the FDCA and MDA. Allowing state-law claims alleging fraud on the FDA would have interfered with the delicate federal statutory scheme empowering the FDA to punish and deter fraud against it. *See id.*

The Fifth Circuit recently found that *Buckman* does not preempt violations of "the underlying state duty to warn about the dangers or risks of [a] product" premised on the defendant manufacturer's breach of applicable *federal* regulations. *See Hughes*, 631 F.3d at 775. In *Hughes*, the manufacturer allegedly failed to adequately report serious injuries caused by its device, reports which summary judgment evidence demonstrated would have been disseminated by the FDA to the public and to physicians. *See id.* at 765-67, 770-71. Thus, in Hughes the

plaintiff alleged a state tort for breach of the state-law duty to warn but sought "to prove ... breach of the state duty by showing that" the defendant violated regulations requiring reports to the FDA. *See id.* at 775-76. The Fifth Circuit distinguished those facts from *Buckman* on the grounds that in *Buckman* there was no independent state tort duty implicated, and also that the claims in *Buckman* "depend[ed] on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue." *See id.* at 675.

Plaintiff's claim of "fraudulent concealment" "depend[s] on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue, as in *Buckman*." *Id.* Indeed, Plaintiff argues that "had the FDA classified Thoratec's recall as Class 1, ***it would have likely*** imposed more stringent notice requirements, and expanded the class of recipients of the notice." Moreover, Plaintiff is arguing that Thoratec breached disclosure duties owed to the FDA, not that Thoratec breached a disclosure duty owed to Plaintiff by failing to comply with FDA regulations. Under *Buckman*, such a claim is preempted.

Nonetheless, as *Hughes* recognizes, *Buckman* does not impliedly preclude a "tort claim based on the underlying state duty to warn about the dangers or risks of product." *Id.* Under these circumstances, it is appropriate to allow Plaintiff an opportunity to amend her complaint, consistent with Rule 8 and Rule 11, to attempt to "thread the needle" and state a claim cognizable under Louisiana tort law that is not preempted by the authorities cited in this Order and Reasons.

2) Other Claims

There are two other potential claims which must also be dismissed, although not on

preemption grounds. First, to the extent that Plaintiff's allegation of "negligent manufacture" is an attempt to plead a parallel state-law claim that the LVAS in question did not comply with the FDA's safety or manufacturing requirements, Plaintiff has not pleaded with the requisite factual specificity. *See Funk v. Stryker Corp.*, 631 F.3d 777, 781-82 (5th Cir. 2011) (affirming dismissal of complaint alleging that hip implant had manufacturing defect because allegations were "impermissibly conclusory and vague"). However, it is appropriate under these circumstances to grant Plaintiff leave to amend the complaint to comply with the applicable pleading requirements, if indeed Plaintiff intends to pursue such a claim.

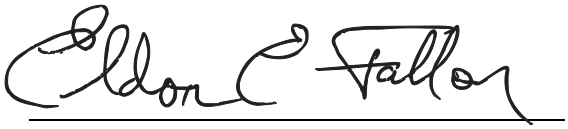
Second, Plaintiff argues that she consented to Thoratec's request to surgically explant the device and analyze it but that Thoratec has refused to produce documents generated by that analysis. She contends that Louisiana law entitles her to that report, citing Louisiana Code of Civil Procedure article 1422, which governs the scope of civil discovery in Louisiana state court. Plaintiff does not cite any authority for the proposition that a party may file a lawsuit in order to pursue discovery available once a lawsuit has been filed. Discovery is a mechanism for obtaining evidence relevant to a claim, not a free-standing claim itself. Upon amending her complaint, if Plaintiff successfully states a legal claim then she may pursue the report in discovery in the normal fashion.

IV. CONCLUSION

To summarize, Plaintiff's complaint does not state a viable, non-preempted claim. Plaintiff's claim for disclosure of the report is dismissed with prejudice. Plaintiff has leave to amend her complaint to attempt consistent with this Order and Reasons and with the operative law. Accordingly,

For the foregoing reasons, IT IS ORDERED that Defendant Thoratec's motion to dismiss (Rec. Doc. 5) is GRANTED. Plaintiff may file an amended complaint on or before Monday, December 19, 2011.

New Orleans, Louisiana, this 28th day of November, 2011.



UNITED STATES DISTRICT JUDGE