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

On March 28, 2012, Plaintiff's Motion for Leave to File Second Supplemental and Amending Complaint [Doc. #55] came on for oral hearing before the undersigned. Present were Marcia Finkelstein on behalf of plaintiff and Mindy Patron on behalf of defendant. After the oral hearing, the Court took the motion under advisement. Having reviewed the motion, the opposition, the case law and thhe parties' arguments, the Court rules as follows.

I. Background

This case arises out of the death of Pete Bush, a recipient of the Thoratec HeartMate II Left Ventricular Assist System ("LVAS"), a surgically-implanted heart pump manufactured by defendant Thoratec Corporation ("Thoratec"). 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 filed suit in the 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 alleged 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 on plaintiff. On July 14, 2011, Thoratec removed to this Court. On October 24, 2011, the District Court denied plaintiff's motion to remand and granted Tulane's motion to dismiss. [Doc. #40].

On November 29, 2012, the District Court granted Thoratec's motion to dismiss and allowed plaintiff to amend her complaint before December 19, 2011. Plaintiff did so, and Thoratec filed a

motion to dismiss the amended complaint.

II. The Parties' Contentions

A. Plaintiff's Motion to Amend

Plaintiff seeks to amend her complaint for a second time based on evidence that she discovered after she filed her amended complaint, evidence that she alleges she could not have discovered earlier. After the deposition of Sabrina White, the LVAS coordinator at Tulane, and Dr. Gundars Katlaps and Lisa Martin, the implanting surgeon and surgeon's nurse/LVAS coordinators at the VA Medical Center, respectively, plaintiff alleges that she discovered information to allege a claim for failure to warn (1) how to tell patients about the LVAS defects and (2) how the hospitals were to monitor for and detect damage to the percutaneous leads.

Citing Rule 15, plaintiff alleges that the amendment will not unduly delay the proceedings given that the District Court only decided jurisdiction on November 29, 2011. Plaintiff also contends that she has been "stymied" in her attempts to conduct discovery. Thoratec allegedly refused to produce its investigative report, and the holidays delayed the deposition of White. Plaintiff argues that she is in good faith and has attempted to move the case forward expeditiously. She contends that she has not filed earlier amendments to cure the alleged deficiency, and this amendment will not prejudice Thoratec.

Plaintiff also asserts that the amendment is not futile. Thoratec's warning letter to hospitals allegedly failed to define crucial terms such as "high" and "reduced." According to plaintiff, Martin and White stated that they monitored Mr. Bush's levels differently. Plaintiff thus contends that Thoratec's instructions and training were confusing and inadequate.

B. Defendant Thoratec's Opposition

Thoratec contends that all of the information that plaintiff has now obtained was available to her before the December 19, 2011 deadline to amend. Thoratec argues that all of the individuals from whom she obtained the information were known to her before the deadline. Thoratec asserts that plaintiff had over seven months – from the date of filing suit – to depose the individuals.

Thoratec also argues that plaintiff's claims are still preempted, and the amendment is thus futile. It notes that her new claims allege that Thoratec's device correction should have included different and/or additional instructions for medical providers. Thoratec thus contends that plaintiff seeks to impose requirements that are "different from, or in addition to" the FDA's requirements. 21 U.S.C. § 360k.

Thoratec further argues that plaintiff has repeatedly attempted to cure the deficiencies of her complaint. It maintains that it will suffer prejudice by incurring the costs to defend against a new complaint because allowing the amendment will only lead to a new motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

C. Plaintiff's Reply

Plaintiff argues that she has arduously pursued the claim. She consulted the attorneys only days before prescription would have run, and, after counsel immediately requested Thoratec's investigative report, Thoratec refused to produce it. Plaintiff propounded discovery on Thoratec on July 5, 2011 – after she had sued – and Thoratec allegedly did not respond to the discovery. Once Thoratec had removed the case, plaintiff argues that it was against her best interests to engage in discovery given the case law that holds that once plaintiff engages in discovery, she waives her right to complain of removal.

Plaintiff also notes that after the District Court granted Thoratec's motion to dismiss and

allowed her to amend by December 19, 2011, she attempted to depose White, who was unavailable until December 20, 2011. Plaintiff further maintains that she only learned of the importance of Katlaps and Martin through exhibits to Thoratec's motion to dismiss. When she noticed their depositions, the VA Hospital objected and refused to produce them. Ultimately, plaintiff and the VA Hospital reached a compromise, and Martin produced a declaration under 28 U.S.C. § 1746 that responded to several of plaintiff's questions. In sum, plaintiff contends that she consulted three experts, sent two FOIA requests, propounded seven sets of discovery to parties and attempted to depose White and the VA Hospital's operating room manager.

Plaintiff maintains that the amendment is not futile. She alleges that Thoratec's notices violated Louisiana Revised Statutes §§ 9:2800.57 and Civil Code Article 2315, which mandate that a manufacturer properly warn about a product defect. Plaintiff argues that the FDA regulations do not regulate the specific substance of a manufacturer's warning. Plaintiff notes that the FDA did not become involved in the recall until two months after Thoratec issued it, thus evidencing that the FDA does not regulate the substance of the warning that Thoratec issued. Citing *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769-71 (5th Cir. 2011), plaintiff argues that her claims are not preempted because she alleges that Thoratec violated FDA regulations.

III. Law and Analysis

Federal Rule of Civil Procedure 15(a), which governs the amendment of pleadings, provides that leave to amend pleadings "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a)(2). This, and other federal rules "reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits." *Conley v. Gibson*, 355 U.S. 41, 48 (1957).

Thus, Rule 15(a) evinces a liberal amendment policy and a motion to amend should not be denied absent a substantial reason to do so. *See Jacobsen v. Osborne*, 133 F.3d 315, 318 (5th Cir. 1998).

However, leave to amend is by no means automatic. *Addington v. Farmer's Elevator Mut. Ins. Co.*, 650 F.2d 663, 666 (5th Cir. 1981). The decision to grant or deny a motion for leave to amend lies within the sound discretion of the trial court. *Id.* As outlined by the Supreme Court, courts in this circuit examine five considerations to determine whether to grant a party leave to amend a complaint: (1) undue delay; (2) bad faith or dilatory motive on the part of the movant; (3) repeated failure to cure deficiencies by amendments previously allowed; (4) undue prejudice to the opposing party by virtue of allowance of the amendment; and (5) futility of the amendment. *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 864 (5th Cir. 2003) (citing *Forman v. Davis*, 371 U.S. 178, 182, (1962)). Absent any of these factors, leave to amend a complaint should be "freely given." *Smith v. EMC Corp.*, 393 F.3d 590, 595 (5th Cir. 2004) (citing *Forman*, 371 U.S. at 182).

There is no evidence of undue delay here. The District Court only determined that it has subject-matter jurisdiction in November 2011. Nor is there evidence of bad faith. While plaintiff has amended her complaint before, she has only done so once, and that is not evidence of repeated failure. While Thoratec argues prejudice, it only does so with regard to the costs of litigation, a prejudice that all defendants must bear.

In addition, while Thoratec argues that the amendment would be futile, plaintiff's reliance on *Hughes* reveals that under the circumstances here, the issue is far from clear-cut. There, the court held that "we are satisfied that Hughes's failure to warn claim is not expressly preempted to the extent that it is based on Boston Scientific's violation of applicable FDA regulations requiring accurate reporting of serious injuries and malfunctions of the HTA device. This claim does not

impose additional or different requirements to the federal regulations, but is parallel to the federal requirements." 631 F.3d at 771. The Court can not say at this time that plaintiff's new claims do not fall under the protection afforded by *Hughes*.

IV. Conclusion

For the foregoing reasons,

IT IS ORDERED that Plaintiff's Motion for Leave to File Second Supplemental and Amending Complaint [Doc. #55] is GRANTED.

New Orleans, Louisiana, this 9th day of April, 2012.

DANIEL E. KNOWLES, III
UNITED STATES MAGISTRATE JUDGE