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. 74). The Court has reviewed the briefs and the applicable law and heard oral argument, and now issues this Order and Reasons.

I. BACKGROUND

Plaintiff Dina M. Robles Bush brings this case on behalf of her deceased husband, Pete Bush. Mr. Bush was a recipient of the Thoratec HeartMate II Left Ventricular Assist System ("LVAS"). The LVAS is a surgically-implanted heart pump manufactured by Defendant Thoratec Corporation. According to the allegations in the Second Amended Complaint, Mr. Bush had an LVAS implanted on September 26, 2008, at the Hunter Holmes McGuire VA Medical Center ("McGuire") in Richmond, Virginia. Mr. Bush returned to McGuire for inspection and monitoring of the LVAS until January 2009, when he and Plaintiff moved to New Orleans, Louisiana. Mr. Bush then made monthly visits to Tulane Medical Center for the same monitoring of the LVAS.

The LVAS system consists of a heart pump, a system controller, and a percutaneous lead connecting the pump to the controller. Because the percutaneous lead runs from the internal heart pump to the external controller unit, it has both an external portion that can be visually

examined for damage and an internal portion that cannot. On October 24, 2008, Thoratec issued a press release announcing a medical device correction related to the risk of failure of the percutaneous lead due to fatigue and wear. The press release was posted on the website of the Food and Drug Administration. In addition, on October 28, 2008, Thoratec sent an Urgent Medical Device Correction letter to its clients, the hospitals who installed and monitored the LVAS device. The letter, which Plaintiff attaches to the Second Amended Complaint, informs hospitals that "Thoratec has become aware that, over time, wear and fatigue of the percutaneous lead connecting the [LVAS] blood pump with the external System Controller may result in damage that has the potential to interrupt pump function and may require a reoperation to replace the pump." (Rec. Doc. 68-1 at 1). The Correction letter warns that "[d]amage due to wear and fatigue of the percutaneous lead has occurred in both the externalized and implanted portions of the lead" and that "[d]amage to the electrical conductors within the lead may or may not be preceded by visible damage to the outer layer of the lead." *Id.* The letter identified certain signs of damage, including "high pump power associated with reduced pump speed," "high pulsatility index and/or the need for frequent replacement of the System Controller." *Id.* Thoratec advised hospitals to request LVAS patients to return for inspection of the percutaneous lead, directed the hospital to review the LVAS Instructions for Use, and attached excerpts from the product label regarding care of the LVAS lead. *Id.* at 2.

Plaintiff alleges that although both McGuire and Tulane received the Correction letter, neither hospital ever informed her or Mr. Bush of the Correction letter or of the risk of fatigue damage to the percutaneous lead. On May 4, 2010, the percutaneous lead in Mr. Bush's LVAS allegedly failed due to wear and fatigue, which led to failure of the pump and Mr. Bush's death

by cardiac arrest. Thoratec's investigation of the device revealed "multiple areas of breakdown to the braided shield along the entire length of the internal portion of his percutaneous lead." (Second Am. Complt., Rec. Doc. 68 at ¶ 13).

Plaintiff filed suit in Civil District Court for the Parish of Orleans against Defendants Thoratec, a California citizen, and Tulane, a Louisiana citizen. 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 on the basis that Plaintiff had not proceeded through a Medical Review Panel with respect to her claims against Tulane. (Rec. Doc. 40).

On November 29, 2011, the Court granted Thoratec's motion to dismiss Plaintiff's claims on the grounds of preemption pursuant to 21 U.S.C. § 360k(a) and the Supreme Court's opinion construing that express preemption provision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2007). (Rec. Doc. 41). However, the Court granted Plaintiff leave to amend her complaint to attempt to state a non-preempted claim. Plaintiff filed an Amended Complaint (Rec. Doc. 44) and then sought and received leave to file a Second Amended Complaint (Rec. Doc. 68), which is now the operative pleading.

In the Second Amended Complaint, Plaintiff articulates three potentially parallel state law claims. She argues that because the FDA had no requirements for recall communications, state law warning requirements are therefore consistent with federal law; or alternatively that Thoratec failed to comply with 21 C.F.R. § 7.49, which provides guidelines for recall notices; or alternatively that Thoratec violated federal regulations either by failing to include adequate notice and instructions in its Correction letter, or by failing to identify the design defect in the percutaneous lead and to take appropriate corrective action. However, in opposition to the

motion to dismiss, Plaintiff has abandoned all but one theory: that Thoratec violated 21 C.F.R. § 7.49 by failing to include suggested content in its Urgent Medical Device Correction letter, and that violation of federal law also violated Thoratec's duty to warn under Louisiana law.

II. PRESENT MOTION

Defendant Thoratec moves to dismiss the Second Amended Complaint on the basis of the express preemption clause of the Medical Device Amendments to the Food, Drug, and Cosmetics Act. 21 U.S.C. § 360k(a). Defendant argues that Plaintiff has not stated a parallel state law claim that avoids express preemption for three reasons. First, Defendant argues that the claim is preempted because it conflicts with or "second-guesses" the actions that the FDA actually took with respect to the Correction letter and the LVAS. Second, Defendant argues that 21 C.F.R. § 7.49 is too general to support a parallel state law claim. Third, Defendant argues that 21 C.F.R. § 7.49 provides non-mandatory guidance that cannot support a parallel state claim. And fourth, Defendant argues that the content Plaintiff alleges was missing from the Correction letter goes beyond the § 7.49 guidelines and is not genuinely equivalent or parallel.

Plaintiff responds that the FDA did not provide meaningful review of the Correction letter, and therefore, the claim does not conflict with FDA action. Furthermore, Plaintiff argues that 21 C.F.R. § 7.49 regulates the content of the Correction letter, such that Defendant's alleged violation of this regulation is a proper basis for a parallel state law claim.

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 v+alid 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. Express Preemption of Medical Device Claims After *Riegel*

Congress included an express preemption clause in the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetics Act:

> (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). In *Riegel v. Medtronic*, the Supreme Court held that § 360k preempts state tort law with respect to medical devices if (1) "the FDA has established requirements applicable to the device at issue" and (2)"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) (internal quotation marks

omitted). Class III medical devices have gone through the rigorous Premarket Approval (PMA) process, which forbids the manufacturer from making any "changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319. Consequently, state tort law cannot impose different requirements as to design, manufacturing, or labeling. *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."); *Hughes*, 631 F.3d at 769 (explaining that state tort law cannot "question the sufficiency of the FDA-approved labeling, warnings, and instructions for the [device] or require [defendant] to have included different warnings, labels, or instructions with the device").

But *Riegel* left a door open. The Supreme Court explained that § 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." *Riegel*, 552 U.S. at 330 (emphasis added). Because the issue had not been raised in lower proceedings, the Supreme Court did not have occasion to flesh out what kinds of "parallel" claims survive preemption. *See Riegel*, 552 U.S. at 330; *see also* Elliot Sheppard Tarloff, Note, *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, 86 N.Y.U. L. Rev. 1196, 1198 (2011) ("But the Riegel Court's description of parallel claims—the claims that survive preemption—was brief, vague, and consequently very difficult for subsequent courts to interpret.").

Two recent Fifth Circuit opinions shed some light on the kinds of parallel state law claims that survive express preemption. In *Hughes v. Boston Scientific Corp.*, the plaintiff

suffered second-degree burns caused by a leaking Class III medical device. 631 F.3d at 765. The plaintiff's main theory was that the manufacturer violated the FDA's Medical Device Reporting ("MDR") requirements by under-reporting deaths or serious injuries caused by the device, and she argued that this failure to comply with federal warning guidelines violated a parallel state law duty to warn of product risks. *See id.* at 765-66. The district court granted summary judgment and dismissed all claims as preempted. *Id.* at 767. Building on the *Riegel* exception for parallel claims, the Fifth Circuit held that a state law failure-to-warn claim predicated on the manufacturer's failure "to provide adequate warnings or sufficiently communicate information about the risks associated with the . . . device" was not preempted "to the extent that this claim is predicated on [defendant's] failure to report 'serious injuries' and 'malfunctions' of the device *as required by the applicable FDA regulations*." *Id.* at 769 (emphasis added). That kind of state law failure-to-warn claim was "parallel" to the requirements imposed by federal law and therefore not preempted. *See id.* at 769-71.[1] Thus, the Fifth Circuit held that "[t]o 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.

In *Bass v. Stryker Corp.*, the plaintiff alleged a defect in a component of his hip replacement. 669 F.3d 501, 506 (5th Cir. 2012). The plaintiff alleged that the component failed

[1]There is a circuit split on whether parallel failure-to-warn claims are permissible. The Eighth and Ninth Circuit Courts of Appeals have held that failure-to-warn claims are impliedly preempted by a separate provision, § 337(a). *See Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1164 (9th Cir. 2012); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010). The Fifth Circuit rejected that argument in *Hughes*. 631 F.3d at 774-76. Since this Court applies the law of the Fifth Circuit, it does not need to address the split of authority.

to attach to the bone because of contamination stemming from the manufacturer's failure to comply with the FDA's current Good Manufacturing Practices ("cGMPs"), and that the resulting defect caused his injury such that the violation was remediable through a state tort claim. *See id.* at 510. The district court dismissed this claim as preempted, but the Fifth Circuit reversed, finding that the plaintiff had successfully alleged "that his injury plausibly resulted from a violation of FDA standards in connection with his manufacturing defect claims." *Id.* at 510; *see also id.* at 510-11. Accordingly, the plaintiff's state law claims were not preempted "to the extent that the claims are based upon manufacturing defects *resulting from violations of federal regulations*." *Id.* at 510 (emphasis added). The Fifth Circuit also rejected an argument that the cGMPs were too general to support a parallel claim because they applied to all devices and not specifically to the hip component. *See id.* at 511-13. That is, the court held that generally applicable, non-device-specific regulations, if violated, can still support a parallel state law tort claim.

To sum up, *Riegel* left open the possibility of parallel state tort claims predicated on violations of federal regulations. In *Hughes*, the Fifth Circuit permitted a state failure-to-warn claim predicated on a defendant manufacturer's failure to comply with generally applicable FDA incident reporting regulations. In *Bass*, the Fifth Circuit permitted a state law defective manufacturing claim predicated on a defendant manufacturer's failure to comply with generally applicable FDA quality-control regulations.

C. Analysis

With *Riegel*, *Hughes* and *Bass* as guidance, the Court now turns to whether Plaintiff has stated a non-preempted claim. The Court applies the two-prong *Riegel* test and examines

whether the LVAS was subject to federal requirements and, if so, whether Louisiana state law creates requirements "different from" or "in addition to" those federal requirements. *See Hughes*, 631 F.3d at 767-68 (citing *Riegel*, 522 U.S. at 322).

The first prong of the *Riegel* test is easily satisfied. The parties do not dispute that the LVAS is a Class III medical device that went through FDA Premarket Approval. "*Riegel* established that any Class III device receiving PMA approval by the FDA will satisfy this first prong of the test . . . ." *Hughes*, 631 F.3d at 768. Therefore, the device is subject to federal safety and labeling requirements. The second prong requires the Court to consider whether the applicable state law creates requirements "different from" or "in addition to" those federal requirements, or, put another way, whether the state law claim is "premised entirely on violation of the applicable federal requirements," *Id.* at 770. With respect to the state law side of the equation, Plaintiff cites the Louisiana Products Liability Act, which imposes on manufacturers a duty to warn of product defects that are discovered post-sale:

> A manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

La. Rev. Stat. § 9:2800.57(C).

As the federal hook on which to hang the parallel state law failure-to-warn claim, Plaintiff cites 21 U.S.C. § 7.49. Section 7.49 sets forth guidelines for the content of recall communications regarding medical devices:

> (a) General. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. *The format, content, and extent of a recall communication should be commensurate with the hazard of the*

product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

(1) That the product in question is subject to a recall.

(2) That further distribution of or use of any remaining product should cease immediately.

(3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.

(4) Instructions regarding what to do with the product.

. . .

(c) Contents.

(1) *A recall communication should be written in accordance with the following guidelines*:

(i) Be brief and to the point;

(ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;

(iii) *Explain concisely the reason for the recall and the hazard involved, if any*;

(iv) *Provide specific instructions on what should be done with respect to the recalled products . . . .*

21 U.S.C. § 7.49 (emphasis added). Defendant does not argue that § 7.49 does not apply to Urgent Medical Device Correction letter at issue in this case. Accordingly, the Court assumes that the regulation applies.

Thus, Louisiana law requires a manufacturer to give post-sale "adequate warning" of a potentially dangerous and damaging characteristic of a product to users or "handlers" of the product. La. Rev. Stat. § 9:2800.57(C). Federal law dictates that recall notices should be "commensurate with the hazard of the product being recalled," and should be drafted in accordance with "guidelines" to include "the reason for the recall and the hazard involved" and "specific instructions on what should be done with respect to the recalled products." 21 C.F.R. § 7.49(c)(1)(iii), (iv). Putting the two together, Plaintiff argues that Defendant violated § 7.49 by failing to include sufficiently specific instructions or a more emphatic description of the risks to

the LVAS percutaneous lead, and that the violation of that *federal* requirement is remediable through a *state* failure-to-warn claim.

Defendant offers several arguments as to why Plaintiff's failure-to-warn claim is preempted. First, Defendant argues that because the FDA exercised oversight of Thoratec's Urgent Medical Device Correction letter but did not criticize the letter, require additional disclosures, or otherwise take any action, Plaintiff cannot now argue that Thoratec violated any federal requirements. The FDA's conduct is not part of the record at this stage, and accordingly, this argument would better be raised in a motion for summary judgment after an opportunity for discovery. However, the Court also notes that Defendant's argument is not legally well founded. In both *Hughes* and *Bass*, the Fifth Circuit held that an FDA finding that a manufacturer violated regulations is not an "implicit precondition" to a parallel state tort claim predicated on those violations. *See Hughes*, 631 F.3d at 772-73; *Bass*, 669 F.3d at 509 ("Importantly, a formal finding of a violation by the FDA was not required to plead a parallel action."). While the FDA's action or inaction is relevant to assessing whether the manufacturer violated any regulations, it is not a prerequisite to a parallel claim.

Second, Defendant argues that § 7.49 provides only vague guidelines, and thus Plaintiff cannot base a parallel claim on that regulation. Because § 7.49 does not mandate any precise language or define the parameters of what constitute "specific instructions" in a recall notice, Defendant argues there is no specific requirement to be violated, and any requirement imposed by state tort law would necessarily be a preempted "additional" requirement inconsistent with federal regulation. To put it in terms used by the Fifth Circuit in *Hughes*, the concern is that "the jury in this case may apply the plain terms of [§ 7.49] in a different or more stringent manner

than the FDA intended," which would be a preempted different or additional state law requirement. *Hughes*, 631 F.3d at 773.

This is not an appropriate basis for a 12(b)(6) motion. Both *Hughes* and *Bass* permitted a parallel claim to proceed based on violations of generally applicable guidelines—the Medical Device Reporting requirements in *Hughes*, and the cGMPs in *Bass*—that apply across the board to all manufacturers. Admittedly, the § 7.49 provision that a recall notice include "specific instructions on what should be done with respect to the recalled products" is more general than the MDR reporting requirements allegedly violated in *Hughes* or the cGMPs allegedly violated in *Bass*. In *Hughes*, the MDR reporting regulations defined the types of events that should be reported, 631 F.3d at 765-66, and in *Bass* the generic cGMPs could be buttressed by device-specific manufacturing parameters approved by the FDA in the PMA process, 669 F.3d at 512.[2] But § 7.49 does include an underlying principle that the "format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled." And Louisiana law requires an "adequate warning." Putting the two together, Plaintiff argues that Thoratec, having elected to send the Urgent Medical Device Correction letter,[3] was bound by federal regulations to draft the letter in accordance with the § 7.49 guidelines but failed to do so.

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[2]Also, in both *Hughes* and *Bass*, the record suggested that the FDA actually disapproved of the manufacturer's incident reporting or its manufacturing process. *See* 631 F.3d at 773; 669 F.3d at 513. However, as noted above, both cases expressly held that an FDA finding of a violation is not an "implicit precondition" to predicating a parallel state claim on that violation.

[3]Thoratec issued the Urgent Medical Device Correction letter, and therefore this is not a situation in which state law requires an act that is merely discretionary under federal law. Thus, Defendant's citation to *McMullen v. Medtronic, Inc.*, is inapposite. 421 F.3d 482, 489 (7th Cir. 2005) ("Where a federal requirement *permits* a course of conduct and the state makes it *obligatory*, the state's requirement is in addition to the federal requirement and thus is preempted.") (emphasis added).

In particular, Plaintiff argues that the letter did not "[p]rovide specific instructions on what should be done with respect to" the LVAS and "[e]xplain concisely the . . . hazard involved." *Id.* at § 7.49(c)(iii), (iv). As set forth above, the letter (which has been entered in the record) warned of the risk of fatigue wear and tear to the internal and external portions of the percutaneous lead, and recommended inspection. Plaintiff contends that these instructions did not specifically notify hospitals of the risk of internal damage to the percutaneous lead and how to test for such damage. The letter also listed some indicia of damage to the lead, but Plaintiff alleges that the indicia were vague and insufficient to notify medical personnel, including specific personnel at Tulane, what test results were abnormal. (Second Am. Complt. at ¶¶ 17-18). Since these allegations must be viewed in the light most favorable to Plaintiff, they are sufficient for Plaintiff to survive a motion to dismiss.

Third, Defendant argues that the standards laid out in § 7.49 are not mandatory for manufacturers issuing voluntary recalls, and therefore, a state tort claim enforcing those standards would be "different from or in addition to" federal requirements. Defendant emphasizes the context of the FDA regulations governing recalls to support its argument that it was not required to follow § 7.49 exactly. *See, e.g.*, 21 C.F.R. § 7.49(c) ("A recall communication *should* be written in accordance with the following *guidelines* . . . .") (emphasis added); *id.* § 7.40(a) ("This section and §§ 7.41 through 7.59 recognize the *voluntary nature* of recall by providing *guidance* . . . .") (emphasis added). Thus, Defendant argues, requiring Thoratec to adhere to these discretionary guidelines would create a state requirement "in addition to" a federal requirement, in violation of § 360k.

Defendant's emphasis on this factor is misplaced. The fact that Defendant voluntarily

initiated the recall process cannot shield Defendant from any liability for the content of its recall communications. Furthermore, other language in the governing regulations casts significant doubt on the proposition that the guidelines in § 7.49 are completely discretionary. *See, e.g.*, 21 C.F.R. § 7.49(a) ("A recalling firm *is responsible* for promptly notifying each of its affected direct accounts about the recall."); *id.* § 7.40(a) ("This section . . . provid[es] guidance so that *responsible firms* may effectively discharge *their recall responsibilities*.").[4] The Court observes that this language may not ultimately be enough to support Plaintiff's specific contentions about the deficiency of Defendant's recall communications. However, for the purpose of a motion to dismiss, Plaintiff has sufficiently alleged a violation of a federal requirement to support a parallel state tort claim.

Fourth, Defendant argues that the content Plaintiff alleges was missing from the Correction letter goes beyond the § 7.49 guidelines, rendering Plaintiff's state claim not genuinely equivalent or parallel to the corresponding federal violation. Defendant continues to emphasize the general nature of the § 7.49 guidelines and further argues that the FDA did not explicitly require the specific additional instructions that Plaintiff claims were missing from Defendant's recall notice. Defendant argues that because the FDA has not defined the meaning of "specific instructions" as required by § 7.49, the Court cannot determine whether Defendant's notice met this requirement. Defendant also argues that § 7.49 does not explicitly require that a recall instruct customers on how to avoid injuries. Therefore, Defendant concludes, Plaintiff's proposed definition would create an additional requirement forbidden by *Riegel*.

[4]Moreover, if Defendant were correct that § 7.49 is completely advisory, it is possible that the preemption clause of the MDA would not apply at all, as there would be no relevant federal "requirement" for state law to preempt.

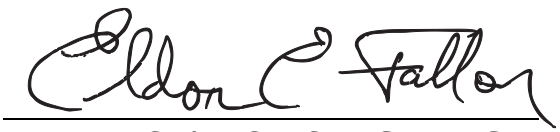
Ambiguity in the meaning and application of § 7.49 is not a sufficient reason to dismiss Plaintiff's complaint. It is enough that Plaintiff "raises a right to relief above the speculative level." *Twombly*, 550 U.S. 554, 555 (2007). Here, Plaintiff has alleged facts that plausibly constitute a violation of § 7.49. As noted above, the meaning of § 7.49 may be more thoroughly explored in a motion for summary judgment, and it is entirely possible that Plaintiff's claim will be defeated at that stage. At the present stage of the litigation, however, it is sufficient for Plaintiff to allege, with plausible justification, that Defendant's warning did not meet the guidelines laid out in § 7.49. As explained above, Plaintiff has met this standard. Therefore, Defendant's motion should not be granted on this basis.

IV. CONCLUSION

Most of Defendant's arguments boil down to two contentions: (1) that the FDA actually approved Defendant's communications, and (2) that those communications did not actually violate § 7.49. Both of these arguments are enshrouded in fact. The Court cannot grant Defendant's motion to dismiss based on these factual arguments. For the purpose of deciding a motion to dismiss, this Court must assume that all plausible allegations are true.

For the foregoing reasons, IT IS ORDERED that Defendant Thoratec's motion to dismiss (Rec. Doc. 74) is DENIED with respect to Plaintiff's claim for failure to warn and GRANTED with respect to Plaintiff's claim for failure to take corrective action.

New Orleans, Louisiana, this 27th day of June, 2012.



UNITED STATES DISTRICT JUDGE