UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

RAUL R. BENCOMO	CIVIL ACTION
VERSUS	NO: 06-2473
GUIDANT CORPORATION, ET AL	SECTION: “J” (1)

ORDER AND REASONS

Before the Court is the defendant’s Motion for Summary Judgment (Rec. Doc. 109). This motion, which is opposed, was set for hearing on May, 27, 2009 with oral argument. Upon review of the record, the memoranda of counsel, oral argument, and the applicable law, this Court now finds, for the reasons set forth below, that defendant’s motion should be granted.

Background Facts

This products liability case was brought by plaintiff Raul Bencomo alleging injuries as a result of a medical procedure performed on May 12, 2005. On that day, Bencomo had a carotid stent procedure performed by Dr. Stephen Ramee. As a part of the procedure, Dr. Ramee used the ACCULINK system, which includes the ACCUNET system, and is manufactured by defendant Abbott

Laboratories, Inc. (“Abbott”). These devices are designed to capture emboli that might escape during the procedure and travel to other parts of the body causing stroke. During Bencomo’s procedure emboli did escape causing a stroke and loss of sight in one of his eyes. Bencomo alleges in this suit that the ACCULINK and ACCUNET systems were unreasonably dangerous because Abbott breached an express warranty related to the risk of escaping emboli.

Prior to agreeing to have the surgery performed by Dr. Ramee, Bencomo consulted another doctor, Dr. Samuel Money. Dr. Money recommended an endarterectomy procedure that would have left a scar on Bencomo’s neck and possibly impacted his vocal chords. Bencomo then sought consultation with Dr. Ramee who stated he could perform a procedure to address the partially blocked carotid artery without damaging Bencomo’s vocal chords.

Only one of the plaintiff’s original claims remains before the Court. Plaintiff’s remaining claim is for breach of an express warranty regarding the ability of the ACCULINK system to capture escaping emboli. In support of this claim the plaintiff asserts that prior to deciding to have the stenting procedure he read part of the Abbott Patient Guide (the “Guide”) and that the Guide stated that the ACCULINK and ACCUNET systems would capture all emboli. Based on his reading of part of the Guide, the plaintiff decided to have the stenting procedure instead of the

endarterectomy procedure.

The Parties' Arguments

The defendant has filed this motion arguing that the plaintiff's lone remaining claim must be dismissed because it is preempted and because there is no evidence to support such a claim. Specifically, the defendant argues that ACCULINK is a class III medical device which is subject to Food and Drug Administration ("FDA") regulation and approval. The Medical Device Amendments ("MDA"), 21 U.S.C. § 360c et seq., to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., provide the FDA with the authority to regulate medical devices. Under the MDA, medical devices are identified in three categories. Class III devices, such as ACCULINK, are the most heavily regulated. See 21 U.S.C. § 360c(a)(1)(C); Lohr v. Medtronic, Inc., 518 U.S. 470, 476-77 (1996). Before a Class III medical device can be sold the manufacturer must provide the FDA with reasonable assurances about the safety and effectiveness of the device. This can be done through a 510(k) process or a premarket approval process. See Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 344-45 (2001). The 510(k) process can be used when the device is substantially similar to a medical device that was already on the market prior to the enactment of the MDA in 1976. The more rigorous pre-market approval process is used in other cases and

was used in the case of ACCULINK. Prior to selling ACCULINK on the market, Abbott's predecessor Guidant, sought approval from the FDA through the premarket approval process. All of the information required by the FDA was submitted, including the Guide that was read by the plaintiff. ACCULINK and ACCUNET were subject to clinical testing and the FDA approved the warnings contained in the Guide. As a result of the FDA approving the warnings in the Guide, the defendant argues that the plaintiff is preempted from using a state law tort suit to attack the Guide. The defendant contends that in order for the plaintiff to win this case a jury would have to determine that the Guide should have included different language, which would constitute a state requirement that is "different or in addition to" the federal requirements set and approved by the FDA through the premarket approval process. As a result, the defendant contends that the plaintiff's claim is preempted.

The defendant further argues that the plaintiff cannot create a triable issue of fact with regard to the language of the Guide because the Guide in fact warns of the danger of emboli escaping the device. In pressing his claim the plaintiff relies on one phrase from the Guide, which the plaintiff identifies as stating that the device will "capture any plaque or particles that could travel into the smaller vessels in the brain." Patient

Guide at 11 (underline in original)[1]. However, the defendant argues that this excerpt takes the phrase out of context because the entire sentence in which the phrase the plaintiff relies on is contained states: "The ACCUNET Embolic Protection System will stay in place during the procedure to help capture any plaque or particles that could travel into the smaller vessels in the brain." Id. In addition, the defendant identifies that several other sections of the Guide specifically warn about the risk of emboli and the risk of blindness, the exact injury suffered by the plaintiff.

The plaintiff opposes the motion arguing that his claim is not preempted and that there are issues to be tried to a jury. The plaintiff asserts that documentation provided by the defendant to physicians and not available to the public, called IFUs, correctly does not state that the ACCULINK and ACCUNET systems will capture any or all emboli during the procedure. The plaintiff asserts that this inconsistency between the IFU and the Guide supports his breach of express warranty claim and that in such an instance the claim is not preempted. Also, the plaintiff argues that the claim is not preempted because it is a parallel claim. The plaintiff contends that he is not seeking to impose a

[1]It appears from a review of the Guide that the underlining of the word "plaque" is not for the purpose of emphasizing that word. Rather, throughout the Guide medical terminology is underlined and then defined in the last section of the Guide.

requirement that is different than or in addition to a requirement created by the FDA. Instead, he argues that the state tort law suit parallels the federal regulation and only seeks to hold the device to the standard set and approved by the FDA. Finally, the plaintiff argues that he has presented a claim triable to a jury because of the language of the Guide. To support this contention the plaintiff asserts that the express warranty is created by the language stating that the device will capture "any plague or particles." The plaintiff also argues that the term "any" has the same meaning as "all."

The defendant submitted a reply memorandum that addresses the plaintiff's opposition arguments. Specifically, the defendant discusses at length the Supreme Court's decision on preemption in Riegel v. Medtronic, 128 S.Ct. 999 (2008) and the Fifth Circuit case, Gomez v. St. Jude Medical Daig Division, Inc., 442 F.3d 919 (5th Cir. 2006). The defendant further argues that the Gomez decision forecloses the plaintiff's alternative argument that his breach of warranty claim is a parallel claim. Lastly, the defendant reiterates its argument regarding the plain language of the Guide and its lack of any warranty.

In response, the plaintiff filed a surreply memorandum to argue that Riegel and Gomez are legally and factually distinguishable from this case because here the IFU produced for physicians and the Guide produced for the public are

contradictory and the statements in the Guide are factually false. Further, the plaintiff argues that the "Guide violates the FDA's labeling regulations requiring accuracy and consistency, and is the precise parallel claim attempting to enforce applicable FDA regulations that the Supreme Court and Fifth Circuit expressly acknowledged are saved from preemption." Rec. D. 139. The plaintiff also reasserts his claim that he reasonably interpreted the word "any" in the Guide to mean that the ACCUNET device would capture "all" plague and particles.

Discussion

The plaintiff's sole remaining claim in this case, which the defendant seeks to dismiss on this motion for summary judgment, is for the breach of an express warranty. The plaintiff claims that the Guide he partially read and subsequently relied on in deciding to have this particular procedure created an express warranty that the ACCULINK and ACCUNET systems would capture all plague and particles that might escape during the procedure. The plaintiff specifically asserts this claim pursuant to the Louisiana Products Liability Act ("LPLA"). The LPLA provides that "[a] product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the

product and the claimant's damage was proximately caused because the express warranty was untrue." La. R.S. § 9:2800.58.

In support of this motion for summary judgment the defendant makes two arguments. First, the defendant argues that the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360, et seq., expressly preempts the plaintiff's state law breach of express warranty claim. Additionally, in response to the plaintiff's opposition to the motion, the defendant argues that the plaintiff cannot maintain his breach of express warranty claim as a so-called parallel state claim to avoid preemption. Second, the defendant contends that the plain language of the Guide contradicts the plaintiff's claim and cannot be read to state that the ACCULINK and ACCUNET systems will prevent all plague or particles from escaping during the procedure.

Prior to the enactment of the MDA in 1976, regulation of medical devices was largely left to the states. However, the MDA enacted a regime of detailed federal oversight of medical devices. See Riegel v. Medtronic, Inc., 128 S.Ct. 999, 1003 (2008). The MDA contains an express preemption provision that states:

> 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 applicable 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). Subsection (b) referenced above permits the FDA to exempt some state and local requirements from preemption. The MDA created a classified regulatory scheme. Three separate classes of medical devices were created. Class I devices are subject to the least amount of regulations. Riegel, 128 S.Ct. at 1003. Class II devices are subject to additional scrutiny, including performance standards and postmarket surveillance. Id. Class III devices are subject to the highest level of federal oversight. Id. The MDA created a process of premarket approval for Class III devices, which requires that new devices must be submitted to the FDA for approval. Id. at 1004. The premarket approval process for new Class III devices requires the manufacturer to submit a multivolume application. Id. This information includes studies and investigations of the device's safety and effectiveness. Id. The process includes a review of the device's proposed labeling and instructions. Id. The FDA determines whether the proposed labeling is false or misleading. Id. The Supreme Court has described the premarket approval

process for Class III devices as “rigorous.” Id. Premarket approval is only granted if the FDA finds that there is a “reasonable assurance” of the subject device’s “safety and effectiveness.” Id. quoting 21 U.S.C. § 360e(d). The FDA is granted discretion to “approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives.” Id. “Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.” Id. at 1005.

It is undisputed that the ACCULINK and ACCUNET systems involved in this case constitute a Class III device under the MDA. The systems along with all supporting documentation, including any IFUs and the Guide were submitted to the FDA as part of the premarket approval process for new devices. ACCULINK and ACCUNET were subject to the highest scrutiny under the MDA. The FDA specifically reviewed and approved the IFUs at issue and the Guide that the plaintiff later read when considering the procedure.

Recently, in the seminal case on this issue, Riegel v. Medtronic, the Supreme Court laid out a two-prong analysis for determining whether a plaintiff’s state law claims are preempted by the MDA. First, it must be determined that the federal

government has established requirements that are applicable to the device. Id. at 1006. If there are federal requirements for the device, then a court must next determine whether the plaintiff's state law claim is based on a state requirement with respect to the device that is "different from or in addition to" the federal requirements, and that relates to the safety and effectiveness of the device. Id. citing 21 U.S.C. § 360k(a). The purpose of this analysis is to determine whether the state requirement is a requirement that is "different from, or in addition to, any requirement applicable . . . to the device" under federal law. Id. If the state requirement is different from or in addition to the federal requirements then such a state requirement is preempted by the MDA.

In Riegel, the plaintiff filed suit after a catheter used in his medical procedure ruptured. Id. at 1005-06. The plaintiff's suit alleged that the device was designed, labeled, and manufactured in a manner inconsistent with New York state law. Id. The Supreme Court affirmed the circuit court and district court's dismissal of the action based on MDA preemption. Id. The catheter device at issue was a Class III device that had undergone the FDA's premarket approval process. Id. In addressing the first prong of the preemption analysis the Court reasoned that premarket approval "imposes 'requirements' under the MDA." Id. at 1007. The premarket approval is specific to

that individual device. Id. The premarket approval process does not constitute an exemption from federal safety review, instead the premarket process is the federal safety review. Id. The premarket approval process itself establishes federal requirements for a device, so any device that has been approved by that process will satisfy the first prong of the preemption analysis. Id. The Supreme Court then went on to discuss the second prong of the preemption analysis. In the Riegel case the plaintiff had based his claims on state common-law duties. The Court equated state common-law duties with state "requirements" and determined that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties." Id. at 1008. Such state "requirements" the Court held were preempted when applied to a specific medical device that has undergone premarket approval. Id. at 1007-08. Additionally, the Court reaffirmed its holding in Lohr, 518 U.S. at 512, that common-law causes of action for negligence and strict liability impose state "requirements" and are preempted when applied to a specific medical device. Id. at 1007. Finally, Justice Scalia, writing for the majority, addressed Justice Ginsberg's concern in dissent that it is "'difficult to believe that Congress would, without comment, remove all means of judicial recourse' for consumers injured by FDA-approved devices." Id. at 1009. Justice Scalia confirmed that this removal of all judicial recourse "is exactly

what a pre-emption clause for medical devices does by its terms." Id. The Court's analysis along with this statement signify the breadth of MDA preemption post-Riegel.

Applying the two-prong preemption analysis to the present case the Court is compelled to conclude that the plaintiff's claim is preempted. First, there can be no argument that the device at issue was subject to the premarket approval process and the federal government established requirements for the device through that process. The specific Guide that forms the basis of the plaintiff's remaining claim was approved by the FDA as a part of the MDA premaket approval process on August 30, 2004. This approval set federal requirements for the Guide. The analysis then shifts to the second prong for a determination of whether the plaintiff's state law claim is based on a state requirement with respect to the device that is "different from or in addition to" the federal requirements, and that relates to the safety and effectiveness of the device. The plaintiff's state law claim in this case is based on the LPLA. Although Riegel did not directly address a claim for breach of express warranty there is no need for speculation as to whether the LPLA is a state requirement that is "different from or in addition to" the federal requirements. In Gomez v. St. Jude Medical Diag Division, Inc., 442 F.39 919 (5th Cir. 2006), the Fifth Circuit directly addressed this question. The plaintiff in Gomez brought a

products liability suit against the manufacturer of collagen plugs that were used to close a hole in her artery. Id. at 925-25. Among other claims, the plaintiff alleged that the defendant had breached an express warranty that arose from an IFU for the device. Id. at 931-32. The device was a Class III device and the parties agreed that the IFU at issue had been approved by the FDA as part of the premarket approval process. Id. The plaintiff's breach of warranty claim in Gomez was based on the exact same statute, Louisiana Revised Statute § 9:2800.58, as the plaintiff's claim in this case. The Fifth Circuit analyzed the Louisiana express warranty statute and concluded that when the representations at issue are approved by the FDA through the premarket approval process "the duties arising under the Louisiana breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme" and as a result any such claim is preempted. Id. at 932.

The plaintiff cannot escape this controlling authority. The Guide at issue was approved by the FDA through the premarket approval process. The state law that forms the basis for the plaintiff's claim creates a state requirement that is "different from or in addition to" the federal requirement. As a result, the plaintiff's claim is preempted. Furthermore, the plaintiff cannot avoid preemption based on his argument that there are inconsistencies between the IFU provided to physicians for the

ACCULINK and ACCUNET devices and the Guide that he partially read. The plaintiff raises this issue of an alleged discrepancy in an effort to prove that the Guide that he read was untrue, while the revised IFU and other labeling accurately described the device's capabilities. Even assuming arguendo that there are inconsistencies between the IFU and the Guide, the plaintiff's argument is of no moment. Both the IFU and the Guide were approved by the FDA as a part of the premarket approval process and thus necessarily comply with federal requirements. The plaintiff argues that the inconsistency is important because it will enable him to prove that the statements he relied on in the Guide are untrue. While proving the untruthfulness of the representations in the Guide might be an essential element of the plaintiff's LPLA claim, it is for the precise reason that the plaintiff must demonstrate untruthfulness under the LPLA that the Fifth Circuit has concluded that a breach of express warranty claim brought under the LPLA is preempted. Id. The plaintiff's claim for breach of an express warranty must be preempted.

In an attempt to salvage his breach of express warranty claim, the plaintiff argues that his claim is in fact a parallel claim that is permitted to escape preemption. "A lawsuit that simply parallels or enforces the federal regulatory requirements without 'threatening' or interfering with them is not preempted." Gomez, 442 F.3d at 932 (citing Lohr, 518 U.S. at 495). The

plaintiff asserts that in pursuing his breach of express warranty claim he simply seeks to enforce a violation of FDA regulations. The plaintiff argues that FDA regulations require that all labeling of a medical device must accurately represent the device's indications for use consistent with statements contained in the IFU. See Pl.'s Mem. in Opp., Rec. D. 117. Here the plaintiff contends that the Guide is not consistent with the statements contained in the IFU and thus he is seeking to enforce this alleged violation of FDA regulations. However, this argument cannot save the plaintiff's breach of express warranty claim. In the Gomez case the Fifth Circuit directly addressed the question of whether a claim based on the LPLA could be maintained as a parallel claim. 442 F.3d at 932. The court specifically determined that the LPLA's requirement of a finding that the subject representation is untrue precluded a claim based on the LPLA from proceeding as a parallel claim. Id. This conclusion is necessitated by the express requirements for liability under the LPLA and the Gomez case cannot be distinguished by the plaintiff.

The Guide that the plaintiff partially read and relied on in deciding to undergo the carotid stent procedure was approved by the FDA as a part of the premarket approval process. The IFUs for the ACCULINK and ACCUNET systems were also approved by the FDA. The Fifth Circuit has held that the duties arising under

the state statute that forms the basis of the plaintiff's claim "relate to, and are potentially inconsistent with, the federal regulatory scheme." Gomez, 442 F.3d at 932. Thus, the plaintiff's claim for breach of an express warranty must be preempted and the plaintiff cannot maintain a parallel claim. Since the Court finds that the plaintiff's claim is preempted it is not necessary to address the defendant's alternative argument that the Guide did not in fact create an express warranty. Accordingly,

IT IS ORDERED that the defendant's **Motion for Summary Judgment (Rec. Doc. 109)** is hereby **GRANTED**

New Orleans, Louisiana, this 30th day of June, 2009.

CARL J. BARBIER
UNITED STATES DISTRICT JUDGE