

U.S. DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
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TONY R. MOORE
BY  DEPUTY

UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF LOUISIANA

SHREVEPORT DIVISION

JAMES P. MCQUISTON, ET AL.

versus

CIVIL ACTION NO. 07-1723
JUDGE TOM STAGG

BOSTON SCIENTIFIC CORP, ET AL.

JUDGMENT

Based on the foregoing Memorandum Ruling;

IT IS ORDERED that the motion for summary judgment (Record Document 27) filed by Boston Scientific Corporation ("Boston Scientific") be and is hereby **GRANTED**. All claims by the plaintiffs against Boston Scientific are **DISMISSED WITH PREJUDICE**.

THUS DONE AND SIGNED at Shreveport, Louisiana, this the 14th day of November, 2009.



JUDGE TOM STAGG

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CIVIL ACTION NO. 07-1723
JUDGE TOM STAGG

BOSTON SCIENTIFIC CORPORATION
and ABC INSURANCE COMPANY

MEMORANDUM RULING

Before the court is a motion for summary judgment filed by the defendant, Boston Scientific Corporation (“Boston Scientific”). See Record Document 27. For the reasons set forth below, Boston Scientific’s motion is **GRANTED**.

I. BACKGROUND

A. Facts.

On September 1, 2006, Dr. Thomas Brown performed a percutaneous transluminal coronary angioplasty and stent procedure on the plaintiff, James P. McQuiston. Mr. McQuiston had been to his cardiologist on August 29, 2006, with a history of coronary artery disease, including prior coronary artery bypass graft surgery in 1989 and 1997, a history of congestive heart failure, valvular heart disease, hypertension, hypothyroidism, and a history of having suffered a previous

myocardial infarction and a previous transient ischemic attack. Mr. McQuiston's physician scheduled him for a heart catheterization procedure on September 1, and he had a TAXUS Express Paclitaxel-Eluting Coronary Stent System ("TAXUS Stent") implanted in his coronary artery. Mr. McQuiston was discharged from the hospital the next day. See Record Document 27, Exs. M and N. He alleges that he "experienced significant deterioration during the treatment period post-stent placement." Record Document 10 at 2.

Boston Scientific designed, manufactured and sold the TAXUS Stent. Mr. McQuiston and his wife (hereinafter collectively referred to as "McQuiston") filed suit in state court against Boston Scientific, alleging that the TAXUS Stent "malfunctioned and failed to deflate, causing permanent and serious injuries" to him. Record Document 1, Petition at 1. McQuiston contends that the TAXUS Stent was negligently designed, manufactured, marketed, sold, tested and distributed. See id. McQuiston further asserts claims for breach of warranty, failure to warn and fraud. See id. Boston Scientific removed the case to this court on the basis of diversity jurisdiction and filed the instant motion for summary judgment, arguing that McQuiston's claims are preempted. See Record Document 27.

B. History Of The Taxus Stent And The Medical Device Amendments.

Congress passed the Medical Device Amendments ("MDA") to the Food,

Drug and Cosmetics Act in 1976. The MDA places each medical device into one of three classes depending on the degree of risk the device poses to the public. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 476, 116 S. Ct. 2240, 2246 (1996) (citing 21 U.S.C. §§ 360c-360k) (“Lohr”). Devices are classified as Class I and subject only to minimal regulation by “general controls” if they present no unreasonable risk of illness or injury. See Lohr, 518 U.S. at 476-77, 116 S. Ct. at 2246. Class II devices are potentially more harmful than Class I and, although they can be marketed without prior approval, manufacturers of such devices must comply with federal performance regulations known as “special controls.” See id. at 477, 116 S. Ct. at 2246. Class III is reserved for devices that “either present a potential unreasonable risk of illness or injury, or which are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.” Id. (internal marks omitted). The manufacturer of a new Class III device must provide the Food and Drug Administration (“FDA”) with a “reasonable assurance” that the device is both safe and effective through the rigorous premarket approval process (“PMA”) before the device may be introduced to the market. See id. The TAXUS Stent is a Class

III medical device.¹

The Food and Drug Administration granted Boston Scientific's premarket approval application for the TAXUS Stent on March 4, 2004. According to the FDA's "Premarket Approval (PMA) Database," to date Boston Scientific has submitted, and the FDA has approved, a least forty-five supplements to the TAXUS Stent premarket approval application since granting approval on March 4, 2004. These include FDA approval of three updates to the TAXUS Stent Directions for Use.

The information on which the FDA made the determination of premarket

¹McQuiston attempts to argue otherwise in her opposition, contending that the TAXUS Stent contains a "pharmaceutical component." Boston Scientific counters that McQuiston has, in a previously filed motion to compel, admitted that the TAXUS Stent is a Class III device. See Record Document 37 at 8. Boston Scientific, however, notably fails to mention that McQuiston asserts that "the stent also has a pharmaceutical component" in the very next sentence of the same document. Id. However, the court notes that in McQuiston's opposition to Boston Scientific's motion for summary judgment, McQuiston specifically states: "Defendants are right in identifying the Taxus Stent as a Class III medical device." Record Document 47 at 5. Regardless, it is clear to the court that the TAXUS Stent is a Class III device under the MDA and that the presence of a pharmaceutical component does not prevent it from being such. The Secretary of Health and Human Services had the duty of determining the "primary mode of action" of a combination product pursuant to 21 U.S.C. § 353(g) (2002). In May of 2001, following a request for designation from Boston Scientific pursuant to 21 C.F.R. § 3, the FDA determined that "the paclitaxel- eluting stent primarily fulfills a device function" and would be subject "to premarket review and approval under the medical device provisions" of the Federal Food, Drug and Cosmetic Act. See Record Document 55, Ex. A.

approval for the TAXUS Stent came from Boston Scientific or was based on information provided by Boston Scientific. The premarket approval application and its amendments contained over 40,000 pages. The information included results of clinical studies, non-clinical studies and additional information all generated by and/or based on information provided by Boston Scientific.

II. ANALYSIS

A. Summary Judgment Standard.

Summary judgment is proper pursuant to Rule 56 of the Federal Rules of Civil Procedure “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552 (1986). “Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 263 (5th Cir. 2002). If the movant demonstrates the absence of a genuine issue of material fact, “the nonmovant must go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial.” Gen.

Universal Sys., Inc. v. Lee, 379 F.3d 131, 141 (5th Cir. 2004) (citations and quotations omitted). Where critical evidence is so weak or tenuous on an essential fact that it could not support a judgment in favor of the nonmovant, then summary judgment should be granted. See Boudreaux v. Swift Transp. Co., 402 F.3d 536, 540 (5th Cir. 2005).

B. Preemption Analysis.

Congress enacted the MDA “to provide for the safety and effectiveness of medical devices intended for human use.” Lohr, 518 U.S. at 474, 116 S. Ct. at 2245 (citing the preamble to the MDA of 1976, 90 Stat. 539). Prior to the enactment of the MDA, 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., 552 U.S. 312, 128 S. Ct. 999, 1003 (2008). The MDA’s preemption provision, 21 U.S.C. § 360k(a), governs the extent to which the MDA preempts state law. It reads:

[N]o 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 a device or to any other matter included in a requirement

applicable to the device under this chapter.

Id.

The FDA has promulgated regulations interpreting section 360k, which state:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d).

Class III devices, like the TAXUS Stent at issue in this case, are subject to the highest level of federal oversight. See Riegel, 128 S. Ct. at 1003. The premarket approval process for new Class III devices first requires the manufacturer to submit a multivolume application. This information must include the results of a good faith investigation and studies of the device's safety and effectiveness. The process also includes a review of the device's proposed labeling and instructions. The FDA determines whether the proposed labeling is false or misleading. The Supreme Court has described the premarket approval process for Class III devices as "rigorous." Id. at 1004 (citing Lohr, 518 U.S. at 477, 116 S. Ct. 2240). 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 process, labeling, or any other attribute, that would affect safety or effectiveness.” Id. at 1005.

Boston Scientific claims that every detail of its TAXUS Stent and its packaging have been approved by the FDA. Therefore, Boston Scientific argues, state law claims alleging that these specifications are inadequate would conflict with the FDA’s determination and are preempted by federal law.

C. The Supreme Court’s Decision In Riegel.

In Riegel v. Medtronic, decided in 2008, the Supreme Court set forth 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. See Riegel, 128 S. Ct. 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)). 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. See 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. The Supreme Court affirmed the circuit court and district court's dismissal of the action based on MDA preemption. See id. The catheter device at issue was a Class III device that had undergone the FDA's premarket approval process.

In addressing the first prong of the preemption analysis, the Riegel Court reasoned that the premarket approval process "imposes 'requirements' under the MDA." Id. at 1007. The premarket approval is specific to the individual device. The premarket approval process does not constitute an exemption from federal safety review but instead, the process *is* the federal safety review. See 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. See 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" 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 512,² that common-law causes of action for negligence and strict liability imposed state "requirements" and were preempted when applied to a specific medical device. Id. at 1007. In his opinion for the court, Justice Scalia confirmed that removal of all judicial recourse "is exactly what a pre-emption clause for medical devices does by its terms." Id. at 1009. The Court's analysis, along with Justice Scalia's statement, indicates the

²In Lohr, the plaintiff claimed she was injured when her pacemaker failed. See Lohr, 518 U.S. at 480-481, 116 S. Ct. at 2248. She and her husband brought claims against Medtronic. In a plurality decision, the Supreme Court analyzed whether the claims, brought under Florida state law, were preempted by the MDA's section 360k preemption provision. See id. at 481-482, 116 S. Ct. at 2248-49. After extensive analysis, the Court found that none of the Lohrs' claims based on allegedly defective manufacturing or labeling were preempted. See id. at 502, 116 S. Ct. at 2259. The Court emphasized the fact that the pacemaker at issue was approved after the manufacturer submitted a premarket notification, a process also known as a section 510(k) process. See id. at 478, 116 S. Ct. at 2247. Through this process, if the FDA concludes on the basis of the premarket notification that the device is substantially equivalent to a pre-existing device, the device can be marketed without further regulatory analysis. See id. The Court stated that the section 510(k) process, which typically takes about twenty hours to complete, is by no means comparable to the PMA process, which requires 1,200 hours. See id. at 478-479, 116 S. Ct. at 2247.

breadth of MDA preemption post-Riegel.³

D. Preemption Analysis Of McQuiston's Claims.

As previously stated, the TAXUS Stent is a Class III device under the MDA. Thus, the TAXUS Stent was subject to the highest scrutiny under the MDA by virtue of its approval through the "rigorous" premarket approval process set forth for Class III devices. See Riegel, 128 S. Ct. at 1004 (citing Lohr, 518 U.S. at 477,

³In Gomez v. St. Jude Med. Daig Div., Inc., 442 F.3d 919 (5th. Cir. 2006), a case decided by the Fifth Circuit prior to Riegel, the Fifth Circuit stated that this circuit uses the Martin/Lohr test to analyze products liability claims against PMA-approved devices. See id. at 928-30 (citing Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001) and Lohr, 518 U.S. 470, 116 S. Ct. 2240). The test requires a court to analyze the claims and determine whether the duties enforced by such claims would threaten the federal duties imposed by the PMA process. See id. at 930. The Gomez court found that the plaintiff's claims for negligent design and defective design were preempted because the FDA studied and approved the device's design through the PMA process. See id. The FDA also approved the labeling, warnings, instructions, and training process for the device during the PMA process; therefore, any claims of inadequacy in any of these areas were also preempted. See id. at 931.

The plaintiff in Gomez also argued that her warranty claims should not be preempted because after the completion of the PMA, the manufacturer acquired additional information about the risks associated with the product but did not provide updated warnings. See id. The court stated that because the manufacturer had an ongoing obligation to the FDA to report new information obtained after the approval of the device, any related state law claims would interfere with the federal scheme and were preempted. See id. at 931-32. The court also found that a claim for the breach of any express warranties provided under Louisiana law would also be preempted because the duties imposed by such claims were potentially inconsistent with the federal regulatory scheme. See id. at 932. The only claim that the court found was not preempted was a defective manufacturing claim alleging that the device did not comply with the FDA-approved specifications. See id.

