UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION at LEXINGTON

CIVIL ACTION NO. 09-177-KSF

GUY RANKIN, III and ANN RANKIN PLAINTIFFS

v. **OPINION & ORDER**

BOSTON SCIENTIFIC CORPORATION DEFENDANT

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Currently before the Court is the motion of the defendant, Boston Scientific Corporation ("Boston Scientific"), for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure on the grounds that the plaintiffs' claims are preempted by federal law. This matter is fully briefed and is ripe for review. For the reasons set forth below, Boston Scientific's motion for summary judgment will be granted.

I. FACTUAL AND PROCEDURAL BACKGROUND

The plaintiffs, Guy Rankin, III and his wife Ann Rankin (the "Rankins"), filed this personal injury civil action in Fayette Circuit Court on April 10, 2009. The Rankins allege that on May 9, 2008, Guy Rankin underwent a scheduled angioplasty performed by Dr. Jonathon Waltman, a cardiologist, at St. Joseph's Hospital in Lexington, Kentucky. During the procedure, Dr. Waltman utilized a Maverick™ Balloon catheter designed, manufactured, and sold by Boston Scientific in an attempt to clear an obstructed coronary artery. Although the Maverick™ Balloon catheter had a rated burst pressure of 12 atm, it ruptured during the procedure at only 6 atm, and Dr. Waltman was unable to retrieve a segment of the balloon from his artery. As a result, the Rankins contend that

Guy Rankin was required to undergo an emergency two vessel coronary artery bypass graft procedure. The Rankins now assert the common law tort claims of negligent design and negligent manufacture against Boston Scientific.

Boston Scientific has removed the action to this Court based on diversity of citizenship under 28 U.S.C. §§ 1332 and 1441(b) [DE #1]. Pursuant to the Court's Order of November 11, 2009, discovery has been suspended pending the Court's ruling on Boston Scientific's motion for summary judgment [DE #9]. In this motion, Boston Scientific contends that the plaintiffs' claims are preempted by the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 360(k).

II. SUMMARY JUDGMENT STANDARD

Under Rule 56(c) of the Federal Rules of Civil Procedure, summary judgment is proper "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." *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In reviewing a motion for summary judgment, "this Court must determine whether 'the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.' " *Patton v. Bearden*, 8 F.3d 343, 346 (6th Cir. 1993) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986)). The evidence, all facts, and any inferences that may permissibly be drawn from the facts must be viewed in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

Once the moving party shows that there is an absence of evidence to support the nonmoving party's case, the nonmoving party must present "significant probative evidence" to demonstrate that

"there is [more than] some metaphysical doubt as to the material facts." *Moore v. Phillip Morris Companies, Inc.*, 8 F.3d 335, 340 (6th Cir. 1993). Conclusory allegations are not enough to allow a nonmoving party to withstand a motion for summary judgment. *Id.* at 343. "The mere existence of a scintilla of evidence in support of the [nonmoving party's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmoving party]." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. at 252. "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (citations omitted).

IV. ANALYSIS

At the center of this lawsuit is Boston Scientific's Maverick™ Balloon catheter. According to the affidavit of Melanie Raska, the regulatory manager at Boston Scientific with regulatory support responsibility for the Maverick ™ Balloon catheter, it is a medical device designed and sold to physicians for the treatment of narrowed or clogged coronary arteries or coronary bypass grafts. [DE #9-4] The balloon is placed in the patient's artery or graft, inflated, then deflated and removed, with the goal of improving blood flow to the patient's heart muscle. Designated as a Class III medical device, the Maverick™ Balloon Catheter was designed, manufactured, sold and distributed only after receiving premarket approval from the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 360(a)(1)(C). Because Class III medical devices "present a potential unreasonable risk of illness or injury" or are devices "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," they must undergo "premarket approval to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360(a)(1)(C). This premarket approval imposes "specific requirements applicable to a particular device" based on the FDA's extensive review and analysis. *Id.*; *see also* DE #9-4,Raska Affidavit ¶ 2.

While it is unclear which version of the Maverick™ Balloon was used in Guy Rankin's angioplasty, Raska states that all versions of the Maverick Balloon underwent premarket analysis and approval by the FDA. [DE #9-4 Ex. 2, ¶ 3]. The plaintiffs do not dispute this fact. Boston Scientific contends that any common law negligence or strict liability claim asserted against a premarket approved device are barred by the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act, which provides:

> 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.

21 U.S.C. § 360(k)(a). In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court applied this preemption provision to preclude the plaintiff's common-law claims of negligence, strict liability, and implied warranty against the manufacturer of a balloon catheter similar to the one at issue in this case. There, the Supreme Court explained that when a medical device undergoes the rigorous premarket approval process and is approved for use, the public is assured that the product is reasonably safe as viewed from the perspective that some risk is always inherent in those medical procedures aimed at "supporting or sustaining human life." *Id*. at 322. Noting that the preemption clause removes all means of judicial recourse for consumers injured by FDA-approved devices, the Supreme Court noted that the statute is clear. *Id*. at 325. Thus, while it was not necessary to infer the intent of Congress to construe the statute, the Supreme Court stated:

> It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available - the text of the statute - suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.

Id. at 1009.

The Supreme Court then fashioned a two-part test for determining whether a claim is preempted. First, the Court must determine whether the Federal Government has established requirements applicable to the medical device. *Riegel*, 552 U.S. at 321-22. Then, the Court must determine whether the state common-law claims impose requirements that are "different from, or in addition to" those imposed by federal law. *Id*. Based on Raska's affidavit and the plaintiffs' pleadings, there appears to be no dispute that the FDA has established certain requirements applicable to the Maverick ™ Balloon; thus, the first component of the test is satisfied.

The remaining issue for the Court is whether the plaintiffs' common law claims based on Kentucky law impose different or additional requirements to those imposed by the FDA. However, *Riegel* makes clear that common-law claims like those asserted by the plaintiffs in this case are allowed only where the claims are "premised on a violation of FDA regulations" relating to the device. *Id*. at 330. As *Williams v. Cyberonics, Inc.*, 654 F.Supp.2d 301, 306 (E.D.Pa 2009), recently held: *"Riegel* is loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass . . . No state or common-law claims can survive if it allows a claimant to proceed without showing a departure from federal standards. There is simply no wiggle room to find otherwise."

The plaintiffs argue that their state tort claims should be allowed to proceed because the Maverick™ Balloon, which was rated for 12 atm, burst at 6 atm. In other words, the plaintiffs contend that because the device failed during normal use, Boston Scientific has violated some federally imposed requirement or regulation. However, Boston Scientific received premarket approval for the Maverick ™ Balloon at issue in this case. The fact that the Maverick™ Balloon allegedly failed during normal use does not override the clear language of § 360(a) or the Supreme Court's ruling in *Riegel* that the plaintiffs' claims are preempted by federal law. Because the

plaintiffs have failed to raise any issue of material fact sufficient to overcome Boston Scientific's properly supported motion for summary judgment, judgment will be entered in favor of Boston Scientific.

IV. CONCLUSION

For the reasons set forth below, the Court, being fully and sufficiently advised, hereby **ORDERS** as follows:

(1) Boston Scientific's motion for summary judgment [DE #9] is **GRANTED**; and

(2) judgment in favor of Boston Scientific will entered contemporaneously with this Opinion & Order.

This February 19, 2010.

Signed By:
Karl S. Forester KSF
United States Senior Judge