UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
06-CV-4078(JMR/AJB)

Demetrus Claude Clark	)	
	)	
v.	)	ORDER
	)	
Medtronic, Inc.	)	

Plaintiff, Demetrus Claude Clark, claims defendant, Medtronic, Inc. ("Medtronic"), was negligent in manufacturing and marketing its Model 7278 Maximo implantable cardioverter-defibrillator ("ICD"). Medtronic moves for summary judgment based on federal preemption. Defendant's motion is granted.

I. Background[1]

A. Federal Premarket Approval Process

ICDs are implantable, silver-dollar size, highly-technical electronic devices designed to detect, and almost-instantaneously treat, ventricular tachycardia, or fibrillation, a life-threatening condition. A properly functioning ICD administers an electrical pulse which reestablishes a regular heartbeat. The United States Food and Drug Administration ("FDA") classifies ICDs as Class III medical devices.

Class III devices are used in extraordinarily dangerous situations. They frequently represent the cutting edge of

[1]When considering a motion for summary judgment, the court views the facts most favorably to the plaintiff, the nonmoving party. See Ludwig v. Anderson, 54 F.3d 465, 470 (8th Cir. 1995). The facts set forth in this opinion are based on the parties' pleadings, and are not binding determinations.

medicine. The devices are used only when the patient is in such danger that, although the devices themselves may subject the patient to risks, those risks are less than those faced if the device is not used. See 21 U.S.C. § 360c(2)(C) ("[T]he safety and effectiveness of a device are to be determined . . . weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.").

Class III medical devices are regulated under the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act. 21 U.S.C. § 360e; Riegel v. Medtronic, Inc., 128 S.Ct. 999, 1003-04 (2008). A manufacturer which markets a Class III device must meet the FDA's rigorous premarket approval standards. It must also demonstrate a "reasonable assurance" that the device is both "safe . . . [and] effective under the conditions of the use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 360e(d)(2)(A)(B)(2004).

On September 8, 2003, as part of Medtronic's application for ICD Model 7278 premarket approval, defendant submitted (i) a multivolume application for the device, including full reports of "all information published . . . or which should reasonably be known to the applicant concerning investigations which have been made to show whether or not such device is safe and effective"; (ii) a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation";

(iii) a full description of the "methods . . . facilities and controls used for, the manufacture" of the device; (iv) samples of the device; and (v) a sample of the proposed label. 21 U.S.C. § 360e(c)(1). Model 7278's application was submitted as a supplement to a prior premarket approval granted for its predecessor, Model 7271. The FDA granted premarket approval for Model 7278 in October, 2003.

Once FDA Class III approval is granted, a manufacturer is restricted in the device's design specifications, manufacturing processes, and labeling. Any proposed change is allowed only after submission and approval of a supplemental application, which must provide a detailed description of the change, data in support thereof, and a statement that the change complies with all requirements of the Food, Drug, and Cosmetic Act. 21 U.S.C. § 360e(d)(6)(A)(i). The manufacturer must also report the results of new scientific studies or investigations related to the safety or effectiveness of the device on an ongoing basis, 21 C.F.R. § 814.84(b)(2), along with any incidents where the device caused death or serious injury, or where it malfunctioned in a way that could lead to death or serious injury if the malfunction recurred. 21 C.F.R. § 803.50(a).

The Commissioner of the FDA is authorized to withdraw approval upon a finding of new information indicating the device is either ineffective or unsafe. 21 U.S.C. § 360e(e)(1). Here, no

supplement was filed, meaning the FDA's initial Model 7278 approval remained in effect at all times relevant to this case.

B. Plaintiff's Device

Plaintiff received a Medtronic Model 7278 Maximo ICD on September 8, 2004. The device was implanted after plaintiff was diagnosed with non-ischemic cardiomyopathy, a disease of the heart muscle which is not caused by coronary artery disease. Non-ischemic cardiomyopathy leads to arrhythmia, and, in some cases, causes heart failure.

After the implantation, plaintiff returned to the hospital six times complaining that the ICD was delivering "inappropriate shocks." Eventually, hospital staff determined the "inappropriate shocks" were caused by T-wave oversensing. T-wave refers to that portion of an electrocardiogram representing the repolarization, or recovery, of the ventricles in the heart. This is one of the elements measured to detect arrhythmia. On September 28, 2006, plaintiff's Model 7278 was replaced with a different ICD manufactured by St. Jude Medical, Inc. Plaintiff has not reported any misfirings since.

Plaintiff, a citizen of Mississippi, filed his complaint in the United States District Court for the District of Minnesota. Defendant is headquartered in Minnesota, and concedes personal jurisdiction and venue. Plaintiff alleges multiple state tort claims including strict liability, breach of warranty, negligence,

misrepresentation, and violation of Minnesota's consumer protection laws. Plaintiff claims defendant (1) was negligent in the design and manufacture of ICD Model 7278; or (2) failed to warn him, his doctor, or the FDA of unreasonable risks in its manufacture or reliability. Defendant moves for summary judgment, invoking federal preemption, and argues plaintiff's claims challenge and conflict with the FDA's regulatory judgment and its ICD labeling and manufacturing process requirements.

II. Legal Standard

Summary judgment may be granted only when there are no material facts in dispute and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). The question of federal preemption under the MDA is reserved to the Court and is properly resolved on summary judgment. See Riegel v. Medtronic, Inc., 451 F.3d 104, 105 (2nd Cir. 2006), aff'd, 128 S.Ct. 999 (2008).

Federal preemption derives from the Supremacy Clause of the United States Constitution. The Constitution establishes the laws of the United States as "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. State laws which conflict with federal laws or regulations are preempted. Malone v. White Motor Corp., 435 U.S. 497, 504 (1978).

The United States Supreme Court extensively examined federal preemption in the context of medical devices in Riegel v. Medtronic, Inc., 128 S.Ct. 999 (2008). Riegel considered an inflatable catheter which ruptured in a patient's artery. The catheter was a Class III medical device which had received FDA premarket approval. The Supreme Court affirmed the district court's decision "that the MDA pre-empted Riegel's claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter." The Court also "pre-empted a negligent manufacturing claim insofar as it was not premised on the theory that Medtronic violated federal law." Riegel, 128 S.Ct. at 1005-06.

In Riegel, the Supreme Court established a two-part test to decide whether the MDA preempts a state claim. A court must first determine whether "the Federal Government has established requirements applicable to" the particular medical device. Id. at 1006. Second, a court must determine whether the state law claims are based on requirements "different from, or in addition to" the federal requirements, relating to safety and effectiveness or any requirement under the MDA. Id. (quoting 21 U.S.C. § 360k(a)). In applying the two-part test, the Court distinguished premarket approval from substantial equivalence review. Substantial equivalence review under § 510(k) of the MDA is essentially an

exemption from federal safety review focused merely on whether a device is substantially equivalent to a device that has been grandfathered, by being marketed prior to the MDA's effective date.[2] Id. at 1007. Unless a device is grandfathered, premarket approval is the mechanism by which the federal government reviews the safety of, and approves specific requirements for, individual devices having no MDA exemption. Id. Therefore, the Court noted, "[p]remarket approval . . . imposes [federal] 'requirements'" under the MDA preemption clause. Id. at 1007.

The second part of the Riegel test asks whether state tort laws are "different from, or in addition to" federal requirements. 21 U.S.C. § 360k(a)(1). Preemption applies to both state statutory and common law. Riegel, 128 S.Ct. at 1008. However, state laws which "parallel" federal laws are not preempted, so long as they neither add to nor vary from federal requirements. Id. at 1011. While the Supreme Court conceded the possibility of a private action for violation of FDA regulations, it held Riegel's plaintiff alleged "the device violated state tort law notwithstanding compliance with the relevant federal requirements." Id. Consequently, the Court found federal preemption.

III. Analysis

The ruling in Riegel is directly on point. Here, plaintiff's

[2]There is absolutely no suggestion that Medtronic's Model 7278 Maximo ICD at issue before this Court is grandfathered in any respect.

claims parallel those in Riegel. And, perforce, the MDA preempts them. As in Riegel, plaintiff alleges his device did not perform as expected; he particularly claims his ICD fired inappropriately instead of maintaining and regulating his heart's rhythm. The Court assumes this to be true, but the assumption does not save his claim. In Riegel, the balloon catheter exploded instead of expanding the plaintiff's arterial lumen.

In fine, plaintiff claims Medtronic violated the premarket approval requirements when it manufactured a defective ICD, or, alternatively, that premarket approval was fraudulently obtained by Medtronic's having concealed known defects in its ICD's design or manufacture. The gravamen of plaintiff's argument is that he would not have endured "inappropriate shocks" if Medtronic's Model 7278 had been manufactured in compliance with a properly obtained premarket approval, or that premarket approval would not have been granted had defendant told the FDA of the risks of T-wave oversensing.

Plaintiff's claims fail because, faced with Medtronic's motion for summary judgment, he offers no evidence to support his assertions. He relies, instead, on the doctrine of res ipsa loquitur for the proposition that full compliance would have resulted in a problem-free device. Res ipsa loquitur does not suffice. Res ipsa loquitur permits an inference of negligence when there can be no other explanation. But this is not a barrel

falling from a second-story warehouse door. See Byrne v. Boadle, 159 Eng. Rep. 299 (1863).

A Medtronic ICD is a complex device which "can fail for a variety of reasons, including medical complications, body rejection phenomena, allergic reaction, and surgical techniques, all of which occur without someone acting in a negligent manner." Mozes v. Medtronic, Inc., 14 F. Supp. 2d 1124, 1129 (D. Minn. 1998). If negligence were the only cause of a Class III device's failure, there would be no need for the MDA's ongoing reporting requirements. See 21 C.F.R. § 814.84(b)(2). Plaintiff is ultimately wrong when he assumes that premarket approval guarantees the device is completely safe. As the Supreme Court aptly recognized, the premarket approval process is ultimately a cost-benefit analysis in which the potential health benefits are weighed against the potential risks. Riegel, 128 S.Ct. at 1008.

Plaintiff's res ipsa loquitur argument is undermined when he asserts that the most likely cause of the inappropriate shocks was T-wave oversensing, and Medtronic's representative was negligent in recommending this model to treat his condition. In making this allegation, plaintiff essentially concedes Model 7278's susceptibility to T-wave oversensing was possibly caused by plaintiff's unique physiology, rather than any general defect. Because defendant's negligence is not the only possible explanation for this device's failure, plaintiff's reliance on res ipsa

loquitur cannot be sustained.

His case also fails because T-wave oversensing is a recognized risk in this product. Plaintiff is plain wrong when he claims Medtronic violated its premarket approval authority knowing of the risk of T-wave oversensing without informing the FDA. The record shows the FDA was fully informed of this risk. The device's FDA-approved manual includes warnings about T-wave oversensing; therefore, it is simply not true defendant concealed this risk. More importantly, Congress has granted the FDA exclusive power to enforce MDA premarket approvals. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001). In fact, private actions to enforce the MDA are expressly prohibited under 21 U.S.C. § 337(a). Consequently, plaintiff would not be able to raise this claim even if it were supported by the facts.

Plaintiff tries to save his claims from preemption by resorting to the Supreme Court's allowance of state claims narrower than federal claims, and its concession that "a narrower requirement might be 'different from' the federal rules in a literal sense." Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996). This argument is unavailing.

Plaintiff fails to show which of his state claims are, in any fashion, "narrower" than those which are MDA/Riegel preempted. Nor has he shown how any of his claims might be "narrower." It is difficult to imagine precisely which "narrower" state claims still

exist after Riegel, but, in any case, plaintiff has failed to show how his claims are among them. Because plaintiff's claims are not based on a breach of the MDA as enforced by the FDA, the claims are not grounded in state laws that "parallel" federal requirements. Thus, plaintiff's claims are preempted.

III. Conclusion

For the foregoing reasons, the Court finds plaintiff's claims are preempted by federal law, and therefore fail as a matter of law.

Accordingly, IT IS ORDERED that defendant's motion for summary judgment [Docket No. 23] is granted. Plaintiff's claims are dismissed with prejudice.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: August 18, 2008

S/ JAMES M. ROSENBAUM
JAMES M. ROSENBAUM
United States District Judge