FOR PUBLICATION

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IN THE
COURT OF APPEALS OF INDIANA

MEDTRONIC, INC.,	)	
	)	
Appellant-Defendant,	)	
	)	
vs.	)	No. 49A02-1211-CT-925
	)	
LORI A. MALANDER, Individually and as Personal Representative of the Estate of DAVID M. MALANDER, SR., Deceased and KATHLEEN MALANDER,	)	
	)	
Appellees-Plaintiffs.	)	

APPEAL FROM THE MARION SUPERIOR COURT
The Honorable Theodore M. Sosin, Judge
Cause No. 49D02-0901-CT-537

October 11, 2013

OPINION - FOR PUBLICATION

BARNES, Judge

Case Summary

Medtronic, Inc., ("Medtronic") appeals the trial court's denial of its motion for summary judgment in an action against it by Lori Malander, individually and as the personal representative of the Estate of David Malander, deceased, and Kathleen Malander (collectively, the "Malanders"). We affirm.

Issues

Medtronic raises two issues, which we restate as:

I. whether the trial court properly found that the Malanders' claim was not preempted by federal law; and

II. whether the trial court properly denied summary judgment regarding whether Medtronic voluntarily assumed a duty to David.

Facts

We first note that many of the facts of this case are subject to a stipulated protective order. As such, portions of the briefs and appendices are excluded from public access. See Ind. Admin. R. 9(G)(4)(c). Indiana Administrative Rule 9(G)(4)(d) provides:

> Orders, decisions, and opinions issued by the court on appeal shall be publicly accessible, but each court on appeal should endeavor to exclude the names of the parties and affected persons, and any other matters excluded from public access, except as essential to the resolution of litigation or appropriate to further the establishment of precedent or the development of the law.

We have attempted to exclude matters covered by the protective order from this opinion. However, to the extent such matters are included in this opinion, we deem such information to be essential to the resolution of the litigation or appropriate to further the establishment of precedent or the development of the law. See, e.g., Recker v. Review Bd. of Ind. Dep't of Workforce Dev., 958 N.E.2d 1136, 1139 (Ind. 2011) ("As to the facts of the case that derive from the records of the Department and are discussed in this opinion, we deem such information to be public as essential to the resolution of the litigation and appropriate to further the establishment of precedent and the development of the law.").

Due to heart problems, Dr. Lawrence Klein implanted a Medtronic defibrillator and a Medtronic Transvene Model 6936 right ventricular lead ("Lead") in David Malander in 1997. The Lead was a Class III medical device subject to premarket Food and Drug Administration ("FDA") approval. Dr. Klein upgraded the defibrillator in 2004, but left the Lead in place.

During a follow-up appointment, Dr. Klein learned that the device had experienced nine episodes of random short V-V intervals. A short V-V interval is "an interval where the device is sensing electrical activity . . . in the heart or perhaps in the lead, that has a very . . . short interval." Appellant's App. p. 402. The Malanders

describe a short V-V interval as when the defibrillator "incorrectly senses electrical activity in the heart, or in the lead, at a much faster rate than the heart is capable of." Appellees' Br. p. 7. Medtronic describes a short V-V interval as "a false-positive; in more technical terms, it is an abbreviated sensing interval in which the [defibrillator] senses electrical activity that is not actually related to the heart's rhythm." Appellant's Br. p. 9. In 2006, Dr. Klein scheduled David for another surgery to upgrade the defibrillator and possibly replace the Lead. Dr. Klein was aware that the Lead had a high failure rate of 34.6% and was concerned about the short V-V intervals.

During the December 7, 2006 surgery, Joseph von Weigandt, a Medtronic Clinical Specialist, was present and assisted Dr. Klein with testing the Lead. The testing did not reveal any problems with the Lead. Dr. Klein also called Medtronic during the surgery and talked to Peter Choukalas and Don Ruzin of Medtronic's technical services department. Dr. Klein requested all of the information they possessed on short V-V intervals. Dr. Klein asked, "Did we test it properly, is this lead functioning normally . . . is there any information about the short V-V intervals that I need to know about. Are they okay, do they indicate a lead failure?" Id. at 681. Ruzin responded, "Don't worry about that; it doesn't mean anything. . . . I don't think that's a problem . . . ." Id. at 685. Dr. Klein chose not to replace the Lead.

David died on January 2, 2007, following an incident of ventricular tachycardia on December 31, 2006. Testing revealed 361 short V-V intervals of his defibrillator between December 14, 2006, and December 31, 2006.

The Malanders filed a complaint against Medtronic and Dr. Klein. As to Medtronic, the Malanders alleged in Count 7 that Medtronic was negligent by:

> a. Failing in its design of the 6936 lead, failing to properly warn and instruct as to the hazards of use of that model lead, and failing to recall that lead, in that the 6936 lead had an usually [sic] high incidence of fracture and failure of the lead;
>
> b. Failing to recall this lead, and further failing to give adequate warnings to purchasers and users of the 6936 Transvene lead about the unreasonably dangerous and defective condition of the lead and of the dangerous propensity of the lead to fail without warning; and,
>
> c. Failing to recommend that the 6936 lead be removed or capped off during David Malander's December 7, 2006 surgery.

Id. at 10. The Malanders claim that internal Medtronic memorandums distributed to their technicians prior to David's surgery indicated that short V-V intervals were indicative of lead failure and that the technicians should have recommended replacement of the Lead.

In October 2011, Medtronic filed a motion for summary judgment. Medtronic alleged that the Malanders' claims were preempted by federal law pursuant to the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. Section 360k(a), and Riegel v. Medtronic, 552 U.S. 312, 128 S. Ct. 999 (2008). In the Malanders' response to Medtronic's motion for summary judgment, they acknowledged that Count 7(a) and 7(b) of their complaint were preempted by federal law. However, the Malanders argued that Count 7(c) was based on Medtronic's negligence during the December 2006 surgery and was not preempted. The Malanders argued that Medtronic assumed a duty to David when its technicians advised Dr. Klein regarding the

Lead but did not advise him to replace the Lead. Medtronic filed a response, and after a hearing, the trial court denied Medtronic's motion for summary judgment. The trial court certified the order for interlocutory appeal, and we accepted jurisdiction over the appeal pursuant to Indiana Appellate Rule 14(B).

Analysis

Medtronic argues that the trial court erred by denying its motion for summary judgment. Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Ind. Trial Rule 56. We liberally construe all designated evidentiary material in a light most favorable to the non-moving party to determine whether there is a genuine issue of material fact. Bradshaw v. Chandler, 916 N.E.2d 163, 166 (Ind. 2009). The party that lost in the trial court has the burden of persuading the appellate court that the trial court erred. Id. Our review of a summary judgment motion is limited to those materials designated to the trial court. Mangold v. Ind. Dep't of Natural Res., 756 N.E.2d 970, 973 (Ind. 2001).

I. Preemption

Medtronic argues that the Malanders' claim in paragraph 7(c) of the complaint is preempted by federal law. The federal law at issue is part of the MDA, which "swept back some state obligations and imposed a regime of detailed federal oversight" on medical devices. Riegel, 552 U.S. at 316, 128 S. Ct. at 1003. The regulatory scheme "established various levels of oversight for medical devices, depending on the risks they present." Id., 128 S. Ct. at 1003. At issue here are Class III devices, which receive the most federal oversight. Id. at 317, 128 S. Ct. at 1003.

Class III devices are subject to "a rigorous regime of premarket approval," which includes review of the device's proposed labeling. Id., 128 S. Ct. at 1004. "The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, [21 U.S.C.] § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, [21 U.S.C.] § 360e(d)(1)(A)." Id. at 318, 128 S. Ct. at 1004. "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 319, 128 S. Ct. at 1005 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." Id., 128 S. Ct. at 1005 (citing 21 U.S.C. § 360e(d)(6); 21 CFR § 814.39(c)).

After premarket approval, the devices are also subject to reporting requirements. Id., 128 S. Ct. at 1005 (citing 21 U.S.C. § 360i). The reporting requirements include "the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2)," and the obligation "to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, [21 CFR] § 803.50(a)." Id., 128 S. Ct. at 1005.

Additionally, the MDA 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 or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a).

The Supreme Court analyzed this preemption clause in Riegel. There, the plaintiffs brought an action against the manufacturer of a heart catheter after the catheter ruptured in his coronary artery during heart surgery. The complaint alleged that the catheter "was designed, labeled, and manufactured in a manner that violated New York common law." Riegel, 552 U.S. at 321, 128 S. Ct. at 1005. The Riegel court held that the preemption clause establishes a two-pronged test for determining if state law claims are preempted. First, we must determine whether the Federal Government has imposed "requirements" on the device. Id., 128 S. Ct. at 1006. If so, we must then determine whether the state law claims impose requirements "different from, or in addition to" the federal ones and whether the requirements relate to "safety and effectiveness" or to "any other matter included in a requirement applicable to the device." Id. at 321-22, 128 S. Ct. at 1006 (citing 21 U.S.C. § 360k(a)).

The Court answered the first prong in the affirmative. The Court found that premarket approval imposes "requirements" in the case of Class III devices. Id. at 322, 128 S. Ct. at 1007. In considering the second prong, the Court concluded that common

law causes of action for negligence and strict liability impose "requirements" and are preempted by the MDA. Id. at 323-25, 128 S. Ct. at 1007-08. The Court explained:

> State tort law that requires a manufacturer's catheters 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. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

Id. at 325, 128 S. Ct. at 1008.

The Court noted that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." Id. at 330, 128 S. Ct. at 1011 (quoting 21 U.S.C. § 360k(a)(1)). The preemption clause "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." Id. (quoting Medtronic v. Lohr, 518 U.S. 470, 495, 116 S. Ct. 2240 (1996)). "Parallel" claims would not be preempted. Id. Ultimately, the Court held that the plaintiffs' claims were preempted because they asserted that the device violated state tort law notwithstanding compliance with the relevant federal requirements.

Medtronic argues that the Malanders have not alleged a parallel claim and that it is entitled to summary judgment as a matter of law. According to Medtronic, this action involves a claim that their technicians should have provided additional warnings above and beyond the warnings on the device's label, and the MDA preempts such claims. The Malanders counter that their claim is not preempted because it involves negligent oral representations by Medtronic's technicians, not the device's labeling.

Indiana courts have only addressed the MDA's preemption clause once. In McGookin v. Guidant Corp., 942 N.E.2d 831 (Ind. Ct. App. 2011), a child died after receiving a pacemaker. The parents brought an action against the manufacturer of the pacemaker for wrongful death, product liability, breach of express and implied warranties, actual fraud, constructive fraud, negligence, violation of the Indiana Deceptive Consumer Sales Act, and intentional and negligence infliction of emotional distress. The basis of their claim was that "the labeling for [their daughter's] pacemaker was inadequate because it failed to warn of a lack of testing of the Automatic Capture feature with small children, unipolar epicardial leads, and abdominal implantation." McGookin, 942 N.E.2d at 833. "In other words, their complaint challenge[d] labeling expressly approved by the FDA." Id.

Based on the MDA's preemption clause and the United States Supreme Court's opinion in Riegel, we concluded that the plaintiffs' claims were preempted. We noted that the plaintiffs did not allege that the manufacturer violated federal requirements. Rather, the plaintiffs contended that the manufacturer "should be liable for its failure to add warnings that are permitted, but not required, by federal law." Id. at 838. We

concluded that this allegation was "an attempt to impose a standard of care in addition to the FDA's specific federal requirements" and that the claim was preempted. Id.

The facts of this case, however, are distinguishable from Riegel and McGookin. The Malanders' claim here relates to oral representations made by a manufacturer's representatives during a surgical procedure regarding a specific device's performance, not general allegations regarding the labeling, design, or manufacture of the device. Few courts have considered this issue.

Medtronic relies on Baker v. Medtronic, Inc., No. 2:99-CV-1355, 2002 WL 485013 (S.D. Ohio, Eastern Div. Mar. 28, 2002). In Baker, the battery on the plaintiff's anti-spasm medication pump failed. The physician had noted that the low battery alarm was occurring, scheduled a surgery for three weeks later, and contacted Medtronic's representative, who informed the physician's nurse that the pump would continue working for approximately four weeks. Four days before the surgery, the battery failed. The plaintiff brought an action against Medtronic and argued, in part, that the technician's representations were "off label representations" that were not regulated by the FDA. Baker, 2002 WL 485013, *8. The court noted that the labeling information contained detailed graphs regarding the pump's battery life, and the information given to the physician's nurse was consistent with the information in the labeling. The court concluded that the information was not an "off label" representation, and the claim was preempted. Id.

Medtronic also relies on Wolicki-Gables v. Arrow Intern., Inc., 641 F. Supp.2d 1270 (M.D. Fla. 2009).[1] There, the plaintiff was implanted with a drug delivery pump and catheter for the treatment of chronic pain. The device manufacturer's independent contractor sales representative, Nelson, was present during surgery to replace the allegedly malfunctioning pump. More complications ensued, and the plaintiffs filed an action against the device's manufacturer, Nelson, and others. The plaintiffs alleged Nelson, "as a sales representative, owed a duty to Plaintiffs to instruct and educate [the plaintiff's] operating surgeon to ensure that the pain pump was functioning properly, to verify Plaintiff's consent to Defendant Nelson's presence in the operating room, and to not dispose of any devices removed from Plaintiff." Wolicki-Gables, 641 F. Supp.2d at 1291.

The district court granted summary judgment to Nelson. The court first noted that, because it had granted the manufacturer's motion for summary judgment based on preemption, it also granted summary judgment to Nelson, who had joined in the manufacturer's motion. The court did not differentiate the claim against Nelson and the claim against the manufacturer and gave no analysis of the preemption of the claim against Nelson. The court then noted that, even if the plaintiffs' negligence claim against Nelson was not preempted, the claim still failed. In particular, the court noted that

[1] Medtronic also relies on Franklin v. Medtronic, No. 09-CV-02301, 2010 WL 2543579 (D. Col. May 12, 2010). In Franklin, the plaintiff alleged, in part, that Medtronic should have recalled its defibrillators or warned physicians and users of defects. The district court concluded that Medtronic was not required to issue a recall or warning under the FDA regulations and that the plaintiff's claim would establish requirements different from or in addition to the federal requirements. Thus, the plaintiff's claim was preempted. Here, however, the plaintiffs' claim relates to oral representations given to David's physician during his surgery, not the failure to issue a recall or the failure to give a warning.

Nelson did not participate in the surgery, did not advise the doctor or interact with him, and did not improperly dispose of the removed device. The Eleventh Circuit affirmed the district court's decision but likewise gave no analysis of the preemption of the claim against Nelson. Wolicki-Gables v. Arrow Intern. Inc., 634 F.3d 1296 (11th Cir. 2011).

Given the lack of analysis in Wolicki-Gables, we find Adkins v. Cytyc Corp, No. 4:06CV00053, 2008 WL 2680474 (W.D. Va. July 3, 2008), more persuasive. There, the plaintiff suffered thermal burns to her sigmoid colon and a perforated uterus during an endometrial ablation procedure. The procedure was performed with a NovaSure device, and the manufacturer's representative was in the operating room "and advised and directed [the doctor] on the proper way" to use the device. Adkins, 2008 WL 2680474, *1. The plaintiff brought an action against the manufacturer "alleging breach of implied warranty of merchantability, breach of express warranty, negligence through inadequate design and negligent warnings or instruction of the surgeon by defendants' corporate representative." Id.

The manufacturer filed a motion to dismiss based on preemption. The district court agreed that the plaintiff's common law claims for negligence and breach of warranty were preempted under the MDA. However, the court concluded that the Plaintiff's cause of action regarding the representative's direct actions "during the surgery in negligently instructing the operating physician" were not governed by Riegel's preemption holding. Id. at *2. The court noted:

> The FDA does not regulate interactions between corporate representatives and physicians on-site at a particular surgery, and where it does not mandate special physician

> training for a drug, it does not specify how such an interaction at surgery must be performed. These localized situations are traditional matters for the common law, not the FDA's regulatory approval process. Such a claim does not challenge the design, manufacture, and labeling of the NovaSure device so as to implicate Riegel preemption, but rather challenges negligence by a corporate agent acting as a de facto physician's assistant during a surgical procedure.

Id. at *3. The district court ultimately dismissed the claim because of the lack of specific allegations in the complaint but allowed the plaintiff to amend the complaint.

Likewise, we conclude that the Malanders' claim concerns the allegedly negligent interaction between the physician and Medtronic's technicians. Unlike Baker, the Malanders' claim does not involve the mere restatement of information given in the labeling. As in Adkins, their claim does not concern the design, manufacture, or labeling of the lead. Rather, the Malanders' challenge involves negligence of Medtronic's technicians in giving David's physician allegedly faulty advice regarding the performance of one specific lead. As such, we conclude that the Malanders' claim is not preempted by the MDA, and the trial court properly denied Medtronic's motion for summary judgment on this issue.

II. Assumed Duty

On appeal, Medtronic also argues that it did not assume a duty to the Malanders.[2] To prevail on a claim of negligence, the plaintiff must show: (1) a duty owed to the

[2] We note that Medtronic did not request summary judgment on the assumption of a duty issue. Rather, in responding to Medtronic's preemption agreement, the Malanders discussed Medtronic's assumption of a duty to David, and Medtronic addressed the issue in its reply brief. On appeal, Medtronic argues that it did not assume a duty to David. It is unclear why the Malanders argued the assumption of duty issue in response to Medtronic's motion for summary judgment on preemption. It is also unclear why Medtronic

plaintiff by defendant; (2) breach of duty because of conduct falling below the applicable standard of care; and (3) compensable injury proximately caused by defendant's breach of duty. Kroger Co. v. Plonski, 930 N.E.2d 1, 6 (Ind. 2010). The parties here argue only regarding whether Medtronic had a voluntarily assumed duty.

"A duty of care may . . . arise where one party assumes such a duty, either gratuitously or voluntarily." Plan-Tec, Inc. v. Wiggins, 443 N.E.2d 1212, 1219 (Ind. Ct. App. 1983). "The assumption of such a duty creates a special relationship between the parties and a corresponding duty to act in the manner of a reasonably prudent person." Id. Failure to act in a reasonable manner will give rise to an action for negligence. Id. "The existence and extent of such a duty are ordinarily questions for the trier of fact." Merrill v. Knauf Fiber Glass GmbH, 771 N.E.2d 1258, 1270 (Ind. Ct. App. 2002), trans. denied. However, the court will decide the issue as a matter of law when the record contains insufficient evidence to establish such a duty. Id.

Section 324A of the Restatement (Second) of Torts parallels Indiana's doctrine of assumed duty. Ward v. First Indiana Plaza Joint Venture, 725 N.E.2d 134, 136 (Ind. Ct. App. 2000), trans. denied. Section 324A provides:

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if

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is now requesting summary judgment on the issue not raised in its summary judgment motion. Regardless, as neither party raises the issue of waiver, we will address Medtronic's assumption of a duty.

(a) his failure to exercise reasonable care increases the risk of such harm, or

(b) he has undertaken to perform a duty owed by the other to the third person, or

(c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Id.

Medtronic argues that it did not assume a duty to make a medical recommendation regarding the removal of the Lead, that it did not control the "instrumentality" or assume a duty owed by Dr. Klein, that it did not have superior knowledge to Dr. Klein, and that its internal documents did not give rise to a duty to make medical recommendations. Appellant's Br. p. 31. According to Medtronic, Dr. Klein was in charge of the surgical procedure regardless of any advice given by the technicians, Dr. Klein had the same information that the technicians had, and its technicians are prohibited from practicing medicine.

The Malanders, however, argue not that Medtronic had a duty to make medical recommendations, but rather that it assumed a duty to make "technical" recommendations to Dr. Klein regarding the Lead. Appellee's Br. p. 17. The Malanders do not allege that Medtronic should have participated in the surgery, was responsible for deciding whether to remove the Lead, or was involved with the physician/patient relationship. Rather, the Malanders argue that, having voluntarily agreed to give technical support, the technical support should have been made in a "reasonable and prudent manner." Id. at 21.

We agree with the Malanders. In fact, Medtronic concedes that, "[h]aving volunteered to provide technical support, Medtronic at most assumed a duty to provide that support in a reasonable and prudent manner." Appellant's Br. p. 32. Medtronic's failure to exercise reasonable care in giving technical support would clearly increase the risk of harm to a patient. Medtronic voluntarily undertakes to perform the technical support for physicians to assist the physician in using their devices. The Malanders designated evidence that Medtronic's technician was present in the operating room and that Dr. Klein talked on the telephone to additional technicians regarding the short V-V intervals experienced by David's Lead. The Malanders also designated evidence that Medtronic's technicians failed to follow the recommendations of its own internal memoranda regarding the short V-V intervals associated with this particular lead. Appellant's App. p. 508. Although Medtronic designated deposition testimony that the small number of short V-V intervals associated with David's lead would not have been concerning, the designated evidence creates a genuine issue of material fact. Because "[t]he existence and extent of such a duty are ordinarily questions for the trier of fact," Merrill, 771 N.E.2d at 1270, and genuine issues of material fact exist regarding whether Medtronic assumed a duty here, summary judgment on this argument would have been improper.

Conclusion

We conclude that the MDA does not preempt the Malanders' claim against Medtronic and that genuine issues of material fact exist regarding whether Medtronic

assumed a duty to David. Consequently, the trial court properly denied Medtronic's motion for summary judgment. We affirm.

Affirmed.

CRONE, J., and PYLE, J., concur.