

DRUG, DEVICE AND BIOTECHNOLOGY

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In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the U.S. Supreme Court articulated the boundaries of federal preemption of state law claims concerning certain Class III medical devices. This article analyzes lower courts' applications of Riegel in cases involving claims based on the actions of sales representatives and suggests approaches that may preserve the viability of a preemption defense in such cases.

Assessing the Post-Riegel Landscape: The Effect of Sales Representatives' Actions on Preemption Analyses



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In *Riegel v. Medtronic, Inc.*,¹ the United States Supreme Court held that the Medical Device Amendments of 1976 (“MDA”),² which shifted oversight of medical devices from states to the federal government, preempts certain state law claims against manufacturers of Class III devices that have been authorized through the Food and Drug Administration’s extensive Premarket Approval (“PMA”) process. Under *Riegel*, the MDA expressly preempts all state law claims that seek to impose a “requirement” that is “different from, or in addition to” FDA-imposed federal requirements for Class III PMA medical devices.³ State law claims merely “parallel” to applicable federal requirements are not preempted.^{4,5}

In the wake of *Riegel*, plaintiffs who bring suits concerning Class III PMA devices must proffer theories that avoid preemption. Pleading facts that implicate the actions or inactions of medical device sales representatives may become a favored strategy. This article analyzes some of the emerging law and offers guidance for maintaining a preemption defense in such cases.

¹ 552 U.S. 312 (2008).

² 21 U.S.C. § 360c *et seq.*

³ *Riegel*, 522 U.S. at 330.

⁴ *Id.*

⁵ In addition to express preemption under *Riegel*, the United States Supreme Court previously held, in *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001), that the no-private-right-of-action clause of the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §337(a), impliedly preempts state law claims seeking to enforce its provisions. For an excellent review of both express and implied preemption in the medical device arena, see Andrew Tauber, Max Heerman & Brian Wong, *How to Argue Medical Device Preemption: A Powerful Tool to Wield Early*, FOR THE DEFENSE (Oct. 2012).

Sales Representative and Manufacturer as Analytically Indistinct

In some preemption cases, courts have treated the sales representative and the manufacturer as a single analytical unit. In *Wolicki-Gables v. Arrow International, Inc.*,⁶ for example, after complications arose following revision of an implanted pain pump, the patient and her husband brought a products liability action against the manufacturer of the pump and catheter, the distributor of the manufacturer’s products, and one of the distributor’s sales representatives. That sales representative was in the operating room during the procedure, and he was sued for breach of various supposed duties – “to use reasonable care in the instruction and education of physicians as to the implantable drug delivery system so that it would be reasonably safe for its intended use” and “to ensure that the implantable drug delivery system was functioning properly before allowing it to be implanted.”⁷ The defendant manufacturer moved for summary judgment on both strict liability and negligence claims of design defect, manufacturing defect, and failure to warn. In its preemption analysis, the *Wolicki-Gables* court found all such claims expressly preempted under the MDA, as interpreted in *Riegel*, as to the manufacturer, the distributor, and the sales representative.⁸ The court’s preemption analysis did not differentiate between the claims against the manufacturer and the claims against the sales representative.⁹ The

⁶ 641 F. Supp. 2d 1270 (M.D. Fla. 2009).

⁷ *Id.* at 1279.

⁸ *See id.* at 1291.

⁹ Of note, the court also noted that, even if the claims were not preempted as to the sales representative, the claims still failed because the implanting surgeon had testified that he relied exclusively on his own knowledge and experience in performing the revision

United States Court of Appeals for the Eleventh Circuit subsequently affirmed, again without addressing the impact of the sales representative's actions on the preemption defense.¹⁰

More recently, in *Suckow v. Medtronic Inc.*,¹¹ a patient and her husband sued the manufacturer of an automatic implantable cardiac defibrillator and associated defibrillation lead, as well as its sales representative, for damages related to malfunction of the device. Plaintiffs brought various state law claims against the manufacturer, including strict liability manufacturing defect and breach of express warranty. They also brought negligence and misrepresentation claims against the sales representative, alleging that the sales representative had "tested, reviewed, and evaluated the device and informed and advised her and others that it was operating and performing normally and within expected standards, and that it was fit and safe for continued use."¹² The court dismissed the claims against the manufacturer on preemption grounds without considering what impact, if any, the alleged actions of the sales representatives had on that analysis.¹³ The court also dismissed the claims against the sales representative for failure to state a cause of action under applicable state law.¹⁴

Preemption May Turn on the Sales Representative's Behavior

Other courts have scrutinized sales representatives' words and actions in their *Riegel* analyses, finding that preemption turns on whether the agent's behavior went beyond the scope of the FDA-approved product labeling and/or the FDA's regulatory authority. *Adkins v. Cytyc Corporation*¹⁵ is illustrative. In *Adkins*, plaintiff experienced complications after an endometrial ablation, which she attributed to NovaSure, a Class III PMA device indicated for use in the endometrial ablation of patients with an intact uterus and a uterine wall that measures at least four centimeters. She claimed that the manufacturer's sales representative, who was present in the operating room during the procedure, negligently instructed the attending physician about how to measure uterine wall thickness and that, after following those instructions, the measurement was wrong. A correct measurement, plaintiff argued, would have precluded use of NovaSure and avoided the complications. Plaintiff alleged breach of implied warranty of merchantability, breach of express warranty, negligent design, and negligence on an agency theory based on the sales representative's instructions to the physician. Defendants filed a FRCP 12(b)(6) motion to dismiss and argued that the MDA preempted plaintiff's claims.

In an unpublished opinion, the court agreed that causes of action "that sound in negligence or breach of a duty related to the design, manufacturing, and labeling of the NovaSure device" were preempted.¹⁶ But it also held that a cause of action "implicating

procedure, and not on anything the sales representative had said. *Id.* at 1291.

¹⁰ *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300-02 (11th Cir. 2011).

¹¹ --- F. Supp. 2d ---, 2013 WL 5302223 (D. Nev. Sept. 20, 2013).

¹² *Id.* at *1.

¹³ *Id.* at *5-6.

¹⁴ *Id.* at *5.

¹⁵ No. 4:06CV00053, 2008 WL 2680474 (W.D. Va. July 3, 2008).

¹⁶ *Id.* at *2.

the direct actions of Cytyc's representative during the surgery in negligently instructing the operating physician . . . is not governed by *Riegel's* preemption holding."¹⁷ As it explained,

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.¹⁸

Plaintiff had "potentially" stated a tort claim under state law, but because the pleadings lacked sufficient specificity, the court dismissed the complaint with leave to amend.

Recently, the Indiana Court of Appeals followed the reasoning of *Adkins*. In *Medtronic, Inc. v. Malander*,¹⁹ the appellate court affirmed a decision rejecting a preemption defense. In that case, a ventricular lead (a Class III PMA device) allegedly malfunctioned. According to the pleadings, during surgery to upgrade the associated defibrillator and possibly replace the lead, the manufacturer's representatives, both in the operating room and by phone,

tested the lead and advised the surgeon that it was functioning normally. Allegedly relying on those representations, the surgeon kept the same lead in place. The patient died shortly thereafter, allegedly due to lead failure. In the ensuing lawsuit, plaintiffs brought claims of negligent design, negligent failure to adequately warn, and negligent failure to recall the lead. In addition, plaintiffs alleged negligence by the company representatives in failing to recommend that the lead be removed or capped off during the revision procedure.

The defendant manufacturer moved for summary judgment on all claims on preemption grounds. In their response, plaintiffs conceded that the first three claims were preempted under the MDA but argued that their claim involving the company representatives were not. The manufacturer, they said, had assumed a duty to the decedent when its company representatives advised the surgeon that the lead was functioning properly and did not need to be replaced. The trial court agreed, holding that the claim involving the question of whether the manufacturer "assumed a duty to [the patient] when its technicians advised [the surgeon] regarding the Lead but did not advise him to replace the Lead" could go forward.

On appeal, the Indiana Court of Appeals analyzed whether the MDA preempted "oral representations made by a manufacturer's representatives during a surgical procedure regarding a specific device's performance."²⁰ In its view, plaintiffs' remaining claim turned on an "allegedly negligent interaction between the physician and [the manufacturer's] technicians" and not "the mere restatement of information given in the labeling" or a challenge to the "the design,

¹⁷ *Id.*

¹⁸ *Id.* at *3.

¹⁹ 96 N.E.2d 412 (Ind. Ct. App. 2013).

²⁰ *Id.* at 418.

manufacture, or labeling of the lead.”²¹ “Rather,” as the plaintiffs argued, “having voluntarily agreed to give technical support, the technical support should have been made in a ‘reasonable and prudent manner.’”²² Thus, the appellate court agreed with the trial court – the MDA did not preempt plaintiffs’ claim about alleged negligence of the manufacturer’s representatives. Because genuine issues of material fact existed as to whether the manufacturer had assumed such a duty by voluntarily providing technical support to assist the physician in using its device, summary judgment was improper.²³

Similarly, in *William Beaumont Hospital v. Medtronic, Inc.*,²⁴ a manufacturer’s sales representative gave three “pain pump refill kit” samples to a hospital for use by anesthesiologists. As it turned out, only two of the samples were refill kits; the third was a “catheter access kit.” Although catheter access kits were not indicated for pain pump refills, the sales representative allegedly stated that all three kits were suitable for refill use. Later, a nurse retrieved the catheter access kit to refill a patient’s implanted pain pump. Because the medication was delivered directly to the patient’s intrathecal space instead of the pump, the patient was overdosed. After the healthcare providers settled a tort claim brought by the patient, they sued the manufacturer seeking contribution for the settlement. The manufacturer moved to dismiss the complaint pursuant to FRCP 12(6)(b).

The court denied the motion, holding that preemption did not apply to a claim that a sales representative made negligent

representations about the catheter access kit. According to the court, that claim did not implicate the adequacy of the label. It turned on responsibility for a mistake: “negligently holding out a catheter access kit for use in a refill procedure.”²⁵ While the nurse may have been a superseding cause of the overdose – she should not have retrieved a catheter access kit in the first instance – the court found that the sales representative might have contributed to the injury. That issue was fairly within the purview of the jury.

Lessons from the Emerging Case Law

In light of these cases, we offer the following thoughts to medical device manufacturers and defense counsel seeking to maximize the protection afforded by *Riegel* preemption:

1. *Consider judicious dispatch of sales representatives.*

Prior to *Riegel*, plaintiffs proffered so-called “failure to train” or “failure to instruct” claims, alleging that a manufacturer’s sales personnel should have provided different guidance to physicians regarding the use of medical devices. Plaintiffs may plead these claims with increasing frequency in an attempt to end-run preemption. Before dispatching company representatives to provide guidance to healthcare providers, manufacturers should remember that courts have repeatedly found that they have no duty to do so. As one federal court recently explained, “[E]ven assuming *arguendo* that plaintiff’s failure to train/instruct claims are not preempted, plaintiff has failed to state a claim for which relief can be granted. It is well established that a medical device manufacturer is not responsible for the

²¹ *Id.* at 419.

²² *Id.* at 420-21.

²³ *Id.* at 421.

²⁴ No. 09-CV-11941, 2009 WL 2849546 (E.D. Mich. Aug. 31, 2009).

²⁵ *Id.* at *7.

practice of medicine.”²⁶ However, as cases like *Malander* show, voluntarily providing such guidance may create a duty to do so in a prudent and reasonable manner and thereby create a basis for liability unshielded by MDA preemption. However, if the FDA requires or otherwise approves company representatives to train physicians or attend surgeries, then such training or operating room presence arguably should not undermine a preemption defense – assuming such actions do not go beyond what the FDA specifically required or approved. Still, behaviors or discussions that do go beyond what the FDA specifically required or approved may fall beyond the reaches of MDA preemption.

2. Expect scrutiny of sales representatives' actions as part of a preemption analysis.

Although some courts have glossed over the actions of sales representatives in their post-*Riegel* preemption analyses, we would not be surprised to see increased judicial attention to the nuances of the sales representative interactions with healthcare providers. Did the company representative do or discuss anything that fell outside the scope of the FDA-approved label? Is there a plausible argument that, for a particular case, the actions of the sales team were overseen or regulated by the MDA or that the FDA considered the sales team's scope in the device application? Manufacturers should consider whether their representatives should be trained to stay squarely within the scope of the FDA-approved label and the documentation given to FDA as part of the premarket approval process. As *Adkins*, *Malander*, and *Beaumont* suggest, extra-label

behavior may not be within the scope of preemption.

3. Obtain testimony from medical personnel that they did not rely on sales representatives' statements.

Defense attorneys should secure testimony from the relevant healthcare providers that they did not rely on information that the sales representative provided and that they exercised independent judgment. *Wolicki-Gables v. Arrow International, Inc.*²⁷ offers guidance. That court found that even if plaintiffs' claim about the negligence of a sales representative survived a preemption analysis, it would still fail because the sales representative was essentially superfluous. He did not scrub in. He did not participate in the surgery. He did not influence any surgical decision-making. In fact, the attending surgeon testified that he “relied on his own experience” and not anything the sales representative did, said, or failed to do or say.²⁸ As the court explained, “As to Plaintiffs' claim for negligence based on Plaintiffs' alleged injury from the revision procedure, there is a complete absence of evidence establishing a causal connection between [the sales representative's] presence in the OR” and the injury.²⁹ And manufacturers may want to take affirmative steps to ensure that their representatives do nothing to induce a healthcare provider's reliance in the first instance.

4. Challenge the specificity of plaintiffs' pleadings.

Motions to dismiss under 12(b)(6) continue to have traction. Regardless of the preemption

²⁶ *Sons v. Medtronic Inc.*, 915 F. Supp. 2d 776, 783 (W.D. La. 2013). See also Jennifer A. Eppensteiner & Regina M. Nelson, “*Failure to Train*” and *Medical Device Misuse Claims*, FOR THE DEFENSE (Apr. 2013).

²⁷ 641 F. Supp. 2d 1270 (M.D. Fla. 2009).

²⁸ *Id.* at 1291.

²⁹ *Id.* at 1292.

status of their claims, plaintiffs still need to state claims with the requisite specificity. Defendants may successfully argue that plaintiffs' pleadings lack sufficient specificity about supposed regulatory violations or "parallel claim" theories. As the United States Court of Appeals for the Eighth Circuit has stated, a plaintiff cannot "simply incant the magic words '[the manufacturer] violated FDA regulations' in order to avoid preemption."³⁰ However, the usefulness of that defense may depend on the jurisdiction. The Seventh Circuit, for example, has found that "[f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her [parallel] claim."³¹

5. *Rethink corporate "best practices" to stave off sales representatives' mistakes and subsequent negligence claims.*

Situations like that alleged in *William Beaumont Hospital* – a sales representative giving two pain pump refill kits and one catheter access kit and then erroneously stating that all were good for refills – should be avoided. Would a checklist for the sales representative have been helpful?³² Could the samples have been divided between representatives, so that those with refill kits did not also have catheter kits? Those who choose to be part of the medical system need

to have a measure of obsessiveness about the materials and information they provide. Manufacturers should have systems in place – systems that are revised and improved over time – that instill the importance of extreme care and, to preserve a preemption defense, the need to stay "on script" with FDA-approved information. Understandably, it may be very difficult for sales representatives to deny requests for information or assistance from medical personnel. But the cases we have reviewed illustrate the importance of staying on label and leaving the provision of healthcare to healthcare providers.

* * *

Emerging case law suggests that while *Riegel* offers significant protection against claims concerning Class III PMA devices, plaintiffs have and will continue to proffer claims based on the actions of sales representatives in an attempt to avoid MDA preemption. Manufacturers and defense counsel should take appropriate steps to maintain the viability of this powerful defense in their cases.

³⁰ *In re Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010); *see also Dawson v. Medtronic, Inc.*, No. 3:13-cv-663, 2013 WL 4048850, at *7 (D.S.C. Aug. 9, 2013) (vague claim that "the Infuse Device that was used in [plaintiff's] surgery contained a manufacturing defect and did not meet the specifications set for the Infuse Device during PMA . . . lacks the specificity required").

³¹ *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010).

³² ATUL GAWANDE, *THE CHECKLIST MANIFESTO: HOW TO GET THINGS RIGHT* (2011).

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