Negligent Advice of a Class III Medical Device Sales Rep

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The Medical Device Amendments of 1976 call for federal oversight of medical devices, which varies with the type of device at issue. The most stringent oversight is reserved for a Class III medical device, which is one used in sustaining human life, one of substantial importance in preventing impairment of human health, or one that presents a potential unreasonable risk of illness or injury. 21 U.S.C.S. Section 360c(a)(1)(C)(ii). As a result, Class III devices undergo a rigorous pre-market approval process before the Food and Drug Administration (FDA) will allow them to be sold and used. Therefore, Congress has expressly pre-empted state law tort claims regarding Class III medical devices approved by the FDA via the pre-market approval process. Based on Congress' express pre-emption, courts throughout our nation have preempted all types of state law claims, including manufacturing defect, design defect, failure to warn, breach of express and implied warranty and fraud. For a thorough breakdown, see Riegel v. Medtronic , 552 U.S. 312 (2008).

For many years, the pre-emption defense has served as a Goliath in the courtroom for Class III medical device manufacturers. Manufacturers were able to wield the pre-emption defense as a mighty sword during the pleadings stage to obtain early victory and avoid the high costs of discovery and trial. In recent years, however, we have seen new liability theories raised to circumvent pre-emption by asserting claims of negligent advice of the device sales representative.

For example, in *Adkins v. CYTYC*, No. 4:07-CV-00053 (W.D. Va. July 3, 2008), a sales representative of a Class III device used to treat menorrhagia was in the operating room during an ablation procedure. The sales representative advised the surgeon how to properly measure the uterus and test the integrity of the uterine wall. During the surgery, the plaintiff suffered an injury, and it was determined post-procedure that her actual uterine measurements were 2.5 cm less than the surgeon's pre-procedure calculations, which were performed according to the sales representative's advice. At the pleadings stage, the Class III device manufacturer brought a motion to dismiss all of the plaintiff's claims, i.e., breach of warranty of merchantability, express warranty, negligent manufacture and design, and negligence on an agency theory. In support, the manufacturer asserted the preemption defense, relying on *Riegel*.

The court found that all claims related to the design, manufacture, and labeling of the device were pre-empted and, thus, dismissed the claims with prejudice. However, the court allowed the plaintiff to proceed on her claim of negligence against the sales representative due to the representative's direct actions and advice during the surgery. The court ruled that negligent advice of a sales representative is not governed by *Riegel*'s pre-emption holding.

The court reasoned that interactions between sales representatives and physicians during a particular surgery are not subject to the FDA's pre-market approval process, noting instead that such interactions are traditional matters for the common law. The court explained that claims for negligent advice of a sales representative do not challenge the design, manufacture, and labeling of the device so as to implicate pre-emption but, instead, challenge negligence by a manufacturer's agent acting as a de facto physician's assistant during a surgery.

Additionally, in Medtronic v. Malander , 996 N.E.2d 412 (Ind. Ct. App. 2013), the decedent underwent implantation of a defibrillator and ventricular lead in 1997. In 2004, the defibrillator was upgraded, but the lead was left in place. Through 2006, the decedent's defibrillator showed episodes of short V-V intervals, which, according to the plaintiffs, were indicative of lead failure. In 2006, the decedent's cardiologist scheduled him for another surgery to upgrade the defibrillator and possibly replace the lead. During the surgery, the cardiologist tested the lead to determine whether there was any evidence of potential lead failure. The manufacturer's sales representative was present and assisted with the testing. Ultimately, the testing did not reveal any lead problems. The cardiologist also spoke to the device manufacturer's technical services department about the testing and potential lead failure. The sales representative and technicians assured the cardiologist that he properly tested the lead and that the lead was functioning normally. Based on that advice, the cardiologist chose not to replace the lead and only upgraded the defibrillator. Approximately one month later, the decedent died following an incident of ventricular tachycardia. There were over 300 episodes of short V-V intervals within that month, which the plaintiffs alleged was evidence of lead failure.

The plaintiffs' complaint contained claims against the manufacturer for manufacturing and design defect, failure to warn, failure to give proper instructions, failure to recall the lead, and failure to recommend that the lead be removed during the 2006 surgery. Asserting federal preemption, the manufacturer moved for summary judgment on all claims. The plaintiffs conceded that all claims were pre-empted except for their claim based on the negligent advice of the sales representative and technicians during the 2006 surgery. The plaintiffs argued that the manufacturer assumed a duty to the decedent because its representatives made negligent oral representations to the cardiologist and failed to advise him to replace the lead.

Relying on *Adkins*, the court concluded that the plaintiffs' claim was not pre-empted. The court explained that the claim did not involve the mere restatement of information given in the FDA-approved labeling. Instead, the claim was based on negligence of the manufacturer's representatives in giving advice regarding the performance of one specific lead. Notably, the court not only rejected the manufacturer's preemption defense, but it also found that a question of fact existed as to whether the representatives assumed a duty to the decedent by volunteering advice and participating in the lead testing. Therefore, the manufacturer's motion for summary judgment was denied, and the court left the negligent-advice claim to the jury.

Be Prepared for the 'David' Argument

Riegel and Section 360k created a narrow gap through which a plaintiff's state law claim must fit in order to escape pre-emption. *Bryant v. Medtronic, 623 F.3d 1200, 1204* (8th

Cir. 2010). By merely asserting negligent advice claims, counsel continue to infiltrate that narrow gap with more precision than David's sling. *Adkins* and *Malander* are just two cases that demonstrate the growing number throughout our nation which hold that these claims are not preempted. Regardless, the main lesson to be learned is that Class III medical device manufacturers should expect a negligent advice claim in nearly every lawsuit and be prepared to defend against it. Manufacturers should also ensure that their insurance policies provide coverage for these new claims.

In this new day and age of the negligent-advice cause of action, manufacturers must be mindful of their sales representatives' practices and procedures in order to increase their defensibility against such inevitable claims. The following are a few rules of thumb that will limit liability, with the understanding that, as long as a representative is participating in the care of a patient, there is a good chance the manufacturer will be named a party to the action. Advice should be strictly technical. If it's potentially medical, it should be left to the physician. Technical advice should be directed to the doctor, not the patient. Representatives should attempt to "stick to the script" and only offer advice contained within FDA-approved warnings and instructions. Representatives should not decide whether a device ought to be replaced or upgraded. The physician is ultimately the "captain of the ship," and the line between physician and sales representative must not become blurred. Manufacturers should establish written policies to enhance uniformity amongst their representatives. If feasible, it might be beneficial to consider removing sales representatives from the operating room altogether.

Manufacturers are not left without recourse if a negligent-advice claim survives preemption. The learned-intermediary and captain-of-the-ship doctrines could prove to be successful defenses for Class III device manufacturers. See, e.g., Kennedy v. Medtronic, 851 N.E.2d 778 (Ill. Ct. App. 2006). While pre-emption, the learned-intermediary rule, and the captain-of-the-ship doctrine are all strong defenses for device manufacturers, they will be futile if a question of fact exists as to the sales representative's advice and actions within the operating room. Taking necessary precautionary measures may avoid questions of fact in defending a sales representative liability claim.

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