

# Valuable Resource, Potential Liability, or Both?

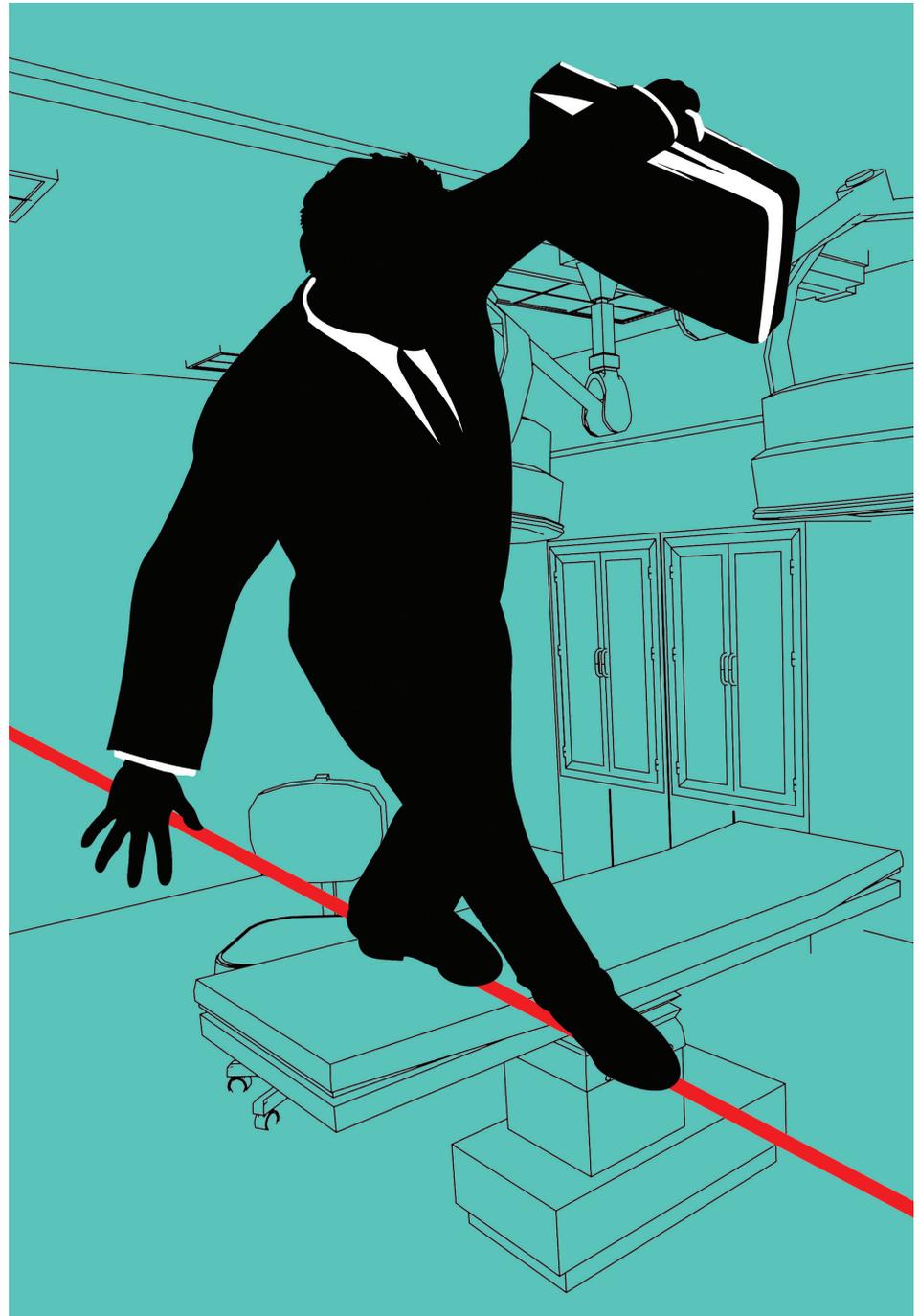
In the medical device industry, sales representatives hold a particularly unique role. Medical devices, such as joint implants, pacemakers, bone screws,

stents, and spinal implants are highly technical and complex products. Adding to the complexity, these medical devices are often on the cutting edge, and the end users, medical professionals, have limited experience with them. Given the complexity and the novelty of such devices, it is common for representatives to be in the operating room or to be involved indirectly in a patient's treatment. As a result, manufacturers have seen a rise in product liability claims stemming from representations, instructions, and omissions of sales representatives and product trainers.

This litigation trend involves both a rise in the number of claims as well as the *types* of claims asserted by plaintiffs. In addition to conventional tort claims, including strict liability and negligent failure to warn, plaintiffs allege various novel theories of action. Accordingly, claims adjusters and claims counsel for medical device manufacturers must become familiar with the ever-expanding world of medical device liability.

## After *Riegel*: A Brave New World of Medical Device Claims

Contemporary claims against manufacturer sales representatives take a number of forms, including failure to train, educational malpractice, failure to warn, fraudulent or negligent misrepresentation, and agency and vicarious liability. Why? In a



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word, the answer is preemption. The U.S. Supreme Court, federal procedure, and Congress have given birth to novel medical device claims.

As Congress slowly extends its reach throughout manufacturing industries, federal laws often conflict with state product liability statutes. This is exactly what happened in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The Medical Device Amendments to the Food, Drug, and Cosmetic Act (MDA) prohibited the states from imposing requirements relating to safety, effectiveness, or any other area covered by the MDA different from, or in addition to any requirement applicable to the medical device. *Id.* at 321. In *Riegel*, the United States Supreme Court held that common law claims for products that received premarket U.S. Food and Drug Administration (FDA) approval regarding safety and effectiveness were preempted by federal law. Of course, preemption potentially disposes of entire cases, thereby avoiding the enormous costs associated with discovery and the trial of these actions. But the Court carved out a lifeline for plaintiffs: common law claims and duties that parallel MDA laws, as opposed to claims that add or otherwise abrogate federal law, were not preempted. After *Riegel*, plaintiffs have alleged a variety of novel theories attempting to parallel federal law.

Federal pleading standards have also led to a rise in the number of medical device theories. Federal pleading standards are typically more stringent than state law requirements. The likelihood that a federal court will dismiss a medical device suit is greater than at the state court level. In response, plaintiffs' attorneys have added novel state common law-based theories and include state manufacturers and state sales representatives in lawsuits to ensure that cases stay in state court and cannot be removed to federal court.

### Preemption: A Basis

After the Supreme Court released the *Riegel* holding, courts struggled to apply a consistent preemption analysis. As seen below, the preemption analysis varies from jurisdiction to jurisdiction, and it is therefore difficult to provide a broad, sweeping summary of the type of claim that will

or will not be preempted. However, as a general rule, the greater the involvement and the responsibility that a representative assumes, the more likely it is that a court will conclude that a claim survives preemption. In addition, off-label statements appear to have a greater chance of surviving preemption arguments.

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Although claims against sales representatives increased largely as a way to avoid preemption, only a handful of courts have actually analyzed whether claims against manufacturer sales representatives survive preemption. For example, in *Adkins v. CYTYC Corporation*, No: 4:07CV00053, 2008 WL 2680474 (W.D. Va. Jul. 3, 2008), the plaintiff alleged that the manufacturer was liable in negligence for the sales representative's directions for surgery. The court concluded that because the FDA does not regulate interactions between corporate representatives and surgeons in the operating room, not to mention require specific training, the claims were outside the purview of the FDA and thus not preempted. *Id.* at \*3.

On the other hand, other courts have concluded that claims that a sales representative failed to train a physician were expressly preempted. *Gomez v. St. Jude Med. Diag. Div., Inc.*, 442 F.3d 919 (5th Cir. 2006). In *Gomez*, the plaintiff alleged a biological device manufacturer failed to train the physician properly. The United States Court of Appeals for the Fifth Circuit ruled that the allegation was preempted because

the manufacturer's training requirements and informational materials had been previously approved by the FDA as part of the premarket approval process. *Id.* at 932–33. Similarly, in *Rollins v. St. Jude Medical*, the manufacturer allegedly failed to train her surgeon on the proper use of the Angio-Seal device implanted during an angiogram. 583 F. Supp. 2d 790, 801 (W.D. La. 2008). The court ruled that the failure-to-train claim pleaded by the plaintiff was preempted, but it noted that a claim that the defendant manufacturer failed to abide by the training requirements imposed by the FDA would survive preemption as a parallel claim. See also *Mattingly v. Hubbard*, No. 07CI12014, 2008 WL 3895381 (Ky. Cir. Ct. July 30, 2008) (failure-to-train physician claims preempted because such claims were a requirement in addition to FDA requirements).

### Recent Theories of Law Against Medical Device Manufacturers

The theories asserted by plaintiffs after *Riegel* share a common thread: duty. The cases illustrate that liability for sales representatives typically turns on the role of a representative. The extent of a sales representative's involvement is critical because the allegations against representatives generally allege some kind of inappropriate statement or behavior. The following highlights the various forms of claims that plaintiffs pursue against medical device sales representatives today.

#### Sales Representatives' Promotion of Off-Label Use

One common avenue used by plaintiffs to avoid preemption is off-label use. Off-label use occurs when a device is used in a manner different from the use specified by the FDA. Off-label use is tricky, however. Federal law affords physicians great discretion, and even though the FDA has the power to regulate off-label uses, it lacks the power to limit physician decisions to prescribe a product for any condition. 21 U.S.C. §396. Some courts have held that off-label use claims are not preempted by the MDA. For example, in *James v. Stryker Corporation*, the United States District Court for the Middle District of Pennsylvania reasoned that claims attacking a manufactur-

er's off-label promotion of a device differed from a failure-to-warn claim and survived preemption. *James v. Stryker Corp.*, 1:10-CV-2082, 2011 WL 292240 (M.D. Pa. Jan. 27, 2011).

But what if a sales representative has been in an operating room during a procedure? Plaintiffs have recently alleged that a sales representative's mere presence alone during a procedure involving off-label use escapes preemption. In *Riley v. Cordis Corporation*, 625 F. Supp. 2d 769, 778–79 (2009), the United States District Court for the District of Minnesota reasoned that if off-label claims were not preempted, a manufacturer could perfectly adhere to every FDA requirement and nevertheless be sued under state law due to off-label use of which they were unaware.

A good example of sales representative conduct in off-label claims recently arose in *Hall v. Horn Medical, L.L.C.* No. 11-1032, 2012 WL 1752546, at \*1 (E.D. La. May 16, 2012). This case involved a spinal intradiscal sphere, manufactured by Verticor and intended to be used in fusion bone grafts. Horn Medical, a medical device supplier, partnered with an independent contractor sales representative to sell and to distribute the device. In accordance with the FDA regulations, the spinal device was accompanied with specific instructions that it was intended to be used in bone grafts. However, the patient's physician inserted the device without doing a bone graft. The patient sued multiple parties, including the independent sales representative, alleging, among other things, that the sales representative failed to advise that the spinal device should only be used with bone grafts. At trial, the physician claimed that the sales representative told him that he could use the spinal disc without a bone graft.

The court characterized the claims against the sales representative as negligent misrepresentation and held that even if the misrepresentation was made, reliance by the physician on the statement would be unreasonable as a matter of law. The court highlighted that the statements were not about the physical properties of the spinal spheres or how to operate the device, indicating that such statements could create a cognizable claim. Because the statements

addressed the type of spinal procedure that the physician should have performed—clearly a medical decision—it was unreasonable to rely on a sales representative's statements.

### Sales Representatives and the Duty to Warn

Failure-to-warn claims are most prevalent against medical and pharmaceutical manufacturers. There is little uniformity from jurisdiction to jurisdiction regarding these types of claims. Medical device sales reps are unique in that they are often involved with the treatment of the patient. They often can stand side by side with a surgeon in an operating room offering technical information about the medical device being used by the surgeon. Despite this relationship with the surgeon and the patient, many courts have rejected arguments that a sales representative's presence in an operating room during the implantation of a medical device creates an additional duty to provide certain advice or warnings to a physician. In *Wolicki-Gables v. Arrow International, Inc.*, the court rejected the plaintiff's attempt to impose an affirmative duty on a sales representative who was present during the implantation of a pain pump. 641 F. Supp. 2d 1270, 1291–92, (M.D. Fla. 2009), *aff'd*, 634 F.3d 1296 (11th Cir. 2011). The representative allegedly failed “to instruct and educate” the surgeon. Even if the sales representative did have some interaction with the surgeon during the surgery, the court concluded that he did not have an affirmative duty to tell the doctor while he was performing the surgery how to use the device. *Id.*

Similarly, in *Kennedy v. Medtronic*, 851 N.E.2d 778, 786 (Ill. App. Ct. 2006), a pacemaker manufacturer's representative attended the plaintiff's surgery to provide technical support and to ensure that parameters were correctly calibrated and functioning properly. The plaintiff claimed that the manufacturer of the pacemaker owed the plaintiff two duties. First, the manufacturer had “a duty to refrain from providing a pacemaker... and participating in the [surgery] once [the representative] discovered the procedure was being performed in a setting that was not part of a hospital.” *Id.* at 786. Second, plaintiff

argued that the manufacturer voluntarily assumed a duty of care for the decedent by sending a representative to the surgery.

The court held that no duty of care existed for the representative (manufacturer) largely because the burdens placed on the manufacturer would be unprecedented:

It would be unreasonable, and potentially harmful, to require a clinical specialist... to delay or prevent a medical procedure simply because she believes the setting is not appropriate or the doctor is unqualified. *To hold otherwise would place a medical device manufacturer in the middle of the doctor-patient relationship.*

*Id.* at 778 (emphasis added). See also *Labzala v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346, 1355 (S.D. Fla. 2003) (prescription drug case concluding “that Florida law does not impose a duty on the defendants to interfere with the physician-patient relationship, even if they were aware that the product may have been prescribed inappropriately”); *Oconnell v. Biomet, Inc.*, 250 P.3d 1278 (Colo. App. 2010) (applying the captain of the ship doctrine and holding that the plaintiff's claims against the sales representative, present in the operating room during the procedure, were discharged by a settlement with the doctor who was the captain of the ship); *Cf. Chamian v. Sharplan Laser, Inc.*, 2004 WL 2341569 (Mass. Super. Ct. Sept. 24, 2004) (“The fact that individuals who have received training on medical equipment subsequently misused the equipment to the detriment of the patient, standing alone, is insufficient to establish a breach of a duty to the injured patient on the part of the entity that provided the training. By providing training, [the manufacturer] became a guarantor of the competence of [those trained]. It did not certify their competency.”). However, this rule is far from absolute.

For example, in *Zappola v. Leibinger*, the court held that the written instructions for a device to close a cranial bone flap did not satisfy the manufacturer's duty under the learned intermediary doctrine. 2006 WL 1174448 (Ohio Ct. App. May 4, 2006). The sales representative recommended the product to the physician but neglected to convey certain recommendations contained in the device's instructions. The rep-

representative attended the surgery, during which the physician decided that he could not use the device as planned. The surgeon specifically asked the sales representative “to observe the size of the cranial defect in [the plaintiff’s] skull” and discussed possible methods of closing the skull with other products. *Id.* at \*2. When the surgeon expressed concern about using the device based on his past experience, the sales representative told the surgeon that the device “had been improved.” *Id.* The surgeon used the product, which ultimately fragmented and caused a cerebrospinal fluid leak.

In its defense, the manufacturer argued that it sufficiently warned the surgeon because it provided written instructions and guidance for curing the kind of defect from which the plaintiff suffered. In finding that the representative did not uphold his duty of ensuring that the product was used properly, the court reasoned that the sales representative’s presence in the operating room was decisive. *Id.* He personally observed the plaintiff’s condition and was obliged to inform the surgeon about the product’s uses because he recommended using it after observing the plaintiff. *Id.*

### **Sales Representatives and the Duty to Train**

Courts much more uniformly interpret duty-to train claims involving physicians, generally rejecting the argument that manufacturers have a duty to train them how to use medical devices. On the other hand, in *Lemon v. Anonymous Physician*, No. 1:04CV2083LJMWT, 2005 WL 2218359 (S.D. Ind. Sept. 12, 2005), the court denied the manufacturer defendant’s motion to dismiss claims for failure to instruct and train the physician. The court reasoned that “a medical device manufacturer does not automatically have a duty to properly train, instruct, or assist a physician on the surgical implantation and use of the device. However, the manufacturer can affirmatively undertake that duty.” *Id.* at \*2.

In *Harrington v. Biomet, Inc.*, the plaintiff alleged that the sales representative failed to advise and to train the surgeon regarding the size and type of components necessary in a hip replacement. No. CIV-07-25-R, 2008 WL 2329132, at \*6–7 (W.D. Okla. June 3, 2008). The plaintiff further claimed the

representative should have instructed the physician that a different implant was more appropriate. The court rejected the duty, holding that the plaintiff failed to show a duty to advise the surgeon or that the representative voluntarily undertook to advise which sizes and types of components to use and that it breached that duty.

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Courts often reject that medical sales includes the duty to train on the grounds that to recognize it automatically would disregard the learned intermediary doctrine. In *Rounds v. Genzyme Corporation*, the plaintiff claimed a biologic device manufacturer failed to train the physician properly regarding which patients were proper candidates for the product. 440 Fed. Appx. 753 (11th Cir. 2011). The holding recognized the inherent contradiction between a duty to train and the well-established learned intermediary doctrine.

The plaintiff’s attempt to circumvent the learned intermediary doctrine by characterizing the issue as one of training rather than of warning... this is a distinction without difference... [the manufacturer] satisfied its duty... by providing clear, unambiguous information concerning the contraindications for [the product] as well as the risks associated with it. Whether [the manufacturer] was ‘training’ or ‘warning’ of these risks when it provided him the package insert is... an issue of semantics only.

*Id.* Despite the efficacy of the learned intermediary doctrine as a defense, sometimes invoking the doctrine has proved unsuccessful in dispositive pretrial motions.

In *Hurley v. The Heart Physicians, P.C.*, 898 A.2d 777 (Conn. 2006), the plaintiff

sued Medtronic, which manufactured a pacemaker that the plaintiff received when she was seven days old to manage problems from a congenital heart blockage at birth. *Id.* It was replaced periodically. When she was 14, the battery on her pacemaker seemed not to function right, and the physician contacted the sales representative to test the battery and to try to determine if the pacemaker needed replacing. *Id.* However, problems arose when the mother refused to allow the pacemaker to be replaced, and as a compromise, the sales representative suggested adjusting the paces per minute from 60 to 40 to conserve battery life. The patient alleged that this caused her to suffer brain damage.

The trial was limited to considering the issue of whether the representative’s oral statements and adjustment of the pacemaker were for “diagnostic” purposes or whether they “actually contradicted” the technical manual and therefore nullified the accompanying warnings. *Id.* at 899–900. The jury specifically found that the sales representative’s actions did not nullify the written warnings. Thus, even though the court exposed the sales representative to liability, the defense ultimately prevailed.

### **Sales Representatives in the Operating Room and the Unauthorized Practice of Medicine**

All states have laws that in some form or another prohibit the practice of medicine without a valid license. Plaintiffs will attempt to portray a sales representative working with a physician and giving treatment advice as unauthorized medicine practice. See *People v. Smithtown General Hosp.*, 93 Misc. 2d 736 (Suffolk Co. 1978). For example, in *Wilkerson v. Christian*, the plaintiff’s wife underwent a procedure to remove tumors through ablation, during which the physician burned the tumors with electrodes. No. 1:06CV00871, 2008 WL 483445 (M.D.N.C. Feb. 19, 2008). She eventually suffered liver failure and died. A wrongful death action ensued, and the plaintiff alleged that the sales representative personally performed the ablation procedure when “she operated medical equipment that was directly, by way of continuous circuit, inserted into

[the deceased's] body." *Id.* While the case was dismissed on statutes of limitations grounds, the court wrote the following *in dicta*:

Plaintiff alleged facts, in good faith, that raise serious questions regarding the propriety of sales representatives in the operating room. The gravity of Plaintiff's allegation that a sales representative performed, or participated in, [the deceased's] tumor ablation procedure is not lost on this court.

*Id.* at \*13. Accordingly, the possibility remains that a court might hold a manufacturer liable for the unauthorized practice of medicine if a sales representative actually participates in treating a patient even though the majority of courts agree that a manufacturer cannot be held liable for the unauthorized practice of medicine. See *Chamian v. Sharplan Lasers, Inc.*, No. 20000171, 2004 WL 2341569 (Mass. Super. Sept. 24, 2004); *Disbrow v. Richards, Inc.*, No. 14-95-00759-CV, 1996 WL 593780 (Tex. App. Oct. 17, 1996).

### Sales Representatives' Duty to Prevent Misuse

In fact, not only do courts appear to agree that it is a good idea for sales representatives to avoid being involved in treating patients, many jurisdictions take this idea a step further and hold that a manufacturer cannot have a duty to ever interfere with the physician-patient relationship, even if the manufacturer knows that a product may have been prescribed inappropriately. See, e.g., *Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346 (S.D. Fla. 2003).

The Illinois Appellate Court followed this logic and reasoning in a case involving a medical device in the 2006 decision in *Kennedy v. Medtronic*, 851 N.E. 2d 778, 780 (Ill. App. Ct. 2006). There, a retired cardiac surgeon with surgical privileges placed a pacemaker lead into the wrong side of the plaintiff's father's heart. During the outpatient procedure, the Medtronic representative provided the pacemaker and leads, and after the physician placed the leads into the patient's heart, the representative checked to make sure that the pace was proper and the device was calibrated correctly. It turned out that the physician improperly placed the leads, and the

plaintiff's father died. The plaintiff, as the administrator of her father's estate, subsequently alleged in part that Medtronic owed a duty to refrain from providing a pacemaker and from participating in the surgery once the representative discovered the procedure was being performed in a setting that was not part of a hospi-

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tal with adequate resources and personnel. In the alternative, the plaintiff alleged that by sending a representative to the surgery, Medtronic had voluntarily assumed a duty of care for the decedent.

The court affirmed the trial court's summary judgment for Medtronic. First, the court ruled that in simple negligence, no duty of care existed, largely because the burden of imposing a duty on a manufacturer would be substantial because it would require interfering in the doctor-patient relationship. Second, by providing the pacemaker and leads and attending the surgery, the representative had not voluntarily undertaken a duty to do anything more than her clearly defined role of ensuring that the leads were properly calibrated. Because there was no contention that the representative performed that role negligently, summary judgment was proper.

### Commonly Asserted Defenses

In these cases, the most commonly asserted defenses are based on the learned intermediary doctrine, the captain of the ship doctrine, no additional duties exist, and insufficiently proven causation.

### The Learned Intermediary Doctrine

Although discussed previously here, the learned intermediary doctrine remains perhaps the strongest defense against many of the claims against manufacturers. The learned intermediary doctrine theorizes that patients receive medical products, including devices and medications, through a prescription by a physician. As a licensed and experienced health-care provider and with knowledge about the specific patient, the treating physician is in the best position to warn the patient of necessary dangers or complications.

The defense applies with equal force to failure-to-train claims and failure-to-warn claims. As illustrated by the Eleventh Circuit in *Rounds*, many courts view the distinction between failure-to-warn claims and failure-to-train claims as an issue of "semantics only." *Rounds* 440 Fed. Appx. 753 (11th Cir. 2011). Almost every jurisdiction will apply this doctrine to a medical device sales representative's conduct.

### Captain of the Ship Doctrine

Another defense that shares much reasoning with the learned intermediary doctrine is the captain of the ship doctrine. This defense blends the learned intermediary doctrine with respondeat superior, and posits that the treating physician is the master while performing medical services. Other personnel assisting the treating physician are borrowed servants working and conforming to the physician's directives. Hence, the directing physician assumes any liability related to the work of such an individual that the physician directs.

For example, in *O'Connell v. Biomet, Inc.*, an elbow fixator manufacturer's sales representative was saved by the learned intermediary doctrine and the captain of the ship doctrine. 250 P.3d 1278, 1280 (2010). There, the sales representative physically delivered the fixator and attended the surgery. The plaintiff suffered a permanent injury during the surgery, and afterwards, the physician submitted recommendations for improvements to the manufacturer. After settling with the physician, the plaintiff sued the manufacturer. The manufacturer moved to dismiss, asserting the captain of the ship defense against the negligence claims and the learned interme-

diary defense against the failure-to-warn claims.

The Colorado Court of Appeals held that the sales representative was under the control of the physician and dismissed the plaintiff's negligence claims. First, the court ruled that the captain of the ship doctrine was not limited just to hospital employees. Second, while the court agreed with the plaintiff that there was a dispute regarding the role that the sales representative played, the court explained, "[b]ecause [the physician] remained in control of the surgery, anything [the representative] might have done during that surgery, including any advice he allegedly gave or should have given to [the physician] was done as a crew member, so to speak, of the surgical ship." *Id.* at 1283–84.

#### No Additional Duty to Train

As the holdings in *Wolicki-Gables* and *Kennedy* indicate, the majority of courts hold that sales representatives' presence during a procedure does not create any additional duty. Although some courts have found such a duty when claims assert a duty to train, courts far more frequently find that manufacturers do not have this additional duty. See *Zappola*, 2006 WL 1174448, at \*6–7. Perhaps most illustrative is a case outside the medical field. In *Glorvigen v. Cirrus Design Corp.*, 816 N.W.2d 572 (Minn. 2012), a case involving the crash of a general aviation airplane, the Minnesota Supreme Court rejected the failure-to-train theory entirely.

In *Glorvigen*, the plaintiffs sued a private plane manufacturer, Cirrus, alleging that Cirrus' two-day transition training failed to instruct properly on maneuvers and techniques needed to avoid crashes inherent in the plane. The manufacturer provided written materials, including an FAA-approved Pilots Operating Handbook and conducted a two-day training course. *Id.* at 578. The late pilot attended the training, but the parties disputed whether he completed the training, including a specific autopilot-assisted recovery technique, the maneuver that he needed to avoid the crash. The plaintiffs did not argue that the instructions were incomplete or inaccurate; rather, they argued that the materials alone could not

adequately instruct the pilot in the safe use of the plane. *Id.* at 582.

The Minnesota Supreme Court characterized the failure-to-train theory as an extension of the duty to warn and rejected this in part as a camouflaged educational malpractice claim. The court further recognized that the duty to warn requires

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suppliers to warn end users of a dangerous product if it is reasonably foreseeable that an injury could occur in its use. The duty has two elements: (1) the duty to give adequate instructions for safe use, and (2) the duty to warn of dangers inherent in improper usage. *Id.* at 581. But the "duty to warn has never before required a supplier or manufacturer to provide training," and in reaching its conclusion that there is no duty to train, the court noted that "imposing a duty to train would be wholly unprecedented." *Id.* at 583 (emphasis added). Because the written instructions were sufficient in their form, the manufacturer sufficiently discharged its duty without providing any training. To hold that the manufacturer "must provide training would either create a new common law duty to train or expand the duty to warn to include training" and would "require an unprecedented expansion of the law," which the court refused to do. *Id.*

#### Causation

The defense of lack of causation has also proved effective against many claims against manufacturers, and by extension, sales representatives. With failure-to-warn claims, courts have refused to find that a

plaintiff has demonstrated causation when a physician has testified that he or she would have still prescribed a particular device even with a stronger warning. *Johnson v. Zimmer, Inc.*, No. 02-1328 JTNFLN, 2004 WL 742038, at \*10 (D. Minn. Mar. 31, 2004) (holding that the plaintiff could not demonstrate causation because the physician testified that he never saw the warnings that accompanied the hip implant).

Similarly, the learned intermediary doctrine can be used to eliminate the necessary causal link between a manufacturer and a physician when the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated. *Christopher v. Cutter Labs*, 53 F.3d 1184, 1191–92 (11th Cir. 1995). And finally, when a sales representative was present during a procedure, courts have dismissed such claims based on the elementary principle that the plaintiff could not show how the representative's presence actually caused injury. See *Wolicki-Gables*, 641 F. Supp. at 1292.

#### Conclusion

In the medical device field, manufacturers' defense counsel should always examine the potential defense of federal preemption. While courts have found many product-related claims to be preempted, off-label representations are more difficult to defend in a preemption-based pretrial motion. Beyond procedural issues, the majority of courts have ruled in favor of manufacturers regarding other defenses. Courts typically have found that sales representatives have no duty to train, and due to the learned intermediary doctrine, any failure-to-warn claim must be aimed at the physician and the manufacturer, not the representative and the physician. Yet, plaintiffs have certainly had success attaching a representative's or a trainer's statements to a product manufacturer. Regardless of success, the fact remains that the number of claims against sales representatives has increased markedly and will continue to rise. Counsel for manufacturers should, therefore, become familiar with the more expansive range of claims alleged against sales representatives and product trainers. 