Unique Scenarios, Unique Defenses

The Medical Device Manufacturer's Alleged "Duty to Instruct or Train"

By John P. Lavelle, Jr. and Jacqueline C. Gorbey

Attorneys for device manufacturers should be aware of "duty to instruct" and "duty to train" claims, which are becoming increasingly frequent.

Two new types of claims are appearing with increasing frequency in medical device personal injury litigation: the claims for breach of a "duty to instruct" and a "duty to train." Several factors have produced the recent rise in such claims. Plaintiffs are eager to find a route to evade preemption for premarket approval (PMA) medical devices. Over time, medical devices have become more and more complex, imposing greater demands for technical knowledge. And medical device companies have responded to rising complexity, as well as the demands of health-care providers, by providing technical support in an ever-expanding variety of channels—for example, by having company representatives present during procedures and offering on-call support and educational programs.

Typically, plaintiffs allege that the "duty" arises from voluntary conduct of a medical device company. The theory is that even when a duty to instruct or a duty to train would not ordinarily exist, a medical device company can create such a duty by a *voluntary undertaking*. If a company voluntarily undertakes instructing or training a health-care provider, under this theory, the company has effectively undertaken a duty to instruct or train reasonably and correctly. Some might view this as a legal application of the aphorism "no good deed goes unpunished."

There are two scenarios common in the medical device world in which such a duty may arise:

1. A company provides technical support in connection with a medical procedure, such as an implant surgery, by having a representative present in an operating room or available remotely for consultation. In this setting, there is the risk that the representative may voluntarily assume a duty to a patient by providing information to a health-care provider in connection with a procedure. For the purposes of clarity in this article, we will refer to the alleged duty in this setting as the duty to instruct.

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2. A company offers training or an educational program to health-care providers concerning the company's products, implantation, and use. Such programs may be required as a condition of approval by the U.S. Food and Drug Administration (FDA), or it may be offered by the company for business purposes. In this setting, there is the risk that a company may voluntarily assume a duty to future patients who are treated by those health-care providers. In this article, we will refer to the alleged duty in this setting as the duty to train.

While there may be some overlap between these two scenarios in practice, in the reported cases, there are some important unique defense considerations for each one. This article will therefore address each of these scenarios in turn. We will close with some recommended defense strategies for both types of claims.

Failure to Instruct Claims

With failure to instruct claims practitioners need to understand what constitutes instruction, the voluntary undertaking theory, how various jurisdictions have treated the theory as it applies to these claims, and the defenses against the claims that medical device companies may assert.

What Constitutes Instruction?

A medical device company representative who is present in an operating room during a procedure may potentially be perceived as "instructing" a health-care provider. Frequently, a representative will provide technical support or answer questions about a device during a procedure. In this setting, there is a risk that a company representative may cross the line from providing information at the request and direction of a physician to making decisions concerning patient care. It is this dividing line, sometimes difficult to define, that appears repeatedly in the failure to instruct cases and can determine whether liability will be imposed.

Voluntary Undertaking Theory

In the failure to instruct cases, plaintiffs typically argue that once a manufacturer undertook to instruct a physician or a patient, it had a duty to do so in a reasonable manner. The primary legal basis for a failure to instruct claim is the voluntary undertaking theory. Section 324A of the Restatement (Second) of Torts imposes liability on a person who voluntarily undertakes to provide services to a third person if that third person suffers physical harm from the failure to exercise reasonable care if (1) the failure increased the risk of harm, (2) the volunteer undertook to perform a duty owed by the other to the third person, or (3) the harm is suffered because the other or the third person relied on the voluntary undertaking. Restatement (Second) of Torts §324A (1965).

Most states have adopted the voluntary undertaking theory in at least some context. Courts in at least 35 states have explicitly adopted or cited and relied on §324A of the Restatement (Second) of Torts. These are Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, Nevada, North Dakota, Ohio, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Vermont, Wisconsin, and Wyoming. Several other jurisdictions, including Washington and South Carolina, have declined to adopt §324A of the Restatement (Second) but generally recognize a voluntarily assumed duty of care in some situations. *See, e.g.*, *Martin v. City of Seattle*, No. 52950-1-I, 125 Wash. App. 1041, at *12, n.3 (Feb. 14, 2005) (recognizing a voluntary undertaking duty in context of rescue operation and defining parameters of duty based on case law); *Miller v. City of Camden*, 494 S.E.2d 813, 815 n.2 (S.C. 1997) (declining to adopt the §324A "expanded liability" as owed to third person). Rhode Island also recognizes a voluntarily assumed duty of care that is more onerous than the §324A duty. *Brown v. Stanley*, 84 A.3d 1157, 1163 (R.I. 2014) (stating that "one who assumes a duty to perform an act must do so with reasonable care whether or not that person had an obligation to perform the act or repairs prior to assuming that duty").

A small but growing number of cases have addressed the voluntary undertaking theory for a failure to instruct claim in the medical device context.

Medical Device Cases Rejecting Voluntary Undertaking Theory

One of the most extensive analyses of the potential application of a "voluntary undertaking" theory in the medical device context is in *Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778 (Ill. App. Ct. 2006). In *Kennedy*, the manufacturer's clinical representative attended a pacemaker implant surgery and provided technical support to ensure that the leads were properly calibrated. *Id.* at 781. After the surgery, it was discovered that the physician had inserted the lead in the incorrect ventricle of the patient's heart. *Id.* at 780. The plaintiff relied on Restatement §324A in support of her claim that the manufacturer "owed a duty to assist in a reasonable manner with the surgery once it voluntarily undertook to participate." *Id.* at 786. The plaintiff cited the representative's providing technical support during the surgery and alleged reassuring statements made by the representative about the physician's capabilities before the surgery. *Id.* The court rejected this argument and upheld summary judgment for the defendant, explaining that "[t]his limited role did not entail her voluntarily assuming a duty, under section 324A of the Restatement (Second) of Torts, for the placement of the lead into the correct ventricle of the patient's heart." *Id.* at 787. The representative was not responsible for inserting the pacemaker, nor was she able to make a judgment about lead placement. *Id.* at 785. Thus, central to the court's decision was the evidence that the representative's conduct did not cross over the

> **The theory** is that even when a duty to instruct or a duty to train would not ordinarily exist, a medical device company can create such a duty by a *voluntary undertaking*.

dividing line between providing information requested by the physician and providing patient care.

Also of concern to the *Kennedy* court was the potential improper interference with the doctor-patient relationship that would result from imposing a duty to train on a manufacturer. *Id.* at 786 ("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."). Holding that a device manufacturer has to a duty to train would effectively make the manufacturer responsible for the practice of medicine, which would constitute an unprecedented expansion of the law.

In this setting, there is a risk that a company representative may cross the line from providing information at the request and direction of a physician to making decisions concerning patient care.

More recently, a California court relied on *Kennedy* in granting a summary judgment to a manufacturer, stating that "[t]he result in *Kennedy* is consistent with California law." *Smith v. St. Jude Medical, Inc.*, 158 Cal. Rptr. 3d 302, 310 (Cal. Ct. App. 2013). In *Smith*, the plaintiffs sued the manufacturer of pacemaker leads and its sales representative for wrongful death as a result of alleged negligence on the part of the defendants for failure to recognize, both during and after the pacemaker implantation surgery, the perforations in the heart made during the implantation. *Id.* at 303–04. The plaintiffs argued that the sales representative was liable under a voluntary undertaking theory, alleging that the representative "came under a duty of care to [the patient] when he undertook to guide [the doctor's] placement of the insertion of the pacemaker leads into [the patient's] heart." *Id.* at 305–06.

The manufacturer and the representative in *Smith* successfully defeated the plaintiffs' allegations by submitting declarations and identifying relevant deposition testimony that emphasized the lack of any duty on the part of the manufacturer or its representative during lead placement surgery. Here, again, the key to the favorable outcome for the defendants was a record establishing that the representative had not crossed the line from providing information at the doctor's request to making decisions concerning the patient's care. Although the plaintiffs argued that the representative "played an active role" in the procedure by guiding the doctor "in his placement of the leads," the court found that the declarations and deposition testimony established that the representative "did not direct or instruct [the doctor] how or where to insert the leads into [the patient's] heart[,]" nor did he undertake to guide the doctor in lead placement or "otherwise assume any duty to do so with reasonable care." *Id.* at 310–11.

At least one federal court has also rejected imposing a voluntarily assumed duty to instruct on a manufacturer whose representative was present during a procedure. *See Harrington v. Biomet, Inc.*, No. Civ. 07-25-R, 2008 WL 2329132 (W.D. Okla. June 3, 2008) (applying Oklahoma law). In *Harrington*, the plaintiff argued that the manufacturer of a prosthetic hip breached a duty to the plaintiff because the manufacturer's representative was present during implantation surgery and failed to instruct the surgeon about the size and the type of components to use with the device or to suggest to the surgeon that a different implant may have been better for the plaintiff. *Id.* at *7. The court held that the manufacturer was entitled to summary judgment on the plaintiff's negligence claim. *Id.* Explaining the rationale, the court wrote,

> [The] plaintiff fail[ed] to show either that [the manufacturer] had a duty to advise the surgeon and breached that duty or that [the manufacturer] voluntarily undertook to advise [the surgeon] as to what size and types of components to use and that it breached that duty, much less that such negligence was the cause of plaintiff's injuries.

Id.

Even when a plaintiff does not specifically allege a voluntarily undertaken duty, device manufacturers have been successful by offering evidence that a representative did not cross the line between simply providing information to a physician at the physician's request and providing patient care. Recently, in *Suckow v. Medtronic, Inc.*, 971 F. Supp. 2d 1042 (D. Nev. 2013), the court dismissed claims against both a sales representative and a manufacturer. The patient and her husband had alleged that the manufacturer's sales representative "tested, reviewed, and evaluated the [pacemaker and lead] 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." *Id.* at 1044. The representative submitted a declaration stating that "any work he performed in interrogating a device was done at the request of a physician, and that it is the physician who interprets any data and makes decisions." *Id.* at 1047. The court held that the plaintiffs had failed to state a claim for negligence or misrepresentation against the representative, further illustrating the importance of establishing a clear record that a representative did not cross a line into providing patient care. *Id.* at 1048.

Medical Device Cases Adopting Voluntary Undertaking Theory

Not all duty to instruct cases have ended favorably for manufacturers. In *Medtronic, Inc. v. Malander*, 996 N.E.2d 412 (Ind. Ct. App. 2013), the court upheld the trial court's denial of a manufacturer's motion for summary judgment because genuine issues of material fact existed whether the manufacturer assumed a duty to the plaintiff. In *Malander*, a clinical specialist working for the manufacturer was present during a defibrillator upgrade surgery during which the physician considered replacing the Class III lead. *Id.* at 414. The clinical specialist assisted with testing the lead, and the test did not reveal any problems. The surgeon also called the manufacturer's technical

support department, asking whether the lead was functioning normally. The technical support members advised that they did not see a problem with the lead. The patient passed away less than one month later. The plaintiffs argued that the technical support representatives should have recommended replacing the lead. *Id.*

The *Malander* plaintiffs alleged that the manufacturer assumed a duty to make technical recommendations to the surgeon "in a reasonable and prudent manner" when it voluntarily agreed to provide technical support. *Id.* at 420–21. The plaintiffs argued that the manufacturer breached that duty when its technicians made alleged negligent oral representations. *Id.* at 417. Notably, the court first concluded that this claim was not preempted. *Id.* at 419 (citing *Adkins v. Cytyc Corp.*, No. 4:06CV00053, 2008 WL 2680474 (W.D. Va. July 3, 2008)). The court distinguished the plaintiffs' claim from *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), stating that the plaintiffs' "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." *Malander*, 996 N.E.2d at 418.

Turning to the plaintiffs' voluntary undertaking claim, the *Malander* court found the evidence sufficient to create a genuine issue of material fact about whether there was a voluntary undertaking, such as the clinical specialist's presence in the operating room and the surgeon's phone call to two technical support members, whose recommendations strayed from those in the manufacturer's own internal documents. *Id.* at 421. In denying the manufacturer's motion for summary judgment on the plaintiffs' negligence claim, the court considered evidence that the manufacturer "voluntarily undertakes to perform the technical support for physicians to assist the physician in using their devices." Although the *Malander* court reached the opposite result from the *Kennedy* court, *Malander* may be distinguishable based on that court's reliance on evidence that the manufacturer's "technicians failed to follow the recommendations of its own internal memoranda." *Id.*

Another case favorable to plaintiffs is *Zappola v. Stryker Leibinger*, Nos. 86038, 86102, 2006 WL 1174448, at *13 (Ohio Ct. App. May 4, 2006). The court upheld the denial of the defendant's motion for summary judgment on appeal, finding that a sales representative present in the operating room "had a duty to instruct the physician regarding the proper use of the product." In *Zappola*, the manufacturer's representative recommended use of a product to close the patient's skull during a craniotomy. *Id.* at *2. The product was intended for repair of cranial defects that were 25 centimeters or less. *Id.* The instructions for use recommended using wire mesh to support application of the product as well as a drainage procedure. *Id.* at *3. The representative observed that the patient's cranial defect was 48 centimeters, but did not inform the doctor that the product should not be used on defects that size. The representative also did not inform the doctor of the manufacturer's wire mesh and drainage recommendations. During his deposition, the representative testified that he had a duty to "make sure that the product is being used according to the way it's supposed to be used." *Id.* at *5. Based on these facts, the court held that the representative—and the manufacturer for whom he worked—had a "duty to provide [the surgeon] with adequate information" and did not fulfill that duty. Here, again, the representative allegedly provided instructions to the physician that were inconsistent with the manufacturer's written recommendations for the product. Thus, representatives who provide information that is inconsistent with a manufacturer's instructions may be perceived by courts as crossing over the dividing line and improperly providing patient care.

Likewise, in *Lemon v. Anonymous Physician*, No. 1:04CV2083LJMWTL, 2005 WL 2218359 (S.D. Ind. Sept. 12, 2005), the court permitted the plaintiff to conduct discovery on whether the device manufacturer's representative affirmatively undertook a "duty to instruct and assist" when the representative allegedly provided guidance and directions during implantation surgery.

Other courts have held that a manufacturer may be liable to a patient based on the actions of its representatives under analogous theories beyond the confines of a voluntary undertaking theory. In *Hurley v. Heart Physicians, P.C.*, 898 A.2d 777 (Conn. 2006), the plaintiff attempted to assert claims under the Connecticut Product Liability Act, alleging that the manufacturer's representative's statements and conduct essentially "nullified" the warnings contained in the technical manual for the patient's device. Specifically, the representative warned that the battery in the patient's pacemaker was wearing down and needed to be replaced as soon as possible. *Id.* at 780. The plaintiff's mother, however, was against replacing the pacemaker. For this reason, the representative allegedly reduced the pacemaker rate from 60 paces per minute to 40 paces per minute to extend the lifespan of the device. *Id.* at 780–81. The FDA-approved pacemaker manual allowed rate reductions below 40 paces per minute for "diagnostic purposes." *Id.* at 782. The court held that a genuine issue of material fact existed regarding whether the representative's action was for diagnostic purposes, or whether he acted inconsistently with the technical manual. *Id.* at 787. For that reason, the court denied the manufacturer's motion for summary judgment. *Id.* at 788.

Holding that a device manufacturer has to a duty to train would effectively make the manufacturer responsible for the practice of medicine, which would constitute an unprecedented expansion of the law.

Defenses to Failure to Instruct Claims

Device manufacturers have successfully defeated failure to instruct claims by emphasizing the role of a physician in

delivering care to a patient and the lack of any causal connection between the alleged failure to instruct and a plaintiff's injury, often relying on the learned intermediary and the captain of the ship doctrines.

Learned Intermediary Doctrine

Device manufacturers should rely on the learned intermediary doctrine when defending failure to instruct claims. The doctrine acknowledges that a physician acts as a "learned intermediary" between a device manufacturer and a patient. *Kennedy*, 851 N.E.2d at 784. Thus, the manufacturer's duty to warn of the risk involved with a device "runs to the physician, not directly to the patient." *Rounds v. Genzyme Corp.*, No. 11-11025, 2011 WL 3925353, at *2 (11th Cir. Sept. 8, 2011).

Thus, representatives who provide information that is inconsistent with a manufacturer's instructions may be perceived by courts as crossing over the dividing line and improperly providing patient care.

Device manufacturers have successfully defeated failure to instruct or train allegations by asserting the learned intermediary doctrine as a defense. As one court stated, "The adequacy of the warning is both relevant to, and dispositive of, the plaintiffs' failure to train claim. The difference between a failure to train and a failure to warn is semantic." *Rounds v. Genzyme Corp.*, No. 8:10-cv-2479-T-23TBM, 2011 WL 692218, at *3 (M.D. Fla. Feb. 18, 2011), *aff'd*, 2011 WL 3925353 (11th Cir. Sept. 8, 2011).

To use the learned intermediary doctrine as a defense successfully, the instruction or the training provided must be adequate: "A manufacturer's duty can only be discharged upon providing a learned intermediary with an adequate warning." *Zappola*, 2006 WL 1174448, at *5. In *Zappola*, the manufacturer could not rely on the defense because its sales representative—who failed to inform the doctor of critical product information during a surgical procedure—did not provide the surgeon with adequate information. *Id.* at *6.

Captain of the Ship Doctrine

The "captain of the ship" doctrine is another defense available to device manufacturers that emphasizes a physician's ultimate control over an operating room. This defense recognizes that "once the operating surgeon assumes control in the operating room, the surgeon is liable for the negligence of all persons working under the surgeon's supervision." *O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1283 (Col. App. 2010). The *O'Connell* decision affirmed application of this doctrine to situations in which a manufacturer's sales representative is present in an operating room. In that case, the role of the sales representative was to provide the surgeon with information about the device, which the surgeon then used to make his own medical judgments. *Id.* The court recognized that the surgeon remained in control of the surgery and appropriately, the others in the room. *Id.* Any alleged advice of the sales representative "was done as a crew member, so to speak, of the surgical ship." *Id.* at 1284.

Lack of Causation

Device manufacturers have successfully defeated failure to instruct claims when plaintiffs have not shown that such alleged failure caused an injury at issue. *See, e.g.*, *Harrington*, 2008 WL 2329132, at *7.

Failure to Train Claims

Similar to a failure to instruct claim, a failure to train claim focuses on guidance that was provided or allegedly should have been provided by a manufacturer. These claims typically allege that a company should have provided training to a clinician but did not. Similarly, some plaintiffs allege that a company did provide training to a clinician but did so in a negligent manner.

PMA-Imposed Duty to Train

The FDA may—and often does—require training as a condition of premarket approval. Section 360k of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act preempts all state law claims that would impose different or additional requirements on PMA-approved medical devices. 21 U.S.C. §360k. *See Riegel*, 522 U.S. at 324–25. When a manufacturer's "training requirements were… subjected to, and approved in, the PMA process," courts have held that "[t]o permit a jury to decide [plaintiff's] claims that the… training material the FDA required and approved through the PMA process was inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [the manufacturer]." *See, e.g.*, *Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919, 931 (5th Cir. 2006). Accordingly, "state-law claims that [a manufacturer's] training [is] inadequate or incomplete are preempted." *Id.* In contrast, a failure to train claim may not be preempted if the FDA required training and the manufacturer did not fulfill those requirements. *Chao v. Smith & Nephew, Inc.*, 2013 WL 6157587 (S.D. Cal. Oct. 22, 2013), is instructive. In *Chao*, a surgeon sought indemnity for a medical malpractice arbitration award in favor of a patient on whom he performed a hip replacement. *Id.* at *1. The surgeon alleged that the manufacturer of the hip resurfacing system used in the procedure was responsible for the arbitration award because, among other reasons, the manufacturer failed to train the surgeon appropriately. In granting premarket approval, the FDA required the manufacturer to provide a surgical technique brochure, instructive videos, and in-person training. *Id.* at *3. The surgeon alleged that the training videos that he received diverged from the instructions in the surgical technique brochure. He also disputed that he received sufficient in-person training. The court found that genuine issues of material fact existed but explained that "[i]f [the] defendant failed to provide [the surgeon] with the training required by the FDA's PMA, then [the] Plaintiff's indemnity claim would not be barred by Section 360k," the express preemption provision of the MDA. *Id.* at *4 (citation omitted). The court noted: "Section 360k does

not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Id.* (quoting *Riegel*, 552 U.S. at 330). In other words, §360k may not preempt a plaintiff's claim if the FDA required a device manufacturer to provide certain training and the manufacturer did not provide it.

Alleged Independent Duty to Train

Some plaintiffs go as far as to argue that a manufacturer owes a broad, independent duty to train users of its products. In one recent case against a medical device manufacturer, the U.S. District Court for the Western District of Louisiana rejected a plaintiff's allegations that a manufacturer failed to (1) train doctors and surgical technicians properly, (2) ensure that the device was properly installed, (3) provide a representative during surgery, and (4) provide a representative to educate the implanting physician. *Sons v. Medtronic, Inc.*, 915 F. Supp. 2d 776, 783 (W.D. La. 2013) (holding that the plaintiff's failure to instruct or train claim failed to state a claim for which relief could be granted). The court held that the "failure to train/instruct claims" were preempted but noted that even if they were not preempted, it would refuse to impose a duty to train on the manufacturer because "[i]t is well-established that a medical device manufacturer is not responsible for the practice of medicine." *Id.*

This theory has also been pursued recently in the aviation context. *See Glorvigen v. Cirrus Design Corp.*, 816 N.W.2d 572 (Minn. 2012); *Sheesley v. Cessna Aircraft Co.*, No. Civ. 02-4185-KES, 2006 WL 1084103 (D. S.D. Apr. 20, 2006). *Glorvigen* is a state supreme court decision rejecting an independent duty to train. *Glorvigen* involved a pilot who purchased an airplane. The manufacturer provided a training program to new owners as part of the purchase price to help pilots learn to use the new plane. *Id.* at 575. The plaintiff's decedent attended the training; however, there was a dispute whether he attended the particular training session that would have taught him how to perform the maneuver that could have prevented him from crashing the plane. *Id.* at 578–79. Although the manufacturer provided written instructions and warnings, the plaintiff argued that these written materials could not adequately instruct the plaintiff's decedent because they did not contain a particular flight lesson that was offered in its training session. *Id.* at 582.

The *Glorvigen* court held that the manufacturer "adequately discharged its duty to warn without providing any training." *Id.* at 583. It refused to hold that a manufacturer must provide training because that would "create a new common law duty to train or expand the duty to warn to include training." Notably, the court stated that "imposition of a duty to train would require an unprecedented expansion of the law." *Id.* In so holding, the Supreme Court of Minnesota affirmed the appellate court's reversal of the jury's verdict in favor of the plaintiff. *Id.* at 575. The facts of *Glorvigen*, and the policy reasons for not imposing a broad duty to train on a manufacturer, can be easily analogized to the medical device context.

Defenses to Failure to Train Claims

Medical device manufacturers have defeated failure to train claims by arguing that no duty to train exists, federal law preempts the claims, these claims impermissibly masquerade as educational malpractice claims, companies that train bear no responsibility when physicians misuse devices, and plaintiffs have failed to establish causation.

No Duty to Train

Unless there are PMA conditions of approval establishing a training requirement, a device manufacturer should argue that it does not owe a duty to train. Manufacturers can rely on case law that stands for the proposition that imposing a duty to train would constitute an unwarranted and unprecedented expansion of the law and risks interfering with the doctor-patient relationship. *See, e.g.*, *Kennedy*, 851 N.E.2d at 786; *Glorvigen*, 816 N.W.2d at 583. Finally, a manufacturer that does offer training—as many do—should be prepared to argue that it did not assume a duty to train by voluntarily undertaking the training.

Preemption

If a device's PMA required a manufacturer to offer training, claims that would impose different or additional training requirements should be preempted under 21 U.S.C. §360k(a), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

Educational Malpractice

Courts have widely rejected attempts to impose a duty to train as impermissible claims for educational malpractice. Such claims "raise[] questions concerning the reasonableness of the educator's conduct in providing educational services." *Glorvigen v. Cirrus Design Corp.*, 796 N.W.2d 541, 552 (Minn. Ct. App. 2011), *aff'd*, 816 N.W.2d 572 (Minn. 2012) (quoting *Dallas Airmotive, Inc. v. FlightSafety Int'l, Inc.*, 277 S.W.3d 696, 700) (Mo. Ct. App. 2008). Likewise, "if the claim requires an analysis of the quality of education received and in making that analysis the fact-finder must consider principles of duty, standards of care, and the reasonableness of the defendant's conduct, then the claim is one of educational malpractice." *Id.*

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Sheesley provides a useful example of a rejected educational malpractice claim. In *Sheesley*, a group of plaintiffs argued that a pilot who crashed a plane that killed the plaintiffs' decedents was negligently trained. *Sheesley*, 2006 WL 1084103, at *15. The plaintiffs' claims essentially challenged the "substance and manner" of the training. *Id.* at *16. Although the plaintiffs argued that their claims did not sound in educational malpractice, the court held otherwise, recognizing that the claims "encompass[ed] the traditional aspects of education, and thus, sound[ed] in educational malpractice." *Id.* (internal quotation marks and citation omitted).

Significantly, the educational malpractice defense is not limited to only "traditional" educational institutions. In *Waugh v. Morgan Stanley and Co., Inc.*, 966 N.E.2d 540, 548–56 (Ill. App. Ct. 2012), the court dismissed claims against individual instructors pertaining to teaching, training, and instructing a pilot and refused to classify the claims as ones for "ordinary negligence." The court explained that "[u]se of the educational malpractice defense doctrine turns on the type of claim raised, not the type of defendant facing the claim. Allowing otherwise would create an unworkable, fact-intensive exception to the rule." *Id.* at 555.

Manufacturers can rely on case law that stands for the proposition that imposing a duty to train would constitute an unwarranted and unprecedented expansion of the law and risks interfering with the doctor-patient relationship.

Public policy supports rejecting educational malpractice claims. Indeed, there is no concrete, satisfactory standard of care to which to hold an educator and the causation element is inherently uncertain. *Glorvigen*, 796 N.W.2d at 554. These concerns remain present for a medical device manufacturer that offers training to physicians or to patients. When a doctor or a patient misuses a medical device, a resulting injury cannot simply be blamed on or traced back to the device manufacturer that offered the training. Accordingly, a device manufacturer facing a plaintiff's failure to train claim can argue that the claim is really one of educational malpractice.

Misuse

A manufacturer that provides training owes no duty to a patient when a physician misuses the device. In *Chamian v. Sharplan Lasers, Inc.*, No. 200000171, 2004 WL 2341569 (Mass. Super. Sept. 24, 2001), the court rejected the plaintiff's claims against the device manufacturer predicated on negligent training. The court granted the manufacturer's motion for summary judgment and recognized "the fact that individuals who have received training on medical equipment subsequently misuse the equipment to the detriment of a 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." *Id.* at *7. Explaining further, the court wrote, "By providing training, [the manufacturer] did not become a guarantor of the competence of [the surgeon or technician]. It did not certify their competency." *Id.*

Lack of Causation

A basic but essential defense to a failure to train claim is lack of causation. Device manufacturers have successfully argued that there is no causal connection between an allegedly defective training and a plaintiff's alleged injury. In *Rounds*, for example, the manufacturer successfully obtained dismissal of the plaintiff's complaint by arguing that the plaintiff failed to allege that the physician would have performed the surgical procedure differently with better training, that the physician would have recommended a different course of treatment with better training, and that the training was causally connected to the plaintiff's injury. *Rounds*, 2011 WL 692218, at *2.

Similarly, in *Woodhouse v. Sanofi-Aventis U.S. LLC*, No. EP-11-CV-113-PRM, 2011 WL 3666595 (W.D. Tex. June 23, 2011), the court recognized that a purported claim for inadequate training and warning failed because of the lack of a causal connection to the injury. *Id.* at *3.

Strategies for Defending Duty to Instruct or Duty to Train Claims

An initial 12(b)(6) motion to dismiss should be successful when a complaint contains only boilerplate allegations of an alleged duty without specifying how a device manufacturer voluntarily assumed a duty or without specifying particular actions taken and statements made by the manufacturer or its representative during the alleged "training."

In addition, if the FDA required training as a condition of a premarket approval of a device, the defense should move to dismiss the claim on grounds of express preemption unless there are specific allegations of failure to provide the FDA-required training.

When cases involve detailed factual allegations precluding a motion to dismiss, the goal should be to set up an early dispositive motion based on limited discovery focused on the alleged training or instructions. In most cases, a physician can be expected to admit that he or she made the decisions concerning patient care, not a company representative, and that he or she relied on his or her general training and knowledge, not solely on anything that a company representative said. An affidavit or testimony from the company representative can also be important. For example, as in *Smith* and *Suckow*, an affidavit may be submitted to establish that a company representative did not cross the line from providing requested technical support to making decisions concerning patient care. *See Smith,* 158 Cal. Rptr. 3d at 305; *Suckow*, 971 F. Supp. 2d at 1046-7.

Conclusion

Attorneys for device manufacturers should be aware that some courts have held that a manufacturer may voluntarily assume a duty to instruct or train reasonably but that the cases are fact specific. Device manufacturers will have the most success defending these increasingly popular failure to instruct or train claims by building and relying on a record that demonstrates that it or its representative simply provided technical information requested by a physician and did not cross over the line into making decisions concerning patient care.