Case Law Developments

"Failure to Train" and Medical Device Misuse Claims

By Jennifer A. Eppensteiner and Regina M. Nelson

The current state of the law leans away from imposing on manufacturers any heightened liability associated with physician training programs.

Medical device manufacturers often find themselves having to defend unique theories of liability. "Failure to train" arguments are becoming increasingly popular among plaintiffs, and while no court has ruled directly on the argument in a medical device or pharmaceutical case, this has not prevented this theory from appearing in newly filed product liability actions against device manufacturers. Even in many instances when medical device manufacturers have offered programs to train physicians on the proper use of their products, when the procedures have resulted in adverse outcomes, plaintiffs still have argued that those companies were liable. In other cases, plaintiffs seek to impose heightened duties on device manufacturers to prevent misuse of their products by physicians. Recent case law may be instructive in responding to these arguments.

This article will first discuss recent developments in case law addressing the "failure to train" argument and respond to the argument that by training these physicians, manufacturers are automatically liable for injuries resulting from a physician's negligence. This article will then review cases in which plaintiffs have alleged that manufacturers have new and heightened duties to prevent misuse of their products and how the courts have ruled on these theories. While the case law in these areas is not well developed, the available decisions provide device manufacturers with strong defenses to these plaintiffs' claims.

Liability Premised on the "Failure to Train"

Medical device companies create products that are used for a variety of purposes, whether they are spinal cord stimulators for use in patients with severe pain or foley catheters to help drain urine. Use of many of these products has become standard, making manufacturer-sponsored training unnecessary. However, with many devices training programs may be beneficial to doctors and patients alike.

Plaintiffs essentially argue that once a manufacturer does offer a training program, the company has agreed to become a guarantor of a physician's abilities. The

■ Jennifer A. Eppensteiner and Regina M. Nelson are associates in Reed Smith's Life Sciences Health Industry Group, both practicing in the firm's Philadelphia office. Their practices focus on defending pharmaceutical and medical device product liability cases, both in mass tort litigation and single plaintiff matters. Ms. Eppensteiner is also a member of the DRI Drug and Medical Device, Young Lawyers, and Women in the Law Committees.

court in *Chamian v. Sharplan Lasers, Inc.*, No. 200000171, 2004 WL 2341569 (Mass. Super. Sept. 24, 2004), addressed below, rejected this argument, finding that it is not a medical device company's responsibility to ensure that a physician uses a product correctly.

Plaintiffs have also attempted to bolster their arguments using the requirements of hospital boards. As more and more physicians move away from private practice to become affiliated with large health-care systems, they become more likely to report to a hospital board and to become subject to the requirements that the hospital board establishes for practicing physicians. Plaintiffs use this to argue that medical device companies *must* train the physicians because some hospitals require that a physician be "certified" before using a product. Plaintiffs contend that a device manufacturer is uniquely suited to provide this certificate showing that a physician has taken a course and demonstrated his or her ability to use or to implant that particular medical device. As the case law discussed below explains, this duty to certify does not exist. Further, if manufacturers do opt to provide trainings, they are not necessarily responsible for any negligence on the part of the physicians whom they train.

Currently, neither case law or nor statutes impose an "affirmative duty" to train physicians in the drug or device context.

Generally No Affirmative "Duty to Train"

While plaintiffs make "failure to train" arguments fairly commonly in medical device cases, research has not revealed a court ruling directly on the argument in a medical device or a pharmaceutical case. The Minnesota Supreme Court did rule directly on this theory in an aviation product liability matter. In *Glorvigen v. Cirrus Design Corp.*, 816 N.W.2d 572 (Minn. 2012), the court held that a manufacturer does not have a "duty to train" when the plaintiffs alleged that a two-day on-the-ground and in-flight transition training course provided by an airplane manufacturer as part of the purchase price of the airplane was deficient. The manufacturer in this case provided written materials, including an FAA-approved Pilot's Operating Handbook. *Id.* at 576. In addition to the written materials, the pilot in the case received a two-day training session, although the parties disputed whether he actually completed the training. *Id.* at 578. Such "transition trainings" are standard in the general aviation industry, providing training to already licensed pilots who plan to fly a new or unfamiliar airplane. *Id.* at 576. This training builds on a pilot's previous experience and teaches the differences between the previous airplane and the new airplane. *Id.* The plaintiffs argued that the instructions alone could not adequately instruct the pilot in the safe use of the plane and therefore a flight lesson was required. *Id.* at 582.

In *Glorvigen*, the court acknowledged that the duty to warn requires 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 (citing *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 787 (Minn. 1977)). However, the court also acknowledged that 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, noted that "*imposing a duty to train would be wholly unprecedented.*" *Id.* at 583 (emphasis added). The court held that the written instructions were sufficient as required under the law, and because the manufacturer "adequately 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." *Id.* Imposing a duty to train would "require an unprecedented expansion of the law," and the court declined to do so. *Id.*

Currently, neither case law or nor statutes impose an "affirmative duty" to train physicians in the drug or device context. In a recent Texas case, the court held that a defendant could not have "failed to train, warn or educate" physicians because the defendant did not have a duty to do so. *Woodhouse v. Sanofi-Aventis U.S. LLC*, No. EP-11-CV-113-PRM, 2011 WL 3666595 at *3 (W.D. Tex. June 23, 2011). In *Woodhouse*, a doctor prescribed Ambien CR to the plaintiff to help her sleep. *Id.* at *1. The plaintiff then suffered the side effect of somnambulism, or sleepwalking, causing her to drive, then crash, her vehicle and become injured. *Id.* The defendants filed a motion to dismiss the plaintiff's claims that the manufacturer failed to warn and had "failed to train" prescribing doctors, and specifically, the plaintiff on the adverse side effects of Ambien CR. *Id.* at *2. Because the plaintiff had alleged that the defendants "failed to train, warn or educate" the physician rather than that the doctor had relied on an inadequate warning, the court found that the plaintiff had failed to establish that the defendants owed her a duty. *Id.* at *3. To impose liability, a court must first find that a duty exists. *Id.* Furthermore, even if a device manufacturer does train the physicians, this does not automatically make the manufacturer responsible for a physician's competency in actually using the product. In *Brown v. Drake-Willock International, Ltd.*, the Michigan Court of Appeals held that "[a] manufacturer should be able to presume mastery of basic operations by experts or skilled professionals" such as doctors and therefore "should not owe a duty to warn or instruct such persons on how to perform basic operations." 530 N.W.2d 510, 515 (Mich. Ct. App. 1995). The Michigan Court of Appeals found that the manufacturer did not owe a duty to the plaintiff because it had sold the equipment to a "sophisticated" user and could depend on the ability of the expert or physician to perform the basic operations of the product. *Id.* These cases, particularly *Glorvigen*, are helpful in defending against claims that manufacturers failed to train physicians on the use of their products.

Defending "Failure to Train" Claims

Even though medical device companies do not have an affirmative duty to train,

unfortunately they still have to defend failure to train claims in the courts. *Glorvigen* is instructive. Most medical devices come with instructions on how to use a product, just as the manufacturer in *Glorvigen* provided instructions on how to use the new aircraft model. In addition, the "transition training" provided to pilots using a new aircraft is arguably similar to the training provided by medical device companies. When a medical device manufacturer introduces a new device to physicians, it sometimes provides a one- or two-day training course on how to use the device. Of course, the training presumes that the physicians are building on skills that they already have and that learning about a new device will build on previous medical knowledge; therefore, the medical device company cannot be liable for not providing full and complete training under the rationale in *Glorvigen*. Additionally, as noted in *Brown*, the manufacturer should be able to rely on the physicians' ability to perform the basic skills or operations necessary to use the medical device.

Even if a manufacturer has provided physicians with training on its device, as will be discussed below, current case law holds that a medical device manufacturer is not liable for the misuse of its product by a physician or a skilled professional. Attorneys for medical device manufacturers must therefore analyze each claim to determine whether it was actually the product that caused the injury or whether the injury alleged was caused by something else.

Misuse of a Product

Some case law does support the argument that even if a physician attends a manufacturer-sponsored training, the manufacturer is not liable for either the failure of the physician to use the product correctly or an adverse outcome experienced by a patient, especially if the warnings accompanying the product mentioned the adverse outcome as a possibility. In *Chamian v. Sharplan Lasers, Inc.*, No, 20000171, 2004 WL 2341569 (Mass. Super. Sept. 24, 2004), the plaintiff suffered injuries from a laser used during a cosmetic procedure. The physician in this case had attended numerous training sessions and workshops on laser resurfacing. *Id.* at *2. The physician also had undergone a preceptorship with an experienced surgeon and had received training from the laser manufacturer. *Id.* The Massachusetts court found that "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 duty to the injured patient on the part of the entity that provided the training." *Id.* at *7. The defendant manufacturer did not become a "guarantor of the competence" of the physicians who the manufacturer trained just because it provided training. *Id.*

Plaintiffs have also argued that when a manufacturer is aware of widespread misuse of its product, such awareness imposes a heightened duty on the part of the manufacturer to protect consumers by warning them directly. In some cases plaintiffs have claimed that manufacturers knew that unqualified persons were using their products in violation of the law. In *Swayze v. McNeil Labs. Inc.*, the plaintiff's son died due to complications caused by an overdose of a narcotic that the defendant manufactured. 807 F.2d 464, 465 (5th Cir. 1987). Although the narcotic was a prescription drug that could only be prescribed, administered, and dispensed under the direction and supervision of a licensed physician, the plaintiff argued that the learned intermediary doctrine did not apply because the defendant should have known about the widespread misuse of its product, where certified registered nurse anesthetists (CRNAs) routinely determined dosages during surgical procedures. *Id.* at 466. The evidence confirmed that during the procedure at issue a CRNA determined the dose of the narcotic to administer without receiving supervision from an anesthesiologist or supervising surgeon. *Id.* The plaintiff argued that the manufacturer had heightened duties to provide warnings to consumers directly regarding the operating room practice, to pressure the medical community to heed the warnings provided to it, and ultimately to remove the product from the market. *Id.* at 469. The trial court rejected the plaintiff's arguments, and the Fifth Circuit affirmed the lower court's ruling.

In rejecting the plaintiff's claims, the Fifth Circuit emphasized that the manufacturer had discharged its duty by providing a warning to the physician and explained the further warnings to consumers regarding the potential misuse of a product "would only lead to confusion, and perhaps undermine the physician-patient relationship." *Id.* at 470–71. The Fifth Circuit then stressed the importance of the physician-patient relationship, explaining "[w]hen the physician-patient relationship does exist, as here, we hesitate to encourage, much less require, a drug manufacturer to intervene in it." *Id.* at 471. Because the physician took responsibility for the patient's care, a "special relationship, between physician and patient, thus formed," which the court noted "receives special protection in law, and, at the same time, creates a great responsibility for every physician." *Id.* The doctor, therefore, assumed the role of the "learned intermediary" and the burdens associated with it. *Id.* Although the facts of the case revealed that physicians routinely allowed CRNAs to use too much discretion, the Fifth Circuit found that the physicians had undertaken the responsibility of supervising the CRNAs, and that responsibility could not be shunted onto, or shared with, the drug manufacturers. *Id.*

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The Fifth Circuit also rejected the plaintiff's argument that the manufacturer should have done more to force physicians and hospitals to heed its warnings, stating "[i]t is both impractical and unrealistic to expect drug manufacturers to police individual operating rooms to determine which doctors adequately supervise their surgical teams." *Id. See also Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346, 1354–55 (S.D. Fla. 2003) (finding that the duty of a physician "to exercise an inde-

pendent judgment" based on his or her knowledge of a patient's medical condition and a drug cannot be shifted to the manufacturer, and the drug manufacturer did not have a duty to intervene in physician-patient relationship even when the manufacturer had knowledge that the drug may have been prescribed inappropriately). Nor should the manufacturer have been required to remove the product from the market even if it was aware of misuse because the

> defendant cannot control the individual practices of the medical community… and we decline to impose such a duty. Drug manufacturers must adequately warn physicians of the potential side-effects of their prescription drugs; thereafter, the physician, with his special knowledge of the patient's needs, assumes the burden of presiding over the patient's best interests.

Id. at 472.

The court stated that the manufacturer's clinical specialist "was not responsible" for the insertion of the device and "could not make a judgment" about where to place the lead.

The ruling in *Swayze* highlights the issues associated with requiring a manufacturer to police the misuse of its product once it gives adequate warnings and further stresses the concerns related to forcing a manufacturer to step into the middle of the doctor-patient relationship.

The Appellate Court of Illinois followed similar reasoning when affirming a lower court's finding that a medical device manufacturer did not owe any duty to the patient decedent to prevent a surgeon from implanting a pacemaker as an outpatient procedure in his office. *Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778 (Ill. App. Ct. 2006). In *Kennedy*, at the decedent's request, a physician implanted a cardiac pacemaker manufactured by the defendant as an outpatient procedure in his clinic, as opposed to performing the procedure in a hospital. *Id.* at 780. The physician had a dentist monitor the decedent's vitals during the procedure; in addition to two registered nurses who were also present, the device manufacturer provided a clinical specialist to provide technical support. *Id.* Following the procedure, the decedent experienced various health problems, was forced to undergo a second procedure to remove his device and to have a new pacemaker implanted due to the surgeon's error in placing the electrode, and subsequently, died. *Id.* The decedent's daughter instituted a wrongful death action against the manufacturer. *Id.*

Although the safety of the implanted device was not at issue, the plaintiff alleged liability on the part of Medtronic, claiming that the manufacturer had a duty: (1) to refrain from providing a pacemaker to the physician and from participating in the insertion of the pacemaker, knowing that the physician intended to proceed in an inadequate facility without qualified personnel present and without monitoring any of the patient's vital signs; (2) to warn of the dangers inherent in proceeding with the surgery under the conditions; and (3) to assist with the insertion in a reasonable manner once it voluntarily undertook to participate. *Id.* at 782. In a case of first impression, the court rejected these arguments after finding that no such duties of care existed, and further, that the burden and consequences of imposing such duties on the manufacturer would be substantial. *Id.* at 785–86.

First, the court stated that the manufacturer's clinical specialist "was not responsible" for the insertion of the device and "could not make a judgment" about where to place the lead. *Id.* at 785. Furthermore, the court explained that the decedent's injuries were not reasonably foreseeable, noting that the same injuries could have occurred in a hospital setting. *Id.* The court also emphasized the burden that it would place on a manufacturer to require the manufacturer to monitor the conditions under which a doctor performed surgery. *Id.* at 786. More importantly, however, the court refused to place a device manufacturer in the middle of a doctor-patient relationship, finding that a central aspect of the learned intermediary doctrine is that "a licensed physician… has the knowledge of his patient's medical history and background, and, therefore, he is in a better position, utilizing his medical judgment, to determine a patient's needs and what medical care should be provided." *Id.* The court went on to explain that 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." *Id.* Furthermore,

> the consequences of requiring such screening by [a manufacturer] would run the risk of imposing additional liability on the manufacturer in the event it determined a physician was not in a position to properly implant a device, refused to provide one, and the patient suffered adverse medical consequences because he did not have access to a needed device.

Id.

The court also rejected the plaintiff's argument that because the manufacturer's clinical specialist reassured the plaintiff about the implanting physician's qualifications before the surgery and participated by providing technical support, the clinical specialist voluntarily assumed a duty to assist with the surgery in a reasonable manner. *Id.* The court held that taking a limited role did not mean that the specialist voluntarily assumed a duty to ensure that the physician placed the lead in the correct ventricle of the patient's heart. *Id.* A federal court rejected a similar argument in *Harrington v. Biomet, Inc.*, in which the plaintiff alleged that a device manufacturer representative failed to act with ordinary care when the representative did not advise the plaintiff's surgeon about which size and type of prosthetic hip component to implant, claiming that the representative should have recommended a different implant than the one chosen by the physician. No. CIV-07-25-R, 2008 WL 2329132, at *7 (W.D. Okla. June 3, 2008). The court granted summary judgment to the manufacturer on the plaintiff's negligence claim

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jury may appreciate this approach more than we will ever know. Indeed, this type of strategy was reportedly implemented by defense attorneys in a case against Keenan himself, resulting in a defense verdict.

These are just some of the many ways to deal with the "reptile" trial strategy. I am sure there are others. During the seminar that I attended in which Keenan spoke to the plaintiffs' bar of my state, he indicated that he has collected more than 85 motions filed by "black hat defense attorneys" seeking to exclude the strategy. He also indicated that at least one court has specifically excluded the "reptile" strategy, causing him some heartburn. However, Keenan remained steadfast in his faith about the propriety and effectiveness of the "reptile" strategy, and he criticized the plaintiff's attorney in that case for implementing the strategy incorrectly after simply reading the book and not attending any of the seminars or workshops. Nevertheless, with the growing number of resources available to plaintiffs' lawyers, one thing appears certain: the emerging "reptile" strategy is sure to remain at the forefront of the legal community for years to come.

Conclusion

The plaintiffs' bar is banding together to implement new trial strategies to frame cases in ways to obtain the best possible verdicts and maximum damages awards. As a defense bar, we must keep up with their efforts and confront them head-on. Be ready to recognize the "reptile" strategy in your cases, and prepare yourself and your witnesses to deal with it. FD

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after their filing dates. Do not be lulled by this long waiting period. Deadlines come quicker than you expect so stay vigilant rather than procrastinate and find yourself scrambling at the last minute. Plus, as a defense attorney, while procrastinating, you might miss valuable opportunities to save your client money by settling early.

Posting everything on social media. Every defense attorney can appreciate the joy in finding that compromising photo of a plaintiff on Facebook or Twitter—the smoking gun to win your case. However, this situation is not nearly as joyous when that compromising photo is of you. Take a lesson from plaintiffs who share too much and carefully guard your online presence. Make sure that your privacy settings on public media sites are set so that only friends may view your profile and be sure to maintain a professional image. Do not post photos or messages that may harm you or your firm's reputation.

Demonizing your opponent. Believe it or not, opposing attorneys are not always out to get you. Try giving them the benefit of the doubt until they prove otherwise. A friendly working relationship can make litigation go smoothly. Do not treat every request to delay a hearing or to extend discovery as an opponent's latest attempt to trick you. Hopefully, he or she will return the favor.

Showing up late and unorganized. Just don't do it! Now that everyone has a computer in their pocket, there is no excuse to be late to a meeting or to forget your files. Keep your calendar up-to-date and find secure ways to gain access to your files from anywhere. If you will be late, call ahead. FD

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against the manufacturer, holding that the plaintiff had failed

> to show either that Defendant had a duty to advise the surgeon and breached that duty or that Defendant voluntarily undertook to advise [the implanting physician] 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.

Conclusion

As failure to train claims become more common and as medical device manufacturers continue to develop more sophisticated and useful products for which physician training programs would be beneficial, the current state of the law leans away from imposing any heightened liability on manufacturers associated with these training programs. As the Minnesota Supreme Court stated in *Glorvigen*, a manufacturer cannot take responsibility to make sure that the end user of a product knows how to use the product, particularly when the manufacturer includes written instructions on product use to a purchaser and the manufacturer cannot control how someone uses the product. Additionally, courts have consistently held that a manufacturer cannot be held liable if the manufacturer provided training but the product was not used properly anyway. Existing case law is also favorable regarding product misuse, rejecting plaintiff's arguments that manufacturers have heightened duties to warn consumers directly when they know or should suspect that their products might be misused. FD