A brief overview of case law on ‘failure to train’ claims and its implications for medical device manufacturers

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In recent years, causes of action for “failure to train,” or allegations predicated on a duty to train, have been on the rise in cases against medical device manufacturers. Historically, however, such claims and allegations have made relatively few appearances in the case law — even fewer in the context of prescription products. Where claims and allegations have arisen, the case law seems to have congealed into three approaches. The first approach involves cases in which there is a refusal to recognize a duty to train or, conversely, in which a failure-to-train claim is allowed as a mere derivative of a “failure to warn” claim. The second approach involves cases that either allow or disallow such claims as a form of an educational malpractice cause of action. In the third approach, cases specifically involve a medical device that has received premarket approval, or PMA, and there is either recognition or denial that such claims are preempted by the Food, Drug and Cosmetic Act. Each approach is outlined briefly below.

FAILURE TO TRAIN VS. FAILURE TO WARN

Some courts consider any alleged duty to train as a novel allegation with no basis in law. Probably the most prominent example comes from the Minnesota Supreme Court, and it involves an aircraft, rather than a medical device.

The Minnesota Supreme Court rejected this theory, holding that “[t]he duty to warn has never before required the supplier or manufacturer to provide training, only to provide accurate and thorough instructions on the safe use of the product.”

The alleged duty to train has been rejected in the medical device context as well. In doing so, courts often point out that such a duty is novel and it would impermissibly interfere with the physician–patient relationship.

Some cases reject liability for failure to train even when that duty to train has been voluntarily assumed. In Chamian v. Sharplan Lasers Inc., the Massachusetts Superior Court provided a good example of the underlying rationale: “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. By providing training, [the defendant] did not become a guarantor of the competence of [those it trained].”

Other cases allow for the assumption of the duty to train: “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,” the U.S. District Court for the Southern District of Indiana has said.

Finally, some courts have allowed failure-to-train claims to proceed as an unremarkable subspecies of a failure-to-warn claim. For example, in another Southern District of

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In Glorvigen v. Cirrus Design Corp., the plaintiffs brought suit against the manufacturer of a private plane on behalf of the owner/pilot and his passenger, who had died when the plane crashed. The plaintiffs alleged that the plane manufacturer’s two-day “transition training” (in which an experienced pilot’s previous training and experience are built upon to familiarize him or her with the new plane) failed to train the pilot on precisely the maneuver he would have needed to avoid the crash.

“It is well established that a medical device manufacturer is not responsible for the practice of medicine.”

In such cases, the alleged failure to train is often characterized as an inept attempt to expand the duty to warn. Moreover, as the 5th U.S. Circuit Court of Appeals observed, “[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.”

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Some courts have analyzed failure-to-train claims under the rubric of “educational malpractice,” a largely discredited theory that attempted to hold educational institutions liable — either by their students or third parties allegedly harmed by their students — for doing their jobs poorly. This has arisen primarily in the aviation context. Thus, in Sheesley v. Cessna Aircraft Co., the plaintiffs were representatives of airplane passengers killed in a crash that was allegedly caused by the pilot’s poor training.13

In that case, the U.S. District Court for the District of South Dakota held that “[t]he gravamen of plaintiffs’ claims are that [the defendant] negligently trained [the pilot] by failing to provide him the skills and training necessary. ... Further, plaintiffs contend that [the defendant] used negligent teaching techniques. ... In other words, plaintiffs are contesting the substance and manner of [the defendant’s] training. Plaintiffs’ claims encompass the traditional aspects of education, and thus sound in educational malpractice.”12 Such claims, the court found, were not cognizable.19

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Other courts have found that the public policy rationales behind the refusal to recognize an educational malpractice claim — such as the lack of a satisfactory standard of care, the vagaries of external causes affecting a student’s failure to learn and the potential of court involvement in day-to-day school operations — do not extend beyond traditional educational institutions.

In Newman v. Socata SAS, the U.S. District Court for the Middle District of Florida held that a failure-to-train claim brought against a flight training school was not an educational malpractice claim, and it could thus proceed.14 “Allowing the claims at issue (that a for-profit commercial entity, teaching a narrowly structured course on the operation of a specific type of aircraft, owed and breached a duty to warn and train regarding a known lethal propensity of the aircraft to torque roll) to proceed does not implicate the public policy concerns [barring educational malpractice claims],” the court said.15

Other courts allow “failure to train” claims to proceed as an unremarkable subspecies of a “failure to warn” claim.21

Such a result is probably distinguishable in the medical device context, however, because it does not involve a “learned intermediary” physician, who is already an expert in the field and is under an independent professional duty to use any such device pursuant to the standard of care.

PREEMPTION OF FAILURE TO TRAIN

When failure-to-train claims involve devices approved pursuant to the FDA’s rigorous PMA process, some courts have held that such claims are preempted by the FDCA because they would constitute a state requirement different from or additional to the federal requirements, the 5th Circuit has ruled.16 This analysis does not apply in cases in which the defendant fails to provide training mandated by the FDA’s PMA.17 Other courts, including the Indiana Court of Appeals, have held that interaction between sales representatives and physicians is outside the ambit of FDA regulation, and thus failure-to-train claims escape federal preemption.18

CONCLUSION

If a rational conclusion can be discerned from this discussion, it is perhaps that the most thoughtful opinions in the medical device context recognize that failure-to-train claims interfere with the practice of medicine and would impose an impractical duty on medical device manufacturers to “oversee” doctors in their operating rooms and offices. The unique aspects of the doctor–patient relationship thus help to distinguish cases — such as aviation cases analyzed under educational malpractice theory — that find against the defendant. That analysis, however, is complicated when a manufacturer voluntarily trains the physician and thus potentially undertakes a duty to do so reasonably.

Arguably, the “learned intermediary” doctrine should prevail over the voluntary assumption of a duty, but that remains to be hashed out in case law. Considering that courts have come out on both sides of what should be a straightforward application of the preemption doctrine, the courts’ ongoing treatment of the voluntary assumption question is likely to remain mixed as well.22

NOTES

2 Id. at *10.
3 Id.
5 Sons v. Medtronic Inc., 915 F. Supp. 2d 776, 783 (W.D. La. 2013); see also Wolicki–Gables v. Arrow Int’l, 641 F. Supp. 2d 1270 (M.D. Fla. 2009), aff’d, 634 F.3d 1296 (11th Cir. 2011) (no affirmative duty to advise physician on how to use the product; the physician must use the product according to his or her medical judgment).
6 See, e.g., Rounds v. Cenzyme Corp., 2011 WL 3925353 at *3 (11th Cir. Sept. 8, 2011) (“[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 a difference. ... [The defendant] satisfied its duty ... by providing clear, unambiguous information concerning the contraindications for [the product], as well as the risks associated with it. Whether [the defendant] was ‘training’ or ‘warning’ [the treater] of these risks when it provided him the package insert is ... an issue of semantics only.”).
7 Swayze v. McNeil Labs., 807 F.2d 464, 468 (5th Cir. 1987).
NEWS IN BRIEF

TANDEM’S T:SLIM INSULIN CARTRIDGES RECALLED OVER LEAKAGE FEAR

Tandem Diabetes Care Inc. is recalling nearly 50,000 insulin cartridges, designed for use with its t:slim insulin pump, after product testing showed they may pose a leakage risk. The San Diego-based firm said the recall involves 4,746 boxes, each with 10 cartridges, shipped on or after Dec. 17. In a Jan. 14 announcement, the Food and Drug Administration said cartridge leaks could result in the delivery of incorrect insulin dosages to t:slim pump users, possibly leading to an adverse medical event. There have been no complaints of such problems, according to Tandem. Customers and distributors can contact the company at 877-801-6901 for product replacement details.

FDA APPROVES AFFYMETRIX’S CHROMOSOMAL VARIATION TEST

The Food and Drug Administration has approved what it calls the first ever post-natal test to identify chromosomal variations that could cause childhood developmental delays or intellectual disabilities. In a Jan. 17 announcement, the agency said the CytoScan Dx Assay, made by California-based Affymetrix Inc., can use a small blood sample to analyze a child’s entire genome and detect “large or small chromosomal changes.” Identification of such changes can alert health care providers and parents to intervene with “appropriate care and support for the child,” the FDA said. The test was approved through an FDA process that speeds certification of “novel, low-moderate-risk medical devices,” the agency said. In certifying the test, the FDA specified that “this device should not be used for stand-alone diagnostic purposes, pre-implantation or prenatal testing or screening, population screening, or for the detection of or screening for acquired or genetic aberrations occurring after birth, such as cancer.”

U.S. COURT AWARDS EDWARDS DAMAGES IN MEDTRONIC PATENT FIGHT

(Reuters) – Medtronic Inc. said a U.S. jury ruled that its heart valve implant infringed a patent held by Edward Lifesciences Corp. and awarded Edwards $392.5 million in damages. Medtronic said it would appeal the Jan. 15 ruling made by a jury in the federal district court of Delaware. The medical device maker said it would oppose any request for an injunction by Edwards. Medtronic said it expected U.S. approval for the CoreValve heart implant system by the end of its fiscal year ending April 2014. (Reporting by Vrinda Manocha in Bangalore; editing by Kirti Pandey)
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<td>Bradshaw et al. v. Howmedica Osteonics Corp. dba Stryker Orthopedics, No. 13-1216819, complaint filed (Or. Cir. Ct., Multnomah County Dec. 11, 2013)</td>
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