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A Lesson On Liability Risks For Device And Pharma Cos.

Law360, New York (October 21, 2013, 12:42 PM ET) -- An Oct. 11, 2013, decision by the Indiana Court of Appeals highlights the risk to manufacturers of Class III medical devices, and other devices and pharmaceutical products, where company representatives provide information to physicians beyond the scope of the package insert.

In Medtronic Inc. v. Malander, the Indiana Court of Appeals held that the plaintiff's claim of common-law negligence — based on allegedly faulty information provided by Medtronic representatives directly to plaintiff's surgeon — was not expressly preempted by the Medical Device Amendments, 21 U.S.C. § 360k(a) (MDA), as interpreted by the U.S. Supreme Court in Riegel v. Medtronic, 552 U.S. 312 (2008).

Moreover, the court rejected Medtronic's substantive challenge to the plaintiff's claim, based on the absence of a duty of care, because Medtronic voluntarily undertook to provide technical assistance to the plaintiff's surgeon and thereby assumed a legal duty to do so in a reasonable and prudent manner.

Background

David Malander received a defibrillator and a Transvene Model 6936 right ventricular lead in 1997 as part of his cardiovascular treatment. The lead was a Class III medical device subject to premarket approval by the U.S. Food and Drug Administration and was manufactured by Medtronic.

Years after the procedure, and following an upgrade to the defibrillator, the plaintiff's surgeon discovered that the device had, on nine occasions, registered a "short V-V interval" — a false positive where the defibrillator sensed electrical activity unrelated to the heart's rhythm. The surgeon thereafter scheduled a surgery to replace the defibrillator and possibly to replace the lead.

During the surgery, a Medtronic clinical specialist was present in the operating room and assisted the plaintiff's surgeon with testing the lead. After testing did not reveal any problems, the surgeon telephoned Medtronic and spoke with two additional company representatives in the technical services department to determine the significance of the short V-V intervals he had previously observed.

The technicians assured him that the short V-V intervals were not a problem, and the surgeon chose not to replace the lead. The plaintiff died less than a month following surgery, and testing revealed that the defibrillator had registered 361 short V-V intervals in the two weeks leading up to his death.

The plaintiff's survivor filed a wrongful death action against Medtronic, alleging, among other things, that Medtronic was negligent for "[f]ailing to recommend that the [lead] be removed or capped off during David Malander's … surgery." To support this claim, the plaintiff alleged that internal Medtronic memoranda from before the plaintiff's surgery concluded that short V-V intervals were indicative of lead failure and that the technicians should have recommended replacement of the lead.

Medtronic moved for summary judgment, contending that the plaintiff's claims were expressly preempted by the MDA. Medtronic also substantively challenged the plaintiff's negligence claim on the basis that it did not owe a duty to the plaintiff.

The trial court denied Medtronic's motion. Medtronic appealed, and the Indiana Court of Appeals affirmed.

The Court's Decision

Regarding preemption, the Court of Appeals recognized the general rule, pursuant to Riegel, that state-law causes of action are expressly preempted under the MDA when they seek to impose requirements on the subject device that are "different from, or in addition to" requirements imposed by federal law.

In the case of Class III devices — like the lead at issue in Malander — the premarket approval process imposes strict federal requirements on the device related to its design, labeling and other matters. Accordingly, the court recognized that preemption would apply to traditional product liability claims challenging the lead's design or written package insert, which were expressly approved by the FDA.

However, the court distinguished plaintiff's claim for common-law negligence, which did not relate to "general allegations regarding the labeling, design, or manufacture of the device" but rather related to "oral representations made by a manufacturer's representatives during a surgical procedure regarding a specific device's performance."

After a review of the very few cases touching upon preemption in this context, the court upheld the plaintiff's claim:

[W]e conclude that the Malanders' claim concerns the allegedly negligent interaction between the physician and Medtronic's technicians. Unlike Baker, the Malanders' claim does not involve the mere restatement of information given in the labeling. As in Adkins, their claim does not concern the design, manufacture, or labeling of the lead. Rather, the Malanders' challenge involves negligence of Medtronic's technicians in giving David's physician allegedly faulty advice regarding the performance of one specific lead.

As such, the court concluded that the plaintiff's claim was not preempted by the MDA, and the trial court properly denied Medtronic's motion for summary judgment on that issue.

The court likewise affirmed the denial of summary judgment as to duty of care. Under the doctrine of assumed duty, the court held that Medtronic assumed a duty to provide technical support in a "reasonable and prudent manner," having voluntarily agreed to provide such support to plaintiff's surgeon.

The plaintiff offered evidence that one Medtronic technician was present in the operating room during surgery, that two other Medtronic technicians spoke to the surgeon by telephone and that these technicians failed to follow Medtronic's internal recommendations regarding the short V-V intervals associated with the lead.

Although Medtronic offered evidence that the small number of short V-V intervals observed at the time was not indicative of failure, there was enough evidence to raise a genuine issue of fact for purposes of summary judgment.

Analysis

The Malander decision is significant for two reasons. First, in the context of Class III medical devices that have received the FDA's premarket approval (PMA), it recognizes a novel exception to preemption under the MDA.

Following the Supreme Court's decision in Riegel, only a small minority of claims implicating PMA devices have survived preemption challenges. Riegel itself carved out one exception for so-called "parallel claims," which has been recognized and applied by some lower courts. See, e.g., Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013).

Additional exceptions have also been recognized, for example, when a plaintiff is injured as a result of active off-label promotion. See, e.g., Ramirez v. Medtronic Inc., No. CV-13-00512, 2013 U.S. Dist. (D. Ariz. Aug. 21, 2013). The Malander opinion is another such exception, imposing the risk of civil liability upon PMA device manufacturers who interact directly with surgeons.

More broadly, the Malander opinion is significant in the context of all pharmaceutical and device products because it recognizes a common-law negligence claim based on a manufacturer's interactions with physicians.

With some exceptions, traditional products liability cases focus on theories of design defect, manufacturing defect and failure to warn. The claim upheld in Malander — which focused on Medtronic's direct interactions with the plaintiff's physicians — could feasibly survive in circumstances with undisputed evidence of an adequate design, manufacture to specifications and an adequate warning label.

The bottom line is that Malander highlights the liability risk for device and pharmaceutical manufacturers who interact directly with physicians. In both industries, this is a widespread practice that is integral to marketing, education and other efforts.

While physician interaction was no doubt subject to considerable company oversight before, the Malander decision provides additional incentive for device and pharmaceutical companies to erect appropriate safeguards and to mitigate the risk associated with this important practice.

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