

## **PRACTICAL APPROACHES TO AVOID MEDICAL DEVICE SALES REPRESENTATIVE LIABILITY**

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### **INTRODUCTION**

Because of numerous advances in science and technology, the medical sector has seen dramatic growth in the use of medical devices to treat patients. In many cases the devices are complex and dynamic, therefore, manufacturers and physicians have recognized the need to have a sales representative present during their surgical implantations. Beyond merely observing a surgical procedure, sales representatives are often called upon to assist the physician with the proper implantation and calibration of the device. This has created a window for plaintiffs' attorneys to impose a heightened duty on the sales representative, and therefore on the manufacturer. While medical device manufacturers have historically insulated themselves from this liability, the case law makes it clear that they may no longer be shielded when it comes to the conduct of their sales representatives.

### **RECENT CLAIMS AGAINST MEDICAL DEVICE COMPANY SALES REPRESENTATIVES**

When determining medical device manufacturer liability based on the presence of a sales representative in the operating room, courts repeatedly look at the actual conduct of the sales representative. As the cases below illustrate, where a sales representative's conduct goes outside of the scope of the recommendations and guidelines provided by the manufacturer, courts will impose liability on the manufacturer as well as the sales representative.

For example, in *Zappola v. Leibinger*, 2006 WL 1174448 (Ohio App. 8 Dist. 2006), plaintiff brought a negligence suit against defendants, Stryker and Stryker's sales representative. During surgery to remove plaintiff's brain tumor, plaintiff's physician discovered that the tumor was larger than anticipated and that the fixation system he originally planned on using would not be feasible. Defendant's sales representative suggested and, although hesitant, the physician complied with the use of a product called BoneSource, which was approved to repair cranial defects with a surface area no larger than 25cm. Plaintiff's cranial defect, however, was approximately 48 cm. After the surgery, the BoneSource application fragmented and plaintiff developed a cerebrospinal fluid leak requiring him to undergo five invasive neurological surgeries. The court held that the sales representative did not provide the physician with an adequate warning as to the risks inherent with the use of BoneSource. Defendants, therefore, breached the duty owed to plaintiff and the court affirmed the denial of defendants' motion for summary judgment.

In *Adkins v. Cytac Corp.*, 2008 WL 2680474 (W.D. Va. 2008), plaintiff sued defendants, Cytac and Cytac's corporate sales representative under a negligence theory. Plaintiff's claim arose when she underwent an endometrial ablation procedure in which defendant's device, the NovaSure, was used. During the procedure, defendant's representative was present in the operating room and advised and directed the physician on the proper way to measure the size of

plaintiff's uterus and test the integrity of her uterine wall, which was necessary before using the device. Under the representative's directive, the physician measured plaintiff's uterus at 4.5 centimeters. Plaintiff's uterus was only two centimeters. This incorrect measurement caused plaintiff to suffer a thermal burn to her sigmoid colon, resulting in a perforation across the dome of her uterus. The court described the sales representative's actions as those of a "*de facto* physician's assistant during a surgical procedure." Based on these facts, the court determined, plaintiff stated a valid claim for relief against Cytac and Cytac's sales representative.

Finally, in *Hurley v. The Heart Physicians, P.C.*, 898 A.2d 777 (Conn. 2006), plaintiff brought an action to recover damages against Medtronic, Inc. under the Connecticut Products Liability Act. Due to a congenital complete heart blockage at birth, when plaintiff was seven days old, she received a pacemaker manufactured by defendant. When she was fourteen years old, her pacemaker indicated its battery was wearing down so her physician contacted defendant's sales representative to test the battery. After testing the battery, the sales representative determined that the device needed to be replaced. Due to the mother's reluctance to replace the device, however, the sales representative opted to adjust the pacemaker down from 60 paces per minute to 40. This adjustment, according to plaintiff, caused plaintiff to suffer permanent brain damage. Based on these facts, the court held that the sales representative behaved in a manner inconsistent with the device's technical manual and, accordingly, the learned intermediary doctrine was not an available defense for the company. Therefore, the court refused to grant summary judgment for the defendant.

## RISK REDUCTION STRATEGIES

The message is clear – there is a real risk of liability for both the medical device manufacturer and the sales representative in situations where a sales representative acts in a *de facto* medical role or is present in the operating room during the implanting of a medical device. It is, therefore, imperative that manufacturers take precautions to educate and prepare their sales representatives before sending them into an operating room.

One very important tactic for medical device manufacturers to avoid liability is to train their sales representatives to conduct themselves in a manner that will shield them from liability under the well-known defense called the "learned intermediary doctrine." First used as a defense to insulate pharmaceutical companies from liability, and now used as a defense by medical device manufacturers, this doctrine provides that adequate warnings to physicians obviate the need for manufacturers to warn the ultimate consumer directly. *See Figueroa v. Boston Scientific Corp.*, 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003) ("[T]he informed intermediary doctrine applies not only to prescription drugs, but also to medical devices.").

In both contexts, this principle rests on the theory that the prescribing physician is the "learned intermediary" between the manufacturer and the consumer. Thus, the physician is the "captain of the ship" and in the best position to evaluate the patient's needs and to assess the risks and benefits of a particular course of treatment. *See O'Connell v. Biomet, Inc.*, 250 P.3d 1278 (Colo. App. 2010). In order to successfully use this defense, manufacturers should instruct their representatives not to interfere with the doctor-patient relationship -- the sales representative should not interfere with the physician's judgment nor provide any direct

warnings or instructions to the patient. *See Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778 (Ill. App. 2006); *Labzda v. Purdue Pharm, L.P.*, 292 F. Supp.2d 1346 (S.D. Fla. 2003).

In addition, the sales representative should only provide adequate, non-misleading instructions to the physician. The representative should know the product literature well, document the literature given to the physician, and constantly update the literature provided. The representative should never engage in conduct that is outside the recommendations for the product provided by the manufacturer.

Further, the sales representative should avoid involvement in the surgical implantation of a medical device. The American College of Surgeons (ACS) recommends that sales representatives act as advisors only to ensure the safe and effective use of their medical devices. Specifically, the ACS recommends that sales representatives:

- Should not engage in the practice of surgery, nursing or medical decision making
- Should not scrub or be involved in direct patient contact
- May be involved in the remote calibration or adjustment of medical devices to the surgeons' and manufacturers' specifications (e.g. pacemakers, laser technicians)
- Should have his or her activities monitored and supported by the surgeon (or, at the surgeon's direction) by the perioperative nurse responsible for the patient's care.

*See American College of Surgeons, "Statement of Health Care Industry Representatives in the Operating Room," Vol. 85, No. 5 (May 2000).*

Similar recommendations are made by the Emergency Care Research Institute (ECRI), which suggests that in order to protect the safety of the patient, staff, and sales representatives, the sales representatives must be educated about and show an understanding of the following:

- Aseptic technique
- Hand hygiene
- Infection control practices
- The sterile field
- Proper surgical attire
- Standard precautions/bloodborne pathogens
- Tuberculosis
- Fire safety (e.g., use of fire extinguishers, locations of fire exits)
- Electrical safety in the OR
- Radiation safety
- Traffic patterns in the OR
- Appropriate behavior and conduct in the OR
- Patient rights, confidentiality issues, and HIPAA compliance
- Other relevant issues (e.g., roles of OR staff, equipment or product authorization)

*See* ECRI Institute, “Operating Room Risk Management: Sales Representatives and Other Outsiders in the OR,” Volume 2 (Nov. 2007).

By following these guidelines and recommendations, both the sales representative and the medical device manufacturer will be in the best position to shield themselves from liability arising from the necessary presence of the sales representative in the operating room.

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