Legal Backgrounder

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Medical-Device Makers' Representatives in the O.R.: Patient-Care Benefits and Legal Ramifications

by Max Heerman and Daniel Smulian

When a doctor implants a medical device, he or she often requests the presence of a representative of the device manufacturer (a "rep") in the operating room. Some observers are critical of this practice, demanding that reps be barred from the O.R. At the same time, some lawyers think reps in the O.R. should be subject to liability in the court system. This LEGAL BACKGROUNDER explains why reps often play an important, if limited, role in the O.R., and why that role should not expose reps to lawsuits.

Reps Play an Important Role in the O.R.

The presence of reps in the O.R. is not just common, but often necessary. The policy of the American College of Surgeons (ACS) states "Health care industry representatives (HCIR), by virtue of their training, knowledge, and expertise, can provide technical assistance to the surgical team, which expedites the procedure and facilitates the safe and effective application of surgical products and technologies."[1] The Association of periOperative Registered Nurses (AORN) has a similar policy: "AORN acknowledges and values the role of the health care industry representative in perioperative settings."[2]

Prestigious hospital systems also endorse having reps in the O.R. The Mayo Clinic, for example, "recognizes that representatives, by virtue of education, training, and expertise, often serve as a resource for physicians, researchers, and allied-health staff through the sharing of product information, technical information and the provision of education and training." Mayo further notes that doctor-rep relationships "have been important to the advancement of clinical practice, education, and research."[3]

Despite these endorsements, some critics fear that reps will overstep their bounds and influence the surgical team to act in a manner that benefits the medical device company at the expense of the patient's best interests. However, reps are present in the operating room only to provide "technical support," not to participate in the practice of medicine. Unfortunately, this distinction is not necessarily meaningful to those outside the healthcare industry. What, exactly, is "technical support"? And how does it differ from practicing medicine?

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[1] ACS, Revised Statement on Health Care Industry Representatives in the Operating Room, Oct. 1, 2016, *available at* http://bulletin.facs.org/2016/10/revised-statement-on-health-care-industry-representatives-in-the-operating-room/.

[2] AORN, AORN Position Statement on the Role of the Health Care Industry Representative in the Perioperative Setting, Apr. 2014, *available at* https://www.aorn.org/-/media/aorn/guidelines/position-statements/posstat-personnel-health-care-reps.pdf.

[3] The Mayo Clinic, Standardizing Credentialing Requirements for Health Care Industry Representatives, June 12, 2012, *available at* http://www.mayoclinic.org/documents/standardizing-credentialing-requirements-for-health-care-industry-representatives-pdf/doc-20079745.

Max Heerman is Principal Litigation Counsel in the Legal Department of Medtronic. **Daniel Smulian** is a Shareholder with Greenberg Traurig LLP in its New York, NY office.

Technical support takes many forms. Some medical devices have complicated settings requiring the rep's assistance. For example, a spinal cord stimulator—a device that reduces pain by sending electronic signals to a patient's spine through a wire or "lead"—can send current with differing amplitude, frequency, and pulse width. After the device is implanted, it is often necessary to test various stimulator settings to optimize the patient's pain relief. Reps may be more knowledgeable than treating physicians about available ranges for these settings, and they may be more familiar with how the treating physicians can choose to adjust those settings using the device's software interface. So, a treating physician will often ask a rep questions, and then direct the rep—who is in contact with the device interface—to adjust the settings before the physician reviews the new settings and finalizes the adjustments. This is one example of a rep providing "technical support."

Other forms of "technical support" include working with scrub nurses to familiarize them with a medical device and answering questions about how to prep a device for surgery. Also, many devices are comprised of, or are capable of being used with, multiple other devices and/or accessories, and the possible combinations may vary widely. The rep helps the O.R. team ensure that the potential range of necessary devices and accessories are available at the surgery by arranging to have the manufacturer send them to the hospital—a more complicated process than many people realize. In addition, medical devices often have short product cycles, and new models are released relatively frequently. Doctors and other healthcare providers cannot reasonably be expected to have in-depth knowledge of the functionality of every new model of every new product. Reps, however, do have that knowledge, and they are present to answer any questions.

Underscoring these points, in 2010, a surgeon wrote the *Washington Post* in response to an article about reps in the O.R., explaining "many products in the operating room are complex and change almost every year; they are getting better that fast." "[H]aving the rep in the room ensures that the system is functional," and gives the surgeon and O.R. staff confidence that "all the parts will be there."[4]

Appreciating the role of reps in the O.R. not only requires an understanding of what they do—providing technical support—it also requires an understanding of the limitations and restrictions placed on them. AdvaMed, the Advanced Medical Technology Association, supports three core restrictions:

- First, reps should be present only at the request of the physician.
- Second, reps "should never engage in medical decision making and should not enter the sterile field or be involved in direct patient contact."
- Third, the patient should be informed of the presence and purpose of the rep in the O.R. and give informed consent.[5]

In addition to these core restrictions, many hospitals also credential reps. Credentialing requirements might include immunization, drug screens, criminal background checks, and verifications from the manufacturers that the reps completed comprehensive product training and demonstrated knowledge of O.R. protocols, the privacy requirements of HIPAA, and the adverse event reporting requirements promulgated by FDA, among others. Credentialing might also require reps to agree to hospital ethics policies and guard against conflicts of interest.

Reps are also restricted in how they can discuss "off-label uses." Generally the FDA-approved labelling of medical devices contains information about certain "uses" of the device, known as "indicated uses" or "indications." For example, a certain ankle-implant system is indicated for patients with rheumatoid

[4] "In Support of Sales Reps in the Operating Room," Wash. Post, Letter to the Editor, Jan. 5, 2010, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2010/01/04/AR2010010403155.html.

[5] https://www.advamed.org/issues/legal-compliance/hcir-access-requirements.

arthritis, post-traumatic arthritis, or degenerative arthritis. Doctors are free to use this device for patients who have other ankle conditions, because FDA does not regulate the practice of medicine. But if they do, the devices are said to be used "off label." The American Academy of Orthopaedic Surgeons (AAOS) has published guidance stating that manufacturers and their reps can only respond to "*unsolicited* inquiries from physicians" regarding off-label use. AAOS further explains an "unsolicited" inquiry "must not have been prompted by any design or artifice by the company through sales and marketing efforts."[6] Other organizations have similar guidelines, which underscore that it is the doctor's role—not the rep's—to propose to his patient that a device should be used off-label.

Reps as Defendants in Lawsuits

Despite their limited role in the O.R., reps are sometimes the focus of personal-injury lawsuits arising from procedures they attend. This may be an unintended consequence of tort reform—caps on damages in medical-malpractice actions against physicians do not apply to claims against reps and their employers, who present an attractive deep pocket from whom to seek compensation. It may also be a by-product of the strength of a legal doctrine known as federal preemption. Class III medical devices approved pursuant to FDA's rigorous Pre-Market Approval process are immune from suits alleging that they were improperly designed or labeled. *See Riegel v. Medtronic,* 552 U.S. 312 (2008); *In re Medtronic, Inc. Sprinter Fidelis Leads Prods. Liability Litigation*, 592 F. Supp. 2d 1147 (D. Minn. 2009). Thus plaintiffs look for ways to plead un-preempted, rep-related claims.

In these cases, plaintiffs typically allege the rep owes or has assumed a duty to provide warnings to the patient—to be one of the patient's healthcare providers. *See*, *e.g.*, *Patterson v. DePuy Orthopaedics, Inc.*, No. 1:11-DP-20521, 2011 WL 3047794 (N.D. Ohio 2011). The problem with these allegations should be clear from the discussion above: physicians ask reps to be present to provide technical support, not to provide surgical assistance or to evaluate the physician's technique. Because reps are not healthcare providers, and are not qualified to provide medical care and treatment to patients, they should not be subject to lawsuits alleging that medical care was negligently performed.

Many courts that have addressed these types of cases recognize the distinction. For example, in *Kennedy v. Medtronic*, the court understood the limited role played by reps. 851 N.E.2d 778 (Ill. App. Ct. 2006). The patient there underwent a surgery to implant a pacemaker and lead. He would only agree to the surgery if it was performed in an outpatient facility, and the physician agreed to perform the implantation procedure at his clinic. The patient experienced ill health in the months after the surgery, and a physician discovered that the lead had been placed in the wrong ventricle of his heart. The patient underwent surgery to replace the lead, and died four months later.

The patient's family sued the company that made the pacemaker and leads, whose employee was present during the patient's initial surgery at the clinic. The family charged that the employee both should have (i) warned the physician, the patient, or the patient's family of the inherent dangers of an outpatient setting, and (ii) assisted with the proper placement of the pacemaker's lead.

The court decided that assigning these legal duties to a medical-device company's representative was unwise. Because the rep does not have the physician's medical skill or judgment or knowledge of the patient's history and condition, the court recognized it was not reasonable—and potentially harmful to patient health and safety—to compel the employee "to delay or prevent" a medical procedure. "To hold otherwise," explained the court, "would place a medical device manufacturer ... in the middle of the doctor-patient relationship." *Id*. at 784 (citation omitted).

[6] AAOS, Practice Issues: The Orthopaedic Surgeon in the Managed Care Setting, Dec. 2008, at 30, *available at* http://www.aaos.org/workarea/DownloadAsset.aspx?id=31349 (emphasis added).

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The court also rejected the claim that the manufacturer had voluntarily assumed a duty to assist with the surgery. The medical-device company's employee had only undertaken to:

> Attend[] the surgery to provide technical support and ensure that the lead parameters were correctly calibrated and the lead was functioning properly. This limited role did not entail her voluntarily assuming a duty ... for the placement of the lead into the correct ventricle of the patient's heart.

Id. at 787.

Finally, the court did not fault the device-company employee for briefly reassuring the patient's family prior to the surgery. The employee told the family that "everything would be fine" and described the physician's prior experience with pacemaker procedures. Based on this brief conversation, the court determined "there is no basis for us to conclude that [the patient] would not have proceeded with the surgery without [the employee's] alleged reassurance." *Ibid*.

Although *Kennedy* does not go so far as to suggest there should be a blanket rule barring lawsuits against reps, it does demonstrate that claims against a rep should be permissible only in very narrow circumstances, if at all. In fact, one court has persuasively noted that, *even if* a rep oversteps his role and provides medical advice, there should be no claim against the rep because it would be "patently unreasonable" for an experienced surgeon "to rely on a sales representative's opinion about the type of procedure that should be employed." *Hall v. Horn Medical, L.L.C.*, 2012 WL 1752546, *3 (E.D. La. May 16, 2012).

Malander v. Medtronic, 996 N.E.2d 412 (Ind. Ct. App. 2013) may be the rare case where a rep provided technical assistance and the plaintiff's allegations survived a motion to dismiss. *Malander* involved a defibrillator replacement surgery in which the physician also considered replacing the patient's ventricular lead. During the replacement procedure, the rep tested the leads without identifying short-sensing intervals or other problems. The physician called the medical-device company's helpline and obtained additional information about the lead's functionality, without being told that readings arguably weighed in favor of lead replacement. The patient died approximately one month later. Subsequent testing revealed hundreds of readings that could indicate an impending lead failure had occurred between the replacement surgery and the patient's death.

Based upon the oral representations during the surgery, the plaintiffs sued the manufacturer, asserting that the rep and the individuals on the helpline had assumed, and breached, a duty by giving the physician faulty information about the lead and failing to advise him to replace it.

Unlike *Kennedy*, the court in *Malander* did not dismiss the case. But cases like *Malander*, which genuinely focus on the technical support the rep was present to provide, are few and far between. More typically, claims against reps attempt to impose duties beyond the scope of the rep's actual and acknowledged role.

Courts have misunderstood the role of reps in the operating room too often. Reps should continue to be allowed in the O.R., where they are a constructive presence, providing technical support to doctors and their staffs—and improving outcomes for patients. Trade associations, hospital systems, and manufacturers alike have put reasonable restrictions in place, and these measures should allay any concerns that reps will overstep their bounds. Moreover, doctors have ultimate authority in the O.R., and reps are present at doctors' request. Given their important and useful role and these reasonable restrictions, reps should not be targeted in lawsuits, and lawsuits against reps should not be permitted to proceed in all but the rarest factual circumstances.

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