Sales Representatives In The Or – Real Risks

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Today we look at a common topic – sales representatives – in a slightly different light. We are all well-versed in the learned intermediary doctrine. More and more often, plaintiffs' failure to warn claims in pharmaceutical and medical device cases are thwarted by knowledgeable physicians who apply their independent medical judgment in deciding whether a course of treatment is in the best interests of their patients. This is a good thing – and often relegates the role of the sales rep in a products case to the back burner.

Of course, when we think about sales reps we typically picture a rep standing in a doctor's office with a sample case and some handouts trying to get a few minutes of a doctor's time to laud our clients' products. But there is another arena in which sales reps play a critical role – the operating room. A modern surgical suite can look something like a cross between a NASA command center (if they were still in business) and your local auto repair shop. Because of both the high tech nature of surgical equipment and the vast array of options available to surgeons, it is increasingly common for medical device manufacturers to have representatives attend surgeries. Often this is just to observe the use of the company's product, but sometimes the sales rep can "assist" the medical team by making sure the right product is available, helping nurses locate the proper instruments, or calibrating a product before use. From our experience in the Bone Screw litigation, for instance, we know that sales reps often stand outside the sterile field and use laser pointers to help nurses pick out the size instrumentation the doctor asks for.

Indeed, the AMA Code of Medical Ethics states:

> "Manufacturers of medical devices may facilitate their use through industry representatives who can play an important role in patient safety and quality of care by providing information about the proper use of the device or equipment as well as technical assistance to physicians."

AMAssociation. Opinion 8.047 Industry representatives in clinical settings. *Code of Medical Ethics*.

With new and more complex medical devices and equipment entering the market each year, it is easy to understand why surgeons favor the availability of consulting technicians or medical device specialists. But, from a legal standpoint, the presence of medical device sales

reps in the OR raises issues of proximity and temporality that are not typical in a pharmaceutical case (although there have been cases in which plaintiffs have tried to argue that a pharmaceutical representative should be held to an affirmative duty to take action. See Labzda v. Purdue Pharma L.P., 292 F.Supp.2d 1346, 1354 (S.D. Fla. 2003) (sales rep and pharmaceutical manufacturer have no duty to control doctor's prescribing practices)).

While we have dipped our toe into this pond in the past (see prior post Riegel Toothpaste (Adkins v. Cytyc)), we decided to wade in a bit further and gather what we could find from courts that have addressed the issue. What we found were essentially two types of cases – those in which a plaintiff accuses the sales rep of the unauthorized practice of medicine (less common) and those in which plaintiff attempts to impose on the representative, and therefore on the manufacturer, a heightened duty based simply on the representative's presence in the OR. The results in both categories of cases are split and appear to be largely fact sensitive – in other words, there is a fine line that when crossed turns the sales representative from a valuable asset to the surgical team into a potential liability for the manufacturer. While there are few reported decisions on this topic, the takeaway, despite some of the favorable outcomes, is that there is real risk of liability – for both the sales rep and the manufacturer – if the sales rep gets too involved in the actual treatment of the patient or use of equipment during surgery.

Unauthorized Practice of Medicine: Any discussion of this topic would be incomplete without talking about one of the oldest and most extreme cases – the grandfather of the genre so to speak – People v. Smithtown General Hospital, 93 Misc.2d 736 (Suffolk County NY, 1978). Yes, this is a criminal action brought against the surgeons and the hospital. The surgery at issue was a hip replacement during which the sales manager who sold the hospital the hip prosthesis was present. Smithtown, 93 Misc.2d at 738. An x-ray taken after the surgery revealed that the hip was dislocated, so the surgeon called the sales manager back in. First no-no -- the sales manager scrubbed in. Next problem, after the surgeon couldn't remove the prosthesis, the sales manager "offered to and did take it out." Don't think it can get worse? Think again. The sales manager volunteered that he could fix the "thing" and "put it back." And so, with the surgeon's consent, the sales manager finished the rest of the three and a half hour surgery, including reinsertion of the hip prosthesis. During which time the surgeon sometimes left the table and maybe even left the OR once. Id. at 739. We said this was an extreme case.

Not surprisingly, the court held that the doctor "abdicated his role as surgeon in that operating room and permitted the judgment and skills of a layman to prevail," and that the sales manager's "involvement in the surgical procedure extended beyond instruction as to the use or manner of implant of the device." Id. While this case was brought against the hospital and the medical personnel, the court did also state: "From the evidence presented, the Grand Jury could conclude that the salesman . . .unlawfully engaged in the practice of medicine without the prior informed consent of the patient under circumstances which did not constitute an emergency." We would have to agree.

Fortunately, we have not uncovered any other cases involving such a blatant surgeon-sales rep role reversal – but there are other examples where plaintiffs have attempted to hold sales reps and manufacturers liable on the theory of the unauthorized practice of medicine. At the opposite end of the spectrum is Disbrow v. Smith & Nephew Richards Inc., 1996 WL 593780 (Tx. App. Oct. 17, 1996). During another hip replacement surgery, a handle broke on a tool being used by the surgeon. Plaintiffs sued the surgeon for medical malpractice and the device manufacturer and its sales rep for "practicing medicine without a license." Disbrow, 1996 WL 593780, *1. The sales rep -- who was present during the surgery and who was responsible for locating a new handle for the tool -- did not scrub in, was "positioned at the back of the table", and his only role was assisting the scrub nurse get equipment. Finding no evidence of the practice of medicine without a license, the court granted defendants' summary judgment motion. Id. at *2.

We also found a more recent case that gave us pause because it started off sounding more like Smithtown. The case was dismissed on the pleadings on statute of limitations grounds, but we include it to demonstrate that these type of allegations persist and as a word of caution to our medical device clients. In Wilkerson v. Christian, 2008 WL 483445 (M.D.N.C. Feb. 19, 2008), plaintiff underwent a procedure to remove tumors from her liver by burning them with an electrode, a procedure known as ablation. Within a week of the surgery, plaintiff's liver failed, a transplant was unsuccessful and she died. Wilkerson, 2008 WL 483445, *1. Plaintiff brought a wrongful death action against the manufacturer of the electrode and its sales representative alleging that the sales representative "personally performed the ablation procedure when she operated medical equipment that was directly, by way of a continuous circuit, inserted into [plaintiff's] body." Id. Because the case was dismissed early on before discovery, there is no further discussion of what role the sales rep actually played

during the surgery. The court, however, while finding the case barred by the statute of limitations did have this say:

"Plaintiff alleged facts, in good faith, that raise serious questions regarding the propriety of sales representatives in the operating room. The gravity of Plaintiff's allegation that a sales representative performed, or participated in, [plaintiff's] tumor ablation procedure is not lost on this court."

Id. at *13.

Duty to Protect the Patient: These cases are more common and closer to traditional failure to warn cases – but again, there is something about the reps' actual presence in the OR during surgery which has allowed some courts to find a duty that seems to trump the learned intermediary doctrine. Since the case law is split largely based on fact sensitive issues, we'll lead with one where we think the court got it right -- Kennedy v. Medtronic, 851 N.E.2d 778 (Ill. App. 2006). The case involved medical malpractice and products liability claims stemming from the surgical implantation of a pacemaker in an outpatient facility (as opposed to a hospital). Kennedy, 851 N.E.2d at 780-781. Present at the surgery was the manufacturer's clinical specialist whose primary responsibility was "to provide technical support and ensure that the [pacemaker's] lead parameters were correctly calibrated and the lead was functioning properly." Id. at 787. So, plaintiff's theory against the manufacturer was that it owed a duty of care to the plaintiff (1) to "refrain from providing a pacemaker" to the surgeon when she knew the procedure would not be performed in a hospital, (2) to warn of the dangers of the procedure under those conditions and (3) "to assist with the insertion in a reasonable manner once it voluntarily undertook to participate." Id. at 782.

Affirming the trial court's granting of defendant's summary judgment motion and relying on the learned intermediary doctrine, the appellate court found:

"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. 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. To hold otherwise would place a medical device manufacturer . . . in the middle of the doctor-patient relationship."

Id. at 786. The court also rejected plaintiff's claim that based on her limited role, the defendant's clinical specialist voluntarily assumed a duty under section 324A of the Restatement (Second) of Torts. Id. at 787.

We've previously discussed Wolicki-Gables v. Arrow International, Inc., 641 F.Supp.2d 1270 (M.D. Fla. 2009), aff'd on other grounds, 634 F.3d 1296 (11th Cir. 2011) favorable preemption ruling here. But the court also was unwilling to find that a sales representative's presence in the OR during implantation of a pain pump created a duty for the medical device manufacturer. Plaintiff's negligence action against the sales rep alleged "breach of the duty to use reasonable care in the instruction and education of physicians." Wolicki-Gables, 641 F.Supp.2d at 1279. Sounds like failure to warn, right? So, quite correctly the court kicked the claim based on the learned intermediary doctrine:

"The undisputed facts show that [the sales rep] did not participate in the decision-making during [the] procedure. [His] role was limited to carrying "back up" products in their sterile packages to have available for the surgeon's use, if necessary, and to observe preparation of the products. [He] did not "scrub in" for the procedure . . . and did not enter the sterile field. . . . [The surgeon] testified that the decisions made while he performed surgery were his own decisions."

Id. at 1291. More importantly, the court went on to say that "[e]ven if . . .[the sales rep] did have some interaction with [the surgeon] during that surgery", the sales rep did not have "a duty to affirmatively tell" the surgeon how to use the device. Id. In other words, the surgeon is still in charge of the surgery – he is the captain of the ship.

We picked up this expression from O'Connell v. Biomet, Inc., 250 P.3d 1278, 1283-84 (Colo. App. 2010) in which the court found that plaintiff's claims against a sales rep were discharged by the surgeon's settlement agreement which included "agents" based on Colorado's "captain of the ship doctrine." Id. The description of the roles of the surgeon and sales rep was too good not to include:

"The sole purpose of [the sales rep] being in the operating room was to provide [the surgeon] with information about the fixator, which information [the surgeon] then used to make his medical judgments. That is, [the surgeon] remained in control of the surgery vis-à-vis [the sales rep] and all other non-physicians in the operating room. Because [the surgeon] remained in control of the surgery, anything [the sales rep] might have done during that surgery, including any advice he allegedly gave or should have given to [the

surgeon], was done as a crew member, so to speak, of the surgical ship."

Id. We wish the next few courts shared Colorado's understanding of the sales rep-surgeon relationship.

So as to not give the false impression that that defendants win all these cases, we give you the case of Zappola v. Leibinger, 2006 WL 1174448 (Ohio App. May 4, 2006), in which a jury found both plaintiff's surgeon and the medical device manufacturer and sales rep liable for negligence. During surgery to remove a brain tumor, based on the size and location of the tumor, plaintiff's surgeon concluded that he could not use the manufacturer defendant's device to reattach the plaintiff's bone flap as planned. Zappola, 2006 WL 1174448, *2. The surgeon asked the sales rep "to observe the size of the cranial defect in [plaintiff's] skull." Id. The two then discussed possible methods of closing the skull, and the sales rep suggested another of his employer's products. The doctor expressed some concerns based on his past experience with similar products. The sales rep told the surgeon that the product "had been improved." Id. The surgeon decided to use the product. The product fragmented and plaintiff suffered a cerebrospinal fluid leak resulting in four additional surgeries. Id. at *3.

The written warnings that accompanied the product provided specific instructions and guidance for using the product to close a cranial defect the size of plaintiff's. Id. at *2-3. So, the defendant manufacturer argued that it satisfied its duty to warn the surgeon under the learned intermediary rule. The court disagreed:

"Although the written instructions [provided recommendations for use], [the sales rep] did not make these recommendations to the doctor. Despite the fact that he was professionally obligated to inform [the surgeon] about the use of the product and personally observed the size of [plaintiff's] cranial defect, [the sales rep] did not uphold his duty of ensuring that the product was used properly."

Id. at *6. The pivotal factor for the court seemed to be the fact that the sales rep was present and observed the plaintiff's condition. That appears to have been enough to impose on the sales rep and the manufacturer a heightened duty to warn – despite the fact that the learned intermediary in this case was a neurosurgeon who had past experience with the product.

Although not a case involving the operating room, Hurley v. Heart Physicians, P.C., 898 A.2d 777 (Conn. 2006) is worth a quick mention regarding the interplay between the learned intermediary rule and the "hands on" sales rep. Here, plaintiff's cardiologist asked a

pacemaker sales rep to attend an examination of plaintiff "to test the battery in her pacemaker" and "to make adjustments" as needed. Hurley, 898 A.2d at 780. Because the battery was low, the cardiologist and the sales rep discussed options regarding the downward adjustment to the rate of the pacemaker. Id. at 780-81. After the pacemaker was adjusted, plaintiff suffered a cardiac event and resulting permanent brain damage. Plaintiff admitted that the pacemaker's manual contained an adequate warning – so, the trial court granted defendant manufacturer's motion for summary judgment based on the learned intermediary doctrine. Id. at 779, 786. In reversing that decision, the Connecticut Supreme Court focused on the sales rep's presence at and involvement with the adjustment of the pacemaker:

"What is at issue …is whether, notwithstanding the FDA approved written pacemaker replacement warnings, [the sales rep], by his *oral* communications to [the physician] that turning down the pacemaker was an option, accompanied by his *physical* adjustment of the pacemaker . . ., actually contradicted the manual, thereby vitiating and nullifying the manual's warnings."

Id. at 786-87. Did the sales rep's suggestion also vitiate and nullify the cardiologist's medical judgment? Finding a question of fact, the case was remanded for trial on this issue. We are happy to report that a jury eventually found in favor of the defendant and that verdict was upheld on appeal. See Hurley v. Heart Physicians, P.C., 3 A.3d 892, 899-900 (Conn. 2010). But we are again left wondering, if a sales rep had discussed downward adjustment with the cardiologist at some earlier time and then the cardiologist later decided to turn down the pacemaker – would this case have ever reached a jury?

Temporality and proximity also won out in Chamian v. Sharplan Laser, Inc., 2004 WL 2341569 (Mass. Super. Sep. 24, 2004) in which defendant's technician was present during plaintiff's plastic surgery "to test the [laser] to ensure that it is working properly and to assist the physician by entering and adjusting settings as directed by the physician." Chamian, 2004 WL 2341569, at *3. Again, there was evidence that the surgeon consulted with the sales rep on the appropriate settings during surgery. Id. at *5. The court found

"[Defendant] provided a technician to assist in the surgery, and, by doing so, assumed a duty to [plaintiff] to ensure that the technician . . . was knowledgeable about the equipment and competent to provide technical assistance to physicians using the equipment. . . . The fact that [the surgeon] had the responsibility to exercise his clinical judgment to determine appropriate settings and was required by the standard of care to confirm that the settings he selected had been entered does not preclude negligence on the part of [the technician] from being a substantial contributing cause of [plaintiff's] injuries."

Id. at *8. Doesn't it? Isn't that what the learned intermediary doctrine (and the captain of the ship doctrine) is all about? The surgeon has the specialized medical training and knowledge of his/her patient to make informed and independent treatment decisions. Unfortunately, at least a few courts have been swayed by the sales reps presence in the OR to forego the learned intermediary doctrine. So, while the advantages of having a device representative present are readily apparent, so too are the risks.