# Know Your Medical Devices

**By Jamie Wyatt, JD**

The United States is the largest medical device market in the world, generating over $180 billion in annual revenue. [1] An area of growing concern for some in the healthcare community, but often unknown to patients, is the role of medical device sales representatives in patient care. Among these concerns are ethical issues surrounding a representative's presence in the operating room, his or her influence in device choice, and a physician's reliance on a medical device sales representative as a resource for treatment decisions during surgery.[2] Proponents of the practice argue that attendance by the sales representatives allows them to provide expertise on the use of a particular product device due to the hands-on training and overall knowledge of the sales representative. They support the development of a loyal relationship between the physician and the representative because they believe it fosters a comfort level among them to freely exchange information while keeping up with technological developments, all said to benefit the practice of medicine. It is important to point out, though, that there needs to be a balance between reliance on a medical device sales representative and independent knowledge when determining the appropriate device and use for your patient. Keep in mind that the ultimate goal of a medical sales representative is to increase awareness of his or her product in order to create sales volume for profit. Relying solely on just your interactions with a representative and knowledge obtained from him or her for a surgical procedure can be a risky proposition for any physician. While there is a joint goal for quality patient care, what happens when reliance on a medical sales representative is misplaced?

This brings us to the case of Dr. Strobl. [3] The patient, a 60-year-old-male, was admitted to the hospital following a motor vehicle accident. An MRI upon arrival revealed moderate stenosis at C3-C4 and severe stenosis at C4-C5 and C6-C7. The patient was advised that he would need decompression surgery at some point. Four months after the accident, the patient consulted with Dr. Strobl for complaints of constant burning pain in both arms and loss of feeling in his hands. Dr. Strobl performed an anterior cervical discectomy C3-C4, C4-C5 and C5-C6 with partial corpectomy at C4, full at C5. The medical device sales representative was in the operating room while Dr. Strobl placed an interbody spacer without plating. After initial assembly of the device, it fell apart and was put back together before being placed during surgery.

On the morning after the surgery, the patient was doing well and walked nearly 100 feet in the ICU. However, there was a dramatic change later that day when the patient was assisted from the bed to a chair by the nurse. When he sat in the chair, he suddenly lost motor function in his left upper extremity. A CT of the cervical spine study revealed that the

strut between C4 and C5 had become dislodged causing stenosis on the left side of the spinal canal. Dr. Strobl performed emergency surgery to retrieve and remove the C5 cage interbody spacer and place a C5 titanium cage. He found a retropulsed spacer causing spinal cord impingement and cervical stenosis. He noted separation of the spacer part. Dr. Strobl performed a fusion surgery and later transferred the patient to a rehabilitation facility. At the time of discharge from the rehab facility, the patient could ambulate independently but complained of chronic pain.

Following his recovery, the patient filed suit against Dr. Strobl alleging breach of the standard of care for the use of a prosthetic modular interbody spacer device in the cervical spine without plating. The allegations asserted against the device manufacturer consisted of a claim of negligent design and manufacturing of a device, asserting that defects in the design and construction rendered the product unreasonably dangerous. Damages included, but were not limited to, pain and suffering (both past and future), additional surgery, lost wages, and medical expenses.

The defensibility of the claim was difficult. The medical sales device representative testified in his deposition that his device recommendation was based on the type of surgery Dr. Strobl was to do that day. He gave assurances that off label use was appropriate, but when defending his actions, he and the manufacturer asserted that the product insert for the device clearly stated that it was not intended for the cervical spine and should be used in conjunction with a plate for additional stability. The representative testified in his deposition that Dr. Strobl discussed during the surgery that he would be unable to fit a plate. The representative admitted he acquiesced to Dr. Strobl using the device without plating, testifying that the physician made the decision to go forward after their discussion. Matters got more complicated when conflicting testimony developed wherein Dr. Strobl testified that the manufacturer's representative encouraged him to use the product and assembled the device. However, the representative testified that the product came apart and then Dr. Strobl handed it to the nurses to reassemble. Despite knowing that the literature said that the product was not to be used if this occurred, the medical device sales representative said nothing. He testified that he believed it was the surgeon's responsibility to know this information, as he was the one putting it in the patient's body. The representative also testified that he didn't think the placement was correct, but did not say anything because he was not the physician. In fact, all of this testimony hurt Dr. Strobl as it was clear that he relied on the representative to put the device together, agreed to move forward without the necessary plating, used the device off label, and had little personal knowledge of the product when it fell apart. In most cases, it is reasonable to look to a representative to provide pertinent information about their device, but it is necessary to have a working knowledge of such a device, risks associated with its use, and contraindications. In this case, Dr. Strobl admitted he did not spend any time familiarizing himself with the device nor reading about it.

The attorney for the manufacturer and representative defended the case with arguments that are typical in these circumstances, such as the device was installed by the physician who should have had a working knowledge of the device, its components, and the

possible damages caused by a device since he/she is in the best position to know. In essence, the physician has a duty to know what he or she is installing in the patient's body.

In the end, due to the physician's reliance on the sales representative's assistance regarding the component's use and placement, a settlement was made on behalf of our insured surgeon. The manufacturer also entered into a separate settlement with the patient. The takeaway here should be that a medical device sales representative can be a useful resource in determining the appropriate device for your patient; however, it is necessary to have your own knowledge base when working with a device. While a medical sales manufacturer can certainly face liability on a products claim for a defective product, it will not prevent an action from being filed against you for improper use of such a device, leaving you to defend the adverse outcome.

[1] Zacks Equity Research, *Medical Device Industry Outlook-June 2018*, (June 2018), https://www.nasdaq.com/article/medical-device-industry-outlook-june-2018-cm978557

[2]Relias Media, *Physicians Rely on Device Reps, but have ethical concerns*, (March 1, 2018), https://www.reliasmedia.com/articles/142271-physicians-rely-on-device-reps-but-have-ethical-concerns.

[3] Names and identifying details have been changed for confidentiality

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