Nutter insights

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Sales Representatives Face Increased Risk of Being Named in Medical Device Product Liability Litigation

Q Why is there a rise in sales representatives being sued in medical device product liability cases?

Robyn Maguire: Five to ten years ago, the primary reason sales representatives were sued in product liability cases was tactical: to name a local defendant, thereby preventing removal of cases to federal court—the much-preferred jurisdiction for defendants. Today, sales representatives are facing lawsuits for more substantive reasons, including allegations that they promoted a product for an off-label use or breached a duty of care to a patient during the course of a surgical procedure, potentially imparting liability on the representative under common law negligence theories. These alleged duties had not previously been recognized under the law, and courts are just beginning to decide whether they exist at all and, if so, the nature of their scope.

Q How have the courts decided whether sales representatives owe a duty to the patient?

RM: The few courts that have addressed this issue have found an inherent conflict between the alleged duty to instruct, train, and advise a surgeon on the one hand, versus the longstanding learned intermediary rule, on the other. As one court described it, to hold that a manufacturer's representative has an independent duty to the patient would "place the [manufacturer's representative] in the middle of the doctor-patient relationship." State courts have adopted the learned intermediary doctrine precisely because manufacturers (and, by extension, their representatives) do not belong in that relationship. Rather, a manufacturer discharges its duty by warning the doctor of the risks associated with a prescription drug or device.

Q How have the courts ruled on what constitutes a sales representative's "advice" to a surgeon?

RM: This is still largely an open question. Sales representatives may discuss the product generally with surgeons and repeat the manufacturer's written warnings. However, telling the surgeon how the product can or should be used for a particular patient rests in a grey area, and courts have decided these cases differently, based on the facts. Many jurisdictions have adopted the "captain of the ship" doctrine, which provides that in an operating room setting, the surgeon alone is liable for the acts and omissions of all others present, including nurses, surgical technologists, other hospital personnel, and product representatives. It therefore makes no difference whether the sales representative gave advice to the surgeon because, ultimately, the surgeon has the final decision and is potentially liable for any errors that occurred during the treatment and care of the patient.

Q What are some considerations for sales representatives to limit their exposure in product liability lawsuits?

RM: Representatives should be careful to closely follow the manufacturer's guidelines for conduct during surgery. When discussing a medical device with a surgeon, this may be simply repeating the manufacturer's warnings and instructions for use or directing the surgeon to a technical expert at the company for more sophisticated questions. Sales representatives should also remain outside the sterile field in order to avoid assuming a duty to the patient and for the unauthorized practice of medicine. Finally, sales representatives should focus on the product and curtail discussions about a patient's treatment.

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