"He Did What?" – Recent Trends in the Case Law Affecting Medical Device Sales Representatives

By Jackie Terry Hughes and Carrie Hanger
Womble Carlyle Sandridge & Rice, PLLC

Whether you are a large multinational medical device manufacturer or a smaller start-up, you need to minimize exposure to litigation. With recurring frequency, sales representatives find themselves being named individually in lawsuits alleging strict liability and negligence claims. By working with your sales representatives and reinforcing certain messages in their training, this proliferation in litigation can be minimized.

I. Claims Against Medical Device Sales Representatives Are on the Rise.

In the past, lawsuits against medical device sales representatives, unlike pharmaceutical sales representatives, were uncommon. However, in recent years, plaintiffs' lawyers have recognized that the conduct and statements of medical device sales representatives provide another avenue for potential liability, and lawsuits against medical device sales representatives have multiplied.

A. The Learned Intermediary Doctrine No Longer Offers an Airtight Defense for the Sales Representative.

The learned intermediary doctrine has historically insulated the medical device sales representatives (and manufacturers) from liability so long as the medical provider received adequate warnings. *See, e.g., Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778, 784-87 (Ill. Ct. App. 2006); *see also Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1279-81 (11th Cir. 2002). The doctrine defers to the medical provider to determine what should be communicated to the patient and how, and seeks to protect the provider-patient relationship from intrusion by the manufacturer and its representatives. *See, e.g., Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1287 (M.D. Fla. 2009).

Today, more actions are proceeding against device sales representatives based on their conduct and statements to medical providers. *See, e.g., Adkins v. Cytyc Corp.*, No. 4:07CV00053, 2008 WL 2680474, at *3 (W.D.Va. July 3, 2008) (denying a sales representative's motion to dismiss); *McDaniel v. Synthes, Inc.*, No. 2:07-CV-245RM, 2007 WL 3232186, at *3 (N.D. Ind. Oct. 29, 2007) (remanding an action against an implant manufacturer and its sales representative); *Stibor v. Wisconsin Physicians Serv. Ins. Corp.*, No. 04 C 1255, 2005 WL 1793589 (E.D. Wis. July 27, 2005)(remand); *Hurley v. Heart Physicians*, 898 A.2d 777 (Conn. 2006)(denying summary judgment); *Zappola v. Leibinger*, Nos. 86038, 86102, 2006 WL 1174448 (Ohio Ct. App. May 4, 2006)(denying summary judgment and directed verdict). [1]

Courts across the country are concluding that the learned intermediary doctrine does not shield sales representatives if their conduct and/or statements deviated from the manufacturers' written warnings and instructions or if the manufacturers' warnings and instructions themselves were inadequate. *See id; for analogous pharmaceutical cases, see In re Zyprexa Prod. Liab. Litig.*,

649 F. Supp. 2d 18, 31-32 (E.D.N.Y. 2009); *Del Bosque v. Merck & Co., Inc.*, No. C-06-510, 2006 WL 3487400 (S.D. Tex. Dec. 1, 2006). These courts are parsing the language and actions of the sales representatives in greater detail and holding the sales representatives responsible for any deviations from the manufacturer's approved language and uses.

B. Where Does the Sales Representative Draw the Line?

Recent decisions suggest that medical device sales representatives should take pains to ensure that the treating physician or surgeon has received *and reviewed* all available product literature and warnings before a procedure is performed. The question of how much detail a sales representative must provide about the device and its appropriate use was the subject of an appeal from a plaintiff's jury verdict in Ohio. In *Zappola v. Leibinger*, Nos. 86038, 86102, 2006 WL 1174448 (Ohio Ct. App. May 4, 2006), the plaintiff sued, among others, the sales representative and manufacturer of cement used to repair cranial defects. The sales representative was in the operating room, observed the plaintiff's wound, and suggested the cement when asked to recommend a product. *Id.* at *2. The learned intermediary doctrine did not relieve the manufacturer and sales representative of liability to the ultimate user because the warning provided was inadequate or misleading. *Id.* at *5.

In upholding the denial of summary judgment and directed verdict, the court considered the sales representative's testimony that he knew (1) the surgeon did not read the instructions before using the cement; (2) the instructions advised against using the cement for wounds larger than 25 centimeters; and (3) the plaintiff's wound was larger than 25 centimeters. The sales representative never advised the surgeon that the cement was inappropriate for the wound, and the subsequent application of the cement caused the plaintiff to undergo numerous additional surgeries. *Id*. at *3, 5-7. Accordingly, a question of fact existed about the adequacy of the warning provided. *Id*. at *5. This ruling is even more compelling because the surgeon admitted he never read the instructions for use of the cement. *See id.* at *2.

In another recent decision, a court kept the door open for litigation to proceed against a sales representative under state tort claims and found specifically that the claims were not preempted under the *Riegel v. Medtronic*, 552 U.S. 312 (2008) [2] decision. *Adkins v. Cytyc Corp.*, No. 4:07CV00053, 2008 WL 2680474, at *3 (W.D. Va. July 3, 2008). The court noted:
[T]he FDA does not regulate interactions between corporate representatives and physicians on-site at a particular surgery, and where it does not mandate specific training for a drug, it does not specify how such an interaction at surgery must be performed. These localized situations are traditional matters for common law.

Id. at p. 3. This decision seemingly allows additional claims against manufacturers based on their representatives' conduct.
The matter of *Wehner v. Linvatsch Corp.*, No. 06-CV-1709, 2008 WL 495525 (D. Minn.. Feb. 20, 2008) provides insight into another avenue where a sales representative can subject themselves and the manufacturer to liability. The *Wehner* court denied summary judgment to a device manufacturer. The court noted that the treating physician received and read the product handout but not the package insert, which contained the warning relevant to the plaintiff's alleged injury. *Id*. at * 4. The plaintiff presented evidence that the sales representative never provided the

package inserts to the physician. *Id*. The court reasoned that the treating physician never received that warning, and a question of fact existed regarding the manner in which the warning was given. *Id*. at *5.

Nonetheless, not every case has held against the sales representative. In *Wolicki-Gables v. Arrow International, Inc.*, 641 F.Supp.2d 1270 (M.D. Fla. 2009), the court granted summary judgment to a sales representative in a negligence claim for the alleged failure to educate the surgeon and ensure that the device (a pain pump) was functioning properly. *Id*. at 1295. The court in granting summary judgment noted that on t: the sales representative: (1) was present in the operating room only to ensure that "back-up" products in the manufacturer's service packages were available for the surgeon's use; (2) never broke the sterile barrier; and (3) did not make any decisions for the surgeon.

II. Tips Going Forward: What Should We Discern From These Recent Trends?

With case law trending toward holding individual sales representatives liable, medical device manufacturers should take heed from these cases and consider the following tips and suggestions when training (and re-training) their sales staff:

1. Your sales representative must know every word of the product literature and never stray from that language.

2. Your sales representative should document exactly what literature or material was provided to the treating physician and when, including all revised literature.

3. Your sales representative must provide the treating physician with all available and updated product literature as soon as reasonably possible.

4. You should specify exactly what your sales representatives must do with their "old" product literature.[3]

5. Your sales representative must be careful when communicating with the treating physician in email and all other outgoing communications.

6. Your sales representative must never engage in conduct which can be construed to be outside the recommendations contained within the instruction manual and package insert.

7. Your surgical sales representative must NEVER act as the physician's assistant inside the operating room.

8. Your sales representative must not take any action which could give rise to a claim for the unlawful practice of medicine.

9. Your sales representative must take all steps necessary to ensure the medical provider is aware of the proper use of the particular device (i.e., confirming the provider has received and reviewed all literature and warnings).

10. Your sales representative should not vouch for the qualifications of the surgeon implanting a device or make any other statements to the patient about the surgeon's qualifications.

Jacqueline Terry Hughes
Womble Carlyle Sandridge & Rice, PLLC
Raleigh, NC
jaterry@wcsr.com

Carrie A. Hanger
Womble Carlyle Sandridge & Rice, PLLC
Winston-Salem, NC
changer@wcsr.com

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[1] For analogous cases in the pharmaceutical context, see *In re Avandia Marketing, Sales Practices & Prods. Liab. Litig.*, MDL Nol. 1871, Nos. 07-md-1871, 2:09-cv-00809, 2:08-cv-05847, 2009 WL 1708079, *6-*7 (E.D. Pa. June 17, 2009)(remanding an action against a pharmaceutical manufacturer and its sales representative); and *Del Bosque v. Merck & Co., Inc.*, No. C-06-510, 2006 WL 3487400, at *3 (S.D. Tex. Dec. 1, 2006) (remanding an action against Merck and its sales people).

[2] In *Riegel*, the Supreme Court found that state law claims sounding in negligence and strict liability were preempted for Class III devices approved by the FDA.

[3] We also recommend a repository of written materials be maintained by the device manufacturer, including copies of all outdated product literature.