

What's up, Doc? Risk Management Issues in Promotional Practices to Physicians

Transparency has become the watchword for our times. States are increasingly regulating how medical device companies can and cannot deal with the physician community. According to a national survey of doctors published in the *New England Journal of Medicine*, 94 percent of physicians have “a relationship” with the pharmaceutical, medical device or related industry. Integrated Medical Systems, a research firm in Birmingham, Ala., estimates drug companies annually spend more than \$20 billion marketing to physicians.

A consumer survey by the Pew Prescription Project showed that 68 percent of respondents support legislation that would require public disclosure of financial ties between doctors and industry. In 2003, Washington, D.C., passed a law requiring drug makers to disclose marketing expenditures to the city health department. Several states have passed or considered similar laws, some including a ban on all industry gifts to physicians.

States aren't the only entities regulating and probing the issue. The federal government is scrutinizing promotional practices toward doctors, casting wary eyes on business relationships between medical device firms and physicians. Congress shows no reluctance to subpoena medical device firms to determine what kinds of payments they made to private practice physicians, and why.

In 2009, Sen. Chuck Grassley (R-Iowa) and Sen. Herb Kohl (D-Wis.) introduced legislation—the Physician Payments Sunshine Act—that would require drug and medical device firms to report payments to any doctor of more than \$100, whether as a gift or for research, and to publish the information online. Trade associations such as the Advanced Medical Technology Association and PhRMA, both in Washington, D.C., have issued models of appropriate conduct. In product liability claims and lawsuits against life science companies,

plaintiff attorneys often argue there are ominous ties and business relationships between these companies and physicians.

Risk Management Issues

Aggressive marketing to physicians raises various questions:

- What are the risk management implications of promotional practices between medical device companies and doctors?
- What tips and tactics should device firms embrace in order to navigate the mine field?
- Is there a happy medium in reconciling legitimate promotion and doctor partnerships without risking claims of conflicting interests?

Any of these situations is fodder for personal injury attorneys to use to pursue lucrative injury claims. The personal injury bar is eager to portray medical manufacturers as greedy companies undermining doctors' objectivity through financial inducements. The latter—in the view of personal injury attorneys—include:

- Fellowships
- Royalties
- Consulting agreements
- Stocks and stock options
- Travel junkets and “educational trips”
- Freebies

For example, a lawsuit against a manufacturer of continuous passive motion devices alleged that the company gave doctors trips, cruises, money through “directorship” agreements, jewelry for wives and—for one doctor—a leased Jaguar. In another case, a large device firm allegedly zeroed in on surgeons while they were still in training, paying doctors to attend any of 200 professional meetings a year. If the doctors wanted to golf or go snorkeling, the complainant alleged that the device



Kevin Quinley

firm paid for the outings. (When doctors visited Memphis, Tenn., company employees took them to the “Platinum Plus” strip club and then wrote off the expense as an evening at the ballet.)

When injured patients file lawsuits, medical device firm managers and executives may find themselves in court having to explain, rationalize and defend the propriety of the close ties they have spent much time and money developing with physicians. After all, doctors represent the chief target market for medical device companies.

If they sequester themselves from physicians, how can they market products, educate and train doctors on proper use and get needed intelligence that result in product improvements?

Medical device firms need a risk management global positioning system (GPS) to navigate in order to find a happy medium between reasonable marketing overtures to physicians without exposing themselves to claims of co-opting the medical community or creating conflicts of interest. Since neither GPS makers Garmin nor Tom-Tom make such a product for device companies, here are seven risk management strategies:

1. Exercise care when retaining physician consultants to boost product sales and development. Clearly separate the sales function from internal testing being conducted with outside consultants. Also, exercise care when collaborating with academic centers in developing or promoting a product. Further, cover disclosure issues with physician consultants so they are well aware what needs to be divulged.

2. Involve legal and regulatory teams early. Work with in-house legal and regulatory teams to understand safe promotional activities and avoid those that invite criticism and questioning. In one case, a group of cardiovascular physicians gathered monthly for dinner and discussions. Sales reps from different medical device firms alternated picking up the dinner tab. Some discussions included mention of possible off-label device use. The fact that the device companies paid for dinner exposed them to claims of promoting off-label use. The in-house attorney restructured the arrangement so the device firm made a grant to the society that sponsored the dinners and, in her mind, this circumvented potential legal problems.

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3. Watch “detailing” visits by medical device representatives. They also are areas to monitor carefully. Nowadays, it is probably safer to avoid providing food and entertainment to physicians. Further, the practice of handing out samples will be heavily scrutinized.

4. Closely manage sales representatives in the operating room. These can represent a danger area that should be avoided. Sometimes in the event of an adverse patient outcome, allegations arise that sales reps exceeded their sales role and became unlicensed healthcare practitioners. Alternatively, there may be allegations that the sales rep gave bad advice to the physician and contributed to or caused an adverse patient outcome. In one medical malpractice lawsuit, a jury awarded more than \$480,000 against an orthopedic implant firm’s sales representative on such grounds.¹

5. Carefully operate trade show exhibit booths. These also can represent an area of marketing that is frequently under the microscope. The U.S. Food and Drug Administration and the U.S. Department of Justice conduct surveillance at such events. What are your sales reps really saying to customers in the trade show exhibit halls? Do you have products and samples available on the table when some of the physicians are attending from states that ban such practices? Do you have permis-

sible giveaways planned? Are you prepared to track and disclose such giveaways? Device company management must know in the answers to these questions and step in to take appropriate action if needed.

6. Thoroughly vet internal documents regarding sales and marketing. Hot spots for plaintiff and government fishing expeditions can include three-year business plans, publication strategies and long-term marketing plans. Have legal counsel review such documents, since these statements often make headlines and are magnified as jury exhibits in lawsuits. This caution extends to e-mails, since e-mails are like diamonds—they last forever. In one trial, a device firm’s documents contained an innocuous reference in marketing literature to “massaging the data.” By the end of trial, an observer might have thought that the case involved a physical therapy spa, given the multiple references by the plaintiff to *massaging*.

7. Be meticulously accurate in sales and marketing literature. Communications by sales and marketing personnel are particularly vulnerable to criticisms for inaccuracy. Salespeople are paid to advance the best presentation of their company’s products. Sometimes, however, a thin line separates puffery from communication that a jury could find as a material misrepresentation. Device companies often have promotional literature reviewed for accuracy by corporate counsel before it is approved for external use. However, letters, notes for e-mails by sales persons or customer service representatives often do not receive this degree of quality assurance.

Courtroom drama is better left to TV shows like “Law & Order.” Device firms should assess the risks of zealous marketing to leave such legal drama on the tube and out of their daily operational challenges. ❖

References

1. *Zappola v. Stryker Corp. et al*, Nos. 86038 and 86102, 2006 WL 1174448 (Ohio Ct. App. May 4, 2006).

Kevin Quinley is vice president of risk services for Berkley Life Sciences LLC. He is the author of 10 books, including “Managing Product Liability and Avoiding Litigation.” You can reach him at kquinley@berkleyls.com. This article, which does not purport to offer legal advice, is adapted from his September 2009 presentation at a pharma-medical device conference.