

How Far is Too Far with Marketing Promotions?



■ By John Latsko

Every business must promote its products and services if it wants to be successful, but marketing strategies that work well for other industries may be problematic if used by healthcare companies. Here are some things to look out for to keep your marketing program on the straight and narrow.

Selling requires a combination of product, reputation, customer, price, and access. Advertising and marketing play important roles in bringing a buyer and seller together, and creativity and innovation are important to successful promotions. Many use price discounts, coupons, rebates, points toward gifts such as airline tickets, entertainment, and free samples to market their products. These financial incentives can be effective in gaining sales volume and market share. Unfortunately for those in the healthcare industry, marketing programs that are successful in other industries could be illegal if used by healthcare companies.

For example, many companies like to compensate their sales staffs on a commission basis, paying their representatives a percentage-of-sales. In healthcare, this method of compensation might very well be illegal under federal antikickback laws unless it is structured to meet a safe harbor.

While the federal government continually monitors the sales and marketing methods of healthcare companies, several very large settlements over the past two years have made headlines. The four that I will review all relate to the pharmaceutical industry, but major investigations are currently under way in the medical device industry.

In the first matter, Warner-Lambert (now Pfizer) agreed to pay \$430 million in fines and plead guilty to criminal and civil charges related to its promotion of the unapproved use of one of its drugs. Warner-Lambert's marketing plan was to aggressively market the drug, Neurontin®, for "a wide array of ailments for which the drug was not approved" according to the Department of Justice (DOJ). Neurontin was approved by the Food and Drug Administration (FDA) to control seizures, but Warner-Lambert encouraged its promotion for migraines, bipolar disorder, and attention-deficit disorder, among other conditions. The pharmaceutical company sought to achieve its sales goals by encouraging its sales representatives to provide one-on-one sales pitches to physicians about the off-label use of Neurontin. Misleading statements were also alleged to have been made as to FDA approval, and questionable "experts" were used to promote the off-label use of Neurontin. The company also was accused of paying physicians to allow its sales representatives to accompany physicians on their rounds. This matter was exposed when one of the "experts" filed a whistleblower suit under the Federal False Claims Act.

In the second case, Schering-Plough agreed to settle federal civil and criminal charges for \$435 million. The DOJ alleged that Schering promoted its drug Temodar® for certain types of brain cancer for which it was not FDA-approved. The government also claimed that Schering paid illegal remuneration to physicians through "sham advisory boards" and "lavish entertainment" to encourage the use of the drugs.

Eli Lilly was fined \$36 million for the illegal promotion of its drug, Evista®. Evista was approved by the FDA for the prevention and

treatment of osteoporosis. Because of disappointing sales, Lilly was accused of marketing and promoting the drug for unapproved uses. Some of the illegal conduct alleged against Lilly included one-on-one sales pitches to physicians promoting off-label use, encouraging its sales representatives to send unsolicited letters to physicians to promote the unapproved use of Evista, organizing a "market research summit" during which Evista was discussed with physicians for unapproved uses, and organizing consultant meetings for physicians during which unapproved uses of Evista were discussed.

In a whistleblower action filed by five former sales representatives, Serono Laboratories was sued for marketing and promoting off-label use of its drug, Serostim®. The government settled with Serono for \$704 million with \$52 million of it going to the whistleblowers.

Medical Devices in the Crosshairs

In June of this year, the DOJ subpoenaed and served search warrants on DePuy, Biomed, Stryker, Zimmer Holdings, and Smith & Nephew to look at anti-competitive practices in the implant device industry and probe consulting and professional services agreements with physicians. This investigation is ongoing, and the DOJ and the Office of the Inspector General (OIG) have said that medical device manufacturers are their next target because of suspected illegal marketing programs.

Consider Your Marketing Efforts

It is illegal to offer or accept anything of value in return for a referral of a patient paid for by Medicare. Violations of the federal antikickback law are punishable by up to five years in prison, exclusion from the Medicare program, and civil federal false claims liability that can be in the millions of dollars. Every supplier of medical items that files claims with Medicare must control the sales and marketing schemes being incorporated by its representatives. The Advanced Medical Technology Association (AdvaMed) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have both adopted a code of ethics related to the interaction of sales representatives and healthcare professionals. Compliance with guidelines contained in these codes, while not a legal safe harbor, does provide relevant and important information. Marketing your company is important for survival, but you must know how far you can go. Attorneys for the DOJ estimate that there are more than 150 pending investigations going on, and they are not all with large multibillion-dollar companies. Pay attention to how your company markets itself to physicians and patients. **QUICKFIND: [EDPAP0107](#)**

John Latsko is a partner in the health law practice of Schottenstein, Zox & Dunn, Columbus, Ohio. He can be contacted at 614.462.2329; jlatsko@szd.com

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