Contributed by Brian P. Waldman


BRIAN WALDMAN

A WHOLE NEW MEANING TO JUNK MAIL

If you are depressed that the only things you seem to receive in the mail are bills, there may be a cure. Last summer, some sales representatives in southern Florida allegedly orchestrated a promotional scheme, with the cooperation of one or more physician practice groups and Walgreen Co. pharmacies, in which hundreds of consumers taking other anti-depression medications received free samples of Eli Lilly and Co.'s Prozac Weekly (fluoxetine HCl) in the mail. The recipients had not asked for the medication and it is not clear whether there were valid prescriptions for it. One recipient was so incensed that she filed a class action suit against Lilly, her physicians' practice group, and Walgreen. The Florida Attorney General's office also has initiated an investigation into the allegations. Although we may never discover the facts behind this promotional effort, it is clear that, if the allegations are true, the sales representatives, the physician group, and the pharmacy exercised poor judgment and, perhaps, even violated a number of laws.

Given the "creativity" and aggressiveness with which drug company sales representatives promote their products, in combination with increasing government scrutiny and public concern over such practices, drug manufacturers would be well-advised to monitor promotional programs carefully to ensure regulatory compliance. Violations of state/federal laws and regulations may very well result in significant damage awards, fines and penalties, and at a minimum draw increased scrutiny from regulators.

LOOK WHAT I GOT IN THE MAIL

The Florida class action alleges, among other things, that the defendants engaged in unfair, deceptive, and otherwise illegal practices that violated the consumers' privacy and right to confidentiality, and that constituted the unauthorized or unlicensed practice of medicine. According to the complaint, the Walgreen's pharmacy is alleged to have sold its customer/patient list to Lilly so that the drug company could engage in an unsolicited direct mail program of Prozac Weekly. In addition to receiving a one-month supply of the medication, the consumers received a "Dear Patient" letter from their physician. The letter stated that the product offered recipients a more convenient way to take anti-depressant medication and urged them to stop taking their current medication before starting the new product. The complaint further alleges that the pharmacy mailed the samples without receipt of a valid prescription from each patient's treating physician.

News reports suggest that the physician practice group may have provided the patient information to the Lilly sales representatives. Moreover, the "Dear Patient" letters may have been drafted by Lilly representatives without review by the physicians.

Lilly spokespersons have made clear that this was not a company-sanctioned program, but, rather, the totally unauthorized efforts of a small group of local sales representatives. The sales representatives claim to have believed that the doctors knew patients would be mailed the medicine, while physician representatives have indicated that the doctors thought drug vouchers, and not the product itself, would be mailed. Walgreen's officials claim that the pharmacy received (and filled) valid prescriptions from the treating physicians and reimbursement from Lilly.

The truth is probably somewhere in the middle.

POTENTIAL LIABILITY

Putting aside the potential liability of the physicians and the pharmacy, let me focus on the claims against Lilly.

The Florida complaint alleges that Lilly, through the actions of its sales representatives violated Florida laws by: (1) misusing private medical information for its commercial gain; (2) engaging in the unlicensed practice of medicine by coordinating the delivery of a prescription drug without a license to prescribe medication; (3) advertising a drug for the treatment of depression; (4) unlawfully distributing a drug sample; and (5) engaging in deceptive and unfair acts, including the misappropriation and misuse of confidential medical information.

The first three claims are particular to Florida state law, while the last two claims have their federal counterparts. Under both Florida law and the Federal Food, Drug, and Cosmetic Act, it is unlawful for a manufacturer to distribute a prescription drug sample to anyone other than a licensed practitioner or, at the direction of a licensed practitioner, to a pharmacy. If the Lilly representatives coordinated the delivery of the Prozac Weekly samples without a valid prescription from each recipient's treating physician, these representatives, and perhaps the company itself, may have violated both state and federal law.

Further, both Florida's Deceptive and Unfair Trade Practices Act and the Federal Trade Commission Act prohibit unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade. Lilly representatives may have violated these laws in a number of ways. For example, if the Lilly representatives obtained access to the recipient's private medical information or if they drafted the letters accompanying the samples without obtaining physician approval of the text, they (and again, also perhaps the company) could be found to have violated these consumer protection laws, particularly if allegations that the health and safety of the consumers may have been threatened can be sustained.

REMEDIAL MEASURES NOW AND IN THE FUTURE

In response to the complaint and press reports, Lilly officials took quick action. First, the company made clear that the mailings were against company policy. Second, Lilly took disciplinary action against eight employees allegedly involved in the promotional effort — including (if press reports are to be believed) suspending several and firing at

least one. Further, in September, in response to the Florida lawsuit and Attorney General's investigation, as well as to a Federal investigation into the company's possible off-label promotion of Evista as a breast cancer preventative, Lilly announced that it was creating a new executive level position — VP and chief compliance officer — to oversee regulatory issues.

Aggressive promotional practices are inevitable when a sales representative's income is tied to his or her level of sales. While such a method of compensation is generally accepted in most other segments of the marketplace, when prescription drugs are involved, the level of company oversight must increase to prevent abuse and exposure to liability. If, in the past, drug company management concluded that a wink and nudge to sales representatives was in the company's best financial interest, it may now be time to revisit that policy. Federal and state authorities are becoming very active at taking a closer look at overly aggressive marketing practices and the tide of public opinion may be turning more rapidly against drug companies, particularly when privacy issues are involved. While promotional activities should continue to enjoy a certain level of 1st Amendment protection and consumer support, overly aggressive promotional practices may now expose a company to significant financial and regulatory risk and, at a minimum, draw increased scrutiny from law enforcement officials.

To protect themselves, drug manufacturers would be well-advised to create, as Lilly has, a senior-level management position with responsibility for ensuring regulatory compliance. This person's compensation should never be tied to sales or marketing goals or achievements. Further, the manufacturers should have clear and unambiguous policies and procedures covering promotional activities. Regular and substantive compliance training classes for sales representatives can minimize the use of promotional efforts inconsistent with these policies and procedures. Swift and severe disciplinary actions against sales representatives who violate these policies and procedures also may curb the actions of rogue sales representatives. Finally, drug manufacturers may want to consider expanding their practices, if they have not already done so, to implement a pre-approval requirement for all new promotional programs.

And you thought you were depressed.

Brian Waldman heads Arent Fox Kintner Plotkin & Kahn, PLLC's Food & Drug Group located in Washington, D.C. ✦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmalinx.com.