

commitment to training and monitoring its sales force. A pharmaceutical manufacturer should: (i) Develop a regular and comprehensive training program for its sales force, including refresher and updated training on a regular basis, either in person or through newsletters, memoranda, or the like; (ii) familiarize its sales force with the minimum PhRMA Code standards and other relevant industry standards; (iii) institute and implement corrective action and disciplinary policies applicable to sales agents who engage in improper marketing; (iv) avail itself of the advisory opinion process if it has questions about particular practices used by its sales force; and (v) establish an effective system for tracking, compiling, and reviewing information about sales force activities, including, if appropriate, random spot checking.

In addition, manufacturers should carefully review their compensation arrangements with sales agents. Sales agents, whether employees or independent contractors, are paid to recommend and arrange for the purchase of the items or services they offer for sale on behalf of the pharmaceutical manufacturer they represent. Many arrangements can be structured to fit in the employment or personal services safe harbor. Arrangements that cannot fit into a safe harbor should be carefully reviewed. Among the factors that should be evaluated are:

- The amount of compensation;
- The identity of the sales agent engaged in the marketing or promotional activity (e.g., is the agent a "white coat" marketer or otherwise in a position of exceptional influence);
- The sales agent's relationship with his or her audience;
- The nature of the marketing or promotional activity;
- The item or service being promoted or marketed; and
- The composition of the target audience.

Manufacturers should be aware that a compensation arrangement with a sales agent that fits in a safe harbor can still be evidence of a manufacturer's improper intent when evaluating the legality of the manufacturer's relationships with persons in a position to influence business for the manufacturer. For example, if a manufacturer provides sales employees with extraordinary incentive bonuses and expense accounts, there may well be an inference to be drawn that the manufacturer intentionally motivated the sales force to induce sales through lavish entertainment or other remuneration.

c. Drug Samples. The provision of drug samples is a widespread industry practice that can benefit patients, but can also be an area of potential risk to a pharmaceutical manufacturer. The Prescription Drug Marketing Act of 1987 (PDMA) governs the distribution of drug samples and forbids their sale. 21 U.S.C. 353(c)(1). A drug sample is defined to be a unit of the drug "that is not intended to be sold * * * and is intended to promote the sale of the drug." 21 U.S.C. 353(c)(1). Failure to comply with the requirements of PDMA can result in sanctions. In some circumstances, if the samples have monetary value to the recipient (e.g., a physician) and are used to treat federal health care program beneficiaries, the improper use of samples may also trigger liability under other statutes, including the False Claims Act and the anti-kickback statute.

Pharmaceutical manufacturers should closely follow the PDMA requirements (including all documentation requirements). In addition, manufacturers can minimize their risk of liability by: (i) Training their sales force to inform sample recipients in a meaningful manner that samples may not be sold or billed (thus vitiating any monetary value of the sample); (ii) clearly and conspicuously labeling individual samples as units that may not be sold (thus minimizing the ability of recipients to advertently or inadvertently commingle samples with purchased product); and (iii) including on packaging and any documentation related to the samples (such as shipping notices or invoices) a clear and conspicuous notice that the samples are subject to PDMA and may not be sold. Recent government enforcement activity has focused on instances in which drug samples were provided to physicians who, in turn, sold them to the patient or billed them to the federal health care programs on behalf of the patient.

C. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every pharmaceutical manufacturer should designate a compliance officer to serve as the focal point for compliance activities.¹² This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the company and the complexity of the task. If the individual has additional management responsibilities, the pharmaceutical manufacturer should ensure that the individual is able to dedicate adequate and substantive time and attention to the compliance functions. Similarly, if the compliance

officer delegates some of the compliance duties, he or she should, nonetheless, remain sufficiently involved to fulfill the compliance oversight function.

Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official with direct access to the company's president or CEO, board of directors, all other senior management, and legal counsel. The compliance officer should have sufficient funding, resources, and staff to perform his or her responsibilities fully. The compliance officer should be able to effectuate change within the organization as necessary or appropriate and to exercise independent judgment. Optimal placement of the compliance officer within the organization will vary according to the particular situation of a manufacturer.¹³

Coordination and communication with other appropriate individuals or business units are the key functions of the compliance officer with regard to planning, implementing or enhancing, and monitoring the compliance program. The compliance officer's primary responsibilities should include:

- Overseeing and monitoring implementation of the compliance program;¹⁴
- Reporting on a regular basis to the company's board of directors, CEO or president, and compliance committee (if applicable) on compliance matters and assisting these individuals or groups to establish methods to reduce the company's vulnerability to fraud and abuse;
- Periodically revising the compliance program, as appropriate, to respond to changes in the company's needs and applicable federal health care program requirements, identified weakness in the compliance program, or identified systemic patterns of noncompliance;
- Developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeking to ensure that all affected employees and management understand and comply with pertinent federal and state standards;
- Ensuring that independent contractors and agents, particularly those agents and contractors who are involved in sales and marketing activities, are aware of the requirements of the company's compliance program with respect to sales and marketing activities, among other things;
- Coordinating personnel issues with the company's Human Resources/