

5TH ANNUAL NATIONAL CONGRESS ON HEALTH CARE COMPLIANCE

February 6-8, 2002

Washington, D.C.

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**Pharmaceutical Sales and Marketing Compliance:
Are You Afraid to Look Under That Rock?**

Twelve Key Tips To Achieve Effective Training To Pharma Sales and Marketing Personnel

1. **Train. Train. Train.** Train frequently. A company can never do too much compliance training. Prioritize the compliance training focus according to hot topics. For training of the sales/marketing staff, in particular, training should not only be done frequently but also be done in the flesh. Effective training of sales/marketing staff needs some time for the human touch, including time for informal communications with the trainer. There needs to be plenty of time for Q's and A's as well as role-playing. Often, relevant compliance issues will percolate during these in-person-training sessions and side bar conversations.
2. **Document. Document. Document.** Document the training activities and create an archive system that withstands staff changes. The training documentation system needs to become formal institutional memory which is an asset to the company. Remember, if the training is not documented, it did not happen, especially as far as some third parties are concerned.

* These tips were developed with the assistance of Liz Lewis (llewis@ebglaw.com) and Wendy Goldstein (wgoldstein@ebglaw.com). Ms. Lewis and Ms. Goldstein co-chair the EBG's Pharmaceutical Industry Health Regulatory Practice Group. This Practice Group represents all sectors of the pharmaceutical industry including, but not limited to, pharmaceutical manufacturers, pharmacy benefit managers, managed care organizations, as well as retail, mail order and specialty pharmacies.

3. **Seize the Day.** Tell your sales/marketing staff that sales/marketing in the pharma industry is a regulated activity. It is regulated not only by the FDA, but also by the federal and state fraud and abuse laws and Medicaid Drug Rebate law. Also, for those seasoned health care marketing/sales staff, tell them to stop living in the past because past practices may no longer be permitted. This is an area of compliance that is dynamic.

4. **Call It What It Is.** Clearly identify the financial relationship between pharma and physician or pharma and customer or pharma and payor. A discount is a discount, a grant is a grant and a personal services contract is a personal services contract. Be sure the sales/marketing staff know the difference.

5. **No Strings Attached?????** An “unrestricted” educational grant is not totally unrestricted. The term refers to limitations on what the pharma company may do regarding the content of a CME educational program.

6. **Bad Intent Corrupts Good Paper.** Make it clear that “winks” and “nods” are impermissible if they reflect improper or noncompliant conduct even if the paperwork reflects appropriate conduct. The government (and whistleblowers) can use oral testimony to establish a case—not just documentation.

7. **Beware of the Cumulative Effect of Financial Relationships.** The government considers a pharma company to be a monolith and that all employees are acting in concert. Yet, companies often have multiple activities underway as to the same customer. Multiple and uncoordinated financial relationships by the sales/marketing staff could add up to significant funds which—in the aggregate—never would have been approved.

8. **But Everybody’s Doing It!** This is never a justification for permitting conduct which could be risky. Also, train your marketing/sales staff to get the details about competitive “misbehavior” before determining if it is advisable to follow the pack. And, of course, if it is too good to be true, then it probably is.

9. **Risky Business.** One business's tolerance for risk is only one business's tolerance for risk. Much of the business conduct is likely to fall into a legal gray area. Some companies are willing to operate gray towards white (compliance) while other companies are willing to operate gray towards black (noncompliance).
10. **Downsides and Upsides.** Train your sales/marketing staff that no promotional activity is better than bad promotional activity — and that the senior executives **really mean it!** The downside from noncompliance could be a lot worse than the anticipated sales upside.
11. **Big Brother.** Train your sales/marketing staff to ask questions from legal counsel and that such questions are **REALLY** encouraged. Legal review is better than IRO review. Who would you prefer to have looking over your shoulder?
12. **Beware of the Knock.** Educate all employees, especially the sales/marketing staff, as to what constitutes a “knock at the door” by the federal or state government so that they are prepared to contact counsel once a ‘knock’ occurs. Consider using wallet cards. With the increasing use of whistleblower-generated lawsuits and investigations, the company may not receive a subpoena or be served a complaint for a very long time. Indeed, government contacts may begin with former employees who may share the contact information with current employees. Also, the “knock” may end up being about a current employee's former employer. Always let your employees feel “at home” calling counsel or senior management about **ANY** government “knock.

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