

REGULATORY COMPLIANCE LITERACY: AN ESSENTIAL PART OF THE RISK MANAGEMENT FORMULA

Industry Is Only as Compliant as the Weakest Link in the Chain Reality Check

The updated PhRMA Code, now in effect, increases regulatory compliance pressure on companies. The Code's newest provision is clear: Any person or organization engaged in drug promotion, including communication agencies hired by drug and device companies, is accountable for upholding compliance when executing promotional tactics.

Advertising, promotional med ed and PR continue to be the subject of intense regulatory scrutiny as both the FDA and the Department of Justice (DOJ) take enforcement and legal actions against companies believed to be engaged in off-label promotion.

Press releases in particular are ripe for enforcement, as they are publicly available on the Internet. A release was the basis for a government settlement with InterMune, and for the indictment of its CEO. The files of communications agencies have been and continue to be subpoenaed (including boxes of e-mails).

Getting Everyone on the Same Baseline

Not all agency professionals are equipped for this sea change. The simple reason: until now, there has been no standardized, systematic, and comprehensive training customized to the four main communication channels – advertising, promotional medical education, PR and managed care. On the whole, regulatory thought leaders lack confidence in their agencies' level of regulatory understanding. Senior agency management must make four fundamental shifts to address the current climate:

Face Up to the Gap

Industry cannot delay its assessment of regulatory compliance literacy among agency professionals. A free test (5 questions) is available that quickly provides the initial data needed to identify any gaps.

Reprioritize

In today's economy, belts are being tightened. Even so, both agency and corporate management must recognize regulatory compliance as a training priority and invest accordingly. Sales reps are trained and tested periodically to ensure their knowledge of government requirements and voluntary codes. Agency professionals should follow suit.

Cultivate a New Culture

Agencies must ask themselves: Am I abdicating responsibility for regulatory compliance to my clients? And clients must decide whether to require that agencies invest in regulatory compliance training apart from company-provided information. Several pharmaceutical companies have done just that, recognizing the value of working with regulatory-savvy agency teams.

Conduct a Risk-Benefit Analysis

For agencies, will it simply boil down to a client mandate or, worse yet, an indictment, before regulatory compliance is taken seriously? This is hardly an optimal risk-management strategy. Whistleblowers increase everyone's vulnerability: 200+ cases await settlement. There already have been billions in fines and personal indictments ... and the DOJ position is that industry is not doing enough. Some agencies have decided to be proactive. What is everyone else waiting for? It's time to set a new standard related to this issue – *before one is set for us!* Should we be afraid? The reality: rules are constantly changing, and the consequences of noncompliance are severe – for clients and, now, for their agencies. Should we be paralyzed with fear? Absolutely not – we must learn how to be creative in a more regulated environment. We cannot maintain the status quo! Healthcare communicators can take simple, affordable, and actionable steps to reduce risk and increase credibility. Only professionals credentialed in regulatory compliance should be involved and driving the communication train. Noncompliance? Not on our watch! It's time for the agencies to step up.