

Experts outline five steps to help minimize risk from poor supplier literacy

Industry is only as compliant as the weakest link in the chain, say FDA veterans

As the government expands the scope of its pharmaceutical fraud investigations, untrained communications agencies are becoming an increasing liability for the industry, according to several experts in this area.

It is not uncommon for the files of communications agencies, including boxes of e-mails, to be subpoenaed, as part of the government's numerous off-label investigations, says **Michael Misocky**, a former FDA attorney and industry compliance officer. In fact, a press release, likely created by a third-party PR agency, was the basis for the government's investigation of InterMune and the CEO's subsequent indictment, he points out.

This underlines the need for a new emphasis on the level of regulatory compliance that drug companies maintain with third parties, including communications agencies, says **Wayne Pines**, president of regulatory services and healthcare at APCO Worldwide in Washington, D.C. Further evidence of this imperative, says Pines, is a new provision in the revised PhRMA Code, which puts a new focus on agencies by stating that promotional materials provided to healthcare professionals by or on behalf of a company should be accurate and not misleading. "Any person or organization engaged in drug promotion, including communication agencies hired by drug, biotech and device companies, is accountable for upholding compliance when executing promotional tactics," says Pines.

Suppliers can be "Achilles Heel" of compliance

According to Pines, a former FDA associate commissioner for public affairs, compliance officers within drug and device companies must ensure that all communication agencies working for their company are trained in regulatory compliance. "Failure to ensure that communications agencies are properly trained puts companies at unnecessary risk of non-compliance with federal and state requirements," he warns.

On the whole, regulatory thought leaders in the industry appear to lack confidence in their agencies' level of regulatory understanding, according to a preliminary survey conducted by Rx Compliance Report.

Establish a baseline level of competency.

Experts in this area say drug and device companies can implement several steps to minimize their risk from poor supplier literacy:

1. Make compliance a business imperative

It is not only the compliance and regulatory functions within drug and device companies that bear responsibility for monitoring the practices of the company's business operations, says Misocky. Rather, he says, there must be support at every level of the business to maintain a vigilant watch over marketing practices. "It is easy for well-intentioned employees or vendors to execute non-compliant materials on an individual basis," he warns. "Collectively, these minor infractions can become the basis for an indictment."

2. Bring marketing and procurement on board

The benefits of agencies submitting compliant materials the first time around are financial, promotional, and operational, says Misocky. Campaigns get into the field more quickly this way and agencies do not have to continue to redo non-compliant materials, which is inefficient and costly for all parties, he explains.

"Regulatory compliance competency is a win-win for everyone involved because it leads to the creation of high impact promotion that is accurate and balanced," says regulatory expert **Lucy Rose** of Lucy Rose and Associates. "A 'team' regulatory approach leads to a better functioning operation—more productive meetings, programs and materials with longer shelf-lives, and great ideas that see the light of day," she says.

Misocky says procurement departments should build compliance requirements into the agency-of-record contract as a standard operating best practice. This can prevent regulatory departments from wasting valuable time correcting violative materials or programs submitted by untrained agencies, he says.

3. Mandate training and certification

According to Pines, expansion of current compliance training programs to include competency tests for both employees and external partners is another step companies should consider as part of their effort to instill and maintain a culture of compliance throughout their company.

Ilyssa Levins, founder and president of the Center for Communication Compliance (CCC), says the optimal regulatory compliance solution for agencies should reflect what federal and state laws and voluntary industry codes require, based on a consensus perspective of experienced experts. In addition, she says, the content must be directly job-relevant and readily available online.

Levins' firm has developed such a program to train and certify promotional communications agencies that work with drug and device companies. Simply put, says Levins, integrating training with a certification process increases a company's confidence that regulatory literacy objectives have been met. CCC also offers customized online sales and internal training services, as well as online coursework in drug development in both the U.S. and abroad.

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4. Prepare for agency pushback

Levins says there may be "pushback" from communications agencies that are reluctant to acknowledge their staff is not up to speed on regulatory requirements. Moreover, she says, agencies that have received general client training may deem that adequate while others may contend that creativity is curtailed in a regulated climate.

“Clearly, creativity in promotional materials and tactics is critical,” says Misocky, “but some materials and programs are so far removed from being compliant upon submission that they create extra work for everyone involved, increase costs, waste valuable time, and potentially elevate risk.” He says a client mandate for training and certification on the part of promotional agencies is one of the most practical solutions to avoid these problems.

Pines, who chairs CCC’s Advisory Board, takes a similar view. “Like sales reps that are trained and tested periodically to ensure knowledge of government requirements and voluntary codes, agency professionals should follow suit.”

5. Track ongoing commitment

Levins says companies can use a template letter to secure agencies’ written confirmation that they will train and certify all staffers who are involved in promotional efforts or are developing promotional materials on their behalf. Each agency would be required to confirm this annually in writing, she says.

According to Levins, CCC also provides “backdoor access” to its training and certification database, if a company wishes to monitor and track their agencies’ training and certification efforts. Account-specific reports are available that detail these activities by product brand, agency, communication channel.

“CCC’s training and certification costs industry nothing,” says Levins, “as agencies should invest in training and certification as part of their own SOPs.”

“Failure to ensure that communications agencies are properly trained puts companies at unnecessary risk of non-compliance with federal and state requirements,” warns industry veteran Wayne Pines.

Tide begins to turn

According to Levins, many agencies may be abdicating responsibility for regulatory compliance to their clients. However, the tide may be turning, she adds. For example, Diversified Agency Services (DAS), a division of Omnicom Group, has committed to certify their senior team of integrated healthcare strategists in diverse communications channels, which distinguishes DAS as the first holding company to help set a new standard in regulatory compliance literacy.

Compliance training is an important strategic investment for agencies as well as drug and device companies, says DAS Healthcare President **Rob Dhoble**. “It’s time for all of us to take responsibility for developing communications with proper understanding of the complex regulatory environment.”

Weber Shandwick’s healthcare practice has committed to train and certify its entire U.S. public relations staff. The New York office of Porter Novelli is following suit. Euro RSCG Worldwide PR is training one of its largest account groups. The Reilly Group, a boutique group, requires everyone working with its pharma clients to be trained and certified. Lippe Taylor and Chamberlain are also among the growing list of firms taking part in compliance training.

In addition, IMSCI, a global medical education company in Connecticut, has signed on to train and certify its staff, a move that complements a significant investment in compliance-enhancing programs. Likewise, New Jersey-based Integrated Communications Corp (ICC), has invested in regulatory compliance training for its entire team in both advertising and promotional medical education, from senior management to the most junior staffer.

For more information on CCC’s certification program, visit: www.communicationcompliance.com