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Playing by the rules

Doing the right thing has taken on a new meaning for healthcare public relations professionals when it comes to regulatory compliance. That's because doing the wrong thing no longer means you only receive a warning letter from the Food and Drug Administration (FDA).

Non-compliant pharmaceutical and medical device companies and their PR agencies can face criminal prosecution, corporate integrity agreements, negative media attention, loss of business, damage to reputation and high legal fees. The amount paid by the pharmaceutical industry in the past five years for cases brought by the government now totals well over \$3b. US Justice Department attorneys have said that at least 150 and perhaps as many as 500 investigations are now underway involving pharmaceutical companies. In the next few years, we are going to see many more announcements by companies whose drug promotion or pricing policies have been challenged.



When companies settle these cases, which they almost always do, they sign corporate integrity agreements that require them to adopt new internal policies and procedures to follow the rules. The compliance programs are the responsibility of senior management.

PR professionals are right in the middle of this new trend. They not only have to explain the impact of the compliance programs to both external and internal audiences, but they also must adhere to the new rules themselves, when it comes to product claims and promotion.

That's why public relations professionals must join together in establishing and adhering to best practices in regulatory compliance. With 82 percent of PR agencies expecting growth in gross billings in 2006 (HCA Benchmarking Survey), all eyes are on our discipline as PR gains a greater share in the pharmaceutical communications mix.

Key steps

There are six key steps to achieving best practices in regulatory compliance:

Step 1: Align regulatory and PR professionals

The first step for regulatory experts and public

Take This Test

How ready are you to face the regulatory compliance challenges of today? Take this test and see.

relations professionals is to collaborate more closely as government scrutiny of PR programs increases. In fact, there has never been a better time to forge close working partnerships between company regulatory and PR professionals, and their external PR agencies.

Regulatory experts seem to be open to learning more about the PR discipline and the tools of our trade. They need to be, because many of the rules established by the government as part of the settlement agreements involve PR.

Mutual understanding between regulatory professionals and PR experts should lead to productive rather than antagonistic conversations. To truly collaborate, we must all speak the same language. This can be accomplished through facilitated alignment meetings that foster a dialogue between company regulatory experts, PR executives and their PR agencies.

Representatives from all disciplines should agree on their basic approach and policies, and also on some of the basic components of what they do, such as the wording of the boilerplate paragraph at the end of every release. The `what' and `why' behind PR decisions and programs need to be commonly understood. Regulatory officials should share their own examples of concerns and what they define as compliant.

In short, there needs to be consensus upfront so that all participants - regulatory experts, internal PR staff, and outside PR advisors and agencies - understand their roles and responsibilities.

Step 2: Create a culture of compliance

In today's environment, PR departments and agencies should establish their own internal credo to prevent, detect and resolve regulatory compliance problems.

Cementing credibility for a PR or marketing department within a company revolves around the ability to bring forward for internal review press materials and program ideas that are in compliance. For a PR agency, there's nothing more frustrating than presenting a theme, program or language that is, ultimately, considered in violation of the regulations by the client.

But wasted time and effort on an aborted initiative is a small penalty compared to losing business to an agency that has a deeper regulatory know-how, or to losing departmental credibility within a company.

In this day and age, regulatory savvy is a competitive advantage. PR professionals who understand the rules and present concepts that are both effective from a communications standpoint and compliant are positioned to earn the respect of their colleagues and peers.

1. You have been asked to recommend medical meeting premiums. Can you:

- Offer media training to entice MDs to cocktails?
- Create clever CD for booth give-away?
- Hold a raffle at the booth for an evening sail if there will be some education provided on the boat?

2. Your campaign pays a celebrity to promote your product. Do you need to discuss the financial relationship?

3. A patient is willing to talk about personal experience with disease and company's drug. Can he/she say anything?

4. The throw-away: A product has been approved for marketing – which of the following materials need to adhere to labeling?

- Press release
- Video news release
- Spokespeople quotes.

Answers
 1a: No
 1b: Only if the information on the CD will benefit the patient
 1c: No
 2: Yes
 3: No; patient and comments must be typical and within labeling
 4a-c: Yes to all.

Step 3: Establish systems and oversight

An infrastructure must be created for proper regulatory and legal review of all programs and materials. Before a PR agency proposes that 'big idea' or sends a press release to any of its clients, the documents should be correctly vetted for regulatory compliance.

This means that all materials must not only be accurate, but also contain fair balance and disclosure, as well as all disclaimers. It is tricky these days to write a press release that is in full compliance. In some situations, PR agencies may want to seek spot counsel from a regulatory communications expert.

This more compliant approach does add an extra step to business operations, and may be considered a new challenge.

Senior managers need to make clear their absolute commitment to assuring that all materials are reviewed professionally for regulatory compliance before they move to the next tier.

To support the new culture, leadership will need to create a line item in the agency's budget to ensure the development and upkeep of these systems.

Step 4: Make compliance education part of professional development

Ongoing internal education for executive, senior and mid-level staffers in both PR departments and agencies is critical to assure that their regulatory knowledge is current. It's not enough to have only one or two individuals in-house who understand regulatory matters. All staff should be schooled on the basics, with management taking additional time to further expand their own level of knowledge.

Agencies cannot simply rely on their clients' internal legal and regulatory clearances when honing their regulatory compliance skills. It's true that every pharma company, without exception, has an internal review process for promotional materials, including technical, legal and regulatory reviews. But not every company has the internal expertise to conduct proper reviews, especially the smaller firms. And clearly, many violations get past the internal systems - which is why there are so many FDA enforcement actions, with 2005 setting an all-time high for warning letters, and so many investigations going on.

Internal education also needs to be repeated. The rules about what is, and is not, in compliance often change. It is important to keep track of the enforcement actions that other companies receive.

Step 5: Get certified

There is a movement toward the establishment of standards for compliance certification, which would quickly become a mandatory criterion for PR agency selection by pharmaceutical companies.

There's no question that PR professionals must demonstrate competence in the constantly changing and evolving rules from the FDA, the Office of Inspector General in the Department of Health and Human Services, the Accreditation Council for Continuing Medical Education (ACCME), and the Pharmaceutical Research and Manufacturers of America (PhRMA). Most PR professionals do not have the degree of regulatory expertise necessary to protect their clients' or their own reputations. With Medicare Part D having been implemented as of January 1, not only will the marketplace become more competitive on a price basis, but the government will also become by far the biggest source of revenue, further increasing scrutiny over promotional practices.

We work within a unique industry where we are expected to meet a higher standard than other communications agencies, except those that represent clients in financial circles. Spotty staff savvy is not sufficient.

As PR professionals, we must protect our industry's reputation, and that means preventing the likelihood of any regulatory violations. Compliance know-how is clearly an important step to take to help restore trust in the pharmaceutical industry.

In addition to avoiding legal penalties, regulatory compliance ensures that messages that are delivered through the media to our family members, friends, and colleagues are fairly balanced and don't create false hope.

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