



Conflicts
of Interest

Andy Bender and Noah Shannon

The Firewall Mandate



Vendors must establish boundaries between CME and promotion.

Last year, ten investment banks paid a \$1.4 billion settlement to New York State for failing to keep appropriate barriers between their equity analysts and investment bankers. Equity analysts, the supposedly unbiased researchers of publicly traded companies, had been pressured into skewing their advice to reflect the demands of investment bankers, the marketing and sales side. The banking industry's firewall had failed.

A similar issue lurks within the pharmaceutical industry. When meeting planning companies or advertising agencies provide both continuing medical education (CME) and promotional programs for the same brand team, conflicts of interest are inevitable. This article maintains that to avoid those conflicts—and the penalties that go with them—vendors must put up a firewall between CME and advertising. Without that barrier, accredited providers and pharma companies are exposed to risks similar to those of investment banks. But there is one big difference: Pharma can prevent the problem by addressing it now.

This article provides a framework in which pharma companies can recognize conflicts of interest and the associated regulatory risks. It also offers tactical advice on how to avoid, and if necessary remedy, areas of potential liability. Additionally, the article shows pharma companies how to identify and overcome compliance problems with their vendors.

THE BIG SHIFT

New developments in the industry could make things worse before they get better. In response to new promotional guidelines from both the Pharmaceutical Research and Manufacturers

of America (PhRMA) and the Office of the Inspector General (OIG), pharma companies are redirecting promotional funds toward CME and an increasing number of vendors are seeking accreditation. As one industry executive says, “With a shift in budgets from promotion to CME comes additional responsibility to make sure that we stay compliant.” CME is a \$2 billion-dollar-a-year industry, and its executives must develop new ways of dealing with the issues that threaten it.

Accreditation Council for CME (ACCME) guidelines require that CME be “fair and balanced” and “independent from commercial bias.” The principle behind ACCME’s Standards for Commercial Support of Continuing Medical Education is that CME must be designed with the central goal of “enhancing the physician’s ability to care for patients.” Furthermore, CME must be “free of commercial bias for or against any product.” Although

ACCME acknowledges that financial support from commercial organizations can contribute to the quality of CME activities, it is also aware of the risk of sponsors misusing or presenting biased CME for their own promotional benefit.

Some pharma companies have yet to recognize that there is an issue and are still operating under false assumptions. As one product director recently—and mistakenly—said, “We are a non-US based pharma company. US laws do not apply to how we market our products in the United States.” And according to another misinformed product manager, “We outsource all our CME programs to vendors, who are therefore responsible for executing these programs in a compliant manner.”

WHERE IS THE LINE?

To prevent conflicts of interest, companies must first understand how and where they occur. A look at some cases clarifies ambiguous situations.

Medical writers. A vendor’s lead writer has spent years developing promotional content for a successful selective serotonin reuptake inhibitor. The drug’s brand team, impressed with the content, recommends that the writer contribute to an upcoming CME initiative. The writer is familiar with ACCME rules and understands that the content she creates must be free of commercial bias. Does this situation constitute a potential conflict of interest? Could the writer be, or appear to be, biased because of her client’s promotional interest?

The answer is “yes.” Although the conflict may not be visible to the writer, she may inadvertently bias her material simply because of her experience with, and knowledge of, the promotional content. Or she may deliberately present the content in a way that promotes her client’s financial interests. Either way, to eliminate the risk, vendors should allow writers to develop CME only for content areas unrelated to their promotional activities. (See “Vendors’ Brand Choices.”)

Account executives. A pharma company’s brand team selects a single vendor to handle its promotional and CME activities for its new pain medication. One vendor account executive is the primary point of contact with the pharma company, and the same agency meeting planners are used for both the promotional and the CME events. One day a meeting planner receives a call from a company sales rep. The rep asks whether the meeting planner can provide a list of physicians who have registered for an upcoming CME event. The meeting planner is not sure how to respond to the request and asks the account executive for direction. The meeting planner is concerned that failing to fulfill the sales rep’s request will result in a poor year-end evaluation for her company. How should the account

Vendors’ Brand Choices

Having one person work on both CME and promotion for the same brand is always a “no no.”

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* Unless the provider can demonstrate that there are clear firewalls between shareholders and management and content developers and project managers and meeting planners.

The Firewall Mandate

executive answer the request?

The account executive and meeting planner are in a precarious position. They have an incentive to help the sales rep because of their promotional relationship with the pharma company. On the other hand, the rep could use the list inappropriately, such as to recruit physicians to show up for a promotional event, which may threaten the CME program's independence. The company can avoid the situation by using separate account execs for CME and promotional activities and by having a signed vendor/client agreement that includes non-commercial and non-marketing "terms of use" for any information generated.

Both examples describe common day-to-day situations that could easily lead to a conflict of interest—cases in which individuals' financial or career interests affect their commitment to maintaining the integrity of CME. In both cases it would be difficult to defend the notion of complete independence because as one industry executive

says, "The appearance of a conflict of interest is as much an issue as the existence of one."

To ensure compliance, pharma companies and accredited providers must understand the issue's complexities and create the appropriate firewalls. The obligation falls to both vendor and client, and each has unique responsibilities.

PHARMA'S ROLE

In-house marketing teams bear the primary responsibility for erecting and maintaining firewalls. In the words of one executive, "We have to set clear guidelines for our brand teams and vendors. We are ultimately responsible. It's not the vendor who will make the cover of the newspaper when something goes wrong." Marketing departments must establish appropriate barriers and procedures within their own frameworks and require that vendors do the same. To maintain a durable internal firewall, consider the following guidelines:

Separate. Separate. Separate. Main-

tain an organizational structure that divides responsibility for CME and promotional activities. One individual within one brand should not be the decision maker for both CME and promotional programs. By separating the two, the vendor's account executive (if there is only one) will report to different people in the pharma company for CME and promotional programs.

Get proof. Ask CME providers to demonstrate that they have firewalls between CME and promotional units. To test those barriers, pharma companies can give CME providers case studies in which a conflict of interest might arise and ask how they would respond. In addition, the pharma company can audit the CME programs for compliance. Although that may strain long-term vendor relationships, it can pay dividends in avoided liability concerns.

Be diligent. Set up an internal process to ensure ongoing compliance. Three steps will do the job:

- ◆ Set a corporate firewall policy.
- ◆ Communicate the policy internally and with vendors through training.
- ◆ Audit internal personnel and vendors to ensure compliance.

Communicating the policy drives employee and vendor behavior, and periodic auditing shows commitment and helps identify trouble areas and willful non-compliance.

Although those guidelines seem simple, some organizations find them more difficult to follow than others do. Small or single-product pharma companies may have a hard time with the first guideline because decision-making power for selecting CME and promotional vendors typically lies with a single person. Companies that have had long-term relationships with vendors may find it difficult to mandate the second guideline because of concerns about damaging those relationships. But both issues can be overcome. ➤

The Firewall Structure

Separate	Separate	Shared
<p>Management Team (CEOs, VPs)</p> <p>Conflicts arise from competing</p> <ul style="list-style-type: none"> • customer satisfaction issues • interest in ongoing project sales 	<p>Content Developers (writers, editors)</p> <p>Conflicts nearly impossible to avoid because</p> <ul style="list-style-type: none"> • messages are inherently similar • inadvertent bias is a natural risk 	<p>Administrative Support (finance, human resources)</p> <p>The risk is relatively low for conflicts, because</p> <ul style="list-style-type: none"> • staff has limited exposure to content developers • staff has no influence on content
<p>Project Team (account executives, meeting planners)</p> <p>Conflicts arise from competing</p> <ul style="list-style-type: none"> • customer satisfaction issues • desires to enhance overall company results • interest in ongoing project sales 	<p>Infrastructure (physical locations, IT networks)</p> <p>Without firewalls, the risk is high for</p> <ul style="list-style-type: none"> • sharing content • bias resulting from staff's "cross-pollination" 	<p>Stakeholders (owners, shareholders)</p> <p>Conflicts rarely arise, unless they</p> <ul style="list-style-type: none"> • are involved in management • have exposure to content

Source: Polaris Management Partners.



Vendors must separate any staff members involved in CME content development. Other employees and shareholders pose little threat of conflicts of interest.

Small companies with one key decision maker per brand should document a comprehensive and transparent process for vendor selection and management, showing that they have the tools to maintain balance. Using corporate guidelines to enforce rules for vendor firewalls helps vendors see that practice as a top-down requirement instead of a targeted affront.

CME PROVIDERS' ROLE

Although some pharma companies have decided not to contract with CME

FIREWALL CHECKLIST

Pharma companies (internal audit)

- ▶ Employ different decision makers for CME and promotion for a given brand.
- ▶ Contract exclusively with CME providers that have demonstrated firewalls.
- ▶ Set and communicate a corporate firewall compliance policy and conduct periodic audits to ensure adoption.

CME Providers (external audit)

- If a single company provides CME and promotional services, the two business units must have separate
- ▶ physical locations
 - ▶ IT systems
 - ▶ writers and content developers
 - ▶ meeting planners
 - ▶ account executives
 - ▶ management teams.

firms that are owned by an advertising agency or meeting planning company, that may be an excessive response to limiting risk. But it is important to find an agency that takes the proper steps to minimize conflicts of interest. If a single company provides CME and promotional services, the two businesses should be prepared to demonstrate the separation between

- ◆ senior management (involved in content and business development)
- ◆ CME and promotional medical writers
- ◆ sales staff, account managers, and project managers
- ◆ meeting planners (who work on both CME and promotional assignments for the same brand team)
- ◆ IT systems (access to shared servers and networks).

If vendors house their promotional and CME businesses at separate locations it strengthens the separation argument. (See "The Firewall Structure," page 24.) But there can be overlap when it comes to

- ◆ shareholders—as long as they are not involved in the day-to-day management of both the CME and promotional teams and are not involved in business development for both promo and CME of the same brand
- ◆ non-content-related support staff such as finance, accounting, and human resources departments.

It is clear that, under certain circumstances, staff at almost every level can have a conflict of interest if they work on both CME and promotional programs for the same brand team. Therefore, firewalls must be defined throughout the entire vendor organization, from meeting planner to account executive to shareholder. Although meeting planners may not have a direct financial incentive to stand in the way of CME independence, their career prospects and, potentially, their compensation are directly tied to customer satisfaction.

By maintaining separate meeting planning staffs, vendors can keep their planners focused on projects and adherence to guidelines rather than distracted by potential conflicts.

PHARMA FIRST

Many vendors are waiting for direction from their pharma clients before they start reorganizing their own organizations. Vendors have an independent interest in compliance, but they may be reluctant to invest in it unless their clients demand that they do. The president of a meeting planning company said it best: "A clear mandate from pharma firms is all that's needed to get firewalls in place; no one wants to lose business over this." So pharma must take the lead.

When both in-house marketing teams and vendors adopt firewalls, there may be no conflicts of interest. But should they arise, CME providers might consider using an independent board comprised of company outsiders who are aware of ACCME guidelines and could develop and manage processes that will help minimize conflicts of interest. Most CME providers have advisory boards that can take the lead in such a role.

If the industry moves forward without a commitment to create firewalls, it is likely to incur regulatory liability. On the other hand, implementing such firewalls may shake up marketing structures and vendor relationships. Individual companies must weigh the tradeoffs. But with more than \$2 billion in government fines levied against the industry so far this year for marketing violations, action is imperative. The risk of regulatory intervention and the loss of credibility outweigh the cost of doing something now. ■

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