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PhRMA Code Helps Re-define Roles of Medical Affairs and Marketing

by John Mack, VirSci Corporation.

Medical affairs and marketing divisions in pharmaceutical companies have historically functioned as two separate entities, rarely relying upon one another to perform their jobs. Some might go so far to say that the relationship between the two functions has been strained. Marketers may feel that medical affairs is a “threat” to their effectiveness, holding them back from employing effective communication programs to extol the benefits of their products. Medical affairs people, on the other hand, sometimes wince at the envelope pushing tactics of their marketing colleagues, claiming that product managers view FDA warning letters as rites of passage, often framing them for display.

Can't We All Just Get Along?

The April 28-29, 2003, Aligning Medical Affairs and Marketing conference organized by Pharmaceutical Education Associates (www.pharmedassociates.com) claimed that “a harmonious partnership between the two areas is critical.” Yet, I came away from the meeting with the feeling that medical affairs people have achieved, in their own minds, a sense of much-deserved vindication. A harmonious partnership may actually require a power shift from marketing to medical affairs, at least when it comes to using field-based medical programs – or what some might call physician “edutainment” – for marketing purposes.

What may aid in this power shift is the new PhRMA Code on Interactions with Healthcare Professionals as well as the final Compliance Program Guidance for Pharmaceutical Manufacturers issued on April 28, 2003, by the HHS Office of Inspector General (OIG). These two guidelines for best practices are related in that the OIG draft guidance states that with respect to arrangements such as entertainment, sponsorship of third-party educational conferences, scholarships, and grants, “a good starting point for compliance purposes” is the PhRMA Code, “which provides useful and practical advice for reviewing and structuring these relationships.” The OIG states that compliance with the Code “will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.”

Price Increases Draw Attention

According to a Wall Street Journal article, “drug makers are pushing up U.S. prices on some of their most important medicines...McKesson anticipates the price of brand-name drugs to rise, on average, about 5.0% to 5.5% this year” (WSJ 4/13/2003). A recent email posted to the PHARMA-MKTING listserv reported that “pharmaceutical industry profitability for 2002 stood at \$39.65 billion (Source: Value line Investment Survey Report; January 24, 2003). The net profit margin comes to 18.4% of ... revenues. Additionally, [F]ortune [M]agazine reported that the % margin for the industry is highest amongst all other sectors/industries.”

Why Now?

Critics have often said that pharmaceutical marketing practices often “push the edge” and these practices have come under increasing scrutiny in the press as the debate over drug prices goes on and as the drug industry reports annual earnings and profits.

A few of the physician marketing tactics that have been “exposed” by the press include “Gas ‘n’ Go,” “Dine and Dash,” and clinical presentations made at expensive dinners preceding sports events or theatre productions or at lavish resorts. Of course, golf outings have been a staple of sales reps for a long time.

Jeffrey B. Spears, Pharm.D., Executive Director, Medical Services at Bertek Pharmaceuticals, mentioned these practices in his presentation at the Medical Affairs conference entitled “Impact of the PhRMA Code on Interactions with Healthcare Professionals.” Dr. Spears allowed that these practices evolved over many years and physicians, not just the industry, bear some responsibility for responding to the criticisms. Indeed, many physicians have benefited from gifts, free lunches, junkets, and honoraria paid for by pharmaceutical companies.

According to Spears, an important goal of the PhRMA Code is to “reinforce the intention that PhRMA’s members’ efforts are to benefit patients and enhance the practice of medicine.” The Code also provides a level playing field for the industry and helps to mitigate the consequences of questionable pharma giveaways to physicians, including:

- Bad press
- Escalating costs
- Unwanted attention from prosecutors, Congress and the HHS Inspector General
- Perception of adding to price concerns
- Whistle-blower scenarios

Provisions of the Code

The Code addresses informational presentations, third-party educational meetings, using physicians as consultants, speaker training meetings, and practice related items as giveaways.

Informational Presentations

Informational presentations by or on behalf of a pharmaceutical company must provide valuable scientific and educational benefits and meals, if provided, must be *modest by local standards*. Spears pointed out that the cost of a meal provided in Peoria, IL should not be “modest” by Manhattan, NY standards, but by Peoria standards. No entertainment or recreational events can be offered in connections with the presentation, and inclusion of spouse or other guest is inappropriate. Offering meals to be eaten without a company representative being present (often referred to as “dine and dash” programs) is not appropriate.

Consultants

Perhaps the most lucrative arrangement some physicians have enjoyed with pharmaceutical companies is to become a “consultant.” Physician consultants often are invited to all-expenses-paid social events, vacation getaways, and golf outings. Sometimes very little “consulting” actually takes place. The Code, which aims to change all that, states: “token consulting or advisory arrangements should not be used to justify compensating health care professionals for their time or their travel, lodging and other out-of-pocket expenses” and “the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.” Spears stated, “I think, as a rule, entertainment is probably gone.”

Third-Party Educational Meetings (CME)

Pharmaceutical companies have long sponsored continuing medical education (CME) for physicians. The PhRMA Code won’t change that, but it does put limits on activities, like meals, associated with sponsored CME events. Meals or receptions should be modest and

be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting. Spears cautions, “although the guidelines do not prevent meals being served at these events, we must be careful to use meals appropriately.”

Under the OIG Guidance it is important that all parties to the CME process train employees in the existing guidances, require strict compliance, and have a mechanism in place to address violations.

The Accreditation Council for Continuing Medical Education (ACCME) recently issued a draft of a new set of Standards for Commercial Support of CME, which has drawn criticism from several quarters. The document states that some relationships that ‘commercial interests’ have with persons and organizations create conflicts of interest that cannot be addressed only by disclosure. Now, a conflict of interest will exclude a person or firm from controlling the content of CME. According to a February 10, 2003, article in Medical Meetings, “...while the PhRMA code and the Office of the Inspector General's guidance for pharmaceutical manufacturers would lead to more money for CME, the revised Standards of Commercial Support might result in a reduction of CME funding.”

Practice-Related Items

Every physician's office is littered with items supplied by pharmaceutical companies. Some of these are purely promotional like pens and clocks with product logos on them. Some are related to the physician's practice such as anatomical charts and models.

The PhRMA Code limits promotional giveaways to items of minimal value if they are primarily associated with a healthcare professional's practice (such as pens, notepads, and similar “reminder” items with company or product logos). Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) should not be offered. Also, no more golf balls!

Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value (\$100 or less). Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly.

To comply with the PhRMA Code and OIG Guidance, pharmaceutical companies will have to update their Standard Operating Procedures and ensure that sales reps are knowledgeable about the new guidelines.

Challenges Ahead

The PhRMA Code is a self-regulatory set of guidelines and, as such, critics may claim it has “no teeth.” Nevertheless, according to John T. Kelly, MD, PhD, senior vice president of scientific and regulatory affairs at PhRMA, “there is overwhelming support for the guidelines within the pharmaceutical industry” at the highest levels - the PhRMA Board of Directors, which approved the Code, consists of the chief executive officers of the major pharmaceutical companies in the U.S.

The Code also has its loopholes. For example, it uses the phrase “modest” without further definition.

Despite all good intentions of the industry, the medical community isn't united in its view on what is appropriate behavior. “Our challenge,” as Kelly sees it, “is to inform all physicians of the code and encourage them to consider the upside of not continuing to receive benefits to which some physicians and their office staffs may have become accustomed. My belief is that most physicians will embrace the code and few physicians will criticize it.”

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John Mack

VirSci Corporation

www.virsci.com

PO Box 760

Newtown, PA 18940

215-504-4164, 215-504-5739 FAX

<mailto:johnmack@virsci.com>