

# Online and Honoraria-Free

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**T**raining healthcare providers to be effective product champions has always been an important part of promotional campaigns. A well-trained physician presenting a slide deck at a dinner program can be an invaluable tool for communicating a product's messages to an audience of other healthcare providers and for solidifying relationships with those key customers.

Increased scrutiny by the Office of the Inspector General (OIG) and FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) of promotional activities has made training speakers more necessary—and more complicated—than ever. Those changes present

an excellent opportunity to redefine speaker training to be better and more cost-effective for all involved. This article will explain how web-based training models may add value and minimize risk.

## Kickback Confusion

One thing the OIG is concerned about is the potential for physicians to receive kickbacks, money or goods in return for endorsement. If a physician presents strictly on-label information about a product at a dinner meeting in return for

an honorarium compensating him for his time, there is no problem.

But consider this common scenario: A physician attends speaker training at an appropriate, PhRMA Code-compliant venue and is paid a reasonable honorarium. Once trained, he is promised speaking engagements, for which he will receive another appropriate honorarium per event. The trainer then presents to him the only slides he is permitted to use, which are promotional, focus only on the brand in question, and use trade names. These slides contain only information found in that product's label, and the program prohibits the presentation of any other data, no matter how relevant.

Because he is not allowed to stray from the pharma company's script, the doctor fears a loss of credibility and suspects that he is functioning as a sales rep. So he decides not to accept any invitations to speak for the brand. Yet, because he already received payment and did not provide any service in return, the original training honorarium could, albeit at a stretch, be considered a kickback.

To avoid this scenario, some companies have begun withholding all or part of speaker training honoraria until a certain number of promotional engagements have been completed. It's a draconian measure, but perhaps the safest option. Unfortunately, it's also unpopular with busy physicians who may have to close their practices for a day or give up part of a weekend to be trained. "Why should I go through the time and expense to attend a meeting," a physician may wonder, "and not even be paid for my time?"

## Off-Label Worries

What if the speaker agrees to the speaking engagement but not to the materials provided? He takes away the slides, modifies them, picks and chooses which ones to use, adds a few, and ends up breaching promotional guidelines because he has presented information that is not part of

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the product's label. Both the company and the speaker—if he convinces another doctor to prescribe the product for a Medicare-reimbursable, off-label indication—risk severe government sanctions.

The FDA and the OIG take an especially hard line against off-label promotion. Effective speaker training goes straight to the heart of this issue. A promotional slide kit must be entirely consistent with the labeling for that product. Claims of efficacy can be made only when supported by two FDA-approved, adequately powered, randomized, controlled clinical trials. Fair balance must be added with an appropriate discussion of side effects, particularly when described in a black-box warning.

Yet many physicians don't realize that when a pharma company pays them to speak, the presentation has to be medically accurate, legally appropriate, and compliant with regulations. No one will ask them to present an opinion they do not hold, and there is nothing to stop them from answering unsolicited questions as they see fit, as long as they fulfill their contractual obligations to the company to only discuss claims consistent with product labeling and to emphasize important safety information.

### A Better Way

Clearly, a change is needed. While live meetings will always have a critical role to play in the development of a pool of trained speakers, online solutions may offer the best option for a new paradigm of speaker training. These solutions can help with reaching hard-to-reach preferred speakers, for both initial training and refresher courses.

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which would work much better with physicians' busy schedules, while eliminating the company's obligation to pay an honorarium for the training itself. This avoids the tricky issue of unintentional kickbacks. Such short training sessions would not warrant an honorarium; reps can even go over the material with the doctor over lunch.

Switching from a remote, bricks-and-mortar training program to an online one will also save a lot of money. The pharma company would be able to eliminate all those honoraria for training—say, \$1,000 each for 1,000 trainees, for a total of \$1 million for one campaign—in addition to the cost of renting the space and paying the trainers. The company would also save the cost of travel and accommodation, and the proposed speakers would gain the convenience of attending training sessions at a time that best suits him or her. And if a doctor decides after training that she does not want to accept future speaking engagements, the company is not put in the potentially illegal position of paying for a service that is never rendered, nor in the awkward situation of having to track her down and demand return of the original honorarium.

Plenty of online solutions are available. Companies can purchase packages that provide trackable, secure, and cost-effective programs to enroll speakers to carry their messages forward. Each online session could offer talking head presentations of each promotional slide kit so that the trainee can see the correct use of the approved slides. Another short presentation, ideally from the company lawyer, could explain the importance of promotional compliance and the consequences—to both the company and the physician—of noncompliance.

Once he or she has viewed the training program, the trainee simply completes the online certification process that confirms his understanding of the requirements and willingness to be compliant. A set of the approved slides are then automatically unlocked for the physician to start using to promote the brand.

If the program is integrated with an existing speaker's bureau website, that physician's name can also be automatically exported to a list of fully trained speakers that reps can choose from as needed. That will spare reps the effort of tracking down knowledgeable, certified speakers for their programs.

Such programs also give sales reps more control over their speaker pools. Theoretically, they can offer to help physicians go through the materials, given that those materials are on-label and approved for promotional use. But even if the doctor chooses to go through the materials himself, the programs can be set up to require review of every slide in the deck. At the end of the program, the speaker candidate will be certified only if he agrees to abide by the promotional rules and regulations. This will make the physician accountable and will further counter any risk of the physician backing out later. If he later declines invitations to speak, however, the company is not out an honorarium, as each speaker is paid only upon delivery of the contracted speaking engagement.

Of course, this new approach to speaker training will make product managers miss out on a lot. They won't get to spend a lot of money on travel, expenses, or honoraria. The faculty will not have the chance to miss a flight connection to the speaker training meeting. And the reps will have to lose the cathartic "Will he? Won't he?" internal dialogue accompanying their attempts to figure out if their most important speakers will be able to give up a weekend to be trained without compensation. But surely those are things we all can live without. ☐

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