

## The Revised PhRMA Code April 2009

**Q:** I have been asked by an ophthalmic pharmaceutical company to become a speaker for one of the company's products. After attending a speaker training meeting, I will be paid an honorarium for speaking at local and regional dinner meetings. A colleague has advised me that the updated Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, which took effect Jan. 1, places limitations on speaker training meetings, as well as speaker programs. What do I need to know about the PhRMA code in this regard?

**A:** The updated PhRMA code provides guidelines regarding appropriate interactions between health care providers and pharmaceutical and biotechnology companies, including participation in speaker programs and speaker training meetings. If you are considering becoming a speaker for industry, attending a speaker training session held by the company is strongly advised, as it is important that you are fully aware of the FDA guidelines that govern the content of industry-sponsored presentations. The PhRMA guidelines state that these training meetings be held in venues that "are conducive to informational communication and training" and thus resorts are considered inappropriate venues.

Similarly, with regard to the speaker program itself, the PhRMA code states that speaker programs, which have traditionally been held in private dining rooms of expensive restaurants, should offer only "modest meals" to attendees and also be held in "a venue and manner conducive to informational communication." You, as the speaker, have the responsibility to clearly identify the company sponsoring the presentation and to state that you are presenting on behalf of the company.

In addition, the speaker arrangement with the company must not be an inducement or a reward for specific prescribing patterns and should avoid any possible appearance of such a reward or inducement. Accordingly, the arrangement should be set forth in a written and signed contract with reasonable compensation based on fair market value.

A relatively common and particularly problematic issue that speakers for industry may encounter is the expectation that they will discuss unapproved or off-label uses of a medication. Per the federal government, a physician who accepts compensation for agreeing to promote an off-label use of a medication risks indictment, as does the manufacturer of the medication.

Although off-label prescribing is not specifically addressed by the updated PhRMA code, a physician speaking on behalf of industry should avoid discussing off-label uses of a medication unless a member of the audience asks a question about such a use. In such a case, the physician should feel free to discuss such off-label uses but should clearly state that such uses are off-label.

**For the entire PhRMA Code** on Interactions with Healthcare Professionals, visit [www.phrma.org](http://www.phrma.org) and select the "PhRMA Code" box. **To submit a question** for this column, contact the Ethics Committee staff at [ethics@ao.org](mailto:ethics@ao.org).