

No Pens, No Coffee, No Food: How New Regulations Changed Professional Conferences

Lisa Kennedy Sheldon, PhD, APRN-BC, AOCNP®

The 36th Annual Oncology Nursing Society (ONS) Congress will be held April 28 through May 1, 2011, in Boston, MA. New regulations have changed how healthcare organizations and professional societies such as ONS may run conferences. Conference participants probably will notice the changes.

As most healthcare providers know, pharmaceutical companies no longer distribute brand-name pens, mugs, and notepads (Eisenberg, 2010). Now, all meals in hospital departments, medical offices, and restaurants that are donated by pharmaceutical companies and medical device manufacturers must be accompanied by an educational presentation, with continuing nursing education (CNE), by the industry representative; in fact, in some states, meals may not be provided at non-CNE events (Jutel & Menkes, 2008; Katz, Caplan, & Merz, 2003). In addition, the participation of these industries at national conferences has been tightly regulated at the federal and state levels (see Figure 1). Massachusetts, the site of the upcoming Oncology Nursing Society (ONS) Congress, is one of nine states that has passed strict legislation regarding how the pharmaceutical industry and medical device manufacturers participate in professional conferences, especially in terms of giveaways and meals (Jutel & Menkes, 2008; Katz et al., 2003).

Legal and Political Influence

What led to the changes? In the late 1990s and early 2000s, concerns regarding the financial relationships between healthcare providers and pharmaceutical and medical device manufacturers were

called into question. Most likely, ethical questions arose, such as

- How is the provider's judgment affected by the relationships?
- Will conflict of interest arise in purchasing and/or prescribing?
- Will the relationships influence independent judgment?

Prior to the new regulations, the pharmaceutical industries often were paying healthcare providers to promote their products. Although paying providers to speak about the "on-label" uses of products approved by the U.S. Food and Drug Administration (FDA) is acceptable, paying providers to speak about "off-label" uses of a drug or product is not (Katz et al., 2003). In 1996, an employee of Pfizer, the world's largest drug manufacturer, filed a civil suit regarding the company's promotion of Neurontin® (gabapentin) for uses that had not been approved by the FDA (U.S. Department of Justice, 2004). In 2004, Pfizer paid \$430 million in a stunning criminal and civil settlement, the second-highest amount

paid for a case of healthcare fraud (U.S. Department of Justice, 2004). In addition, Pfizer pleaded guilty to two penalties for aggressively marketing the drug in off-label promotion, including ghost writing and educational programs for healthcare providers (U.S. Department of Justice, 2004).

Pfizer was not the only company under scrutiny. Because of increasing concerns, the government began tightening regulations regarding relationships between the pharmaceutical industry and healthcare providers. In 2003, the federal Office of Inspector General issued the first compliance guidelines for pharmaceutical companies (Office of Inspector General, 2003). In 2007, the U.S. Senate Committee on Finance investigated company grant-making policies and found that drug and device companies provided educational grants for continuing medical education (CME) in excess of \$1 billion annually (Katz et al., 2003). Although providing educational opportunities and CNE and CME programs is

Lisa Kennedy Sheldon, PhD, APRN-BC, AOCNP®, is an assistant professor in the College of Nursing and Health Sciences at the University of Massachusetts–Boston and an advanced oncology certified nurse practitioner at St. Joseph Hospital in Nashua, NH. The author takes full responsibility for the content of this article. The author did not receive honoraria for this work. No financial relationships relevant to the content of the article have been disclosed by the author or editorial staff. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the *Clinical Journal of Oncology Nursing* or the Oncology Nursing Society.

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