

FDA Regulation of Product Promotional Activities
Industry's sponsorship of FDA-regulated product promotional activities should not be confused with their financial support for independent continuing medical education

As part of marketing and sales operational plans, pharmaceutical, biotechnology and medical device companies provide healthcare professionals the opportunity to learn about a company's products or disease states of interest through industry-developed, U.S. Food and Drug Administration (FDA)-regulated promotional activities. The pharmaceutical, biotechnology and device companies have an obligation and an important role to play in informing healthcare professionals about the availability, safety and effectiveness of medications, vaccines and devices they produce. Accordingly, the timely and appropriate dissemination of information consistent with the FDA-approved product labeling is important if health care professionals are to have access to the latest information for use in the treatment of their patients. The content of "promotional information" is controlled by the pharmaceutical, biotechnology, or device company as mandated by the FDA and is distinct and separate from industry support for independent certified continuing medical education (CME). The facts regarding commercial support for independent certified CME are described in a previously published Fact Sheet titled *Pharmaceutical, Biotechnology and Medical Device Company Support of Continuing Medical Education*.

- The FDA regulates the marketing of pharmaceutical products and medical devices and permits promotion of these products by drug and device manufacturers to the indications that it has approved. These are often referred to as "on label" indications or "approved uses". FDA-approved uses of prescription drugs and medical devices are specific with respect to medical condition and dosage or application of the regulated product. The FDA product approval and monitoring systems have an impact on the processes for development and review and the content and delivery mechanisms for all promotion of regulated products.¹
- FDA-regulated promotional activities are defined as those activities over which the sponsoring company (manufacturer) has both control of and responsibility for the content.² Such activities often focus on one product, or device, from a company including the latest science within labeling and FDA-approved uses. The roles and responsibilities for faculty participation in these activities are determined by the FDA regulations that control dissemination of promotional product information. For reasons of compliance, faculty are described as being an agent of company, paid directly by company; presenting content developed or approved by company; and limited to proactively discussing only information they provide in compliance with the FDA-approved label for the product. For example, faculty speaking for a company at an FDA-regulated activity are bound by the same FDA regulations that govern a sales representative detailing a physician.¹
- Content for FDA-regulated promotional activities undergoes a review by the organization's medical, legal and regulatory staff to ensure medical accuracy, regulatory compliance with FDA-approved labeling and to achieve a balanced presentation of both the benefits and the risks associated with the advertised product.³ Once approved, the information may be proactively communicated by the company or expert faculty contracted by the company and acting on its behalf.

Experts involved in FDA-regulated promotional activities need to be trained on the subject matter, should clearly identify the company that is sponsoring the presentation, acknowledge the fact that they are presenting on behalf of the company, and that they are presenting information that is consistent with FDA guidelines.³

- FDA-regulated promotional activities directly sponsored by industry may include dinner / speaker informational programs hosted by the organization's sales representative at a local restaurant, company branded web sites, the company's sales and advertising promotional materials, and other activities such as exhibits, product theatres and disease state programs that may be held in conjunction with a medical organization such as a specialty society or state medical association. *The US Department of Health and Human Services, Food and Drug Administration stated the following: "Two important sources of information on therapeutic products [human and animal drugs, biological products, and medical devices regulated by the Food and Drug Administration (FDA) for health care professionals] are: (1) activities (programs and materials) performed by, or on behalf of, the companies that market the products, and (2) activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company. Although both provide valuable and sometimes vital information to health care professionals, the programs and materials performed and disseminated by the companies are subject to labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act, whereas the independent and non-promotional industry-supported activities have not been subject to FDA regulation."*²

- FDA-regulated promotional activities provide industry with a venue for sharing approved product information based on safety and efficacy data of their products with the goal of increasing appropriate use in the appropriate patients. Physicians and other health care professionals need the most current product information as they consider options for the care of their patients. According to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, *"Appropriate marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to – inform healthcare professionals about the benefits and risks of our products to help advance appropriate patient use, provide scientific and educational information, support medical research and education, and obtain feedback and advice about our products through consultation with medical experts."*⁴

References:

- 1) FDCA <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCA/default.html>
- 2) Federal Register / Vol. 62, No. 232 / Wednesday, December 3, 1997 / Notices. Guidance for Industry: Industry-supported Scientific and Educational Activities.
- 3) <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf>. PhRMA Code Section 7; <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.
- 4) Pharmaceutical Research and Manufacturer's Association (PhRMA) Code on Interactions with Healthcare Professionals, January, 2009.