

# **Risk Stratification and Monitoring of Industry-funded Third Party Educational Activities, Grants and Charitable Contributions**

Peg Bollella, PharmD, CCMEP

Edmund Greenidge, Jr. , JD

Maureen Doyle-Scharff, MBA, FACME, CCMEP

# Disclosure

Views of all presenters are their own and do not represent those of their respective employers nor the pharmaceutical industry.

# Video

# Current CME Environment

- Industry funding for certified CME
  - Quadrupled from \$302 million to \$1.2 billion between 1998 and 2006. 2009 funding was reported at \$856,098,804.00
  - Dropped 14% in 2008, and another 17% in 2009, as a result of the current regulatory, political and economical environment
- Legal cases involving CME
  - Federal and state cases
  - Over \$4.9 Billion in pharmaceutical settlements since 2000 (not all CME)
- Numerous recent changes in ACCME policies and requirements

# Ongoing Scrutiny

- Institute of Medicine (IOM) report on Conflict of Interest in Medical Research, Education and Practice (April 2009)
- Institute of Medicine (IOM) Redesigning Continuing Education in the Health Professions (December 2010)
- AMA Council on Ethical and Judicial Affairs (CEJA) reports on Financial Relationships with Industry in Continuing Medical Education (November 2009)
- Josiah Macy Foundation report on *Continuing Education in the Health Professions: Improving Healthcare Through Lifelong Learning* (2008)
- U.S. Senate Special Committee on Aging hearing on Medical Research and Education: Higher Learning or Higher Earning? Medical Research and Education: Higher Learning or Higher Earning?



# Certified CME vs. Promotional Education

|   | <b>Certified Continuing Education</b>   | <b>Promotional Education</b>  |
|---|---|---|
| Basis of Need                             | Independent assessment of knowledge, skill, competence and/or performance gaps  | Market research<br>New product use  |
| Regulator                                 | ACCME, AAFP, AOA, ACPE, ANCC, AMA and other accrediting bodies  | FDA   |
| Responsible party                         | Accredited Provider   | Pharmaceutical/Device Company   |
| Content controlled by                     | Accredited Provider   | Pharmaceutical/Device Company   |
| Focus                                     | Disease state/therapeutic area  | Product   |
| Most Important Elements Regarding Content | <ul style="list-style-type: none"> <li>•Off-label discussion permitted</li> <li>•Content validity stressed</li> <li>•Desire for evidence-based conclusions</li> <li>•Focused on practice improvement and patient outcomes</li> <li>•Balanced, objective, and free from commercial bias</li> </ul> | <ul style="list-style-type: none"> <li>•FDA-approved uses only</li> <li>•Not false or misleading</li> </ul> |
| Use of Brand vs. Generic Names            | Generic names encouraged to foster impartiality   | Brand/trade names used  |

# Regulations and Ethical Codes

- CME Accreditation Standards
  - Accreditation Council for Continuing Medical Education (ACCME)
  - American Medical Association (AMA)
- Federal Regulations
  - Food & Drug Administration (FDA)
  - Health and Human Services, Office of Inspector General (OIG)
- Professional Standards
  - American Medical Association (AMA)
- Industry Codes
  - Pharmaceutical and Research Manufacturers of America (PhRMA)
  - Advanced Medical Technology Association (AdvaMed)

# Definition of Conflict of Interest

ACCME defines “conflict of interest” as:

- Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.



# Case 1

# Case 1: Why Monitor?

- New therapeutic agent in class
- Single support
- Innovative Instructional Method

# Case 2

# Take-away Points

- A formal monitoring system can help mitigate risk associated with a medical program
  - Objectivity, transparency and standardization decrease that risk even more
- Data gathered through a monitoring program can help improve the quality of a medical program



# Take-away Points

- Monitoring validates the internal grant review process providing evidence that approved programs are as listed below:

## – **Validate Grant Review Process**

- Approved program
  - Educational Design/Effectiveness
  - Scientific Merit
  - Compliance
  - Unbiased
  - High Quality programs

**Questions?**