CME Programs: Guidelines and Pitfalls for Sponsorship

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CME Objectives

- CME is intended to contribute to keeping physicians up to date with medical developments and to encourage practice improvements for providing optimal patient care.
- Physicians – licensed by state to practice medicine
- Each state has requirements for continuing medical education hours to renew medical license
- Required CME hours vary by state

CME Objectives (cont.)

- Accreditation Council for Continuing Medical Education (ACCME) certifies providers to conduct CME programs
- Accredited providers
  - Medical centers/universities
  - Medical professional societies
  - Commercial providers
- Companies can fund CME programs through monetary grants to accredited providers (educational grant)

The reach of the Federal AKS is broad

- Any person who receives or pays remuneration, in cash or in kind, in return for, or to induce, referrals for items or services, in return for health care business, for which payment may be made by a federal health care program. 42 U.S.C. §1320a-7b.
- "One purpose" test
- Civil, criminal, administrative exposure
- Some "aggravating conditions" – the potential to interfere with or skew clinical decision making.

The False Claims Act may be implicated

- Knowing submission of false claims
- Whistleblower exposure
- Violation of FDA prohibition on off-label promotion can violate the False Claims Act (e.g. resulting Medicaid payment for non-covered items or services

FDA Restrictions

- Focus on the "intended use" concept – objective intent standard
- Prohibition on false or misleading statements on drug labels
- Prohibition of false statements in promotion or marketing of drugs or certain devices ("restricted devices")
- Not a prohibition on scientific dialog

Applicable Guidance Documents and Codes

- FDA Regulations and Guidance
- AdvaMed Code of Ethics on Interactions with Health Care Professionals
- AMA Opinions
- ACCME Standards of Commercial Support (www.accme.org)
- Senate Finance Committee CME Report
- OIG Compliance Program Guidance for Pharmaceutical Manufacturers
- Fraud and Abuse Law/False Claims Act Cases

FDA Guidance for Industry regarding Industry-Supported Scientific and Educational Activities

- Twelve factors the Agency will consider in evaluating CME activities
- If industry sponsor complies with 12 factors, FDA has said such activity will not be used as evidence of adulteration or misbranding in an enforcement action based on other off-label dissemination.

FDA Guidance on Medical Education

- Factors considered in evaluating activities and determining independence, (factors are considered as part of overall evaluation of an activity no individual factor is likely by itself to stimulate an action)
  - Control of content, selection of presenters
  - Disclosures
  - Focus of program – educational content free from commercial influence or bias; representative title; provides discussion of treatment options
  - Relationship between provider and supporting company
  - Provider involvement in Sales and Marketing
  - Provider's demonstrated failure to meet standards of independence, balance objectivity, and scientific rigor
  - Multiple presentations
  - Audience selection
  - Opportunities for discussion
  - Dissemination
  - Ancillary promotional activities
  - Complaints
  - Additional considerations: documentation

AMA

- Guidelines for physicians serving as faculty
  - Research findings and therapeutic recommendations based on scientifically accurate, up-to-date information and presented in a balanced, objective manner
  - Content not modified/influenced by industry representatives or other financial contributors

Senate Finance Committee CME Inquiry and Report

- See http://www.finance.sentate.gov.senate.gov/press/Bpress/2007/press/prb042507a.pdf
- Committee inquiry into 23 pharma companies' use of educational grants
- Committee inquiry into ACCME enforcement
- Committee found pharma companies have used educational grants as way to increase market share
- Committee found ACCME's failure to enforce standards
- Committee focused on lack of real-time oversight for educational grant programs

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

- While educational funding can provide valuable information to the medical and health care industry, manufacturer grants raise concerns under the Anti-Kickback Statute
- Risk is that education program may be used for inappropriate marketing purposes if manufacturer has influence over the substance of an educational program

Letters of Agreement: Why are they necessary?

- Spell out expectations between provider and the commercial supporter
- Legal document that helps companies separate marketing from education
- Enforceable standards of the ACCME
- Assure that provider can develop CME activities in an independent manner

Include in Letter of Agreement (LOA) Provisions Documenting 12 Factors in FDA's CME Guidance

- Appropriate terms of agreement with the provider
- Ensure compliance with the agreement

Provisions to Include in LOA

- Provider agrees to maintain full control over program content, planning of program content and over selection of speakers and moderators.
- CME provider agrees to disclose to the program audience the industry's funding of the program, any significant relationship between the provider, presenters, and the supporting industry, and whether any unapproved uses of products will be discussed.

Provisions to Include in LOA

- The provider agrees to produce an independent and non-promotional activity that is focused on educational content and is free from commercial influence and bias.
- Provider agrees to ensure that the title of the program fairly and accurately represents scope of presentation.

Consider Prior to Signing the LOA

- Are there any legal, business, or other relationships between the company and the provider that could place the company in a position where it could be perceived as inappropriately influencing the content of the activity?
- Provider's demonstrated failure to meet standards of independence.

Provisions to Include in LOA

- Ensure that individuals employed by the provider and involved in designing educational activities are not also involved in advising or otherwise assisting the company sponsor with respect to sales/marketing of the company's product.

Provisions to Include in LOA

- Ensure that no ancillary promotional activities, such as presentations by sales representatives or promotional exhibits are permitted to take place at educational activity.

To Reduce Risks, Ensure by LOA

- Separation of grant-making functions from sales and marketing functions
- Provide that no inappropriate influence by sales/marketing motivations
- Compliance with LOA and procedures should be documented and regularly monitored

AdvaMed – Supporting Third Party Conferences

- Bona fide independent conferences
- Grant to conference sponsor
- Support for conference or faculty costs
- Support for attendance of students and fellows

ACCME

- Independence
- Disclosure of relevant relationships
- Control of relevant decision making
- Product promotion not part of program
- Disclosure of support
- Balanced view of therapeutic options
- Content and Format without Commercial Bias

What do the ACCME Standards say?

- 3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

What do the ACCME Standards say?

- 3.5 The written agreement must specify the commercial interest that is the source of commercial support.
- 3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Fraud and Abuse / False Claims Act Cases

Franklin v. Parke-Davis - 2002

Ad Agency Helped Push Neurontin, Documents Show
Posted: 11/08/2002

THE WALL STREET JOURNAL, 11/8/2002

By Rachel Zimmerman

A drug company now owned by Pfizer Inc., in an alleged effort to promote epilepsy drug Neurontin for unapproved uses, went so far as to hire a New York advertising agency to wage an all out marketing "war," according to documents that are part of a lawsuit.

***

The campaign by Cline Davis & Mann Inc., the Manhattan advertising firm, lays out a "tactical plan" with detailed strategies to increase prescriptions and sales of Neurontin for uses such as pain management, psychiatric disorders, migraine headaches and a condition related to diabetes.

***

The newly released documents, including a 1996 report written by the Cline Davis agency for Parke Davis called "Neurontin War Games," show "an advertising company creating illegal marketing strategies to promote off-label uses of Neurontin under the guise of medical-education seminars, advisory-board and consultants meetings," said Thomas Greene, Mr. Franklin's lawyer.

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Legal Background

- Medicaid generally covers drugs for uses approved by FDA or uses listed in certain official compendia.
- Neurontin was not approved by FDA for the off-label uses at issue listed in those compendia.
- Approximately 50% of Neurontin off-label sales thought to be reimbursed by Medicaid (25% of total sales) or VA.
- Allegations that Warner-Lambert/Pfizer* caused submission of false claims. Foreseeable that company's conduct would result in false Medicaid claims (off-label promotion and kickbacks).

* - Parke-Davis was purchased by Warner-Lambert which was subsequently purchased by Pfizer.

CME Allegations**

- Pfizer had control of virtually every aspect of the events and paid all expenses including seminar companies' fees.
- Although the seminar companies acted as conduit for payments and gratuities given to the physician attendees, Pfizer controlled every aspect of the CME programs.

** See amended complaint, Franklin v. Parke-Davis, filed under seal in D. Massachusetts.

CME Allegations (cont'd)

- Pfizer
  - Designed and approved the programs.
  - Hand-picked the speakers for the seminars.
  - Approved the seminar presentations.
  - Previewed, in most cases, the contents of the seminars prior to delivery.
  - Selected the attendees based on their ability and willingness to prescribe high quantities of Neurontin.
  - Evaluated the presentations to make sure their "message" was appropriately delivered.
  - Black-listed presenters whose presentations were not sufficiently pro-Neurontin.
  - Monitored the prescribing patterns of the physicians who attended to insure the purpose of the conference – increased writing of Neurontin prescriptions – was achieved.
- Follow-up reports to marketing executives highlighted that attendees received presentations regarding off-label marketing and recommendations for doses larger than those labeled effective by FDA.

Schering-Plough Settlement

- Allegation
  - Schering knowingly and willfully made material false statements to the Health Care Financing Administration regarding best price of Claritin RediTabs by concealing that Schering was providing free drug to an HMO contingent on purchases of drug from Schering
    - *Blended price of samples and drug purchased was $1.10 per RediTab*
    - *HMO did not allow physicians to receive samples except in small quantities*
    - *Full trade packs shipped and distributed via pharmacies no differently from purchased drug*

Schering-Plough Settlement (cont'd)

- Schering knowingly and willfully made material false statements to the FDA in order to avoid scrutiny by the FDA of Schering's off-label promotional activities regarding Temodar and Intron A
  - Untitled letter from FDA re: promotional activities at ASCO meeting
  - Sales force trained to seek off-label sales through training classes, ride-alongs and sales meetings
  - Marketing department provided sales force with plan of action that targeted off-label sales
  - Clean copies of "for your information only" articles for use with physicians
  - Goals/compensation for off-label sales as well as budget for advisory boards, speakers, entertainment and preceptorships to assist in sales

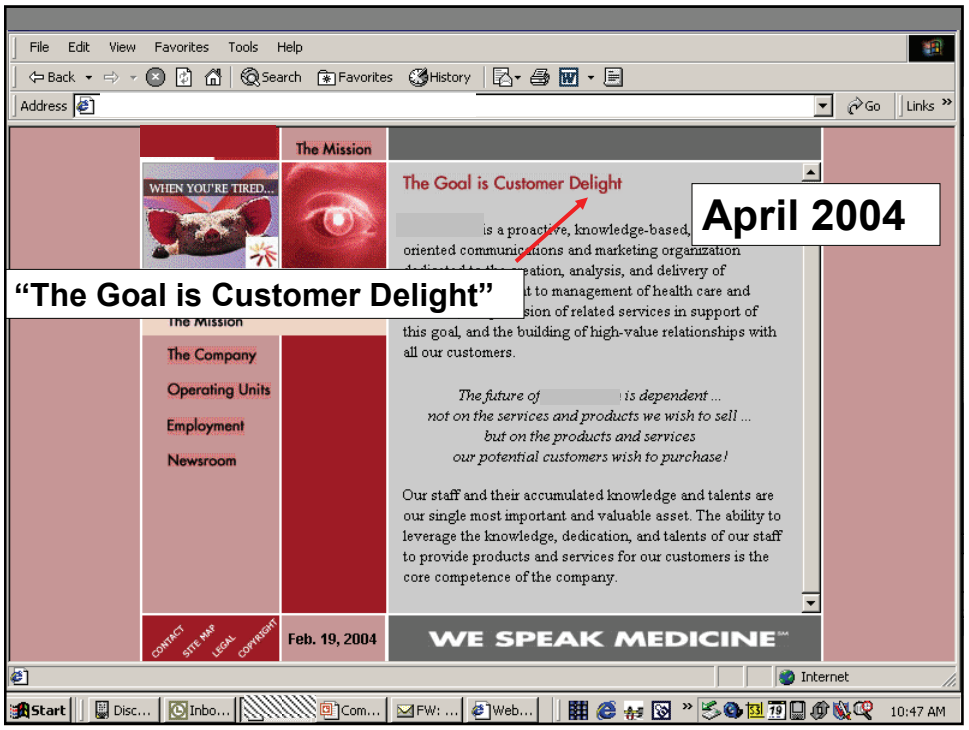
Schering-Plough Settlement (cont'd)

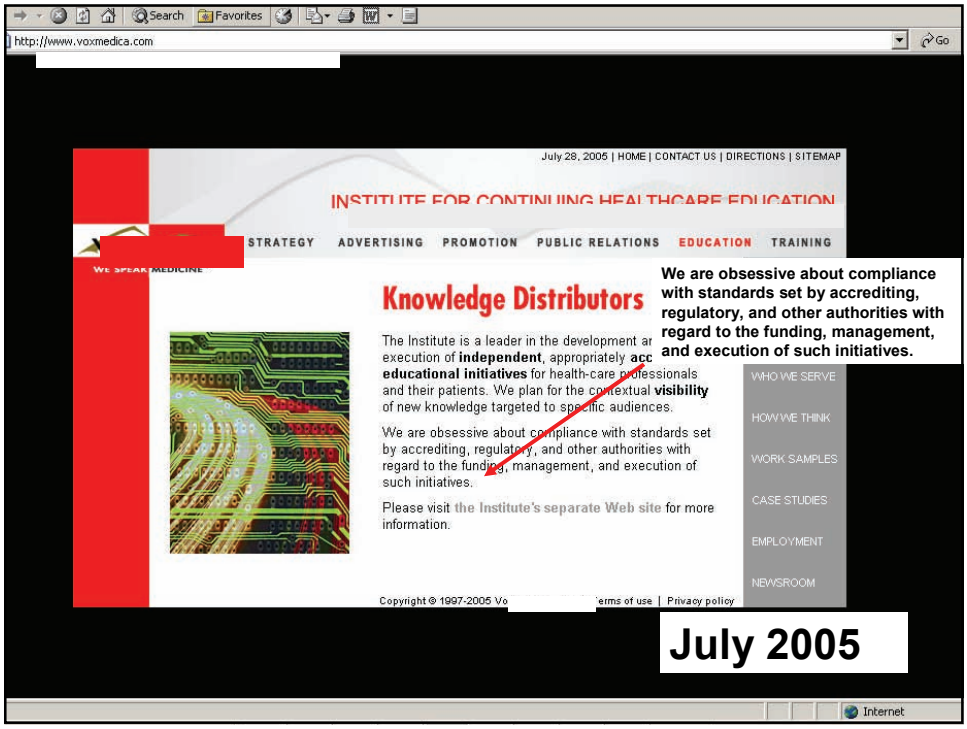
- Settlement
  - $435,000,000 ($180,000,000 – criminal and $255,000,000 – civil)
  - Addendum to Corporate Integrity Program
    - *Five years from effective date*
- Corporate Integrity Agreement
  - Compliance Program
  - Notification of communications regarding off-label uses issues
  - Specialty Field Sales Force Promotion Monitoring Program
    - *Inspection of messages and materials delivered to HCPs*
  - Monitoring and review of requests for off-label information
    - *Policies and procedures, document and record inquiries*
  - Message recall monitoring program

Schering-Plough Settlement (cont'd)

- **Independent Review Organization**
  - Promotional and Product Services Engagement
    - *Review of systems*
    - *Transaction review*
  - Systems Review
    - *Field sales force handling of requests for off-label information*
    - *Medical liaisons*
    - *Medical information*
    - *Criteria to hire HCPs*
      - Role of field
      - Written agreements
      - Fair market value
      - Tracking of services
    - *Grants and sponsorships*
    - *Research agreements/grants*
    - *Compensation of field sales force*
  - **Transaction Review**
    - *Speaker programs, advisory boards, consulting, promotional support*

- How Have CME Providers Responded?

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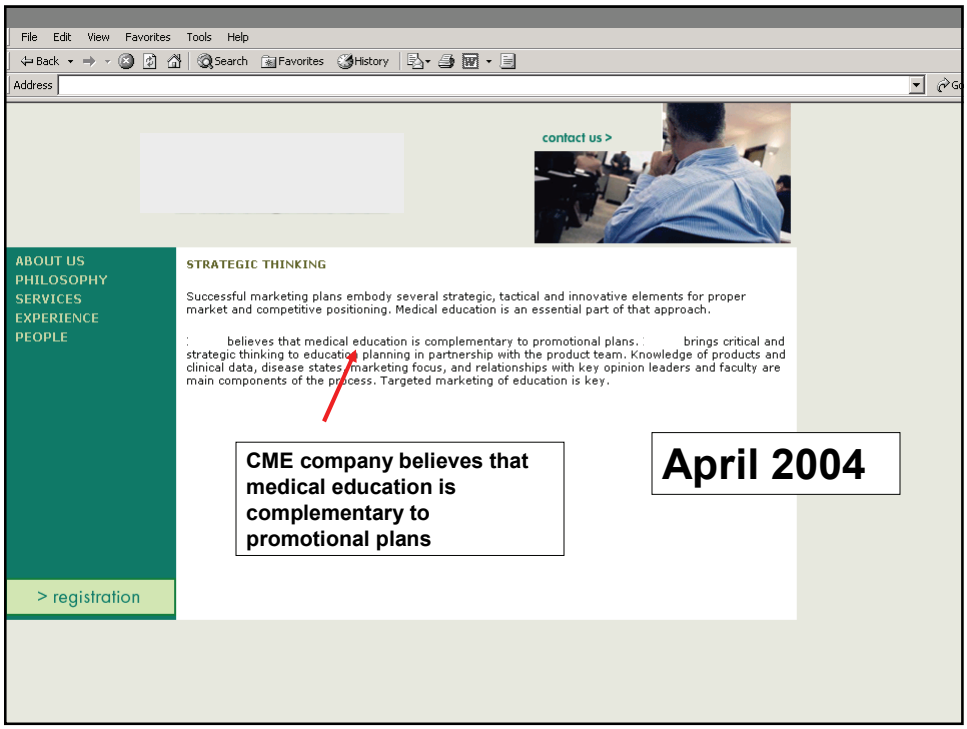
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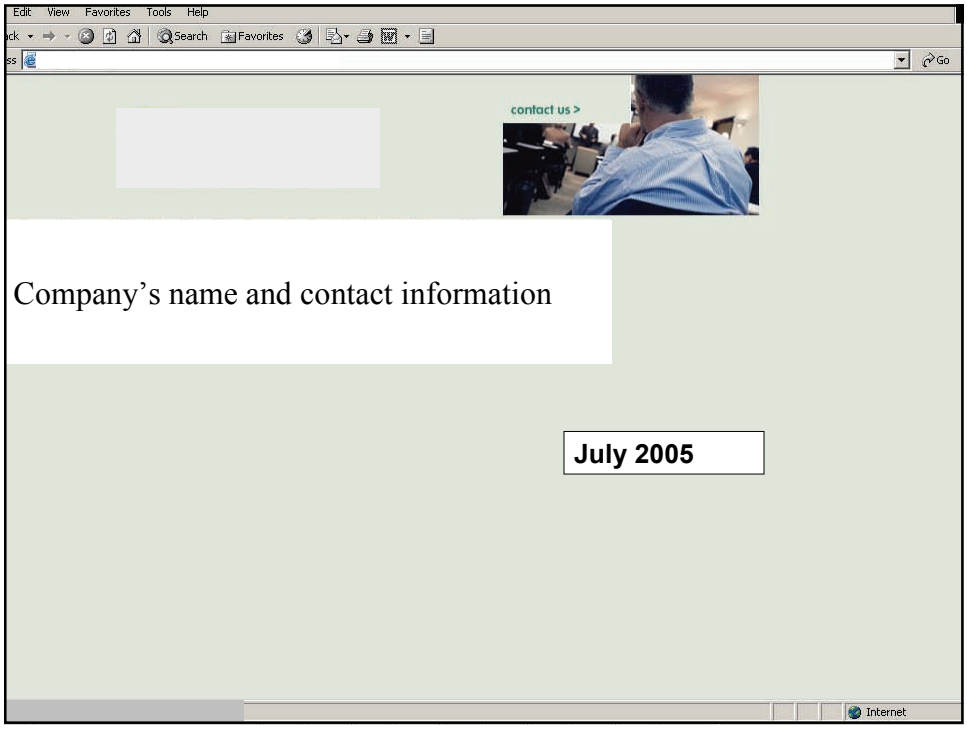
STRATEGIC THINKING
Successful marketing plans embody several strategic, tactical and innovative elements for proper market and competitive positioning. Medical education is an essential part of that approach.
believes that medical education is complementary to promotional plans. brings critical and strategic thinking to educational planning in partnership with the product team. Knowledge of products and clinical data, disease states, marketing focus, and relationships with key opinion leaders and faculty are main components of the process. Targeted marketing of education is key.
CME company believes that medical education is complementary to promotional plans
April 2004



Potholes in the Road of Appropriate CME

- The Vendor and the Contract
  - "We've hired a vendor to do the program. The vendor is going to have an accredited organization provide the CME accreditation. The vendor's proposal states that the program will "build brand awareness and will be essential to the success of our business plan."
  - This should be a great program for us! We've worked with this vendor before with no problems. They've done lots of programs just like this for other pharmaceutical companies.
  - Why do we need a contract anyway? It only slows things down."

The Vendor/Contract (cont'd)

- The objective of "building brand awareness"
  - FDA/ACCME
    - *Activities must be free of commercial bias…present objective information about products based on accepted scientific methods*
    - *Materials shall not advance the specific proprietary interests of the sponsor*

The Vendor/Contract (cont'd)

- FDA Guidance
  - One factor: Is the central theme of the program based on a single product marketed by the sponsor?
  - One factor: Is the [vendor] also involved in advising/assisting the sponsor in the sales or marketing of the sponsor's product?

Avoiding the Vendor Pothole

- Work with accredited CME providers
  - Institutional or commercial
- Use only vendors who have a reputation for developing rigorous, objective scientific & educational programs

Avoiding the Vendor Pothole (cont'd)

- First rule: GET IT IN WRITING
- ACCME Standards require that accrediting provider has a signed contract with supporter/sponsor
  - FDA Guidance: Contract is optional, but provides evidence of independence; should contain FDA Guidance factors

Potholes in the Road of Appropriate CME

- The Roadshow …or "That was so good let's do it again!"
  - "If the program turns out really good for our product, we'll go back to the vendor who says they can get the speaker to give this program 15-20 more times over the next year…all with CME accreditation!"

The Roadshow (cont'd)

- ACCME Standards: CME providers must demonstrate that repeated activities all meet the requirements of the Standards
- FDA Guidance: Multiple presentations of the same program are a factor FDA will consider in determining the independence of the program

Avoiding this Pothole

- The contract with the accrediting organization should provide for a specified number of programs

Potholes in the Road of Appropriate CME

- Outreach efforts
  - Can medical device companies sponsor outreach efforts to accredited providers to generate proposals for CME?

Potholes in the Road of Appropriate CME

- Review of CME Presentations
  - Can company review content of CME written/video materials to decide whether to provide funding for CME provider to distribute?
  - What if a CME presenter requests your company to review his/her presentation and provide comments? Can you do it?

Potholes in the Road of Appropriate CME

- Disclosure Requirements
  - Question: If a speaker has a financial relationship with a company sponsoring the CME, can the speaker still present at the CME?
  - Answer: ACCME requires potential planners, presenters, or authors of CME programs to disclose relationships with manufacturers to the accredited CME provider. The CME provider is then required to resolve those conflicts prior to permitting the speaker to present or to create CME materials. Individuals must disclose any financial relationships with the company (or any other "commercial interest") within the last year, if that individual has the opportunity to affect the content of CME about the company's products or services. Financial relationships include, but are not limited to salary, royalty, intellectual property rights, consulting fees, honoraria, ownership interest (e.g., stocks, stock options, but not diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management, independent contractor status (including contracted research), consulting, speaking and teaching, membership on advisory or review panels, board membership or other activities where remuneration is received or expected. Relationships with a spouse or partner are also included, and must be disclosed. Prior to allowing the speaker to participate in the CME activity, the CME provider must resolve any conflicts discovered. Resolution of conflict could be achieved through effective peer review by commercial disinterested peers. In addition, the CME provider could resolve conflict by disclosing all financial relationships prior to an activity, so participants or reader can evaluate the objectivity of the presentation or publication.

Potholes in the Road of Appropriate CME

- Independence
  - Question: May a manufacturer provide a grant to a CME provider after the conclusion of a CME meeting to distribute enduring materials from the CME program to attendees?
  - Answer: No. A manufacturer must decide to fund the distribution of enduring materials up front as part of the initial grant agreement.

Potholes in the Road of Appropriate CME

- Independence
  - Question: When we contract with a CME provider, what types of terms might we want to include if we wish to emphasize independence?
  - Answer: Examples of provisions relating to independence include:
    - *The CME provider's responsibility to select presenters (the company should not select or designate funding for specific speakers)*
    - *The CME provider must not use materials created or reviewed by the company (except to check for accuracy in very limited circumstances)*
    - *The CME provider must commit to providing a scientifically balanced program*
    - *The CME provider's responsibility to resolve any speaker conflicts prior to the presentation.*
    - *The CME provider's responsibility to send invitations to attendees*

Potholes in the Road of Appropriate CME

- Focus of CME - Can CME Have a Predominant Focus on Unapproved Uses?
  - Given the current enforcement climate and scrutiny of CME by private litigants, DOJ and Congress, can companies continue to sponsor CME that end up focusing predominantly on off-label uses, even if all of the criteria of independence are followed?
  - If companies are not supposed to control the content of independent CME, how do companies manage sponsorship of CME in the current enforcement climate? Do they ask more questions about content to verify upfront where the focus of the CME is on off-label uses?
  - How do companies address the fact that the Senate Finance Committee has recently stated that an ACCME program is no assurance of independence? Do companies need to have an audit program of third party providers? What type of company compliance effort is necessary?

- Questions?