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Physician/Industry Contacts:

Updated Focus on CME & Grassley Looks at Possible Research Conflicts

AdvaMed
Webinar // October 28, 2008

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Our Topics

- Context
- Continuing Medical Education ("CME") – Update from the Last Six Months (Waltz)
- Senator Grassley's Latest Areas of Focus, and the Status of the Sunshine Act (Scarano)
- OIG Perspectives on Industry Contacts with Health Care Practitioners (Sorensen)

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Context for Concerns

- Improper Contacts with HCPs May Form the Basis for:
  - Investigations and Settlements: *e.g.*, the Orthopedic Device Manufacturers' DPAs and FCA settlements
  - FCPA Allegations
  - Shareholder Derivative Suits
  - Actions Against HCPs

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CME – The Last Six Months

- Massachusetts Legislation – Passed 8/2008, Effective 1/2009
- Revised PhRMA Code – Issued 7/2008, Effective 1/2009
- Revised Stanford Policy – Issued 8/2008, Effective 9/1/2008
- AAMC (Association of American Medical Colleges) – Task Force Report: Industry Funding of Medical Education – 6/2008
- Grassley Says No Additional Legislation to Limit CME Besides the Sunshine Act – 4/2008

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CME – Heavily Scrutinized Activity

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- ACCME
- FDA
- Industry Codes (e.g., AdvaMed, PhRMA)
- AMA
- State Codes, e.g., MA
- OIG/DOJ Investigations
- Senate Finance Committee

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CME: Massachusetts Legislation

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- Applies to practices conducted in Massachusetts, regardless of where manufacturer is headquartered
- Applies to medical device manufacturing companies, agents, marketers, physicians and other prescribers, etc.
- Mandatory Marketing Code of Conduct to be adopted by state DPH to be "no less restrictive" than PhRMA and AdvaMed Codes
- Code shall not allow sponsorship for CME which does not meet ACCME Standards for Commercial Support
- Code shall not allow payment directly to HCP

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CME: Massachusetts Legislation (Cont'd)

- Code "shall not allow"
  - Costs of travel, lodging, other personal expenses of *non-faculty practitioners* attending CME, third-party scientific or educational conference, or professional meeting, directly or "indirectly to the event's sponsor"
  - Funding to compensate for the time of practitioners participating in CME, third party scientific or educational conferences, or professional meeting
  - Payment for meals directly at CME, third party scientific or educational conferences, or professional meetings
  - Payments in cash or cash equivalents to practitioners "either directly or indirectly, except as compensation for bona fide services."

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2008 PhRMA Code Revisions re CME

- Not directly applicable to device companies
- Pre-revisions, PhRMA and AdvaMed Code were substantially similar:
  - Financial support for events primarily devoted to promoting scientific and educational activities is permissible.
  - Financial support should be provided to conference sponsors (not individuals).
  - Financial support for scholarships for HCPs in training is permissible.
  - Financial support should be given directly to the CME provider, which must make all decisions regarding the content, faculty, and fees associated with a particular CME session, independent of the sponsor.

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2008 PhRMA Code Revisions (Cont'd)

- New Provisions to PhRMA Code
  - Distinguish between CME and other third-party educational and professional meetings. CME now has additional restrictions.
  - Companies should separate their CME grant-making functions from their sales and marketing activities.
  - Companies should follow standards for support established by the ACCME.
  - Companies should develop objective criteria for making CME grant decisions to ensure that the funding cannot be viewed as an inducement to prescribe or recommend a particular medicine or course of treatment.

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2008 PhRMA Code Revisions (Cont'd)

- Implications of Changes for Device Mfrs
- OIG reference the PhRMA Code in its Compliance Guidance for Pharmaceutical Manufacturers, and has said it thinks that Guidance also applies to device manufacturers.
- State Code Provisions Reference the PhRMA Code – May Impact on Device Mfrs as well.
  - E.g., NV, DC, MA
  - California Health & Safety Code § 119400 *et seq.*
    - Pharmaceutical companies must adopt comprehensive compliance program consistent with OIG Compliance Guidance for Pharmaceutical Manufacturers, PhRMA Code
    - Conforming changes due within 6 months of an update

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Stanford's Revised Policy on CME

- Policy issued 8/2008, under review since 2005. Guiding principle is that all CME programs must be free of commercial influence, be based on the best scientific evidence available, and be focused on improving the knowledge of learners.
- Effective 9/1/2008, new commercial funding for specific CME courses or programs is prohibited. Commercial support includes monetary contributions as well as "in kind" support such as a loan or donation of equipment or supplies as well as services from a commercial entity.
- Applies to both on and offsite venues and functions that propose to use the Stanford name or that are directed or initiated by Stanford School of Medicine Faculty.
- Also applies to payments for third party sources or for-profit course organizers that have received industry support.
- Exhibitions by commercial organizations are not permitted at CME activities whether onsite or offsite locations.

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Stanford's Revised Policy (Cont'd)

- Industry will be allowed to provide CME program support that is not designated to a specific subject, course or program, but intended for use in a broadly defined field or discipline or field of study. Any such support must be directed to the Office of Continuing Medical Education.
- Commercial support received by faculty or academic units for other purposes cannot be used to support CME.
- Policy applies to all CME activities, whether ACCME accredited or non-ACCME accredited.

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AAMC Task Force Report – ‘‘Industry Funding of Medical Education’’

- 40 page report, released June 2008
- **CME:** Academic medical centers offering CME programs should:
  - develop audit mechanisms to assure compliance with the standards of ACCME including those with respect to content validation and meals.
  - establish a central CME office through which all requests for industry support and receipt of funds for CME activity are coordinated and overseen.
  - To the extent that educational programs for physicians are supported by any commercial entity, the programs should be offered only by ACCME-accredited providers according to ACCME standards.

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ACCME Standards for Commercial Support (Updated through 2007)

- Independence
- Resolution of Personal Conflicts of Interest
- Appropriate Use of Commercial Support
- Appropriate Management of Associated Commercial Promotion
- Content and Format without Commercial Bias
- Disclosures Relevant to Potential Commercial Bias

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CME: Grassley says no additional legislation besides Sunshine Act

M E M O R A N D U M

TO: Reporters and Editors
FR: Jill Kozeny, 202/224-1308 for U.S. Senator Chuck Grassley of Iowa
RE: Industry support for continuing medical education
DA: Friday, April 11, 2008

Copies of letters that Senator Grassley received from drug makers in response to his request for them to follow Eli Lilly's lead and disclose financial contributions to continuing medical education are posted with this statement at http://finance.senate.gov. Right now, Senator Grassley does not plan to pursue disclosure legislation separate from the Physician Payment Sunshine Act. He will carefully monitor implementation of the disclosure plans described in these letters and consider additional initiatives, including legislation, if transparency is not achieved. [additional comments omitted]

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Updated Status of the Sunshine Act And Senator Grassley's Latest Areas of Concern

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The Physician Payments Sunshine Act (S. 2029)

- Introduced September 6, 2007 by Senators Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.)
- Would amend the Social Security Act to require transparency in payments by drug, device and medical supply companies to physicians and entities with which they are affiliated
- Amendments agreed upon, but not yet published
- Would preempt all state reporting requirements

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Entities Required to Report

- Would require annual reporting by covered companies of "all payments or other transfer of value, directly or indirectly," made to a physician, a medical practice or any entity that receives payment at the request of or designated on behalf of a physician
- Would also require reporting of physician ownership of any drug or device manufacturer, distributor or GPO

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Entities Required to Report (Cont'd)

- Covered companies include entities that
  - Manufacture, label, package or distribute drugs, devices or medical supplies
  - Paid for by Medicare, Medicaid or SCHIP
  - Original version: with annual gross revenues in excess of $100,000,000
    - AdvaMed has proposed a threshold based on dollars paid to physicians, rather than gross revenues, with an exemption for companies which make payments less than $250,000 annually

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Payments or Transfer of Value

- Compensation
- Food, entertainment or gifts
- Trips or travel
- Any item provided at less than FMV
- Participation in conferences or CME, or remuneration for such participation
- Consulting fees or honoraria
- Any other economic benefit, as defined by HHS

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Value Thresholds

- The aggregate amount transferred to a covered recipient in a calendar year must exceed $500, excluding any individual items with a value of less than $25

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Exclusions from Reporting

- Product samples intended for patients
- Certain educational materials
- Certain direct training
- Equipment loans
- Discounts and Rebates
- Transfer of anything of value provided to the physician in his/her capacity as a patient
- Anything of nominal value
- In kind items used for charity care

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Required Information

- The name, city and state of the physician or affiliated entity
- The nature and value of the payment or transfer
- Reason for the payment
- The date provided

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Use of the Information

- HHS must make annual reports to Congress
- HHS must make the information publicly available on a website pursuant to procedures to be established, including proper context and an appeal/correction process

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Penalties

- Up to $5,000 per failure to report, with an annual cap of $50,000, unless failure was knowing
- For knowing failure, up to $50,000 per failure, up to an annual cap of $250,000

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Grassley Letters

- Nearly two dozen research universities received letters from the Senate Finance Committee, signed by Sen. Grassley, seeking information regarding conflict of interest disclosures by some of their faculty
  - NIH regulations require such disclosures for NIH-funded research
- Grassley also sought corresponding information from the companies
- In at least one case, significant discrepancies were found

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University of Texas Letter

- In a letter to UT dated September 9, 2008, Grassley detailed discrepancies involving two faculty members
  - In one of the cases, the letter details more than $150,000 in undisclosed income
- Grassley asks UT to conduct a follow-up investigation and to report the results to his Committee

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Recent Letters

- On October 16, Sens. Grassley and Kohl sent letters to Columbia University and an affiliated research entity, the Cardiovascular Research Foundation, which sponsors an annual major device conference
- Express concern about "strong ties between the medical device industry and nonprofit organizations" and the appearance that "funding from the ... industry may influence the practices of nonprofit organizations that purport to be independent in their viewpoints and actions."

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Columbia/CRF Letters

- Request an accounting of funding provided by five cardiovascular device companies since Jan. 1, 2003
- Also request details regarding outside support provided to 22 physicians and researchers
- Request information regarding CRF's policies for accepting $$ and whether contributing companies can restrict the use of their money

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OIG Perspectives on Industry Contacts with Health Care Practitioners

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OIG Perspectives on Industry Contacts with Health Care Practitioners

- Industry/HCP Relationships
- Compliance Perspectives
- Enforcement Perspectives
  - Medical Device Focus
  - HCP Relationships
  - Using the CMPL for Interstitial Enforcement
  - Policy Considerations

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Industry/HCP Relationships

- Travel, Gifts, Entertainment, Recreation, Meals
- Physician Consulting and Royalty Arrangements
- Physician Participation in Sales and Promotional Meetings
- Support for Third Party Educational Conferences (CME)
- Vendor-Sponsored Product Training and Education
- Charitable Donations
- Research Grants

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Compliance Perspectives

- Compliance Program Guidance for Pharmaceutical Manufacturers
- Effect of CIA obligations – some isolation of sales and marketing staff
- Performance and documentation of needs assessments

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Enforcement Perspectives: Medical Device Focus

- Why the device industry?
  - Both competitors and physicians have been source of qui tam complaints and other allegations
  - OIG perception that device industry is somehow "behind" traditional health care providers and even pharmaceutical industry.
  - "Bang for the buck" – focusing limited resources.

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Enforcement Perspectives: Medical Device Focus (Cont'd)

- OIG focused primarily on Anti-kickback Statute allegations
- Enforcement focus on arrangements that include travel, entertainment, consulting, and royalties.
- Multiple arrangements with single physician will be evaluated in the aggregate.
- DOJ and OIG particularly interested in industry/physician financial arrangements they believe may intersect with off-label or other marketing activities or implicate quality issues.

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Enforcement Perspectives: HCP Relationships

- Physician ownership of device companies
- Consulting agreements
  - Value to manufacturer
  - FMV
  - Accountability and documentation of services
  - "Piling on" – combining with royalty agreements
- CME and Training
  - Resort locations
  - Articulated and legitimate business purpose for any off-site activity
  - Balance between CME and free-time or recreation
  - Plant tours
  - Sales representatives in OR

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Enforcement Perspectives: Using the CMPL for Interstitial Enforcement

- OIG strategy first initiated in investigations of clinical laboratories in Clearwater, Florida in 2001
- Used extensively by OIG in the AstraZeneca and TAP investigations (2003-2004).
- Also used in Lincare (2006).
- Divide and conquer
  - Individuals or smaller entities targeted by OIG under CMPL
  - Larger entities targeted by DOJ under FCA
- Particularly effective in context of kickback investigations

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Enforcement Perspectives: Using the CMPL for Interstitial Enforcement (Cont'd)

- OIG has stated that disclosures by device manufacturers would be a "starting point for federal enforcers."
- OIG stated goal of holding physicians equally accountable.
- OIG also stated intention to target individual employees or officers at manufacturing entities under CMPL if OIG believes they are responsible.

(Lewis Morris, Presentation to Pharmaceutical Regulatory and Compliance Congress, 2007)

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Enforcement Perspectives: Policy Considerations

OIG has expressed concerns regarding a number of considerations in evaluating industry contacts with health care professionals:

- Increased charges or costs reported for items paid by Medicare or Medicaid.
- Unfair competition.
- Possible encouragement of over-utilization or steering.
- Inappropriate influences on patient treatment decisions.
- Inappropriate influences on research independence or standards of scientific integrity.

(Testimony of Gregory Demske Before Senate Special Committee on Aging, 2008)

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Enforcement Perspectives: Policy Considerations (Cont'd)

Conversely, OIG has recognized benefits:

- Improved patient care
- Promoting innovation
- Physician role in development, testing, and training of devices is "essential."
- Physicians can "share their knowledge" through participation in CME.
- Device companies can "legitimately compensate" physicians for "actual time and intellectual contributions" to training.

(Testimony of Gregory Demske Before Senate Special Committee on Aging, 2008)

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