

The Physician – Industry Relationship

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Management of Conflicts

- Does a MD have a financial relationship with a drug or device company concurrent with having an R & D, clinical, product approval, academic or publication role that could unduly influence the independence of the MD's judgment in carrying out that role?
- Can concurrent interests/roles be effectively managed to avoid a conflict?
- Are there conflicting roles that should be deemed illegal or unethical?
- Will transparency through public disclosure of industry relationships result in an effective check on conflicts without undermining R & D, CME or proper flow of product information?

New Developments – 2009

- Tougher Voluntary Trade Associations Codes
 - PhRMA Code – (1/1/09)
 - AdvaMed Code – (7/1/09)
- Medical School/AMC Col Policies
- Professional Medical Association Policies
 - AMA CEJA
 - Specialty Societies (e.g. APA)
- Institute of Medicine Col Report
- Proposed federal laws
- Enacted and proposed state laws

Sources of Legal and Ethical Rules for Industry Relationships

- Federal and State Anti-kickback Laws
 - OIG 2003 Compliance Guidance for Pharmaceutical Companies
- Federal and State False Claims Acts
 - Violations of Anti-kickback Laws
 - Claims for off-label uses
 - Whistleblower Provisions
- FDA Guidance – Education, Off-Label

Sources of Legal and Ethical Rules

- Federal Public Financial Disclosure
 - Terms of Settlement with federal government
 - Proposed: *The Physician Payments Sunshine Act of 2009*
 - Would pre-empt state disclosure laws except for those that require reporting of information not required under the PPSA.
- Voluntary Company and Health System Disclosure
- State Registry and Reporting Laws (MA, VT, ME, WV, CA, MN and DC)
 - Gifts
 - All Financial Relationships Over Certain \$ Limit
 - Marketing Codes
 - Licensing of Detailers
 - Gift Bans
 - Prescription data-mining regulation

Beyond Fraud and Abuse

- Gift Bans and limits
- Limits on funding meals on and off-site
- Legal and ethical barriers to direct commercial funding of CME
- Aggregate spend rules
- Restrictions/limits on speakers' bureaus
- Multiple reporting and disclosure systems

Massachusetts Law: Drug and Device Marketing

- M.G.L. c. 111N: Pharma and Device Manufacturer Conduct (Enacted under Chapter 305 of the Acts of 2008, An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care)
- Mass DPH Final Regulations, 105 CMR 970.000 finalized on March 11, 2009
 - Drug and device manufacturer/distributor must certify it has a Code of Conduct/Compliance Plan that meets 105 CMR 970.000 by July 1, 2009
 - \$2,000 Annual Fee
 - Certification of Annual Compliance Audit by July 1, 2010
 - Financial reporting by July 1, 2010

Other Barriers to Physician-Industry Relationships

- Outside Activity Clauses in Employment Agreements
- Health System/Group Practice Col Policies
- Academic Medical Center Col Policies
 - Annual Disclosure
 - Prohibitions on Ownership Interests
 - Limits on Educational and Marketing Activities
- Specialty Society Policies
- Media Coverage

Compliance Steps for MDs

- Is the relationship prohibited, restricted or subject to internal pre-review and/or disclosure by my group, health system, AMC or Society under any contract or policy?
- Is the relationship prohibited, restricted or subject to public disclosure under any applicable state laws?
- Is the relationship in compliance with anti-kickback laws?
 - Can it qualify for a safe harbor?
 - Is the compensation fair market value?
 - Has the company issued a fair and compliant contract?
 - Do I have too many relationships with any company?

Compliance Steps for MDs

- **Will the Company voluntarily disclose the relationship publicly?**
- **Will I need to disclose the relationship as part of my other activities: e.g. formulary committee, government agency appointment, CME faculty, journal editor/author?**
- **How will a disclosed relationship, when viewed with other disclosed industry relationships, appear to the media, patients, employers, colleagues, referral sources?**

MD – Industry Relationships: Continuing Challenges

- Will disclosure diminish the pool of available U.S. MDs for industry relationships?
- Will tougher Col AMC policies diminish the pool of academic MDs for industry relationships?
- If industry funding for CME is additionally restricted who will make up the difference?
- Can industry effectively redesign its marketing to MDs from reward/perk based to information focused models?
- Continued government enforcement, private lawsuits and public scrutiny focused on “stealth” marketing
- Continued efforts toward broader access and cost containment drives increased regulation

Questions & Thank You

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