



HCCA's 12TH ANNUAL COMPLIANCE INSTITUTE

APRIL 13-16, 2008 | NEW ORLEANS, LA | HILTON RIVERSIDE NEW ORLEANS

The Debates Surrounding Healthcare Professional-Vendor Relationships

Robert A. Pelaia, Esquire
Senior University Counsel for
Health Affairs - Jacksonville
University of Florida
653-1 West 8th Street
Jacksonville, FL 32257
(804) 244-3146
robert.pelaia@jax.ufl.edu

Jana Kolarik Anderson, Esquire
Epstein Becker & Green, P.C.
1227 25th Street, NW
Suite 700
Washington, D.C. 20037
(202) 861-1804

Remote Office:
Jacksonville, FL
(904) 714-3948
jkolarik@ebglaw.com



www.hcca-info.org | 888-580-8373

April 2008

Road Map

- Pop Quiz (How did you do?)
- Key Laws impacting vendor-healthcare professional relationships
- OIG Guidance and Government Investigations/Industry Settlements
- Industry-developed compliance and ethical guidelines
- Recent initiatives at medical centers
- Best practices for your organization



www.hcca-info.org | 888-580-8373

April 2008

2

Examples of Vendor-Healthcare Professional Arrangements

- Free samples
- Pens or other items of low value
- Meals with or without educational component
- Continuing medical education (CME) grants or other financial support
- Compensation for participation in speakers bureaus
- Consulting or research agreements



www.hcca-info.org | 888-580-8373

April 2008

3

Legitimate Function VERSUS Conflict of Interest /AKS Violation

- Legitimate Functions
 - The federal Food and Drug Administration's (FDA's) Prescription Drug Marketing rules allow sample distribution to practitioners that are licensed to prescribe the drugs. See 21 CFR part 203.
 - The federal FDA requires vendor education for some products.
 - The HHS' Office of Inspector General (OIG) has blessed vendor provision of reimbursement support programs and some charitable giving programs.



www.hcca-info.org | 888-580-8373

April 2008

4

Legitimate Function VERSUS Conflict of Interest /AKS Violation

- Conflict of Interest or Anti-Kickback Issues
 - CONFLICTS OF INTEREST: Various physician groups have raised the conflict of interest concern, as have recent publications. The claim is that practitioners are making decisions NOT based on what is best for the patient, but based on influence from other sources, e.g., vendor influence.
 - ANTI-KICKBACK ISSUES: The OIG has found that certain arrangements implicate the federal Anti-Kickback Statute (AKS), stating:

[O]ne does not have to be a "provider" or make an actual "referral" to be covered by the anti-kickback statute. The statute covers any persons who offer, pay, solicit, or receive any unlawful remuneration. The scope of prohibited conduct includes not only that which is intended to induce referrals, *but also that which is intended to induct the purchasing, leasing, ordering or arranging for any good, facility, service or item paid for by Medicare or Medicaid.*



www.hcca-info.org | 888-580-8373

April 2008

5

AKS Penalties

- AKS penalizes payments made purposefully to induce or reward the referral or generation of federal healthcare program business.
- Violations of the AKS are punishable by:
 - criminal fines up to \$25,000 per offense, and/or five years imprisonment with a felony conviction; and
 - civil monetary penalties of up to \$50,000 for each violation plus treble damages.



www.hcca-info.org | 888-580-8373

April 2008

6

AKS Exceptions and Safe Harbors

- Although the AKS ultimately turns on a party's intent, vendors and healthcare professionals should identify any financial arrangements or practices that present a potential for abuse.
- Congress created several statutory exceptions to the AKS and, in addition, delegated to the OIG the responsibility of creating safe harbor regulations. If an arrangement satisfies an exception or safe harbor it is immunized from prosecution, and if it does not, it is subject to a facts and circumstances analysis (and potentially the "one purpose" test).



www.hcca-info.org | 888-580-8373

April 2008

7

AKS Exceptions and Safe Harbors (cont.)

- Exceptions and safe harbors applicable to vendor-healthcare professional relationships, including:
 - personal services and management contracts safe harbor
 - discount exception and safe harbor
 - space and equipment lease safe harbors
 - investment interests safe harbors



www.hcca-info.org | 888-580-8373

April 2008

8

Potential Collateral Consequences of AKS Violations

- Federal and State False Claims Acts
- Civil Monetary Penalties Law (CMPL)
- Federal Healthcare Program Exclusion



www.hcca-info.org | 888-580-8373

April 2008

9

Collateral Consequences: Federal False Claims Act

- The federal civil False Claims Act (31 U.S.C. § 3729 et seq.) ("FCA") imposes civil liability on parties that:
 - knowingly present, or causes to be presented, a false or fraudulent claim, record or statement for payment or approval;
 - conspire to defraud the government by getting a false or *fraudulent* claim allowed or paid;
 - use a false record or statement to avoid or decrease an obligation to pay the Government; and
 - violate other fraudulent acts enumerated in the statute.
- Penalties. Potential civil liability under the FCA includes penalties between \$5,500 and \$11,000 per claim, treble damages, and the costs of any civil action brought to recover such penalties or damages.
- Qui Tam Actions.



www.hcca-info.org | 888-580-8373

April 2008

10

Collateral Consequences: State False Claims Act Laws

- ❑ Section 6031 of the Deficit Reduction Act of 2005 provides a financial incentive for States to enact false claims acts similar to the Federal FCA.
- ❑ If a State false claims act is determined to meet certain enumerated requirements, the State is entitled to an increase of 10 percentage points in its share of any amounts recovered under a State action.



www.hcca-info.org | 888-580-8373

April 2008

11

Collateral Consequences: State False Claims Act Laws

- ❑ In order for a State to qualify for the incentive the State must have in effect a law that meets the following requirements:
 - Establish liability to the State for false or fraudulent claims described in the FCA with respect to any expenditures related to State Medicaid plans described in Section 1903(a) of the Social Security Act (the "Act").
 - Contain provisions that are *at least as effective* in rewarding and facilitating qui tam actions for false or fraudulent claims as those described in the federal FCA;
 - Contain a requirement for filing an action under seal for 60 days with review by the State Attorney General;
 - Contain a civil penalty that is not less than the amount of the civil penalty authorized under the FCA.



www.hcca-info.org | 888-580-8373

April 2008

12

Recent State Marketing Laws and Legislation

- These state laws and legislation seek to prohibit or limit gifts, free samples and other promotional items given by vendors to healthcare professionals
- Current Laws
 - Examples: CA, DC, ME, MN, NV, VT and WV require gift reporting
 - CA – goes a step beyond disclosure, requiring pharma companies to adopt and publicly disclose compliance programs that are in compliance with the OIG Pharma Guidance and PhRMA Code
 - MN – prohibits gifts by pharma manufacturers and distributors to practitioners of over \$50 with certain exceptions



www.hcca-info.org | 888-580-8373

April 2008

13

Recent State Marketing Laws and Legislation

- Proposed Legislation
 - Examples: HI, IL, MA, NY, OH, PA
 - Most require public disclosure of any gifts from pharma manufacturers valued at \$25 or more, while others go further and require public disclosure of pharma manufacturer marketing budgets



www.hcca-info.org | 888-580-8373

April 2008

14

Government Guidance

- Office of Inspector General (OIG)
 - 1992 Report and Investigation
 - 1994 Special Fraud Alert
 - OIG Compliance Guidance for Physicians (2000)
 - OIG Compliance Guidance for Pharmaceutical Manufacturers (2003)
- Prescription Drug Marketing Act (PDMA)
 - One of the acts prohibited is knowingly selling, purchasing, trading or offering to sell, purchase, or trade a prescription drug sample. This offense is punishable by up to 10 years in prison.



www.hcca-info.org | 888-580-8373

April 2008

15

Enforcement Trends

- FY 2006 – OIG reported savings and expected recoveries of \$38.2 BILLION.
- FY 2006 – OIG reported exclusions of **3,425** individuals and entities for fraud and abuse; **472** criminal actions; **272** civil actions.



www.hcca-info.org | 888-580-8373

April 2008

16

Recent Investigations/Settlements

□ TAP Pharmaceuticals (2001)

- \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent drug pricing and marketing conduct with regard to Lupron®, a drug sold by TAP primarily for the treatment of advanced prostate cancer. TAP signed a 7-year Corporate Integrity Agreement (CIA).
- Allegations:
 - Kickbacks in the form of free samples of Lupron® to physicians, who then billed Medicare the full price for the drug.
 - Paying physicians sham consulting fees;
 - Sponsoring speaking engagements and meetings and giving money disguised as educational and research grants, which was used to cover cocktail party bar tabs, office holiday parties, medical equipment, travel expenses and discounts on Lupron®.



www.hcca-info.org | 888-580-8373

April 2008

17

Recent Investigations/Settlements

□ AstraZeneca Pharmaceuticals (2003)

- Pleaded guilty and agreed to pay a total of \$355 million in a criminal and civil settlement relating to the pricing and marketing of Zoladex®, a drug used for treating prostate cancer. AZ signed a 5-year CIA.
- Allegations –
 - Provided thousands of “free samples” of Zoladex® to physicians “knowing and expecting” that some of these physicians would prescribe the drug samples to their patients and bill Medicare, Medicaid, and other federal healthcare programs for the samples
 - Unrestricted educational grants, funding business assistance grants and services and paying for travel and entertainment, consulting and honoraria to induce physicians to prescribe the drug.



www.hcca-info.org | 888-580-8373

April 2008

18

Recent Investigations/Settlements

□ Pfizer, Inc. (2004)

- Pfizer, Inc. agreed to pay \$430 million to settle charges in connection with its Warner Lambert/Parke-Davis division's illegal and fraudulent promotion of unapproved uses of the drug Neurotin®. Pfizer signed a 5-year CIA.
- Allegations –
 - "Consultants' meetings" in which physicians received a fee for attending expensive dinners or conferences, including trips to Florida, the 1996 Olympics and Hawaii
 - Grants to physicians who advocated the drug's off-label uses;
 - Honoraria for the use of their names on scientific articles
 - Speaker fees in large amounts for making presentations in which they advocated the drug's off-label uses.



www.hcca-info.org | 888-580-8373

April 2008

19

Recent Investigations/Settlements

□ Serono (2005)

- Swiss corporation Serono and its U.S. subsidiaries agreed to pay \$704 million to settle criminal charges and civil allegations. Serono signed a 5-year CIA.
- Allegations –
 - Paid illegal remuneration including free bioelectrical impedance analysis devices and software, free trips to Cannes, France and SeronAIDS and SALSA survey payments to physicians.



www.hcca-info.org | 888-580-8373

April 2008

20

Recent Investigations/Settlements

□ Schering-Plough (2006)

- Schering-Plough reached a \$435 million settlement with the US Attorney's Office to resolve criminal charges and civil liabilities in connection with allegedly illegal sales and marketing programs for its drugs Temodar® and Intron A®. S-P was subject to an amendment of its existing 5-year CIA.
- Allegations –
 - S-P knowingly caused the submission of false and/or fraudulent claims for drugs that were not eligible for reimbursement
 - Induced physicians to start patients on Intron A® for Hepatitis by paying them remuneration through 3 marketing programs
 - Induced patients to use both drugs through improper preceptorships, sham advisory boards, lavish entertainment and improper placement of clinical trials.



www.hcca-info.org | 888-580-8373

April 2008

21

Recent Investigations/Settlements

□ Medtronic (2006)

- Medtronic Sofamor Danek, a division of one of the country's largest medical device makers, Medtronic, Inc., agreed to pay \$40 million to settle civil allegations that it paid kickbacks to spine surgeons to induce them to use MSD's spinal implant devices. MSD also entered a 5-year CIA.
- Allegations –
 - Paid kickbacks in the form of sham consulting agreements, sham royalty agreements and trips to desirable locations, in addition to hosting medical conferences where the company's main objective was to persuade the physicians "through any financial means necessary" to use its devices



www.hcca-info.org | 888-580-8373

April 2008

22

Recent Investigations/Settlements

- Advance Neuromodulation Systems, Inc. (2007)
 - ANS agreed to pay \$2.95 million and enter into a 3-year CIA to resolve allegations that it paid and gave gifts to physicians in exchange for using the company's products.
 - Allegations –
 - Payments of \$5000 to physicians for every 5 new patients tested with an ANS product
 - Sports tickets, free trips, free dinners, grants and other gifts during the relevant time period.



www.hcca-info.org | 888-580-8373

April 2008

23

Recent Investigations/Settlements

- Zimmer, Inc., Depuy Orthopaedics, Inc., Biomet Inc., Smith & Nephew and Stryker Orthopedics, Inc. (2007)
 - Brought by NJ U.S. Attorney Chris Christie
 - Zimmer, Depuy, Biomet and S&N signed Deferred Prosecution Agreement (will expire in 18 months); paid \$311 million and entered into 5-year CIAs.
 - Stryker signed a Non-Prosecution Agreement – “voluntarily cooperated with the U.S. Attorney’s office before any other company”
 - All 5 companies have federal monitors to review compliance with corporate reforms.
 - Allegations –
 - Using consulting agreements with orthopedic surgeons paid tens to hundreds of thousands of dollars per year as inducements to use a particular company’s artificial hip and knee devices from 2002-2006
 - Lavish trips and other expensive perquisites.



www.hcca-info.org | 888-580-8373

April 2008

24

Industry/Professional Guidance

- Pharmaceutical Research & Manufacturers of America (PhRMA)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- Advanced Medical Technology Association (AdvaMed)
- Medical Device Manufacturers Association (MDMA)
- American Medical Association (AMA)
- American College of Physicians
- American Association of Orthopaedic Surgeons (AAOS)



www.hcca-info.org | 888-580-8373

April 2008

25

Gifts

JAMA

- Prohibits payments of cash or cash equivalents, except as compensation for *bona fide* services.

PhRMA

- Prohibits payments of cash or cash equivalents, except as compensation for *bona fide* services.
- Permit items primarily for benefit of patients (valued at \$100 or less); of minimal value if associated with a healthcare professional's practice (e.g., pens, notepads)
- Does NOT permit items intended for the personal benefit of healthcare professionals (tickets, flowers).



Note: JAMA refers to recommendations in a 2006 article.

www.hcca-info.org | 888-580-8373

April 2008

26

Gifts

ADVAMED

- Prohibits payments of cash or cash equivalents
- Permit items primarily for benefit of patients or that serve educational purpose. Other than textbooks or anatomical models used for educational purposes, gifts should be \$100 or less.
- Promotional items of minimal value related to the healthcare professional's work or the benefit of patients is acceptable.
- Personal gifts (tickets, flowers) to Health Care Professionals or office staff prohibited

OIG Pharma Guidance

- Pharmaceutical companies and their employees and agents should determine whether a particular gift, gratuity or other business courtesy is for the purpose of generating business for the company.
- Compliance with the PhRMA Code with respect to these arrangements should substantially reduce a manufacturer's risk.



www.hcca-info.org | 888-580-8373

April 2008

27

Drug Samples

JAMA

- Prohibits providing samples to physicians and replaces with voucher system for low-income patients

PhRMA

- Providing samples for patient use in accordance with the PDMA is acceptable.

Note: JAMA refers to recommendations in a 2006 article.



www.hcca-info.org | 888-580-8373

April 2008

28

Drug Samples

ADVAMED

- Not covered by Code – signaling that these practices may be legitimate and deserve a distinct analysis

OIG Pharma Guidance

- Samples are acceptable, but it is an area of potential risk.
- Pharmaceutical manufacturers should closely follow the PDMA requirements.



www.hcca-info.org | 888-580-8373

April 2008

29

Drug Formulary Committees

JAMA

- Formulary Committees should exclude physicians and all healthcare professionals with financial relationships with vendors

PhRMA

- No specific policy.

Note: JAMA refers to recommendations in a 2006 article.



www.hcca-info.org | 888-580-8373

April 2008

30

Drug Formulary Committees

ADVAMED

- Not covered by Code

OIG Pharma Guidance

- Any remuneration from a manufacturer or its agents directly or indirectly to person in a position to influence formulary decisions related to the manufacturer's products are suspect and should be carefully scrutinized.
- Manufacturers should also review their contacts with sponsors of formularies to ensure that price negotiations do not influence decisions on clinical safety or efficacy.



www.hcca-info.org | 888-580-8373

April 2008

31

Informational Presentations

JAMA

- All gifts from vendors to physicians should be prohibited.

PhRMA

- Occasional meals, but NO entertainment or recreational events, may be offered during informational presentations by or on behalf of pharma companies as long as the meals are "modest as judged by local standards" and "occur in a venue and manner conducive to informational communication and provide scientific or educational value."

Note: JAMA refers to recommendations in a 2006 article.



www.hcca-info.org | 888-580-8373

April 2008

32

Informational Presentations

ADVAMED

- FDA mandates training and education to facilitate the safe and effective use of certain medical technology – such programs occur at centralized locations (necessitating travel) and may extend to more than one day
- It is appropriate to pay for occasional hospitality only in the form of modest meals and receptions for healthcare professional attendees that are conducive to the exchange of information. It is also appropriate to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment).

OIG Pharma Guidance

- Not specifically addressed.
- Generally, the OIG guidance states that anytime a pharma manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals, which would be problematic under the AKS.



www.hcca-info.org | 888-580-8373

April 2008

33

Educational Conferences/CME

JAMA

- Prohibits direct support of ACCME-accredited programs, but allows support paid to a central repository, such as a subsidiary of an academic medical center

PhRMA

- Financial support for CME should be given to the conference's sponsor, who can use the money to reduce overall conference registration fees for all attendees.
- Responsibility for the selection of content, faculty, educational methods, materials and venue belongs to the CME organizers.
- It is NOT appropriate to pay travel, lodging or other personal expenses of non-faculty healthcare professionals attending CME. Neither is it appropriate to compensate for the time spent by healthcare professionals attending the CME.

Note: JAMA refers to recommendations in a 2006 article.



www.hcca-info.org | 888-580-8373

April 2008

34

Educational Conferences/CME

ADVAMED

- Financial support of bona fide CME is acceptable and should be paid to the program sponsor directly to reduce conference costs or for reasonable honoraria, travel, lodging and meals for faculty.
- Prohibits payments for lodging, travel or personal expenses of non-faculty.

OIG Pharma Guidance

- Grants or support for educational activities that are sponsored and organized by medical professional organizations raise little risk of fraud, provided that the grant or support is not restricted or conditioned with respect to content or faculty.



www.hcca-info.org | 888-580-8373

April 2008

35

Speaker Bureau/Ghost Writing

JAMA

- Academic medical center faculty should not serve as members of speaker bureaus for pharmaceutical or device companies, nor should they be able to publish articles ghostwritten by industry employees.

Note: JAMA refers to recommendations in a 2006 article.

PhRMA

- Token consulting and advisory arrangements should NOT be used to justify payments
- Speaker Training Meetings – Pharma companies may offer healthcare professionals who recruit and train speakers for speaker bureaus reasonable compensation and reimbursement for travel as long as (1) the participants receive extensive training on the company's product and compliance with FDA requirements; (2) training will result in participants providing a valuable service to the company and (3) the participants meet the criteria for consultants (discussed elsewhere).



www.hcca-info.org | 888-580-8373

April 2008

36

Speaker Bureau/Ghost Writing

ADVAMED

- Not covered by Code

OIG Pharma Guidance

- Use of healthcare professionals for marketing purposes – including, e.g., ghost-written papers or speeches – implicates the anti-kickback statute. While full disclosure by physicians of any potential conflicts of interest and of industry sponsorship or affiliation may reduce the risk of abuse, disclosure does not eliminate the risk.



www.hcca-info.org | 888-580-8373

April 2008

37

Consulting/Research Contracts

JAMA

- Can enter into consulting and research agreements pursuant to a written contract with specific deliverables, and information regarding such agreements should be made public.

PhRMA

- Reasonable compensation is appropriate for *bona fide* services as well as reimbursement for travel, lodging and meals.
- The PhRMA Code lists factors supporting a *bona fide* arrangement

Note: JAMA refers to recommendations in a 2006 article.



www.hcca-info.org | 888-580-8373

April 2008

38

Consulting/Research Contracts

ADVAMED

- Reasonable compensation is appropriate for bona fide consulting services, including research, participation on advisory boards, presentations at member-sponsored training and product collaboration.
- Factors of a bona fide consulting arrangement that are similar to those outlined in the PhRMA Code are taken into consideration.

OIG Pharma Guidance

- In general, fair market value payments to small numbers of physicians for *bona fide* consulting or advisory services are unlikely to raise any significant concern.
- Research contracts that originate through the sales or marketing functions – or that are offered to physicians in connection with sales contacts – are particularly suspect.



www.hcca-info.org | 888-580-8373

April 2008

39

The Journals Speak

Journal of the American Medical
Association, January 19, 2000
Physicians and the Pharmaceutical
Industry – Is a Gift Ever Just a Gift?
JAMA. 2000; 283:383-380



www.hcca-info.org | 888-580-8373

April 2008

40

The Journals Speak

Journal of the American Medical
Association, January 25, 2006
Health Industry Practices that Create
Conflicts of Interest – A Policy Proposal
for Academic Medical Centers
JAMA. 2006; 295:429-433



www.hcca-info.org | 888-580-8373

April 2008

41

The Journals Speak

Academic Medicine, February 2006
Guidelines for Interaction Between
Clinical Faculty and the Pharmaceutical
Industry: One Medical School's
Approach
Academic Medicine. 81(2):154-160



www.hcca-info.org | 888-580-8373

April 2008

42

The Journals Speak

Academic Medicine, July 2006

Resident's Perceptions Over Time of
Pharmaceutical Industry Interactions
and Gifts and the Effect of an
Educational Intervention

Academic Medicine. 81(7):595-602



www.hcca-info.org | 888-580-8373

April 2008

43

The Journals Speak

New England Journal of Medicine, April
2007

A National Survey of Physician-
Industry Relationships

N Engl J Med 2007; 356:1742-50



www.hcca-info.org | 888-580-8373

April 2008

44

The Journals Speak

Journal of the American Medical
Association, October 17, 2007
Institutional Academic-Industry
Relationships
JAMA. 2007;298:1779-1786.



www.hcca-info.org | 888-580-8373

April 2008

45

The Journals Speak

American Journal of Public Health,
January 2, 2008
Characteristics of Recipients of Free
Prescription Drug Samples: A
Nationally Representative Analysis
2008 0: AJPH.2007.114249.



www.hcca-info.org | 888-580-8373

April 2008

46

Academia Responds

The Accreditation Counsel for Graduate Medical Education (ACGME)

The ACGME implemented new Institutional Requirements mandating that all member institutions implement a policy of vendor relationships effective July 1, 2007

Vendor interactions: Provision of a statement or institutional policy (not necessarily GME-specific) that addresses interactions between vendor representatives/corporations and residents/GME programs.



www.hcca-info.org | 888-580-8373

April 2008

47

Academia Responds

The Association of American Medical Colleges (AAMC)

The Scientific Basis of Influence and Reciprocity: A Symposium. June 17, 2007 – Washington D.C.

- The AAMC published the findings of a symposium on the scientific basis of influence and reciprocity.
- The symposium summarized the latest evidence from neuroscience and the behavioral sciences that addresses the challenges to objectivity presented by gifts, favors, and influence in academic medicine.



www.hcca-info.org | 888-580-8373

April 2008

48

Academia Responds

The Association of American Medical Colleges (AAMC)

Reciprocity Symposium, continued

- Jointly sponsored by the AAMC and the Baylor College of Medicine Department of Neuroscience and its Computational Psychiatry Unit, the symposium provided a forum for review and discussion of the latest scientific research documenting the important role played by unconscious influences that affect behavior and may lead to unwitting conflicts of interest.
- The symposium report is available for free online <http://www.aamc.org/reciprocity>



www.hcca-info.org | 888-580-8373

April 2008

49

Academia Responds

American Medical Student Association (AMSA)

With a membership of more than 68,000 medical students, premedical students, interns, residents and practicing physicians from across the country, AMSA is the oldest and largest independent association of physicians-in-training in the United States.



www.hcca-info.org | 888-580-8373

April 2008

50

Academia Responds

American Medical Student Association (AMSA)

AMSA's PharmFree Movement

Medical Student PharmFree Pledge:

"I am committed to the practice of medicine in the best interests of patients and to the pursuit of an education that is based on the best available evidence, rather than on advertising or promotion.

I therefore pledge to accept no money, gifts, or hospitality from the pharmaceutical industry; to seek unbiased sources of information and not rely on information disseminated by drug companies; and to avoid conflicts of interest in my medical education and practice."

<http://www.amsa.org/prof/pharmfree.cfm>



www.hcca-info.org | 888-580-8373

April 2008

51

Academia Responds

No Free Lunch Movement

- No Free Lunch is a not-for-profit organization incorporated in the State of New York as the Corporation for Non-Promotion-Based Medicine.
- No free Lunch believes that pharmaceutical promotion should not guide clinical practice.
- Their mission is to encourage health care providers to practice medicine on the basis of scientific evidence rather than on the basis of pharmaceutical promotion.
- They discourage the acceptance of *all* gifts from industry by health care providers, trainees, and students.



www.hcca-info.org | 888-580-8373

April 2008

52

Academia Responds

No Free Lunch Movement

- No Free Lunch believes that:
- There is ample evidence in the literature--contrary to the beliefs of most health care providers -- that drug companies, by means of samples, gifts, and food, exert significant influence on provider behavior.
- There is ample evidence in the literature that promotional materials and presentations are often biased and non-informative.
- Health care professionals, precisely because they are professionals, should not allow themselves to be bought by the pharmaceutical industry: It is time to "Just say no" to drug reps and their pens, pads, calendars, coffee mugs, and of course, lunch.
- www.nofreelunch.org



www.hcca-info.org | 888-580-8373

April 2008

53

Academia Responds

Yale University

The Board of Governors of the Yale Medical Group (YMG), a group practice composed of Yale full-time faculty, approved a policy banning all gifts and on-campus meals from drug representatives. Under the policy, members of the medical staff are urged to use discretion in participating in off-campus industry-sponsored meals. Yale also limits participation in pharmaceutical industry-sponsored conferences.



www.hcca-info.org | 888-580-8373

April 2008

54

Academia Responds

University of Pennsylvania

In July 2006, the University of Pennsylvania Health System broadened its policies surrounding pharmaceutical marketing to include accepting honoraria for talks, free lunches and sales visits by pharmaceutical marketing. The rules prohibit students, faculty and medical staff from accepting "even small gifts."



www.hcca-info.org | 888-580-8373

April 2008

55

Academia Responds

Stanford University

In October of 2006, Stanford University Medical Center prohibited its physicians from accepting even small gifts like pens and mugs from pharmaceutical sales representatives under a new policy intended to limit industry influence on patient care and doctor education.



www.hcca-info.org | 888-580-8373

April 2008

56

Academia Responds

Henry Ford Health Center

Detroit-based Henry Ford Health System banned no-cost lunches, gifts and other incentives to physicians from medical equipment and pharmaceutical Company representatives beginning Jan. 1, 2007. Under the policy, representatives will be required to schedule appointments before visiting physicians and obtain a \$100 certification with the health system to conduct business with a health care provider.



www.hcca-info.org | 888-580-8373

April 2008

57

Academia Responds

University of California

The University of California, Davis, Health System decided in late November 2006 to forbid its Medical staff to accept any gifts from drug salesmen, including drug samples, pens, mugs and meals, however small they might be.



www.hcca-info.org | 888-580-8373

April 2008

58

Academia Responds

University of Minnesota

In July of 2007, the University of Minnesota Medical School asked for an internal panel to examine payments some university physicians have received from pharmaceutical companies, and consider whether the money creates a conflict of interest or influences patient care decisions.



www.hcca-info.org | 888-580-8373

April 2008

59

Best Practices: GAP Analysis

- Prohibit all gifts, including samples, or adopt a less extreme approach
- Gap Analysis
 - Where are pharmaceutical representatives allowed in the organization?
 - Promotional activities?
 - Grants, sponsorships, conferences, scholarships?
 - Differentiate between device reps and pharmaceutical reps?
 - Does the organization maintain a formulary? If so, how are drugs chosen for the formulary?
 - How are medical devices (implantable) chosen at the organization?



www.hcca-info.org | 888-580-8373

April 2008

60

Best Practices: GAP Analysis

- Develop Balanced Policies that Address Educational Issues Confronting Physicians and Patients
- How do current and any future policies impact patient access to drugs?
- Consider limiting access
 - Pharma/device rep registration
 - Pharma/device mfg relationship tracking
 - Disclosure of pharma/device relationships to patients
 - Committees to evaluate drugs and devices



www.hcca-info.org | 888-580-8373

April 2008

61

Best Practices: GAP Analysis

- Invite pharma/device companies to participate. Consider options for manufacturers to gain access to physicians
 - Structured times for clinical presentations
 - Educational presentations
 - Same or similar events sponsored by pharma/device companies
- Medical staff-bylaw considerations



www.hcca-info.org | 888-580-8373

April 2008

62

Best Practices: GAP Analysis

- Train and Test
 - Incorporate pharma/device policies into compliance training
 - Include "real world" examples in training
 - Test understanding of training
 - Invite pharma/device reps to education sessions; consider possible question and answer session for companies



www.hcca-info.org | 888-580-8373

April 2008

63