Institute on Medicine as a Profession

Standards and Best Practices for Promoting Change: A Web-based Curriculum

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Introduction

- This web-based curriculum offers a comprehensive guide to the issues surrounding conflicts of interest in clinical care, professionalism in medicine, and best practices for the management of physicians' relationships with industry. The past two years have seen considerable changes in the policy environment around the management of provider-industry relationships, particularly at AMCs. While this has been a time of interesting developments there is much still to be accomplished and we believe that this curriculum will play an integral part in IMAP's work of promoting change.

- The materials provided here have been designed for use by medical professionals, particularly those in leadership positions at AMCs and other health care settings, and any other potential change agents as a resource to move institutions toward policy change. We provide links/hyperlinks to relevant websites and journal articles. A variety of IMAP designed Power Point presentations are also being made available for use as teaching aides and resources.

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Chapter I. A Time for Change: Legislation, Settlements, Media

- Changes in the policy environment come in the face of increasing public scrutiny evidenced by political action, legislative initiatives, lawsuits, settlements and media coverage.

I. A. Legislation and Regulation:

In the past decade, state and federal oversight of relations between the pharmaceutical industry and physicians has increased dramatically. Heightened concerns around kickback and high costs of healthcare and rise in drug spending are reflected in a series of investigations, inquiries and legislative initiatives in the past decade. The following list represents (not in any chronological order) some prominent events in the politics of regulation physician-industry ties at the federal and the state level:

- Physician Payments Sunshine Act, 2009 – was originally introduced in 2007 by U.S. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) and reintroduced in January 2009. The Act aims "To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP." If passed, beginning in 2010, the government will require yearly reporting of all physician payments over a cumulative value of $100 dollars - with the first report being due by March 31, 2011 - and made available to the public by September 30, 2011.
  http://www.govtrack.us/congress/billtext.xpd?bill=s111-301

- The Drug and Device Accountability Act, 2009 was introduced in Congress in April 2009 by Sen. Edward Kennedy [D-MA] and Chuck Grassley (R-IA) The bill "amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to revise provisions regarding the registration of drug and device establishments, including to: (1) expand the information required to be included in a registration; and (2) provide for risk-based inspections."

  http://www.govtrack.us/congress/bill.xpd?bill=s111-882
  http://finance.senate.gov/press/Gpress/2009/prg042309j.pdf or
  http://thomas.loc.gov/cgi-bin/query/z?c111:S.882.IS:

- In 2007, the FDA tightened conflict of interest rules and guidelines for membership on its advisory panels

http://www.fda.gov/oc/advisory/waiver/coiguidedft.html
http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/LawsRegulationsGuidance/default.htm

- In January 2009, a report released in by the Department of Health and Human Services' Office of Inspector General stated that the FDA's regulations for managing potential financial conflicts of interest were inadequate.
  http://www.oig.hhs.gov/oei/reports/oei-05-07-00730.pdf
  Kuehn BM (2009) Report: FDA Exerts Too Little Oversight of Researchers' Conflicts of Interest JAMA. 2009;301(7):709-710
  http://jama.ama-assn.org/cgi/content/full/301/7/709?etoc
- US FDA modification of list of recognized medical device standards in January 2008. Prior to this, the FDA Modernization Act of 1997 had authorized the FDA to recognize voluntary consensus standards developed in an open and transparent process, such as those developed by American National Standards Institute accredited standards developing organizations, as well as the International Organization for Standardization (ISO) and the International Electrotechnical Commission.
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm

- In April 2003 the Office of Inspector General (OIG) issued a "Compliance Program Guidance for Pharmaceutical Manufacturers". It addressed not only patently illegal practices but also the "gray areas" of physician-industry relations, including consultancies, conference grants, and gifts. Although these exchanges were not illegal, they carried "significant potential for abuse" under the anti-kickback statute. The OIG Guidance represents an unprecedented effort by a federal body to regulate arrangements previously left to the discretion of physicians and companies (Chimonas and Rothman 2005).
  http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf
  (Federal Register / Vol. 68, No. 86 / Monday, May 5, 2003 / Notices, page 23731-23743)

- Vermont gift ban 2009: The Vermont Senate and House recently agreed on a sweeping law to close loopholes in the state's existing gift and payment disclosure law, and to ban many gifts from manufacturers of prescription drugs, medical devices and biological products. The gift ban includes food and free meals. The new law will also require public disclosure of physicians who receive industry money and free drug samples.
  http://www.leg.state.vt.us/docs/2010/bills/Intro/S-048.pdf
  Chimonas SC, Rozario N, Rothman, DJ. Show us the money: Lessons in Transparency from State Pharmaceutical Disclosure Laws. Forthcoming in *Health Services Research*

- In August 2008, Massachusetts enacted a state marketing disclosure law that requires pharmaceutical and device manufacturers to report marketing activities with physicians and other health providers. The Act is effective January 1, 2009. Companies must disclose any economic benefit with a value of at least $50 that they provided to any recipient in conjunction with marketing activities, gifts, cash or in-kind payments (entertainment or recreation), or financial support to physicians-in-training. http://www.mass.gov/legis/bills/senate/185/st02/st02526.htm

- In 1993 the Minnesota legislature passed a law that would limit drug companies from giving gifts to doctors with a value of over $100 a year. Under this legislation drug companies were required to report and make public any consulting fees paid to doctors. Updated in 2008, it made it "unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner". https://www.revisor.leg.state.mn.us/statutes/?id=151.461

- Maine and Washington DC have laws requiring disclosure of gifts or payments of more than $25. West Virginia only requires disclosure of payments of more than $100 per year for a single health care practitioner. http://www.mainelegislature.org/legis/bills/bills_124th/billpdfs/HP088101.pdf

➢ For a comprehensive list of state-wise prescription drug legislation see: http://www.ncsl.org/IssuesResearch/Health/2008PrescriptionDrugStateLegislationNCSL/tabid/14418/Default.aspx

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I. B. Lawsuits and settlements

A series of whistle-blower alerts and class action lawsuits brought against pharmaceutical and device manufacturers in the past decade have resulted in millions of dollars in settlements and greater public awareness of high costs of prescription medication related to industry practices. Some significant lawsuits and settlements are described below. For a more comprehensive listing, see http://www.prescriptionaccess.org/

- Vioxx (Merck)

On September 30, 2004, Merck, voluntarily recalled its blockbuster arthritis drug Vioxx (rofecoxib), in light of a recent clinical trial that confirmed previous studies linking Vioxx to serious cardiovascular problems, including heart attack and stroke. The worldwide withdrawal of Vioxx was the biggest drug

recall in history. In years to follow, hundreds of lawsuits were filed against Merck. The first Vioxx trial resulted in a $253.4 million settlement by a Texas jury.

http://www.law.com/jsp/article.jsp?id=1098108217558
http://www.vioxxnews.com/index.html
http://www.prescriptionaccess.org/lawsuitssettlements/current_lawsuits?id=0028

- Neurontin (Pfizer)

In 2004, Pfizer pleaded guilty to criminal fraud in the promotion of Neurontin (gabapentin). The settlement amount was $430 million. It became the most well known case of the dangers of off-label promotion and marketing of prescription drugs. Gabapentin was originally approved in the U.S. by the FDA in 1994 for use as an adjunctive medication to control epileptic seizures. The first of over 1,200 lawsuits against Pfizer alleging that Neurontin side effects increase the risk of suicide begins trial in the last week of July 2009.

http://www.ahrp.org/infomail/04/05/16.php
http://www.essentialdrugs.org/edrug/archive/200901/msg00023.php
http://www.aboutlawsuits.com/neurontin-lawsuit-trial-begins-5074/
Landefeld CS, Steinman MA. The Neurontin Legacy — Marketing through Misinformation and Manipulation. NEJM 2009; 360: 103-6 (8 January)
http://content.nejm.org/cgi/reprint/360/2/103.pdf

- Celebrex and Bextra (Pfizer)

In the wake of the Vioxx recall, Pfizer withdrew one of its two cox-2 inhibitors, Bextra in 2005. It left the other drug, the bestselling Celebrex, on the market, with stronger warnings. In 2008, Pfizer agreed to set aside $894 million to settle lawsuits related to the two drugs.
http://www.aboutlawsuits.com/celebrex-bextra-lawsuit-settlements-121/
http://www.nytimes.com/2008/10/18/business/18drug.html
http://www.prescriptionaccess.org/lawsuitssettlements/current_lawsuits?id=0009

- Zyprexa (Eli Lilly)

Eli Lilly agreed in 2007 to pay up to $500 million to settle 18,000 lawsuits from people who claimed to have had developed diabetes or other diseases after taking Zyprexa, Lilly's drug for schizophrenia and bipolar disorder. Six whistleblowers filed a complaint in 2003 alerting the courts to the tactics used by Eli Lilly to push Zyprexa sales beyond the drug's approved use. Zyprexa is approved by the U.S. Food and Drug Administration ("FDA") for very limited conditions - schizophrenia and a specific type of bipolar disorder. Under FDA rules, prescription drug manufacturers and marketers may only promote their products

for approved uses. However, Eli Lilly marketed Zyprexa for numerous off-label uses including Alzheimer's, depression and dementia.
http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lilly_remarks.pdf
http://www.google.com/hostednews/afp/article/ALeqM5iBtvz9G1kw59Nc-Io4FZUuxyVZgw
http://www.justice.gov/opa/pr/2009/January/09-civ-038.html
http://www.rollingstone.com/politics/story/25569107/bitter_pill

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I. C. Media

The news media and investigative reporting (notably in the New York Times and the Wall Street Journal) have been central to the process of creating public awareness of industry-medicine ties and their effects on patients' interests, and in moving institutions to change their practices to avoid negative press and publicity. The following is a sample of some influential pieces:

- As Doctors Write Prescriptions, Drug Company Writes a Check (06/27/2004) Gardiner Harris, New York Times
http://www.nytimes.com/2004/06/27/business/27DRUG.final.html?scp=5&sq=Drug%20companies%20physicians&st=cse&pagewanted=print

- Despite Warnings, Drug Giant Took Long Path to Vioxx Recall (11/14/2004)Alex Berenson, Gardiner Harris, Barry Meier and Andrew Pollack, New York Times
http://www.nytimes.com/2004/11/14/business/14merck.html

- Possible Conflicts for Doctors Are Seen on Medical Devices (09/22/2005) Reed Abelson, New York Times
http://www.nytimes.com/2005/09/22/business/22devices.html?sq=device%20kickback&st=cse&scp=10&pagewanted=print

- Psychiatrists, Children and Drug Industry's Role (05/10/2007) Gardiner Harris, Benedict Carey and Janet Roberts, New York Times
http://www.nytimes.com/2007/05/10/health/10psyche.html?scp=1&sq=Psychiatrists%20Children%20Drug%20Industry&st=cse

- Dr. Drug Rep (11/25/2007) Daniel Carlat, New York Times
http://www.nytimes.com/2007/11/25/magazine/25memoir-t.html?scp=1&sq=Daniel%20Carlat&st=cse

- Medical Journal Editor Nemeroff Steps Down Over Undisclosed Ties (08/28/2006) David Armstrong, Wall Street Journal
http://online.wsj.com/article/SB115654102420045878.html

- Doctor didn't disclose Glaxo payments (10/04/2008) David Armstrong, Wall Street Journal
  http://online.wsj.com/article/SB122304669813202429.html

- Research Center Tied to Drug Company (11/24/2008) Gardiner Harris, New York Times
  http://www.nytimes.com/2008/11/25/health/25psych.html

- Prosecutors Plan Crackdown on Doctors Who Accept Kickbacks (03/04/2009) Gardiner Harris, Duff Wilson contributed reporting, New York Times
  http://query.nytimes.com/gst/fullpage.html?res=9507E1DC163BF937A35750C0A96F9C8B63

- Drug Maker Told Studies Would Aid It, Papers Say (03/19/09)), Gardiner Harris, New York Times
  http://www.nytimes.com/2009/03/20/us/20psych.html

- 3 Researchers at Harvard Are Named in Subpoena (03/27/09), Gardiner Harris, New York Times
  http://www.nytimes.com/2009/03/28/health/policy/28subpoena.html

- Medical Papers by Ghostwriters Pushed Therapy (08/04/2009) Natasha Singer, New York Times
  http://www.nytimes.com/2009/08/05/health/research/05ghost.html?_r=1&em

Chapter II. Conflicts of Interest, Industry Influence and Professionalism in Medicine: A Guide to the Issues

II. A. Conflicts of Interest among Physicians: Definition and Scope of the Problem

- Conflict of interest: "A set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest", where the primary interests include "promoting and protecting the integrity of research, the welfare of patients, and the quality of medical education"; and secondary interests include "not only financial gain but also the desire for professional advancement, recognition for personal achievement and favors to friends and family or to students and colleagues." (Conflict of Interest in Medical Research, Education, and Practice. Institute of Medicine, 2009, page 38-39; http://books.nap.edu/openbook.php?record_id=12598&page=38)

- "Although the principle that the integrity of decision making should not be undermined by self-interest may seem self-evident, not until the 1960s was this concept applied to government office holders and attorneys, and then sporadically in the 1980s and 1990s to physicians and clinical researchers." (Rothman 2008, JAMA; http://jama.ama-assn.org/cgi/content/full/299/6/695)

- Conflicts of interest in clinical care can arise at the level of the individual physician or that of the institution. Academic medical centers and professional medical societies are only now beginning to address many of the critical issues involved in institutional conflicts of interest (Rothman DJ, JAMA, 2008 http://jama.ama-assn.org/cgi/content/full/299/6/695). "Institutional conflicts of interest arise when an institution's own financial interests or the interests of its senior officials pose risks to the integrity of the institution's primary interests and missions". (Conflict of Interest in Medical Research, Education, and Practice. Institute of Medicine, 2009, page 176; http://books.nap.edu/openbook.php?record_id=12598&page=176

Power Point Resources

- *Susan Chimonas (IMAP) - Health Industry Practices that Create Conflicts of Interest: An Action Plan for Physician –Industry Relationships (Appendix 1 Health Industry Practices.pdf)*

- *David J. Rothman (IMAP) – "Physician-Industry Relationships: Promoting Professional Integrity and Medical Progress" (Appendix 2 Promoting Professional Integrity.pdf)*

II.B. Industry Influence and Prescriber Behavior

II.B.1. Industry Practices

The pharmaceutical industry makes essential products and plays a critical role in the healthcare system. Yet marketing excesses compromise patient care by influencing prescribing and raising healthcare costs. It exerts influence over prescribers through sales representatives, offering gifts, meals, promotional items, medical equipment, free drug samples, financial ties and relationships in the form of funds for CME and conferences, consulting fees, research contracts, stipends and honoraria, research support, and providing product information through ghostwritten articles, treatment guidelines and CME material. The pharmaceutical industry influences consumers primarily through direct to consumer advertising (Angell 2005)
http://www.nybooks.com/articles/22237

Power Point Resources

- *Susan Chimonas (IMAP) - Under the Influence: How the Pharmaceutical Industry Affects Prescribing and Increases the Cost of Drugs (Appendix 3 Under the Influence.pdf)*

II. B.2. Prescriber attitudes and behavior

There is a strong body of evidence to show that industry marketing practices influence prescriber behavior. Some findings from the literature:

a. Gifts, however small, influence prescriber behavior -- "Many physicians deny the potential for the receipt of small promotional items to undermine their professional objectivity. In fact, the more gifts a physician receives, the more likely he or she is to believe that they do not influence behavior… Those who do not acknowledge the power of small gifts are the ones most likely to be influenced, because their defenses are down" (Katz, Caplan and Merz 2003 http://www.informaworld.com/smpp/content~db=all~content=a713607086)

Studies in anthropology, psychology and sociology show that gifting engenders feelings of indebtedness and the need to reciprocate; behavioral economists have shown that unconscious motivations and calculations affect rational decision-

making; neuroscientists are using MRI and mapping to understand the effects of gifts and rewards on brain activity. (AAMC's "The Scientific Basis of Influence and Reciprocity: A Symposium https://services.aamc.org/publications/showfile.cfm?file=version106.pdf&prd_id=215&prv_id=262&pdf_id=106)

b. Physicians' attitudes towards drug promotion differ substantially from those of the public -- "Patients feel pharmaceutical gifts are more influential and less appropriate than do their physicians" (Gibbons et al 1998 http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1496923)

c. Commercial sources of information, although not rated highly, were cited more often than professional sources for providing first information (Peay and Peay 1984 http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6VBF-466KR2M-WG&_user=18704&_coverDate=12%2F31%2F1984&_alid=979825747&_rdoc=5&_fmt=high&_orig=search&_cdi=5925&_sort=r&_docanchor=&view=c&_ct=5&_acct=C000002018&_version=1&_urlVersion=0&_userid=18704&md5=b32324eaf46946c72215972898c95184). Also, physicians appear to have "cognitive dissonance" when talking about their relationships with drug representatives -- they rely on detailing for information on new drugs even though they consider much of it with a "grain of salt"; (Chimonas, Brennan and Rothman 2007 http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1824740)

d. Residents/doctors in training are a vulnerable target for industry influence, even though they themselves do not perceive this (Sigworth et al 2001 http://jama.ama-assn.org/cgi/content/full/286/9/1024-a ; Zipkin and Steinman 2005 http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1490177 ; Keim et al 1993 http://www.annemergmed.com/article/S0196-0644(05)81262-4/abstract Physicians and residents tend to believe that the average doctor is more likely to accept most items and is more likely to be influenced in their prescribing practices by accepting an item than they are they are, ie, considering their colleagues more vulnerable to conflict (McKinney, W.P. et al 1990 http://jama.ama-assn.org/cgi/content/abstract/264/13/1693 ; Morgan MA et al 2006 http://jme.bmj.com/cgi/content/full/32/10/559?ijkey=e319ff7bdff2e776112ae0e11247a6fe72f79402 ; Chimonas, Brennan and Rothman 2005) http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1824740)

e. Physicians often fail to recognize inaccurate, false or incomplete information provided by industry representatives and promotional material (Ziegler et al 1995 http://jama.ama-assn.org/cgi/content/abstract/273/16/1296 ; Wazana 2000 http://jama.ama-assn.org/cgi/content/full/283/3/373

f. Physicians rely on industry representatives for pricing data

g. Prescribers relationships with industry influence their prescribing behavior and leads to non-rational prescribing not consistent with patient needs: more interactions (including accepting free samples) are linked to higher cost prescribing, decreased prescribing of generics or OTC drugs (Katz, Caplan, and

Merz 2003; Watkins et al 2003; Adair and Holmgren 2005; Cleary 1992; Chew et al 2000; Schwartz et al 2001).

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Gibbons RV et al. A Comparison of Physicians' and Patients' Attitudes Toward Pharmaceutical Industry Gifts," *J Gen Intern Med 1998 March; 13(3): 151–154.* http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1496923

Katz D, Caplan AL, Merz JF. All gifts large and small: toward an understanding of the ethics of pharmaceutical industry gift-giving. *Am J Bioeth*. 2003 Summer;3(3):39-46. http://www.informaworld.com/smpp/content~db=all~content=a713607086

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Peay MY and Peay ER. Differences among practitioners in patterns of preference for information sources in the adoption of new drugs. *Social Science & Medicine*, 1984; Volume 18, Issue 12, 1984, Pages 1019-1025 http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6VBF-466KR2M-WG&_user=18704&_coverDate=12%2F31%2F1984&_alid=979825747&_rdoc=5&_fmt=high&_orig=search&_cdi=5925&_sort=r&_docanchor=&view=c&_ct=5&_acct=C000002018&_version=1&_urlVersion=0&_userid=18704&md5=b32324eaf46946c72215972898c95184

Sigworth SK, Cohen GM: Pharmaceutical branding of resident physicians. JAMA 2001; 286:1024–1025 http://jama.ama-assn.org/cgi/content/full/286/9/1024-a

Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA* 2000;283(3):373-380 http://jama.ama-assn.org/cgi/content/full/283/3/373

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Resources

- The Drug Promotion Database established in 1999, with funding from the WHO Department of Essential Drugs & Medicines Policy and Health Action International Europe is available to the public, free of charge at http://www.drugpromo.info

Power Point Resources

- *Susan Chimonas (IMAP)– The Impact of Industry Relationships on Physician Behavior: What does the Literature Show? (Appendix 4 Drug Promotion Database.pdf)*
- *Susan Chimonas, Troyen Brennan, David J. Rothman. Physicians and Drug Reps: Exploring the Dynamics of the Relationship. (Appendix 5 Physician Drug Rep Dynamics.pdf)*

II. C. Professionalism in Medicine

- A powerful antidote to conflicts of interest in medicine lies in the principle of professionalism. "Professionalism is the basis of medicine's contract with society. It demands placing the interests of patients above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health. The principles and responsibilities of medical professionalism must be clearly understood by both the profession and society. Essential to this contract is public trust in physicians, which depends on the integrity of both individual physicians and the whole profession." (ABIM Foundation)

- The primary attributes of professionalism in medicine are altruism and commitment to patients' interest, self-regulation, maintenance of technical competence and civic engagement.

- Challenges to professionalism come in the form of:

    a) Financial conflicts of interest
    b) HMO / Hospital / Group Practice / Financial Incentive
    c) Drug Company Gifts / Travel / Speaker's Bureau / etc.
    d) Weak historical record of self-regulation
    e) Pass on troublesome colleagues to the next institution
    f) Failure to police activities such as whole body scans and anti-aging clinics and cosmetic claims
    g) Making the chart transparent / IT
    h) Sharing decision-making data
    i) Recertification
    j) Balancing discretion with protocols
    k) The loss of monopoly over technical and valued information
    l) The impact of the web
    m) The self-directed patient

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Power Point Resources

- *David J. Rothman (IMAP) – Medicine as a Profession: A look back and a look ahead (Appendix 6 Professionalism.pdf)*

Chapter III. Conflicts of Interest in Academic Medical Centers

III.A. Why are AMCs important?

"Academic medical centers, which include medical schools and their affiliated hospitals, should provide leadership for medicine in the United States. Just as pharmaceutical manufacturers look to AMCs for influential advice and support, so does the medical profession. Academic medical centers also have a major responsibility for training medical students and house staff. Research reveals that the habits learned or acquired during training persist into practice. Objectivity and scientific integrity should be central tenets of physician training. Academic medical centers are also in a position to take immediate action. They are sufficiently well organized to gain commitments to a set of new principles in relatively short time. Moreover, independent research into the impact of medications and devices on population health is concentrated in AMCs; therefore, unwarranted influence by manufacturers must be avoided. For these reasons, academic medicine should take the leadership in reforms, and other physicians and medical institutions should adopt their standards." (Brennan TA et al. , JAMA, 2006 http://jama.ama-assn.org/cgi/content/full/295/4/429)

❖ Areas for potential conflicts:

- Gifts
- Meals
- Pharmaceutical samples
- Drug Formularies and P&T Committees
- Continuing Medical Education
- Funds for Physician Travel
- Speakers Bureaus
- Ghostwriting
- Consulting and Research Contracts
- Stipends and honoraria
- Contributions to medical societies and professional organizations

http://jama.ama-assn.org/cgi/content/full/295/4/429

Key references:

Brennan TA et al. Health industry practices that create conflicts of interest: a policy for academic medical centers. *JAMA.* 2006;295(4):429-433. http://jama.ama-assn.org/cgi/content/full/295/4/429

Association of American Medical Colleges Task Force on Financial Conflicts of Interest in Clinical Research. Protecting Subjects, Preserving Trust, Promoting Progress

II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research. http://www.aamc.org/research/coi/2002coireport.pdf

Rothman DJ. Academic medical centers and financial conflicts of interest. *JAMA*. 2008;299(6):695-697. http://jama.ama-assn.org/cgi/content/full/299/6/695

Coleman DL. Establishing Policies for the Relationship Between Industry and Clinicians: Lessons Learned From Two Academ2ic Health Centers. *Acad Med* 2008;83(9):882-887. http://journals.lww.com/academicmedicine/Abstract/2008/09000/Establishing_Policies_for_the_Relationship_Between.22.aspx

III.B. State of AMCs: Assessing institutional policy environment

- There is now a growing body of empirical data to support the establishment and evaluation of institutional policies and practices aimed at managing individual and institutional conflicts of interest in clinical care, particularly in the setting of academic medicine.
- In September of 2007, IMAP undertook a survey of the nation's 125 academic medical centers and their conflict of interest policies in clinical care. In addition to the questionnaire that focused on ten basic areas of policy, we requested copies of the schools' policies. The result was an impressive and varied collection of policies and guidelines from well over three quarters of the schools surveyed.
- Our forthcoming analysis of the survey indicates that only a fifth of all AMCs have strong policies restricting gifts, and even fewer than that have policies addressing meals, ghostwriting, speakers bureaus, samples among others
- Our research shows that many schools are in the process of revising and adding to their policies, a finding that is not surprising considering the increasing attention to transparency and addressing conflicts with industry among the healthcare profession.

Key References:

Campbell EG, Weissman JS, Ehringhaus S; et al. Institutional academic-industry relationships. *JAMA*. 2007;298(15):1779-1786. http://jama.ama-assn.org/cgi/content/full/298/15/1779

Ehringhaus SH, Weissman JS, Sears JL, Goold SD, Feibelmann S, Campbell EG. Responses of medical schools to institutional conflicts of interest. *JAMA* 2008;299(6):665-671 http://jama.amaassn.org/cgi/content/full/299/6/665?ijkey=9efc9c978a5e8b9c8294e820af811828a00c495d

Resources

- IMAP's COI Policy database: http://www.imapny.org/coi_database/

Chapter IV. Guidelines and Best Practices for Management of Conflicts of Interest

- A process of change is underway in how physicians' relationships with pharmaceutical and device companies are perceived and in the policy environment governing their interactions. In 2004, a joint task force appointed by the American Board of Internal Medicine Foundation (ABIM) and the Institute on Medicine as a Profession (IMAP) concluded that existing guidelines and policies were inadequate in managing physician-industry relationships and resulting COI. The ABIM-IMAP task force published its policy recommendations on conflict of interest in JAMA in 2006. The proposals stimulated many academic medical centers (AMCs) to evaluate existing guidelines or formulate new ones. In 2008 the Association of American Medical Colleges (AAMC) issued its recommendations on conflict of interest that echoed and reinforced those of the ABIM-IMAP taskforce.

- While the larger number of AMCs have still to adopt stringent policies addressing the relationships between their physician faculty and industry, an influential body of prominent medical centers around the country have put into place exemplary COI guidelines and policies. These include at least 25 institutions from both the public and the private sectors and from all regions of the country, including Boston University, University of Massachusetts–Worcester, and Yale University; University of Pennsylvania, University of Pittsburgh; the Universities of Michigan, Wisconsin, and Chicago; and the entire University of California system. These AMCs are joined by such health care delivery organizations as the Henry Ford Health Systems (Detroit), Kaiser Permanente (northern California), and the US Veterans Administration network.

  Studies are ongoing to document the process of policy and behavior change at some of these institutions and to compile exemplary practices and policies for dissemination. The following represent IMAP's recommendations for best practices in specific areas. Complete best practices documents can be found at http://www.imapny.org/amc_toolkits/

IV.1. Vendor Relations

Pharmaceutical vendors have often had relatively unrestricted access to large academic medical centers (AMCs), community hospitals, and physicians' offices. Vendor visits are often accompanied by gifts and meals that have been shown to influence prescribing. Indeed, the pharmaceutical industry spends around $15,000 per physician in marketing (not including samples), a sum that produces significant returns on investment. Moreover, industry sales representatives

frequently do not provide complete and accurate information regarding the efficacy of their products.

AMCs should provide quality, evidence-based care, and create an educational environment that is free of the undue influence of pharmaceutical and device industry marketers. AMCs must ensure the privacy of their patients. To this end, leading AMCs have begun to implement policies that limit the access of pharmaceutical and device industry representatives to students, residents, physicians and patients. Most policies controlling the access industry representatives have to medical center areas require: registration of all vendors; badges for vendors that distinguish them from hospital employees; access to physicians only by prior appointment; no gifts or meals.

Policy considerations:

- Compliance with state and local law.
- Restrict interactions between industry representatives and staff to meetings by appointment only.
- Patient Privacy
- Shaping behavior of trainees (residents, students, interns)

Implementation strategies:

- Establish a compulsory registration process for any sales or marketing representatives who will be on medical center grounds for work purposes
- Establish a process for determining who is responsible for enforcing vendor liaison policies
- Enforcement
- Create mechanism to replace industry information.

Model policies:

University of Pittsburgh

http://www.coi.pitt.edu/IndustryRelationships/Policies/IndustryRelationshipsPolicy.pdf

Stanford University

http://med.stanford.edu/coi/siip/faqs.html

IV.2. Samples

Of the $29 billion spent by the pharmaceutical industry to promote its products, over 60%, or about $18 billion a year goes to "free" samples. Samples encourage physicians and patients to rely on medications that are expensive, but often not

more effective than other available drugs. Samples have been shown to increase physician prescribing of the marketed product, independent of the effect of detailing by industry sales representatives.

Developing a samples policy requires consideration of the marketing impacts of samples, the needs of under-insured patients, patient safety concerns associated with dispensing samples, compliance with accreditation standards and the invisible overhead costs associated with logging, tracking and dispensing medications from a traditional sample closet.

Model policies:

Hospital of the University of Pennsylvania

http://www.imapny.org/usr_doc/Guidelines_for_Interactions_between_Healthcare_Professionals_and_IndustryP4.pdf

http://www.imapny.org/usr_doc/Pharmaceutical_Company_Representative_ActivityP4.pdf

University of Wisconsin

http://www.imapny.org/usr_doc/Control_of_Trial_Supplies_of_Prescription_MedicationW4.pdf

IV.3. Gifts and Meals

The pharmaceutical and medical device industries give gifts to medical professionals to cultivate goodwill, influence prescribing behavior, and gain access to prescribers. Gifts may include items such as pens and notepads, textbooks, travel support, lunches, meals at five-star restaurants, entertainment, and other items of value. Such gifting, however small, influences prescriber behavior.

Numerous health care organizations and academic medical centers (AMCs) have adopted no-gifts, no-meals policies.

Policy considerations:

- Gifts should be banned in their entirety, regardless of nature or value.
- Industry-sponsored meals and snacks should be banned in their entirety within the institution. (Some departments have budgeted to replace industry-funded meals, while others require that medical residents and staff purchase their own meals.)
- Enforcement strategies focused on vendors

- Acceptance and implementation

Model Policies:

The University of Pittsburgh
http://www.coi.pitt.edu/IndustryRelationships/Policies/IndustryRelationshipsPolicy.pdf

Stanford University

http://med.stanford.edu/coi/siip/faqs.html

Boston University

http://www.bumc.bu.edu/www/busm/ood/images/policies/BMC-BUSM%20Industry%20Interactions%20_July%2026_.pdf

IV.4. Ghostwriting and Speakers Bureaus

Ghostwriting and speakers' bureaus present work created to further industry marketing goals as the independent work of leaders in academic medicine. Ghostwritten articles appear to be authored by a prominent physician, but are in fact the work of an industry employee or a freelancer working closely with a pharmaceutical, medical device, or medical education and communication company. Speakers' bureaus are speaking events where physicians give presentations based largely or entirely on material provided by a pharmaceutical or medical device company. The role of industry in organizing the data, and drafting the article is obscured by excluding the true author, and only including the apparently independent academic physician.

Policy considerations

- Ensuring faculty members only participate in legitimate speaking engagements
- There is no room for industry ghostwriting in an academic environment

Model Policies

The University of Pittsburgh

http://www.coi.pitt.edu/IndustryRelationships/Policies/IndustryRelationshipsPolicy.pdf

IV.5. Drug and Medical Device Procurement

Pharmacy and therapeutics (P&T) committees are an effective tool for hospitals and health centers to ensure the practice of quality, cost effective and evidence-based medicine. Conflict of interest issues arise when individuals who have a direct role in decisions related to drug or medical equipment procurement also have financial relationships with manufacturers, including any receipt of gifts, grants, contracts or an otherwise compensated relationship. It is essential that academic medical centers (AMCs) establish policies to ensure that conflicts of interest do not influence purchasing decisions and jeopardize quality, evidence-based care.

Policy Considerations

- Disclosure
- Recusal
- Compliance with state law
- Reinforcing the formulary
- Implementation strategies

Model policies:

Yale University

"YMG physicians who are involved in institutional decisions concerning the purchase of or approval of medications or equipment, or the negotiation of other contractual relationships with industry, must not have any financial interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in pharmaceutical companies that might benefit from the institutional decision. This provision is not intended to preclude the indirect ownership, through mutual funds or other investment vehicles, of equities in publicly traded pharmaceutical companies by Yale faculty."

Veterans' Affairs

"In service training, continuing education presentations and promotional materials that primarily focus on non-formulary drugs/supplies are prohibited. Exceptions may be granted by the VISN committee responsible for such oversight.

IV.6. Continuing Medical Education (CME)

In 2006, pharmaceutical and medical device industry support for continuing medical education (CME) totaled $1.45 billion, accounting for 60

percent of all income from CME (up from 34 percent in 1998). Industry support of CME has grown in recent years as other avenues of pharmaceutical promotion have come under increased scrutiny and regulation.

Pharmaceutical companies often control events indirectly through Medical Education Communication Companies (MECCs). The MECCs organize events for physicians, but serve the needs of their clients – the industry that pays the bills.

The Accreditation Council for Continuing Medical Education (ACCME) has established standards for commercial support. However, ACCME does not audit individual programs and its standards have not been effective in ensuring the independence of CME events. Many programs continue to receive accreditation, despite serving primarily marketing purposes.

It is critical that policies to address conflicts of interest at academic medical centers (AMCs) include provisions to maintain the independence and rigor of CME. A model CME policy for an academic medical center should aim to eliminate both real and perceived conflicts of interest derived from the involvement of pharmaceutical and device companies playing such a central role in physician education.

Policy considerations:

- Incorporation of ACCME standards
- Disclosure is not sufficient
- Reviewing CME for bias
- Establishing a central education fund
- Funding CME solely through academic medical center support and attendance fees

Model Policies:

Memorial Sloan-Kettering Cancer Center (MSKCC), New York

http://www.mskcc.org/mskcc/shared/graphics/Research_Resources/RRM/Policies_and_Procedures/Interaction_with_Industry.pdf

Power Point Resources

- *David J. Rothman (IMAP). Managing Physician and Pharmaceutical Industry Interactions: Exemplary Policies. (Appendix 7 Exemplary Policies.pdf)*
- *Susan Chimonas (IMAP). Understanding Education from a Social Science Perspective (Appendix 8 CME social science perspective.pdf)*
- *Susan Chimonas (IMAP), David J. Rothman. Managing Provider-Industry Conflicts of Interest: A Professionalism Impact Analysis for CME (Appendix 9 CME impact analysis.pdf)*

Chapter V. Making Change: Some findings on dynamics of change

- This curriculum is part of an action oriented program to facilitate change by outlining the dynamics of institutional and behavior change and by identifying and mobilizing change agents. Some findings on how change occurs and who is instrumental in bringing it about:

  - Change comes from the top down
  - Deans are key players in leading change
  - Pharmacy and Therapeutics (P&T) Committees and particularly Chairs are important supporters
  - Faculty leadership must endorse new policies
  - Consensus building and debate is important to the process
  - No noticeable faculty flight; in fact, support for more stringent policies is usually strong
  - Some compromise is necessary
  - No reported decrease in pharmaceutical company funding for research
  - No complaints about disappearance of free stuff (stationery etc.) or even meals

Key references:

Coleman DL. Establishing Policies for the Relationship Between Industry and Clinicians: Lessons Learned From Two Academic Health Centers. *Acad Med* 2008;83(9):882-887. http://journals.lww.com/academicmedicine/Abstract/2008/09000/Establishing_Policies_for_the_Relationship_Between.22.aspx

Rothman DJ and Chimonas SC. New Developments in Managing Physician-Industry Relationships. JAMA. 2008;300(9):1067-1069 http://jama.ama-assn.org/cgi/content/full/300/9/1067