

CONFLICT OF INTEREST



Elizabeth A. Kitsis, MD, MBE

Bioethics 1

May 5, 2011

No conflicts to disclose

Learning Objectives

1. To define “conflict of interest” (COI)
2. To appreciate the potential impacts of COI
3. To understand ways in which COI can be prevented or managed

Anyone can have a COI...

Justice Clarence Thomas and COI

Famous people...

Schwarzenegger's \$8 million deal
Is California governor's fitness magazine
contract a conflict of interest?



July 14, 2005



Aqueduct Racino



- Acqueduct Raceway to become Casino
- Paterson chose Aqueduct Entertainment Group in Jan, 10
- Met with Reverand Floyd Flake 3 days later
- Flake had expressed support for Cuomo 1 week earlier

Journalists...

Corrections: For the Record NYTIMES EDITORIAL



Advertising □ "The Times acknowledges that accepting money from the very corporations whose activities we are responsible for reporting on — running ads from ExxonMobil while reporting on climate change, for example, or from weapons manufacturers while reporting on the Iraq War — represents an obvious conflict of interest."

Government institutions...

Former FDA Chief Lester Crawford to Plead Guilty in Fraud Case



WASHINGTON — Former FDA chief Lester Crawford will plead guilty for failing to disclose a financial interest in companies his agency regulated, his lawyer said Monday.

The Justice Department accused the former head of the FDA with falsely reporting that he had sold stock in companies when he continued holding shares in the firms governed by FDA rules."

(Feb 15, 2005)

www.foxnews.com

Prestigious medical centers...

Wait, wait, don't tell me...



Wait, wait, don't tell me...



Joseph Biederman, MD
Director, Pediatric Psychopharmacology Unit
Massachusetts General Hospital

- Work fueled 40X increase in diagnosis of bipolar disorder in kids between 1994-2003, with associated increase in antipsychotic Rx's
- Accused of earning \$1.6 M in consulting fees from 2000-07 with minimal disclosure (NY Times, 2008)
- Accused of promising J&J that research on company drugs would yield positive results before beginning studies (Boston Globe, 2009)

Wait, wait, don't tell me...



Wait, wait, don't tell me...



Charles Nemeroff, MD
(Former) Chairman of Psychiatry
Emory University

- Accused of earning \$2.8 M from drug companies from 2000-2007, failing to disclose at least \$1.2 M (New York Times, 2008)

Wait, wait, don't tell me...





Conflict of Interest Definition



“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.”

Elements of COI

- Primary interests—determined by professional duties
 - ❖ Patient welfare
 - ❖ Scientific integrity
 - ❖ Quality of medical education

Elements of COI

- Secondary Interests

- ❖ *Financial gain*

- Personal

- Institutional

- ❖ Grant support

- ❖ Publications

- ❖ Prestige

- ❖ Career growth

Conflict

- Circumstances or relationships that increase or create risk that primary interests will be neglected because of pursuit of secondary interests
- Primary interests are not necessarily compromised, but the risk exists that they could be

Conflict of Commitment

- Conflict between what institutions view as employees' primary responsibilities to the institution and the employee's outside commitments
- Difficult decisions about how to divide time between research and other responsibilities
- Concern is about time and effort, not undue influence

Conflict of Obligation

- Individual or institution has duties that require different actions, but only one action can be taken in the given circumstance
- Ethical dilemma in which two values conflict and difficult choice between them must be made
 - ❖ Maintaining confidentiality of patient with infectious disease may conflict with maintaining safety of patient's contacts

Non-Financial COI

What should be done?

- Expect that physicians, researchers & IRBs will act with these conflicts in mind
- Acknowledge COI are intrinsic to the practice of medicine and research
- Create institutional policies and cultures that address both financial and nonfinancial COI

Identify a conflict of interest,
commitment, or obligation

Approach to a potential COI

- Is there a COI?
- If so, how severe is it?
- Importance of financial relationship for furthering primary medical values?

Criteria for Assessing the Severity of COI

- Likelihood of undue influence by a secondary interest
- Seriousness of the possible harm that could result from such an influence

Severity of COI: Likelihood of Undue Influence?

- What is the value of the secondary influence?
 - ❖ Greater value, more likely its influence
- What is the scope of the relationship?
 - ❖ Duration & depth of relationships
- What is the extent of discretion?
 - ❖ Latitude in decision-making

Severity of COI: Seriousness of Possible Harm

- What is the value of the primary interest?
- What is the scope of the consequences?
 - ❖ Greater scope, more serious potential for harm
- What is the extent of accountability?
 - ❖ Less accountability, more serious harm
 - ❖ Accountability is also greater if sanctions for violations are significant and imposed in timely fashion

“All Gifts Large and Small”

- Presumption is that large gifts influence behavior, but small gifts do not
- Gift exchange underlies human tendency to engage in networks of obligation
- Obligation to directly reciprocate, conscious or unconscious, tends to influence behavior

Case Study

- Approximately 4,000,000 Americans have Alzheimer's
- P. Trey Sunderland—leading NIH psychiatric researcher
- Led an NIH study of Alzheimer's patients in collaboration with Pfizer (Aricept)
- Accepted \$300,000 from Pfizer from 1998-2003 and did not disclose this income
- Caught by NIH ethics officer
- Congressional Subcommittee Hearing
 - ❖ Sentenced to two years probation
 - ❖ Pay \$300,000
 - ❖ Perform 400 hours of community service

What do you think?

- Likelihood
 - ❖ What is the value of the secondary interest?
 - ❖ What is the scope of the relationship?
 - ❖ What is the extent of discretion?
- Seriousness
 - ❖ What is the value of the primary interest?
 - ❖ What is the scope of the consequences
 - ❖ What is the extent of accountability?

COI can happen in multiple medical settings

- Clinical Practice
- Medical Education
- Clinical Research
- Academic Medical Centers
- Professional Societies
- Practice Guideline Development
- Pharmaceutical Companies

COI in Clinical Practice

- Physician payment
- Self-referral and MD ownership of health care facilities
- Industry-related activities

COI in Clinical Practice

Physician payment

- Fee for service--↑ volume of services?
- Capitated payment--↓ provision of care?
- Payments related to:
 - ❖ Quality
 - ❖ Patient satisfaction
 - ❖ Outcomes

Self-Referral & MD Ownership

- 35% increase in number of ambulatory surgery centers between 2000 and 2004; 83% partly or wholly owned by MDs (Pham & Ginsburg, 07)
- # of cardiac and orthopedic specialty hospitals serving Medicare patients grew from 21 in '98 to 67 in '03
- Secondary interest (income from increased services) may compromise primary interest in patient welfare

COI in Medical Education

How pervasive is it?

2006 survey of department chairs at medical schools & 15 largest independent teaching hospitals re industry support

- 65% of clinical departments for CME
- 37% for residency or fellowship training
- 19% unrestricted funds for department operations
- 17% for research & equipment

AMSA Pharm-Free Scorecard

- Evaluates conflict of interest policies at U.S. medical and osteopathic schools
- Uses letter grades to assess schools' performance in 11 potential areas of conflict
- Focuses on individual physician and trainee
- Started in 2007

NYC Medical School Grades AMSA Pharm-Free Scorecard

School	Grade 2010	Grade 2009
Mount Sinai	A	A
Einstein	B	C
New York University	B	B
Columbia	C	B
Touro	C	F
Weill-Cornell	D	D
SUNY Downstate	D	I

I = Policies are under revision

COI in Continuing Medical Education

% of support from industry (approximate)

- 1998 35%
- 2002 53%
- 2006 55%

COI in Clinical Research

Where does it occur?

- Investigator
- IRB
- Academic Medical Center
- Pharmaceutical Industry

Investigator COI

- Primary Interests
 - ❖ Patient Welfare
 - ❖ Science
- Secondary Interests
 - ❖ Financial
 - ❖ Individual Recognition
 - ❖ Publication
 - ❖ Grant Support
 - ❖ Career Ladder

Institutional COI in Research

- Primary Interest
 - ❖ Patient Welfare
 - ❖ Scientific Advancement
- Secondary Interests
 - ❖ More Patients
 - ❖ Financial
 - ❖ Institutional Reputation

Bayh-Dole Act of 1980

- “Erased an ethical bright line between academic and corporate medicine”
- Allowed institutions to patent discoveries resulting from federally funded research
- Universities could retain licenses and royalty fees, which they typically share with the scientists who developed the discovery

Why Allow Ties to Industry?

The Value of Academia-Industry Collaborations

- **Cortisone:** Philip Hench + Merck
- **Insulin:** Banting & Best + Lilly
- **Penicillin:** Alexander Fleming + Pfizer
- **Gleevec:** (Druker & Lydon & Sawyers) + Novartis

U.S. Pharmaceutical industry invested \$47.9 billion in R&D in 2007

A few bad eggs, imperfect disclosure, or the tip of the iceberg?

What's going on?

“Framing Bias”

- “Conflict” has negative connotation
- Negates alignments and common interests
 - ❖ Society wants effective new treatments
 - ❖ Academia wants to translate basic science discoveries into new treatments
 - ❖ Industry wants to develop new products

The Value of Academia-Industry Collaborations

Association of Clinical Researchers & Educators

- Thomas Stossel, Avi Markowitz
- Emphasizes value of physician-industry interactions
- “The entire field is being punished for the actions of a couple of Bernie Madoffs.” (Markowitz)
- Advocate treating financial COI like scientific misconduct; weed out those who misbehave

Willyard, 2009

Impact of COI

What do the data show?

How Extensive are Academia-Industry Relationships?

2006 national survey of department chairs

- 67% of departments had relationships with industry
- 60% of department chairs had relationships
 - ❖ Consultant (27%)
 - ❖ Advisory Board member (27%)
 - ❖ Paid speaker (14%)
 - ❖ Board member (11%)
 - ❖ Officer (7%)
 - ❖ Founder (9%)

(Campbell, et al, 2007)

“Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?”

Results

- Meetings w/ reps were associated w/ requests by MDs to add drugs to formularies
- Meetings w/ reps were associated w/ changes in prescribing practices
- Industry-sponsored CME programs highlighted the sponsor's drugs compared w/ other CME programs
- Attendance at sponsored CME events was associated w/ increased prescription rates of sponsor's product

“Scope & Impact of Financial COI in Biomedical Research”

Results

- 25% of investigators had industry ties
- 67% of academic institutions held equity in start-ups that sponsored research at their institutions
- Eight articles (which together reviewed 1140 original studies) assessed the relationship between industry sponsorship and study outcome.
- There was a statistically significant association between industry sponsorship and pro-industry conclusions.

So what should we do?

Possible Solutions

Potential Remedies for Financial COI

- Policies
- Disclosure
- Management (COI Committees)
- Distancing
- Divestiture of Interest
- Prohibition

IOM General Recommendations

1. Adopt & implement COI policies
2. Strengthen disclosure policies
3. Standardize disclosure content and format
4. Create a national program for the reporting of company payments

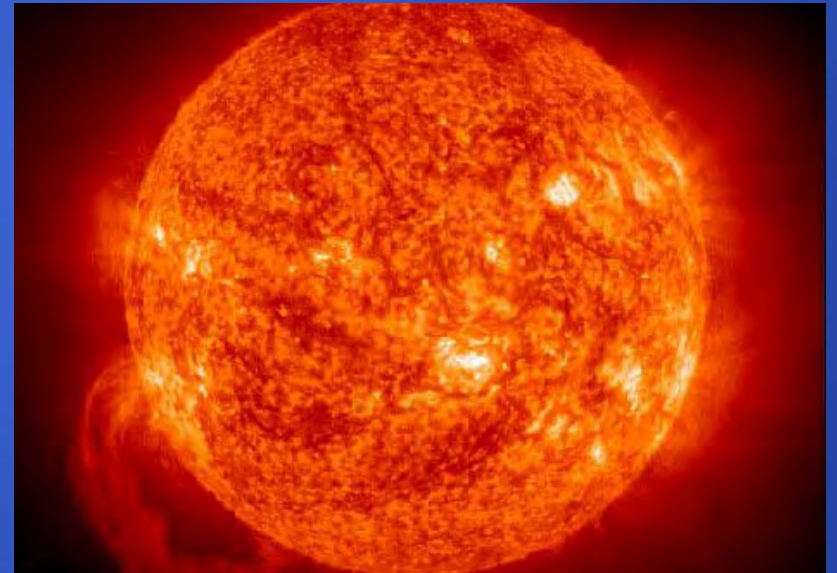
IOM Report: Disclosure

- Essential, but limited first step
- Advocates standardizing content, format & procedures
- Allows for assessment of severity, requiring:
 - ❖ Management of relationship
 - ❖ Elimination of relationship

Weaknesses of Disclosure

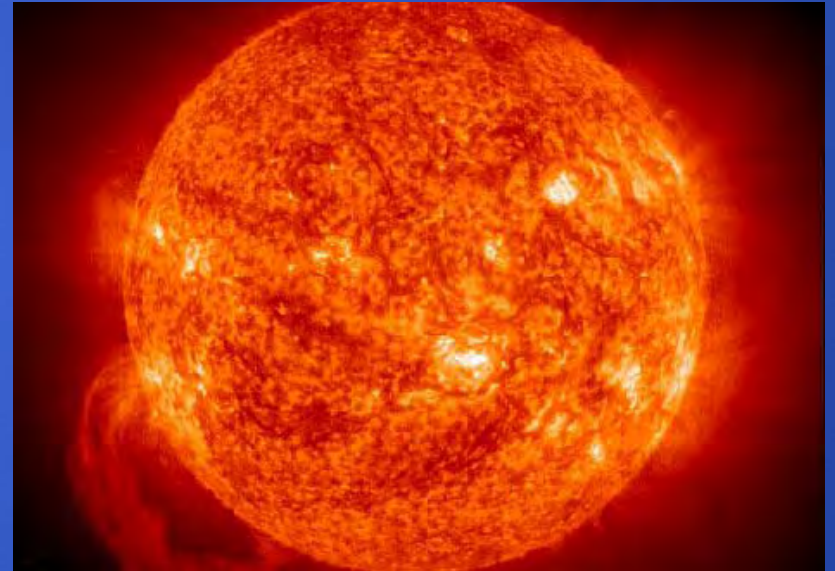
- Reveals a problem; does not resolve it
- Individuals may not know how to interpret information
- Individuals may think if MD is involved in research, it might be more likely to benefit them
- Disclosure may not provide protection from legal liability
- No data indicate that disclosures deter MDs from entering into COI

Wait, wait, don't tell me...



Senator Charles Grassley-- Iowa (R)

Physician Payments Sunshine Act



Sunshine Act Passed

- Start recording Jan 1, 2012
- Start reporting March 31, 2013
- Definition of payment: gift, food, entertainment, honoraria, travel, research funding, education, charitable contribution, compensation for faculty or speaking engagement, consulting fees, ownership or investment interest, royalties, license fee, dividends, profit distribution, stock or stock option grant
- Excluded: anything of value <\$10