

Conflicts of Interest: The Final Research Compliance Frontier

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Conflicts of Interest

Introduction

Few weeks go by without media coverage of a high profile researcher, administrator or physician running afoul of institutional or regulatory policies.

Why do conflicts of interest provoke such extreme media backlash, public outrage, and undermine the credibility of research and continue to inspire waves of contemplated legislative reform?

Perceived and actual conflicts of interest inevitably lead us to pose questions about how individuals and organizations negotiate ethical quandaries – often involving large sums of money, patient care and societal well being.

Conflicts of Interest

Introduction

Unlike many federal regulatory requirements, conflicts of interest policies and procedures are devised to prevent the potential as well as the actual incidence of bias.

The ‘appearance’ of a conflict of interest or failure to effectively manage them can be enough cause organization-wide fallout and reputation and/or compliance risks.

A Cautionary Tale: Emory

Conflicts of Interest A Cautionary Tale: Emory

“[National Institutes of Health or NIH] gives \$24 billion worth of grants...The law requires the universities to have their researchers report outside income. We found out the law wasn't being followed. The universities were not doing their job of gathering the information. We started looking into it and got inconsistent information between the researchers and what the university had. We found out that NIH was not really enforcing current law. It's a matter of making sure the law is followed and making sure that we make all this information transparent. Let the sun shine in...NIH has a lot of power...And I want the director of NIH to use that muscle to make sure universities are doing what they're required to do. That, they've been very lax in. I think that the NIH director ought to be as aggressive as he can...All he'd have to do is withhold one grant or bring back money from a grant if somebody's not doing their job. The message would get out pretty fast...”

- Senator Charles Grassley, Ranking Republican (Iowa), US Senate Finance Committee

Conflicts of Interest

A Cautionary Tale: Emory

- In a correspondence publicly released on February 24, 2009, Sen. Grassley requested that the Inspector General of the US Department of Health and Human Services (HHS) investigate whether Dr. Charles B. Nemeroff, formerly the Chair of the Psychiatry Department at Emory University, had fully discharged his required time commitments as Principal Investigator of multiple research grants from the NIH.
- In addition to raising this conflict of commitment matter, Sen. Grassley reiterated concerns as to whether Emory had reported conflict of interest issues to the NIH in good faith.
- This was not Sen. Grassley first contact with Dr. Nemeroff or Emory University's conflict of interest management infrastructure.
- His efforts unleashed both an internal investigation at Emory University culminating in reform, the stepping down of Dr. Nemeroff from his chair, a statement of apology and his barring from sponsored research grants for the next two years – and federal action.

Conflicts of Interest

A Cautionary Tale: Emory

- In October 2008, the National Institute of Health (NIH) suspended a five year \$9.3 million grant (<http://grants.nih.gov/grants/guide/pa-files/PAR-05-039.html>) to Emory University. Emory's Centers for Intervention Development and Applied Research had been the beneficiary, with its research exploring common treatment regimens for depression.
- An investigation by the US Senate Finance Committee – spearheaded by Sen. Grassley – into the financial relationships of academic researchers who are federal grant recipients with pharmaceuticals triggered the suspension.
- Sen. Grassley details a disturbing timeline of payments received by Dr. Nemeroff during a timeframe when he assured Emory administrators he would receive no more than \$10,000 annually in consulting fees from GlaxoSmithKline (<http://www.policymed.com/files/Chart.pdf>). In fact, December 5, 2008, suggests Dr. Nemeroff's unreported income neighbored on roughly \$800,000 from 2000 to 2006.

Conflicts of Interest

A Cautionary Tale: Emory

- Emory University was not only institution with undisclosed conflicts. Why was federal attention and action was so swift and such a price exacted?
- We can make some educated guesses as to why an example was and, in some sense, continues to be made of Emory University. (Despite, its remedial efforts being “swift and surefooted” – as acknowledged even by Sen. Grassley prior to his most recent critique).
- In a nutshell: Sen. Grassley’s original probe unearthed a indisputable example of violations of University and federal conflict of interest policies involving:
 - (a) sizable federal grants;
 - (b) a big pharmaceutical (Glaxo Smith Kline);
 - (c) a high profile individual (Dr. Nemeroff); and
 - (d) institutional officials who failed act despite have sensed the existence of a problem over an extended timeframe.

Conflicts of Interest

A Cautionary Tale: Emory

- What could Emory University have done to prevent the “Nemeroff conflict of interest debacle”? Or, more importantly, what can similarly situated research institutions learn from this incident?
- Emory University rightly relied on its conflict of interest committee (COIC) to procure information from Nemeroff about his financial relationships. In fact, the COIC discovered his consulting in 2004 and, in a 14-page report, and documented suspicions of “serious” and “significant” violations of university procedures intended to protect patients.
- The organization failure was in failing to enforce or verify the ‘management’ outlined by the COIC – limiting consulting income. Emory administrators appear to have made no attempt to independently audit Nemeroff’s consulting income and his violations continued unchecked.
- Mechanisms such as a periodic, random audits of principal investigators and/or research contributors by a Compliance Office or Internal Audit are one option.

Conflicts of Interest Defined

Conflicts of Interest Defined

- **A conflict of interest is when a person or entity has an obligation or relationship to other parties and the relationships/obligations have the potential to compromise objectivity or prejudice performance.**
 - Conflicts of Interest always involve the use of a person's authority for personal and/or financial gain.
 - Conflicts may involve both individuals and institutions
- **In health care, the focus is on individual financial conflicts of interest**
 - Although conflicts can vary from moral conflict of conscience to institutional conflicts, individual financial conflicts of interest are easily identifiable and there is general acceptance that money can cause undue influence.

It is important to note that professional groups, academia, and the federal government (PhRMA, AdvaMed, AAMC, AAU, IOM, OIG) have begun to examine all types of conflicts of interest and are offering guidance for the creation of local and national policies.

Conflicts of Interest Defined

- **Public Health Service Definition (Regulations at 45 CFR 50, Subpart F):**
 - Only defines Significant Financial Interests:

“...anything of monetary value including but not limited to salary or other payments for services (e.g. consulting fees, or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

 - (1) Salary, royalties, or other remuneration from the applicant institution;
 - (2) Any ownership interests in the institution, if the institution is an applicant under the SBIR [*Small Business Innovation Research*] Program;
 - (3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
 - (4) Income from service on advisory committees or review panels for public or nonprofit entities;
 - (5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
 - (6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

Conflicts of Interest Defined

- **Institute of Medicine (IOM) Committee on Conflict of Interest in Medical Research, Education and Practice report (April 2009):**
 - IOM operationalized conflict of interest in broad terms not limited to financial interests:

“A conflict of interest is 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”

 - (1) Primary Interests include promoting and protecting the integrity of research, the welfare of patients and the quality of medical education
 - (2) Secondary Interests include financial gain, desire for professional advancement, recognition for personal achievement, and favors to friends, family, students or colleagues.

Conflicts of Interest Defined

- **Institutional Conflict of Interest**
 - An institutional conflict of interest occurs when the financial interests of the institution or financial interests of the leadership/senior officers affect, appear to affect or pose undue influence on institutional operations and administrative processes.
 - Institutional financial interests include its holdings, contracts, patents and relationships and financial interests of board members and top-level executives.

Conflicts of Interest Defined

- **Conflict is Not Synonymous with Corruption**
 - People regularly navigate competing priorities and use a variety of tools to cope with conflicts that seem to be omnipresent. There is recognition that this is part of our professional world.
 - Government and industry support of academia and academia's contributions to industry and the government have resulted in numerous innovations that have positively advanced medical care and medical science
- **However, Conflicts May Be Cause Concern**
 - Conflicts of interest can not be avoided.
 - The concern arises when the conflicts unduly influence (or appear to) objectivity, integrity, betrays public trust, and/or results in increased risk to patients.

Management of conflicts of interest preserves objectivity and ensures that risks to patients are not increased as a result of the conflicts.

Conflicts of Interest Regulations

Conflicts of Interest Regulations: Current and Proposed

- **Provided in the section of the presentation is an overview of the current and proposed legislative action in the conflicts of interest arena:**
 - Current
 - (a) PHS
 - (b) FDA
 - (c) OHRP
 - Proposed
 - (a) Advanced Notice of Proposed Rulemaking (ANPRM)
 - (b) Physician's Sunshine Act

Conflicts of Interest Regulations

- **Federal Regulations related to COI In Healthcare and Clinical Research**
 - Public Health Service (PHS)- PHS regulations address reporting requirements applicable to individual investigators and also provide general guidelines on institutional obligations to manage conflicts-of-interest. Defines Significant Financial Interest (listed on earlier slide)
 - Food and Drug Administration (FDA)- FDA regulations discuss minimizing bias in design, conduct, reporting, and analysis of clinical studies or its resulting data.
 - Office of Human Research Protections (OHRP)- OHRP regulations relate only to conflict of interest in IRB review of research.
- **Failure to Comply Carries Penalties**
 - PHS and FDA regulations cite to other federal regulations regarding failure to comply with federal policy. Penalties range from debarment to fines to prison time.
- **None address institutional conflicts of interest**
 - As stated earlier, conflicts of interest can be individual and/or institutional. However, federal regulations do not cover institutional conflicts of interest.

Conflicts of Interest PHS

- **45 CFR 50, Subpart F- Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought**
 - This federal regulation affects PHS governed agencies (e.g., the NIH) and applies specifically to grants and cooperative agreements (42 CFR 94- Contracts).
 - Any institution that applies for PHS grants or cooperative agreements and any investigator that participates in PHS funded research (except SBIR Program Phase I) is subject to this regulation.
 - Institutions must ensure that there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting interest.
 - Institutions must:
 - (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart (investigators and sub-award recipients must be informed and comply),
 - (b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research,
 - (c) Require that investigators submit a listing of all known significant financial interest (of spouse and dependent children also) as part of the application to PHS,

Conflicts of Interest

PHS

- **45 CFR 50, Subpart F- For Institutions and Investigators (42 CFR 94-Contracts) cont.**
 - (d) Provide guidelines for the designated official(s) on how to identify, manage, reduce, or eliminate the conflicting interest,
 - (e) Maintain records on all disclosures and actions taken on each conflict for three years (from date of final expenditure submission),
 - (f) Establish mechanism to enforce sanctions where appropriate,
 - (g) Certify that there is a written and enforced COI policy and report existing conflicts of interest before PHS funds are expended.
- **PHS Regulations Provides Sample Approaches for Management of Conflicts of Interest**
 - These regulations state that the designated official must review and determine whether the financial disclosures represent a significant financial Interest that could directly and significantly affect the design, conduct and reporting of PHS funded research.
 - If a significant financial interest exists, the designated official impose the following ensure that conflicts are managed, reduced, or eliminated :
 - (a) Require public disclosure of significant financial interests
 - (b) Require monitoring of research by independent reviewer

Conflicts of Interest

PHS

- **PHS Regulations Provide Sample Approaches for Management of Conflicts of Interest (cont.)**
 - If a significant financial interest exists, the designated official may impose the following ensure that conflicts are managed, reduced, or eliminated:
 - (a) Require public disclosure of significant financial interests,
 - (b) Require monitoring of research by independent reviewer,
 - (c) Modification of the research plan,
 - (d) Require monitoring of research by independent reviewer Disqualification from participation in all or a portion of the research funded by the PHS;
 - (e) Divestiture of significant financial interests;
 - (f) Severance of relationships that create actual or potential conflicts.
- **Remedies**
 - The regulation states that institutions must report noncompliance and any correction actions taken or to be taken:

“If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken.”

Conflicts of Interest

PHS

- **Remedies (cont.)**
 - The regulations list when PHS and HHS gets involved:

“HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS- funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart”
 - The regulation states that PHS may suspend funding if it determines a conflict of interest will bias objectivity of PHS funded research:
 - If HHS determines that there was a conflict of interest that was not managed reduced or eliminated, the institution must require that the investigator disclose the conflicting interest in each public presentation of the results.

Conflicts of Interest

FDA

- **42 CFR 54, Financial Disclosure by Clinical Investigators**
 - This federal regulation affects clinical investigators linked to clinical data submitted in marketing applications for drugs, biological products, and devices.
 - Applicants must disclose or certify information concerning the financial interests of a of all clinical investigators who conducted covered clinical studies:
 - (a) Attestation to the absence of financial interest and arrangements (completed FDA Form 3454)
 - (b) Disclosure (FDA Form 3455) of:
 - financial arrangements between sponsor and investigator,
 - significant payments from sponsor to investigator
 - proprietary interest (patent, trademark) in the test product held by investigator
 - significant equity interest held by investigator

Significant payments are more than \$25,000. Significant equity interest is any ownership interest, stock options, or other financial interest in a public corporation that exceeds \$50,000. These thresholds are applicable during the time project and for 1 year after completion of the study.

Conflicts of Interest

FDA

- **42 CFR 54, Financial Disclosure by Clinical Investigators (cont.)**
 - Applicants must ensure that appropriate steps have been taken in the design, conduct, reporting, and analysis of the studies to minimize bias.
- (c) Clinical investigators must provide the sponsor with accurate financial information for its certification or disclosure statements.
- (d) FDA may refuse to file a marketing application if there was no certification or disclosure of financial information.
- **The FDA Evaluates the Disclosures**
 - There is an evaluation of the submitted information to determine the impact of financial interest on the study.
 - The FDA may consider both the size and nature of a disclosed financial interest
 - The FDA will take into account the study purpose and design
 - The FDA may take the following actions if to ensure the reliability of the data:
 - (a) Audit the data derived from the investigator in question
 - (b) Request additional analyses to evaluate the impact of the investigators data on the entire study
 - (c) Request independent studies to confirm results in question
 - (d) Refuse to use the data as the basis for any agency action

Conflicts of Interest

FDA

- **The FDA Requires Recordkeeping**
 - Applicants must keep complete records showing:
 - (a) any financial interest or arrangement
 - (b) Any significant payments to investigators by sponsors
 - (c) Any financial interests held by investigators
 - Records must be retained for two (2) years after FDA approval

Conflicts of Interest OHRP

- **45 CFR 46.107(e), IRB Membership**
 - This regulation (and 21 CFR 56.107(e)) pertains to the IRB review of HHS supported research.
 - The rule is not specific to investigators or sponsors, only IRB members:

“No IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.”
 - The common understanding of the regulation is that IRB members with a conflicting interest should recuse him/herself from the review of research.
- **HHS Guidance: Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection**
 - In May 2004 HHS published guidance recommending that IRBs, investigators and institutions consider whether financial relationships/interests adversely affect human subjects
 - The guidance document provides specific points of consideration for Institutions, IRBs and Investigators:

Conflicts of Interest HHS Guidance

Financial Interests and the Safety/Welfare of Human Subjects Points of Consideration		
Institutions	IRBs	Investigators
Establish a Conflicts of Interest Committee and Policies/Procedures on its Operation and Communication with the IRB	Determine If Methods to Manage Conflicts Adequately Protects Human Subjects or Whether Additional Actions are Necessary	Modify the informed consent process when a potential or actual financial conflict exists, by either <ul style="list-style-type: none"> • Having a another individual involved in the consent process or, • Using independent monitoring of the research.
Determine What Constitutes an Institutional Conflict of Interest	Determine the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.	
Develop Policies/Procedures on the Financial Relationships that may/may not be held by those involved in research		

Conflicts of Interest Proposed PHS Legislation

- **Item:**
 - On May 8, 2009, The National Institutes of Health (NIH) issued an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register.
 - The purpose was to gain public input on whether modifications are needed to the PHS regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94).
- **Background:**
 - In 1995, the Public Health Service (PHS) and the Office of the Secretary of Health and Human Services (HHS) published the regulations at 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94:
 - (a) Provisions devised to promote objectivity in PHS-funded research.
 - (b) Establish standards to ensure that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, or contracts was unbiased by any conflicting financial interest of an Investigator.
 - Since the promulgation of these regulations, rapid advancement in biomedical research and in bench to bedside research has led NIH to consider whether revision of policies would be advisable.

Conflicts of Interest Proposed PHS Legislation

- **The NIH is specifically interested in comments regarding the:**
 - Expansion of the scope of the regulation and disclosure of interests;
 - Definition of “significant financial interest”;
 - Identification and management of conflicts by institutions;
 - Assurance of institutional compliance;
 - Provision of additional information to federal officials by research institutions; and
 - Broadening of the regulations to address institutional conflicts of interest.

Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

- In January 2009, U.S. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) introduced The Physician's Sunshine Act which requires the reporting of payments made to physicians and physician-owned entities by group purchasing organizations and manufacturers.
- Originally introduced in 2007, but not taken up by Congress, this version still incorporates the bulk of the recommendations made by the Medicare Payment Advisory Commission (MedPAC).
- The Bill's Provision (if passed in 2010) will require:
 - Annual reporting of all physician payments with a cumulative value in excess of \$100.00 on the following deadlines: March 31, 2011, to be made publicly available September 30, 2011.
- The scope of the bill now includes many additional physician relationships, including health related business interests.
- Since "direct payment" systems are referenced, most company grants provided to education providers appear to be excluded.

Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

Items Required to be Reported	
Consulting Fees	Compensation for Services other than Consulting
Honoraria	Gifts
Entertainment	Food
Travel	Education
Research	Charitable Contributions
Royalties or Licenses	Current Prospective Ownership Contributions
Compensations for serving as faculty or speaker at continuing medical education program	Grant
Any other nature of payment or other transfer of value as defined by the secretary.*	
*If related to marketing, education, or research concerns, a specific covered drug device, biological or medical supply, companies will be obligated to report and include link to drug – also on whatever deemed appropriate by the Secretary of HHS.	

Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

- **Some Reporting of Research Payments may be delayed by whichever date is earlier:**
 - Two (2) years after date or transfer of value occurred.
 - After the date of FDA approval.
- **Also Required: Reporting of Physician Ownership Interests in Private Companies:**
 - Dollar Amount Invested
 - Current Value
 - Any payment or transfer of value to the owner, including dividends or other payments.

Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

Excluded from the Reporting Requirement	
Payments of less than \$100 in aggregate	Product Samples
Patient education materials	Items for use as a patient
The loan of a device for fewer than 90 days	Warranty replacements
Discounts and rebates	In-kind items used in charity care
Dividends or distributions from a publicly traded company	

Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

- **Penalties:**
 - Unintentional failure to report: \$1,000 to \$10,000 per offense with a cap of \$150,000 per year.
 - Intentional failure to report: \$10,000 to \$100,000 per offense with a cap of \$1 million per year.

- **Summary:**
 - The short implementation timeframe (bill affords Secretary of HHS until November 2009) to establish procedures and incomplete preemption of state reporting requirements make the future of this bill and its enactment somewhat unpredictable.
 - However, legislated transparency as to physician's financial relationships that may impact the delivery of patient care appear to be a trend receiving increasing traction.

Conflicts of Interest In Context

Conflicts of Interest

Analysis Institute of Medicine Report

- **Conflict of Interest in Clinical Research, Medical Education, and Practice**
 - The National Academy of Sciences Institute of Medicine published a comprehensive report on conflicts of interest in April 2009.
 - The goal of the report was to conduct a comprehensive examination of conflicts of interest in medicine and provide recommendations on policies and practices for medical institutions.
- **IOM Report and Conflicts of Interest in Context**
 - While there are some general thematic similarities between the concerns presented by conflicts of interest in Clinical Research, Medical Education and Practice – each possesses distinct challenges and regulatory approaches and therefore warrants some individual discussion.

Conflicts of Interest

Clinical Research

- **Federal regulations (PHS and FDA) focus primarily on minimizing the occurrence of conflicts of interest in Clinical Research.**
- **The concerns revolve around risks posed by researchers' financial interests to human subjects' safety and potential for bias in the design, conduct and reporting of research.**
- **The threats can be immediate – unsafe or ineffective clinical care – or more broadly applicable to the general public if a device or drug is approved based on flawed findings.**

Conflicts of Interest

Clinical Research

- **Research institutions and academic medical centers must adopt and enforce conflict of interest policies that counterbalance often competing priorities and anticipate difficult deliberations – such as when an individual has significant financial interest (e.g. a consulting relationship or intellectual property) but may be essential to the conduct of the forecasted research.**
- **Entities such as conflict of interest committees (COIC) – made up of ex-officio members (Compliance, General Counsel) and voting members (department heads, community members, faculty researchers) – are well situated to determine how best to manage the conflict and protect the integrity of the research.**

Conflicts of Interest

Medical Education

- **As the IOM observes, medical educations prepare physicians for a lifetime of professional work.**
- **Notably, industry is increasingly present in Medical School, Residency and Continuing Medical Education settings in myriad forms:**
 - Financial supporters of institution's core educational mission
 - Sponsors of scholarships and training positions
 - Sponsors of research
 - Sponsors of continuing medical education
 - Purveyors of gifts and meals
 - Employers of faculty
- **In difficult fiscal times, categorically rejecting industry support may be untenable.**
- **For instance, per Dr. Steinbrook (Controlling Conflicts of Interest – Proposals from the Institute of Medicine), half of the \$2.54 billion in income for CME providers was from commercial.**
- **Commercial refers to companies with products in the marketplace.**

Conflicts of Interest

Medical Education

- **Recommendations to prevent conflicts of interest include tactics such as:**
 - Limiting and prohibiting access of sales representatives, for instance, are among the strategies that an academic medical center or teaching hospital might adopt.
 - A NY Times article entitled, Harvard Medical School in Ethics Quandary published on March 2, 2009, focused on “a full-blown movement by more than 200 Harvard Medical School students and sympathetic faculty, intent on exposing and curtailing the industry influence in their classrooms and laboratories, as well as in Harvard’s 17 affiliated teaching hospitals and institutes.”
 - Incentives to review and discuss such matters include:
 - (a) Harvard’s “F” Grade from American Medical Student Association (a group that rates how well medical schools monitor and control drug industry money).
 - (b) New Massachusetts law (effective July 1, 2009) requiring doctors to disclose corporate gifts over \$50

Conflicts of Interest

Medical Education

- **Consensus does not necessarily exist at Harvard.**
 - A smaller group of Harvard’s 750 medical students has circulated a petition signed by about 100 people that calls for “continued interaction between medicine and industry at Harvard Medical School.”
 - Encouraged by some faculty, this group focus on the benefits of academic-industry ties with medical discoveries.
- **It is clear few easy answers are apparent and it may ultimately students and not educators alone who determine how best to resolve competing priorities posed in the provision of unbiased medical education and training.**

Conflicts of Interest Medical Practice

- **Patients First?**
 - The public expects that physicians will “first do no harm” when treating patients for medical conditions.
 - The understanding is that the care of the patient is always the primary motivator for any medical decision or actions.
 - However, conflicts of interest may influence professional judgment, objectivity and integrity.
 - Conflicts of interest in medical practice arise from physician relationships with industry and entrepreneurial activities.
 - These conflicts can introduce bias in prescribing patterns, treatment recommendations and may result in diminished patient care.

Conflicts of Interest Medical Practice

- **Sources of Conflicts of Interest in Medical Practice**
 - IOM Report lists the following activities as opportunities to create conflicts of interest in medical practice:
 - (a) Physicians accepting company gifts including meals and drug samples
 - (b) Physicians acting as promotional speakers or writers on behalf of companies
 - (c) Physicians with financial interest in medical product companies whose products they use, prescribe or recommend
 - (d) Physician Payment
 - (e) Referral Facilities Where Physicians Have Ownership Interests

Conflicts of Interest Medical Practice

Example of Conflict of Interest and Medical Practice

- **Store-Based Health Clinics**
 - Since 2000 there has been an exponential increase in the number of health clinics based in retail stores.
 - Many of these clinics are located in shopping malls, pharmacies and “big box” retail stores.
 - Store-based clinics provide limited medical services to walk-in patients.
 - Most store-based clinics are staffed by Nurse Practitioners and Physician’s Assistants. Supervising Physicians do not need to be onsite.

Conflicts of Interest Medical Practice

Example of Conflict of Interest and Medical Practice

- **The Conflicts**
 - In 2007 the American Medical Association (AMA) called for an “investigation” into store-based health clinics.
 - The AMA’s main argument was that there is an inherent conflict of interest when places like Wal-Mart, Walgreen’s, CVS, and Rite Aid have walk-in clinics because the clinic and its staff is not independent of the entities that sell prescriptions- the implication was that store traffic and prescription sales were key, not patient care.
 - There was also concern that store based health clinics adversely impact physician/patient relationships, coordination of care, and put patient’s health at risk.

Conflicts of Interest

Medical Practice

- **Recommendations for Conflicts in Medical Practice**
 - IOM recommends that individual physicians take the following voluntary actions to ensure professionalism and minimize undue influence:
 - (a) Do not accept items of material value from pharmaceutical, medical device and biotechnology companies except when it is a fair market value payment for a legitimate service,
 - (b) Do not make presentations or publish articles that are controlled by industry or serve as a ghostwriter,
 - (c) Do not enter into consulting arrangements unless there are contracts for expert services paid at fair market value,
 - (d) Do not meet with pharmaceutical and medical device sales representatives except by documented appointment and at by physician invitation,
 - (e) Do not accept drug samples except for specific situations (patients who lack financial access to medications)
 - IOM recommends that industry continue to take steps to manage relationships with physicians and acknowledges the recent revisions to PhRMA and AdvaMed codes on interactions with healthcare professionals.

Conflicts of Interest

Clinical Practice Guidelines

- **Evidence Based**
 - Good practice guidelines are developed by people with high expertise that evaluate scientific evidence and provide objective clinical judgment.
 - Clinical practice guidelines establish the standards by which medical practitioners are trained, and how they diagnose, treat, and monitor the health of patients.
 - Conflicts of interest in the development of clinical practice guidelines can be either individual or institutional, and can adversely influence the selection topic or condition for consideration, the review of evidence, deliberations or the dissemination of guidelines.
- **Sources of Conflicts of Interest in Clinical Practice Guidelines**
 - IOM Report lists the following activities as opportunities to create conflicts of interest in the development of practice guidelines:
 - (a) Financial interests
 - (b) Professional affiliations
 - (c) Reimbursement incentives
 - (d) Intellectual preconceptions
 - (e) Desire for recognition and career advancement

Conflicts of Interest Clinical Practice Guidelines

Example of Conflict of Interest and Clinical Practice Guidelines

- **United States Senate Committee on Finance**
 - In April 2007 the Senate Committee on Finance issued a report Use of Educational Grants By Pharmaceutical Manufacturers.
 - The report was based on direct inquires to 23 pharmaceutical manufacturers, enforcement actions of federal agencies, popular press and medical journals.
 - The report found that drug companies had routinely used educational grants as a way to increase the market for their products.

Conflicts of Interest Clinical Practice Guidelines

Example of Conflict of Interest and Clinical Practice Guidelines

- **Findings Related to Guideline Development**
 - The Committee on Finance Report found that several companies funded a program to develop psychiatric treatment algorithms in Texas and program to define optimal treatment regimens in Florida.
 - The report acknowledged that it was difficult to determine any bias.
 - However, the report noted that, "The experts tasked with developing the guidelines often have preexisting relationships with companies that market drugs the protocols will evaluate. 'As many as 59 percent of the authors of clinical guidelines endorsed by many professional associations have had financial relationships with companies whose drugs might be affected by those guidelines.'"

Conflicts of Interest Clinical Practice Guidelines

- **Recommendations for Conflicts in Guideline Development**
 - IOM recommends that groups tasked with the development of practice guidelines take extra steps to minimize undue influence.
 - Groups should:
 - (a) Exclude as panel members individuals with conflicts of interest,
 - (b) Not accept direct funding for clinical practice guideline development from medical product companies or foundations,
 - (c) Publicly disclose their conflict of interest policies/procedures with each guideline, and the disclose the sources and amount of funding received.
 - IOM suggest the following if a group is unable to avoid inclusion of a panel member with a conflict:
 - (a) Publicly document the good faith effort to find experts with out conflicts of interest,
 - (b) Appoint a chairperson with conflicts of interest ,
 - (c) Limit members with conflicting interest to a distinct minority of ht e panel,
 - (d) Exclude individuals with fiduciary or promotional relationships with a company that makes products affected by the guidelines,
 - (e) Exclude individuals with conflicts from deliberating, drafting or voting on recommendations,
 - (f) Publicly disclose the relevant conflicts of interest of the panel members.

Strategies for Managing Conflicts of Interest

Conflicts of Interest

Strategies for Managing Conflicts of Interest

- **Every institution or organization should first assess whether it encounters conflicts of interest and the appropriate infrastructure to cope with assessing and managing them.**
- **A self-assessment should include the types of conflicts of interest that predominate:**
 - Are they individual or institutional?
 - Do they involve procurement?
 - Are they primarily research related?
- **Then policies, procedures and process flows need to be developed, vetted and disseminated organization wide – prioritizing federally regulated areas such mechanisms to ensure as research contributors are disclosing “significant financial interests” on an annual basis.**
- **If such policies, procedures and process flows do already exist, it is advisable to review and update them periodically to ensure they remain operationally relevant.**

Conflicts of Interest

Strategies for Managing Conflicts of Interest

- **Institutions should prioritize implementing a reporting, evaluation and management process reliant on review by either:**
 - An internal conflict of interest committee (COIC) or, if a smaller entity with limited resources, an external reviewer.
 - COIC should ideally have an administrative arm that assists with tasks such as documenting minutes, collection of annual disclosures, maintenance of records (e.g. issued management plans) and coordinates meeting with Principal Investigators.
 - Reporting of conflicts of interests can be effectuated by use of either a manual or electronic/automated solution.

Conclusion

Conflicts of Interest

Conclusion

Conflicts of interest are growing inevitable in a “bench to bedside” research environment which encourages innovation and entrepreneurship.

How else will we cure cancer? How else will we find a vaccine for HIV?

The idea conflicts of interest can be wholly avoided is unrealistic.

What is the solution?

Careful observation and management to ensure relationships between industry and medical practice, research and education do not adversely affect society.

Example of Tools Available to Assist with COI Management and Disclosure

University of Chicago/HCCS Tool

- Improved, Centralized Collection of Disclosures
 - Secure single sign-on
 - Centralized system and database
 - System can create multiple questionnaires or automatically direct different questions to individuals with different roles in the organization

UCMC/HCCS Tool

- Improved, Centralized Collection of Disclosures
 - Secure single sign-on
 - Centralized system and database
 - System can create multiple questionnaires or automatically direct different questions to individuals with different roles in the organization

UCMC/HCCS Tool

- Auto-Emails & Reminders
 - Scheduled announcements
 - Automatic reminders of deadlines
 - Automated late notices
 - Ability to create e-mail templates for easy follow-up

UCMC/HCCS Tool

- Improved Completeness of Disclosures
 - Respondents get only appropriate questions based on their role (or roles) within the organization
 - All questions must be answered in the affirmative or negative
 - Questionnaire can not be submitted if incomplete
 - Attestation form and electronic signature attest to completeness and accuracy of disclosures
 - Distributed reporting so departments can take responsibility for seeing that disclosures are completed

UCMC/HCCS Tool

- Simple (one-click) reporting can tell:
 - How many questionnaires were distributed
 - How many returned
 - How many opened
 - How many resolved
 - How many resulted in management plans
 - Etc.

UCMC/HCCS Tool

- Ease of Use, Especially for Faculty & Physicians
 - Navigation is self explanatory
 - Help screens and FAQ's built in to each question
 - Color coding indicates question status
 - Respondent can leave and return to questionnaire
 - Multi-leveled questions based on responses
 - View prior year's disclosure (at the question level) and bring forward responses for easy editing

UCMC/HCCS Tool

- Improved, Centralized Review Process
 - Reviewers are assigned based on department and roles
 - Different questions can be directed to different reviewers
 - Reviewers are presented with a queue of respondent questions to review and resolve
 - All review actions are automatically tracked in the "Review History"
 - Outgoing and incoming e-mail is captured and retained in the system automatically

UCMC/HCCS Tool

- Improved Follow-up and Management of Personal and Institutional Conflicts
 - Customized list of “Review Actions”
 - Each review action assigned a “Step” number so progress can be tracked in the aggregate
 - Management plans approved, stored and tracked in the system

UCMC/HCCS Tool

- Improved Documentation at all Stages
 - “Permitted Value” lists correct spelling errors, helping to standardize responses
 - Comprehensive database design allows for data mining to track individual and institutional conflicts

UCMC/HCCS Tool

- System had to be flexible and adaptable to other uses
 - Accommodates annual disclosure questionnaire and transactional disclosures
 - Useful for other survey functions
 - Provider exclusion from Medicare or Medicaid
 - Faculty surveys

UCMC/HCCS Tool

- System Administration had to be user friendly (minimal IT involvement)
 - User friendly administrative interface to create:
 - Questionnaires
 - Email templates
 - Review actions
 - Easy assignment of reviewers by department and role
 - Security Profiles to determine system access

UCMC/HCCS Tool

- Reporting System had to be robust
 - A series of “one click” reports available
 - Custom reports can be created “on the fly”
 - Database can be exported for manipulation in Excel, Access

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My Questionnaire » My Questionnaire » My Profile

Home Help Logout

My Questionnaire

My Profile

Answer Questions

Support/Help

Resources

Resource Links | Document Library

- Trustee disclosure requirements
- P&T disclosure requirements
- Physician disclosure requirements

★ My Profile

Please review and update the information below

User Name : bsacks

New User Name :

Confirm User Name :

New Password :

Confirm Password :

First Name :

Middle :

Last Name :

E-mail Address :

Job Title :

Department :

Primary Role(s) :
(Assigned by the system administrator.)

Center of Excellence

Employee

Other Role(s) :
(Please check any additional roles that apply to you.)

Board Member

Committee Member

Hospital-Based Physician

IRB Member

Medical Staff/Committee Member

Medical Staff/Faculty

Principal Investigator

Vendor

Vice President

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Resources

Resource Links Document Library

- Trustee disclosure requirements
- P&T disclosure requirements
- Physician disclosure requirements

★ Question list

Year	Status	Result	Actions
2008	InProgress (click here to edit)	-	
2007	Closed	COI-Managed	

★ Questions - 2008

FINANCIAL AND OTHER INTERESTS	Question ID	Date Submitted	Status	Action
1. Do you or does any family member hold any of the following financial...	COI.2008.01		Completed	Edit
2. Do you or does any family member hold any position or have any...	COI.2008.02		Completed	Edit
3. Did or do you or a family member have access to confidential...	COI.2008.03		Completed	Edit
4. Do you hold any of the following financial interests or relationships...	COI.2008.04		Completed with Disclosure	Edit
IRS REQUIRED QUESTIONS				
5. Have you or any family member received any of the following from a...	COI.2008.05		Completed	Edit
6. Do you use or propose to use University facilities or personnel, or...	COI.2008.06		Incomplete	Edit
7. Do you have a financial interest with any commercial organization that...	COI.2008.07		Incomplete	Edit
8. Do you spend significant effort, on external professional or commercial...	COI.2008.08		Completed	Edit
9. Do you own stock in one or more pharmaceutical companies or another entity that...	COI.2008.09		Completed	Edit
CMS QUESTIONS				
10. Have you been investigated for, or been alleged of, charged with, or convicted...	COI.2008.10		Unanswered	Edit
11. Do you own stock in one or more pharmaceutical...	COI.2008.11		Completed	Edit

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★ Questionnaire - 2008

Financial And Other Interests

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First Previous **1** 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 ... Next Last 1 of 23

► Your own or your family's Financial Interests (Question ID: COI.2008.01)

To your knowledge, do you or does any family member hold any of the following financial interests in a business or other entity currently doing business with or seeking business from UCMC (including any sale, lease, grants, contract, research funding, or other deal).

Interests:

- ownership interest or voting stock in excess of 5% or \$5,000, whichever threshold is less
- compensation or other payment (e.g. consulting fee, honoraria, professional or administrative services payment, speaker's bureau, travel support, finders fee, or bonus)
- other interest that benefits you or the family member (e.g. offer of employment, stock options, fees, loans, forgiveness of a loan or debt)

Disclosure Requirements

Yes No View Previous Year's Disclosure

Indicate the company or organization: Describe the PERSON with the interest, (whether it is you or a family member), the NATURE of the company's business, a DESCRIPTION of the interest, and the VALUE of the interest below:

Pfizer	I own 2000 shares of Pfizer common stock. Pfizer is a pharmaceutical company. Stock is valued at \$31,300.
Medtronic	I own 500 shares of Medtronic Inc. Medtronic is a Medical Device Manufacturer. Stock is valued at \$16,500.

(Disclosure Alert: Your answer requires you to disclose additional information related to this question. Please make sure your disclosure is complete and correct. Additional help is available below by clicking on either the Disclosure Requirements or the Disclosure Help icons.)

Disclosure Help

(Upload one or more files as attachments to this response if you have supporting documentation.)

Save Save & Continue Skip

[<< Return to Question List](#)

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Reviewer > Reviewer > In Review

Account Admin
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 Reviewer
 In Review
 Email
 Support/Help
 Reports

User Details
 Respondent : Ruth Fengold
 Filing Year : 2008
 Job Title : Director
 Department : Administrative Services
 Phone : (555) 602-4131
 Email : rfengold@univ.edu
 Emp. Status : Full-Time Employee

Resources
 Resource Links
 Document Library
 • Trustee disclosure requirements
 • P&T disclosure requirements
 • Physician disclosure requirements

★ In Review
 Respondent : [] Year : 2008
 Advance Search
 Search

★ My Reviewer Queue

Year	First Name	Last Name	Department	Qst	Status	Action																		
2008	Ruth	Fengold	Administrative Services	2	In Review	[] [] [] []																		
<table border="1"> <thead> <tr> <th>Question</th> <th>Response</th> <th>Comment</th> <th>Show All Questions</th> <th>Status</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td>COI2008.7</td> <td>Yes</td> <td>Do you have a financial interest with any commercial organization that...</td> <td></td> <td>In Review</td> <td>[] [] [] []</td> </tr> <tr> <td>COI2008.8</td> <td>Yes</td> <td>Do you spend significant effort, on external professional or commercial...</td> <td></td> <td>In Review</td> <td>[] [] [] []</td> </tr> </tbody> </table>							Question	Response	Comment	Show All Questions	Status	Action	COI2008.7	Yes	Do you have a financial interest with any commercial organization that...		In Review	[] [] [] []	COI2008.8	Yes	Do you spend significant effort, on external professional or commercial...		In Review	[] [] [] []
Question	Response	Comment	Show All Questions	Status	Action																			
COI2008.7	Yes	Do you have a financial interest with any commercial organization that...		In Review	[] [] [] []																			
COI2008.8	Yes	Do you spend significant effort, on external professional or commercial...		In Review	[] [] [] []																			
2008	Jack	Erickson	Pharmacology	2	COI	[] [] [] []																		
2008	Charlie	Rutherford	School of Medicine	1	In Review	[] [] [] []																		
2008	Mike	Edson	School of Nursing	1	COI - Managed	[] [] [] []																		
2008	Austin	Edwards	Radiology	3	In Review	[] [] [] []																		
2008	Hal	Nahendo	Orthopedics	1	Resolved	[] [] [] []																		
2008	Roy	Hobcock	Human Resources	2	COI	[] [] [] []																		

★ Review Actions

Review Action Date	Review Action Type	Reviewer	Question	Comment	Step	Action
09/22/08 11:10 am	Sent to Research	Bill Summers	COI2008	Additional review into the issues pertaining to ...	2	[] [] [] []
09/19/08 08:53 am	Escalate to Mngt	Judy Long	COI-2008.06	Additional review of the management level is needed ...	2	[] [] [] []
08/09/08 02:37 am	Enabled policy doc	Mark Abonzo	COI-2008.07	After further review, it is clear that the current ...	1	[] [] [] []

★ History

Year	Qst	Completed	Result									
2007	1	04/16/2007	COI - Managed									
<table border="1"> <thead> <tr> <th>Question</th> <th>Response</th> <th>Comment</th> </tr> </thead> <tbody> <tr> <td>COI2007.12</td> <td>Yes</td> <td>Do you own stock in one or more pharmaceutical companies or any other manufacturer of...</td> </tr> </tbody> </table>				Question	Response	Comment	COI2007.12	Yes	Do you own stock in one or more pharmaceutical companies or any other manufacturer of...			
Question	Response	Comment										
COI2007.12	Yes	Do you own stock in one or more pharmaceutical companies or any other manufacturer of...										
2008	2	05/21/2008	Resolved									
<table border="1"> <thead> <tr> <th>Question</th> <th>Response</th> <th>Comment</th> </tr> </thead> <tbody> <tr> <td>COI2008.3</td> <td>Yes</td> <td>Did or do you or a family member have access to confidential...</td> </tr> <tr> <td>COI2008.12</td> <td>Yes</td> <td>Do you own stock in one or more pharmaceutical companies or any other manufacturer of...</td> </tr> </tbody> </table>				Question	Response	Comment	COI2008.3	Yes	Did or do you or a family member have access to confidential...	COI2008.12	Yes	Do you own stock in one or more pharmaceutical companies or any other manufacturer of...
Question	Response	Comment										
COI2008.3	Yes	Did or do you or a family member have access to confidential...										
COI2008.12	Yes	Do you own stock in one or more pharmaceutical companies or any other manufacturer of...										
2005	1	Not Submitted	-									

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Reviewer > Reviewer > In Review > Review Action

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 Reports

User Details
 Respondent : Jack Erickson
 Filing Year : 2008
 Job Title : Pharmacist
 Department : Pharmacology
 Phone : (555) 602-4612
 Email : jerickson@univ.edu
 Emp. Status : Full-Time Employee

Resources
 Resource Links
 Document Library
 • Trustee disclosure requirements

★ Add Review Action

Respondent Name : Jack Erickson
 Filing Year : 2008
 Question # : COI2008.12
 Review Action Date : 07/03/2008 07:32am
 Review Action Type : Escalate
 Comments : Review actions are documented by the reviewer
 Quick Text

Current Review Level : 2 Escalate
 Send Notification to Escalated Reviewers :
 Next Action Date : [] [] [] []
 Send Email :

[] Browse [] Document Library

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