Strategies for Managing Conflict of Interests in the World of Innovation

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11:00-12:00

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Objectives of the Presentation

As outlined in the Program

- Managing individual conflict of interests can pose challenges at institutions where innovation is both encouraged and rewarded. Review strategies for balancing entrepreneurial goals of individuals while maintaining compliance with institutional policies
- Organizations are engaging in new and innovative relationships with industry as a means to achieve research and organizational objectives. Learn strategies for managing conflicts to avoid the appearance of bias in research
- Building trust and communication is essential to a conflict of interest program. Discuss ways in which compliance officers can achieve these essential tools

Conflicts of Interest

- When an individual person, group, or organization represents multiple interests, one or more of which could corrupt the overall motivation
- This is frequently considered having multiple financial interests, but may involve other situations

Classifications of Conflicts

- Personal
- Professional
- Financial

- Clinical
- Research
- Business
- Purchasing
- Fundraising
- Educational

Let's Get Into It!

"Try this—I just bought a hundred shares."

Clinical Conflicts of Interest

Financial relationships involving cash or something of value (e.g., consulting fees, advisory board payments, honoraria, ownership interest such as stock, stock options) from a commercial company that produces, manufactures, or distributes medical products that are prescribed for, recommended to or used in the care of patients.

Issues to Consider with Clinical COIs

- How will clinical conflict(s) be collected?
  - Centrally vs. Departmentally
- How often do you require reporting (e.g., annually)?
  - How will you handle changes in status throughout the year?
- Will you have a threshold (e.g., >$25,000 should be reported)?
- Who needs to "sign off"? Supervisor? Chief Medical Officer?
- How/Will you disclose to patients?
  - How will you document this?
  - How will you monitor this?
  - What else needs to be considered? Monitoring of prescribing patterns?

Strategies for Managing Clinical COI

- Consider the individual's participation on committees that approve the drug formulary and purchasing for the institution.
- Does the conflict need to be communicated to the patient/patient's family?
- Does the conflict need to be disclosed to other medical professionals?
- Do you need to transfer clinical care to another provider?
- Is the individual amenable to eliminating or reducing the conflict?

Who Owns the Process?

- Do you have a COI department?
- Is it part of clinical or administrative operations?
- Do you have a champion in leadership?
- Do you have a committee that will review these issues?

Promoting Objectivity in Research

PHS Regulations

Revised regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought* and *Responsible Prospective Contractors*

42 CFR Part 50 Subpart F (grants and cooperative agreements)
45 CFR Part 94 (contracts)
Initial Regulation effective 10-1-95

Published in Federal Register August 25, 2011; Implemented August 24, 2012

Applies to all PHS funded research

What's the Big Deal?

The purpose of the regulation is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Bayh-Dole Act of 1980

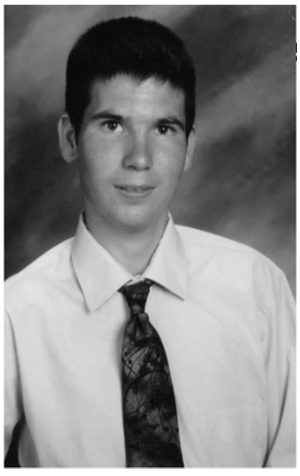
- Federal law that enables Universities, non-profit research institutions, and small businesses to own, patent and commercialize inventions developed under federally funded research programs.
- AKA the "Patent and Trademark Act Amendments of 1980."

Key Provisions of Bayh-Dole

- University retained ownership of any inventions created as a result of federal funding.
- Once the innovator disclosed the creation of an invention, disclosure to the appropriate funding agency must occur in 2 months.
- University must patent all inventions it elects to own and commercialize.
- University must attempt to develop and commercialize the invention.
- Excess revenue must support research & education.
- University must share a portion of the royalties with the inventor.

Jesse Gelsinger

- 18 year old who suffered from a rare metabolic disorder
- His disease was managed with a low-protein diet & medication.
- Consented to participate in a Phase 1 gene-therapy trial at the University of Pennsylvania knowing that he would not benefit; the study was designed to test the safety of the treatment for babies with a fatal form of his disorder.
- In September 1999, Jesse died as a result of his participation in the trial.



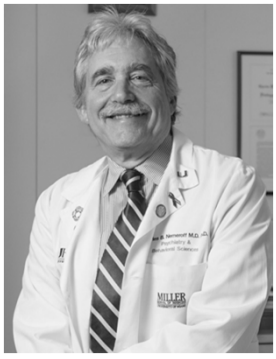
Gelsinger Case: COI Issues

- The PI held patents on several gene therapy delivery techniques.
- The PI founded and held a significant amount of equity in a biotech company.
- The University also held a significant amount of equity in the same biotech company.
- The biotech company invested large amounts of money in The Gene Therapy Institute at the University.
- The PI led The Gene Therapy Institute; all investigators (and the IRB) reported to him.
- None of this information was disclosed in the informed consent document signed by Jesse or the other 17 research participants.

A Case that led the 2011 Reform

Emory University 2008

- Dr. Charles Nemeroff, Professor & Chairman of Psychiatry
- Failed to disclose at least $1.2M in income from drug companies.



Paving the Way for Change

Iowa Senator Charles Grassley led the charge to change the way the NIH evaluates researchers who accept money from industry:

- Decreased the threshold for reporting
- Greater detail in reporting to NIH
- Institutions are responsible for determining which conflicts are problematic & managing them

PHS Regs – Required Disclosures

A financial interest of the investigator (includes those of the investigator's spouse & dependent children) related to the Investigator's institutional responsibilities.

1. IP rights/interest (e.g., patents, copyrights) upon receipt of income more than $5,000 in the preceding 12 months
2. Reimbursed or sponsored travel
3. Publicly traded entities
   - Any payments over $5,000 (preceding 12 months)
   - Any stock or equity valued in excess of $5,000
   - Any combination of above which exceeds $5,000
4. Non-Publicly traded entities
   - Any payments over $5,000 (preceding 12 months)
   - Any stock or equity

What is NOT a Significant Financial Interest

- Income from investment vehicles including mutual funds and retirement accounts.
- Income or sponsored travel from seminars, lectures, teaching engagements, services on advisory committees, etc. sponsored by:
  - Federal, state or local government agency
  - Institution of higher education (research institute)
  - Academic teaching hospital or medical center
- IP Rights assigned to current institution & agreements to share in royalties related to such rights.

Financial Conflict of Interest

FCOI: A SFI that could directly and significantly affect the design, conduct, or reporting of research.

A FCOI requires a Management Plan unless the conflicted investigator divests of the interest.

Developing Management Plans

Questions to Ask

- What is the conflicted investigator's role in the research?
- Are other investigators involved in the research at the site?
- How many sites are participating in the study?
- Are there enrollment expectations for the site?
- Will the conflicted investigator be included in publications?
- Will he/she conduct data analysis?
- Will he/she make important decisions about the data?

Questions to Ask Continued…

- Will the sponsor or Clinical Research Organization (CRO) be responsible for monitoring data? If so, how often?
- Will a data coordinator or other individual collect/input data?
- Is the conflicted investigator amenable to:
  - Abstaining from consenting subjects?
  - Limiting the number of subjects recruited?
  - Having a co-signer on adverse events/serious adverse events?
  - Routine monitoring by compliance?

Research Management Controls

- Disclosure to research subjects in the informed consent document
- Disqualification of the conflicted Investigator/Key Personnel from participating
- Additional requirements/restrictions for data analysis
- Monitoring of the Investigator/Research by impartial observers capable of taking measures to protect the design, conduct or reporting of the Research against bias
- Modification of the Research or project
- Divestiture or minimization of the SFI
- Severance of the relationship that created the actual or potential FCOI

Who Adopted the PHS Regulations?

Agency for Healthcare Research and Quality (AHRQ)
Agency for Toxic Substances and Disease Registry (ATSDR)
Centers for Disease Control and Prevention (CDC)
Food and Drug Administration (FDA)
Health Resources and Services Administration (HRSA)
Indian Health Service (IHS)
National Institutes of Health (NIH)
Office of Global Affairs (OG)
Office of the Assistant Secretary for Health (OASH)
Office of the Assistant Secretary for Planning and Evaluation
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Public Health and Science
Substance Abuse and Mental Health Services Administration (SAMHSA)

Federal Demonstration Partnership (FDP)

http://sites.nationalacademies.org/PGA/fdp/PGA_070596

FDP Institutional Clearinghouse includes a list of compliant institutions and entities

- Important for site subcontracting with other institutions
- Excellent resource for subaward templates

Institutional Conflicts of Interest

When financial interests of the institution, or of an institutional official, might affect or reasonably appear to affect institutional processes including the conduct, review or oversight of research.

"All of these compliance rules and regulations are such a bother. I never thought we actually had to read our policies and procedures."

Transparency Reports and Reporting of Physician Ownership or Investment Interests

CMS Open Payments/Physician Payment Sunshine Act

- Federal program (Affordable Care Act) that collects information about payments drug and device companies make to physicians and teaching hospitals.
- Includes travel, research, gifts, speaking fees, & meals.
- Includes ownership interests that physicians or their immediate family members have in these companies.
- Data are publicly available each year on the CMS website.
- Individuals have an opportunity to dispute postings each year prior to posting.

Trust but Verify…

A physician at the University of Cincinnati disclosed to university officials that she earned $100,000 from 2005 to 2007 from eight drug makers; however, AstraZeneca compensated her $238,000 during this period.

Three renowned child psychiatrists at Harvard Medical School reported to university officials earning several hundred thousand dollars each in consulting fees from drug makers from 2000 to 2007 when they had earned approxiately $1.6 million each.

https://www.insidehighered.com/news/2008/04/14/grassley
http://www.thecrimson.com/article/2011/7/2/school-medical-harvard-investigation/

Open Payment Report

2016 Data

- $8.18 Billion in payments and ownership/ investment was recorded by Industry:
  - General Payments: $2.80 Billion
  - Research Payments: $4.36 Billion
  - Ownership/Investment Interest: $1.02 Billion

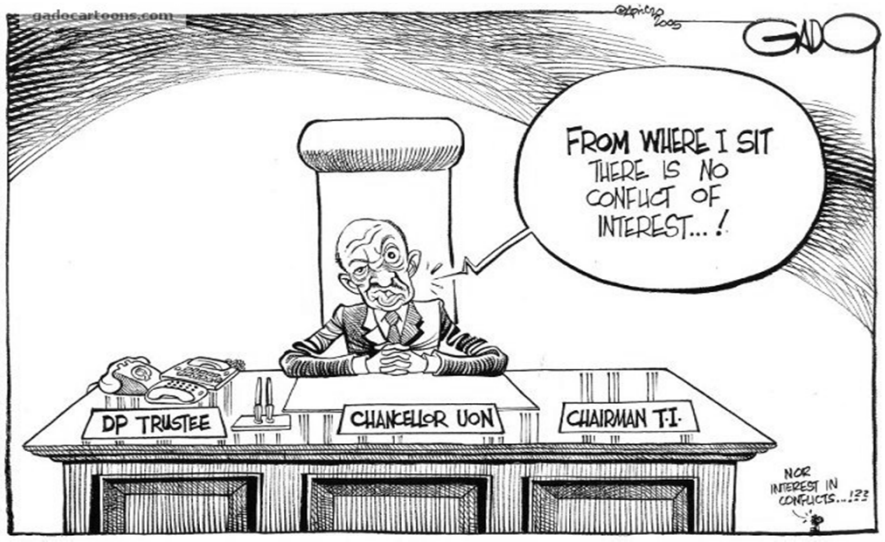
Business Conflicts

Who should disclose?

- **Board members**
- **Executives**
- **Officers**
- **Directors**
- **Key Employees**
- **All Employees**

Managing Business Conflicts

- Exclude from participation on certain committees
- Restrict participation in negotiations of contracts or other agreements
- Abstain from negotiations or decision making for certain business transactions
- Recuse from discussion & voting procedures
- Public disclosure via website
- Ensure transparency by informing workforce



Purchasing & Conflicts of Interest

A COI arises when an individual may be in the position to influence the organization's business, research, or other decisions in ways that could lead to any form of personal gain for the individual or others closely associated with the individual.

Purchasing Controls

- Do you have policy that addresses COI for purchasing?
- Do you have state law that addresses this issue?
- Consider a disclosure process for all purchasing employees.
- Purchasing by employees from vendors with which they have a conflict should be avoided. If unavoidable, they should be managed:
  - Bid/RFP process
  - Secondary/Tertiary approval
  - Annual review of all purchases

Fundraising Conflicts & Controls

Situation: Pharma donates a substantial amount of money to your Foundation as unrestricted funds…

- Do you have policy that defines a threshold for the dollar amount that constitutes an Institutional COI?
- If funds are used for research, do you disclose the ICOI to research subjects?
- Do you disclose ICOI at fundraising events?

Educational Conflicts

Consider these situations:

1. A for-profit company offers to provide an unrestricted grant to fund a symposium, including a keynote speaker and panel.

2. A for-profit company would like your institution to develop an educational conference on a certain topic/disease.

3. A for-profit company wants to assist in conducting a symposium by offering a list of speakers, including physicians from other institutions. The company would pay for the selected speakers' honoraria and travel.

Educational Conflict Controls

- Consider composition of the planning committee and any conflicts that may exist
- Consider following *Accreditation Council for Continuing Medical Education (ACCME) Standards to Ensure Independence in CME Activities* for all educational events

ACCME Standards to Ensure Independence in CME Activities

- Independence
- Resolution of Personal Conflicts of Interest
- Appropriate Use of Commercial Support
- Appropriate Management of Associated Commercial Support
- Content and Format without Commercial Bias
- Disclosures Relevant to Potential Commercial Bias

How to Make it Work!

- Be open
- Be visible
- Be flexible
- Be creative
- Be the “go to”

Questions?

Phone a Friend!

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