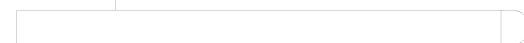


Responsible Conduct of Research: Managing Conflicts of Interest

Conference for Effective
Compliance Systems in
Higher Education
Larry Plutko and Bill Sacks



Objectives



- Review the historical and legal background of conflicts of interest-related regulation since the Bayh-Dole Act (1980)
- Offer recommendations for managing conflicts of interest to meet regulatory, policy, and ethical requirements at research universities
- Discuss the implementation of an e-solution system for COI management and real time tracking

Part One: Background and Recent High Profile Controversies



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Bayh-Dole Act of 1980

- The Building of Biotech
- The Law of Unintended Consequences
- A Collision Course for Conflicts of Interest

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An Implied Duty to Commercialize

- Legislative Debate
- Bayh-Dole's Implied Duty to Commercialize
- Technology Transfer
- Criticism of Academia-Industry Partnerships
- Financial Conflicts of Interest

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Fundamental Differences Between Academic Research and Industry

	Industry	Academia
Governing Ethic	Business	Professional
Basis	Commerce	Oath
Responsibility to...	Investors	Humankind
Mode of Operation	Competition	Collegial
Motivation/Goal	Financial	Knowledge

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Bayh-Dole and Recognizing the Academia-Industry Partnership

- A Complex Relationship
- Balancing Risks and Benefits
- Two Goods and Two Cultures
- Disclosure or Transparency of Interests
- The Appearance of Impropriety
- The Management of Right Relationships

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Growing Concerns

- Mounting pressure to establish strict guidelines governing industry-researcher relationships:
 - Recent studies indicate:
 - Industry-sponsored education is often biased and intended primarily to improve product sales
 - Industry-sponsored research lacks objectivity
 - Marketing tactics and gifts/payments unduly influence researcher behavior and decision-making
 - Increased instances of ethical misconduct has led to intense media attention, costly legal settlements, and public backlash

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High Profile Cases

- Artificial-Joint Makers Settle Kickback Case
 - 9/2007: Four makers agree to pay \$311M to settle DOJ investigation into alleged violations of federal anti-kickback statute
 - Lawsuit claimed the companies used consulting agreements as inducements for surgeons to use their products
- 2008 Grassley congressional investigation into financial ties between pharmaceutical companies and prominent academic physicians

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Marcia Angell, MD

- “Drug Companies and Doctors: A Story of Corruption,” *The New York Review of Books* 56:1, 1/15/2009
- “Industry-Sponsored Clinical Research: A Broken System,” *JAMA* 300, 9/3/2008, 1069-1071

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Other High Profile Cases

- Gene Transfer Study at University of Pennsylvania (Jesse Gelsinger) – 1999
- Parke-Davis/Warner-Lambert Type II Diabetes Drug, Rezulin – 1997
- *LA Times* Expose on Pharma Industry and NIH Senior Scientists Ties – 2004-2005
- FDA Advisory Panel Inaction on Celebrex, Bextra, and Vioxx – 2005

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Surveys and Studies - I

- Ashley Wazana, “Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?”, *JAMA* 283, 1/9/2000, 373-380
- Jason Dana and George Loewenstein, “A Social Science Perspective on Gifts to Physicians from Industry,” *JAMA* 290, 7/9/2003, 252-255

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Surveys and Studies - II

- Dana Katz et al., "All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving," *AJOB* 3:3, Summer 2003, 39-46
- Troyen A. Brennan et al., "Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers," *JAMA* 295, 1/23/2006, 429-433

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Surveys and Studies - III

- Joseph S. Ross et al., "Pharmaceutical Company Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota," *JAMA* 297, 3/21/2007, 1216-1223
- Eric Campbell et al., "A National Survey of Physician Industry Relationships," *NEJM* 356, 4/26/2007, 1742-1750

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“On Marketing”

- If the circus is coming to town and you paint a sign saying, “Circus is coming to Fairgrounds Sunday,” that’s **Advertising**.
- If you put the sign on the back of an elephant and walk him through town, that’s a **Promotion**.
- If the elephant walks through the mayor’s flower bed, that’s **Publicity**.
- If you get the mayor to laugh about it, that’s **Public Relations**.
- And, if you planned the whole thing, that’s **Marketing**.

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Professional Associations Statements - I

- Association of American Medical Colleges (AAMC) and Association of American Universities (AAU)
 - “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subject Research” (2008)
 - “Report of the AAMC Task Force on Industry Funding of Medical Education” (2008)
- American Council on Education (ACE)
 - “Working Paper on Conflict on Interest”

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Professional Associations Statements - II

- American Medical Students Association (AMSA)
 - “PharmFree Scorecard” (2009)
- Institute of Medicine (IOM)
 - “Conflict of Interest in Medical Research, Education and Practice “ (2009)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
 - “Code of Ethics on Interactions with Health Care Professionals” (2009)

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Federal and State Legislation

- Federal Oversight: 2010 PPAC Act contains Physician Sunshine Provisions
- National Institutes of Health (NIH) Notice of Proposed Rule Making (ANPRM – 5/8/2009)
- New state laws setting limits on industry gifts/payments and/or require public disclosure of cash and in-kind payments (MN, CA, VT, WV, MA, and DC)

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Amended False Claims Act

- Fraud Enforcement and Recovery Act (2009)
 - Expands liability to indirect recipients of government funds
 - Expands liability for the retention of overpayments
 - Expands the “relation back” doctrine
 - Expands CID authority and government disclosure rights

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FERA Expands Scope and Enforcement of FCA

- Time and Effort Reporting
- Conflicts on Interest Disclosures
- Research Integrity
- Payments made to subcontractors and sub grantees
- Federal student financial aid
- Federal grant applications

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Part Two: Recommendations for Managing RCOIs



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Recommendation #1: RCOI Committee Charter

- Purpose
- Background
- Organizational Goals
- Scope
- Deliverables
- Timeline
- Critical Success Factors
- Roles
- Approvals

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Recommendation #2: Committee with Work Groups

- Appointment of committee members by presidents as well as ad hoc members based on expertise
- First meeting agenda items:
 - Review and approval of charter
 - Commission policy analysis and assessment
 - Assigning committee members to work groups with specific assignments
 - Preliminary project timeline

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Recommendation #3: Policy Analysis and Assessment - I

- Call for all existing RCOI policies from Handbooks of Operating Procedures (HOPs)
- Gathering of key source material to determine “state of the art” performance standards (Federal Law & Regulations, Proposed Congressional Legislation, Professional Societies and Standards Organizations, and Exemplary Institutional Model Policies)

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Recommendation #3: Policy Analysis and Assessment - II

Issue	Requirement	Standard/ Principle	UT System Policy	Exemplary Model Policy	Comments and Potential UT System Actions	UT System Actions Taken

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Recommendation #4: Work Groups

- Policy Work Group
- Disclosure Form and Conflict Resolution Work Group
- E-Solution Work Group
- Education Work Group

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Recommendation #5: Projected Implementation Timeline - I

- Review/Approval of Draft Policy: Chancellor and EVCs
- Chancellor Transmits Draft Policy to Presidents: Campus Vetting Process
- Board of Regents Endorses Policy and Disclosure Form
- Adoption of RCOI Policies and Incorporation into Handbook of Operating Procedures at Campuses

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Recommendation #5: Projected Implementation Timeline - II

- E-Solution Implementation at Institutions
- Policy and Disclosure Form Education at Institutions
- New Policy Implemented and Disclosure Form Electronically Delivered to Covered Individuals at Institutions (45-Day Turnaround)

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Recommendation #6: Recognize Cultural Tensions

- Individual Rights ❖ Common Good
- Free Market ❖ Social Justice
- Privacy ❖ Disclosure of Interests
- Freedom of Association ❖ Limitations on Freedom
- Maximizing Profit ❖ NFP Advancement of Science, Technology, and Medicine
- Self-Regulation ❖ Mandatory Participation

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Recommendation #7: Philosophical Assumptions Guiding Policy

- Legal and Regulatory Level
- Organizational Ethics Level
- Institutional Policy and Guidelines Level

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Part Three: Implementing an E-Solution System



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