

CONFLICT OF INTEREST AND COMMITMENT

AN OVERVIEW

Based on material available at
<http://ori.hhs.gov/education/products/columbia>

WHO CAN GIVE ME AN EXAMPLE OF
CONFLICT OF INTEREST?

ME, ME!

SKOOL

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OKAY, JOHNNY,
WHAT IS IT?

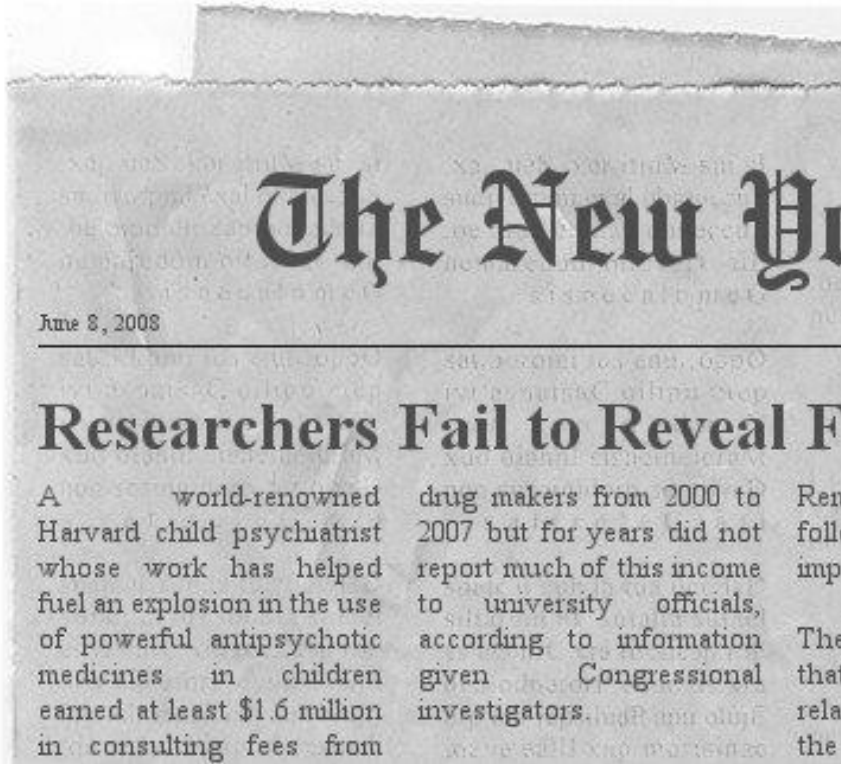
A DRUG STORE THAT SELLS
GET WELL CARDS.

SKOOL

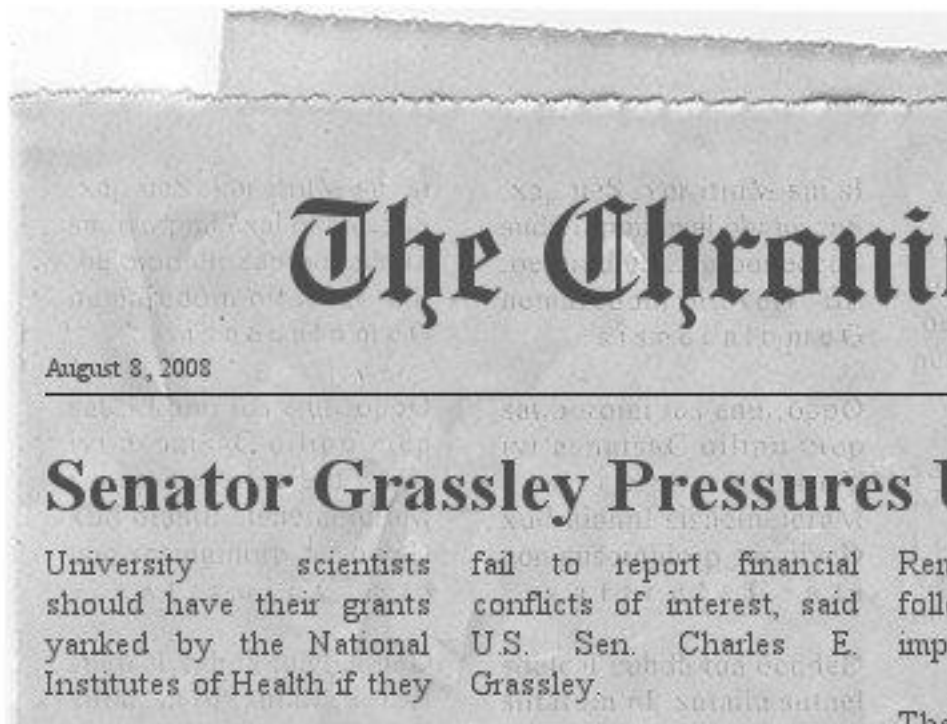
4/1/04

hart

Public Pressure:



- THE NEW YORK TIMES
- Title: Researchers Fail to Reveal Full Drug Pay
- Authors: Gardiner Harris and Benedict Carey
- Published: June 8, 2008
- A world-renowned Harvard child psychiatrist whose work has helped fuel an explosion in the use of powerful antipsychotic medicines in children earned at least \$1.6 million in consulting fees from drug makers from 2000 to 2007 but for years did not report much of this income to university officials, according to information given to Congressional investigators.



- THE CHRONICLE OF HIGHER EDUCATION
- Title: Senator Grassley Pressures Universities on Conflicts of Interest
- Author: Jeffrey Brainard
- Published: August 8, 2008
- University scientists should have their grants yanked by the National Institutes of Health if they fail to report financial conflicts of interest, said U.S. Sen. Charles E. Grassley.
- <http://chronicle.com/article/Senator-Grassley-Pressures/29846>

Colorado doctors still accepting money from drug companies



- THE DENVER POST
- Title: Colorado doctors still accepting money from drug companies
- Author: Michael Booth
- Dozens of Colorado doctors have continued to accept hundreds of thousands of dollars from drug companies

The New York Times

May 4, 2011

N.J. Board Disciplines Doctors

The Board of Medical Examiners in New Jersey, which is responsible for licensing doctors practicing in the state, said on Tuesday that it had disciplined three orthopedic surgeons because they did not disclose their personal financial interests in the success of an artificial spinal disk they were studying in clinical trials that were used by federal regulators to approve the disk.

- THE NEW YORK TIMES
- Title: N.J. Board Disciplines Doctors For Financial Links to Device
- Author: Reed Abelson
- The Board of Medical Examiners in New Jersey, which is responsible for licensing doctors practicing in the state, said on Tuesday that it had disciplined three orthopedic surgeons because they did not disclose their personal financial interests in the success of an artificial spinal disk they were studying in clinical trials that were used by federal regulators to approve the disk.

Memorial Sloan Kettering Leaders Violated Conflict-of-Interest Rules, Report Finds

- **By Charles Ornstein and [Katie Thomas](#)**
- April 4, 2019
- Top officials at Memorial Sloan Kettering Cancer Center repeatedly violated policies on financial conflicts of interest, fostering a culture in which profits appeared to take precedence over research and patient care, according to details released on Thursday from an outside review.

A dollar sign is hoisted, obscuring the good work of Dana-Farber cancer center

Updated October 15, 2021, 2:30 a.m.

Boston Globe

- **Disturbing to see that trustees stand to profit from their role with the institute**

What impression do these types of articles give the public? (**Vote**)

Working with pharma companies:

- Makes researchers rich
- Is good for scientific development
- Needs to be disclosed
- Should not happen

The Death of Jesse Gelsinger

- Clinical protocol “Recombinant Adenovirus Gene Transfer in Adults with Partial Ornithine Transcarbamylase Deficiency”
- The death of 18-year-old Jesse Gelsinger in 1999, at the University of Pennsylvania in a gene-transfer trial, triggered the debate about ethics and financial interest.
- The university, the Institute of Human Gene Therapy, and the trial sponsor, have come under scrutiny because the researchers involved with the trial and the university had apparent financial conflicts of interest.
- The tragic results of this widely publicized trial alarmed the public and the research community.

Categories of Conflict of Interest

- Intangible = those involving academic and scholarship endeavors
- Tangible = those involving financial relationships

Why should you care about conflicts of interest?

Trust is essential in the scientific pursuit of truth

Science is conducted in collaboration with:

- Colleagues
 - Government
 - Study Sponsors
 - The Public
-
- Real and perceived conflicts of interest are intrinsic to the research enterprise

Conflicts at an individual level - Intangible

- Pressure to publish, get funding, appointments, promotions and to earn respect from peers
- Risk of bias impossible to eliminate but important to recognize
- Blumenthal et al in JAMA 1997; 277 (15) 1224-1228 reported 20% of researcher delayed publication of results for their own advantage

How do you manage intangible conflicts of interest?

Conflicts at an individual level - Tangible

A conflict of interest may exist when an investigator, co-investigator, study coordinator or others involved in the design and conduct of research, or **their family members** have an interest in or relationship with an entity which provides outside investment or compensation that could be **perceived** by others as potentially influencing activities and judgments in patient care, research, administrator decisions, or business transactions.

Foreign Influence:

- Diversion of intellectual property (IP) in grant applications or produced by NIH supported biomedical research to other entities, including other countries;
- Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and
- Failure by some researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds.

What dollar amount should be classified as a significant financial interest? (Vote)

- \$1 million
- \$500,000
- \$100,000
- \$50,000
- \$25,000
- \$5,000
- Any amount

What is a “Significant Financial Interest”?

- Equity value greater than \$5,000 or 5% ownership in a single entity.
- Serving as a director, officer or other decision-maker for a commercial sponsor of human subjects research.
- Receiving compensation for services as a consultant or advisor to a commercial (including a not for profit) sponsor of research in excess of \$5,000 annually.
- Royalty income or the right to receive future royalties under a patent, license or copyright, where the research is directly related to the licensed technology or work of any amount.
- Personally accepting payment from the human subjects research sponsor, for non-research related travel or gifts.

The Bayh-Dole Act (1980)

- Permits recipients of federal funds to obtain the title to the inventions they develop under their federally funded projects, and to transfer the technology to the private sector.
- Requires federally funded researchers to obtain a patent for products developed, to seek commercial opportunities, and to report to the National Institutes of Health (NIH) on the use of their discoveries.
- Removed the ban on campus entrepreneurship and allowed academic researchers to take an active role in the private applications of their research

Federal Conflict of Interest Regulations

- 1995 the US Public Health Service, which includes the NIH, and the National Science Foundation (NSF) enacted regulations entitled "Responsibility of Applicants for Promoting Objectivity in Research".
- 1998 FDA issued its final rule
- 2010 Physician Payment Sunshine Act
- 2011 PHS Regulations updated effective 8/24/12

Sloane Kettering Cancer Center – Could a Similar Situation Happen Here?

Commercialization of a Product:

- Immunotherapy treatments developed by the lab of a pediatric oncologist earned \$64.5 million in a commercialization agreement.
- Company's market value is currently \$867 million

Dr. Gregory Raskin:

- Bought discounted stock now worth \$106,000
- Hospital has an equity stake in the start-up of 8.45 percent – now worth \$73 million
- Received personal stock options for representing hospital on company board –vested options worth \$675,000 with future options worth \$616,000
- Also Vice President overseeing hospital ventures with for-profit companies

How can / should we manage financial conflicts of interest?

Faculty has done some consulting for a pharma company and now wants to be the PI on a research study funded by the same pharma company?

Should this be allowed? How can it be managed?

Faculty has started their own company based on intellectual property that they developed at another institution. They now want to do work in their CU lab to continue working on this patent because the company does not have a lab?

Should this be allowed? How can it be managed?

Does the situation change if the intellectual property was developed at this institution?

Should this be allowed? How can it be managed?

Managing Conflict of Interest

Specific steps may include:

- The investigator's financial interests with the sponsor of the trial could be fully disclosed to any human research volunteers.
- The investigator's financial relations to the sponsor should be included in all written and oral presentations, publications, and abstracts.

Other strategies include:

- Modifying the research plan, including changing the site(s) of the trial.
- Monitoring of research by independent reviewers. This could include special oversight and approval of any consulting agreement language when faculty consult with companies in which they also hold equity interests. In a clinical study, oversight could include participant recruitment and enrollment, the informed-consent process, analysis of the study data, and the subsequent reporting to the sponsor.
- Divestiture of significant financial interests.
- Severance of relationships that create actual or potential conflicts.
- Disqualification of the researcher from part or all of the research project

Conflicts at an institutional level

- Many universities have thrived on their relationships with industry since the approval of the Bayh-Dole Act
- Financial arrangements with sponsors are having effects on publication practices, on the prescribing patterns of investigators and clinicians, and even on the assignment of students or trainees to work on projects from which the researcher is likely to benefit financially

Definition

- According to the Council on Government Relations, "institutional conflicts of interest may occur when one or more aspects of either internal relationships between different units within the university or external relationships between the university and other entities are incongruent with institutional core values, and result, or have the potential to result in choices or actions that are harmful to the missions, the obligations, or the values of the university."

Adapted from: Council on Government Relations. Institutional Conflicts of Interest Points for Consideration. November 21, 2000

Can you identify potential institutional conflicts of interest at CU Anschutz?

- How are these managed?
- How could/should they be managed?

Emerging strategies

- Encourage transparency via disclosure of conflicts of interest among trustees and former trustees as well as university officials who often have close connections with boards of companies doing business with the institution.
- Place limits on involvement of faculty members and other institutional officials in companies.
- Exercise caution when technology-transfer official's remuneration is tied to stock values, as personal biases can influence judgments regarding stock sales or the acceptance of sponsored research agreements.

- Manage and review conflicts of interest using independent sources and external reviewers.
- Build organizational firewalls so that potentially conflicted parties do not interact. The institutional technology-transfer office should not be in the decision chain of identifying or managing conflicts of interest.
- Anticipate situations that could be perceived as compromising research and fiduciary integrity.

Questions?

- If you have questions concerning Conflict of Interest at UC Denver, please contact:

E- Mail: coi@ucdenver.edu

Website: <https://research.cuanschutz.edu/regulatory-compliance/home/conflict-of-interest/coi-home>