Financial Conflicts of Interest in Research

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Ethical Question

Does a financial interest of a researcher's pose a hazard to the researcher's fiduciary role?

(A *fiduciary* is a trustee, a person trusted with acting on behalf of others or for their benefit.)

Definition: Conflict of Interest

- A conflict of interest (COI) exists whenever one's interests or commitments compromise one's independence or professional judgment.
- COI's can influence action, but are not themselves acts.
- COI's are distinct from breaches of obligation.

Conflict of Interest v. Breach

- COI's have the capacity to cause avoidable harm: the risk is not *potential*
- COI's do not ensure improper conduct, however they do increase the risk that researchers will abuse their trust
- A breach of trust occurs when researchers violate known obligations

Financial Interests

- Employment
- Consultancy
- Stock Ownership
- Patent and Royalty Arrangements
- Honoraria
- Paid Expert Testimony
- Speakers' Bureau
- Gifts, Trips

Non-Financial Interests

- Personal and family relationships
- Academic competition for professional recognition
- Listed as author on articles ghostwritten by interested parties
- Advocacy
- Intellectual Passion

Association Between Competing Interests and Research Conclusions

- Conclusions were significantly more positive towards an experimental intervention in trials funded by for-profit organizations (BMJ Aug 2002)
- Conclusions of review articles are "strongly associated" with the affiliations of their authors (Bodenheimer, NEJM 2000)
- Original research articles that acknowledge industry sponsorship tend to draw pro-industry conclusions (Bodenheimer, NEJM 2000)

Who Can Have a Conflict of Interest?

Anyone with responsibility for the design, conduct and reporting of research:

- Investigators
- Research Staff
- Institutions
- IRB Members
- Journal Editors

Policy Options

- Prohibition
- Limitation
- Disclosure
- Oversight

1989 NIH Guidance (Withdrawn)

- NIH proposes full disclosure and prohibits equity interest
  - Proposal withdrawn: denounced as unacceptably prescriptive, overreaching , intolerably intrusive into affairs that were properly a matter of academic self – governance

1995 Regulations

- Incorporates discretionary approach focusing on internal disclosure and institutional assurance
- Investigators must disclose "significant" financial interests that might reasonably be affected by the research
- Institutions are required to report existence of COI's, but allowed to manage conflicts internally

2001 Draft Guidance (Withdrawn)

- Federal regulations concerning financial COI's in research were intended to promote scientific integrity – objectivity and reliability of data – not to protect human subjects.
- 2001 Guidance explicitly addresses the welfare of human subjects

2004 Guidance

- IRB's should establish policies to address the IRB members' COI's
- IRB should determine the level of information to be provided to subjects

2010 Proposed Regulations

- Decrease threshold for reporting SFI to $5,000 from $10,000
- Information on SFI's to be posted on a publicly accessible website
- FCOI training required for Investigators

Analyzing Risks to Participants

- How strong or direct are the conflicts?
- What is the probability of inappropriate behavior?
- What kinds of risks are posed?
- How serious might conflicts be?

The Case of Jesse Gelsinger 1999

Empirical Findings

II

AAMC 2008
"The Scientific Basis of Influence and Reciprocity"

https://services.aamc.org/publications/showfile.cfm?file=version106.pdf&prd_id=215&prv_id=262&pdf_id=106

AAMC Conclusions

1. There are systematic and predictable ways in which people act unethically that are beyond their own awareness.
2. The more leeway honest persons have, the more likely they are, given the opportunity, to behave unethically, but only up to a point that appears to be determined by the person's own self-concept.

AAMC Conclusions

3. Increasing awareness of moral standards, or mindfulness, at the time of decision making diminishes the tendency to behave unethically.
4. Self-interest unconsciously biases well-intended people, who give themselves bounded "moral wiggle room" to engage in unethical behavior with an easy conscience.

AAMC Conclusions

5. Circumstances that can create conflicts of interest should be eliminated wherever possible in order to decrease temptations and likelihood to act unethically

Implications of Experimental Findings

1. Conflicts of interest will inevitably bias behavior, however honorable and well-intentioned specific individuals may be. Bias may distort their choices, or they may look for and unconsciously emphasize data that support their personal interests.
2. The only viable remedy is to eliminate COIs whenever possible—e.g., eliminate gifts from pharmaceutical companies to physicians. Even small gifts can result in unconscious bias.

Challenges

- The task of convincing people that that they are not reliably reasonable is difficult.
- Though people cannot exercise unlimited control of their instinctive behavior, they are capable of imposing some modifications on it.
- Purposeful structuring of relationships and interactions to diminish potential conflicts of interest reinforces that capability

III

Moral Hazard Analysis (Law and Economics)

A moral hazard refers to the increased probability of a negative outcome because individuals are protected from the negative consequences of their behavior.

Examples: Insurance, Vaccinations

The Case of Spiral CT Cancer Screening 2007

Approaches to FCOI's

- Regulatory
- Moral Hazard
- Virtue