

Conflict of interests in biomedical sciences

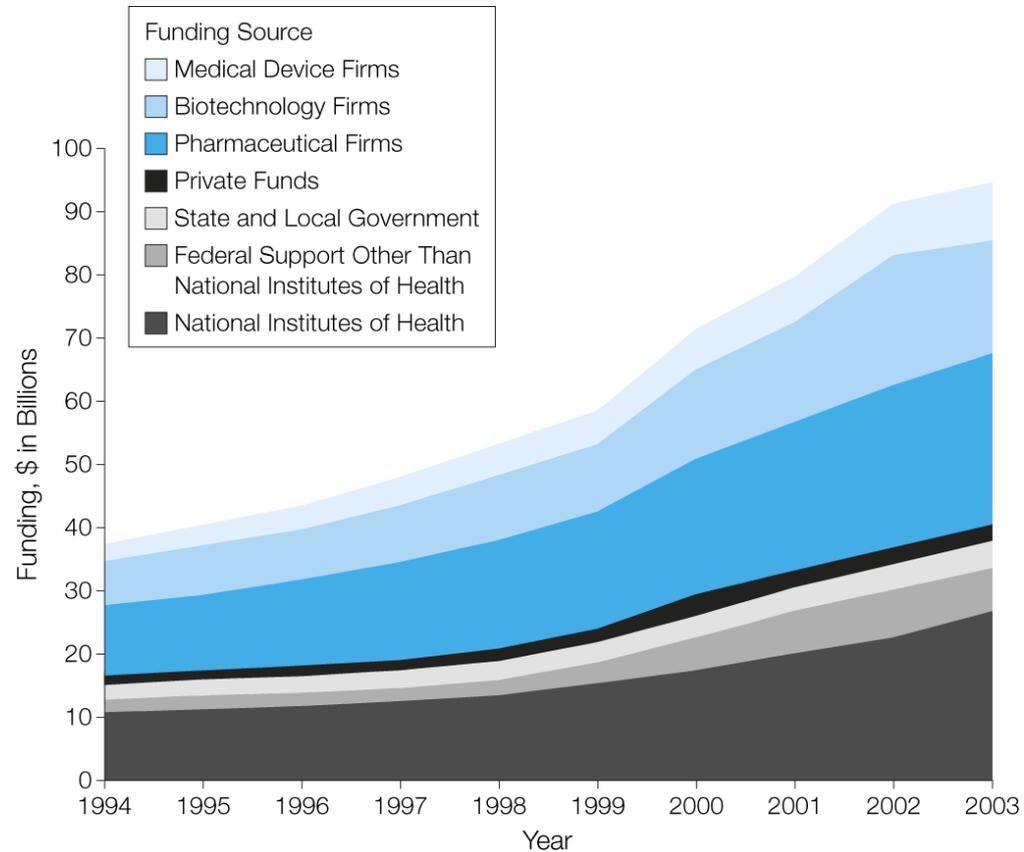


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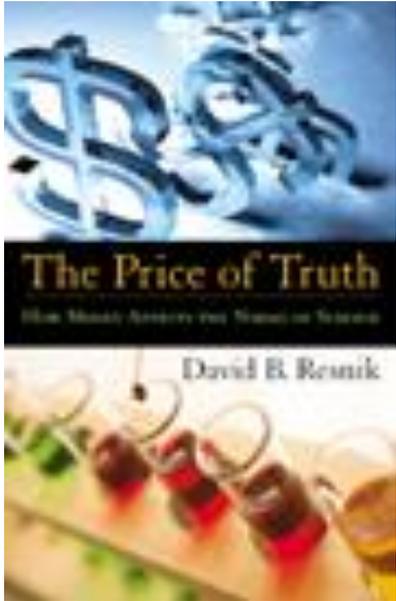
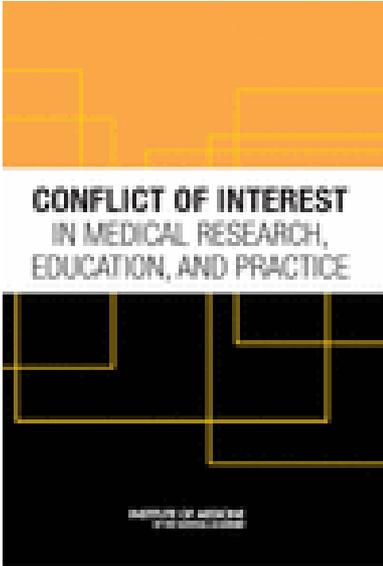
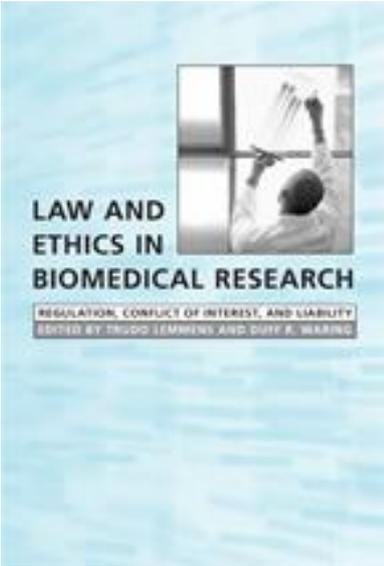
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The duration of the project is 2017-2021.

Financial anatomy of biomedical research



Moses, H. et al. (2005). Financial anatomy of biomedical research. JAMA, 294; 11:1333-1342.



"A scorching indictment of drug companies and their research and business practices... tough, persuasive and troubling."
—JANET MASLIN, *The New York Times*

The Truth About the Drug Companies



HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT

MARCIA ANGELL, M. D.

Former editor in chief of *The New England Journal of Medicine*
Winner of the Polk Award

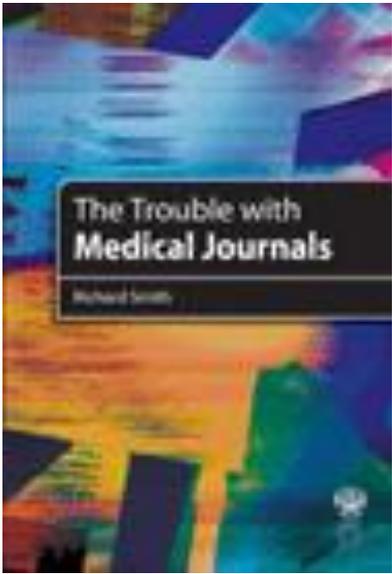
Revised and updated
Includes tips on what you can do to protect your interests



ON THE TAKE

HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH

JEROME P. KASSIRER, M. D.



"A MUST-READ FOR ANYONE INTERESTED IN THE FUTURE OF SCIENCE." —USA TODAY

SCIENCE *in the* PRIVATE INTEREST

HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH?



SHELDON KRIMSKY
FOREWORD BY RALPH NADER

Conflict of interests (COI) definition

- Merriam-Webster:
 - *„a conflict between the private interests and the official responsibilities of a person in a position of trust”*
 - First known usage: 1843
- COI in biomedicine:
- *„circumstances that create a risk that professional judgements or actions regarding a primary interest will be unduly influenced by a secondary interest” **

*Lo, B. & J. Field, M. eds. (2009). Conflict of Interest in Medical Research, Education, and Practice. Institute of Medicine Report, Washington, D.C.: National Academies Press

Primary interests, obligations, rights

- Primary interests are defined by / based on *professional roles*.
- These primary interests might include the integrity of research/science, patient well-being, quality of medical education ...
- Some formulate these primary interests as *aims*, or *obligations* or *rights*:
 - The **aim** of the profession to advance welfare of patients
 - Physician's **obligation** to promote patient's best interest
 - **Rights of patients** that health care staff promote patients' well-being.

Secondary interests are diverse and numerous, BUT

- **financial interests are at the center**, because
- Tangible, observable
- Contemporary changes in academia-industry relationships

- Various forms of financial COI:
 - Salaries
 - Counselling fees
 - Research funding
 - Grants, donations
 - Recruitment fees
 - Patent rights
 - Equity, share
 - Etc.

The severity of financial COI

- Share in stock>> << Conference participation support
- Emerging aspects and criteria for assessing severity:
 - 1.) the probability of professional decision to be biased:
 - Secondary interest's monetary value, duration, depth.
 - The individual (or institution) extent of discretion in making decisions.
 - 2.) potential harm caused by the decision

What is wrong with financial COI?

- Specific risks are associated with it.
- Financial COI:
 - threaten the **objectivity** of scientific investigations,
 - quality of medical education,
 - quality of patient care and
 - the **public's trust** in medicine

*„The credibility of modern science is grounded on the perception of the objectivity of its scientists, but that credibility can be undermined by financial conflicts of interest”
(Krimsky, S.)*

Major sources and references in the fCOI debate

- Cases, scandals and social science research

- Jesse Gelsinger case

- Nancy Olivieri case

- David Healy case

- Wakefield case: MMR vaccine and autism

- NIH failed approach on prohibition

- WHO and the Swineflu epidemic

- Psychological and sociological research on COI

Financial Ties between DSM-IV Panel Members and the Pharmaceutical Industry

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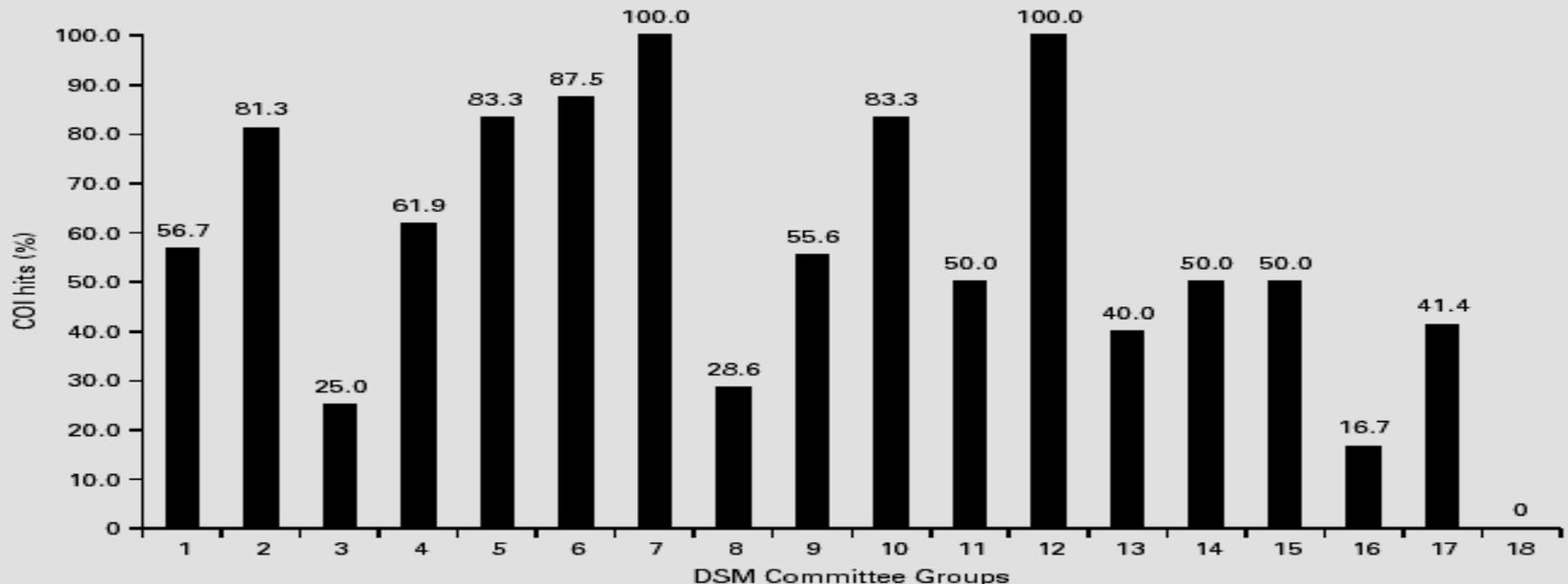


Fig. 1. Percentage of panel members of the DSM with financial ties.

	%		%
1 Task Force-IV	56.7	10 Premenstrual Dysphoric Disorder	83.3
2 Anxiety Disorders	81.3	11 Psychiatric Systems Interface Disorders	50.0
3 Delirium, Dementia, Amnestic and Other Cognitive Disorders	25.0	12 Schizophrenia and Other Psychotic Disorders	100.0
4 Disorders Usually First Diagnosed during Infancy, Childhood and Adolescence	61.9	13 Sexual Disorders (IV)	40.0
5 Eating Disorders	83.3	14 Sexual and Gender Identity Disorders (TR)	50.0
6 Medication-Induced Movement Disorders (TR)	87.5	15 Sleep Disorders	50.0
7 Mood Disorders	100.0	16 Substance-Related Disorders	16.7
8 Multiaxial Issues	28.6	17 Committee on Psychiatric Diagnosis and Assessment	41.4
9 Personality Disorders	55.6	18 Joint Committee of the Board of Trustees and Assembly of District Branches on Issues to DSM-IV	0.0

Anyagi érdekeltségek kategóriák szerinti megoszlása (170 tag)

RF kutatási támogatás

CON konzultáns

SB „szóvivő”

CB vállalat, rt. testületi tag

H honorárium

CIFS ip. szponz. kutatás tag

DINP gyógyszerip. non-profit

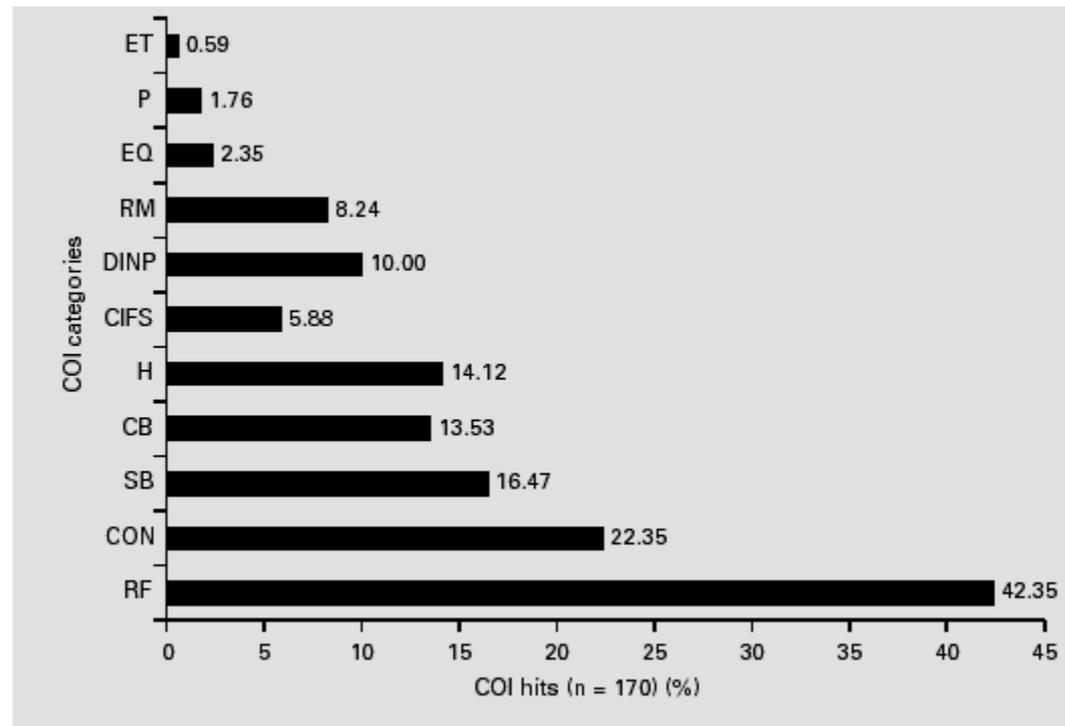
RM kutatási eszköz

EQ részvény

P patent tulajdonos

ET szakértői tanú

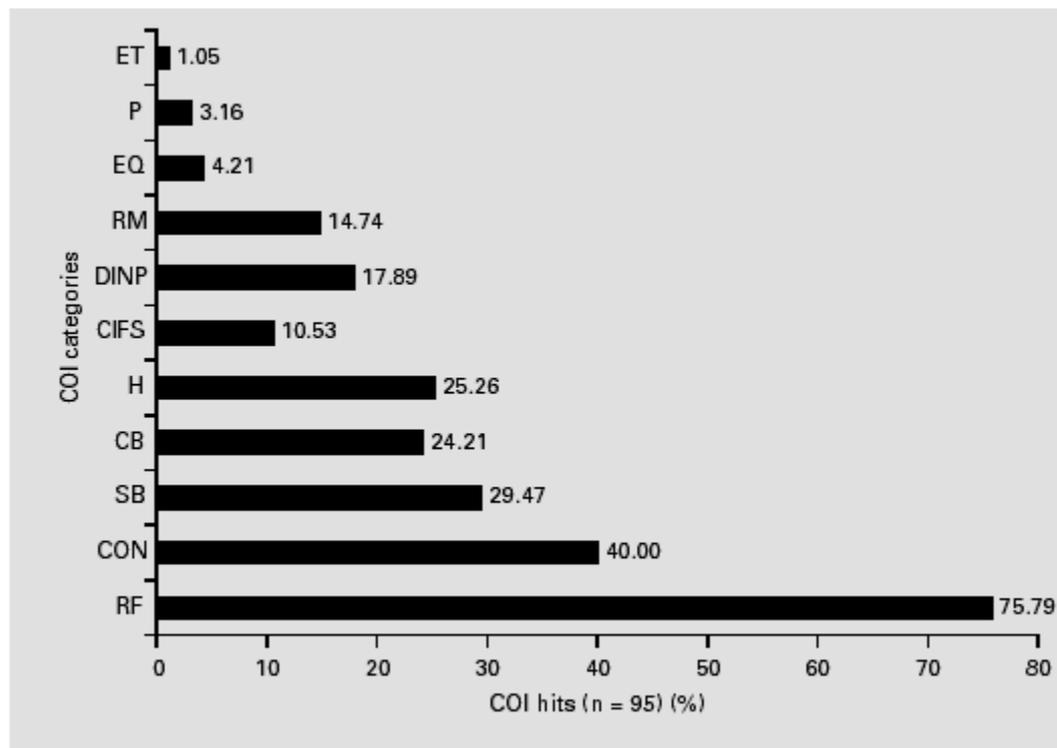
Fig. 2. Categories of financial interest held by DSM Panel Members: total members (n = 170). RF = Research funding; CON = consultant; SB = speakers bureau; CB = member of a corporate board; H = honorarium; CIFS = collaborator in industry-funded study; DINP = drug industry non-profit affiliation; RM = research materials; EQ = equity in a company; P = patent; ET = expert testimony.



Anyagi érdekeltségek kategóriák szerinti megoszlása (95 COI-s tag)

- RF** kutatási támogatás
- CON** konzultáns
- SB** „szóvivő”
- CB** vállalat, rt. testületi tag
- H** honorárium
- CIFS** ip. szponz. kutatás tag
- DINP** gyógysz.ip. non-profit
- RM** kutatási eszköz
- EQ** részvény
- P** patent tulajdonos
- ET** szakértői tanú

Fig. 3. Categories of financial interest held by DSM Panel Members: members with financial interests (n = 95). RF = Research funding; CON = consultant; SB = speakers bureau; CB = member of a corporate board; H = honorarium; CIFS = collaborator in industry-funded study; DINP = drug industry nonprofit affiliation; RM = research materials; EQ = equity in a company; P = patent; ET = expert testimony.



DSM szakbizottsági tagok többszörös anyagi érdekeltséggel

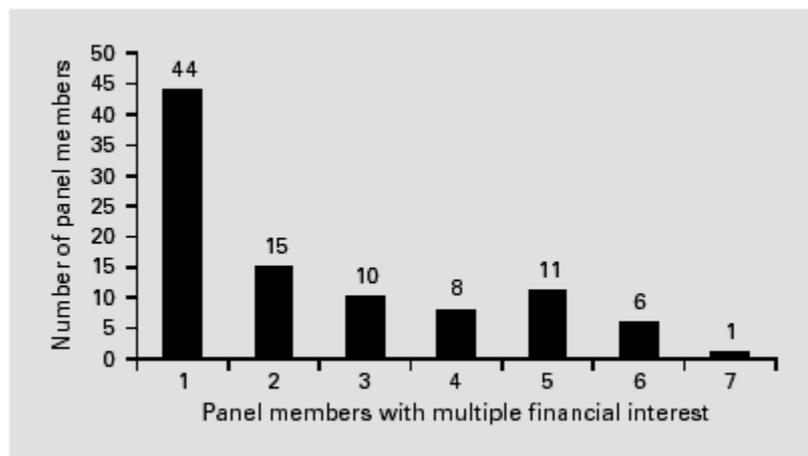


Fig. 4. DSM panel members with multiple financial interests.

Initial „regulatory” approaches (1990’s)

- Zero tolerance:
- fCOI is not managable, no way of controlling its effects. Researchers and physicians should eliminate their secondary financial interests. (Marcia Angell)
- Transparency:
- Zero tolerance is unfeasible. Disclosure of fCOI is a panacea.

Current „regulatory” approaches (IoM Report, 2009)*

- Focuses on three areas:
 - Biomedical research
 - Medical education
 - Medical practice
 - Development of clinical practice guidelines
 - Institutional conflict of interests
- Proliferation of codes, recommendations and guidelines:
 - AAMC, AMA, ACCME, FDA, OECD, ICMJE.....
 - Have a preventive focus, emphasize disclosure,
but
 - Sometimes formulate prohibitions

*Lo, B. & J. Field, M. eds. (2009). Conflict of Interest in Medical Research, Education, and Practice. Institute of Medicine Report, Washington, D.C.: National Academies Press

Critical voices on fCOI rules

- Emerging regulations are excessive, inconsistent, unproportionate, and ill-founded:
 - Bad consequences of fCOIs are rare and problems are smaller
 - Suppress valuable collaborations
 - Bring into question the moral integrity of researchers
 - Instead fCOI, we should focus on realized biases
 - Research participants are not interested in knowing the financial ties of researchers
 - Exclusive focus on fCOI divert our attention from other , more frequent secondary interests
 - Emerging fCOI rules will create a new scientific „*McCarthyism*”!

3 stage anatomy of COI (Stark, 2000)

1. Stage: Antecedents acts are factors that condition the state of mind of an individual toward partiality
2. Stage: States of mind represents the affected sentiments, dispositions, affinities
3. Stage: Behavioural partiality, biased decision

➤ Stark: *„because we cannot prevent officials from mentally taking notice of their own interest, we prohibit the act of holding certain kinds of interest in the first place”*

➤ The prohibitions of COI for public employees are based on the public health *model of primary prevention*.

Ethical framework for prohibiting fCOI: case of government employees and public officials

- Stewards of the public interests (public resources, policies, lands, laws, regulations)
- *Does this ethical framework based on the stewardship model apply to scientists? (Krimsky)*
- Yes, academic research is publicly funded (more/or less)
- No, it would threaten academic freedom and independence
- No, it would contradict with the new science policies that promote intellectual property rights within the

Changing conceptions about SCIENCE

- Certainly, the industry-academy relationship changed in the recent decades.
- But, how do we describe this? How do we interpret this?
- Competing theories: **post-academic science**, mode2 science, post-normal science, triple helix, etc.
- Marketing Based Medicine, entrepreneur science, Commercialization of the University, etc.
- *„Science is a big business, a costly enterprise commonly financed by corporations and driven by the logic of the market. Entrepreneurial values, economic interests, and the promise of profits are shaping the **scientific ethos**.“* (Dorothy Nelkin)

Scientific ethos and the norm of disinterestedness

- **Merton:** system of norms functioning in science, a scientific ethos.
- **Ziman:** Norms of academic science
 - Communism
 - Univerzalism
 - **Disinterestedness**
 - Originality
 - Skcepticism (organized)

These are not moral characteristics of scientists, but regulatory values coded into institutional conditions, academic norms exert control on the functioning of science.

Ziman's final(?) assessment on science

- The norm of disinterestedness does not „function” no more
- Then, what about objectivity ?
- Biases are minimized in the long run
- It is not very reassuring for users of pharmaceuticals
- Cognitive objectivity not (seriously) harmed
- Social objectivity is seriously undermined

➤ Eroding public trust in science

Conclusions 1

- This ethical framework - based on the ethics stewardship - is highly problematic when applied to researchers or scientists.
- It might be more appropriate for physicians.
- It is also problematic because it is grounded on role responsibility that is challenged by the current proliferation of different roles.
- The COI framework in science is also problematic because it has a sociologically simplistic conception of science as such.

Conclusions 2

- COI as a term is too broad:
 - it makes the innocent person, someone, who is not yet proven guilty
 - It takes the guilty under the innocent's umbrella
 - fCOI shall be set back into the context of other secondary interests (eg. Financing system in health care, bribery „gratitude-money“)