

PANEL DISCUSSION SESSION

HALL 2; AUGUST 23, 2021; 07H30–08H30

CONFLICT-OF-INTEREST AND DISCLOSURE IN EPIDEMIOLOGY

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INTERNATIONAL SOCIETY FOR ENVIRONMENTAL EPIDEMIOLOGY (ISEE)

ANNUAL CONFERENCE (VIRTUAL): AUGUST 23-26, 2021

URL: WWW.COLINSOSKOLNE.COM

PANEL MEMBERS

Juan Pablo Ramos-Bonilla (Colombia)

COI and its impact on the research question

Daniele Mandrioli (Italy)

COI as a source of bias in epidemiology

Lisa A. Bero (USA)

What do we know about disclosure?

Carl F. Cranor (USA)

Misusing Bradford Hill's viewpoints

RESEARCH INTEGRITY, HEALTH POLICY, AND THE ADVANCEMENT OF SCIENCE

ASSUMPTIONS:

- Science is used to inform policy
- Scientists are expected to operate with integrity in the application of the scientific method

BUT:

- If the scientist lacks integrity, what then is produced to inform rational policy?
Distorted science undermines health policy and derails the advancement of science

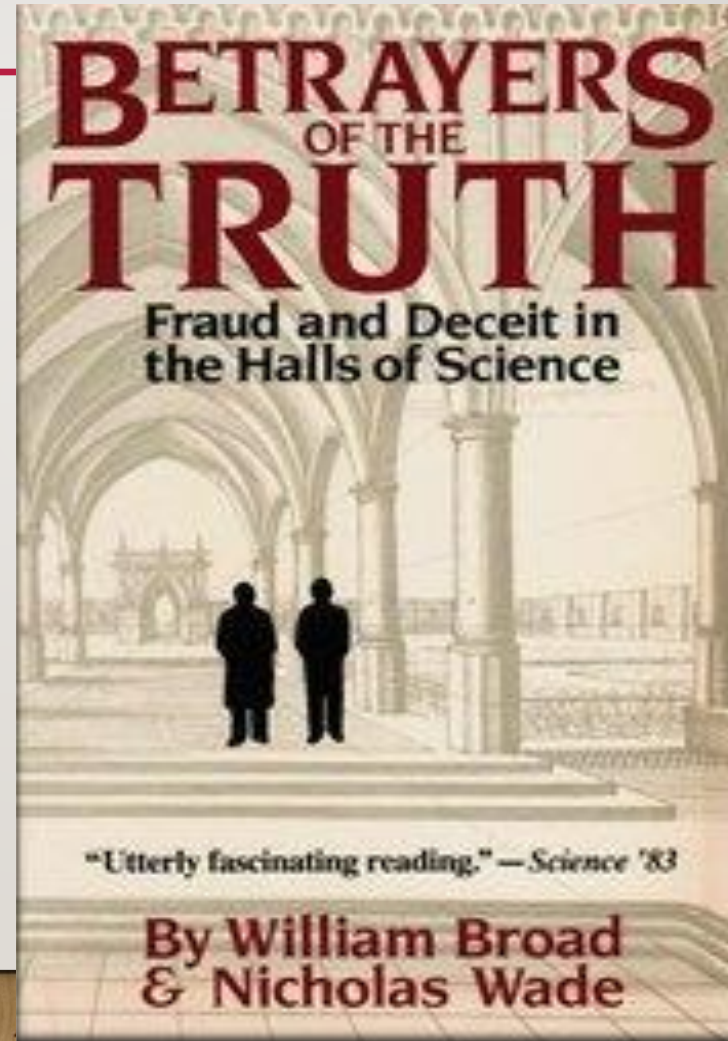
“Industry’s offensive against the regulation of health and safety hazards uses academics to downplay or deny the seriousness of the hazards...”

Clayson and Halpern

J. of Public Health Policy

September, 1983

NOT ONLY IS INDUSTRY INVOLVED – FROM GALILEO AND MANY MORE



Broad & Wade argue that ...

the conventional wisdom of science being a strictly logical process, with objectivity the essence of scientists' attitudes, errors being speedily corrected by rigorous peer scrutiny and replication, is a mythical ideal

MANUFACTURING DOUBT

EPSTEIN

The Politics of Cancer, 1978

DAVIS

When Smoke Ran Like Water: Tales of Environ Deception ..., 2002

The Secret History of the War on Cancer, 2007

Disconnect: The Truth About Cell Phone Radiation ..., 2010

MICHAELS

Doubt is their Product: How Industry's Assault on Science..., 2008

The Triumph of Doubt: Dark Money and the Science of Deception, 2020

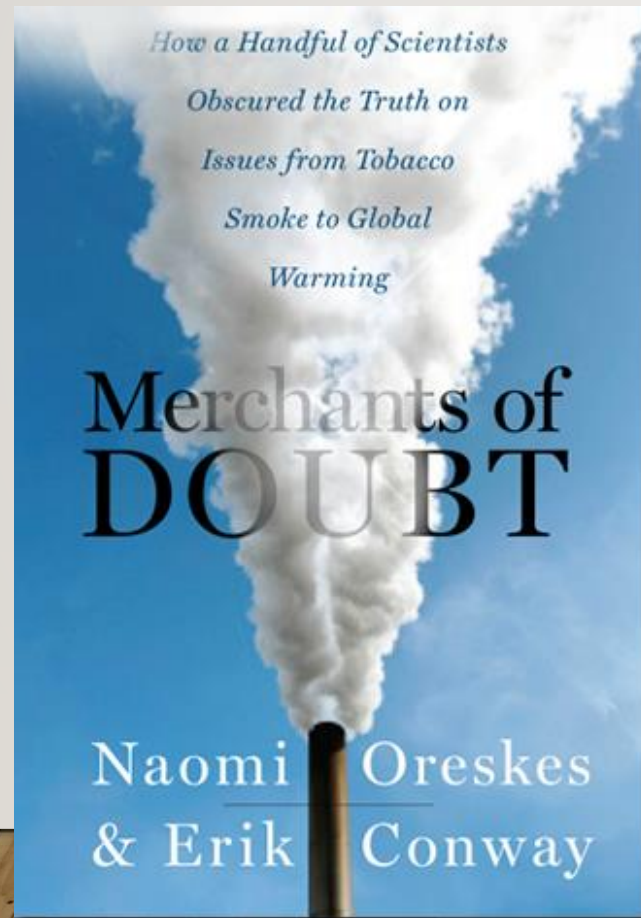
MCCULLOCH & TWEEDALE

Defending the Indefensible: The Global Asbestos Industry ..., 2008

By casting doubt and fomenting uncertainty, the health policy-maker's role is undermined ...

→ the subversion and ambushing of science

MERCHANTS OF DOUBT: HOW A HANDFUL OF “SCIENTISTS” OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO GLOBAL WARMING



*Also made into a movie...
Released in 2015*

EPIDEMIOLOGY... AN APPLIED SCIENCE

- **Knowledge derived from epidemiological evidence is not used solely for discovery purposes. It is also applied to control and prevent health problems and is used to restore, promote, and protect population health across all levels of society**
- **By virtue of their focus on protecting the public's health, epidemiologists, as a profession, are expected to serve the public, with the public interest trumping all others**

THE INEP MISSION



INTERNATIONAL NETWORK FOR
EPIDEMIOLOGY IN POLICY

INTEGRITY, EQUITY, AND EVIDENCE IN POLICIES IMPACTING HEALTH

INEP works at the interface of research and policy to maintain and protect the public's health... by:

- creating and disseminating evidence-based knowledge about epidemiology,
- supporting capacity-building of experts to translate research and science into policy, and
- recognizing and highlighting the misuse of data and potential corruption of the science practiced by epidemiologists.

INEP'S POSITION STATEMENT

CONFLICT-OF-INTEREST AND DISCLOSURE IN EPIDEMIOLOGY

Launched on January 5, 2021

<https://epidemiologyinpolicy.org/coi-d-position-statement>

ON THE SHOULDERS OF OTHERS

INEP's Position Statement

Started in 2014 and written by CLS with 9 co-authors, 8+ contributors, and 6 external reviewers

- Adapted from the work of several professional organizations
- **Unanimously approved** by the INEP Board on September 16, 2020
- Exceeded its required member organization **endorsement threshold** on December 24, 2020; **released** on January 5, 2021

HOW AND WHY CONFLICT-OF-INTEREST?

- **What is conflict-of-interest (COI)?**

If a scientist has a vested interest in how TRUTH is presented, they can distort the truth

A scientist with a COI may have her/his objectivity compromised

- **What drives COI?**

A scientist's vested interests, which could include benefiting financially, promotions, prestige, and so on

BIAS AND UNCERTAINTY CAN BE PROPERLY MANAGED SCIENTIFICALLY, BUT WHAT HAPPENS WHEN COI (A.K.A INVESTIGATOR BIAS) IS AT PLAY?

- **COI introduces a human element into how science is applied. COI can impact all aspects of scientific inquiry, from the framing of a scientific question to the design, analysis, interpretation, and the dissemination of a study**
- **INEP's Position Statement provides a practical approach to managing COI. Its guidance is needed for science to remain credible**

HOW DO COI PRACTICES AFFECT EPIDEMIOLOGY?

RATHER THAN AN IMPARTIAL ANALYSIS,

- Scientists can produce and disseminate misinformation or suppress data
- The association between cause-and-effect can be obscured and denied
- Scientific integrity can be undermined
- Public trust in the science of epidemiology can be eroded
- Workers, the public, and the environment can be harmed
- Distorted science undermines health policy and derails the advancement of science

WHAT'S IN THE INEP POSITION STATEMENT ON *CONFLICT-OF-INTEREST AND DISCLOSURE IN EPIDEMIOLOGY?*

- Recent high-profile cases **exemplifying the misuse of epidemiologic research and the failure to disclose COI reported in the media and scientific literature**
- Recent COI examples **developed by INEP co-authors and contributors**
- A compendium of common practices **used to distort and misapply epidemiological sciences**
- INEP recommendations for COI management by:
Identification, Avoidance, Disclosure, and Recusal
- Appendices that cover responses to the breadth, scope, and growing sophistication of COI

TO FIX IT YOU HAVE TO RECOGNIZE IT!

CASE EXAMPLES: COI IDENTIFICATION, DISCLOSURE, AND GUIDANCES

1. Medical Research, Education, and Practice
2. Tobacco Industry
3. Food Safety Panel
4. 2015 INEP Policy to Avoid COI through Donations
5. Recent Epidemiology-specific Examples of COI and Disclosure Issues (“a” to “l”; n=12)

TWELVE RECENT EXAMPLES ILLUSTRATING THE BREADTH, SCOPE, AND GROWING SOPHISTICATION OF THE PROBLEM

- a) 2016 Center for Public Integrity COI Exposé: “Science for Sale” on Scientific Boards, Councils, and Review Panels
- b) 2018 Collegium Ramazzini Statement: COI-related Principles for Safeguarding the Integrity of Research in Occupational and Environmental Health
- c) 2019 Commentary: How can the integrity of occupational and environmental health research be maintained in the presence of conflicting interests?
- d) 2019 Acquavella Commentary that COI Disclosure Harms Epidemiology: INEP member response
- e) 2020 Graziosi Article: Political COI of False Hurricane Claims
- f) 2020 Kaplan et al Article: COVID Pandemic Lapses in COI and Disclosure
- g) 2020 Unbalanced and Conflicted Science in AJPB Special Issue on E-Cigarettes
- h) 2020 Heindel Article: Undeclared COI in Biased Editorial Duplicated in 8 Toxicology Journals
- i) 2020 Hardell, Rivasi, and Buchner Letters / Reports: RF-EMF Hazard and COI of ICNIRP Analyses and Leadership
- j) 2015-2020 Caldwell-Soskolne Analysis of COPE Failure: Articles and Journal COI for Drinking Water Carcinogenicity
- k) COI and Improper Influence through Meeting / Conference Sponsorship by Vested Interests: ISEE Guidelines for Donor Support
- l) 2020 COI and Hill’s 1965 Viewpoints Used in Testimony for Causation in Civil Litigation

A TOOLKIT OF EPIDEMIOLOGY 'DIRTY TRICKS'



RECOGNIZE THE METHODS

COMMENTARY JUST PUBLISHED IN ENVIRONMENTAL HEALTH (OPEN ACCESS)

A compendium of misapplied methods, often demonstrated in tort actions, the toolkit can be used:

- **By peer-reviewers as a checklist of what to look out for**
- **To train epidemiologists and others on how epidemiology can be distorted**
- **To review the literature for inappropriately conducted science or for uninformative studies (e.g., as in underpowered studies)**
- **To identify who is misusing / abusing epidemiology**
- ***NINE CO-AUTHORS***

TABLE: TOOLKIT OF 33 MISUSED EPIDEMIOLOGICAL METHODS

PART A: 18 EPIDEMIOLOGY-SPECIFIC METHODS/TECHNIQUES USED TO FOMENT UNCERTAINTY AND CAST DOUBT ABOUT CAUSE-AND-EFFECT [through biased study designs/measurements producing invalid science]

PART B: 8 ARGUMENTS USED TO DELAY ACTION, MAINTAIN THE STATUS QUO, AND CREATE DIVISIONS AMONG SCIENTISTS [imposing inappropriate standards and methods of suppression]

PART C: 7 TACTICS INVOKED TO MISDIRECT POLICY PRIORITIES THROUGH INFLUENCE [imposing undisclosed values from the positions taken by special interests]

GOING FORWARD: INEP-SPECIFIC RECOMMENDATIONS FOR COI

- a. Identification
- b. Avoidance
- c. Disclosure
- d. Recusal

JUAN PABLO RAMOS-BONILLA:

COI AND ITS IMPACT ON THE RESEARCH QUESTION (1 OF 2)

- **Public funding expended for research has decreased at a global level**
- **An increased number of research institutions and scientists currently rely on corporate funding and its vested interests¹**
- **It is expected that the current pandemic will result in more reductions in public funding for R&D in many disciplines²**
- **How can this influence the research agenda? A critical issue is the formulation of the research question**

1 – https://www.collegiumramazzini.org/download/2017_10_20_Unpublished_Integrity_Statement.pdf

2 – *European University Association 2020*

JUAN PABLO RAMOS-BONILLA:

COI AND ITS IMPACT ON THE RESEARCH QUESTION (2 OF 2)

- **Corporate funding can influence the research agenda¹**
- **Unless it is recognized by the researcher, identifying if a research question was censored or modified by vested interests is extremely difficult**
- **Past experiences with endocrine disruptors, fossil fuels, asbestos, to name but a few examples, illustrate how corporate funding can drastically affect both the research agenda and public policy**
- **What are the implications for public health? How can this problem be addressed?**

1 - Fabbri, Lai, Grundy, RN, Bero, The Influence of Industry Sponsorship on the Research Agenda: A Scoping Review, Am J Public Health. Published online ahead of print September 25, 2018: e1– e8. doi:10.2105/AJPH.2018.304677

DANIELE MANDRIOLI:

COI AS A SOURCE OF BIAS IN EPIDEMIOLOGY (1 OF 2)

- **There is sufficient evidence that financial COI is able to affect study outcomes, in both human and non-human studies, in many fields including epidemiology and toxicology**
- **Financial COIs introduce bias at all levels of the research and publication process (author financial ties, review sponsorship, and journal funding)**
- **On the other hand, there is no evidence that the so-called “non-financial COIs” constitute a systematic source of bias.**

Mandrioli D, Kearns CE, Bero LA. Relationship between Research Outcomes and Risk of Bias, Study Sponsorship, and Author Financial Conflicts of Interest in Reviews of the Effects of Artificially Sweetened Beverages on Weight Outcomes: A Systematic Review of Reviews. PLoS One. 2016 Sep 8;11(9):e0162198. doi: 10.1371/journal.pone.0162198.

Bero LA, Grundy Q. Why Having a (Nonfinancial) Interest Is Not a Conflict of Interest. PLoS Biol. 2016 Dec 21;14(12):e2001221. doi: 10.1371/journal.pbio.2001221.

DANIELE MANDRIOLI:

COI AS A SOURCE OF BIAS IN EPIDEMIOLOGY (2 OF 2)

- **Systematic Reviews and Evidence-Based Methodology in epidemiology need to account for financial COI when assessing Risk of Bias and the quality of evidence of the study**
- **Financial COI is already included as an item in the assessment of risk of bias of the Navigation Guide and the WHO-ILO Joint Methodology for estimating the work-related burden of disease and injury**

Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. Environ Health Perspect. 2014 Oct;122(10):1007-14. doi: 10.1289/ehp.1307175. Epub 2014 Jun 25.

Pega F, Norris SL, Backes C, Bero LA, Descatha A, Gagliardi D, Godderis L, Loney T, Modenese A, Morgan RL, Pachito D, Paulo MBS, Scheepers PTJ, Schlünssen V, Sgargi D, Silbergeld EK, Sørensen K, Sutton P, Tenkate T, Torreão Corrêa da Silva D, Ujita Y, van Deventer E, Woodruff TJ, Mandrioli D. RoB-SPEO: A tool for assessing risk of bias in studies estimating the prevalence of exposure to occupational risk factors from the WHO/ILO Joint Estimates of the Work-related Burden of Disease and Injury. Environ Int. 2020 Feb;135:105039. doi: 10.1016/j.envint.2019.105039. Epub 2019 Dec 18.

LISA BERO:

WHAT DO WE KNOW ABOUT DISCLOSURE? (1 OF 2)

- Most frequently used strategy to “manage” financial COI
- Current declarations are not meaningful
 - Poorly accessible (94-page supplementary PDFs)
 - Inconsistent (16+ different headings)
 - Missing information (don’t match other data sources)
 - Obfuscation (“potential,” “relevant,” 706-word statements)
- Not enforced

COMMERCIAL INFLUENCE IN HEALTH: FROM TRANSPARENCY TO INDEPENDENCE

Improving researchers’ conflict of interest declarations

Enforced, structured reporting and processes to assess relevance are required to make conflict of interest disclosures fit for purpose, argue **Quinn Grundy, Adam Dunn, and Lisa Bero**

LISA BERO:

WHAT DO WE KNOW ABOUT DISCLOSURE? (2 OF 2)

- Does not prevent bias in research
- Makes those giving advice *more* biased
- Makes readers more critical
- **Necessary but not sufficient**

CARL CRANOR:

MISUSING BRADFORD HILL'S VIEWPOINTS (1 OF 2)

- 80 U.S. Federal Court decisions referencing Bradford Hill's "methodology" revealed judicial misunderstandings. Non-expert judges have been misled by "*sound science*" *conferences* and *testifying industry experts*. (Neutra, Cranor, Gee,, 2018)
- **Examples:**
 - Demanding epidemiological studies as evidence of adverse health effects
 - Requiring conventional and low statistical significance

CARL CRANOR:

MISUSING BRADFORD HILL'S VIEWPOINTS (2 OF 2)

- **Additional Examples:**
 - Requiring epidemiological studies show relative risks >2.0
 - Demands for a biologically plausible mechanism
 - Only one court of 80 recognized the importance of statistical power
- These misuses of epidemiological studies can become conditions for testimony, preclude relevant scientific evidence, and preclude accurate science

REVIEW

- Never has **TRUTH** been under such assault and needed more to protect the public's health
 - **Science can be misused either intentionally, through error, or from bias**
 - For centuries, intentional distortion of scientific methods, evidence, and miscommunication have been associated with COI
 - **COI-associated misuse of science can result from self-interest (financial stakes, liability protection, political interests, self-advancement, etc.)**
 - Increasing levels of sophistication are being employed that include coopting regulatory bodies, scientific panels, and communication forums
- ➔ INEP recognizes this and recommends ways to better manage it [in the public interest](#)

WE MUST NOT BE NAÏVE

Be aware of the forces at play that influence both science and policy

... Great vigilance and personal integrity are required to counter the influence of financially interested parties and corrupt and/or morally bankrupt governments

TAKE HOME MESSAGES

- **Uncertainty is inherent to science**
- **Science strives to be value-neutral/-free, but the human instrument is not**
- **Look first to ourselves, because causal inference is a function of who it is that is making the inference which, in turn, is a function of how we apply our scientific methods**

DISCUSSION: QUESTIONS TO PANELISTS

- Colin Soskolne
- Juan Pablo Ramos-Bonilla
- Daniele Mandrioli
- Lisa Bero
- Carl Cranor

URL: www.colinsoskolne.com