

SCIENTIFIC SESSION 4

DAY 2; OCTOBER 29, 2021; 11:30–13:00 (NEW YORK-TORONTO TIME)

CONFLICT-OF-INTEREST AND DISCLOSURE IN EPIDEMIOLOGY

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COLLEGIUM RAMAZZINI

VIRTUAL RAMAZZINI DAYS 2021: OCTOBER 28-30

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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 and distorting science

DISCUSSANTS

- **Kurt Straif** (Spain - USA)
- **Michael Gochfeld** (USA)

EVAGGELOS VALLIANATOS IN THE HUFFPOST

HISTORIAN AND ENVIRONMENTAL STRATEGIST, ANNIHILATING THE NATURAL WORLD

07/15/2017

A successful business strategy of global corporations is to buy politicians and scientists to legitimize and protect their products. Second, they maintain political dominance at home and abroad by keeping the world in turmoil. They do that by bribing politicians who globalize corporate economic and consumption models — and fight wars for petroleum and other resources.

The tobacco industry became the paradigm of covering up the harm of their product by recruiting Hollywood, the media, lobbyists and advertisers. Lobbyists purchased federal and state politicians.

The chemical industry even outsmarted the tobacco companies. Its lobbyists and scientists drafted the laws “regulating” petrochemicals and other synthetic chemicals. The result is chemical companies “test” their own products.

https://www.huffpost.com/entry/annihilating-the-natural-world_b_596a9443e4b022bb9372b23a

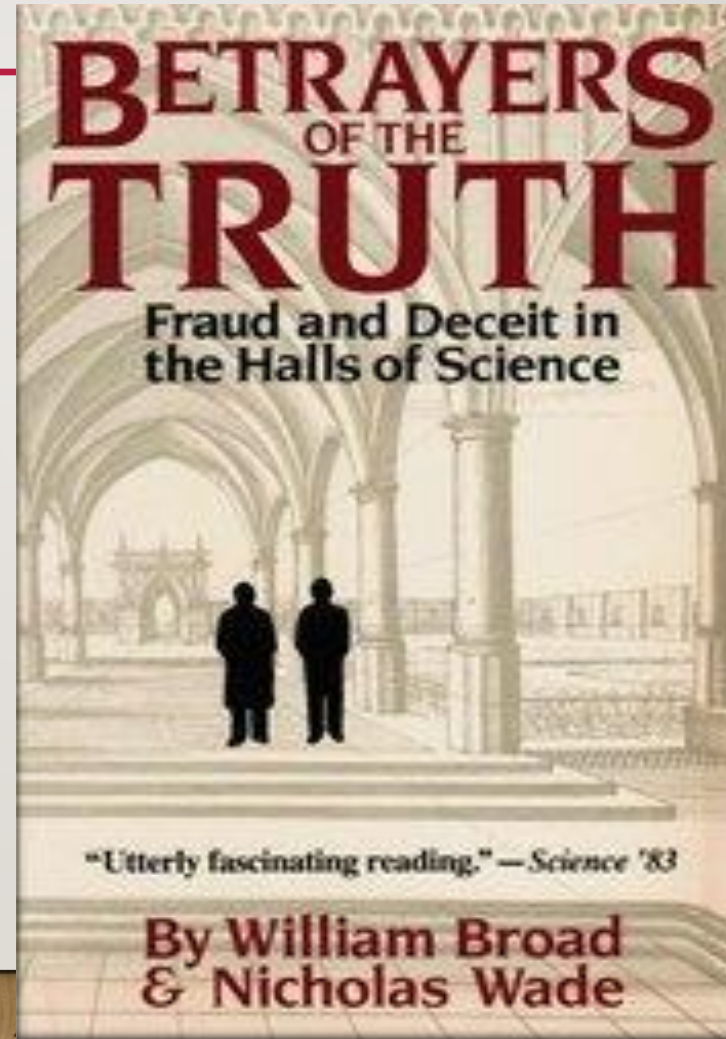
“Industry’s offensive against the regulation of health and safety hazards uses academics to downplay or deny the seriousness of the hazards...”

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

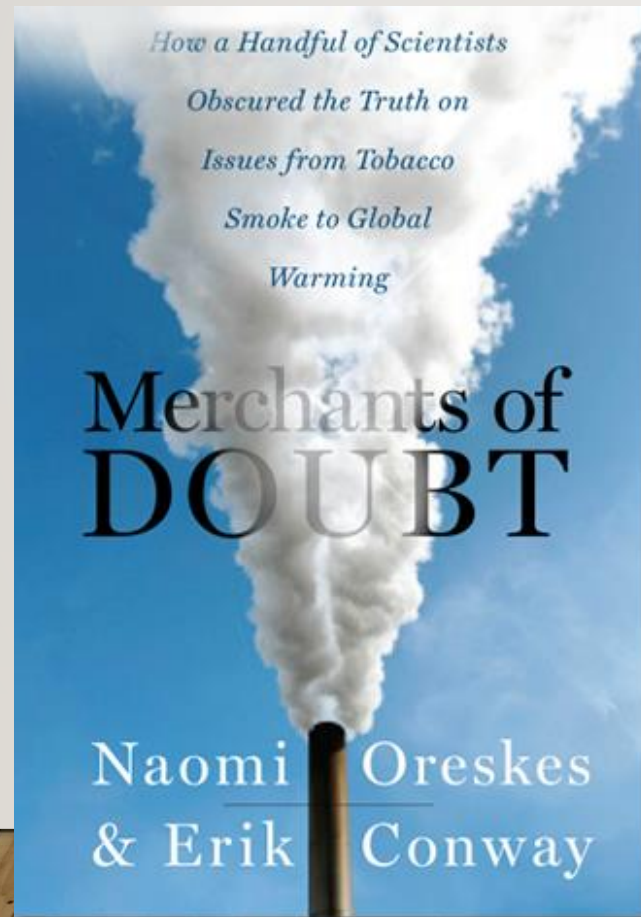
MCCULLOCH & TWEEDALE

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**

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

THE INEP MISSION



INTERNATIONAL NETWORK FOR
EPIDEMIOLOGY IN POLICY
INTEGRITY, EQUITY, AND EVIDENCE IN POLICIES IMPACTING HEALTH

INEP, comprising 24 national and international volunteer member associations and societies of epidemiologists, works at the interface of research and policy to maintain and protect the public's health, serving as a counter-balance to powerful interests 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.

ON THE SHOULDERS OF OTHERS

INEP's *Position Statement* (<https://epidemiologyinpolicy.org/coi-d-position-statement>)

Started in 2014 and written by 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 AJPH 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 (OPEN ACCESS) PUBLISHED AUGUST 19, 2021 ENVIRONMENTAL HEALTH
([HTTPS://DOI.ORG/10.1186/S12940-021-00771-6](https://doi.org/10.1186/s12940-021-00771-6))

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

THE LATEST IN ADVANCING THIS TOPIC

- I have had the pleasure and honor to have worked with four internationally-recognized contributors to the topic:
- **Dr. Juan Pablo Ramos-Bonilla** (Colombia)
- **Dr. Daniele Mandrioli** (Italy)
- **Dr. Lisa Bero** (USA)
- **Dr. Carl Cranor** (USA)

Specific dimensions that they respectively bring to the topic follow:

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 AND DISTORTING SCIENCE (1 OF 6)

Conflicting Interests Distort Epidemiology in Court

- **Austin Bradford Hill's, "*The Environment and Disease: Association or Causation*" became a major guide to assisting causal inferences from statistical associations**
- **His article has also been become a legally recognized methodology that experts may use to support testimony for causation in civil litigation**

CARL CRANOR:

MISUSING BRADFORD HILL'S VIEWPOINTS AND DISTORTING SCIENCE (2 OF 6)

Conflicting Interests Distort Epidemiology in Court

- Bradford Hill was a cautious, thoughtful scientist seeking to understand when scientific associations could support inferences of causation
- He presented examples to illustrate how his “factors,” “viewpoints,” or “considerations” could contribute to causal inference, but also noted counter-examples illustrating their limitations

CARL CRANOR:

MISUSING BRADFORD HILL'S VIEWPOINTS AND DISTORTING SCIENCE (3 OF 6)

Misunderstandings of Epidemiology in Court

- Courts often demand epidemiological studies as evidence of adverse health effects as a prerequisite of testimony. No epi, no testimony
- Too often courts require conventional and low statistical significance to support testimony. (Neutra, Cranor, Gee, 2018)
- Amicus Brief (4th Circuit Court of Appeals): Trial judge did not permit a UCSF expert to testify because his studies only had statistical significance to 0.065 instead of 0.05 (Cranor, McCloskey, Ziliak, 2017)

CARL CRANOR:

MISUSING BRADFORD HILL'S VIEWPOINTS AND DISTORTING SCIENCE (4 OF 6)

Misunderstandings of Epidemiology in Court

- Courts often require epidemiological studies show relative risks >2 . But studies with $RR < 2$ can contribute to causal understanding, e.g., environmental tobacco smoke has $RR = 1.2$ to 1.4 or ingestion of red meat $RR = 1.17$. (Neutra, Cranor, Gee, 2018)
- Some extreme courts require mechanistic understanding of every biological step from exposure to disease or expert may not testify. (Neutra, Cranor, Gee, 2018)

CARL CRANOR:

MISUSING BRADFORD HILL'S VIEWPOINTS AND DISTORTING SCIENCE (5 OF 6)

Misunderstandings of Epidemiology in Court

- Only one court of 80 recognized the importance of statistical power. (Neutra, Cranor, Gee, 2018)
- These misuses of epidemiological studies can become conditions for testimony, preclude relevant scientific evidence, and preclude accurate science
- When these problems occur, they can bar injured parties from receiving compensation for injuries caused by defendants; an injustice

CARL CRANOR:

MISUSING BRADFORD HILL'S VIEWPOINTS AND DISTORTING SCIENCE (6 OF 6)

Second Prong: Industry Tries to Block the Use of Epi Studies to Assess the Toxicity of Pesticides

- **Companies appear to want the underlying and likely private epi data from studies that researchers have ethical duties to protect**
- **There may be more going on, such as well-worked out animal studies that rarely show adverse effects to humans, at least at ambient exposures. This may not be correct science**
- **This view results from failure to conduct honest science using the full panoply of data to assess causation**

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**

DISCUSSANTS

- Kurt Straif
- Michael Gochfeld

GENERAL DISCUSSION, QUESTIONS TO:

PANELISTS

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

DISCUSSANTS

- Kurt Straif
- Michael Gochfeld

URL: www.colinsoskolne.com