

INEP Position Statement:
***CONFLICT-OF-INTEREST AND DISCLOSURE
IN EPIDEMIOLOGY***

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ZOOM WEBINAR

JOLINE YOUNG HERITAGE CONSULTANCY, CAPE TOWN, SOUTH AFRICA

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Thank you, Joline Young, for hosting this webinar on your Heritage Consultancy Web Platform and for your support of the PHA Farmworkers Kitchen in the Western Cape, South Africa.

THE TOPIC FOR TODAY'S WEBINAR

- ▶ We will address two questions in our 1-hour webinar, followed by a half-hour of discussion:
- ▶ How is it that public health policy remains under siege?
- ▶ How can public health be better protected through the improved management of *Conflict-of-Interest and Disclosure in Epidemiology*?

What is EPIDEMIOLOGY?

- ▶ Epidemiology is a public health science. Epidemiologists study the patterns, causes, and possible control of diseases in populations (both in people and in animals). Clinical epidemiology is related by its scientific methods, but is more a branch of medicine.
- ▶ Epidemiologists are disease detectives who search for the cause of disease, who is at-risk, and how to prevent or control disease or adverse health impacts.
- ▶ Epidemiology findings can help to inform health policy by providing a rational basis for new policy, or for changes to existing policy.

SCIENCE AND THE EPIDEMIOLOGICAL METHOD

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The strength of the epidemiologic method is its application to control three important biases. These are produced in the definition and selection of the study population, data collection, and the association between different determinants of an effect in the population, respectively: Selection bias, Information bias, and Confounding.

→ As with any science, there is a degree of uncertainty associated with what is measured. We express this in terms of probability; e.g., as “**a finding is accurate 19 times out of 20**”. The scientific method requires the transparent control of bias by the application of standard methodologic tools.

HOW DOES CONFLICT-OF-INTEREST AFFECT EPIDEMIOLOGY FINDINGS?

▶ What is conflict-of-interest (COI)?

If a person has a vested interest in how TRUTH is presented (e.g., like the outcome of an epidemiology study) they can distort the truth.

A person with COI may have their objectivity compromised.

▶ What causes COI?

A person's vested interests can include benefiting financially, promotions, prestige, etc.

CONFLICT-OF-INTEREST (COI) IN ACTION

- ▶ Suppress data so that the relationship between cause-and-effect is obscured.
- ▶ Can affect researchers, scientific journal authors, reviewers, editors, and involve corporate sponsors of scientific journals.
- ▶ Undermine scientific integrity, erode public trust in the science of epidemiology, and harm workers, the public, and the environment.

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

- ▶ Conflict-of-interest (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 dissemination of a study.
- ▶ The INEP Position Statement provides a practical approach to managing COI. This is needed for science to remain credible.

EPIDEMIOLOGY AS AN APPLIED SCIENCE

Because it is possible to manipulate experimental and control groups in ways that introduce bias and thus fail to serve the public interest through the pursuit of truth (as expected of scientists), it is more and more recognized that ethical training and oversight are crucial.

Our ethics and values determine in large part our behaviours and the choices we make.

INDUSTRIES INFAMOUS FOR THEIR COI ACTIVITIES

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Overwhelming evidence of this has been provided for:

the lead industry, the tobacco industry, the asbestos industry, the fossil fuel industry, the chemical industry, the fast food industry, the mining industry, the sweetened beverage industry; the list is endless

FIRST, A REALITY CHECK ...

**WHAT CONSTITUTES
VIRTUOUS PROFESSIONAL
CONDUCT?**

VIRTUES EXPECTED OF PROFESSIONALS

Humility – Respect the input and opinions of others/Self-effacement

Fidelity – Honour one's commitments/Promote trust

Justice – Act fairly

Patience – Take time to hear others' viewpoints

Industry – Do your level best/Excel

Veracity – Tell the truth/Be honest

Compassion – Empathize

Integrity – Demonstrate good moral character

Serve – Protect the most vulnerable/Serve the public interest

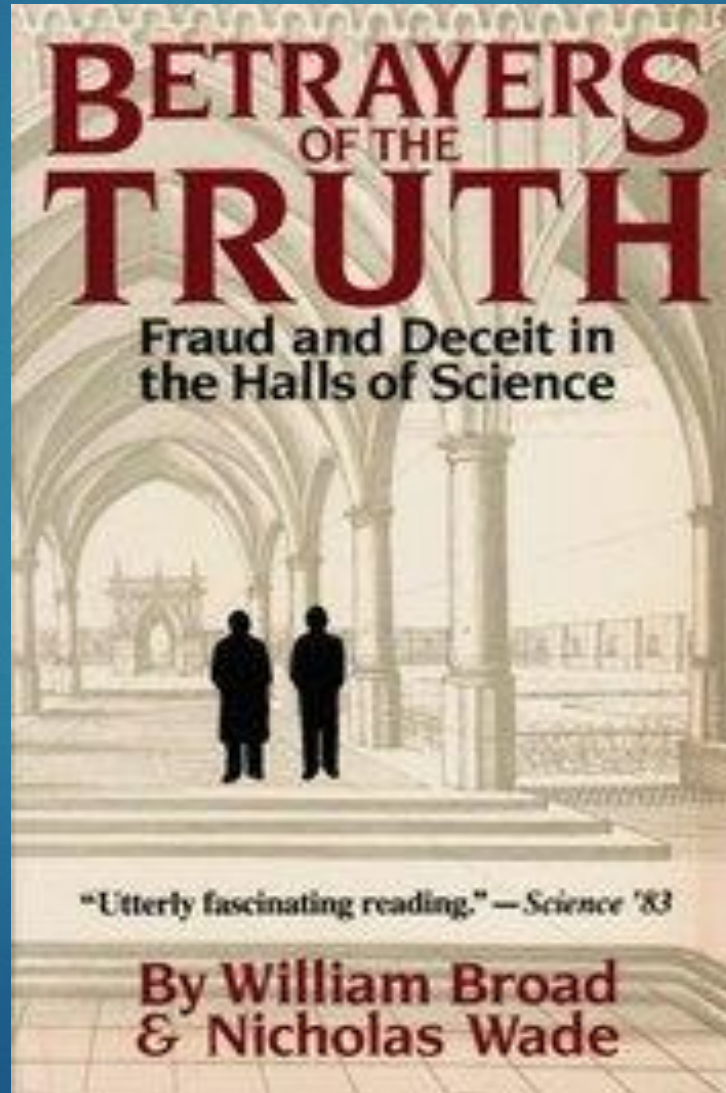
Prudence – Err on the side of caution/Demonstrate good judgment

EXAMPLES OF MISCONDUCT AND DISHONESTY FROM THE BASIC AND PHYSICAL SCIENCES

- ▶ Ptolemy who took the credit from another Greek astronomer, Hipparchus (second century B.C.E.)
- ▶ Galileo, father of empiricism, whose experiments defied replication in the early 1600's
- ▶ Newton who, from his lofty seat as president of the Royal Society, accused Leibniz of plagiarism while doctoring supporting measurements to make his own Principia more persuasive (late 1600's)

NOT JUST INDUSTRY IS INVOLVED: FROM GALILEO AND MANY MORE

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The book argues 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.

WHAT ARE WE UP AGAINST?

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- ▶ What creates/drives misconduct in science?
- ▶ What tempts scientists away from the pursuit of truth?
- ▶ How does misconduct derail scientific discourse?
- ▶ How does misconduct influence public policy and hence population and global environmental health?

Confrontation, and the challenge of speaking truth to power!

NATIONAL ACADEMY OF SCIENCES, WASH., DC (1992)

RESPONSIBLE SCIENCE: ENSURING THE INTEGRITY OF THE RESEARCH PROCESS

- PANEL ON SCIENTIFIC RESPONSIBILITY AND THE CONDUCT OF RESEARCH
- COMMITTEE ON SCIENCE, ENGINEERING, AND PUBLIC POLICY

“THE RIGHT TO SEARCH FOR TRUTH IMPLIES ALSO A DUTY; ONE MUST NOT CONCEAL ANY PART OF WHAT ONE HAS RECOGNIZED TO BE TRUE”

– ALBERT EINSTEIN

DANIELE FANELLI , 2009

How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data

This is the first meta-analysis of surveys asking scientists about their experiences of misconduct. It found that, on average, **about 2%** of scientists admitted to have fabricated, falsified or modified data or results at least once ...

and **up to one-third** admitted a variety of other questionable research practices including “dropping data points based on a gut feeling”, and “changing the design, methodology or results of a study in response to pressures from a funding source”

In surveys on the behaviour of colleagues, questionable practices were reported in **up to 72%**

RELENTLESS PRESSURE FROM VESTED INTERESTS

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Manoeuvre their way onto review panels, influence Boards of our professional associations, and infiltrate the literature with junk science.

Expert witness tensions arise between the plaintiff and defence sides of the argument in tort actions where the rubber hits the road concerning policy decisions.

David vs Goliath?

An initiative of INEP since 2014 is its Working Group on *Conflict-of-Interest and Disclosure*

COI CAN ARISE IN EVERY AVENUE OF OUR ENDEAVOUR

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- ▶ Serving as a peer reviewer
- ▶ Publishing
- ▶ Receiving financial support
- ▶ Election to office and having a vote
- ▶ Serving on boards and on review / editorial / advisory panels
- ▶ Interpreting the evidence before us
- ▶ Receiving donations (from vested interests?)
- ▶ And so on ...

MANUFACTURING DOUBT

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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

McCulloch & Tweedale.

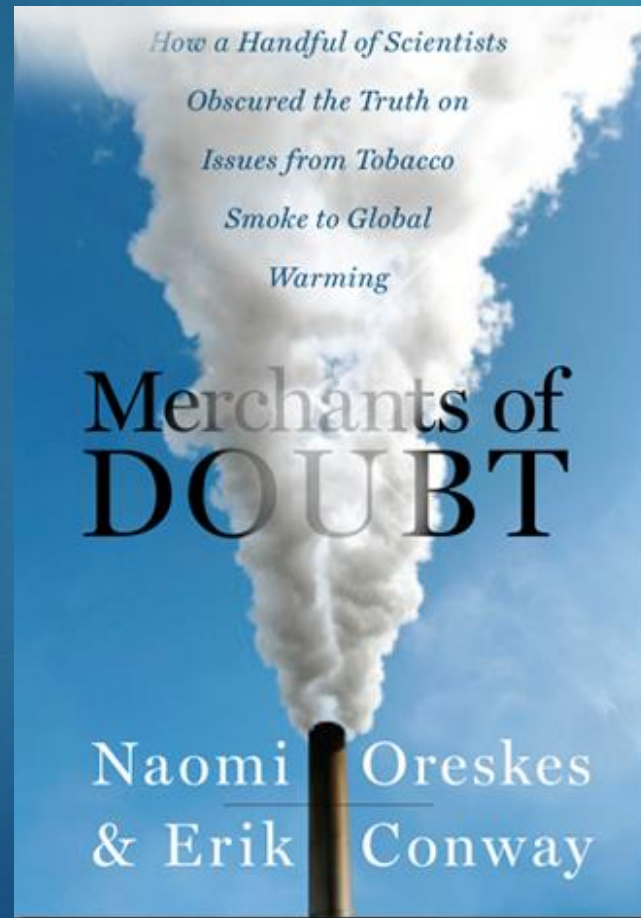
Defending the Indefensible: The Global Asbestos Industry ..., 2008

*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

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

ETHICS GUIDELINES

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The International Society for Environmental Epidemiology (ISEE) approved its new edition *Ethics Guidelines* on April 25, 2012

- ▶ [https://iseepi.org/Public/Public/About Us/ISEE Committees/Ethics and Philosophy.aspx](https://iseepi.org/Public/Public/About%20Us/ISEE%20Committees/Ethics%20and%20Philosophy.aspx)

THE FOUR D'S APPLIED TO SCIENTISTS STUDYING THAT WHICH DOES NOT SUPPORT THE *STATUS QUO*

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- ▶ Deny
- ▶ Delay
- ▶ Divide
- ▶ Discredit

Judge Miles W. Lord, 1982

On “*Corporate Ethics and Environmental Pollution*”:

“Corporations create 80% of our GNP. They, of all entities working, have the most potential for good or evil in our society.”

“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



MAGS
Edmonton
Journal

TWO RICHLY DESCRIBED EXAMPLES THAT DATE BACK SOME 50 YEARS AND REMAIN ONGOING

- ▶ In a 2017 lecture by Welch actor and community activist, **Michael Sheen**, around the 1:26:00 mark and for ~7.5 minutes at: <https://www.youtube.com/watch?v=bbVdA7zS8dE>, he speaks about high levels of morbidity and mortality among livestock around a disused quarry in relation to a consultant epidemiologist, **Sir Richard Doll**, being paid for his expert opinion about PCB-health effects dumped by **Monsanto**.
- ▶ See “**Profits before People**” on Teflon and related commercial products using PFAS (perfluoroalkylated substances) from Virginia, USA, to Veneto, Northern Italy, and the ongoing legal battles. **Marina Forti**, 26 January 2021. <https://newleftreview.org/sidecar/posts/profits-before-people?pc=1313>

THE INEP MISSION

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INTERNATIONAL NETWORK FOR EPIDEMIOLOGY IN POLICY

INTEGRITY, EQUITY, AND EVIDENCE IN POLICIES IMPACTING HEALTH

INEP works at the interface of research and policy, serves the public interest, and maintains and protects 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.

An initiative of INEP since 2014 is its Working Group on *Conflict-of-Interest and Disclosure*

ON THE SHOULDERS OF OTHERS

This INEP Position Statement:

- ▶ Was started in 2014 and brought to fruition by a number of authors, contributors, and reviewers.
- ▶ Was adapted from the work of several professional organizations.
- ▶ **Was unanimously approved** by the INEP Board on September 16, 2020.
- ▶ Exceeded its required member organization **endorsement threshold on December 24, 2020, and was released publicly** on January 5, 2021.

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INEP's Executive Committee and Board comprise over 60 members detailed at the link below:

- ▶ <https://epidemiologyinpolicy.org/members>

INEP MEMBERSHIP

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AAP SOEPHE	American Academy of Pediatrics Section on Epidemiology, Public Health and Evidence
AEA	Australasian Epidemiological Association
APHA (Epi)	American Public Health Association, Epidemiology Section
CaSE	Cameroon Society of Epidemiology
CR	Collegium Ramazzini
CSEB	Canadian Society for Epidemiology and Biostatistics
DGEpi	German Society for Epidemiology
EOM	European Society for Environmental and Occupational Medicine
ISCHE	International Society for Children's Health and the Environment
ISEE	International Society for Environmental Epidemiology
ISPE	International Society for Pharmacoepidemiology
NACCHO	National Association of County & City Health Officials
RSE	Romanian Society of Epidemiology
RSPH	Royal Society for Public Health
SAAPHI	Society for the Analysis of African American Public Health Issues
SEE	Spanish Society of Epidemiology
* ABRASCO	Brazilian Association of Public Health
* ACE	American College of Epidemiology
* ADELF	Association of French Language Epidemiologists
* AIE	Italian Association of Epidemiology
* CSTE	Council of State and Territorial Epidemiologists
* IEA	International Epidemiological Association
* JEA	Japan Epidemiological Association
* PHASA	Public Health Association of South Africa

* Eight of the 24 member organizations have yet to vote

INTRODUCTION

- ▶ 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 Conflict-of-Interest (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, through its Position Statement, proposes ways to better manage the problem in the public interest.

SCIENCE IS ABOUT TRUTH AND NOT SPIN

Opinion

Publisher: Linda Hughes
Editor in Chief: Murdoch Davis
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Associate Editor: Duart Farquharson



SAME PLANET, DIFFERENT WORLDS.

WHAT IS IN THE INEP POSITION STATEMENT on *Conflict-of-Interest and Disclosure in Epidemiology?*

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- ▶ **Recent high-profile cases exemplifying the misuse of epidemiological 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 that include guidance and strategies for COI management by **Identification, Avoidance, Disclosure, and Recusal.**
- ▶ **<https://epidemiologyinpolicy.org/coi-d-position-statement>**

TO FIX IT YOU HAVE TO RECOGNIZE IT!

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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” – “l”, n=12)

WHY SO MANY RECENT EXAMPLES?

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TO ILLUSTRATE THE BREADTH, SCOPE, AND GROWING SOPHISTICATION OF THE PROBLEM

- a) 2016 CPI 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

THE ISEE EXAMPLE (Example “k”): IF YOU SEE SOMETHING, DO SOMETHING!

k) COI and Improper Influence through Meeting/Conference Sponsorship by Vested Interests: ISEE Guidelines for Donor Support

- ▶ A problem of improper donor support was **identified**
- ▶ The problem was **disclosed** in meeting communications
- ▶ New guidance was given to **avoid** the problem in future

The ISEE example is helpful, showing us how to not cover things up, but rather confront them constructively.

A TOOLKIT OF EPIDEMIOLOGY DIRTY TRICKS – RECOGNIZE THE METHODS

The toolkit can be used:

- ▶ By peer reviewers as a checklist of what to look for.
- ▶ To train epidemiologists and others on how epidemiology can be distorted.
- ▶ To review the literature for junk science or uninformative studies (e.g., underpowered studies).
- ▶ Identify who is misusing epidemiology.

The COPE guidelines are not enough to stop manipulation of the literature. The actions of the epidemiology community can help change this as the problems are recognized.

EXAMPLES OF CLASSICAL TECHNIQUES THAT SKEW RESULTS: FROM BIASED METHODS TO JUNK SCIENCE

- ▶ Under-powered studies
- ▶ Inadequate follow-up methods
- ▶ Inadequate follow-up time
- ▶ Contaminated controls
- ▶ Unbalanced discussion
- ▶ Selective disclosure of competing interests

CLASSICAL TECHNIQUES THAT SKEW RESULTS:

- ▶ **Biased/selective interpretation**
- ▶ **Mechanistic information is ignored for inferring effects**
- ▶ **Exaggerated differences are made between human and toxicology studies, the insistence being on separating effects seen in animals from effects in humans**
- ▶ **The fact that molecular structures predict hazard potential is ignored**

TECHNIQUES THAT SKEW POLICY

- ▶ The insistence on first demonstrating effects in local populations of exposed people despite demonstrated effects in humans elsewhere
- ▶ The failure to make explicit the implicit value judgements that go into deciding appropriate standards of evidence for drawing policy-relevant conclusions (i.e., suppressing dominant interests and values)

GOING FORWARD: INEP-SPECIFIC RECOMMENDATIONS FOR COI

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

FUTURE USES OF THE INEP POSITION STATEMENT

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- ▶ The Scientific community can recognize and call out common practices used to distort and misapply epidemiological science.
- ▶ INEP member organizations can adopt, update, and monitor COI disclosure protocols and scientific practices for their members; train young scientists to recognize and avoid COI.
- ▶ INEP member organizations, academic institutions, and other public health professionals can adopt INEP recommendations and strategies for COI management that include **identification, avoidance, disclosure, and recusal**.
- ▶ Expand upon the INEP example, using it as a launching pad to write other documents (e.g., commentaries, letters, editorials, policy briefs, to extend the reach of INEP's Position Statement).
- ▶ Expose the public and policy-makers to the INEP Position Statement.

WE MUST NOT BE NAÏVE

Be aware of 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.

HUMAN AND SYSTEM FRAILTIES

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Junk science: Our professional obligation to be vigilant and especially careful in peer review

Need for oversight (as in Human Research Ethics Boards/IRBs)

The need to keep ourselves on track with ETHICS GUIDELINES and related professional activities

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

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Address any questions via e-mail to:
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This PPT presentation will be accessible on Colin Soskolne's website under **ARCHIVE & LINKS** at www.colinsoskolne.com