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

INEP Position Statement Series
Conflict-of-Interest and Disclosure in Epidemiology

DATED 24 December, 2020

EXECUTIVE SUMMARY

Science can be misused either intentionally, through error, or from bias. For instance, distortion and disinformation practices regarding scientific methods and evidence were intentionally employed by the lead industry in the early 1900s, and since the 1950s, by the tobacco industry. The *International Network for Epidemiology in Policy* (INEP) focus in this Position Statement is on Conflict-of-Interest (COI) because it has been associated with the misuse of epidemiological science. Practices associated with COI have been adopted by a range of entities including businesses, agencies, academic institutions, and non-profits. In particular, COI is observed across a range of industries where self-interest includes financial stakes, liability protection, political interests, and other motivations.

COI is typically created in the scientific community by confidential financial incentives, the award of scientific grants and contracts, or by promises of job security. Rather than conducting impartial analysis, scientists in a COI situation may produce and disseminate misinformation and suppress data so that the association of cause-and-effect is obscured and denied. In addition to individual researchers, COI can similarly affect scientific journal authors, reviewers, editors, and involve corporate sponsors of journals. The effects of COI can include the undermining of scientific integrity, the erosion of public trust in the science of epidemiology, and harm to workers, the public, and the environment.

INEP is well-positioned internationally to develop strategies to combat the misuse of epidemiological science. INEP is the only global network of epidemiologists with a focus on providing a bridge between epidemiological research and evidence-based, rational, and government-formulated health policy that serves the public interest. It provides a unique global forum to protect and promote public health and works to ensure scientific integrity, promote ethical conduct in research, and support evidence-based research findings that are both independent and transparent.

The misuse of epidemiological science that is associated with COI has been successful and thus continues to grow to the detriment of public health. This Position Statement provides high profile examples on the misuse of epidemiological research and the failure to disclose COIs that have been reported in the media and scientific literature; also included are recent examples developed by INEP co-authors and contributors. Identification and disclosure of misuse are fundamental to the protection of both scientific integrity and the public's health. Accordingly, there is an expanded need for professional organizations to adopt, update, and monitor COI disclosure protocols and scientific practices for their members, and to lead in providing training to young scientists so that

they can recognize and avoid COI. In addition, the common practices to distort and misapply epidemiological science should be recognized and called out when they occur.

Information published between 2004 and 2020 has been collected, analyzed and presented in this INEP Position Statement and in its attached appendices.[1] Along with a background section on COI, the Position Statement includes examples of COI identification/disclosure failure, specific tactics used to distort epidemiological science, and INEP recommendations. These recommendations include guidance and strategies for COI management by **identification**, **avoidance**, **disclosure**, and **recusal**. INEP's goal is to have this Position Statement adopted and its recommendations applied by its member organizations, academic institutions, and other public health professionals, as well as epidemiologists, so that scientists can better ensure that they fulfil their roles both in informing and protecting the public's health.

[1] Appendices include a compendium of disclosure tools for all major steps in the research process: (a) formulation of the research question, (b) research proposal development, (c) data collection, measurement, analyses, and interpretation, (d) peer-review, and (e) dissemination/publication and communication. Appendices also include examples of COI issues associated with service on boards and advisory committees that direct research and its application in protecting the public's health.

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Disclosure

All of the authors of this Position Statement declare no conflict-of-interest per INEP's standard Disclosure Form introduced in 2015.

Citation

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BACKGROUND

INEP AND ITS GOALS

The *International Network for Epidemiology in Policy* (INEP), prior to 2019 known as the *International Joint Policy Committee of the Societies of Epidemiology* (IJPC-SE), is a global network of epidemiological organizations. These organizations are national and international in scope, span five continents, and include voluntary societies and associations comprised of professional epidemiologists.

INEP was founded in 2006 at the 2nd five-year North American Congress of Epidemiology in Seattle, Washington, USA. INEP currently includes twenty-four member organizations across five continents (see https://www.epidemiologyinpolicy.org/members) as follows:

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

INEP is the only international voice whose goal is to coordinate and unify joint policy actions globally among its member organizations. INEP supports the proper use of epidemiology to better ensure health-for-all through ethical, independent and transparent science. The *American College*

of Epidemiology has provided substantial administrative and logistical support to INEP since its inception.

PROCESS FOR POSITION STATEMENT DEVELOPMENT

INEP's Executive Committee (EC) considers developing position statements on topics in relation to its approved Strategic Plan and before bringing the matter to the attention of the Board. INEP's Board then decides whether to embark on the process of developing a proposed statement. Once INEP decides to develop a position statement on a specified topic, a Working Group is formed to oversee the development of the statement. The names of all members of the Working Group are listed on the INEP website, together with a link to each member's Conflict-of-Interest Disclosure Statement.

INEP develops position statements through a participatory, transparent process under the guidance of a Working Group comprising of Board members and approved volunteers serving as interested parties and/or consultants/expert advisors. The Working Group generally makes explicit its *modus operandi* in a Terms of Reference (TOR) document. The TOR document is considered by the EC and, once approved, it is submitted for Board consideration and approval. The Working Group then operates in accordance with its approved Terms of Reference.

The Working Group assembles an External Advisory Panel (the Panel). Those nominated for the Panel submit their Conflict-of-Interest Disclosure Statements for review by the Working Group. After review, the nominees are submitted for review and approval by the INEP EC and ratified by the Board prior to assuming their voluntary roles as Panel members. The names of the External Advisory Panel members and their Conflict-of-Interest Disclosure Statements are posted on the INEP website.

Panel members review initial drafts of the position statement as written by the Working Group. The Working Group revises the draft position statement in response to Panel member feedback and then submits it to the EC for review and further critique. The Working Group considers the EC's feedback and produces a new draft for review and critique by the INEP Board and its Interested Parties/Invited Guests/Expert Advisers. The version arising from this latest round of reviews is returned to the Board for a vote of approval. Once approved by a majority of the Board, it is submitted to each member organization's Board/Council for endorsement; they may vote either to endorse or to abstain.

The names of the members of the EC, the Board and Interested Parties/Invited Guests/Expert Advisers of INEP are listed, together with each person's Conflict-of-Interest Disclosure Statement, on the INEP website.

To finalize any position statement, an invitation is sent by the INEP Secretary to each of the member organizations for its endorsement of the Board-approved statement. Any substantive feedback will be considered a friendly amendment; the document, already approved, will be revised by the Working Group, which will respond to the member organization explaining how the feedback has been addressed, or not; approval will be sought for any revisions made in a timely manner. Only if proposed changes by any member organization would require a significant change

in the substance of anything conveyed in the previously approved document, will the revised position statement be resubmitted for EC and Board re-approval. A further iteration of seeking full member organization endorsement will then be undertaken, pointing to where changes have been made. This process is deemed necessary to ensure maximal buy-in by INEP's member organizations.

Once endorsed, a position statement becomes an official statement of INEP. The names of all of the member organizations of INEP that have endorsed the position statement are listed in Appendix I. Any member organization may elect to abstain for any specified reason and this abstention is noted (see Appendix I).

If the above process should fail after a few iterations that take no more than a few months, and if the Board cannot agree on the position statement, or if too few member organizations are willing to endorse it (i.e., fewer than 50% of the Active/Regular member organizations actually voting), INEP will release the document to the Working Group which, at its own discretion, will decide on whether or not it would wish to advance the position statement by a mechanism independent of INEP. It could transpire that the work is published independently of INEP, or it could be shelved indefinitely.

Once approved with an adequate number of endorsements secured, the position statement is posted on the INEP Website. Member organizations are encouraged to disseminate the document among its membership. The Working Group then proceeds, under its lead author on behalf of INEP, to seek a peer-reviewed home for the publication of the position statement. Publication will be at the discretion of the Working Group in a format that fits with the Working Group's sense of how the message might optimally be packaged and disseminated.

INEP CONFLICT-OF-INTEREST AND DISCLOSURE IN EPIDEMIOLOGY STATEMENT DEVELOPMENT

Since the 1980s, when the activities of vested industrial interests to influence regulation and safety hazards were noted, ethics guidelines/codes of ethics have evolved for epidemiologists. Epidemiologists are expected to adhere to their professional codes of ethics, also known as ethics guidelines, in their work.

To address persistent problems in public health that arise from Conflict-of-Interest (COI) and particularly the failure to disclose such conflicts (COI&D) among epidemiologists, the need for a position on this topic was recognized by INEP in 2014. At that time, Terms of Reference were developed and approved in 2015. In 2016, Working Group outlined the steps to be utilized in development of this INEP Statement in a symposium on the topic (4th North American Congress of Epidemiology held in Miami, Florida). INEP tasked an internal working group to develop a position statement that is consistent with INEP's goals and to provide guidance to its member organizations to address the problem. The internal group included representatives of INEP's member organizations as well as with other experts on the topic.

Although the terms "conflict of interest", "conflicts of interest" and "conflict of interests" are used interchangeably in the literature, "conflict-of-interest" is uniformly used throughout this document

unless referring to it as used in a cited publication. The published works cited in this Position Statement appear as footnotes and in other relevant information included as Appendices.

The procedure for approving and endorsing this INEP Position Statement included first a vote for approval by the INEP Board, and then a vote for approval or abstention by its voting member organizations. Some member organizations recuse or abstain when appropriate or necessary (e.g., for some government employees or those that hold the position that epidemiologists should not play any role in advocacy). Per their own internal policies, some of INEP's member organizations do not issue or publicly endorse specific statements.

The INEP Board unanimously approved this Position Statement during its monthly meeting on 16 September, 2020. Of the current 18 voting member organizations, a total of 10 had, by 24 December, 2020, endorsed it, permitting its release (see Appendix I).

DISCLAIMER

Each of the Appendices included in this Position Statement is provided for illustrative purposes only. They were identified through the literature search as well as by the authors and contributors to the Position Statement. Their inclusion as Appendices does not mean that either INEP or the authors of this Position Statement endorse their contents, nor comment on/judge the ability of the source of each Appendix, where applicable, to adhere to its own guidelines.

This work is not intended to cast all industry, whether corporate publicly- or privately-owned business, in a negative light or as irrevocably unethical. It is intended to make clear that the mission of industry is often different from the mission of science. Businesses of all types often have profit maximization and shareholder return protection in their articles of incorporation.

COI is not only a problem in industry. It is also a concern among academic institutions and academic scientists who are motivated by financial and/or career goals. Public agencies, educational institutions, and non-governmental organizations (NGOs) are often required to state lofty, altruistic missions, even the industry-serving ones. It thus behooves those concerned about the impartiality of science to scrutinize any underlying motives that could influence science, derailing it from its mission to advance knowledge in the public interest. Different missions and motivations can result in, at best, tensions and, at worst, polarization resulting in inaccurate or distorted science.

INEP recognizes that important contributions to public health science have emerged thanks to industry support and engagement. However, there have also been biased industry players that analysis has shown cast doubt and foment uncertainty to deliberately delay policy designed to protect public health, or to otherwise protect their financial and reputational interests. Generally, sectors from among academia, industry (including both public and private business enterprises), government, and NGOs found to have minimal motivation for bias are those that, directly or indirectly, do not accept corporate publicly- or privately-owned business-sponsored research funding or respond to politically or financially imposed pressures. While it is true that anyone from any sector with a vested interest, regardless of the funding source, could be biased, evidence shows that business sector-sponsored research more commonly generates biased science.

The goals and potentially positive outcomes of this Position Statement include not only the societal benefits of scientific integrity with respect to advancing knowledge, but also the benefits, both direct and indirect, that protect public health in terms of preventable morbidity and premature mortality. Our purpose in this Statement is thus to shine a light on mechanisms of demonstrated influence and their harmful impact on, respectively, the advancement of science and the protection of the public's health.

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ABBREVIATIONS/ACRONYMS USED IN THIS DOCUMENT

AAP SOEPHE	American Academy of Pediatrics Section on Epidemiology, Public Health and Evidence
ABRASCO	Brazilian Association of Public Health
ACE	American College of Epidemiology
ADELF	Association of French Language Epidemiologists
AEA	Australasian Epidemiological Association
AIE	Italian Association of Epidemiology
APHA (Epi)	American Public Health Association, Epidemiology Section
ASHA	American Speech-Language-Hearing Association
CaSE	Cameroon Society of Epidemiology
CR	Collegium Ramazzini
COI	Conflict-of-Interest, conflicts of interest, conflict of interests, conflicting interests
COI&D	Conflict-of-Interest and Disclosure
COPE	Committee on Publication Ethics
COVID-19	Severe Acute Respiratory Syndrome Coronavirus (SARS CoV 2) causing the Coronavirus Disease (COVID-19)
CSEB	Canadian Society for Epidemiology and Biostatistics
CSTE	Council of State and Territorial Epidemiologists
DBPs	Disinfection By-Products
DGEpi	German Society for Epidemiology
EC	Executive Committee
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
EDCs	Endocrine Disrupting Chemicals
EFSA	European Food and Safety Authority
ENDS	Electronic Nicotine Delivery Systems
EOM	European Society for Environmental and Occupational Medicine
EPA	U.S. Environmental Protection Agency
ENGOs	Environmental Non-Government Organizations
FCOI	Financial Conflict-of-Interest
FDA	U.S. Food and Drug Administration
GNP	Gross National Product
IARC	International Agency for Research on Cancer
ICNIRP	International Commission on Non-Ionizing Radiation Protection
ICMJE	International Committee of Medical Journal Editors
IEA	International Epidemiological Association
IJPC-SE	International Joint Policy Committee of the Societies of Epidemiology

ABBREVIATIONS/ACRONYMS USED IN THIS DOCUMENT (cont.)	
INEP	International Network for Epidemiology in Policy
ISCHE	International Society for Children's Health and the Environment
ISEE	International Society for Environmental Epidemiology
ISPE	International Society for Pharmacoepidemiology
JEA	Japan Epidemiological Association
JPC-SE	Joint Policy Committee of the Societies of Epidemiology
NACCHO	National Association of County & City Health Officials
PHASA	Public Health Association of South Africa
RF-EMF	Radiofrequency Electromagnetic Fields
RSE	Romanian Society of Epidemiology
RSPH	Royal Society for Public Health
SAAPHI	Society for the Analysis of African American Public Health Issues
S-EDCs	Synthetic Endocrine Disrupting Chemicals
SEE	Spanish Society of Epidemiology
SIS	Special Interest Science
TOR	Terms of Reference
WAME	World Association of Medical Editors
WHO	World Health Organization

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

INEP Position Statement Series
Conflict-of-Interest and Disclosure in Epidemiology

INTRODUCTION

Epidemiology is an applied science with policy implications; it is the study of the distribution and determinants of health and disease in populations. While most practitioners of epidemiology have every intention of pursuing truth, scientists, as people, are capable of conscious or unconscious bias.

Given that the goals of verifiable science are to rationally and accurately document, explain, and predict patterns in nature, scientists are expected to logically and objectively adhere to the scientific method. The latter advances through experimentation which tests hypotheses and explores observations. However, scientists are not guided by logic and objectivity alone. As stated by Broad and Wade (1982) "… In the acquisition of knowledge, scientists are not guided by logic and objectivity alone, but also by such nonrational factors as rhetoric, propaganda, and personal prejudice."[2] INEP adds self-interest to this list.

Truth matters, as amply illustrated by the recent example of inaccurate, ill-informed, and inconsistent COVID-19 communications (e.g., in the U.S. and elsewhere). Faulty scientific analyses and misuse of diagnostic tools caused the diversion of COVID-19 resources toward ineffective treatments (e.g., hydroxychloroquine), resulted in failure to identify susceptible subpopulations, and underestimated the spread of contagion. Most recently, the distortion of COVID-19 science and risk-reduction strategies to protect the public have been the subject of still-evolving political manipulation and distortion, placing public health in jeopardy.

The case of Wakefield's false claims regarding vaccine safety is a well-known example of the effects of epidemiological science and disclosure failures. Vaccine development is a cornerstone of the current strategy to quell the COVID-19 pandemic. Vaccines are one of the most important measures of preventive medicine to protect human health and well-being. As noted by Hussain et al. (2018),[3] opposition to vaccines has a history based on theology, skepticism, and legal obstacles; opposition was rejuvenated by Wakefield's claim that MMR vaccination was associated with the development of autism in young children. Wakefield's research was criticized not only for flawed science, but a journalistic investigation revealed that he had undisclosed conflict-of-interest (COI). Despite *The Lancet* retracting the study and declaring it "utterly false" and Wakefield being barred to practice medicine by the UK Medical Registry due to abuse of his position of trust and the

[2] Broad W.J. and Wade N. (1982) Betrayers of the Truth: Fraud and Deceit in the Halls of Science. Simon & Schuster, New York, USA. 256 pages. ISBN 0-671-44769-6.
[3] Hussain A, Ali S, Ahmed M, et al. (July 03, 2018) The Anti-vaccination Movement: A Regression in Modern Medicine. Cureus 10(7): e2919.

disrepute that he brought to the medical profession,[2] the damage was done. Thus, a failure of scientific practice, peer review, and disclosure of COI has resulted in declining vaccination rates, increased disease outbreaks, and diminished public trust in vaccine safety.

An increasing awareness of the negative impacts of COI on public health is illustrated by the call by Kassotis et al. (2020)[4] to establish an agency within the World Health Organization (WHO) to "protect against undue influence from industry" in the field of endocrine disrupting chemicals (EDCs) research. They note that regulatory efforts in past decades have not minimised exposure to the vast majority of EDCs and suggest a shift to an "evidence of hazard" approach that considers the body of evidence from mechanistic, animal, and epidemiological studies.

For some time, there has been a perception that the corporate drive to increase profits frequently does not coincide with public health protection. To counter this perception, scientists have been coopted to further those interests. The producers of tetraethyl lead (TEL, a highly toxic gasoline additive introduced post-World War I) hired an occupational physician (Kehoe) to defend their interests and who, in the process, introduced strategies later adopted by the tobacco industry and, more recently, by the fossil fuel industry for denying the climate crisis. Kehoe not only developed tactics that included distraction, fomenting doubt, calling for more study, and highlighting known benefits versus "unknown" for health impacts that he disputed, he also introduced the concept that a safe, or even natural, threshold existed below which those effects occurred. The Kehoe position was later taken up by Calabrese. In the early 1990s, scientists who questioned the safety of lead (e.g., Needleman) were accused of misconduct. Although lead had been known to be toxic for centuries, phasing it out of gasoline in the U.S. began only in 1970 when the U.S. Congress passed the Clean Air Act. In 1978, lead paint was restricted from use in homes in the U.S. Planet-wide lead contamination and its effects on child IQ have been demonstrated at all lead detection levels. Delays in controlling this exposure has led to persistent lead contamination and its health effects remain a problem.[5,6,7]

The examples above show the development and success of strategies involved in the misuse of epidemiological science and in the production of partial communication about, or reporting of science. The COI that is manifested in these practices should be disclosed so that such misuse of science can better be identified, assessed and judged. In particular, epidemiologists may be in a COI situation (actual or perceived) that affects their rigor in the application of the scientific method, how they interpret and disseminate their research findings, or how they use data to demonstrate outcomes across their respective fields of application. In its basic form, COI is a situation in which a person or organization is involved in multiple interests and serving one interest could involve working against another. Usually, epidemiological research findings have health

[4] Kassotis C.D., Vandenberg L.N., Demeneix B.S., Porta M., Slama R, Trasande L. (2020) Endocrine-disrupting chemicals: economic, regulatory, and policy implications. The Lancet: Diabetes & Endocrinology, Series Endocrine-Disrupting Chemicals; 8(8):719–730.

[5] Nriagu, Jerome O. (1998) "Clair Patterson and Robert Kehoe's Paradigm of 'Show Me the Data' on Environmental Lead Poisoning." Environmental Research 78 (2): 71–78.

[6] Bellinger, David C., and Andrew M. Bellinger. (2006) "Childhood Lead Poisoning: The Torturous Path from Science to Policy." The Journal of Clinical Investigation 116 (4): 853–57.

[7] Lanphear, Bruce. (2017) "Still Treating Lead Poisoning After All These Years." Pediatrics 140 (2).

policy implications because of the role of epidemiology in advancing public health and medicine. As health scientists, epidemiologists can find themselves embroiled in controversy so that they should be aware of COI as a pitfall in their work, especially as they launch their careers in academia, industry, or with key stakeholders across society. Some U.S. government agencies have standing committees, disclosure requirements, and training regarding COI.

In the practice of epidemiology, as well as other sciences, COI can result from divided loyalty between another person(s) or organization(s) and impartial scientific investigation. Actual or perceived COI needs to be recognized and avoided in the pursuit of scientific objectivity. The reasons for COI can be associated with multiple factors, including, but not limited to financial gain and career security or advancement (see Appendices II, III and IV). Although epidemiologists have engaged in this topic later than some professions, recognition of the complexity of the issue has been noted in the context of epidemiological studies (Vineis and Saracci,[8] 2015).

INEP's focus in this Statement is not on inadvertent error that is correctable through peer-review. Nor is this Statement intended to determine the extent to which COI contributes to the failure to practice good epidemiological science. A professional organization may not be homogeneous in regard to the rigor by which its members practice science or of their potential COI. As a whole, industry has incentives to produce safe, reliable, and effective products and may employ scientists as part of those efforts. However, inherent safety cannot always be achieved and entities have and continue to adopt the techniques and strategies honed by the tobacco industry (see case example below). INEP has developed this Statement to help counter this activity.

The field of epidemiology can benefit from the experience and progress of other relevant scientific disciplines in its own ability to address COI. For example, in 2018 the *American Speech-Language-Hearing Association* (ASHA) revised its *Conflicts of Professional Interest* (originally published in 2004; revised in 2011).[9] The ASHA had become increasingly aware of external factors that influence interpretation and undermine objectivity. These concerns are equally pertinent to Epidemiology.

So pervasive is the problem of influence in research and practice, that most professions' codes of ethics (also known as ethics guidelines) specifically prohibit COI although they do not always clearly identify its scope. Like the ASHA, the *International Society for Environmental Epidemiology* (ISEE)[10] advises individuals to avoid engaging in COI whereby personal, financial, or other considerations have the potential to influence or compromise professional judgement and objectivity. In addition, COI can affect the official or professional responsibilities of a person in a position of trust, power, and/or authority and thereby influence or compromise professional judgement in clinical service, research, consultation, instruction, administration, or any other professional activity (ASHA).

[8] Vineis P and Saracci R. (2015) Conflicts of interest matter and awareness is needed. J Epidemiol Community Health ; 0: 1–3.
[9] See https://www.asha.org/Practice/ethics/Conflicts-of-Professional-Interest/.
[10] https://www.dropbox.com/s/7arpzfyuge3r83x/ISEE%20ethics_guidelines_adopted_april_25_2012.pdf?dl=0

The ASHA Position Statement on COI was developed to heighten sensitivity, increase awareness, and enhance judgements in those circumstances when a COI influences or appears to influence professional conduct. INEP takes a similar approach for development of its own Position Statement to meet its goal of serving the public health interest. However, just as with ASHA, INEP recognizes that no principle or rule of its *Code of Ethics* Statement can address all forms that COI can take. Guidance and specific relevant examples can help to identify and then address COI. Both ASHA and INEP recommend that COI issues be addressed by four key strategies: (1) identification, (2) avoidance, (3) disclosure, and (4) recusal. In addition to these recommendations, this INEP Position Statement provides specific examples to help identify COI, as well as a summary of techniques used to manipulate epidemiological findings. Thus, this Statement can also be used as a teaching tool.

CASE EXAMPLES: COI IDENTIFICATION, DISCLOSURE

INEP began developing its Position Statement by proposing and approving Terms of Reference. Between 2004 and 2016, the literature was searched for examples of COI and disclosure to inform the development of illustrative examples and an understanding of the nature and extent of the problem. In addition, relevant information on COI identification and recommendations to address it were collected from related professions specifically to focus on epidemiology-related analyses and examples (see Appendix V).

Three databases were searched [i.e., Pubmed (MEDLINE), EMBASE (Ovid), and PsycInfo]. A full list of terms and keywords used to identify articles is included in Appendix VI. A Table in Appendix VII shows items retrieved from the database searches as well as additional materials developed by members of the initial writing group and that were adapted and included by INEP. During the process of information gathering, INEP asked members for input and considered it all.

Given that COI issues can arise at all levels of scientific advancement, a series of Appendices is included that contain illustrative examples of: sponsorship (see Appendix VIII); hypothesis formulation, literature gathering, study design, recruitment, measurement, data access, presentation (see Appendices IX, X and XI); and peer-review, dissemination and archival activities (see also Appendices II, III and IV). INEP has included a Dropbox that contains meeting minutes, Terms of Reference, related administrative matters, and Disclosure Statement examples so that they can be used for future COI&D research, adopted, or adapted for use in epidemiology.

The following are selected case examples that illustrate COI identification/disclosure failure (detailed more fully in the Appendices). The more recent examples were identified and developed by the authors of this Statement (see '5' below). In addition, tactics used to distort epidemiological science (see page 34) as well as INEP recommendations/findings for COI management (see pages 37–43) are provided that can aid in both training about and recognition, monitoring, evaluation, and tracking of COI.

1. *Medical Research, Education, and Practice*

Although the 2009 book[11] "Conflict of Interest in Medical Research, Education, and Practice" by the *Institute of Medicine* focuses on medicine rather than public health, it is included in the INEP Dropbox as many of the principles are applicable to both disciplines and are reflective of other information gathered by INEP. As noted, physician/research collaborations with industry can provide valuable benefits to society especially through the translation of basic scientific discoveries to therapeutics and products. However, the book documents disturbing COI examples that risk the integrity of medical research, the objectivity of professional education, the quality of patient care, the soundness of clinical practice guidelines, and the public's trust in medicine.

The book's authors provide principles to aid in policy formulation so that COI may be identified, limited, and managed without damaging constructive collaboration with industry. Both short-term actions and long-term commitments are called for by institutions and individuals, leaders of academic medical centers, professional societies, patient advocacy groups, government agencies, as well as drug, device, and pharmaceutical companies. Without convincing action by the medical community, the book warns that additional legislative or regulatory measures may have to be taken to protect the public.

2. *Tobacco Industry*

Science advances not only by proving theorems, but by removing doubt. In 2009, the World Health Organization (WHO) published "Tobacco Industry Interference with Tobacco Control", a 46-page publication[12] that illustrated how the industry historically employed a multitude of tactics to shape and influence tobacco control policy globally. INEP features it as one of the most relevant examples of COI because the tobacco industry's tactics have been adopted by lawyers and consulting firms employed by other industries (e.g., the asbestos industry). Their goal has been to enable continued global trade in hazardous products that are not only environmental toxicants, but also workplace hazards in both their manufacture and use.

The use of these tactics was recognized in the early 1980s in two articles from which INEP has extracted the following quotes: "Corporations create 80% of our GNP.[13] They, of all entities working, have the most potential for good or evil in our society."[14] and "Industry's offensive against the regulation of health and safety hazards uses academics to downplay or deny the seriousness of the hazards..."[15]

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[11] Lo B and Field MJ, Editors. (2009) Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: The National Academies Press. 436 pages.

[12] World Health Organization. (2009) Tobacco Industry Interference with Tobacco Control. Geneva (Switzerland): World Health Organization; http://www.who.int/tobacco/publications/industry/interference/en/.

[13] GNP = Gross National Product.

[14] Lord M, Editor. (1982) Lord MW. Keynote Address: Corporate ethics and environmental pollution. In: Legal and Ethical Dilemmas in Occupational Health; Ann Arbor Science.

[15] Clayson ZE, Halpern JL. (1983) Changes in the workplace: Implications for occupational safety and health. Journal of Public Health Policy;4(3):279–97.

The WHO document shows how the tobacco industry has used its economic power, lobbying, marketing, and manipulation of the media to discredit scientific research, manufacture doubt, and influence governments so that their products could be sold and distributed. Industry-funded scientists testified in many venues to the effect that "there is no proof that smoking causes cancer," despite numerous studies showing "there is no doubt." These activities were accompanied by large philanthropic contributions into social programs worldwide to create a positive public image under the guise of corporate social responsibility. The WHO document exposes these practices and provides to WHO Member States the background and context so that WHO's Framework Convention for Tobacco Control (FCTC) Article 5.3 guidelines can be implemented without tobacco industry interference in efforts to support tobacco control.

Some of the most valuable information from the WHO document is the identification of how the tobacco industry has been creative and cunning in influencing (i.e., biasing) research by creating COI situations through its sponsorship of programs and projects, manipulation of boards, decision-making committees and advisory boards, and its research project collaboration. The International Agency for Research on Cancer (IARC, a WHO organization) and epidemiology organizations have set policies that exclude donations or participation from them and thus avoid COI (see Appendix VIII). The issue of disclosure is reflected below by Principle 2 in which researchers are required to specifically disclose being paid by an entity whose tactics included spreading disinformation, doubt, confusion and the appearance of controversy in science.

The four WHO guiding principles to protect public health from tobacco industry influence, and that can also be evaluated for application to similar industries, are:

- *Principle 1:* There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests.
- *Principle 2:* Parties, when dealing with the tobacco industry or those working to further its interests, should be accountable and transparent.
- *Principle 3:* Parties should require the tobacco industry and those working to further its interests to operate and act in a manner that is accountable and transparent.
- *Principle 4:* Because their products are lethal, the tobacco industry should not be granted incentives to establish or run their businesses.

3. Food Safety Panels

The U.S. Food and Drug Administration and the European Food Safety Authority evaluate safety and risks of food consumption, both pre- and post-marketing. This includes the effect of artificial

sweeteners on weight to establish an Acceptable Daily Intake (ADI).[16,17,18] For over a decade, the safety of artificial sweeteners has been the subject of safety concerns. Both U.S. FDA and EFSA have both been criticized for their disclosure of interest policy and for the number of panelists with financial interests that raise concerns about the integrity and transparency of their evaluation processes.[19,20,21]

In a systematic review of artificial sweetener review articles, Mandrioli et al. (2016)[22] demonstrated that financial COIs introduced a bias at all levels of the research and publication process, including author financial ties, review sponsorship, and journal funding. This bias was not prevented by the peer-review process. Notably, authors of 42% of reviews had COIs that were not disclosed in the article and most of these were in reviews that also had no disclosed funding sources. Therefore, biased panels and biased input can result in a distortion of risk posed by artificial sweetener consumption.

4. 2015 INEP Policy to Avoid COI Through Donations

Financial contributions, contracts, and grants may come from a variety of sources, some with COI concerns and some without. As a public charity, INEP adopted policies in 2015 on how money will and will not be sought/accepted as well as its disclosure. The INEP policy drew heavily from its equivalent developed by the American Public Health Association (APHA).

Prior to accepting any financial contribution, contract or grant, the INEP Executive Committee reviews each entity for actual or perceived COI. Five types of "interests" that may constitute a COI are defined and described in Appendix II of the INEP policy (see Appendix XIII). They include financial, business, professional, personal, and/or political interests. COI disclosure is always required. This guidance provides an informative description of the nature of COI and those entities that generally do and do not have COI concerns.

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[16] EFSA. (2011) Scientific Opinion on the substantiation of health claims related to intense sweeteners and contribution to the maintenance or achievement of a normal body weight (ID 1136, 1444, 4299), reduction of post-prandial glycaemic responses (ID 4298), maintenance of normal blood glucose concentrations (ID 1221, 4298), and maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 1134, 1167, 1283) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal;9(6):2229.

[17] EFSA. (2010) Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal; 8(3):146.

[18] FDA. (2015) Additional Information about High-Intensity Sweeteners Permitted for use in Food in the United States.

[19] Robinson C, Holland N, Leloup D, Muilerman H. (2013) Conflicts of interest at the European Food Safety Authority erode public confidence. Journal of Epidemiology and Community Health.

[20] Horel S. (2013) Corporate Europe Observatory. Unhappy meal: The European food safety authority's independence problem.

[21] Neltner TG, Alger HM, O'Reilly JT, Krimsky S, Bero LA, Maffini MV. (2013) Conflicts of interest in approvals of additives to food determined to be generally recognized as safe: out of balance. JAMA internal medicine; 173(22):2032–6. Epub 2013/08/09. pmid:23925593.

[22] Mandrioli D, Kearns C.E. and Bero LA. (2016) 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; 11(9):e0162198.

Usually, entities without direct or indirect commercial interests are non-for-profit and government entities, but this may not always be true. Companies/foundations that negatively impact public health are easier to identify and include tobacco companies and those producing polluting chemicals as well as chemicals harmful to the environment (e.g., insecticides, herbicides, etc). INEP does not take donations from entities that demonstrate a lack of ethical standards and promptly responds to concerns brought to the attention of the Executive Committee. Principles for accepting financial contributions from commercial or other entities marketing or promoting products or services appears in Appendix III of the INEP policy included in Appendix XIII.

5. Recent Epidemiology-specific Examples of COI and Disclosure Issues

There are several initiatives that are more specific to epidemiology, published since 2016, and used by INEP to support its Position Statement. They include analyses developed by two organizations [i.e., The Center for Public Integrity (CPI, Washington, DC, USA), The Collegium Ramazzini (CR, an international public health organization based in Carpi, Italy)], one epidemiologist as a commentary [John Acquavella (former industry employee)], and responses to that commentary by several INEP Position Statement authors. In addition, more recent examples of COI issues in public health protection are included.

a) 2016 CPI COI Exposé: "Science for Sale" on Scientific Boards, Councils, and Review Panels

After several years of investigation by David Heath, the CPI published an exposé in 2016 about COI and disclosure in a series of articles entitled "Science for Sale" (i.e., "Meet the 'rented white coats' who defend toxic chemicals." accessible here). The exposé included a video link to Dr. Julie Goodman giving expert testimony that cited junk science. As a member of the American College of Epidemiology (ACE) Board, she attempted to obstruct the ACE endorsement of the 2012 IJPC-SE Position Statement on Asbestos. CPI exposed Dr. Goodman's COI as financially benefiting from vested interests; her employer (Gradient) had been associated with a number of scientists employed to manufacture doubt and foment uncertainty about scientific evidence. Other authors have provided informative articles and books on this topic [e.g., Michaels[23,24] ("Doubt is their product" specifically addresses the role of industry-paid science voices), Oreskes and Conway,[25] Walker[26]] and a docudrama (Merchants of Doubt, released in 2015).

Having a range of scientific viewpoints considered is important for discerning the state of the science of a particular issue. However, INEP considers the CPI example as highlighting the need to protect professional Boards, Councils, and Review Panels from infiltration by people

[23] Michaels D. (2008) Doubt is their product: how industry's assault on science threatens your health. New York: Oxford University Press.
[24] Michaels D. (2020) The Triumph of Doubt: Dark Money and the Science of Deception. New York: Oxford University Press.
[25] Oreskes N. and Conway EM. (2010) Merchants of Doubt: How a Handful of "Scientists" Obscured the Truth on Issues from Tobacco Smoke to Global Warming. New York: Bloomsbury Press.
[26] Walker MJ. (Editor) (2017) Corporate Ties That Bind: An Examination of Corporate Manipulation and Vested Interest in Public Health. New York: Skyhorse Publishers.

with COI issues, from people who may instead act as "industrial apologists" and deter the advancement of scientific knowledge. This is also an example of the importance of supporting "watchdog" activities.

b) 2018 Collegium Ramazzini Statement: COI-related Principles for Safeguarding the Integrity of Research in Occupational and Environmental Health

The Collegium Ramazzini (CR) is a member organization of INEP and an international scientific society that examines critical issues in occupational and environmental medicine with a view towards action to prevent disease and promote health. In 2018, the CR issued a statement addressing financial COI in occupational and environmental health (accessible here, see Appendix XII). Through its statement, the CR recognized the role of conducting impartial epidemiological research to inform rational health-protective public policy.

The CR noted that research supported through the public purse, especially if held accountable to public review and scrutiny, is much more likely to produce accurate impartial results. Research that is hampered or corrupted by funding from commercial interests may seek intentionally to delay or dismiss actions that would require a change in the status quo to protect business operations. INEP notes the examples provided by the CR of such strategies that are particularly relevant to epidemiology:

- Establishing principles of so-called 'good epidemiological practice' to intentionally be misused to dismiss relevant and reliable studies that provide evidence of harm [e.g., ECETOC (European Center for Ecotoxicology and Toxicology of Chemicals) in the 1990s].
- Promoting impossibly difficult criteria for establishing causal relationships such as dismissing relationships unless there is an understanding of underlying mechanisms of toxicity or supporting laboratory evidence in animals.
- Offering scientists generous resources for research, but with restrictions on publication rights that absorbs research capacity and controls the results.
- Designing research protocols that result in a predetermined outcome that is either negative or null (e.g., designing a study without adequate statistical power to provide a positive result that are portrayed as negative, or by diluting exposed groups by including non-exposed individuals).
- Creating scientific journals with a bias toward favoring and publishing studies, editorials, or reviews that underplay or deny risk and can (a) appear to give scientific credibility to biased studies, (b) be used in litigation to defend industry, and (c) allow publication practices that by bypass acceptance norms for scientific integrity.

INEP not only recognizes problematic examples of COI problems at the research level, but also at the decision-making level; the CR noted that a growing industry influence can compromise the credibility and reliability of the process by:

- Making public statements that well-established facts are controversial.
- Providing intense media exposure for industry-sponsored studies to 'disseminate' findings and create a different public narrative than if the evidence were impartially reviewed.
- Organizing lobbying at every level of decision-making relevant to occupational and environmental health.
- Conducting ad-hominem attacks on scientists who have published findings suggesting hazardous associations with industry products or processes.
- Paying scientists for consultancy and for representing industrial interests in science and policy often without disclosing their ties to industry.
- Sponsoring pseudo-scientific think tanks, biased review articles, and special issues of journals to disseminate junk science.

INEP notes and endorses many of the steps identified by the CR to decrease, expose, and help inform policy-makers of such activities (see CR Statement : *Conflict-of-interest declarations, Scientists adherence to ethical principles, Funding, and Decision-making processes*). It encourages its member organizations to similarly monitor and investigate COI.

Relevant input by CR fellows (e.g., Dr. Leslie London and Dr. Jennifer Sass) during CR statement development illustrated attempts by vested interests to extend COI safeguards from financial conflicts to limit the scientific input of others. For example, vested interests have argued that COI takes many forms and can be considered to be equal such that, for instance, an endocrine disruption expert should not be allowed to interpret data from the study of a new chemical. They argue that, since everyone has some form of conflicting interests, COI should not matter. In another variation of this argument, there are no truly 'independent' researchers because universities are dependent on funding streams and, as such, academic researchers holding research grants have conflicting interests that prevent them from serving on scientific advisory committees; yet, they claim that industry-supported scientists can serve on scientific advisory committees. The points are reflected in the peer-reviewed literature.[27,28]

c) 2019 Commentary: How Can the Integrity of Occupational and Environmental Health Research Be Maintained in the Presence of Conflicting Interests?

In 2019, CR Fellows (i.e., Baur, Soskolne and Bero) published a peer-reviewed commentary[29] based on a 2018 CR symposium entitled "Corporate influence threatens the public's health". The commentary draws on the CR's collective experience of misuse of sciences (especially the sub-specialties of occupational and environmental health) and illustrates the manipulative

[27] Bero L and Grundy Q. (2017) Why having a (non-financial) interest is not a conflict of interest (Perspective) PLoS Biology, PLoS Biol; 14(12): e2001221.

[28] Grundy Q, Mayes C, Holloway K, Mazzarello S, Thombs B, Bero L. (2020) Conflict of interest as ethical shorthand: understanding the range and nature of "non-financial conflict of interest" in biomedicine. J Clin Epidemiol; 120: 1–7.

[29] Baur X, Soskolne CL and Bero LA. (2019) Commentary. How can the integrity of occupational and environmental health research be maintained in the presence of conflicting interests? *Environmental Health;* 18:93 | Published on: 4 November 2019.

mechanisms used as well as practical remedies some of which INEP adopted (Appendix XII). The commentary includes recommendations attributed to *A Consensus Study Report of the National Academies of Sciences, Engineering, Medicine* (2017).[30]

The commentary identified several examples of COI industry/corporate/business associated practices that include: (a) insertion of compromised scientists onto editorial boards of peer-reviewed scientific journals that may result in the publication of poorly-designed, misleading research studies, (b) purchase of industry journals and replacement with biased editors, (c) interference with the activities of national regulatory bodies (e.g., USEPA, EFSA) and international review panels (e.g., WHO/IARC), (d) emphasis on uncertainty to undermine scientific consensus and delay regulation of health hazards, (e) promotion of unnecessary "causation" criteria that, in effect, dismiss increased morbidity and mortality from hazardous exposures or practices in the workplace and decrease legal remedies, and (f) provision of financial incentives to facilitate COI associated actions.

The CR commentary also provided examples of mechanisms for investigating scientific misconduct that include those of the Office of Research Integrity (ORI) of the United States Public Health Service (PHS) and a report detailing the resignation or firing of scientists by the United States National Institutes of Health (NIH) for failure of NIH grantees to disclose financial ties to foreign governments. In 93% of those cases, hidden funding was from a Chinese institution (See Appendix XIV).

d) 2019 Acquavella Commentary that COI Disclosure Harms Epidemiology: INEP Member Response

In 2019, Dr. John Acquavella, an epidemiologist whose career had been spent in the employ of two of the world's largest public corporations (i.e., Exxon-Mobil and Monsanto), published a commentary in the *Annals of Epidemiology* entitled "Conflict of Interest: A Hazard for Epidemiology."[31] In it, Acquavella articulated the approach used by vested interests to underplay the role of financial COI. Although noting an issue with financial COI, Acquavella went on to raise concerns that academic epidemiologists who have consulted or conducted research for private industry tend to be excluded from government or non-government panels that are evaluating evidence and advising on public health decisions. He cites warnings about the harm associated with disclosure of financial COI and resulting prohibition of authorship that would distract from scientific evaluation and unfairly limit such experts from contributing to epidemiology and public health.

Several INEP members (Soskolne et al., 2019) responded to Acquavella's commentary.[32] They noted that Acquavella: (1) acknowledges that "Historically, private industry has been on the wrong side of many public health issues"; and (2) argues that journal requirements for disclosure of financial COI have the undesirable consequence of unfairly predisposing the

[30] National Academies of Sciences, Engineering, and Medicine. (2017) Fostering Integrity in Research. Washington, D.C.: The National Academies Press.
[31] Acquavella J. (2019) Conflict of interest: a hazard for epidemiology. Annals of Epidemiology.
[32] Soskolne CL, Advani S, Sass J, Bero LA, Ruff K. (2019) Response to Acquavella J, Conflict of Interest: A Hazard for Epidemiology, Annals of Epidemiology: 62–63.

reader against industry-sponsored studies. However, Soskolne et al. countered the financial disclosure concern by noting accurate disclosure of research sponsorship and any financial COI is considered necessary (but not sufficient) for study evaluation and that overwhelming evidence across sectors has shown that industry-sponsored studies are more likely to report an outcome favorable to its sponsors.

Soskolne et al. also provided examples of industry influence in fomenting uncertainty that includes the links between: smoking and cancer; air pollutants and adverse health outcomes including asthma, neurodevelopmental impacts, and premature death; sugar-sweetened beverages and childhood obesity; pesticides and cancer or developmental toxicity; the promotion of the continued "safe-use" of chrysotile asbestos and e-cigarettes as a safe alternate to cigarette smoking. They also described increased industry influence in regulatory agencies, including that of Monsanto on the United States (U.S.), European Union (EU) and Canadian regulatory processes for glyphosate, as well as concealment of permitting increased corporate influence over universities and research agendas.

INEP notes that by invoking other sources of bias, Acquavella ignored the responsibility of financial COI for documented cases of the derailment of science, policy delays, and injustice in tort actions that may have already resulted in a preventable burden of morbidity, premature mortality, and environmental degradation. INEP also notes that such attempts to shift focus to non-financial COI can also serve to exclude those with no financial COI from science and debate. INEP reiterates is commitment to transparency and support of COI disclosure and notes the importance of its members to speak out and the usefulness of "letters-to-the-editor" as a mechanism to do so.

e) 2020 Graziosi Article: Political COI of False Hurricane Claims

Recent examples of other forms of COI, besides financial ones that influence scientific integrity and the quality of scientific products, include political influence. A new report calls for integrity policy training and reforms to prevent future violations relating to United States government weather experts violating scientific integrity by backing the United States President over false hurricane claims.[33]

f) 2020 Kaplan et al Article: COVID Pandemic Lapses in COI and Disclosure

Issues embedded in COI and disclosure include guest authorship, reporting bias, and lack of transparency that have arisen in the current COVID-19 pandemic. The retraction of two research papers[34] has highlighted the continuing failure of researchers to share their data, with COI concerns driving these behaviors. COI has also been associated with other aspects such as funding and support for companies involved in COVID-19 research for vaccine and therapeutic development. For example, the chief scientist brought on to lead the United States

[33] Graziosi, G. (June 16, 2020) 'Sharpiegate': Government weather experts violated scientific integrity by backing Trump over false hurricane claims. The Independent.
[34] Wise, J. (2020) Data transparency: Nothing has changed since Tamiflu. BMJ 2020;369:m2279.

Government's vaccine efforts is a former pharmaceutical executive who has had his financial interests and corporate roles come under scrutiny.[35]

g) 2020 Unbalanced and Conflicted Science in AJPH Special Issue on E-Cigarettes

COI issues have been identified for the sale of e-cigarettes through the use of a call-for-commentaries that resulted in an unbalanced and biased representation of the state of the science. The *American Journal of Public Health* (AJPH) recently issued a call-for-commentaries on relevant public health issues (June issue *Experimental Forum No.1: The 2020 FDA Guidance on E-Cigarettes article*). The views and opinions expressed by invited participants seemed to reflect an over-representation of industry-funded consultants and other biased, non-evidence-based views that favored Electronic Nicotine Delivery Systems (ENDS). At least five of the 13 individuals featured in the commentaries reported industry conflicts with a bias for supporting electronic cigarettes and opposing policies restricting their sales. This resulted in a lack of counterpoints and scientific inputs from experts in the field of tobacco control, health policy, and adolescent health.

The editors of the forum concluded from this experiment that FDA policies are biased against industry research. This "experiment" by the *American Public Health Association* (APHA) highlights the failure of the entire process of choosing articles for inclusion in the forum. Rather than choosing authors who are leaders in the field (i.e., the Lancet Commission Approach) and who could have accurately reflected the mounting evidence of addiction, morbidity, and mortality associated with vaping and e-cigarettes, the AJPH editors did not acknowledge the non-independence of the published perspectives with COI issues. Consequently, the editors misrepresented the state of the science.

h) 2020 Heindel Article: Undeclared COI in Biased Editorial Duplicated in Eight Toxicology Journals

On 10 July, 2020, Heindel in *Environmental Health News*[36] described an editorial written by a group of 19 toxicologists that had been published verbatim in eight toxicology journals over the prior four months. The editorial was entitled, "Human exposure to synthetic endocrine disrupting chemicals (S-EDCs) is generally negligible as compared to natural compounds with higher or comparable endocrine activity. How to evaluate the risk of the S-EDCs?" According to Heindel, the 19 authors were toxicologists with ties to the chemical industry. However, he noted that one cannot deduce this from the editorial because the authors claimed "no conflicts of interest." A recent article in *Le Monde* detailed their actual and considerable COIs.

Heindel also pointed out that the group of 19 toxicologists has no expertise in the endocrine-disrupting chemical scientific field. He described the editorial as an unethical attempt to foster the views of the chemical industry disguised as an impartial review of the science that, in fact, threatens human health. He noted that the timing of the appearance of this editorial in multiple

[35] Kaplan et al (May 20,2020) 'Trump's vaccine chief has vast ties to Drug Industry, posing possible conflicts'
[36] Heindel J.J. (2020) The dangers of opinion masquerading as fact in science journals: A call for unbiased, honest science in peer-reviewed journals. Environmental Health News (July 10).

journals just before the European Parliament's vote on their resolution on the European Chemicals Strategy for Sustainability.

Despite the wide distribution of the editorial, a decision was taken on 10 July, 2020 by the European Parliament that was consistent with that of the Environmental Non-Government Groups (ENGOs) and not that of the editorial (see here, here and here). This decision is also consistent with the stance taken by Kassotis et al. (2020)[4] who argue for the need for added protection from undue industry influence in assessing the risks of S-EDCs.

Of special note and concern is that six of the eight journals are published by Elsevier Publishing Company, with those journal editors themselves among the 19 authors. The appearance of COI issues, the failure of disclosure, and the participation of journal editors in this example underscore the need to identify and disclose COI in the publication of scientific discourse and in support of healthy public policy.

i) 2020 Hardell, Rivasi, and Buchner Letters/Reports: RF-EMF Hazard and COI of ICNIRP Analyses and Leadership

There are instances in which an organization that has been relied upon to be free from COI and to provide impartial scientific advice is comprised of members who have conflicting interests. In such cases, the judgement of the organization may be compromised as well as that of its individual members.

The *International Commission on Non-Ionizing Radiation Protection* (ICNIRP) has been relied on by many governments (e.g., Germany) to be an authority on the safety of 5G (fifth generation wireless network technology) and cell phone radiation health risks. Issues of COI and biased evaluation of Radiofrequency Electromagnetic Fields (RF-EMF) health risk have been raised by several scientists through letters and reports to the Swiss Confederation and European Members of Parliament (Hardell, 2020 see his evidence here; Rivasi and Buchner; see reports here, here and here) and, most recently, by Hardell and Carlberg[37] as a peer-reviewed commentary.

Miller et al. (2019)[38] laid out the evidence of cancer risk from RF-EMF and noted that, although the ICNIRP has maintained that no evidence of adverse biological effects exists, this conclusion is in contrast to IARC findings from 2011 of possible cancer risk, more recent epidemiological analyses from the US and UK that reported RF-EMF associated cancer risk, and positive findings in animal studies. IARC has placed high priority on non-ionizing radiation (radiofrequency), considering it "ready for evaluation within 5 years."[39]

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[37] Hardell L and Carlberg M. (2020) Health risks from radiofrequency radiation, including 5G, should be assessed by experts with no conflicts of interest. Comment. Oncology Letters 20:15.

[38] Miller AB, Sears ME, Morgan LL, Davis DL, Hardell L, Oremus M and Soskolne CL. (2019) Risks to Health and Well-Being from Radio-Frequency Radiation Emitted by Cell Phones and Other Wireless Devices. Front. Public Health 7:223; 10 pages.

[39] Matilde MM, Berrington de Gonzalez A, Beland FA, Browne P, Demers PA, Lachenmeier DW, Bahadori T, et al. (June 1, 2019) Advisory Group Recommendations on Priorities for the IARC Monographs. The Lancet Oncology; 20 (6): 763–64.

Without both the disclosure and recognition of COI and the development of an impartial and accurate determination of RF-EMF health risks, it is difficult to educate the public and take steps to significantly reduce the public's exposure to and health effects from RF-EMF. In the meantime, 5G technologies are being rolled out with promises of connecting the world with billions of RF-EMF emitting devices.

j) 2015-2020 Caldwell-Soskolne Analysis of COPE Failure: Articles and Journal COI for Drinking Water Carcinogenicity

By the 1990s, scientific journals began to require authors to declare their COI with the Committee on Publication Ethics (COPE) founded in 1997 to promote integrity in scholarly research and its publication. Although publishers may state that they follow COPE guidance on COI, journals, editors, and authors may not follow them. Publishers defer to editors on what may be published in their journals. They provide, among other ethics guidelines, references to COPE guidance regarding COI and disclosure. Whether this system is adequate to address concerns about COI&D has been questioned and there is a need to monitor and track its success.

Ruff[40] pointed out in 2015 that, although organizations such as the International Committee of Medical Journal Editors (ICMJE), the World Association of Medical Editors (WAME), and COPE had launched initiatives to establish COI disclosure, this guidance was largely unenforced. Ruff provided examples from five journals (*Annals of Occupational Hygiene*, *Current Opinion in Pulmonary Medicine*, *Critical Reviews in Toxicology*, I*nternational Journal of Environmental Research*, and *European Journal of Cancer Prevention*) that showed the consequences of COI, failure to disclose it, and subsequent failure of enforcement of COPE's code of conduct. She noted that, although COPE provides a complaint mechanism regarding violation of its code (i.e., COPE will "aim to discuss that with the member and will ask them to consider their membership in the organization"), COPE does not require a journal to comply nor asked a journal to withdraw membership.

A more recent example illustrates how established science, supported by decades of international groundbreaking research, can be erroneously called into question by industry-funded authors, how COPE COI disclosure guidelines were violated, and the public misled. A team of U.S. Government Scientists (Richardson et al.) published an article in 2007 in the highly respected journal *Mutation Research* entitled "Occurrence, genotoxicity, and carcinogenicity of regulated and emerging disinfection by-products in drinking water: a review and roadmap for research."[41] As of July 2020, that seminal work has been cited 2,425 times and was followed up with international collaborative efforts assessing similar health hazards

[40] Ruff K. (2015) Scientific journals and conflict of interest disclosure: what progress has been made? Environmental Health;14:45.

[41] Richardson SD, Plewa MJ, Wagner ED, Schoeny R, DeMarini DM. (2007) Occurrence, genotoxicity, and carcinogenicity of regulated and emerging disinfection by-products in drinking water: a review and roadmap for research. Mutation Res 636:178-242. **Cited 2,425 times as of 7-15-20.**

from swimming pool water (e.g., Zwiener et al. 2007,[42] 336 citations; Richardson et al. 2010,[43] cited 290 times; and Kogevinas et al, 2010,[44] cited 155 times).

In 2013, IARC noted in its general remarks of *Monograph 101*[45] the difficulties in attributing increased bladder cancer risk from drinking water disinfection by-products (DBPs) to a single agent. Biomarkers were noted as being of limited use due to their lack of accumulation in the body, and the absence of biomarkers that represent internal doses from long-term exposure. IARC also noted that the exposure surrogate of total trihalomethanes had been used as a proxy for exposure to the whole mixture in many epidemiological studies and that the correlation between surrogates of DBPs and individual constituents in specific treated water samples is complex and dependent on raw water quality and the type of treatment. However, IARC highlighted the use of mechanistic data, genotypes, and other molecular analyses to identify components of DPB mixtures that contribute to bladder cancer, namely the six-fold increase in bladder cancer risk from drinking water exposure among people with specific genotypes. IARC cited this application of molecular epidemiology (see Cantor et al., 2010) as critical for identifying brominated trihalomethanes and haloacetic acids, as critical components with a potential causative role in bladder cancer risk from drinking water.

In 2020, an international expert in cancer, DM DeMarini[46] published a review article chronicling the 40-year development of the science supporting regulation of DBPs (i.e., DeMarini, 2020).[47] DeMarini noted the great achievement of water disinfection (primarily with chlorine), but, similar to IARC in 2013, the efforts to identify what DBPs contribute to increased bladder cancer risk from drinking water exposure. He also noted the sustained cooperation between government and academic scientists and with public/private water companies. DeMarini declared his EPA connections in his article.

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[42] Zwiener C, Richardson, SD, DeMarini DM, Grummt T, Glauner T, Frimmel FH. (2007) Drowning in disinfection by-products? Assessing swimming pool water. Environ Sci Technol 41:363-372. **Cited 336 times as of 7-15-20.**

[43] Richardson SD, DeMarini DM, Kogevinas M, Fernandez P, Lourencetti C, Heederik D, Meliefste K, McKague AB, Marcos R, Font-Ribera L, Grimalt JO, Villanueva CM. (2010) What's in the Pool? A Comprehensive identification of disinfection by-products and assessment of mutagenicity of chlorinated and brominated swimming pool water. Environ Health Perspect 118:1523-1530. **Cited 290 times as of 7-15-20.**

[44] Kogevinas M, Villanueva CM, Font-Ribera L, Liviac D, Bustamante M, Espinosa F, Nieuwenhuijsen MJ, Espinosa A, Fernandez P, DeMarini DM, Grimalt JO, Grummt T, Marcos R. (2010) Genotoxic effects in swimmers exposed to disinfection by-products in indoor swimming pools. Environ Health Perspect 118:1531-1537. **Cited 155 times as of 7-15-20.**

[45] Some chemicals present in industrial and consumer products, food and drinking-water. (2013) Publications of the World Health Organization, Lyon, France;101.

[46] 182 papers and 21 book chapters, co-author on the Richardson et al. studies, co-author on the 2004 International Agency for Research on Cancer monograph on "Some Drinking Water Disinfectants and Contaminants, Including Arsenic", former president of the Environmental Mutagenesis and Genomics Society, former Editor of Mutation Research, and retired employee with the U.S. Environmental Protection Agency, i.e., EPA.

[47] DeMarini DM. (2020) A review on the 40th anniversary of the first regulation of drinking water disinfection by-products. Environ Mol Mutagen; 61: 588–601.

In contrast, in 2019, Cotruvo and Amato published an article[48] in *Dose-Response: An International Journal*, whose thesis was one of no drinking water-associated cancer risk associated with Total Tri-Halo-Methanes (TTHMs) as a major component of DBPs. Subsequently, in 2020, Cotruvo et al. published an article[49] in the *Journal AWWA* in 2020 entitled "Misleading Research Attempts to Quantify Bladder Cancer Attributable to Drinking Water" that incorrectly cited epidemiology principles to undermine the case for an association with bladder cancer risk. Cotruvo describes himself as a consultant and ex-EPA Division Director who left the Agency in 1990 in his Linkedin profile; he has little scientific publication history.

On close scrutiny, the industry-sponsored 2019 article, described as a review but, in fact, a descriptive epidemiology study comparing population risks, could not have been expected to identify effects for reasons among those included below on pages 31–34 in the sub-section entitled "Summary of epidemiology-specific techniques used to manipulate scientific findings." Not only are there publication issues (see below regarding publication in "pay-to-play" journals), but items e, k, and q described below as epidemiology-specific techniques to manipulate scientific findings are applicable to this example.

In the 2019 article, Cotruvo declared that he had no COI and that he was supported by a grant from the World Chlorine Council to publish his work. SAGE Journals publishes *Dose-Response* which claims to be a COPE member and recommends ICMJE ethics conduct recommendations. SAGE COI declaration policy includes having received fees for consulting or research funding as COI examples.

In addition, the *Journal AWWA* describes itself as the "voice of the water industry and is an authoritative source of information for water professionals and the communities they serve." Although this American Water Works Association (AWWA) journal is published by John Wiley & Sons (also a COPE member), it has no evident COI disclosure requirement. In their 2020 article published there, Cotruvo et al did not provide any information regarding their funding sources.

In the 2019 Cotruvo article, it is noted that *Dose-Response* is published by the International Dose-Response Society (renamed in 2007 from the International Hormesis Society formed in 2005 by Edward J Calabrese). Calabrese serves as its editor. The journal describes itself as "dedicated to promoting thresholds and hormesis in dose-response models." The journal's website features links for donation to its endowment fund, but it does not appear to provide access to corporate funding donors.

In 2010, Shrader-Frechette published an investigation of Calabrese[50] and his "special interest science" (SIS). SIS was defined as science having welfare-related consequences and funded

[48] Cotruvo J.A. and Amato H. (2019). National Trends of Bladder Cancer and Trihalomethanes in Drinking Water: A Review and Multicountry Ecological Study. Dose-Response: An International Journal; pp. 1–19.
[49] Cotruvo JA, Hrudey SE and Fawell J. (2020) Misleading Research Attempts to Quantify Bladder Cancer Attributable to Drinking Water. JOURNAL AWWA: 78–80.
[50] Shrader-Frechette K. (2010) Conceptual analysis and special-interest science: toxicology and the case of Edward Calabrese. Synthese 177:449–469.

by special interests in order to establish predetermined conclusions. Shrader-Frechette noted in particular that the chemical industry sought deregulation of toxic emissions and cleanups through its support of the "hormesis" concept with Calabrese as its main defender and significant recipient of SIS funding. She also noted that that SIS practitioners, like Calabrese, often violate standard disclosure guidelines regarding COI. In addition, she reported that, although his employer (The University of Massachusetts) requires disclosure and review of COI in an aggregate amount exceeding $10,000 within a 12-month period, Calabrese was receiving between $810,000 and $3,000,000 without disclosure of funding source(s).

This example illustrates how an industry-funded consultant with prior EPA employment used a journal vehicle, whose editor has been noted as a SIS practitioner with COI, to put into the literature an article that casts doubt on some 40 years of impartial science by world experts. In addition, this consultant did not disclose his COI when he published a biased view in a trade association journal that does not follow COPE guidelines, despite its publisher's membership in COPE. As a result, the members of that Association may not have the information they need to discern what the true public health risks of DPBs are.

This example also highlights that scientists who leave or retire from government service may have COI and disclosure issues they did not have previously. The need for COPE to enforce its standards on member journals and editors is also illustrated by this example.

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

One tactic that has frequently been utilized by many industries to promote their financial interests and minimize the appearance of COI has been to fund and co-sponsor meetings and conferences of scientific organizations whose mission is to protect human and environmental health. Examples include tobacco, fossil fuels, sugary drinks, pharmaceuticals and chemical industries. This funding benefits the industry by creating the impression that the industry is a virtuous, trustworthy partner pursuing the same goals as the scientific organization. At the same time, that industry may also be engaging in activities described previously to minimize the perception of hazard that their products cause.

In these instances, the corporate donors are acknowledged and openly thanked by the scientific organization for their financial support. The corporations' names and logos are presented in conference materials. Thus, the name and credibility of the scientific organization serves to legitimize the conduct of these co-sponsoring corporations.

Such funding also creates a COI through real or perceived improper influence. No matter how elegantly a statement may be worded, an incentive nevertheless exists for the scientific organization not to jeopardize that funding and the public to question the ability of the organization to challenge misinformation and conduct by the funding industry. Organizations and scientists funded by the fossil fuel industry, the tobacco industry, and other industries that are causing harm to human health, often claim that their work is in no way influenced by their funder. With few exceptions, their work promotes the interests of their funder.

In July 2018, the International Society for Environmental Epidemiology (ISEE) adopted a revised prevention of COI policy entitled ISEE Guidelines on financial support. This policy required ISEE to have a process to identify and resolve any COI before donor support is applied for and/or accepted. The policy states that:

> *At the discretion of the ISEE Council, donations will not be accepted from industries and other entities:*
> *1) with harmful impacts on public health or the environment, or*
> *2) that suppress or distort the scientific evidence regarding environmental pollution and its adverse health effects.*

The policy specifically states:

> *The list of industries and other entities from which donations should not be accepted by ISEE: 1. Tobacco industry; 2. Firearms industry; 3. Pesticides industry; 4. Asbestos industry; 5. Coal and oil industries.*

This update of the ISEE guidelines was prompted by concerns about sponsorship during the then imminent August 2018 annual conference in Ottawa, Canada, organized jointly by ISEE and the International Society for Exposure Sciences (ISES). The joint conference received funds from ExxonMobil, Bayer, Crop Life, Syngenta, BASF the chemical company, North American Metals Council, American Chemistry Council, and the Chemical Industry Association of Canada. ISEE was concerned that funding support from these sources could jeopardize the credibility and reputation of ISEE. In response, it took three steps:

1. Adopted the stricter July 2018 policy to avoid agreeing to such sponsorships in future meetings; see ISEE Guidelines on financial support.
2. For the 2018 meeting, declined to receive any conference funds from the oil extraction industry consistent with the restrictions stated in its previous policy.
3. A disclaimer-acknowledgment was inserted into the conference page of "Sponsors, Grants and Exhibitors" in the scientific program (see ISEE-ISES 2018 Conference Program, p. 175) that stated:

> *The conference organisers welcome and value support from government, commercial organisations and other groups, which allows for dialogue with a broader stakeholder group, increases participation of scientists from lower income countries, and helps us to keep registration costs lower. Financial contributions do not entitle sponsors to any involvement in conference programming or speaker selection.*

In addition to the actions taken by the ISEE, a commentary reflecting these issues was published in *Epidemiology* by Kogevinas and Takaro 2019.[51] An Open Letter by K. Ruff was sent to the ISEE leadership (see Appendix XV) calling on the ISEE to respond publicly to the

[51] Kogevinas M and Takaro T. (2019). Sponsorship by Big Oil, Like the Tobacco Industry, Should be Banned by the Research Community. Commentary. Epidemiology: 30(5); 615–616.

Kogevinas and Takaro commentary as well as to the requests for action made in her Open Letter.

Not only does this example raise issues of conference sponsorship by interests whose goals are not consistent with those of public health, it also shows the importance and positive effects of discovering and responding to problems with transparency as quickly as possible. Of relevance in this Position Statement, INEP also has a policy for avoidance of COI through donations (see 4 above on page 20); indeed, the ISEE 2018 policy cites that of INEP's 2015 policy.

l) 2020 COI and Hill's 1965 Viewpoints Used in Testimony for Causation in Civil Litigation

Hill's seminal presidential address before the Royal Society of Medicine in 1965, became a set of guidelines to assist in drawing causal inferences from statistical associations. His follow-up 1965 article[52] has been invoked in U.S. law as a canonical set of nine viewpoints that experts can utilize to support their testimony for causation in civil litigation. These viewpoints are often misused to dismiss epidemiological findings of potential health risk, especially since several of them are clearly not even relevant.[53]

Hill impressed in his 1965 presidential address that his nine viewpoints are not to be interpreted as "criteria." He concluded that:

> *All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.*

Given this, Neutra et al.[53] described some major shortcomings exhibited by U.S. court decisions involving use of the Hill viewpoints that include the following:

- Demands that all of Hill's nine viewpoints must be satisfied before his approach can be used in litigation.
- Demands that some of Hill's nine viewpoints be treated as "criteria" that must be satisfied instead of simply as aspects for consideration when interpreting an epidemiological study.
- Demands that an observed association between an exposure and disease must be supported by conventional and low statistical significance ($p < 0.05$) or, equivalently, that the results must fall within 95% confidence bands, thus precluding the use of studies with statistical significance slightly higher than 0.05, or with confidence intervals slightly wider, which might include 90%.

[52] Hill B. A. (1965) The Environment and Disease: Association or Causation? Proc Royal Soc Med; 58(5):295–300. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1898525/.
[53] Neutra R.R., Cranor C.F., and Gee D. (2018) The Use and Misuse of Bradford Hill in U.S. Tort Law. Jurimetrics J; 58:127–162.

- Demands that any observed relative risk between exposure and disease must be 2 or greater before the study can be admitted to support expert testimony. Any study not exhibiting this relative risk is excluded from testimony about a causal relationship between exposure and disease. Relative risks <2 can provide evidence of adverse effects from exposures (e.g., exposure to environmental tobacco smoke[54] has a relative risk of about 1.2), and across the population can result in substantial costs to well-being, the environment, and the economy.

- Judges' failure to recognize that a statistical study could be too under-powered to detect an adverse effect when one was indeed present. Put another way, the vast majority of judges showed no sensitivity to the fact that epidemiological studies can mistakenly result in false negatives. Out of 80 federal cases reviewed in the above-noted recent article, only one court recognized that possibility and excluded a defense expert [Ambrosini v. Labarraque, 101 F.3d 129 (D.C. Cir. 1996)].

- A few courts have exhibited skepticism when one substance can cause several different types of disease, or they have required "specificity" between exposure and disease.

- Some courts have required that epidemiological studies must be supported by a biologically plausible mechanism before an expert can testify.

The above examples on the misinformed use of epidemiology in U.S. litigation have been used by industrial interests over decades to define what constitutes "good epidemiological practice."

SUMMARY OF TECHNIQUES USED TO MANIPULATE EPIDEMIOLOGICAL FINDINGS

Epidemiological evidence, derived from the application of epidemiology, can be influenced by interests that manipulate the scientific method to cast doubt and foment uncertainty. Such manipulation can mislead both the public and policy-makers and should not be confused with testing of scientific hypotheses.

Several techniques have been assembled below to help identify how epidemiologists skew results and produce "junk science" (Cranor, 2011;[55] Soskolne 2015,[56] 2019[57]). The products of these techniques are filling the literature and being used in court proceedings to work in favor of

[54] Zhong L1, Goldberg MS, Parent ME, Hanley JA. (2000) "Exposure to environmental tobacco smoke and the risk of lung cancer: a meta-analysis." Lung Cancer;27(1):3–18.
[55] Cranor CF. (2011) Legally Poisoned: How the Law Puts Us at Risk from Toxicants. Boston, MA: Harvard University Press.
[56] Soskolne CL. (2015) Public health and environmental health risk assessment: which Paradigm and in whose best interests? In Westra L, Gray J, Karageorgou V (eds), Ecological Systems Integrity: Governance, Law and Human Rights. Earthscan, London, Chapter 16, 191–200.
[57] Soskolne CL. (2019) The role of vested interests and dominant narratives in science, risk management and risk communication. Chapter 8 in: Environmental Health Risks: Ethical Aspects (Eds. Zölzer F and Meskens G). Routledge Studies in Environment and Health. Routledge, Taylor & Francis. London & New York, NY, USA: 123–134.

defendants whose superseding interest is avoidance of the public health and regulatory consequences of their activities. Techniques are used that manipulate scientific publication. They include the use of unbalanced discussion that emphasize findings not supported by the data, selective disclosure of competing interests, and publication in 'pay-to-play' journals without appropriate peer-review and with COI issues. At the research level, the following epidemiology-specific techniques are methods used to foment uncertainty regarding cause-and-effect; each is briefly described below:

a. **statistically under-powered studies** [e.g., sample size too small to detect an adverse effect, or adverse effect is too rare to be detected by a statistical study; asserting that a "negative" study (even if RR>1) is proof of no effect.]
b. **inadequate follow-up methods** [e.g., not measuring appropriate endpoints through the pathogenesis of a disease process so that adverse effects can be identified (i.e., incomplete accrual problem)]
c. **inadequate follow-up time** [e.g., not allowing sufficient time in a study for disease to manifest as with the latency between *in utero* exposure to diethylstilboestrol (DES) and appearance of cervical cancer of about twenty years or the latency between exposure to asbestos and appearance of cancers of up to 45 years; occupational studies with person-years of exposure representing 1–2 years of exposure to large numbers of usually young workers]
d. **contaminated controls** (e.g., control groups that have people with exposure and early disease manifestation), and a broad range of degree and types of exposure among the presumed exposed group in cohort studies
e. **poorly designed exposure groupings** (e.g., a broad range of degree and types of exposure among the presumed exposed group or unexposed groups in cohort studies)
f. **inappropriate comparisons between exposed and unexposed groups** (e.g., failure to adjust for the "healthy worker effect")
g. **diluting / washing out / averaging effects in descriptive population comparisons** [e.g., combining all risk groups when it is in only a relatively small susceptible group that the signal of effect will be demonstrated (that is akin to toxicology in which the correct strain of rodent is needed for demonstrating effects)]
h. **ignoring known synergies among components of the mixture of chemicals** (e.g., to study a small component of a mixture to which people are exposed in order to dilute the risk of the whole mixture that acts in concert to cause effects and failing to evaluate synergies; to assess the risk of pesticide active ingredients individually, whereas commercial pesticide products contain multiple active ingredients plus adjuvants to enhance toxicity to the target species)
i. **inadequate laboratory measurement practices** (e.g., to use measures of exposure or effects that systematically under-estimate exposures or effects)
j. **inappropriate analytical methods for calculations** (e.g., analyzing matched case-control designs using methods that do not retain the matching; use of varying levels of detection in analyzing blood samples by different laboratory methods)
k. **ignoring Type II errors** [e.g., to ignore errors from underpowered studies (see 'a' above)]

l. **linear-reductionist quantitative methods without post-normal qualitative approaches to complement them** (e.g., the exclusive reliance on quantitative methods when qualitative research can provide both context for the variables included in the quantitative analysis as well as context for the interpretation of the quantitative findings)

In addition, arguments that are used to delay action, support maintaining the *status quo*, and create unhelpful divisions between scientists include the following:

m. **biased or selective interpretation** (e.g., the absence of objectivity/impartiality)
n. **ignoring mechanistic information suggestive of adverse effects** (e.g., ignoring or dismissing information pertaining to susceptible populations having increased risk so they can be studied rather than only studying the whole population; insistence on demonstrating a consistently elevated RR associated with a very rare outcome vs. showing elevated risk for broader categories that are mechanistically related)
o. **making claims of exaggerated differences or dismissing them when human and toxicology studies indicate a potential health hazard** (e.g., failures to synthesize knowledge from all that relates to a disease process)
p. **ignoring consistent molecular structures that predict potential health hazards** (e.g., insisting on the need for more research by ignoring prior knowledge or information on structurally-related compounds)
q. **the insistence on demonstrating effects in local populations of exposed people despite demonstrated effects in humans elsewhere** (e.g., refusing to accept that health effects observed in one exposed population are likely to operate in much the same way in a similarly-exposed population in a different location)
r. **neglecting to apply or dismissing the Precautionary Principle** when there is evidence to justify interventions to reduce/eliminate exposures [e.g., to insist on a body count before action is taken although the risk is high of an adverse effect from exposure (see point 'u' below)]
s. **the failure to make explicit those value judgements that underlie decisions** about selecting appropriate standards of evidence to draw policy-relevant conclusions (e.g., failing to discern acceptable risks as a policy determination vs the actual risk of exposure)
t. **focusing on reporting only general population effects** to the detriment of identifying and protecting the most vulnerable, chemically sensitive, and genetically susceptible in society, including children and pregnant women, from adverse health impacts (e.g., failure to protect the developing brain from neurotoxicants or study these sensitive sub-populations)
u. **demanding an unusually high degree of certainty for the public health problems to be addressed** (e.g., demanding proof "beyond a reasonable doubt," typical of criminal law proof requirements, although risk of health hazard may vary due to differential susceptibility and may not be discernable beyond a reasonable doubt for an individual. In U.S. tort litigation, the typical standard of proof is "preponderance of the evidence" or "balance of probabilities" that require a determination of "more probable than not.") The needed degree of certainty will vary, however, depending on the seriousness of adverse effects and other considerations. Environmental health advocates, on one hand, suggest consideration of a lower level of probabilistic evidence, whereas industry argues for higher

standards of proof. In summary, public interest groups err on the side of caution to protect public health, whereas polluting industries press for an unattainable standard of proof that science often cannot meet. Thus, the appropriate application of science is not used in judgments as to whether industry may continue their activities subject to litigation

v. **demanding that any observed odds ratio / relative risk between exposure and disease must be 2 or greater** before the study can be admitted to support expert testimony (e.g., the odds ratio for a population may be 1.5 and represent millions of people at risk in a large population or as in second-hand tobacco smoke that may have a large public health impact). This demand fails to recognize the public health importance of population attributable risk for prevalent exposures; while risk estimates may be low, the absolute number of affected people can be large.

INEP-SPECIFIC RECOMMENDATIONS

In order for physicians, practitioners, public health and biochemical researchers to speak out on Conflict-of-Interest and Disclosure (COI&D) issues with students, colleagues, peers, and the public through the media and the scientific literature, they must be aware of the above issues. INEP has identified several steps in the production of scientific information where COI can be arrested along with approaches for addressing and minimizing COI and disclosure issues. Specific templates/examples are provided in various Appendices (see also Appendices II, III and IV) that also include recusal of participants with COI from scientific Boards, Committees, and as advisors in Appendices XI, XVI, XVII and XVIII.

Along with these examples, INEP presents a suite of recommended actions that fall under the broader categories of identification, avoidance, disclosure, and recusal. Many of these recommendations are consistent with those of *A Consensus Study Report of the National Academies of Sciences, Engineering, Medicine* (2017)[58] and those recommended by the CR.

These recommendations should facilitate regulatory use, dialogues with stakeholders and policy-makers, as well as training of the next generation of scientists in public health. Although principles for addressing the adverse effects of COI can be universal, there are additional considerations for epidemiologists as they study communities/populations with a focus on maintaining and improving public health on a larger scale (i.e., regional, national and global). Principles originally intended for individuals are thus expanded to encompass population health.

1. Identification

In order to avoid COI, it is necessary to recognize it across the research continuum. Identification of COI-associated behavior can be described by both blatant and subtle activities that compromise or influence a scientist's objectivity. An individual's belief that their professional judgement or objectivity is unaffected by gifts, other economic incentives, career advancement/job security, or personal ties is not sufficient protection against a personal or professional COI. It is not necessary for COI to be definitively identified as a concern for it to be problematic if there is an appearance

[58] National Academies of Sciences, Engineering, and Medicine. (2017) *Fostering Integrity in Research*. Washington, D.C.: The National Academies Press.

or perception that professional judgement has been compromised due to COI. By becoming involved in a COI situation, the public's trust and confidence in a profession at large is diminished (Goldberg[59]).

INEP recommends that potential COI, and the appearance of COI, be identified through disclosure, not only by individuals themselves, but also by organizations, academic institutions, governments, other scientists, policy makers, and members of the media. As an example of industry disclosing payments to researchers, the Open Payments Database and other pharma disclosure databases from Australia[60] is provided. Identification of COI and its associated scientific misuse of epidemiological science can take place in several steps that include letters to an organization or journal editor, public comments or published letters to an editor, published commentaries, or more extensive reviews. Once identified, a journal, organization, or governmental body can consider the issues raised and take appropriate action. This critical first step of identification of COI is needed to prevent harm to both the integrity and function of science.

The specific case examples and, more broadly, the appendices provided by INEP can be used to identify patterns of behavior and methods used by those with conflicting interests. INEP also included epidemiology-specific techniques that have been employed to construct biased, misleading, or, at best, uninformative studies or commentaries. Both the specific case examples and the compendium of epidemiology-specific techniques included in this Position Statement can help identify the products and practices of those with COI concerns.

Many governing councils/boards may be comprised of volunteers. Thus, the enforceability of any of the recommendations, and even of professional ethics guidelines/codes of ethics may occur mainly through peer pressure and it has been suggested that "naming and shaming" of scientists with COI be part of peer pressure.[61] INEP provides tools for identification of potential COI and the mechanisms through which mischaracterization of science may occur so that appropriate actions can be taken.

2. Avoidance

Whenever possible, it is best to avoid situations that could result in a COI. Prevention is the analogous epidemiological concept for avoidance. The most extreme prevention remedy would be the sequestration or elimination of relationships between commercial industries and health professionals. However, INEP does not consider that to be a practical option under all circumstances. A similar position to that of ASHA is recommended along with the recommendation of enhanced identification and disclosure to inform and protect the public from the effects of COI, such as the generation of biased or inaccurate scientific products and to encourage recusal when appropriate.

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[59] Goldberg, DS. (2019) The Shadows of Sunlight: Why Disclosure Should Not Be a Priority in Addressing Conflicts of Interest. Public Health Ethics; 12(2):202–212.
[60] Parker L, Karanges E, and Bero L. (2018) Changes in the type and amount of spending disclosed by Australian pharmaceutical companies: an observational study. BMJ Open; 0:e024928.
[61] McComb, J. (1999) Name and shame the scientific fraudsters. Nature 398: 745.

For ASHA, avoidance does not mean that absolutely no non-wage benefits may be accepted from commercial and financial sources. It does mean that some are prohibited and that all should be scrutinized to ensure that no COI is introduced. INEP endorses the ASHA prohibitions as a starting point such that professionals should not accept gifts or benefits unless it can be clearly demonstrated that such gifts or benefits: (a) primarily contribute to the welfare of persons/communities being professionally served; (b) do not reasonably appear to motivate bias in professional judgement; (c) enhance one's professional knowledge and skills in serving the public; and/or (d) do not diminish the dignity and/or autonomy of any of the professions.

INEP notes, however, that individuals must carefully consider all circumstances surrounding the offer of a gift or an incentive, including the purpose of the donor, how the transaction may be viewed by impartial observers, and the potential impact on the practice of the profession. INEP notes that a number of policies relating to medical researchers ban the acceptance of gifts. Individuals must also be aware of ways in which their personal and family relationships, and other close personal associations, may potentially bias their judgements and motivate impartiality. INEP presents several steps presented by CRI and others for avoidance of COI or its appearance. Templates/examples specific for use in particular circumstances are provided in various Appendices (see also Appendices II, III and IV). In addition to the ASHA prohibitions listed above, INEP recommends that:

a. National and international official bodies should set up evaluation procedures that systematically orient funding towards research centers, researchers, and research activities with demonstrated commitment to competence and impartiality in assessing health effects.
b. Governments should foster the conduct of impartial research with the primary goal of discovering and communicating relevant evidence on factors that affect workers and population health.
c. The creation of independent research funds to which industry may be required to contribute as a buffer to direct influence that poses COI problems.
d. Governments should adopt and apply the Right to Enjoy the Benefits of Scientific Progress, as contained in the United Nations' International Covenant on Social, Economic and Cultural Rights. This action implies an obligation on government entities to create a research environment in which: (a) impartial and relevant scientific knowledge is advanced and disseminated without obstacle; and (b) biased reinterpretation of science or assessments of it that favor economically and politically vested interests is interpreted as interference with that right.
e. In order to prevent the use of biased or inaccurate science in decision-making processes and in assessments of health hazards and risks, published research should be fairly evaluated in the process of peer-review.
f. Research evidence that is used to inform policy should be evaluated according to criteria that are the consensus of the independent impartial scientific community and not the industry being evaluated.
g. Research sponsors as well as science, engineering, and technology publishers should ensure that peer-reviewers are those with sufficient information and knowledge of the field

of epidemiology so that they can discern techniques commonly used by those with COI to manipulate studies and results.

h. The rise of predatory publishing in journals, as well as in pre-print online platforms, without quality standards should be discouraged by avoidance both of their use and their citation by researchers, clinicians, academic and professional scientists.
i. Societies and journals should develop clear disciplinary authorship standards with substantive penalties for breaches of them.
j. When commentaries or scientific contributions are solicited by a journal to represent the state of the science for support or development of public health policies, the journal should follow the Lancet Commission Approach, which seeks to choose authors who are leaders in the field rather than non-independent published perspectives.
k. All professionals in public health should significantly improve and update their practices and policies to respond to threats to research integrity.
l. Research institutions should maintain the highest standards of research conduct. This requires extraordinary vigilance and care, including the need for firewalls between funding sources and the research questions being supported.
m. A research integrity advisory board should be established as an independent not-for-profit organization.
n. Scientists should raise their voices and are encouraged to contact International Organizations (e.g., ISEE and CR) when their independence is threatened in a way that impedes their freedom to conduct, publish, and communicate impartial research.
o. INEP should consider support for the call by Kassotis et al. (2020)[4] for an international body for hazard assessment of endocrine disrupting chemicals (EDCs) to sit within the World Health Organization (WHO) and be funded in a similar way to the International Agency for Research on Cancer (IARC). This arrangement would, according to Kassotis et al., “protect against undue influence from industry or other stakeholders". They assert that "An international organisation is likely to be freer of non-scientific constraints in suggesting regulatory actions than national organisations.”
p. All professional bodies should support scientists who are under threat for speaking the truth. Research institutions and federal agencies should work to ensure that whistle-blowers are protected and that their concerns are assessed and addressed in a fair, thorough, and timely manner.

3. Disclosure

When conflicting interests cannot be avoided, they must be transparent. No researcher is immune to the influence of her/his own biases in conducting and interpreting a study (see Appendices XIX, XX and XXI). Therefore, disclosure of her/his actual or perceived COI can serve to indicate the risk of influence to the science or conclusions presented. Many publications require disclosure statements from their authors (see Appendices XXII, XXIII, XXIV and XXV).

Disclosure can be a self-initiated action or be required (e.g., filling out a financial disclosure form is a requisite for serving on many panels). The goal is to honestly and completely provide personal and professional information that complies with ethic codes or provide transparency in funding sources, collaborative relationships, potential bias, or competing interests. Misrepresentation in a

disclosure statement by both errors of omission and commission can create ethical violation. Although full disclosure is necessary, it does not replace the need for scientific integrity.

INEP recommends universal disclosure of COI and potential bias in all peer-reviewed journals as necessary to protect the integrity of scientific discourse. The concepts of appearance of COI and actual COI vs financial and non-financial relationships should not be confused. The appearance issue can entail owning stock in a company whose product that scientist is studying for hazard potential. The scientist may not have direct say in the company's operations, but there is an apparent COI issue with stock ownership. The U.S. Government directs employees to divest their stock in such cases. Direct employment of a scientist by the entity whose product is under investigation is an actual COI. On the other hand, disclosure of non-financial relationships (e.g., activities that are not directly related to the entity whose product or activity is under investigation) has not been demonstrated as being of benefit. A COI declaration should focus on declarations of financial resources for the research activity, and on any relevant connection of the researchers with industry that might have a financial interest in the outcomes of the study.

INEP recommends more be done to create a uniform and universal procedure for disclosing any actual or perceived COI and hence of potential for bias in research and provides templates which may be used by anyone to evaluate and disclose potential conflicting interests at any stage of the research process. These stages include the problem definition/proposal stage, hypothesis formulation, stakeholder oversight/community engagement, research design, execution, analysis, interpretation, pre-publication conference presentation, peer-review, dissemination of results, statements made to media or policy-makers, serving on board and advisory committees, data-sharing, and data archival.

Scientific journals play a role in deterring COI through disclosure enforcement. In the absence of effective implementation, policies mean little and might have no effect. INEP recommends that scientific journals establish mechanisms, consistent with international best practices, that provide disciplinary action for editors, authors and peer-reviewers who fail to disclose financial conflicts and competing interests. Further, journal editors also must be accountable for taking action when COI is exposed post-publication. The ICMJE considers failure to disclose conflict-of-interest as scientific misconduct.

In regard to defense against the negative influence of conflicted people serving on professional Boards, Review Panels, or the like, INEP suggests steps be taken that include:

a. Those members nominating candidates for election (i.e., nominators) should be required to submit, along with their nominee details, a disclosure statement (see Appendix XXVI) revealing any actual or perceived COI. Nominators having a COI likely would need to be disqualified, along with their nominees.
b. Voting members of professional organizations must be fully informed of COI through having available disclosure statements reflecting any actual or perceived bias of nominees. The nominees must disclose any actual or perceived COI information at the time of running for election. This information must be included on the ballot for each of the nominees running for election (see, e.g., Appendix XXVI).

All public institutions that play a role in risk assessment and public health policy should systematically rely on advice that is transparent, credible and subject to public scrutiny. Regarding the role of government entities, INEP recommends:

a. States or Government entities should ensure transparency in funding research through mandating the open declaration of sources of funding when research is proposed, disseminated, and presented.
b. All decision-making bodies should set up effective COI disclosure policies for all persons involved in the process that recognize that the idea of avoidance would require that anyone with a COI should never be permitted even to influence other committee members in reaching their decision. Procedures should be in place to assess the effectiveness of these policies.

4. Recusal

Recusal is the action of withdrawing from situations when one's participation creates bias that could or be perceived to adversely influence professional judgement. For example, participation on a committee or board that makes decisions about the advancement, benefits, or distribution of resources to others may require recusal due to a COI. Recusal may also be required because of the professional's financial interests in, or personal ties to one or more of the parties involved in a decision. Unfair influence is avoided after disclosure of the nature of such an association and stepping out of the decision-making process.

In 2015, INEP developed its first Disclosure Statement and recusal was incorporated (see Appendix XXVII for how the expectation of recusal is handled). INEP reiterates its 2015 position. All elected officers must sign a disclosure statement to the effect that they will recuse themselves if, in their service to the said Board, Review Panel, or the like, they should ever find themselves in a COI, actual or perceived. If so, they must declare it at the inception and offer to recuse themselves from all circumstances that could in any way influence Board deliberations (see Appendix XXVII).

CONCLUDING REMARKS

In order to ensure impartiality, INEP intends to reduce the incidence of COI to the extent possible by sensitizing both students of epidemiology and career professionals to its nature and the need for disclosure. INEP anticipates that this effort will also sensitize entities that employ epidemiologists (e.g., universities, foundations, government agencies, or consulting firms), users of epidemiological tools and analyses (e.g., regulators), and members of Research Ethics Boards/Ethics committees/Institutional Review Boards that approve and oversee research. It would be beneficial to incorporate this document into the curriculum of (1) graduate training programs in the health sciences, and (2) medical schools.

INEP's Position Statement should also serve to increase public awareness of specific practices and activities that constitute a COI and that can influence the interpretation of scientific reports. As a professional position, INEP's Statement should also help researchers and practitioners of epidemiology to reflect on and evaluate their own biases in conducting their work. INEP's Position

Statement should be promoted by its member organizations by posting and disseminating it via their respective websites and facilitating discussion within each of their organizations.

INEP anticipates that entities employing epidemiologists (e.g., universities, government agencies, foundations, and consulting firms) should be positively influenced as they consider the nature of their own various sources of funding and funding to generate data and/or analyses on which they rely that can result in a COI. Members of Research Ethics Boards/Ethics Committees/Institutional Review Boards that approve and oversee research are also expected to benefit from this Position Statement.

APPENDICES I–XXVII

Procedures and forms provided as appendices to this Position Statement are included for example purposes only. Many others exist through a search of the web [e.g., COI Policy for Cochrane Library Content (2020)]. INEP does not necessarily endorse any of those provided or referenced herein. INEP member organizations are encouraged to adopt or adapt them for application at each step in the advancement of knowledge. In so doing, the overall recommendations contained in this Position Statement, namely the need for **identification**, **avoidance**, **disclosure** and **recusal,** are to be borne in mind.

APPENDIX I: INEP BOARD ENDORSEMENTS, ABSTENTIONS, AND NON-VOTING MEMBERS

This Position Statement was unanimously approved by the INEP Board on 16 September, 2020. By 24 December, 2020, of INEP's 24 member organizations, six of which are Associate Members, the 50% threshold of endorsements by the 18 Member Organizations with Board voting rights was achieved as per their own respective endorsement processes. The lower section indicates member organizations that have yet to vote. This Appendix will be updated with member organization votes of endorsement or abstention received after 24 December, 2020.

Endorsements (Member Organizations) n = 12:

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
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
SAAPHI	Society for the Analysis of African American Public Health Issues
SEE	Spanish Society of Epidemiology

Endorsements (Associate Member Organizations) n = 2:

ABRASCO*	Brazilian Association of Public Health
EOM*	European Society for Environmental and Occupational Medicine

Abstentions (Member Organizations) n = 2:

DGEpi	German Society for Epidemiology
RSPH	Royal Society for Public Health

Abstentions (Associate member Organizations) n = 1:

AAP SOEPHE* American Academy of Pediatrics Section on Epidemiology, Public Health and Evidence

Yet to vote n = 7:

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

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* Associate Member Organizations

APPENDIX II: BRITISH MEDICAL JOURNAL (BMJ) POLICY

(**Access here**) *See also Appendix XXIV from the BMJ. The two Appendices are complementary.*

BMJ is committed to ensuring the independence and integrity of our content, products, and services. We strive, therefore, to be transparent about any interests that our users, customers, and partners might want to know about. This policy on declaration of interests applies to everyone involved in the conception, creation, and delivery of our content, products, and services.

1. What interests should I declare?

We want to hear about interests that might conflict with the work you are doing or have been asked to do for BMJ. A conflict of interest arises when a person has a personal or organisational interest that may influence or appear to influence the work they are doing. Usually this is a financial interest, but it may also be non-financial.

Above all we want transparency about any personal or organisational interests that might be seen as a conflict of interest in relation to the task a person is being asked to do for BMJ.

Conflicts of interest are often unavoidable, and should be managed as far as possible rather than prohibited. But some interests may be so conflicting that the individuals involved should not do the task the BMJ needs doing.

The examples given in this document are not an exhaustive list. Individuals should ask themselves if there is anything that may strongly bias their judgement and potentially preclude them from performing the task requested of them, as well as anything that someone using BMJ products and services might want to know, or that might cause embarrassment or reputational damage if discovered after the event.

We ask people to be as clear and specific as possible about the activities, relationships, and views they are declaring. We may ask for more details about any declaration. We would want to know, for example, what honorariums were for and how much they were for. In declaring travel expenses, we would want to know the task that was carried out during that travel.

To make things manageable we would like to know about interests in the 36 months before the declaration and those known to be going to occur during the next 12 months.

2. How we categorise declaration of interests

We categorise declaration of interests into four main areas:

2.1 Personal financial interests

A personal financial interest is considered present when payments are made directly to an individual, whether as a salary or as fees or honorariums; or where an individual receives benefits from a third party who is not their main employer, such as a fellowship, equipment, writing or administrative assistance, or

travel and accommodation expenses; or where an individual owns stocks and shares, patents, or other assets.

Examples include:
Employment
Paid consultancy or directorship
Ownership of stocks and shares
Patent ownership or applications
Paid membership of speaker panels/bureaus and advisory boards
Acting as an expert witness
Being in receipt of a fellowship, equipment, writing, or administrative support
Travel and accommodation expenses
Writing or consulting for a medical education, promotional or communications company.

We do not consider personal financial interests to be present in the case of assets over which individuals have no control, such as unit trusts, occupational pension funds, and accrued pension rights.

2.2 Organisational financial interests
An organisational financial interest is said to exist where the interest belongs at arm's length to the individual – for example, where payments are made to the individual's organisation rather than to their own bank account.

Examples include:
Research grants
Funds for staff or department

2.3 Non-financial interests
Non-financial interests can take many different forms, including personal or professional relations with organisations and individuals. Those that we want people to declare are unpaid positions that might have a bearing on the product or service being delivered by BMJ. We would also want to know about strongly held beliefs where they are relevant to the task in hand.

In addition, we encourage people to declare other personal interests that they consider may be a conflict of interest in the context of the task they are being asked to perform for BMJ.

Examples include:
Unpaid officership of advocacy, charity, non-governmental organisation, or relevant professional group
Unpaid membership of a guidelines panel
Unpaid advisory positions in commercial organisations
Personal relationships with authors or editors of material, including having held grants, co-authored articles or papers, or worked together.

2.4 Interests of related parties
Conflicts of interest may also arise where a related party (spouse, partner, or other close family member) has a financial or non-financial interest as described above that could be seen to conflict with the task a

person is being asked to do for BMJ.

Examples include:
A spouse holding stocks or shares or being on the board of an organisation that might be affected by the task the person is doing for BMJ.

3. When will you be asked to make declarations of interest?
We expect people to declare their interests before taking up any work for BMJ or entering into a contract with us for your services.

Where we are recruiting new staff, a declaration of interests will be part of the job application.

If we invite you to join an advisory board, or commission an article, lecture, or peer review report from you, we will ask you to declare your interests at the first approach in case there are conflicts of interest that preclude you from accepting the invitation.

Articles submitted for consideration must be accompanied by a completed declaration.

BMJ staff and members of advisory boards will be asked to review their declarations of interests annually (for staff this will be at the time of appraisal).

4. Dealing with declarations of interest
In most cases disclosure will be sufficient, but in some cases an interest may be too conflicting. These are most likely to be current financial relationships or contractual arrangements that appear to prevent an individual from providing an unbiased expert judgement, such as where a person has signed a contract in which he or she agrees to be paid for advocating the opinion of that organisation or company. Any such conflicts would be discussed with the individual who has disclosed them by the person who has asked them to do the work for BMJ.

Decisions about whether or not an interest disqualifies the person from taking on a particular task for BMJ will be taken by the relevant senior staff member. For BMJ staff this would be the person that they report to.

There would be a right for anyone considered to have a conflict of interest sufficient to preclude them from working with BMJ on a particular task to appeal to the head of the relevant department.

If a full declaration was not made at the time and a conflict of interest comes to light after the event, BMJ reserves the right to retract any content affected by this conflict. BMJ may also seek to terminate contracts or employment affected in this way, and may choose not to work with the individual in the future.

5. Who should declare?
All of the following people are asked to declare their interests before working for or undertaking a task for BMJ
● Members of staff

● Members of BMJ board
● Editors in chief of BMJ journals and products
● Members of BMJ advisory boards
● Consultants, contractors, and freelancers producing material for BMJ products and services, authors, series editors, peer reviewers.

We also encourage our partners and the co-owning societies we work with to use our declaration of interest policy and forms.

6. What happens to declarations?
Whenever possible, we will publish declarations of interest statements alongside the material to which it relates: at product level on the relevant website for senior staff, board members, and advisers or otherwise at the level of the article, module, or event. These published statements may comprise the full declarations, or summary statements with full declarations available on request.

Speakers at BMJ Masterclasses or conferences will be asked to show a slide summarising their declaration at the beginning of their talk.

We will review staff, board member, and adviser declarations of interest annually. Signed declarations from BMJ staff will be kept by the Human Resources department in accordance with our information governance policy.

Where material is peer reviewed, requests for declarations will be sent to the peer reviewers, and editors will send any author declaration of interest statements to the peer reviewer.

BMJ has regular brand integrity meetings where it will review declarations of interest policies and audits of decisions.

Declarations of interest are kept on file in accordance with our information governance policies.

Last amended March 2014

BMJ Group declaration of interests statement

Please complete the declaration below. You may complete and return this form electronically in Word format – a physical signature/hard copy is not required.

I have read and understood the BMJ Group policy on declaration of interests and declare the following interests: [list them or state "none"].

Name: **Date:**

Manager sign off (for internal use)
Comments:
Review date
Name: Date:

[For internal use]

Guidance on how to apply the BMJ Group declaration of interests policy

This policy applies to people involved in the conception and creation of content and services or making major business decisions on that content or services.

Who is responsible for getting the declaration of interests?

1) Products and services (boards and advisors): the editorial director of the product of service, or his or her delegate
2) Content or events (authors, speakers and reviewers): the commissioning/handling editor
3) Advice: the person getting the advice (e.g., an editor)
4) Staff: HR is responsible for getting declaration of interests when a new staff member arrives and the line manager is responsible for existing staff. Staff will be told to read the policy and (in line with the Business ethics policy) to inform their manager at any time if they have any personal interest which might affect, could be seen to affect or leave them open to allegations that this could affect their impartiality about the work they are doing.

How/when will the declaration be obtained?

1) Product or service – at the time of convening of boards and advisory groups, and when new members are recruited
2) Content or event – at commissioning or (for research and other unsolicited content) at submission
3) Advice – on requesting the advice
4) Staff – as part of their application for the job.

What should be done with the information?

The person responsible for getting/receiving/using the information provided in the declaration should ask themselves: does anything in this declaration compromise the person's ability to do the task that needs doing—or could be perceived as compromising this. If the answer is yes or possibly, the responsible person should discuss it with their line manager or other appropriate person. Practices may differ between products and department – the point is that there should be some discussion about this before a decision is made and there should be some documentation of the decision, the decision-making process, and the reasons for the decision.

What constitutes "a conflict of interest too far" will differ according to the task the person is being asked to do. As far as possible the types of interest that we have agreed constitute a "conflict of interest too far" will be listed within the quality indicators for individual products and services. At a Group level they would be anything that interferes with the unbiased output of the BMJ Group. This is likely to occur if the person declares a current financial relationships or contractual arrangements that appear to prevent him or her from providing an unbiased expert judgement, e.g., where a person has signed a contract in which he or she agrees to be paid for advocating the opinion of that organization or company, or where he or she is in receipt of significant personal financial benefits.

Where will the declaration be published?

1) Product or service – on the relevant website

2) Content or event – alongside each article/module or at the beginning of each talk
3) Advice – to those receiving the advice (e.g., to authors and editors in the case of reviews)
4) Staff – to line managers and department heads, and on the relevant website for staff making editorial or business decisions (generally staff in grade 4 or above).

How often should declarations be reviewed?
1) Product or service – annually
2) Content or event – for content that is formally updated: at every updating
3) Advice – at least annually for on-going advisors. (For advisors who sit on boards or committees updating declarations should be an agenda item at committee meetings at appropriate intervals, but should be considered formally at least annually)
4) Staff – at every annual appraisal. Staff have an obligation to tell their manager at any time if the information changes.

What happens if a person fails to make a full declaration of interests?
If we are alerted to the fact that someone may have an undeclared and potentially conflicting interest, this will almost always require careful handling. The first step is almost always to raise the concern with the person involved and ask if the conflict does exist and for their reasons for not declaring it.

Based on their response various actions may follow. Their declaration of interests may simply need to be updated or a clarification notice or response published. Where a conflict is substantial and risks the integrity of the content, product, or service, the person is likely to have to be removed from undertaking the relevant task and articles or other content they have been working on may need to be retracted. Such cases must be discussed with senior staff (the line manager in the first instance) and records kept of all decision making.

When documenting the decision-making process care should be taken to only record the facts of the case under review and to avoid any speculation or making any personal comments about a person's declaration of interests.

FG, LD, RM December 2012

APPENDIX III: DISCLOSING A CONFLICT OF INTEREST

(Access here)

Employees in the BC Public Service are required under the Public Service Oath Regulation and Standards of Conduct to avoid conflicts of interest. Employees must arrange their private affairs in a manner that will prevent **actual, perceived** or **potential** conflicts of interest from arising. Employees also have an obligation to proactively disclose information to their manager (or ethics advisor) regarding circumstances that may give rise to an actual, perceived or potential conflict of interest so that any such conflict may be assessed and appropriately addressed. Effectively managing conflicts of interest is one of the primary ways that public confidence in the integrity of the public service is fostered and maintained.

APPENDIX IV: GUIDELINES FOR COMPLETING THE STATEMENT CONFLICT OF INTEREST AND DISCLOSURE OF CONFLICT OF INTEREST

(Access here)

(Note: This document has links to definitions and scope that may be helpful.)

The **Regulation on Conflict of Interest** applies to all members of the University community. Subject to Section 8 of the policy, "Member" means any member of the McGill University community who:
I. is an employee of the University;
II. holds office under the University Charter or Statutes or who serves on any body or committee of the University;
III. holds office on the board of an institution affiliated with McGill University or who serves on a committee established by such board; or
IV. is an appointee (including a volunteer) of the University.

See the **Recognizing Conflicts** document on the Secretariat web site for some illustrative examples of situations which might reasonably be judged to give rise to an apparent or actual conflict of interest, of either a financial or a non-financial nature.

APPENDIX V: METHODS APPLIED IN CONDUCTING THE SEARCH OF THE LITERATURE

A search of the literature was undertaken under the leadership of Leanne Lindsay following the **PRISMA guidelines**.[62]

Literature Search: We sought published, English-language reports of studies conducted with a focus on conflict-of-interest (COI). We excluded all studies that neither focused on COI nor fit within our framework. Our search covered original articles as well as grey literature including conference proceedings. There were no restrictions with respect to area of science or field of study because COI spans most if not all applied science disciplines.

Only articles published in English since January 2004 were considered because a previous review had been published on COI which was conducted prior to 2004. Types of articles included were: cross-sectional, case-control, cohort studies, review articles, commentaries, and other grey literature and communication pieces.

Inclusion Criteria

1. Articles must be written in original English
2. Should be focused on conflict of interest in science
3. Can include gray literature as well

Exclusion Criteria

1. Language other than English
2. COI reported as part of author instructions, and not as part of paper or abstract

Medline (Ovid), PubMed (NLM), and Embase (Ovid), were searched. A combination of MeSH terms (see Appendix IV) and title, abstract, and keywords were used to develop the initial Medline search and then adapted to the other two databases. The date of the last search was December 31, 2015. The literature collection was updated with subsequent relevant materials as we received them, either individually discovered, or referred by key informants. Additionally, selected bibliographies of relevant articles were examined for citations of potential relevance and these were added to the collection.

We used Endnote to store all citations found in the search process and to check for duplicates. The abstracts that were obtained as part of the literature search were reviewed by 4 of us (LL, BR, SA and CLS) in sets of 2, to check if they met the inclusion criteria and could be considered to be relevant to the position statement.

Each of the four reviewers independently screened assigned titles and abstracts, blinded to authors and journal titles, using an Excel workbook designed specifically for this step in the review process. Data from both were then compiled into a single Excel workbook to check for concordance and discordance.

[62] Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, Clarke M, Devereaux PJ, Kleijnen J, Moher D. (2009) The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ 2009; 339.

Discordant items were then reviewed independently with help of a third reviewer. A similar process was repeated by the other two authors.

Abstracts coded as ‘‘no’’ by both independent screeners were excluded; similarly, abstracts coded as “maybe” by both independent screeners were retained. Abstracts coded as ‘‘maybe’’ or “no” by only one reviewer were pooled together as discordant and included/excluded based on mutual consensus. The PRISMA flowchart gives an overview of the screening process from the initial screening to final text review.

Results:

We used two approaches/methods for generating our literature. Our primary method was based on the collection of articles, editorials, communications, grey literature, and other documents which were shared by our colleagues from across the globe. Based on mutual discussion, these articles were broadly classified into the categories and sub-categories as follows:

COI&D Editorials: Editorials, Opinions, Viewpoints, Essays relating to:

- Environment vs. Industry
- Funding in Research
- Medicine and Pharmaceuticals
- Scientific Integrity

COI&D Research Articles: Peer-reviewed literature relating to:

- Corporate ties in public health
- Environment vs. Industry
- Medicine and Pharmaceuticals
- Scientific Integrity

COI&D Communications:

- Emails
- Published Letters

COI&D Grey Literature and Non-Peer Reviewed Reports:

- NGO Reports
- Newspaper, Popular Magazines
- Professional Society Communications
- TV, YouTube, Blogs

All these were placed in a Dropbox folder, which was shared among the four reviewers. The categorization of this Dropbox was independently reviewed by Dr. Daniele Mandrioli, and minor changes were made based on his recommendations. The two teams of two reviewers each, (CS and LL / SA and BR) were independently allotted equal sets of abstracts to review. Each group member was responsible for

independently reviewing the abstracts and combining the responses on completion of their joint reviews. After the process of screening and resolution of discrepancies by both groups, abstracts coded as "maybe" were considered appropriate to the literature collection and were added.

Articles were first assessed based on the abstract. Full articles of studies were reviewed for relevance and those that were found not to fit the inclusion and exclusion criteria were removed.

COI items were renamed in the Dropbox by author name and year of publication to improve their accessibility. Also, a list of references was provided in each subfolder. This was for ease of viewing documents within the Dropbox. The reference lists were to be updated once all Dropbox categories and documents were finalized, but this was not done, recognizing that this effort served specifically as a survey to scope the topic from the perspective of epidemiology. We have provided this information in the event that others might wish to further explore the literature contained in the Dropbox.

APPENDIX VI: MeSH TERMS USED IN LITERATURE DATABASE SEARCHES

academics and institutes/economics
biomedical research/ethics
biomedical research/legislation and jurisprudence
conflict of interest*
corporate ties
disclosure*
drug industry/economics
drug industry/ethics
drug industry/legislation and jurisprudence
editorial policies
ethics
ethics in medical science
fraud
industry or corporate funding
international organizations
international variation
moral dimension of bioscience
organizational culture
organizational policy
outcome research evaluation
peer review, research/ethics
peer review, research/legislation and jurisprudence
periodicals as topic/ethics
policy
policy-making
politics
public health/economics
public health/ethics
public health/legislation and jurisprudence
publication bias
public-private sector partnerships/economics
public-private sector partnerships/ethics
public-private sector partnerships/legislation and jurisprudence
publishing
research design
research misconduct
research support as a topic/economics
research support as a topic/ethics
research support as a topic/legislation and jurisprudence
science/ethics*
science/policy
scientific and medical journals and publishing
scientific misconduct/legislation and jurisprudence
scientific societies and professional associations

APPENDIX VII: DROPBOX OF LITERATURE SEARCH ITEMS BY CATEGORY

(Access source documents here)

Categories in Dropbox	Dropbox of Referred Items	Literature Search Articles	Additions 1/2/2017	Items added 5/16/2017	Row Totals
COI Big Data	8	0	0	0	8
COI Communications (published letters, news, corrections in peer-reviewed journals)	20	0	8	2	30
COI Conference Debates on Disclosure, Webinars	7	0	0	0	7
COI Disclosure Forms – examples found for different contexts	30	0	4	0	34
COI Editorials, Opinions, viewpoints, Essays					
• Comment of a broad nature	3	54	3	8	68
• Environment vs Industry	24	8	5	3	40
• Funding in Research	25	21	0	0	46
• Medicine and Pharmaceuticals	29	91	0	0	120
• Scientific Integrity	25	12	3	2	42
COI Non-peer reviewed reports and documents/Grey Literature					
• Center for Public Integrity, NGOs and related entities (incl. Center for Science in the Public Interest, Health & Environment, Expose Facts, Retraction Watch, RightOnCanada, Professional Ethics Report (PER) of the AAAS, etc.)	37	0	0	0	37
• Newspapers / Popular magazines (like Forbes, The New Yorker, Time, Newsweek, New Republic, etc.)	29	0	10	5	44
• TV / YouTube / Respected BLOGS	12	0	10	1	23
• Professional society/assoc. communications/official newsletters, internal memos, press releases	34	0	2	0	36

COI Policy Documents, Books, Chapters, Training Materials • COPE Documents • Others (incl. National and International Ethics Codes and Guidelines)	 10 47	 41 0	 0 4	 0 0	 51 51
COI Research Papers • Corporate Ties in Public Health/Academia • Environment vs Industry • Medicine and Pharmaceuticals • Scientific Integrity	 14 8 3 17	 34 5 108 13	 0 8 0 2	 0 2 0 1	 48 23 111 33
Total (852)	382	387	59	24	852

APPENDIX VIII: ISEE GUIDELINES ON FINANCIAL SUPPORT

(Access here)

(Approved by ISEE Executive Council July 5, 2018)[63]

General considerations

ISEE will develop and regularly update plans for soliciting donations, contracts, or grants to help meet the mission of the society. The overarching considerations shaping ISEE's acceptance of all donations, contracts or grants are:

- The ISEE will solicit and accept donations, contracts or grants for projects and activities that are consistent with its mission.

- Acceptance of donations, contracts or grants must enhance, and shall not impede, the ISEE's ability to act in the best interests of the public health.

- Sponsors will have no influence in the activities or decisions of the Society.[64]

- The ISEE's name, logo and other intangible intellectual assets must be protected in the context of acknowledgement.

The ISEE will publicly acknowledge its gratitude for the support from and recognition of its generous contributors, whether they be a for-profit or non-profit corporate/business/other entity, or an individual.

[63] The ISEE guidelines are based on the IJPC-SE guidelines. Part I: Guidelines for soliciting financial contributions, contracts or grants; Part II: Principles for guiding the IJPC-SE when considering any potential financial contribution, contract or grant, https://www.dropbox.com/s/m881oy5bmebub0v/IJPC-SE_Financial_Contribution_Policy-June_8_2015_revision_approved_June_26_revised_Sep_16_2015.pdf?dl=0.

[64] This statement would be shared with the sponsors when the money is being raised and noted in any public acknowledgement of the sponsors.

APPENDIX IX: FINANCIAL CONFLICT-OF-INTEREST DISCLOSURE FORM WHEN SUBMITTING ABSTRACTS FOR PROPOSING SYMPOSIA TO THE ANNUAL ISEE CONFERENCES

(Access here)

Authors must disclose actual and/or potential competing financial interests from the last 3 years related to the submitted abstract or symposium. Competing financial interests include but are not limited to: grant support; employment (past, present, or firm offer of future); patents (pending or applied); payment for expert witness or testimony; personal financial interests by the authors, immediate family members, or institutional affiliations that may gain or lose financially through reporting of the communication; and forms of compensation, including travel funding, consultancies, board positions, patent and royalty arrangements, stock shares, or bonds. Diversified mutual funds or investment trusts do not constitute a competing financial interest. Authors should carefully examine the wording of documents such as grants and contracts to determine whether there might be an actual or potential competing interest.

Required text for anyone submitting an abstract or symposia to the conference from the above link:

1. All authors of this presentation have read the definition of Financial Conflict of Interest and

certify:

_ There are no financial conflicts of interests to declare

OR

One or more of the authors <specify the names> have the following financial conflict-of-interest to declare relevant to activities related to the topic of this presentation:

__ Research Contracts or Employment

__ Paid or Unpaid Consulting

__ Stockholder in or industry ownership

__ Other (please specify):
……

2. List ALL funding and employment sources related to this work

[Some examples on how to list funding:
Smith J was partially funded by (Department of Health, Research Institute of the Environment) grant #RX2034, or employed full time by the University of The West Side

The above should be included as a stand-alone slide number 2 after the title slide in an oral presentation, or printed at the lower right or left corners of the poster.

Prevention of conflict-of-interest[65]

The ISEE is required to have a disclosure process to identify and resolve any conflict of interest before donor support is applied for and/or accepted. The process includes the submission and review of applications for proposed contributions of funding, which includes the written disclosure of any actual or perceived conflict-of-interest.

At the discretion of the ISEE Council, donations will not be accepted from industries and other entities:

1) with harmful impacts on public health or the environment, or

2) that suppress or distort the scientific evidence regarding environmental pollution and its adverse health effects.

The list of excluded industries will be updated every 5-years or earlier if a need arises (Annex A). All other entities will be considered on a case by case basis and voted on by the ISEE Council after receiving recommendation from the ISEE Ethics and Philosophy Committee and Policy Committee.

The ISEE Council will develop additional text on procedure for considering and accepting financial contributions to be followed by the Society, in particular in relation to funds supporting organization of ISEE conferences.

Annex A
The list of industries and other entities from which donations should not be accepted by ISEE (version June 2018)

1. Tobacco industry
2. Firearms industry
3. Pesticides industry
4. Asbestos industry
5. Coal and oil industries

[65] A conflict-of-interest is an affiliation or relationship, usually of a financial nature or professional and/or personal nature, with a commercial interest, organization or entity whose financial or other relationship with the ISEE could influence or be perceived to influence the impartiality of the Board or other ISEE Committee in its decision-making in a manner that could advance the interests of the funding or other entity for reasons other than scientific or the public good. Such a relationship constitutes a conflict-of-interest because it might bias an ISEE Board/Committee member's ability to objectively participate in decisions before the Board/Committee. A conflict-of-interest may be actual or perceived. If a person might perceive a conflict-of-interest, then a conflict-of-interest exists. If there is potential for a perceived conflict-of-interest, then it must be treated the same as if a conflict-of-interest actually exists.

APPENDIX X: DECLARATION OF FCOI AT START OF POWERPOINT SCIENTIFIC CONFERENCE SLIDES – DECLARATION OF CONFLICT OF INTEREST

The Congress Programme Committee requests speakers, abstract presenters, judges and chairpersons to disclose potential conflict of interests regarding the topics of the presentations during the introduction of the session for chairpersons or on the first slide of the presentation for speakers. This will allow the audience to take potential conflicts of interest into account when assessing the objectivity of the presentation. A potential conflict of interest may arise from various relationships, past or present, such as employment, consultancy, investments and stock ownership, funding for research, family relationship, etc.

My Declaration of financial conflicts of interest :

_ I have nothing to declare
_ Related Industry Research Contracts or Employment
_ (Paid or Unpaid) Consulting for this or a related industry
_ Stockholder in or ownership of this or a related Industry
__ Other (please specify: .....)

Add paid or unpaid consultation or expert witness work. Serving as a consultant or expert witness can be an important public health function, but some academics do it pro bono or unpaid to avoid any financial conflict-of-interest. It should be transparent that somebody did the consultation or served as an expert witness, but it should also be clear whether they had financial conflicts.

APPENDIX XI: ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF CANADA (RCPSC)

The Royal College of Physicians and Surgeons of Canada requires all **presenters** and **members of Planning Committees** to complete this Disclosure of Conflict of Interest form.

(Note: This form is accessible in the Dropbox)

An example of the RCPSC forms is accessible here.

APPENDIX XII: COLLEGIUM RAMAZZINI STATEMENT ON PRINCIPLES FOR SAFEGUARDING THE INTEGRITY OF RESEARCH IN OCCUPATIONAL AND ENVIRONMENTAL HEALTH

http://www.collegiumramazzini.org/download/2017_10_20_Unpublished_Integrity_Statement.pdf

The Collegium Ramazzini is an international scientific society that examines critical issues in occupational and environmental medicine with a view towards action to prevent disease and promote health. The Collegium derives its name from Bernardino Ramazzini, the father of occupational medicine, a professor of medicine of the Universities of Modena and Padua in the late 1600s and the early 1700s. The Collegium is comprised of 180 physicians and scientists from 35 countries, each of whom is elected to membership. The Collegium is independent of commercial interests.

Scientific research in occupational and environmental health may directly, or indirectly, provide input to governmental decision-making and regulatory processes. This research must therefore provide an evidence base that is as valid and accurate as possible. Accurate information on risks and hazards is essential for effective rule-making and for the prevention of occupational and environmental disease and premature death.

Strict adherence to the principle of scientific integrity is critical to the generation of valid and accurate evidence on occupational and environmental hazards. Scientific integrity in occupational and environmental health is based on the principle that research is conducted as objectively as possible and that it cannot be compromised by special interests whose goals are neither to seek truth nor to protect human health. Protecting the public's health, preventing disease and promoting well-being must be the clear and unambiguous goal of all research in occupational and environmental health.

Conceding to any influence that detracts from the principle of scientific integrity in occupational and environmental research is, by definition, unethical, and has the potential to produce biased scientific assessments that fail to serve the public interest or protect public health.

In recent decades, the Collegium Ramazzini has noted a growing imbalance between the level of funding available for research in occupational and environmental health that derives from public sources and is independent of commercial interests, and the level of funding that is dependent upon, and too often serves commercial interests. The Collegium Ramazzini notes on the basis of long experience in many countries that research supported through the public purse, especially if held accountable to public review and scrutiny, is much more likely to produce accurate unbiased results than research that is hampered or corrupted by funding from commercial interests.

The Collegium Ramazzini expresses its grave concern that scientific integrity is violated through research that is supported by commercial interests, whose primary concern is often to protect markets for hazardous products, and that this phenomenon is rapidly expanding. The impact of corrupted science on legislation, policy-making, standard-setting and legal proceedings is seen

with greater and greater frequency. This trend should alarm authorities, workers, consumers and the public at large.

Many examples exist demonstrating how powerful interests have infiltrated and distorted the scientific literature. Their role is to foment confusion and manufacture unfounded doubt in the minds of both the public and policy-makers. The decision-making processes in assessing hazards, risks and the need for preventive actions regarding tobacco, asbestos, climate change and many others serve as examples of such malfeasance. Their intent is to promote self-interest regardless of the cost to health and welfare of the public. Far too often, early warnings of occupational and environmental hazards are intentionally delayed or dismissed through deliberate techniques applied to sow confusion, make certainty appear controversial with the main purpose being to maintain the status quo and protect business operations.

This trend toward research funding from commercial interests that is unacceptable both scientifically and morally reflects the ever-growing domination of the financial world, which imposes enormous pressure on companies to not make profit and reinvest it in order to give a future to the company and its workers, but instead to make the highest possible short-term profit in order to reward shareholders.

The relative lack of independent funding and/or lack of access to data poses grave dangers for the future of impartial research conducted in the public interest. This imbalance in funding creates a risk that many scientists, in their search for funding, may make opportunistic or naïve compromises with companies that have an interest in particular research outcomes.

Several complementary strategies have been adopted by entities with a commercial interest in the outcome of public health research to sow confusion by creating artificial controversy where there is no scientific basis for it:

– Establishing principles of so-called ‘good epidemiological practice’, as was done in the nineties by ECETOC (European Center for Ecotoxicology and Toxicology of Chemicals). These can intentionally be misused to dismiss studies that provide reliable evidence of harm as irrelevant for decision-making processes.

– Promoting impossibly difficult criteria for establishing causal relationships. For example, with these criteria it could be argued that evidence of adverse health outcomes can be disregarded if not based simultaneously on epidemiological studies and on understanding the underlying mechanism of toxicity, or that laboratory evidence without epidemiological confirmation can be disregarded. The result is that regulatory agencies are under intense pressure not to classify a substance as harmful even if it is obvious that it should be.

– Offering scientists generous resources for research, but with restrictions on publication rights. This serves to absorb research capacity and control the results. Except in very special circumstances, the results of public health research should be published, and research funding that forbids or restricts publication should be prohibited.

– Designing research which does not fit with the principles of science, resulting in manipulated research results. There is a spectrum of commercial-interest research which can include, at one end, well conducted and appropriately interpreted research, and, at the other extreme, complete fraudulent research or publications. Under-powered, 'negative' epidemiological studies, dilution of exposed groups by including non-exposed individuals in exposed groups in environmental/occupational health studies are as common as over-powered 'positive' studies usually in the context of new drug testing.

– Creating industry-driven scientific journals which can steer the perception of 'the evidence' by favouring studies that underplay or deny risk, giving supposed scientific credibility to editorials or poorly designed reviews that can be used in litigation to defend industry and allow publication practices that by pass acceptance norms for scientific integrity.

Unfortunately, despite the lack of scientific credibility, research manipulation strategies may negatively affect decision-making processes in the field of health protection. Not only at the level of research activities, but also at the level of the decision-making process itself, there is a growing influence from industry that compromises the credibility and reliability of the process:

– Making public statements that well-established facts are controversial. Providing intense media exposure for industry-sponsored studies to 'disseminate' findings and create a different public narrative than if the evidence were impartially reviewed.

– Organizing lobbying and infiltration at every level of decision-making relevant to occupational and environmental health.

– Conducting ad-hominem attacks on scientists who have published findings suggesting hazardous associations with industry products or processes.

– Paying scientists for consultancy and for representing industrial interests in science and policy fora often without disclosing their ties to industry.

– Sponsoring pseudo-scientific think tanks, or special issues of journals that present the findings of a series of manipulated studies. Another example from Juan: Sponsoring studies directly for eventual publication in the peer reviewed literature.

Attempts to counter-balance the influence of commercial interests on the integrity of research in occupational and environmental health may be possible at several levels. The following steps can be taken to decrease and expose such influence and help inform policy makers:

- *Conflict-of-interest declarations.* Conflict-of-Interest disclosure policies are considered to be a necessary (but insufficient) tool to identify and address the growing grip of commercial interest on occupational and environmental health science. There are quite a few similar but not congruent definitions of conflict, and related incongruent practices. We are mainly concerned with conflicts that undermine the accuracy, reliability or truth of biomedical research results including the problem definition, research design, execution, analysis, interpretation, or dissemination of results or statements made to media or policy makers.

Conflict-of-interest declarations should therefore focus on declarations on financial resources of the research activity, and on any relevant connection of the researchers with industry that might have a financial interest in outcomes of the study. A detailed questionnaire could reveal unmistakably such conflicts and be obligatory for all authors and participants in scientific assessment bodies, and published in their reports. Such conflict disclosure should not be diluted by a summing up of artificial and theoretical conflict-of-interest considerations of another kind.

Effective enforceable disclosure policies must play an important role in protecting peer review journals, peer review panels or government entities against becoming unwitting agents of misinformation. However, effective COI disclosure policies are necessary but not in themselves sufficient.

- *Scientists adherence to ethical principles.* Ethical research principles may be related to many aspects of research such as conditions of data collection and storage and of access to data; impartiality in treating data; striving for objectivity, including description of findings in such a way that decision makers as well as public opinion can perceive the extent of uncertainty of findings and apply properly the precautionary principle if that is the case; communication aspects and research authorization procedures. The evaluation of the respect of these ethical principles should equally apply to all research activities in the field of occupational and environmental health, no matter who initiates, conducts or finances it.

  Failure to enforce ethical principles is not acceptable. Currently, the control and enforcement of, or de facto obligation to comply with such principles is often stricter for publicly funded research than for private driven research. This is a distortion of the balance between research often driven by commercial interest and research mostly driven by health protection concerns, to the detriment of the latter.

- *Funding.* There is a growing discrepancy between the capacity of impartial research and the need for addressing old and new challenges in occupational and environmental health going from asbestos to manmade mineral fibers (MMMF), from lead to endocrine disruptors, from diesel exhaust to nanoparticles. It is the responsibility of governments to foster the conduct of impartial research of which the primary goal is to discover and communicate relevant evidence on factors affecting population health. Failure to promote such efforts will adversely affect decision-making policies and practices in occupational and environmental health. The creation of independent research funds to which industry must contribute may be a partial solution to this problem.

- *Decision-making processes.* It is not possible to eliminate the production of all bad or misleading science. But it is possible to prevent use of the outcomes of bad science in decision-making processes and in assessments of health hazards and risks (by those entities using research in the formulation of policy).

  Fairly evaluating published research in the process of peer-review is becoming increasingly challenging in a world that is characterized by infiltration of powerful interests at all levels of science, including access to data, study design, study conduct, peer review and publication, and ultimately to government review and use in policy. Applying the principle of COI declaration for

every person involved at each and all levels of decision-making may create the necessary transparency to identify and address distortions by the regulated community.

The Collegium Ramazzini therefore calls upon:

- National and international official bodies to set up evaluation procedures that systematically orient funding towards research centers, researchers and research activities with demonstrated commitment to competence and impartiality in assessing health effects.

- Governments to operationalize the Right to Enjoy the Benefits of Scientific Progress, as contained in the *United Nations' International Covenant on Social, Economic and Cultural Rights* by promoting science of the highest ethical standard as a public good. That right implies an obligation on government entities to create a research environment in which unbiased and relevant scientific knowledge is advanced and disseminated without obstacle. Efforts to reinterpret science or assessments of it in a biased way that apparently favors economically and politically vested interests could be interpreted as an interference with that right. Public policy-makers and the public can benefit from science only if it is allowed to be conducted, assessed, and communicated in an unbiased way, or that recognizes and seeks to diminish bias. States should also ensure transparency in funding of research through mandating open declaration of sources of funding when research is proposed, disseminated, and presented.

- Scientific journals to establish mechanisms, consistent with international best practices that provide disciplinary action for editors, authors and peer reviewers who fail to disclose financial conflicts and competing interests. In the absence of effective implementation, policies mean little.

- All public institutions that play a role in risk assessment and public health policies to systematically rely upon the advice that is transparent, credible and subject to public scrutiny.

- All decision-making bodies to set up effective conflict-of-interest disclosure policies for all persons involved in the process.

- The scientists involved in occupational and environmental health to never divert from the path of scientific integrity in their scientific research, assessments and communications, and that they consistently strive for objectivity, and impartially pursue scientific truth, with a view to public health protection.

- Scientists engaged in decision-making processes on environmental exposures to argue systematically for decisions that protect the most vulnerable, such as children and pregnant women.

- Scientists to raise their voices, and encourages them to contact the Collegium when their independence is threatened, in a way that puts a burden on their freedom to consistently follow that path.

- All professional bodies to support scientists who are under threat for speaking the truth.

APPENDIX XIII: INEP-DEFINED FORMS OF CONFLICT-OF-INTEREST AND PRINCIPLES FOR ACCEPTING FINANCIAL CONTRIBUTIONS

(Access here)

On pages 12 and 13, respectively, in the above document are Appendices II and III as follows:

APPENDIX II: Five types of relationship that may constitute a conflict-of-interest

The five types of relationship that may constitute a conflict-of-interest are categorized as follows and an individual may have more than one type on any one occasion:

• A ***'financial interest'*** may include but is not limited to a financial benefit that an individual who serves on the IJPC-SE Board receives from a third party. These benefits might include employment such as a wage or salary, self-employment, independent contractor, an intellectual property right that results in a royalty or other remuneration, consulting or speaking fee, teaching pay, honoraria, ownership interest (e.g., stocks, stock options, or other ownership interest, excluding diversified mutual funds), membership on an advisory committee, review panel, board, or other activity from which remuneration is received or expected.

• A ***'business interest'*** may include any interest in a decision being taken by the IJPC-SE that could favor the business interests of the donor entity.

• A ***'professional interest'*** may include but is not limited to a situation in which a donor entity provides support, but an individual on the IJPC-SE is directly or indirectly connected with the donor entity such that he/she is in a position to influence the results or outcomes of IJPC-SE deliberations. This applies equally to students in a formal relationship with the IJPC-SE.

• A ***'personal interest'*** may include but is not limited to a financial relationship that is held by one's spouse, partner or other family members or friends. Any of the three relationships noted above may also be a 'personal interest'.

• A ***'political interest'*** may include but is not limited to any interest in a decision being taken by the IJPC-SE that could favor the political interests or advancement of, contribute to the gain of political influence by, or has the potential to lead to policy decisions that mainly benefit the donor entity, its affiliate entity/entities, or the individual providing the donation or support rather than mainly benefiting the public or contributing to the community good

A conflict-of-interest must be disclosed while a conflict is present and for 36 months after it has ended.

Failure to disclose and to recuse oneself will disqualify one from future participation on the IJPC-SE Board for a period of at least three years. All IJPC-SE Board members have the obligation to recuse themselves from any discussion that could influence a decision associated with a Board member's actual or perceived conflict-of-interest.

APPENDIX III: Principles for Accepting Financial Contributions from Commercial or Other Entities Marketing or Promoting Products or Services

The IJPC-SE will focus on purposes consistent with its strategic priorities and comply with the following principles in soliciting all financial contributions; these principles will be discussed with all donors during the early stages of negotiation:

1. The IJPC-SE will at all times maintain an independent position on epidemiological issues and concerns.

2. The IJPC-SE will solicit and accept support only for projects and activities that are consistent with the IJPC-SE's Mission.

3. The IJPC-SE will accept funds for informational and educational activities only when the content is to be determined solely by or in collaboration with the IJPC-SE.

4. The IJPC-SE will maintain complete control of all funds provided from commercial supporters for its activities.

5. The IJPC-SE will not permit specific product endorsements, promotions or perception of such as part of its activities.

6. Acknowledgments for commercial support will be limited to company name, logos or slogans which are an "established part of the supporter's identity," trade names, addresses and telephone numbers. The IJPC-SE will not permit the use of corporate names or names of entities that market or promote products and services in naming future possible IJPC-SE awards.

7. The IJPC-SE's intangible intellectual assets, including its name and logo, will be protected at all times. Donors will not be permitted to use the IJPC-SE's name or logo for any commercial purpose or in connection with the promotion of any product.

8. The IJPC-SE will be vigilant at all times to avoid any real or perceived conflict-of-interest in accepting donations.

9. When the IJPC-SE is recognized as a non-profit, Federal Internal Revenue Service (IRS)-registered 501(c)(3) tax-exempt organization, the IJPC-SE also can provide written acknowledgement to donor entities that the IJPC-SE is a non-profit, Federal Internal Revenue Service (IRS)-registered 501(c)(3) tax-exempt organization as documentation.

Any situation that may be an exception to these principles will be reviewed by the Executive Committee. The Executive Committee will recommend a final course of action and which decision will be taken by a vote of the Board. The Board will have the final decision on any actions related to acceptance of donations.

APPENDIX XIV: FIFTY-FOUR SCIENTISTS HAVE LOST THEIR JOBS AS A RESULT OF NIH PROBE INTO FOREIGN TIES

Mervis J. (2020) Fifty-four scientists have lost their jobs as a result of NIH probe into foreign ties. Science, June 12.

By Jeffrey Mervis

June12, 2020

Some 54 scientists have resigned or been fired as a result of an ongoing investigation by the National Institutes of Health into the failure of NIH grantees to disclose financial ties to foreign governments. In 93% of those cases, the hidden funding came from a Chinese institution.

The new numbers come from Michael Lauer, NIH's head of extramural research. Lauer had previously provided some information on the scope of NIH's investigation, which had targeted 189 scientists at 87 institutions. But his presentation today to a senior advisory panel offered by far the most detailed breakout of an effort NIH launched in August 2018 that has roiled the U.S. biomedical community, and resulted in criminal charges against some prominent researchers, including Charles Lieber, chair of Harvard University's department of chemistry and chemical biology.

"It's not what we had hoped, and it's not a fun task," NIH Director Francis Collins said in characterizing the ongoing investigation. He called the data "sobering."

In the vast majority of cases, Lauer reported, the person being investigated has been an Asian man in his 50s. Some three-quarters of those under investigation had active NIH grants, and nearly half had at least two grants. The 285 active grants totaled $164 million.

Lauer also presented data on the nature of the violations that NIH has uncovered. Some 70% (133) of the researchers had failed to disclose to NIH the receipt of a foreign grant, and 54% had failed to disclose participation in a foreign talent program. In contrast, Lauer said, only 9% hid ties to a foreign company, and only 4% had an undisclosed foreign patent. Some 5% of cases involved a violation of NIH's peer-review system.

Lauer said the fact that 82% of those being investigated are Asian "is not surprising" because "that's who the Chinese target" in their foreign talent recruitment programs. Some 82% are men, and their median age is 56, with the youngest being 48 and the oldest 59. Slightly more than one-half had been an NIH peer reviewer in the past 2 years, and 41% of those under investigation (77 scientists) have been banned from further participation in NIH's well-regarded system of vetting grant proposals.

NIH has been in the forefront of federal efforts to identify and block behavior that many U.S. government officials say poses a significant threat to the country's economic well-being and to national security. Several bills pending in Congress seek to limit that threat in various ways, including by limiting the flow of scientific talent from China to the United States, and by restricting

access to federally funded research that provides a foundation for cutting-edge technologies and new industries.

Lauer's presentation also provided a glimpse into the scope of that broader investigation. There are 399 scientists "of possible concern" to NIH, he told the advisory council, and the Federal Bureau of Investigation has fingered 30% (121) of them. An additional 44 have been flagged by their own institutions. Of that pool, Lauer said, investigations into 63%, or 256 scientists, came out "positive." Investigations into some 19% came up "negative," he noted, whereas the status of the remaining 18% is "pending."

APPENDIX XV: OPEN LETTER TO THE INTERNATIONAL SOCIETY FOR ENVIRONMENTAL EPIDEMIOLOGY (ISEE)

Mark Nieuwenhuijsen, President, ISEE
Michelle Turner, Secretary-Treasurer, ISEE
Beate Ritz, Past President, ISEE
Tony Fletcher, Co-Chair, Policy Committee, ISEE
Audrey de Nazelle, Co-Chair, Policy Committee, ISEE

June 4, 2020

Dear ISEE officers and Policy Committee Co-Chairs,

The International Society for Environmental Epidemiology (ISEE) is to be commended for your excellent Guidelines on Financial Support, your commitment to prevent conflict of interest and your commitment to promote scientific integrity and public health.

The article, *Sponsorship by Big Oil, Like the Tobacco Industry, Should be Banned by the Research Community*, published in *Epidemiology* (Volume 30, Number 5, September 2019), demonstrates that this commitment was not sufficient to prevent the 2018 joint conference of ISEE and the International Society for Exposure Science (ISES) in Ottawa in August 2018 from receiving funding from Exxon-Mobil and providing positive publicity for Exxon-Mobil. Through this sponsorship, ISEE's credibility was used to advance the interests of Exxon-Mobil, whose name and banner were displayed at the conference.

The use of your good name and reputation to enhance Exxon Mobil's image is in direct contradiction with your policy, adopted in June 2018, not to accept funding from industries 1) with harmful impacts on public health or the environment or 2) that suppress or distort the scientific evidence regarding environmental pollution and its adverse health effects and 3) specifically not to accept funding from oil companies. Sadly, Exxon-Mobil falls into all three of these categories.

I appreciate that it was ISES and not ISEE who accepted the funding from Exxon-Mobil. However, since the conference was organised and held jointly by ISES and ISEE, ISEE's conduct and values are also implicated. ISEE has a responsibility for the involvement of Exxon-Mobil in its joint conference.

To prevent a re-occurrence of the misuse of ISEE's credibility to advance the interests of the oil industry, I would like to urge that ISEE add an additional point to your Guidelines on Financial Support stating that ISEE will require that in any joint conference or joint activity that ISEE co-sponsors, ISEE's Guidelines on Financial Support will be followed. These Guidelines specifically state that funding from the Tobacco industry, the Firearms industry, the Pesticides industry, the Asbestos industry and the Coal and oil industries should not be accepted.

The article, *Sponsorship by Big Oil, Like the Tobacco Industry, Should be Banned by the Research Community*, makes a number of requests to ISEE to show leadership and take specific

actions to defend environmental health and confront the large financial interests defended by Big Oil. For example:

> "**ISEE should become more vocal** on the need to ban sponsorship by the fossil fuel industry **and promote other measures** such as divestment from these industries while promoting research, investment, and use of alternative energies. ... **ISEE has to be exemplary on this and cannot afford another scientific conference or event with this type of sponsorship. And we must convince colleagues in other societies that they should do the same.** I**SEE is the largest scientific association on environmental health**, and our members have done outstanding work in promoting health in relation to environmental and occupational exposures. **We have to take widespread initiatives** to promote a world less dependent on fossil fuels that develops in a sustainable way. **Defending our values will require action by our own Society and will require a confrontation with large financial interests defended by Big Oil, analogous to those from the fight against Big Tobacco.**"

In response to the article, three letters were published in *Epidemiology*, all of them opposing the call that environmental health organisations not accept funding from the oil industry. All three authors have past or current ties to the fossil fuel industry. One of the writers (Stanley Young) is a policy advisor for the Heartland Institute, which has been funded by Exxon-Mobil and the tobacco industry and denies human-caused climate change.

In the nine months since the article was published in *Epidemiology*, there has been no response from ISEE to the article or to its requests for actions to be taken by the ISEE. Only opposition to the article has been heard. It thus seems that ISEE is opposed to or disinterested in the requests made in the article or considers them unimportant. The request for ISEE to show leadership and become more vocal seems to have been rejected. No apology or explanation has been given for the fact that ISEE's joint conference with ISES was sponsored by Exxon-Mobil and served to provide positive publicity for Exxon-Mobil. No clarification has been provided as to whether this situation could occur again.

I believe it was incorrect and improper for Dr. Stanley Young to have stated in the disclosure that accompanied his letter in *Epidemiology* that he had no conflict of interest. He failed to disclose the fact that he is a policy advisor to the Heartland Institute, an important spokesperson for the Heartland Institute and a contributor to their report, *Climate Change Reconsidered II Fossil Fuels*, which he misleadingly claims in his letter to be "authoritative". The Heartland Institute is funded by fossil fuel companies and promotes their interests. I believe that Dr. Young had an ethical obligation to disclose these ties.

When wrong-doing is not challenged, particularly when it is not challenged by those with a responsibility to protect human health and scientific integrity, it sends a message that the wrong-doing is acceptable and tolerated. Taking no action and staying silent creates a culture where wrong-doing is normalized and increases.

Silence is the great enabler of wrong-doing. Canada is widely considered to be a scientifically and ethically advanced country. Yet until 2015, the Canadian government denied the indisputable scientific evidence on the harmfulness of all forms of asbestos and supported the

mining, use and export of asbestos. What ended the capture of Canada's policy by the asbestos industry and defeated a multi-million-dollar government loan to expand the asbestos industry was the willingness of scientific organisations to be vocal in challenging the industry's misinformation and the harm this misinformation was causing to public health. These organizations included the Canadian Medical Association, the Canadian Public Health Association, the Collegium Ramazzini and, in particular, all the Quebec government's Directors of Public Health. I was given the National Public Health Hero award by the Canadian Public Health Association and the medal of the Quebec National Assembly for mobilizing scientists to challenge the asbestos industry's misinformation. I accepted those awards not for myself, but on behalf of the scientists and scientific organisations without whose courageous and vocal involvement we could not have stopped the harmful activities of the asbestos industry.

Overwhelming evidence shows that distorted information and corruption of public policy by industries such as the fossil fuel, tobacco, asbestos, sugary drinks, lead and chemical industries have caused widespread harm to health and unnecessary deaths. Unless this major threat is named and addressed by leading scientific organisations, such as ISEE, it will not be possible to effectively protect human and environmental health.

I am therefore respectfully writing to ask that ISEE:

- Publish a statement giving clear responses to the requests addressed to ISEE in the article in *Epidemiology*.
- Post this Open Letter and ISEE's response to it on the ISEE website in order to promote open debate on these critical issues.
- Express regret for the fact that the joint ISES-ISEE conference held in August 2018 received funding from and provided positive publicity for Exxon-Mobil.
- State what measures ISEE has taken to ensure that sponsorship by polluting industries for an ISEE conference held jointly with another organisation cannot re-occur.
- Take a vocal, leadership role in urging ISES and all organisations involved in health protection to adopt a policy similar to ISEE's policy, which refuses funding from industries with harmful impacts on public health or the environment, industries that suppress or distort the scientific evidence regarding environmental pollution and its adverse health effects, and specifically refuse funding from the oil industry.
- Make a complaint to *Epidemiology* requesting that the journal publish a correction that discloses Dr. Young's previously undisclosed involvement in the Heartland Institute and its funding by the oil industry.

I am sure that you will agree that the above matters are extremely serious. I look forward to receiving your response and sincerely thank you for your willingness to examining these critical issues.

Respectfully,
Kathleen Ruff, kruff@starlynx.ca
Former Expert Advisor on Ethics to the Chair and Executive Committee of the IJPC-SE / INEP
Honorary Fellow, Collegium Ramazzini

APPENDIX XVI: UNIVERSITY OF TEXAS HEALTH (UTHEALTH) – RESEARCH CONFLICT OF INTEREST CERTIFICATION FORM

(Access here)

CONFLICT OF INTEREST DISCLOSURE FORM

The potential for conflicts of interest exists when an individual has the ability to control or influence the content of an education activity and has a financial relationship with a commercial interest, the products or services of which are pertinent to the content of the education activity.

A commercial interest, as defined by the American Nurses Credentialing Center (ANCC) and the Texas Nurses Association (TNA), is an entity producing, marketing, reselling, or distributing healthcare goods or services consumed by or used on patients, or an entity that is owned or controlled by an entity that produces, markets, resells, or distributes healthcare goods or services consumed by or used on patients.

All individuals who have the ability to control or influence the content of an education activity must disclose all **relevant relationships**** with any commercial interest, including but not limited to members of the planning committee, presenters, authors, and/or content reviewers. Relevant relationships must be disclosed to the learners during the time when the relationship is in effect and for 12 months afterward. All information disclosed must be shared with the participants/learners prior to the start of the education activity.

****Relevant relationships,** as defined by ANCC/TNA, are relationships with a commercial interest if the products or services of the commercial interest are related to the content of the education activity.

☐ Relationships with any commercial interest of the individual's spouse/partner may be relevant relationships and must be reported, evaluated, and resolved.

☐ Evidence of a relevant relationship with a commercial interest may include but is not limited to receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (stock and stock options, excluding diversified mutual funds), grants, contracts, or other financial benefit directly or indirectly from the commercial interest.

☐ Financial benefits may be associated with employment, management positions, independent contractor relationships, other contractual relationships, consulting, speaking, teaching, membership on an advisory committee or review panel, board membership, and other activities from which remuneration is received or expected from the commercial interest.

As a provider of continuing nursing education by the Texas Nurses Association, it is the policy of The University of Texas Health Science Center at Houston School of Nursing to ensure balance, independence, objectivity and scientific rigor in all of its continuing nursing education activities. **All planning committee members and presenter(s)/author(s)/content reviewer(s) participating in** The University of Texas Health Science Center at Houston School of Nursing **activity must disclose to** The University of Texas

Health Science Center at Houston School of Nursing **any financial relationships that they or an immediate family member may have with any commercial interest in any amount occurring within the past 12 months that create a conflict of interest.** An "immediate family member" is defined as someone with whom you have a relationship involving the sharing of income or assets.

The intent of this disclosure is not to prevent an individual with commercial interest affiliations from participating, but rather to inform The University of Texas Health Science Center at Houston School of Nursing of any financial relationships so that conflicts can be resolved prior to the activity.

**Employees of a commercial interest: An individual who is employed by a commercial interest – ie: receives a W-2 from a commercial interest activity – may not serve on the CNE activity planning committee or be a presenter at a CNE activity. Form22092014

Activity Title:

Activity Date:

Name of person disclosing:

«FIRST» «LAST» «DEGREE(s)»

For all disclosures, complete each section, sign and date the last page. Please spell out all acronyms.

Is there an actual, potential or perceived conflict of interest for yourself or spouse/partner? Yes____ No ____

If yes: Complete the table below for all actual, potential or perceived conflicts of interest*: **Check all that apply**	**Category**	**Description**
Salary/Employment		
Royalty		
Stock		
Speakers Bureau		
Consultant		
Other		

APPENDIX XVII: THE GLOBAL FUND – DECLARATION OF INTEREST FORM

(Access here)

What is the purpose of this Form?
A key element of protecting the Global Fund's integrity and reputation is ensuring that its decision-making processes are not affected by conflicts of interest. This Form is one of the tools used by the Global Fund to identify and address actual or potential conflicts. Conflicts are situations where a Global Fund official could be influenced to make decisions for improper reasons, specifically for reasons that relate to their own financial interests. It is the responsibility of all Global Fund officials to disclose any personal financial interests that could relate to their work for the Global Fund, such that potential and actual conflicts can be appropriately addressed.

Who must complete this Form?
As required by the Global Fund's Ethics and Conflict of Interest Policy (the "Ethics Policy"), this Form must be completed by all Board Members and Alternates, delegation members at Board meetings, Committee Members, members of advisory groups (e.g., TRP, TERG) and non-administrative employees of the Secretariat. The Ethics Policy requires that when completing this Form, Global Fund officials must disclose both their own personal interests, those of their immediate family members, and those of any organizations to which they have a professional relationship.

What is a "conflict of interest"?

(Note: Click on the above link to reveal the complete 8-page form)

APPENDIX XVIII: TECHNICAL ADVISOR: CODE OF CONDUCT, MINISTRY OF FOREIGN AFFAIRS AND TRADE (MFAT), NEW ZEALAND

(**Access here**)

Technical Advisors must maintain proper standards of integrity, conduct, and behaviour whilst working overseas. Among a broad range of considerations, conflict-of-interest is addressed as follows:

Whilst engaged on assignment overseas Technical Advisors should perform their duties with integrity, honesty, impartiality and act in a manner that will bear the closest public scrutiny.

They shall avoid situations that might compromise their integrity and shall ensure that no conflict exists, or appears to exist, between their private interests and their official duties.

They must observe the principles of fairness and impartiality in all official dealings so that no individual, or organisation is given preferential treatment. Where any actual, or potential conflict of interest will be managed in accordance with Schedule 2 clause 9.

Situations of conflict of interest may arise where a Technical Advisor's partner or children takes up local employment and MFAT advice should be sought where any conflict is likely to arise in such cases.

During the course of the assignment the Technical Advisors must not take up secondary employment or be engaged in any other trade, business or occupation without the prior written consent of MFAT.

The MFAT Conflict of Interest Disclosure Form is accessible in the Dropbox

APPENDIX XIX: INTERNATIONAL EPIDEMIOLOGY INSTITUTE LTD. (IEI) FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

(**see: http://www.iei.us/**)

(**see also: https://grants.nih.gov/grants/policy/coi/index.htm**)

Objective research is of paramount importance to IEI to ensure public trust and meet scientific, program and ethical goals of our Department of Health and Human Services (DHHS), National Institutes Health (NIH) and/or other funding agency grants and contracts. To address the increasing complexities related to financial interests held by biomedical and behavioral researchers, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) has published their final rule. IEI believes we have fully addressed the requirements of this ruling and will continue to update this policy as needed.

IEI's policy requires that each investigator affiliated with IEI funded by DHHS or any other applicable grant or contract be in compliance with 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements (and 45 CFR Part 94 for contracts). IEI thus joins NIH's commitment to preserving the public's trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards. IEI intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

The following are key term definitions and IEI's policy guidance for principal or program investigators affiliated with IEI. This policy, and all FCOI IEI guidance is also available at: www.iei.us (or this document, the Financial Conflict of Interest (FCOI) Policy, November 1, 2014) so that all interested parties, including the general public have access to this Company policy.

Investigator

An Investigator is any person (including collaborators, subgrantees, contractors, fee-for services providers and/or consultants) who is responsible for the design, conduct or reporting of research funded by PHS.

Training Requirement

IEI investigators are required to complete training related to Financial Conflict of Interest (FCOI). If any conflicts of interest are found or known, they must be disclosed. The training must be updated no-less than every four years or as designated based on grant or role circumstances. Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site.

Financial Conflict of Interest (FCOI) or Significant Financial Interest (SFI)

An SFI is defined as financial interest greater than $5,000 or that may unduly influence professional judgments about the primary interests or goals of medicine. If the investigator (or an immediate family member) has a Significant Financial Interest (SFI) in any entity that has a business or scientific relationship with IEI it must be reported as a FCOI. Mutual funds or other investments that an investigator doesn't have the capability of influencing management decisions do not have to be disclosed.

Disclosures/Reporting Process

Any Significant Financial Interests (SFI) that might create a conflict of interest must be put on the FCOI report through the eRA Commons FCOI module prior to expending any funds. If any interests are identified as conflicting subsequent to the initial report, they must be reported to IEI within 30 days. IEI will then report it within 60 days to the institution that has issued the award to IEI. Each investigator must submit an updated disclosure of an SFI not less than annually. If a PHS-funded project is conducted by an investigator or SO with a conflict that was not disclosed or managed, IEI is required to disclose the conflict in each public presentation related to the results of the research.

Management of a FCOI

Means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PHS Awarding Component

The PHS awarding component is any sub-agency of the Public Health Service or Department of Health and Human Services.

Records Management

The records of all financial disclosures and all actions taken by IEI will be maintained for at least three years from the date of submission of the final expenditures report.

Research

PHS research is any project governed by PHS regulation, but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Compliance and Penalties for Non-Performance

If an investigator fails to comply with IEI's FCOI policy, within 120 days, IEI shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, IEI shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. IEI will work with the Investigator to set up an FCOI management plan to mitigate the situation. IEI will mandate that the Investigator disclose the FCOI in each public presentation with research results if it was not reported up front. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Point Contact

If you have a conflict of interest or if you have a question to discuss, contact IEI's Administrative Officer. The Administrative Officer is IEI's designated official to solicit and review disclosures of SFIs; this responsibility may be further delegated by the Administrative Officer case-by-case. Please use admin@iei.us and put "Administrative Officer" in the subject line of the email.

APPENDIX XX: TRI-AGENCY (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada)

(**Access here**)

CONSENT TO DISCLOSURE OF PERSONAL INFORMATION

Type of Award Applied for:

Title of Proposal:

Family Name:

Given Name:

I understand that maintaining public trust in the integrity of researchers is fundamental to building a knowledge-based society. By submitting any application, by linking my CV to an application led by another researcher or institution, or by accepting funding from the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and/or the Social Sciences and Humanities Research Council of Canada (SSHRC), I affirm that I have read and I agree to respect all the policies of these agencies that are relevant to my research, including the Tri-Agency Framework: Responsible Conduct of Research (http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/). In cases of a serious breach of agency policy, the agency may publicly disclose my name, the nature of the breach, the institution where I was employed at the time of the breach and the institution where I am currently employed. I accept this as a condition of applying for, or receiving, agency funding and I consent to such disclosure.

I agree / I disagree

Note that if you do not agree to the disclosure of your personal information, you cannot participate in this application.

For further information, see the Questions and Answers on the Consent to Disclosure of Personal Information on NSERC's Web site at address http://www.nserc-crsng.gc.ca/NSERC-CRSNG/governance-gouvernance/consentFAQ-consentementFAQ_eng.asp

Signature: _____ Date: _____

Consent to Disclosure (2011) The information collected on this form will be stored in the Personal Information Bank for the appropriate program. **PROTECTED B WHEN COMPLETED**

APPENDIX XXI: FACTSHEET CONFLICT OF INTEREST – TRANSPARENCY AND OBJECTIVITY ARE ESSENTIAL IN SCIENTIFIC RESEARCH AND THE PEER-REVIEW PROCESS

(Access here) *From: Elsevier | Ethics in Research & Publication*

When an investigator, author, editor, or reviewer has a financial/personal interest or belief that could affect his/her objectivity, or inappropriately influence his/her actions, a potential conflict of interest exists. Such relationships are also known as dual commitments, competing interests, or competing loyalties. The most obvious conflicts of interest are financial relationships such as:

- **Direct:** employment, stock ownership, grants, patents.
- **Indirect:** honoraria, consultancies to sponsoring organizations, mutual fund ownership, paid expert testimony.

Undeclared financial conflicts may seriously undermine the credibility of the journal, the authors, and the science itself. An example might be an investigator who owns stock in a pharmaceutical company that is commissioning the research.

Conflicts can also exist as a result of personal relationships, academic competition, and intellectual passion. An example might be a researcher who has:

- A relative who works at the company whose product the researcher is evaluating.
- A self-serving stake in the research results (e.g. potential promotion/career advancement based on outcomes).
- Personal beliefs that are in direct conflict with the topic he/she is researching.

Not all relationships represent a true conflict of interest–conflicts can be potential or actual. Some considerations that should be taken into account include: whether the person's association with the organization interferes with their ability to carry out the research or paper without bias; and whether the relationship, when later revealed, make a reasonable reader feel deceived or misled. Full disclosure about a relationship that could constitute a conflict–even if the person doesn't believe it affects their judgment – should be reported to the institution's ethics group and to the journal editor to which a paper is submitted. All publishers require disclosure in the form of a cover letter and/or footnote in the manuscript.

A journal may use disclosures as a basis for editorial decisions and may publish them if they are believed to be important to readers in judging the manuscript. Likewise, the journal may decide not to publish on the basis of the declared conflict. According to the U.S. Office of Research Integrity, having a conflict of interest is not in itself unethical, and there are some that are unavoidable. Full transparency is always the best course of action, and, if in doubt, disclose.

Guide to Conflict of Interest and How to Prevent It (Click on the above link to see this guide).

APPENDIX XXII: JOURNAL POLICY: COI DECLARATION REQUIRED OF AUTHORS IN SUBMITTING AN ARTICLE FOR PUBLICATION IN *ENVIRONMENTAL HEALTH PERSPECTIVES* (2016)

(Access here)

Environmental Health Perspectives maintains that authors are accountable for the articles submitted to the journal and requires authors to declare actual or potential competing financial interests that might be perceived as influencing the results or interpretation of a reported study. As indicated in the Instructions to Authors:

Authors must disclose actual and/or potential competing financial interests, including but not limited to grant support; employment (past, present, or firm offer of future); patents (pending or applied); payment for expert witness or testimony; personal financial interests by the authors, immediate family members, or institutional affiliations that may gain or lose financially through publication of the article; and forms of compensation, including travel funding, consultancies, board positions, patent and royalty arrangements, stock shares, or bonds. Diversified mutual funds or investment trusts do not constitute a competing financial interest. Authors employed by a for-profit, non-profit, foundation, or advocacy group must also disclose employment. Authors should carefully examine the wording of documents such as grants and contracts to determine whether there might be an actual or potential competing interest.

All actual or potential competing interests occurring during the last 3 years should be reported. As a general rule, all consultants and contractors must indicate a potential competing financial interest and provide the name of their employer and a description of any specific potential conflicts that exist as a consequence of their employment.

Corresponding authors are required to submit this form declaring actual or potential competing financial interests on behalf of all authors involved. Failure to declare a competing financial interest could result in a ban on publication for 3 years and a retraction of the article. Disclosure of actual or potential competing interests does not imply that the information in the article is questionable or that conclusions are biased. However, the corresponding author must certify that the authors' freedom to design, conduct, interpret, and publish research is not compromised by any controlling sponsor as a condition of review and publication (see below).

APPENDIX XXIII: INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS (ICMJE) FORM FOR DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

(**Download here**)

Your completed form is NOT to be submitted to the ICMJE and it cannot be saved to the ICMJE website. Save the form on your own computer and check with the journal you are submitting to for specific instructions on how to submit your completed form to them.

Instructions:
The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

1. Identifying information.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party – that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes".

3. Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be

disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

5. Relationships not covered above.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

Section 6. Disclosure Statement

Definitions.

Entity: government agency, foundation, commercial sponsor, academic institution, etc.

Grant: A grant from an entity, generally [but not always] paid to your organization

Personal Fees: Monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony, employment, or other affiliations

Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

Issued: The patent has been issued by the agency

Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent

Section 1. Identifying Information

1. Given Name (First Name)
2. Surname (Last Name)

3. Date

4. Are you the corresponding author? Yes / No

   Corresponding Author's Name:

5. Manuscript Title

6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes / No

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were **present during the 36 months prior to publication**.

Are there any relevant conflicts of interest? Yes / No

Section 4. Intellectual Property – Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes / No

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

- Yes, the following relationships/conditions/circumstances are present (explain below):
- No other relationships/conditions/circumstances that present a potential conflict of interest

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Evaluation and Feedback

Please visit http://www.icmje.org/cgi-bin/feedback to provide feedback on your experience with completing this form.

APPENDIX XXIV: BRITISH MEDICAL JOURNAL (BMJ) COMPETING INTEREST POLICY

(**Access here**) *See also Appendix II from the BMJ. The two Appendices are complementary.*

A competing interest – often called a conflict of interest – exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It may arise for the authors of an article in *The BMJ* when they have a financial interest that may influence, probably without their knowing, their interpretation of their results or those of others.

We believe that, to make the best decision on how to deal with an article, we should know about any competing interests that authors may have, and that if we publish the article readers should know about them too. We are not aiming to eradicate such interests across all article types in the BMJ. However, certain articles (see below) fall under a stricter policy announced in 2014. This means that authors whose financial conflicts of interest are judged to be relevant by the BMJ team are not permitted to write these articles. We also ask our staff and reviewers to declare any competing interests.

Competing interests by Article Type

A declaration of interests for all authors must be received before an article can be reviewed and accepted for publication. It should take one of three forms, depending on what type of article you are submitting.

Note*: By clicking on the above link, each of the following categories can be accessed*

Research

Editorials and Education (including clinical reviews, practice articles, minerva pictures, and endgames. Excluding state of the art reviews and therapeutics articles)

All other article types (including blogs)

Reviewers

We also ask reviewers to provide statements of competing interests and we use these when assessing the value of peer review reports. We ask individual reviewers to provide a statement based on BMJ policy at the time they submit their review via our manuscript tracking system.

Staff declarations at ***The BMJ***

You can find information about the competing interests of *The BMJ*'s staff on their profile pages.

APPENDIX XXV: COMMITTEE ON PUBLICATION ETHICS (COPE) – PUBLICATION GUIDELINES

COPE is the authority on publication ethics. Several documents of relevance to this Statement:

https://publicationethics.org/guidance/Guidelines

https://publicationethics.org/guidance/Guidelines?t=conflict+of+interest&sort=score

Guidelines for the Board of Directors of Learned Society Journals

Retraction guidelines

Sharing of information among editors-in-chief regarding possible misconduct

Cooperation between research institutions and journals on research integrity cases: guidance COPE

Principles of Transparency and Best Practice in Scholarly Publishing

https://publicationethics.org/peerreview

APPENDIX XXVI: CONFLICT OF INTEREST DISCLOSURE FORM FOR NOMINATIONS

(**Access here**)

From the Health Resources and Services Administration (HSRA) of the U.S. Department of Health and Human Services (see https://www.hrsa.gov/about/index.html).

Note: A potential or actual conflict of interest exists when commitments and obligations are likely to be compromised by the nominator's other material interests, or relationships (especially economic), particularly if those interests or commitments are not disclosed.

This Conflict of Interest Form should indicate whether the nominator(s) has an economic interest in, or acts as an officer or a director of, any outside entity whose financial interests would reasonably appear to be affected by the addition of the nominated condition to the newborn screening panel. The nominator(s) should also disclose any personal, business, or volunteer affiliations that may give rise to a real or apparent (i.e., actual or perceived) conflict of interest. Relevant Federally and organizationally established regulations and guidelines in financial conflicts must be abided by. Individuals with a conflict of interest should refrain from nominating a condition for screening.

Date:

Name:

Position:

Please describe below any relationships, transactions, positions you hold (volunteer or otherwise), or circumstances that you believe could contribute to a conflict of interest:

I have no conflict of interest to report.

I have the following conflict of interest to report (please specify other non-profit and for-profit boards you (and your spouse) sit on, any for-profit businesses for which you or an immediate family member are an officer or director, or a majority shareholder, and the name of your employer and any businesses you or a family member own:

1.

2.

3.

I hereby certify that the information set forth above is true and complete to the best of my knowledge.

Signature: _____ Date: _____

APPENDIX XXVII: IJPC-SE - CONFLICT-OF-INTEREST (COI) DISCLOSURE FORM

[Note: IJPC-SE underwent a name change in 2018 to:
International Network for Epidemiology in Policy (INEP)]

To: All IJPC-SE Board Members and associated individuals
From: IJPC-SE Chair, Colin Soskolne
Date: January 21, 2015

RE: Conflict-of-Interest (COI) Declaration covering the past 5 years, for completion as soon as possible
Please take about 30 minutes over the next few days to respond to this request.

BACKGROUND:
Following our Founding Bylaws (pages 15-16) that require service for the public good, our Officers, Board Members, as well as Associated Individuals are required to periodically submit a DISCLOSURE STATEMENT that makes transparent any actual or perceived COI of a financial nature, or of any other type. The relevant section in the IJPC-SE Founding Bylaws states in *Article V, Section 2 on "Avoiding External Agency Influence" that:*

> *For any level of participation in IJPC-SE meetings of any type, members (see Article II, Section 3) must provide a Conflict-of-Interest disclosure form, duly completed for … the individual Board member … and on which is included all actual and/or perceived conflicting interests. Such disclosures will be publicly accessible on the IJPC-SE website and will be updated as previously disclosed information changes. Full disclosure is needed to be placed on the record of all participants in meetings related to any IJPC-SE activity.*

While the IJPC-SE *Working Group on Conflict-of-Interest and Disclosure* is fully operational and is soon to develop a template for disclosures of various kinds, we need to align ourselves now with our Founding Bylaws. We cannot wait for the anticipated *Position Statement on Conflict-of-Interest and Disclosure* to be approved and launched later in 2015. Hence, the Working Group and the Executive Committee recommend that we pilot our disclosure process using the interim form below. When the process and forms are further finalized and approved through the Working Groups efforts, we will all be asked to update our reports using revised DISCLOSURE forms, likely in a year's time.

The following form, out of respect for the anticipated more definitive work expected from our Working Group on the topic, we thus call a CONFLICT-OF-INTEREST DISCLOSURE STATEMENT (interim form).

CONFLICT-OF-INTEREST DISCLOSURE STATEMENT (interim form)

INSTRUCTIONS: Before completing the disclosure from below, please review the following definitions, adapted from the International Committee of Medical Journal Editors (ICMJE), as an orientation to sensitize us as to what types of information we are each being asked to disclose.

Definitions applicable and limited to your personal experience over the past 5 years

Entity: Government agency, foundation, commercial sponsor, academic institution, non-governmental organization (NGO), labor union, or any such organization whose self-interest could in any way influence us as scientists engaged in research or practice in the public interest.
Grant or contract: Money paid or donated from an entity, generally [but not always] paid to you or your employing entity.
Financial/Personal Fees: Monies paid to you – directly or indirectly – for services rendered, generally including, for example, honoraria, royalties, stipends, fees for consulting, lectures, speakers' bureaus, expert testimony, and any employment or activity in the service of an entity having a special interest that is not clearly congruent with the public interest. (Note: "indirectly" refers to monies paid to your employing institution, but for which you have access consistent with institutional spending constraints).
Non-Financial (In-Kind) Support: Examples include any quantity of drugs or equipment supplied by the entity, travel paid by the entity, writing assistance, voluntary board positions, and administrative support.
Other: Anything at all that is not covered in your declaration under the above categories of "grant or contract", "financial/personal fees" or "non-financial (in-kind) support" but that could be an actual COI, or be perceived by others as a COI.
Royalties: Funds coming in to you or your entity related to your books, patents, or the like.

PLEASE ANSWER ALL QUESTIONS FULLY AND TYPE ALL ANSWERS USING CAPITAL LETTERS. USE AS MUCH SPACE AS NEEDED. DOTTED LINES ARE PROVIDED SIMPLY TO GUIDE YOU, SO PLEASE REMOVE THEM AS YOU TYPE YOUR ANSWERS (IN CAPS) BELOW.

Name in full:
(First, middle initial, last):
……

Current occupation, if employed; or, "retired":
……

If currently employed:
Name of primary employing entity:
……

Name of secondary employing entity, if applicable:
……

Whether currently employed or not:
Primary professional affiliation taking up most of your volunteer time:
……

Secondary such affiliation, if applicable:
……

OVER THE PAST FIVE YEARS, OR OVER THE LAST FIVE YEARS OF EMPLOYMENT IF NOW RETIRED:

Primary professional employment focus:
……

Secondary professional employment focus, if applicable:
……

Tertiary professional employment focus, if applicable:
……

I represent the following organization on the IJPC-SE (acronym, or "none"):
……

as the Primary (1), Secondary (2), Tertiary (3) or Quaternary (4), or not applicable [N/A]…….. representative; or, as an invited guest/interested party/expert advisor: ……..……

Please include below, and elaborate where needed, all <u>actual</u> conflicting interests, including financial, consultant, institutional and other relationships that might lead or has led to bias or a conflict-of-interest, <u>or</u> that reasonably might create a <u>perception</u> of bias or a conflict-of-interest by your peers or the public. If there are none, please state "None" alongside each item "a" through "e" below. ***If in doubt, rather err on the side of providing more information as this will minimize the need for follow-up.***

With the above definitions in mind relating to my employer and/or volunteer entities, those entities from which I have accepted grants/contracts, salaries/stipends/honoraria/royalties, both monetarily and in-kind, and anything else like personal relationships that could actually introduce, or be perceived to introduce bias into my decision-making, I disclose the following information covering the 5-year period since January 1, 2010:

a) **Financial relationships:**
……

b) **Consultant relationships:**
……

c) **Institutional relationships:**
……

d) **Other relationships:**
……

e) **Any additional information:**
……

If in my service to the IJPC-SE I should ever find myself in a conflict-of-interest, actual or perceived, I will declare it and offer to recuse myself from all circumstances that could in any way influence Board deliberations as per the Founding Bylaws (Article V, *Section 2)*.

Please type your signature here:
……

Enter Today's date (month/day/year) **here**:
……