

**CR Statement on:**

**Principles for Safeguarding the Integrity of Research In Occupational and Environmental Health**

**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 the public's health. 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.

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 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 Col 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 man-made 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 . 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 favours 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.