Scientific Integrity is essential to safeguard public health.

Recommendation

To ensure people are not made sick from toxic chemicals, scientific integrity must be upheld at all levels of decision-making within EPA, including accounting for financial conflicts of interest in the evidence of risk evaluations, eliminating financial conflicts of interest in scientific panels, and preventing political influence in the evaluation, interpretation, and dissemination of research.

SUMMARY

Integrity of the scientific process, including conducting, managing, using the results of, and communicating about science and scientific activities, is essential to ensure that the best available and least biased science is produced, valued, and used to ensure people are not made sick from toxic chemicals.[1] Threats to scientific integrity come from those with a financial stake in the outcome of EPA decision-making, including the chemical industry and their allies, and political appointees at EPA and in the executive branch that advocate on behalf of polluters.

EPA's recently released Scientific Integrity Policy 2025 states: "The environmental policies, decisions, guidance, and regulations that impact the lives of people living in the United States every day must be grounded in robust, independent, high-quality science."[2] However, EPA has not consistently upheld its scientific integrity policy, leading to decisions that underestimate hazards and health risks and undermines the Agency's ability to fulfill its mission to protect health and the environment. The Agency must ensure that the science it evaluates in its decision-making and the peer review and scientific panels it convenes are free from financial conflicts of interest. The scientific processes and rulemaking must be protected from any political influence. These can undermine efforts to ensure that scientific assessments are unbiased and do not underestimate risk.

PROPOSED ACTIONS

To ensure that the Agency's decisions uphold the best available science free of political interference and industry financial conflicts, **we recommend that EPA should:**

1. **Assess study-funding sources and author financial conflicts of interest when evaluating study quality for hazard and risk assessment. Industry sponsorship should be part of risk of bias.**

2. **Ensure EPA's Agency peer review bodies and advisory committees define financial conflicts of interest to include industry funding for research, analysis, or advocacy on any products or chemicals and ensure all financial conflicts are identified, disclosed, and eliminated. (This should apply to all U.S. regulatory agencies.)**

3. **Conduct panel peer reviews for all scientific assessments that have an impact on significant and important policy or regulation.**

4. **Provide effective mechanisms for addressing scientific integrity concerns from career scientists, including but not limited to providing firewalls from political influence in scientific products and remedying violations if substantiated.**

BACKGROUND

Extensive empirical research demonstrates that financial conflicts of interest (study sponsorship and study authors with a financial conflict of interest (COI)) bias the scientific process. The National Academies of Sciences, Engineering, and Medicine (NASEM) report on *Sponsor Influences on the Quality and Independence of Health Research: Proceedings of a Workshop* presented results of decades of empirical research[3] showing that when they fund research on their products, pharmaceutical, and other industries influence processes. This includes the study design, conduct, analysis, and reporting of results; resulting in findings and conclusions that favor the industry sponsor.[3–7]

The NASEM report also outlined solutions to break the "cycle of bias" that results from industry-sponsored studies, including "[r]ecognizing industry funding and COIs as a source of bias and accounting for it" and "[e]liminating sponsor-associated bias at a structural level through policy."[3] The NASEM has additionally recommended in multiple reports to EPA that "funding sources should be considered" when evaluating the quality of a study.[8,9] The influence of financial ties on research needs to be distinguished from non-financial interests in the research, as non-financial interests do not reflect the same systematic biases.[10] However, EPA systematically fails to account for financial bias in its evaluation of COI in scientific research.

The NASEM report on Sponsor Influence also discussed how having financially conflicted members of scientific review panels can also adversely influence the outcome of the panels, and that disclosure of conflicts does not remove the bias of the panel and in some cases exacerbates it.[3,7] The report presented a model for how EPA should handle experts on their scientific panels with a COI based on the approach used by the International Agency for Research on Cancer (IARC).[3] IARC selects Working Group members to evaluate the evidence on the carcinogenicity of a given chemical based on subject matter expertise, relevant methodologies, and "absence of conflicts of interest.[11] "Invited Specialists" who have critical knowledge and experience but who also have a conflict of interest may be invited to participate in limited numbers when necessary to contribute to the discussions and assist the Working Group, but do not draft any section of the Monograph related to the description or interpretation of cancer data, and they cannot participate in the evaluations.[3,12(pp4-5)] EPA has not eliminated financial COI from the scientific process underlying hazard and risk assessment, as those with financial stake in the outcome of the decisions serve on scientific peer review panels.[13]

Maintaining a clear line between science and policy, with transparency for all steps in the agency's scientific analysis, is vital to ensure public confidence in science-based decisions. Agency career scientists, with the advice and guidance of independent peer reviewers, should be free of all influence from political appointees in the assessment of hazard and risk.

Scientific staff, in turn, must transparently and consistently document assumptions, uncertainties, and other judgments used in their scientific analyses. This will ensure that scientific findings and conclusions are objective and unbiased and meet high standards of professional integrity. Political appointees and elected officials should have no input or role in core scientific tasks such as evaluating the strength and quality of studies, determining the strength of evidence, making qualitative and quantitative determinations of exposure and risk, and characterizing uncertainties.

Further, all stakeholder comments should be transparent and fully documented in the record. Off-the-record communications between stakeholders and career scientists pertaining to ongoing EPA scientific activities (e.g. hazard assessments, draft guidance documents, etc.) should be prohibited and, when they do occur, should be disclosed to the public in a timely manner. Attempts by political appointees and senior career managers to override or alter interpretations of the science by career scientists (such as the Trump administration's weakening of EPA staff findings on birth defects caused by TCE)[14] should be strictly prohibited and, where they occur, should be promptly investigated by agency scientific integrity officials, reported to agency leadership and disclosed to the public. More subtle forms of political interference, such as communicating the preferred outcomes of stakeholders to career scientists, highlighting the policy goals of decisionmakers and the scientific findings necessary to support them, or dictating the charge questions for peer reviewers, should be discouraged and carefully monitored.

SUPPORTING EVIDENCE

EPA should assess study-funding sources and author financial conflicts of interest when evaluating study quality for hazard and risk assessment and consider industry sponsorship a risk of bias.

Industry sponsorship can bias research through various mechanisms, including how a study is designed and conducted, selective reporting of the results, skewed or incomplete analyses of study data, misleading or selective presentation of conclusions, and signaling of preferred outcomes in framing the questions to be investigated.[15–18]

A 2023 NASEM report highlighted the "large body of evidence showing that financial COIs lead to systemic biases in research"[3] and has recommended "funding sources should be considered in the risk-of-bias assessment conducted for systematic reviews that are part of an IRIS assessment."[8] To ensure that EPA assessments account for the possible bias in the evidence base, industry sponsorship and author financial COI should be flagged as a risk of bias that could affect the validity of a study's findings and conclusions.

Importantly, including funding as a risk of bias does not mean excluding industry-sponsored studies from EPA's hazard and risk assessment; it only means documenting funding as one of many domains of potential bias and evaluating its impact on the overall quality of the body of evidence.

EPA's peer review bodies and advisory committees must 1) define financial conflicts of interest to include funding from industry or their trade associations for research, analysis, or advocacy on products or chemicals being assessed and 2) ensure all financial conflicts are identified, disclosed, and eliminated early in the process.

Financial ties between scientists serving on peer review bodies or advisory committees and regulated entities that have economic interests that could be harmed by agency scientific findings constitute financial conflicts of interest (COI). The association between the financial COIs of peer reviewers and scientific recommendations that favor the interests of the entities from which they receive financial benefits has been well established.[19,20] Research shows that paradoxically, those members who disclose COI provide more biased advice due to the belief that they have adequately warned recipients of these conflicts or to compensate for the prospect that their advice will likely be disregarded.[21,22] Systematic reviews have established that disclosed financial COI are associated with research outcomes biased towards the sponsor and, therefore, demonstrate why disclosure is not a solution to reducing bias in independent scientific review bodies.[4] Financial COI must, therefore, be identified, disclosed, and those with financial COIs must be disqualified early in the process of identifying candidates for peer review panels and advisory committees.

The Agency's current definition of what constitutes a conflict of interest is too narrow and does not define COI to include receiving financial compensation from companies or their trade associations for performing a range of science-related tasks, including research, preparing and delivering scientific presentations in an EPA proceeding, or providing advice on the interpretation of scientific studies. Where the work performed relates directly to the chemical or product under review by EPA, the financial relationship between the prospective reviewer and the company should be treated as evidence of bias, and the reviewer should be disqualified.

Importantly, conflicts of interest due to financial ties must be distinguished from nonfinancial interest, as these conflicts of interest can create a bias that extends beyond the individual.[10] For example, multiple members of an EPA advisory committee may have financial ties with chemical manufacturers, trade associations or other companies that could financially benefit from the findings of an evaluation or the recommendations of the advisory committee. While in contrast, committee members with a combination of nonfinancial interests such as personal beliefs, theoretical viewpoint, or desire for glory could influence evaluation in different directions and thus not be an overall systematic bias.

EPA should use the model implemented by IARC in developing Monographs that assess the evidence of carcinogenicity for selecting scientific experts. IARC selects Working Group members based on subject matter expertise, relevant methodologies, and "absence of conflicts of interest."[11] IARC allows 'Invited Specialists "who have critical knowledge and experience but who also have a conflict of interest that warrants exclusion from developing or influencing the evaluations of carcinogenicity. Invited Specialists do not draft any Monograph sections or interpretation of cancer data, and they do not participate in the evaluations. These experts are invited in limited numbers when necessary to assist the Working Group by contributing their unique knowledge and experience to the discussions.[12(p5)] This limits any concerns of reduced scientific quality of the Monographs as the best-qualified experts are included, but the monographs and conclusions are developed by independent experts free of any COIs.[3(pp65-68)]

EPA should conduct panel peer reviews for all scientific assessments that have an impact on significant and important policy and regulatory decisions.

EPA and OMB peer review guidelines recognize that panel reviews are the review mechanism of choice where a scientific assessment will have a major impact on policy and regulatory decisions. Panel peer reviews provide the opportunity for greater collaboration and consensus among reviewers, enable the public to present views and concerns to the reviewers, provide greater transparency, and enable the examination of cross-cutting science issues that arise in evaluations. For example, the SACC's reviews of the first 10 TSCA risk evaluations played an invaluable role in identifying key issues of risk assessment methodology, raising concerns about EPA's presumption of personal protective equipment, its failure to assess environmental exposures, and its use of a systematic review methodology that is not aligned with current scientific practice. Similarly, the SACC review of EPA's proposed fenceline risk screening methodology identified important basic issues with EPA's approach that are applicable to the 20 ongoing risk evaluations under TSCA.

Unfortunately, EPA has begun to move towards conducting letter peer reviews of TSCA risk evaluations, which directly determine whether a chemical will be subject to regulation, instead of the more thorough scientific panel peer reviews typically conducted by peer-review bodies like the SACC. Letter peer reviews preclude collaboration and consensus among reviewers, transparency, and public participation in the review process, all of which are critical to the thoroughness and scientific rigor of the peer review.

Moving to a process that prioritizes letter reviews for important scientific assessments could severely hamper the scientific collaboration, consensus, transparency, and public participation that is necessary to promote the scientific integrity that is fundamental for public confidence in policy decisions. Therefore, EPA should conduct panel peer reviews for all scientific assessments that support major policy and regulatory decisions and other influential Agency actions based on science.

EPA should provide effective mechanisms for addressing scientific integrity concerns from career scientists, including but not limited to providing firewalls from political influence in scientific products and remedying violations if substantiated.

Scientific integrity concerns are common among career agency scientists. Scientists who raise these concerns to higher-level managers often put their careers at risk and may be reluctant to come forward for fear of retaliation. While scientific integrity policies have strengthened by President Biden's agencies, the process for acting on complaints is not well-defined or timely and often does not result in effective action against violators. Thus, EPA's inspector general has found that EPA has failed to abide by its own scientific integrity policy, thereby leaving "the public vulnerable to potential negative impacts on human health."[24]

If scientific integrity concerns are not investigated and addressed promptly, staff-level scientists may feel vulnerable to retaliation or career harm. Managers may also conclude that they are unlikely to be held accountable for breaches of scientific integrity and can skirt the boundaries of accepted conduct with impunity. Further, industry stakeholders unhappy with staff-level scientific assessments may seek the intervention of supervisors to soften or rework objectionable findings and overrule subordinate scientists. A rigorous process for enforcing scientific integrity policies after a thorough and expeditious investigation by objective and independent officials is essential to ensure that these policies are effectively implemented. To ensure that scientific integrity complaints receive immediate attention, EPA should complete its investigation and take any necessary action within a timeframe of 6 months or less.

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