We Need the Best Science Free of Conflicts of Interest so Environmental Health Decision-Making Can Protect Public Health

RECOMMENDATION

To reduce biased findings, financial conflicts of interest from industry funding in environmental health research as well as industry ties on EPA advisory committees should be eliminated to the extent possible.

ISSUE SUMMARY

"The biggest threat to [scientific] integrity [is] financial conflicts of interest," *JAMA*'s deputy editor observed in 2010.[1] Actions by the tobacco and pharmaceutical industries over decades demonstrate that when industry sponsors research, the results are more favorable to the sponsoring industry.[2,3] Similar patterns are seen in the research funded by the chemical industry.[4]

The National Academies of Sciences, Engineering and Medicine (NASEM) recommended to the EPA that "funding sources should be considered" when evaluating the quality of a study.[5] Yet EPA does not account for how it will consider funding sources when reviewing scientific evidence. Nor has EPA addressed conflicts of interest among those the Agency appoints to scientific advisory boards.

Financial conflicts of interest from industry funding should be eliminated on advisory committees and boards to the extent possible. The influence of financial ties on research can be traced to a variety of types of biases, and this conflict of interest needs to be distinguished from non-financial interests in the research.[6]

PROPOSED ACTIONS

1. **EPA should assess study-funding source and author financial conflicts of interests when evaluating study quality** for hazard and risk assessment, and consider it a risk of bias.
2. **Financial conflicts of interest from industry funding should be eliminated to the extent possible** among individual advisory members. If individuals with financial conflicts of interest are accepted onto advisory boards, their effects must be minimized and should be balanced by members from the environmental and/or public health nonprofit community that does not have industry funding.
3. **Financial conflicts of interest among EPA advisory board members should be disclosed and reduced.** Before finalizing the selection of individual advisory members the vetting process of conflicts of interest should include: identifying and disclosing any conflicts that include financial ties with industry; determining whether a conflict of interest exists with the committee member; and finally implementing the necessary procedures to manage any conflicts of interest. Further, the committee chair must be free of any financial conflicts of interest.

SUPPORTING EVIDENCE

EPA should assess study-funding source and author financial conflicts of interests when evaluating study quality for hazard and risk assessment, and consider it a risk of bias.

Research of pharmaceutical, tobacco and nutrition industries has shown that research sponsored by industry were more likely to have results that favored the sponsor even when the studies were of the same methodological quality.[7,8,9] Industry sponsorship can bias research through various mechanisms, including how they design and conduct a study, selectively

report the results, code events, analyze the study data, spin conclusions, as well as frame the questions that are asked.[10,11,12,13]

A 2017 Cochrane systematic review of industry sponsorship and research outcomes concluded that "industry sponsorship should be treated as bias-inducing and industry bias should be treated as a separate domain" when evaluating a study's internal validity (study quality).[7] The NASEM in its review of the EPA Integrated Risk Information System (IRIS) program's systematic review method found that "Funding sources should be considered in the risk-of-bias assessment conducted for systematic reviews that are part of an IRIS assessment."[5] Therefore, as EPA assessments depend on an evidence base that should be as free as possible of bias, EPA should assess study-funding source and author financial conflicts of interests when evaluating study quality for hazard and risk assessment, and consider it a risk of bias.

Importantly, including funding as a risk of bias domain 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.

Financial conflicts of interest from industry funding should be eliminated to the extent possible among individual advisory members and financial conflicts of interest among EPA advisory board members should be disclosed and reduced.

EPA's own *Peer Review Handbook* (Science and Technology Policy Council, U.S. EPA, Peer Review Handbook at 22, 80 (4th ed. 2015)) requires prospective peer reviewers, such as the Science Advisory Committee on Chemicals (SACC members), to "disclose any activities or circumstances that could pose a conflict of interest or create an appearance of a loss of impartiality," and calls for EPA to screen for potential conflicts "[b]efore finalizing the selection of reviewers."

Federal ethics regulations also require EPA to "[a]ssure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes" (41 C.F.R. § 102-3.105(h)). When EPA solicited nominations for the Science Advisory Committee on Chemicals (SACC) in March 2020, the Agency announced its selection criteria, including the "[a]bsence of financial conflicts of interest or the appearance of a loss of impartiality." (85 Fed. Reg. 16,094-01 (Mar. 20, 2020)).

Importantly, conflicts of interest due to financial ties from companies that manufacture or distribute chemicals that undergo EPA evaluation, or from any trade associations that may represent those companies, must be distinguished from *nonfinancial interest*, as these *conflicts of interest* can create a bias that extends beyond the individual. For example, multiple members of an EPA advisory committee may have financial ties with chemical manufacturers or other companies that could financially benefit from the findings of an evaluation or the recommendations of the advisory commmitee. 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 bias.

IMPLICATIONS OF FAILING TO DISCLOSE FINANCIAL CONFLICTS OF INTEREST

EPA did not disclose whether any of the candidates under consideration for appointment to the Toxic Substances Control Act (TSCA) and SACC in October 2020 received industry funding from companies that manufacture or distribute the next 22 chemicals that will undergo TSCA risk evaluation, or from any trade associations that may represent those companies. In addition, before requesting public comments on the candidates, EPA failed to make known if the candidates had been screened for any such conflicts of interest. This lack of disclosure is particularly concerning as the SACC will be expected to provide input and advice related to those chemicals.

Therefore, individuals who serve on EPA advisory committees with financial relationships with companies that can benefit from the recommendations of the advisory committee should be excluded from the committee, or those with certain affiliations should be recused when decisions that have financial implications for their profession are made. In addition, advisory committees must always be balanced out by members from the environmental and/or public health nonprofit community that does not have industry funding.[6] However, nonfinancial interests of individuals should not be used as the basis of exclusion from EPA advisory committees, as this would reduce the necessary diversity of thought and perspective required for an EPA advisory committee. Further, such an approach may lead to the overrepresentation of financially conflicted individuals whose interests could financially benefit from the findings of a risk evaluation or the recommendations of the advisory committee.[14]

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