August 9, 2022

Comments on the Request for Nominations for the Science Advisory Board IRIS Hexavalent Chromium (Cr(VI)) Review Panel

Comments submitted via email to Dr. Sue Shallal, Designated Federal Officer

The following comments are being submitted by the University of California, San Francisco (UCSF) Program on Reproductive Health and the Environment (PRHE). We have no direct or indirect financial or fiduciary interest in the manufacture or sale of any chemical that would be the subject of the deliberations of this Committee.

We appreciate the opportunity to comment on the list of candidates nominated to the EPA's Science Advisory Board (SAB) to serve as scientific experts to form EPA's SAB Hexavalent Chromium Review Panel, which will review the draft EPA Integrated Risk Information System (IRIS) Toxicological Review of Hexavalent Chromium (Cr(VI)). This panel will "provide independent scientific and technical peer review, consultation, advice and recommendations to the EPA Administrator on the scientific bases for EPA's actions and programs," and "consider whether the conclusions found in the EPA's draft assessment are clearly presented and scientifically supported…[and] provide recommendations on how the assessment may be strengthened." [1]

In the Federal Register notice for this panel, the selection criteria for panel membership include: "…(a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a loss of impartiality…"[2] The majority of this comment concerns the last two selection criteria regarding financial conflicts of interest (COI) and appearance of a loss of impartiality.

EPA should strive to eliminate or minimize financial conflicts of interest and appearance of a loss of impartiality from selected committee members.

It has been demonstrated across multiple areas of research, including chemicals, that even when controlling for methodological biases, studies sponsored by industry or that have an author with a financial conflict of interest are more likely to have results that favor the sponsor's products than studies with no industry sponsorship or author conflict of interest.[3,4,5,6] 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.[7] Industry sponsorship and authors with a conflict of interest 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

[1] 87 FR 21885-21886
[2] 87 FR 21885-21886
[3] Odierna DH, Forsyth SR, White J, et al. The cycle of bias in health research: a framework and toolbox for critical appraisal training. Account Res. 2013;20(2):127-41. 11
[4] Fabbri A, Lai A, Grundy Q, et al. The Influence of Industry Sponsorship on the Research Agenda: A Scoping Review. Am J Public Health. 2018;108(11):e9-e16. 12
[5] Psaty BM, Prentice RL. Minimizing bias in randomized trials: the importance of blinding. JAMA. 2010;304(7):793-4. 13
[6] Psaty BM, Kronmal RA. Reporting mortality findings in trials of rofecoxib for Alzheimer disease or cognitive impairment: a case study based on documents from rofecoxib litigation. JAMA. 2008;299(15):1813-7.
[7] Bero LA, Grundy Q. Why Having a (Nonfinancial) Interest Is Not a Conflict of Interest. PLoS Biol. 2016 Dec 21;14(12):e2001221. doi: 10.1371/journal.pbio.2001221. PMID: 28002462; PMCID: PMC5176169.

well as frame the questions that are asked. 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.[8,9,10,11]

Federal ethics regulations require EPA to "[a]ssure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes".[12] Therefore, 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. We have made these comments and more in our recommendations to EPA regarding conflicts of interest. (Appendix 1)

We encourage EPA to consider the following when considering nominations:

- **The role of reviewers and the SAB in supporting the mission of EPA in protecting human health and the environment**. As such, EPA has a professional and legal duty to select committee members who will provide credible and independent scientific analysis and advice free from financial conflicts of interest or a strong bias toward the perspective of regulated industries that may have a vested interest in minimizing EPA's regulation of hazardous materials and products.
- **The need for transparent and effective disclosure policies that are strictly enforced.** These disclosure and conflict of interest policies play an essential role in protecting EPA and committee work products from the possibility of biased and distorted scientific conclusions and must be strictly enforced and routinely addressed to ensure the quality of SAB work products.
- **The need for representation from directly impacted, susceptible, vulnerable, and/or highly exposed populations**. We urge the Agency to not only seek representatives that have *specific scientific expertise* in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations, but to incorporate a broader and more inclusive definition to capture representation from individuals with diverse knowledge sources that represent unique perspectives to these critical issues. EPA has encouraged "citizen science" but then has then erected expertise barriers that essentially prevent those with expertise about impacted communities but perhaps without certain privileged credentials (i.e., holding a postgraduate degree) from taking part in critical discussions. There are many examples of successful implementation of such approaches, which have demonstrated that incorporating

[8] Bero L, Anglemyer A, Vesterinen H, Krauth D. The relationship between study sponsorship, risks of bias, and research outcomes in atrazine exposure studies conducted in non-human animals: Systematic review and meta-analysis. Environment International. 2016;92-93:597-604
[9] Yank V, Rennie D, Bero LA. Financial ties and concordance between results and conclusions in meta-analyses: Retrospective cohort study. British Medical Journal. 2007;335(7631):1202-5.
[10] Mandrioli D, Kearns CE, Bero LA. 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. 2016;11(9):e0162198.
[11] Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. The Cochrane database of systematic reviews. 2017;2:MR000033-MR.
[12] 41 C.F.R. § 102-3.105(h)

knowledge resources outside of traditional academics and science fields can greatly enrich the research and policy process.[13]

Regarding financial conflicts of interest, we have concerns about the following nominees to the SAB:

1. **Chad Thompson – ToxStrategies**

Dr. Thompson has a clear conflict of interest, as disclosed in his biosketch, "Dr. Thompson has conducted and published research on the MOA of intestinal tumors in mice following oral exposure to hexavalent chromium. This research was funding by the Hexavalent Chromium Panel of the American Chemistry Council." (ACC) Not only did ACC fund the research via its Hexavalent Chromium Panel, but was actively a part of every phase of the research, as shown by a 2014 paper co-authored by Thompson and published in the journal *Food and Chemical Toxicology* that includes the following disclosure: *"***This work was supported by the Cr(VI) Panel of the American Chemistry Council (ACC). The funders were given the opportunity to review the draft study design, as it went through an external peer review process, and draft manuscripts at the time of external peer review.** The purpose of the review was to allow input on the clarity of the science presented but not in interpretation of the research findings. The contents of this review reflect solely the view of the authors." (emphasis added)[14]
As MOA for tumors from oral exposure to hexavalent chromium is going to be a critical issue for this peer review, the fact that Dr. Thompson's existing body of work on this substance has been funded by and in collaboration with entities that possess a financial conflict of interest such as the American Chemistry Council, should be grounds to exclude him from the list of candidates in order to ensure that the SAB produces an "independent scientific and technical review" as required. Further, Dr. Thompson's publications advocate a particular MOA for cancer outcomes and a for a threshold approach to dose-response assessment of hexavalent chromium cancer risk that would underestimate human risks to chromium indicating an appearance of a loss of impartiality relevant to this review.[15,16,17]

2. **Samuel Cohen – University of Nebraska Medical Center**

Dr. Samuel Cohen has a stated conflict of interest, as disclosed by his bio, "His research is funded from the NIH, Arsenic Science Task Force, and Sumitomo Chemical Company." Further, while he did disclose that he received funding from the Arsenic Science Task Force (ASTF) he failed to disclose transparently the Task Force members. The relationship of Dr. Cohen and the ASTF has been raised previously as a

[13] Anderson, B.E., Naujokas, M.F. and Suk, W.A., 2015. Interweaving knowledge resources to address complex environmental health challenges. *Environmental health perspectives*, 123(11):1095-1099.

[14] Suh, M., Thompson, C. M., Kirman, C. R., Carakostas, M. C., Haws, L. C., Harris, M. A., & Proctor, D. M. (2014). High concentrations of hexavalent chromium in drinking water alter iron homeostasis in F344 rats and B6c3f1 Mice. *Food and Chemical Toxicology*, *65*, 381–388. https://doi.org/10.1016/j.fct.2014.01.009

[15] Thompson, C. M., Suh, M., Proctor, D. M., Haws, L. C., & Harris, M. A. (2017). Ten factors for considering the mode of action of Cr(VI)-induced gastrointestinal tumors in rodents. *Mutation Research/Genetic Toxicology and Environmental Mutagenesis*, *823*, 45–57. https://doi.org/10.1016/j.mrgentox.2017.08.004

[16] Thompson, C. M., Kirman, C. R., Hays, S. M., Suh, M., Harvey, S. E., Proctor, D. M., Rager, J. E., Haws, L. C., & Harris, M. A. (2017). Integration of mechanistic and pharmacokinetic information to derive oral reference dose and margin-of-exposure values for hexavalent chromium. *Journal of Applied Toxicology*, *38*(3), 351–365. https://doi.org/10.1002/jat.3545

[17] Thompson, C. M., Haws, L. C., Harris, M. A., Gatto, N. M., & Proctor, D. M. (2010). Application of the U.S. EPA mode of Action Framework for purposes of guiding future research: A case study involving the oral carcinogenicity of hexavalent chromium. *Toxicological Sciences*, *119*(1), 20–40. https://doi.org/10.1093/toxsci/kfq320

scientific integrity concern.[18] The ASTF is composed of organizations and entities representing a financial conflict of interest,[19] including:

- American Farm Bureau Federation
- Edison Electric Institute
- Juice Products Association
- Mulch and Soil Council
- National Mining Association
- Organic Arsenical Products Task Force
    - Drexel Chemical Co.
    - Luxembourg-Pamol, Inc.
- Rio Tinto, Ltd.
- The Fertilizer Institute
- Treated Wood Council
- USA Rice Federation
- Utility Water Act Group
- Wood Preservative Science Council

Most of Dr. Cohen's research is on arsenic carcinogenicity and threshold dose-response. His only publication on hexavalent chromium on PubMed is a 2020 study, which advocates a particular approach to the assessment of hexavalent chromium cancer risks, co-authored with Dr. Thompson, and is funded by industry ACC and ToxStrategies, representing a financial conflict of interest and the appearance of a loss of impartiality.[20] Finally, he is on the Board of the International Life Sciences Institute (ILSI) which is funded by myriad groups such as Monsanto, Bayer CropScience, Dow, Coca-Cola, Unilever, and the tobacco industry among others.[21,22,23] Similar to Dr. Thompson, if EPA is interested in a "independent scientific and technical peer review" then Dr. Cohen's deep ties to industries with financial investment in the outcomes of this panel should be sufficient to exclude him from the panel.

3. **Joseph Haney – Texas Commission on Environmental Quality**

Dr. Joseph Haney's biosketch indicates that as a regulatory toxicologist and risk assessor for the Texas Commission on Environmental Quality (TCEQ) his work and research "have been fully supported by state funding", however looking through his research background, it is clear that he possesses a conflict of interest through his and TCEQ's known collaborations and relationships with the industries that they are responsible for regulating.[24,25] Many of Dr. Haney's publications, particularly those on hexavalent

[18] Heath, David. (2014) Politics Derail Science on Arsenic, Endangering Public Health. *Scientific American.* Available: https://www.scientificamerican.com/article/politics-derail-science-on-arsenic-endangering-public-health/

[19] US EPA. (2014). Comment submitted by Arsenic Science Task Force et al. Available: https://www.regulations.gov/comment/EPA-HQ-ORD-2012-0830-0026

[20] Bhat, V. S., Cohen, S. M., Gordon, E. B., Wood, C. E., Cullen, J. M., Harris, M. A., Proctor, D. M., & Thompson, C. M. (2020). An adverse outcome pathway for small intestinal tumors in mice involving chronic cytotoxicity and regenerative hyperplasia: A case study with hexavalent chromium, Captan, and folpet. *Critical Reviews in Toxicology*, *50*(8), 685–706. https://doi.org/10.1080/10408444.2020.1823934

[21] Jacobs, A. (2019, September 16). *A shadowy industry group shapes food policy around the world*. The New York Times. Retrieved August 4, 2022, from https://www.nytimes.com/2019/09/16/health/ilsi-food-policy-india-brazil-china.html

[22] Steele, S., Ruskin, G., & Stuckler, D. (2020). Pushing partnerships: Corporate influence on research and policy via the International Life Sciences Institute. *Public Health Nutrition*, *23*(11), 2032–2040. https://doi.org/10.1017/s1368980019005184

[23] UCSF Industry Documents Library. (2022). Query – author: International Life Sciences Institute. Available: https://www.industrydocuments.ucsf.edu/results/#q=author%3A(INTL%20LIFE%20SCIENCES%20INST)&h=%7B%22hideDuplicates%22%3Atrue%2C%22hideFolders%22%3Atrue%7D&cache=true&count=508

[24] Sunset Advisory Commission. (2022). Staff Report - Texas Commission on Environmental Quality Texas Low-Level Radioactive Waste Disposal Compact Commission.

[25] Douglas, E. (2022, June 22). *Texans tell environmental agency: Stop being reluctant to regulate industry*. The Texas Tribune. Retrieved August 4, 2022, from https://www.texastribune.org/2022/06/22/texas-commission-environmental-quality-sunset-hearing/

chromium, have heavily cited or been published in collaboration with both industries with a financial conflict of interest or consulting groups, like Gradient, Exponent, and ToxStrategies, that represent them. [26,27] Additionally, one of his publications which heavily cites researchers and entities with known financial conflicts of interest indicates that he has already taken a position on a key issue to be considered by the peer review panel, which is a threshold for cancer outcomes from hexavalent chromium exposure.[28] This represents the "appearance of a loss of impartiality", one of the criteria for selection of committee members. Considering Dr. Haney and TCEQ's close relationships with regulated industries and the consulting groups that support them, it is clear he will not "bring a fully independent and objective scientific perspective" and should be excluded from consideration for this panel.

We appreciate the opportunity to provide public input. Please do not hesitate to contact us with any questions regarding these comments.

Sincerely,

Swati Rayasam, MSc
Science Associate
Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Courtney Cooper, MPH
Science Associate
Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Nicholas Chartres, PhD
Associate Director
Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Tracey Woodruff, PhD, MPH
Professor and Director
Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Daniel Axelrad, MPP
Independent consultant
Washington, DC

---

[26] Haney, J. (2015). Implications of dose-dependent target tissue absorption for linear and non-linear/threshold approaches in development of a cancer-based oral toxicity factor for hexavalent chromium. *Regulatory Toxicology and Pharmacology*, *72*(2), 194–201. https://doi.org/10.1016/j.yrtph.2015.04.015

[27] Haney, J. (2015). Use of dose-dependent absorption into target tissues to more accurately predict cancer risk at low oral doses of hexavalent chromium. *Regulatory Toxicology and Pharmacology*, *71*(1), 93–100. https://doi.org/10.1016/j.yrtph.2014.11.002

[28] Haney, J. (2015). Consideration of non-linear, non-threshold and threshold approaches for assessing the carcinogenicity of oral exposure to hexavalent chromium. *Regulatory Toxicology and Pharmacology*, *73*(3), 834–852. https://doi.org/10.1016/j.yrtph.2015.10.011

Appendix 1: UCSF PRHE Recommendations to EPA – Conflicts of Interest

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]

REFERENCES

1 Rennie D. Integrity in scientific publishing. Health Serv Res. 2010;45(3):885-96. Epub 2010/03/27. doi: HESR1088 [pii] 10.1111/j.1475-6773.2010.01088.x. PubMed PMID: 20337732
2 Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. Cochrane Database Syst Rev. 2017(2:MR000033.). doi: 10.1002/14651858.MR000033.pub3.; PMCID: 28207928.
3 White J, Bero LA. Corporate manipulation of research: Strategies are similar across five industries. Stanford Law & Policy Review. 2010;21((1)):105-34.
4 Bero, L., A. Anglemyer, H. Vesterinen and D. Krauth (2016). "The relationship between study sponsorship, risks of bias, and research outcomes in atrazine exposure studies conducted in non-human animals: Systematic review and meta-analysis." Environment international 92-93: 597-604.
5 National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process. Page. 79. Washington, DC: National Academies Press; 2014.

6 Bero L. Addressing Bias and Conflict of Interest Among Biomedical Researchers. JAMA. 2017;317(17):1723-4. doi: 10.1001/jama.2017.3854; PMCID: 28464166.
7 Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. Cochrane Database Syst Rev. 2017(2:MR000033.). doi: 10.1002/14651858.MR000033.pub3.; PMCID: 28207928.
8 White J, Bero LA. Corporate manipulation of research: Strategies are similar across five industries. Stanford Law & Policy Review. 2010;21((1)):105-34.
9 Mandrioli D, Kearns CE, Bero LA. 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. 2016;11(9):e0162198.
10 Odierna DH, Forsyth SR, White J, et al. The cycle of bias in health research: a framework and toolbox for critical appraisal training. Account Res. 2013;20(2):127-41.
11 Fabbri A, Lai A, Grundy Q, et al. The Influence of Industry Sponsorship on the Research Agenda: A Scoping Review. Am J Public Health. 2018;108(11):e9-e16.
12 Psaty BM, Prentice RL. Minimizing bias in randomized trials: the importance of blinding. JAMA. 2010;304(7):793-4.
13 Psaty BM, Kronmal RA. Reporting mortality findings in trials of rofecoxib for Alzheimer disease or cognitive impairment: a case study based on documents from rofecoxib litigation. JAMA. 2008;299(15):1813-7.
14 Lenzer J. When is a point of view a conflict of interest? BMJ. 2016;355:i6194.