

Letter to the editors

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We recently read the article *Complexity and conflicts of interest statements: A case-study of emails exchanged between Coca-Cola and the principal investigators of the International Study of Childhood Obesity, Lifestyle and the Environment (ISCOLE)* published by Stuckler and colleagues in *J Publ Health Pol* [1]. We absolutely share the authors' appreciation for the need for transparency, the need to minimize conflicts of interest, and the important role that conflict of interest statements play in the integrity of the research process. We believe that anyone who reads the emails provided in the online appendix of the article by Stuckler et al. [1] will realize that we, as the ISCOLE Principal investigators (PIs), had a cordial and professional relationship with The Coca-Cola Company (TCCC). However, this should not be interpreted as evidence that the TCCC influenced our decisions. TCCC did not have any role and did not exert any influence on the development of the protocol and methods, data acquisition, data management, statistical analysis, interpretation of results, or manuscript development at any stage of ISCOLE.

In trying to make sure that all the facts are clearly reported and properly interpreted, we make the following comments:

First, we agree with a major conclusion of the paper: *Overall, apart from influencing the total number of study sites, we found no evidence of Coca-Cola exerting 'hard power' over the Pennington PIs, where the funder directly changes core methodological principles or points in the research* [1]. We note that this conclusion does not appear in the abstract of the paper. Indeed, the abstract is vague in its conclusion, stating *...the correspondence describes detailed exchanges on the*

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study design, presentation of results and acknowledgment of funding. This statement may lead the reader to erroneously conclude that there was evidence that TCCC exerted their influence on the study.

Second, we acknowledge the number of study sites that was negotiated between the study PIs and TCCC. However, the discussion about the number of study sites was related to developing the contract and budget for the study, which was directly impacted by the number of sites, rather than the study design. ISCOLE was a large cross-sectional, multi-national study of the correlates of obesity in children from all regions of the world, and these design elements, in addition to the study procedures and methods, were not influenced by the number of study sites (i.e., 10, 11, or 12 study sites). Indeed, our sample size was estimated based on a power analysis by our study biostatistician, which indicated that we would require 6000 children spread across 12 sites in order to properly conduct our planned analyses [2]. Due to the hard work of our site PIs, we exceeded this goal, with 7372 children participating in the study [3]. As is evident from the selection of emails in the online attachment of Stuckler et al. [1], TCCC also made suggestions about potential countries to include (i.e., Russia, Finland, Thailand). However, the final decision about which sites to include was solely the decision of the ISCOLE PIs. Evidence to support this contention is that many of the countries suggested by TCCC, including Russia and Thailand, are not sites in ISCOLE.

Third, after the authors concluded that there was no evidence of undue influence from TCCC on the ISCOLE protocol [1], they outline the limitations and reasons why they may not have come to the opposite conclusion. It seems that the authors are disappointed that they could not find evidence to support their *a priori* views. In this regard, the final sentence of the paper does not match their conclusion, as it states: “Is the ISCOLE’s statement *The study sponsor had no role in study design, data collection, analysis, conclusions or publications, accurate?*” [1]. A simple answer here would have been that the conflict statement is indeed accurate.

Fourth, we noted that the “ethnography of emails” presented by Stuckler and colleagues [1] only included emails that give the impression of supporting their thesis but failed to present data that support a different hypothesis. Examples of available email data, not presented in the report, include the following:

11/5/2013:

Thanks Rhona,

We are in agreement. We are very grateful for you allowing us to meet in your facility which this will save money for the study and allow us to preserve our budget for achieving the study objectives. However, we need to maintain the separation between the sponsor and the investigators that we have worked hard to maintain since the beginning of the study. I think we have done a good job of this to date, and we have a bullet-proof relationship that should be the model for these types of industry–scientist partnerships in the future.



Peter

11/12/2013:

Hi Rhona,

I wanted to touch base about our ISCOLE meeting. It went extremely well. Thank you for the space to meet - it was perfect.

One part of our conversation revolved around the relationship with the sponsor. All PIs were extremely complimentary - and really appreciated the hands-off approach of the sponsor - this was promised from the beginning and you have certainly followed through. They felt that this should be a case study in how industry can sponsor research ethically.

Peter

Fifth, the article by Stuckler and colleagues includes a section on “Coca-Cola’s influence on study acknowledgment,” where they take issue with the fact that TCCC specified the text in the funding acknowledgment [1]. However, this is a common practice by both governmental and industry funders of research. For example, the U.S. National Institutes of Health requires that all publications include a similar statement:

Research reported in this [publication/press release] was supported by [name of the Institute(s), Center, or other NIH offices] of the National Institutes of Health under award number [specific NIH Grant Number(s) in this format: R01GM987654] [4].

Therefore, we believe that it was perfectly reasonable that TCCC provided its views on the funding acknowledgment that was used in ISCOLE publications.

As obesity researchers, we must engage the food and beverage industry in research partnerships to advance our science. Indeed, across biomedical research in general, it has been recommended that “...biomedical research must look to the private sector and not the federal government as the source of new funds” [5]. The ISCOLE academic/industry partnership itself was designed as a model for future successful research partnerships. Given that ISCOLE was an experiment in how researchers can properly work with the food and beverage industry, we knew that this partnership would be highly scrutinized. We took extra precautions to ensure that the entire research process was completely transparent and that TCCC did not influence the research process. One measure was the establishment of an External Advisory Board to monitor our progress as well as our relationship with the sponsor [2]. Other measures included publishing our research in open access journals wherever possible, and ensuring that all of our questionnaires, methods, and data algorithms are publicly available.

All of our published papers have undergone peer review, and we remain confident that our results and interpretation of the results were not biased by our relationship with the sponsor. We hope that the intense scrutiny our work has received as illustrated in the article by Stuckler and colleagues [1] will not dissuade other researchers from exploring future industry/academic partnerships to improve public health.



It is our sincere hope that this industry-funded study is viewed as a great success and provides a template for future industry–academic partnerships and research capacity development. Thank you for this opportunity to provide your readers additional information to help them make the most informed evaluation of the work.

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