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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)

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Abstract Statements on conflicts of interest provide important information for readers of scientific papers. There is now compelling evidence from several fields that papers reporting funding from organizations that have an interest in the results often generate different findings from those that do not report such funding. We describe the findings of an analysis of correspondence between representatives of a major soft drinks company and scientists researching childhood obesity. Although the studies report no influence by the funder, the correspondence describes detailed exchanges on the study design, presentation of results and acknowledgement of funding. This raises important questions about the meaning of standard statements on conflicts of interest.

Keywords Conflict of interest · Competing interest · Public health · Soft drinks · Childhood obesity

Introduction

In an ideal world, scientific research would be entirely free from bias, with factors such as the source of funding of the authors playing no role in the design of a study, how it is analysed and how the findings are presented. Unfortunately, this is not

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always the case, and a growing body of work, especially meta-analyses, have shown that the source of funding may be an important determinant of the results, while other research, such as analyses of documents obtained from the tobacco industry, has revealed clear evidence of influence by the funders of research.

This has led scientific journals to require authors to complete statements listing any competing or conflicting interests. A conflict of interest is considered to exist where “professional judgment concerning a primary interest (such as patients’ welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry)” [1]. Thus, conflict-of-interest statements, which should list funding sources, have come to play a fundamental role in managing potential conflicts in scientific research. Their utility, however, depends on the extent to which they accurately report not just who funded research but what role they played. It is common for studies that acknowledge funding to report that “the funder had no influence on the study”. But what does this actually mean?

Answering this question is not straightforward, for several reasons. First, exchanges between researchers and funders are often hidden from view, making it impossible to ascertain whether there really was no influence and, if there was, what form it took. Conflict-of-interest statements are self-reported and concerns about perceived bias may encourage researchers to downplay the funder’s role. Second, the nature of influence is not always observable. Theories of power differentiate three aspects [2, 3]. One is sometimes referred to as “hard power”, where one party instructs another or exerts coercion. This would occur if the funder insisted on changes to study design, for example. Another is “soft power”, where no formal demands are made but one party seeks to please the other. Thus, a researcher may anticipate what the funder would want to see, without being told explicitly, perhaps because of a belief that this would encourage future funding. The third is manipulation, where both parties come to share a set of beliefs about an issue, such as what answers to a problem are or are not acceptable. This is a more radical dimension, more difficult to observe, and involves shaping a party’s cognitions and/or dispositions.

Previous studies have shown that the source of funding, as disclosed in papers, is associated with the findings of research. For example, clinical trials in psychiatry found that those where at least one author reported a financial conflict of interest were 4.9-fold more likely to report positive results than those that did not [4]. Another meta-analysis of systematic reviews conducted in the field of sugar-sweetened beverages found that those with food industry funding were five times more likely to report no positive association between weight gain and obesity than those not reporting funding [5]. Another analysis found that industry-funded reviews were more likely to suggest evidence of a causal relation between sugar-sweetened beverages and that the weight gain was weak [6], and another that industry funding of reviews of research on artificial sweeteners was associated with study findings [7]. Yet another found that the only studies finding an adverse effect of smoking bans on revenues in the hospitality industry were funded by the tobacco industry [8]. However, the reasons underlying these correlations with industry sponsorship are unclear.



Case-study

Here we take advantage of a case-study where we look beneath the surface of disclosure of conflict-of-interest statements to better understand the relationship between an industry sponsor and public health academics. In this case, we focus on researchers in the United States (US), using emails obtained through the Freedom of Information requests (FOI) in the state of Louisiana. In some countries, individuals have a legal right to ask public bodies, which may include public universities, to reveal documentary material that they hold on particular issues. While there are usually many exceptions, such as national security, or personal information, or where finding and retrieving the material would involve excessive cost, a public body receiving such a Freedom of Information request is usually required to disclose the documents, or explain why it is not doing so, within a defined number of days. The title of the pertinent law in the state of Louisiana is the Louisiana Public Records Act (La. R.S. 44:1 et seq.).

Our analysis focuses on a contested area, childhood obesity, where the food industry has a clear interest in the results of scientific research. The food industry has strongly opposed public health interventions such as taxes on sugar-sweetened beverages and emphasizes the importance of physical activity as a solution to obesity, diverting attention from the role of unhealthy diet [9]. Prominent public health actors, such as the new United States CDC director, have seen Coca-Cola as an ally in the fight against obesity [10].

Specifically, we investigate the Coca-Cola-funded International Study of Childhood Obesity, Lifestyle and the Environment (ISCOLE), among the largest multi-country studies of factors driving childhood obesity. The ISCOLE began in 2012, when Coca-Cola awarded a \$1 million contract to the Pennington Biomedical Research Center to coordinate the project. In total, Coca-Cola invested \$6,426,000 in the ISCOLE [11]. Its primary aim was to determine relationships between lifestyle and childhood obesity across countries; it included 6000 ten-year-old children from 12 countries in five major geographical regions of the world [12]. At the time of writing, it has produced at least 40 peer-reviewed publications (Supplementary table 1).

Of these 40, 13 were in a supplement to the International Journal of Obesity, which while noting support from Coca Cola, make no mention of whether it was involved in aspects of the study design etc.. Two other papers included a similar statement. Of the remainder, 24 report that “The funder had no role in the design and conduct of the study, the collection, management, analysis and interpretation of the data, or preparation, review and approval of the manuscript” or some close variant making the same point (Box 1). One paper could not be retrieved.

Here we assess this statement through an ‘ethnography of emails’ regarding the design, conclusions and publications, as revealed in correspondence between the Principal Investigators of the ISCOLE, Timothy Church and Peter T. Katzmarzyk, of Pennington Biomedical Research Center, in Baton Rouge, and Rhona Applebaum, Vice President and Chief Scientific & Regulatory Officer, in Atlanta, until June 2013 and later Chief Science and Health Officer, of Coca-Cola at the time, and



Box 1 Coca-Cola's intention to avoid perception of influencing the study

“With that—I just want to clarify the understanding and agreement we have had regarding ISCOLE meetings held at The Coca-Cola Company. Asking Peter and/or Tim, also copied herein, to confirm same

Due to the potential for this very important study to be intentionally distorted by those who have concerns re our support, it has been agreed that Coca-Cola associates will not be in attendance at either meetings of the Advisors or meetings of the PIs/study personnel. By so doing we maintain the integrity of the statement (below) used in all presentations/publications as well our commitment to published Conflict of Interest Principles

If there has been a change in thinking pls let me know. The last thing we need is for ISCOLE and/or any of the scientists associated with same to be challenged and have the study's and/or the scientists' integrity/credibility compromised

Many thanks

ISCOLE is funded by The Coca-Cola Company

The study sponsor has no role in study design, data collection, analysis, conclusions or publications

The only sponsor requirement was that the study be global in nature”

Beate Lloyd, Senior Director, Nutrition Center of Expertise, Scientific and Regulatory Affairs, in Atlanta. The U.S. Right to Know (USRTK, usrtk.org), a consumer and public health group, obtained the emails and documents. This organization conducts wide-ranging investigations into the food and agricultural industries, examining the health risks of their products, and their public relations, political and lobbying campaigns. Since its founding in 2015, the USRTK (GR) has made a series of public requests to assess potential links between Coca-Cola and public health leaders and academics. For this study, the USRTK sent a state Freedom of Information request, as permitted by the Louisiana Public Records Act, on 19 September 2016 to Louisiana State University, in Baton Rouge seeking emails and other documents exchanged between Professors Church and Katzmarzyk with Coca-Cola or the American Beverage Association. The USRTK received responses from Louisiana State University in batches between 23 September and 14 October 2016.

This analysis shows the complexity of the nature of influence itself, and raises the question of whether existing statements fully capture any influence exerted via “soft power”. If they fail to capture this complexity, does this failure invalidate statements such as that used by the ISCOLE in its papers?

Coca-Cola's influence on study design

The emails suggest that the researchers did consult and include Coca-Cola representatives in making strategic decisions about study design. In the early stages of planning the study, for example, the parties debated which and how many countries are to be included. Applebaum emailed Katzmarzyk on 26 March 2012 saying: “Ok—so with Russia and Finland we are at 13? Or no Finland and at 12. Seriously—our CEO hates the #13” (Appendix 1 in supplementary material; please see <https://link.springer.com/article/10.1057/s41271-017-0095-7>). She continued,



“Serious about this 13 business. We have no FL [floor?] 13 at Coke”. Applebaum asked Katzmarzyk: “What other country should we look at?”, to which he responded, “We should talk about Russia as well—do you have contacts there already?” (Appendix 1 in supplementary material). Applebaum offered a suggestion to Church (in which he copied Katzmarzyk) about adding two more countries, but replies suggest that the researchers were willing to accept her proposals. The reference to the number 13 should be interpreted in light of the widespread view, in many western countries, that this number is unlucky. Katzmarzyk wrote to Applebaum and Church: “We can work out a more detailed budget if this is something you would want to pursue” (Appendix 2 in supplementary material).

This seeming deference by the researchers to Coca-Cola is apparent in subsequent exchanges. Katzmarzyk briefed Applebaum on the potential exclusion of Mexico, noting that it was failing to achieve its study milestones, and presented options for other countries. He solicited Applebaum’s views on how to proceed, saying to her: “Please let us know your thoughts” (Appendix 3 in supplementary material).

Other comments reinforce this apparent willingness by the researchers to please their funders. For example, Timothy Church of Pennington Biomedical Research Center wrote to Beate Lloyd (Senior Director of Nutrition) on 11 July 2013: “we are grateful for the funding and we value our relationship with the TCCC [The Coca-Cola Company]. It is very important to me to have a plan that TCCC is happy with moving forward” (Appendix 4 in supplementary material).

In the published protocol for the ISCOLE, no rationale was given for selecting these particular countries other than to have a wide geographical distribution [12].

Coke’s influence on study progress and publication

The ISCOLE PIs at Pennington kept Coca-Cola informed of their progress and sought to arrange meetings linked to project milestones at Coca-Cola’s offices. They seemed particularly keen to ensure maximum publicity for their findings, itself entirely natural, but in close collaboration with their funder Coca-Cola. Thus, Church and Katzmarzyk wrote to Applebaum in July 2012 updating them on the ISCOLE’s progress: “Tim and I were talking—we would like to come over to Atlanta for a day to meet with you all—to discuss the media strategy and develop key talking points on our partnership” (Appendix 4 in supplementary material).

Frequent contact between PIs and Coca-Cola create an impression that Coca-Cola played a role in shaping research presentations. For example, Katzmarzyk wrote to Applebaum and Church on 19 July 2012 about an upcoming presentation, “Okay, I have drafted an abstract and an agenda for the symposium. Comments and edits welcome. PK” (Appendix 5 in supplementary material).

Despite these interactions, there seemed to be a clear desire among the Pennington PIs to avoid potential public perception that Coca-Cola had influenced the study. For example, Katzmarzyk noted to Applebaum and Church on 7 May 2014 after his presentation, “See below I just got the evaluation form (sic) my TOS [The



Obesity Society] presentation last fall: 99% of the 97 people who responded said the presentation was free of commercial bias!!!”.

But 5% said that I didn’t present faculty disclosures—which is BS [bullshit—a derogatory term meaning “rubbish”]- I just checked my slide deck and I presented this at both the beginning and end. Some people may have been asleep” (Appendix 6 in supplementary material).

The PIs also seem to have felt the need to have Coca-Cola approve their media strategy. For example, Katzmarzyk asked Applebaum and Church whether it would be acceptable to share the ISCOLE slides with a USA Today reporter: “Okay for me to share my slides with Nanci Hellmich?” A short discussion ensued, then Applebaum apparently gave her blessings: “It will be great!” (Appendix 7 in supplementary material).

It is clear that Applebaum did review publications and, at times, stated opinions. In one instance, Applebaum replied to other Coca-Cola representatives, “Hi I’m not comfortable saying this is a study about obesity prevention. Would need to get approval from the researchers” (Appendix 5 in supplementary material).

Coca-Cola’s influence on study acknowledgement

Coca-Cola maintained contractual control over the study’s conflict-of-interest statements. Quoting the study agreement, “PBRC agrees that if Sponsor so requests, and only if Sponsor requests, substantive releases and/or written reports contemplated by this Article 6 may include language to the effect that ‘The Study was funded by Coca-Cola.’” (Appendix 8 in supplementary material).

Applebaum exercised this influence, by specifying the desired conflict-of-interest statement. Katzmarzyk wrote to Applebaum, on 18 January 2013, “Yes, in the acknowledgements section—where this is typically done, we have the language inserted that you wanted (I think) from our meeting with your group in Atlanta: ‘ISCOLE is funded by the Coca-Cola Company. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.’” (Appendix 9 in supplementary material) Applebaum wrote to the ISCOLE researchers on 4 August 2015 “I’m proud to say was supported by The Coca-Cola Company—and that’s it—support only” (Appendix 10 in supplementary material).

Overall, Coca-Cola seemed to be pleased with the ISCOLE. When the journal *Obesity* published a paper, entitled “Relationship between lifestyle behaviours and obesity in children aged 9–11: Results from a 12-country study” in August 2015. The article concluded that “behavioural risk factors are important correlates of obesity in children, including low MVPA (moderate to vigorous physical activity), short sleep duration and high TV viewing”. Rhona Applebaum wrote, “A very happy day!!!...Love the tagline, ‘Global study is first of its kind to survey children across different cultures.’”(Appendix 10 in supplementary material).



Conclusions

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. However, the email exchanges appear to convey evidence of Coca-Cola’s exercise of ‘soft power’, whereby the researchers consistently sought to ensure the funders were satisfied and sought their guidance on choices of study design, framing and public presentation of study findings. It is not possible, using documentary analysis, to identify the third face of power, manipulation, although this should be addressed in future research. That would, most likely, require empirical research by psychologists.

As with all papers based on Freedom of Information requests, our approach had several limitations. First, our analysis examines one major grant between Coca-Cola and the PIs. It is not possible to generalize from this analysis to all conflicts of interest or even other disclosures on Coca-Cola-funded research. Previous investigations into recent Coca-Cola-funded research, however, produce similar findings, including apparent efforts to influence research, suggesting that it may be part of a broader strategy [13]. Second, much of the analysis here draws on what was supplied by Louisiana State University and this may be an incomplete sample of all relevant material. In response to our FOI request on 6 October 2016, an administrator at the University responded thus: “Our information technology system migrated to a new email platform in May 2015. From the point of the migration forward, any emails that were transferred, written, received or deleted are available and readily accessible in current email stores. The file transfer included contains emails that are available and readily. Any emails either archived or deleted prior to the system migration are not readily accessible and would only be attainable through a recovery process... Delivery of any resulting data (of which there may be none) entails a process that could take several weeks to complete, is dependent upon a successful backup tape restore, and such a process would be “unreasonably burdensome or expensive”. To access this material would be expensive and time-consuming for Louisiana State University and could require costly and prolonged legal action by us to exact compliance. That also means that the analysis reported here, while it advances knowledge beyond previous studies of conflicts of interest by looking ‘beneath the surface’ at the process of research and collaboration, is nonetheless incomplete. More generally, further efforts are needed to strengthen and ensure the integrity of FOI laws as a mechanism for transparency.

The use of the FOI laws is also a double-edged sword. The strategy has proven useful in exposing wrongdoing in the tobacco, agricultural, and pharmaceutical industries. However, corporations may also use FOI requests to influence and stymie the activities at public institutions. Researchers and funders who fear that every detail of their correspondence could be made public might be pushed to be more secretive in their exchanges, making it more difficult in the future to bring any wrongdoing into the light.

Given what we have shown, we are left with one important question. Is the ISCOLE’s statement, “The study sponsor has no role in study design, data collection, analysis, conclusions or publications”, accurate?



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