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"Always read the small print": a case study of commercial research funding, disclosure and agreements with Coca-Cola

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Abstract

Concerns about conflicts of interest in commercially funded research have generated increasing disclosure requirements, but are these enough to assess influence? Using the Coca-Cola Company as an example, we explore its research agreements to understand influence. Freedom of Information requests identified 87,013 pages of documents, including five agreements between Coca-Cola and public institutions in the United States, and Canada. We assess whether they allowed Coca-Cola to exercise control or influence. Provisions gave Coca-Cola the right to review research in advance of publication as well as control over (1) study data, (2) disclosure of results and (3) acknowledgement of Coca-Cola funding. Some agreements specified that Coca-Cola has the ultimate decision about any publication of peer-reviewed papers prior to its approval of the researchers' final report. If so desired, Coca-Cola can thus prevent publication of unfavourable research, but we found no evidence of this to date in the emails we received. The documents also reveal researchers can negotiate with funders successfully to remove restrictive clauses on their research. We recommend journals supplement funding disclosures and conflict-of-interest statements by requiring authors to attach funder agreements.

Keywords Coca-Cola \cdot Research funding \cdot Transparency \cdot Industry funding \cdot Conflicts of interest

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Introduction

In the wake of criticisms about a lack of transparency of financial support for medical and scientific research, several multinational corporations (MNCs) recently committed to publishing relevant information on the scale and nature of their investments in research, publishing lists of projects they fund and developing principles to apply to their relationship with researchers. But are these measures sufficient to disclose the potentially complex nature of these relationships and associated contractual obligations?

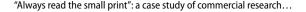
To answer this question, we have undertaken a case study about one of the corporations that seeks to position itself at the forefront of this process, The Coca-Cola Company. The company is an appropriate example to study because, following criticism of its activities, it has published a 'Transparency List' of researchers whom it funded from 2010 to 2017. It also progressively refined an explicit set of principles for the researchers it funds, providing a basis for comparing its stated intentions and its practice. In 2016, it brought together its principles formally [1]. It also released the list of partnerships and research funding with an explicit statement that those researchers that it funded on the list were:

- "expected to conduct research that is factual, transparent and designed objectively";
- (2) to have "full control of the study design, the execution and the collection, analysis and interpretation of the data";
- (3) "encouraged to publish" and
- (4) "expected to disclose their funding sources in all publications and public presentations of the data". It added that the company did not "have the right to prevent the publication of research results" and that funding was not "conditioned on the outcome of the research".[2]

These four major assertions provide a base for comparing Coca-Cola's stated intentions to its actual practices. We see on Coca-Cola's own website that it makes these claim around its research funded since 2010 [2](Fig. 1):

At least on the surface, these principles conflict with anecdotal reports of the corporation's activities following their publication. As one example, in 2015, a *New York Times* exposé revealed that Coca-Cola designed its funding of the Global Energy Balance Network (GEBN) to divert attention from the role that sugar-sweetened beverages play in the obesity epidemic by excessively emphasising the role of lack of exercise [3]. The *Times* article asserted that Coca-Cola, just like Big Tobacco, had sought to influence public health and medical researchers, and to deploy them to promote the Company's agenda, even though some of these researchers reported the funding to be 'unrestricted', meaning that it can be used for any purpose or by an organisation, rather than being given for a specific project or purpose [3, 4]. GEBN was subsequently closed in November 2015, on which Coca-Cola declined to comment [5]. A 2019 article revealed Coca-Cola's funding of bodies like the International Life Sciences Institute in China, showing









how the latter organisation is deployed to shape obesity science and related policy [6, 7]. A feature in the British Medical Journal suggested also that the transparency list was incomplete, and highlighted how Coca-Cola acts to exercise 'soft power' by using its funding to influence everything from conferences to academic positions [8]. So how can these pieces of information be reconciled? Does Coca-Cola really uphold its public commitments on research funding? Have its grants—past and present—really allowed researchers to operate free from influence as Coca-Cola suggests on its website?

Here, we seek evidence supporting or rejecting Coca-Cola's four major research principles detailed above, using information obtained from United States (US) state and federal, as well as Australian, British, Canadian and Danish Freedom of Information (FOI) requests for communications between Coca-Cola and leading public health academics or federal or state agency employees who were known to receive funding from or to collaborate with the company. Our FOI requests yielded a large volume of material on Coca-Cola's engagement in public health-related issues. These include five agreements between researchers or their host organisation and Coca-Cola, plus a large amount of related correspondence that enables us to assess whether these principles were being observed previously as asserted, and are now being upheld in relations with researchers. We look both at the legal (or *de jure*) aspects of the agreements and how they were operationalised in practice in the relationships with researchers (de facto).

Methods

A non-profit consumer and public health research group in the United States, U.S. Right to Know (USRTK), based in Oakland, California, investigates the food and agrichemical industries, examining their public relations, political and lobbying campaigns, as well as the health risks associated with their products [9]. (One author, GR, is a co-director of USRTK). Drawing on the approach used in past studies of corporate behaviour and related litigation [10], between 2015 and 2018, USRTK sent 129 FOI requests to United States (US), Australian, British, Canadian and Danish public bodies related to Coca-Cola's links with public health actors, including academics. USRTK selected the higher education institutions because they were governed by FOI laws (that exist in many jurisdictions around the world to encourage openness and transparency by public bodies, including at the state and federal level in the US, as well as in Australia, Britain, Canada and Denmark where USRTK also sent requests), or because USRTK identified these institutions as having received funding from Coca-Cola through its recent public disclosures [2].

The responses yielded 87,013 pages of documents, including five research agreements made with Louisiana State University [11, 12], University of South Carolina [13], University of Toronto [14] and the University of Washington [15]. The research team archived the FOI responses using document discovery software used across the legal services industry, extracted the research agreement and then two members of the research team read the documents to assess the concordance between Coca-Cola's principles detailed above. One of these researchers is trained as a lawyer (SS) and the other is a public health researcher (DS).

Inevitably, the sample has potential limitations to its external validity. First, the sample is not comprehensive, as redactions and removal of some emails from the batch are allowed in line with certain legislative exemptions, and it is impossible to ascertain whether FOI responses form a complete sample of communications and other contractual documents between Coca-Cola and associated researchers. As with a small number of cases, quantitative study was not feasible, we thematically and legally evaluated the agreements by testing whether there existed evidence to confirm or refute Coca-Cola's four major assertions on research transparency and independence of researchers. To limit the scope for personal biases in interpretation, the entire research team engaged in reflexivity, reviewing the selection and interpretation of the source material. Second, the five research agreements pre-date Coca-Cola's publication of its transparency principles in 2016, although its own website states that all of the disclosed health and well-being research complied with these four assertions. Furthermore, several researchers themselves publicly claim that the funding had no influence on their research, which we examine more fully below [16]. Third, we report extracts as they appear in the agreements and quote any related emails "in their own words" to allow readers to assess critically our interpretations. To ensure reproducibility of our study, all agreements and cited communications are posted on Internet.

Results

We summarise our findings in as they pertain to each of Coca-Cola's four major research transparency assertions [2].

Assertion 1 Researchers retain full control over the design, execution, analysis and interpretation of research

The documents obtained by FOI indicate that, although it does not have the capacity to direct and control the day-to-day conduct of studies, Coca-Cola retains varied rights throughout the research process, including the power to terminate studies early without giving reasons. Several agreements reveal that the company maintains the right to receive and comment on research prior to submission for publication. However, the researchers may reject these changes. Thus, the company can influence but not direct the research output, but may use termination provisions as a mechanism to discontinue research.

The emails we obtained reveal that academic partners recognise Coca-Cola's influence on the research it funds, even where it is not directing the research. For example, Tommy Coggins, Director of University of South Carolina's (USC) Sponsored Award Management and Research Compliance, in an email to Professor Tom Chandler of USC's Norman J. Arnold School of Public Health, explained that several of the research agreements entered into at the University allowed Coca-Cola to have:

a substantial say in how it [the research] was conducted and how results are handled, including ownership of all IP. None of this is wrong or unusual, but it is a typical industry research agreement. Also, contains a good bit of language about confidentiality and sharing results with Coca-Cola, but no bar on publication [17].

Coggins was commenting on a study that aimed to uncover the "extent to which variation in total energy expenditure and variation in total energy intake contribute to changes in body weight and fat among young adults". The agreements we obtained specify that Coca-Cola's comments are non-binding unless its suggested revisions to drafts pertain to information covered in the confidentiality provisions in the agreement, under which Coca-Cola retains the right to redact content accordingly.

Taking a specific example, as part of the "Sponsored Clinical Trial Research Agreement" between Coca-Cola and the Board of Supervisors of Louisiana State University, represented by Pennington Biomedical Research Center (PBRC), we find a 2012 research agreement for a study with Timothy Church as Principal Investigator related to fluid balance and performance with ad libitum water, flavoured placebo or carbohydrate-electrolyte beverage intake during exercise in the heat (known henceforth as the "The APEX Study") [18]. The contract sets out mutual obligations of all parties as including regular reports to and data sharing with Coca-Cola, as well as the standard termination provision, which allows Coca-Cola to retain all data. Article 6.1 specifies:

Publication prior to delivery of the final report of any information gained in the course of performing the Project must be in a peer reviewed journal, must be approved in writing by both parties prior to such publication, and must acknowledge that the Study was funded by The Coca-Cola Company. Notwithstanding the foregoing, the Sponsor will not be approving the content of the publication, but has a right to review and provide comment before submission for publication [12].

Thus, while Coca-Cola contends that its guidance is not tantamount to approval, it does retain the right to comment on papers prior to publication, and holds the ability to terminate studies at any time without reasons.

Indeed, Coca-Cola may simply terminate an agreement if the findings are not in its interests or if its comments and revisions are rejected. Such provisions do, however, vary amongst the research agreements we obtained. As one example, we show a "Research Agreement" between Coca-Cola and the South Carolina Research Foundation, a non-profit entity that accepts donations for USC, to fund a study entitled "Energy Balance" in 2010–2015. Section "Discussion" of the agreement provides that Coca-Cola can make non-binding suggestions and may only redact information covered by its confidential Information" includes disclosures made "orally or in writing" pertaining to "technical or business information regarding the Sponsor's products, marketing plans, public relations plans or Protocol". Notably, this agreement empowers Coca-Cola to terminate the agreement with notice and to require the return or destruction of all of this Confidential Information. Specifically, Section 6.2 states that, as long as 15 days written notice is given and with no need to give a reason:

6.3.4: SCRF shall immediately discontinue any work and shall take such precautions as requested by Sponsor, including returning to Sponsor or certifying in writing to Sponsor that it had destroyed all documents and other tangible items containing Sponsor Confidential Information [13].

Other agreements contain provisions that do allow for recall of all research documents and materials on termination. In the Church APEX study, detailed above, the termination provisions of this agreement are stronger, stating in Article 4.4 that:

Upon receipt of a notice of early termination, PBRC will immediately discontinue all work under this Agreement and return all copies of Sponsor data, or other materials, and deliver to sponsor all work in progress, including incomplete work... [12]

Such termination provisions could, hypothetically, allow Coca-Cola to quash studies progressing unfavourably, or allow Coca-Cola to pressure researchers using the threat of termination. However, we found no evidence that this has occurred in our FOI batches. In one instance, we did find Coca-Cola had ended a study with little or no information being sent to researchers or their institutions. For example, emails between researchers at USC pertaining to the Active Healthy Living Programme funded by Coca-Cola, state:

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As you know, the contract with Coca-Cola to develop and evaluate the Active Healthy Living Program has terminated. While I am not sure, because they have not communicated with us in several months, it appears that Coca-Cola has dropped the program. We put a lot into development of the program, and if possible, I would like to obtain/retain the intellectual property. Please look into where we stand with this, and let's figure out next steps. Thanks [19].

Our FOI, however, does indicate that Coca-Cola may be willing to negotiate the terms of agreements to moderate language regarding pre-publication communication and consultation with Coca-Cola. In emails between University of Toronto Professor John Sievenpiper and Coca-Cola's Susan Roberts regarding a proposed, then signed, research agreement, Sievenpiper requests revision of provisions he regards as restrictive. The original text, which Sievenpiper requests to be deleted in its entirety, states:

U of T will afford TCCC [The Coca-Cola Company] the prior right to review and approve (or reject) any communication or other material developed by U of T or its employees, contractors or agents discussing this Agreement or the underlying grant, the related work or accomplishments of U of T and/or TCCC, or any related or other association between U of T and TCCC, or otherwise mentioning TCCC's name or displaying TCCC's trademarks [14].

Sievenpiper comments that it is "very restrictive for being an 'unrestricted grant", and Coca-Cola agreed to change the wording to "consult with each other in good faith regarding any communication with third party/ies...". This involved significant back and forth emails and discussion, suggesting that the original wording may be standard wording in other Coca-Cola research agreements.

Assertion 2 Researchers are encouraged to publish and Coca-Cola does not have the right to prevent the publication of research results

Our research confirms that Coca-Cola encourages researchers to publish in peerreviewed publications and generally only retains limited rights to delay publication to protect its proprietary interests or to obtain a patent. However, many agreements contain the above-discussed termination provisions, allowing either fixed-notice period termination, or early termination according to the agreement's terms (as described above), some restricting publication following such a termination.

For example, in the agreement pertaining to Church's APEX study, Article 6.1, provided above in full, states that publication "*must be in a peer reviewed journal, must be approved in writing by both parties prior to such publication, and must acknowledge that the Study was funded by The Coca-Cola Company*". While this indicates that Coca-Cola does encourage publication as it states, and does not have a right to prevent publication, only providing comments, Article 6.2 makes clear that Coca-Cola can issue a written notice to require a delay to publishing where its proprietary interests are at stake; but there is no general right to control publication of results unfavourable to Coca-Cola's commercial interests

[12.] The provisions do, however, convey a right of Coca-Cola to comment and prompt revisions, as discussed above.

Similar provisions are found in a "Research Agreement" between Coca-Cola and the South Carolina Research Foundation [13]. Section "Discussion" on "Publication Rights and Use of Project Results" states similarly that Coca-Cola can require a delay where it wishes to file a patent or protect its proprietary interests, and that such a delay should not exceed 120 days. Retention of a capacity to delay publication is consonant with ordinary industry-funded research provisions, but in public health research it may delay significant findings from reaching the public.

Notably, the APEX study agreement does not contain provisions that allow Coke to prevent publication absolutely, but does require written permission for publication of all peer-reviewed publications where such publication would be *prior to the final report to* Coca-Cola (Art 6.2). This, in concert with the termination provisions that require cessation of research and the full and complete handover of all study documents, may enable Coca-Cola to shape unfavourable findings in advance of publication (Art 4.4). Thus, while Coca-Cola cannot stop publication, termination provisions could allow it to prevent publication through termination and recall of documents, along with the written consent requirement obligation in Article 6.2. Notably, this provision only has effect prior to the report to Coca-Cola, and thereby is not absolute in its effect. The agreements themselves are unclear as to the nature of the required reports and whether they will be made public and subject to peer review.

Assertion 3 Researchers are expected to disclose their funding sources in all publications and public presentations of the data

We found that the agreements identified in our study routinely allow for the attribution that a study, paper or report was "funded by The Coca-Cola Company". For example, Article 6.3 of the research agreement between Coca-Cola and the South Carolina Research Foundation states:

Publication shall acknowledge authorship according to generally accepted criteria for authorship and subject to journal requirements, if applicable. 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 The Coca-Cola Company" [13].

Notably, the phrasing "PBRC agrees that if Sponsor so requests, and only if Sponsor requests..." does not grant the University the right to use this attribution on all outputs. However, the peer-review provisions in Article 6 seem to imply that Coca-Cola expects the disclosure of funding sources in publications, as this is routine practice amongst reputable journals. The provision extends to publicity related to the research, placing the funding attribution within the hands of Coca-Cola rather than with the host or researcher. The contracts allow for a funding

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declaration to be phrased in a way that does not extend to a complete and detailed declaration of Coca-Cola's input into the research, although the agreements are silent as to whether more robust statements are allowed.

Assertion 4 Coca-Cola does not make funding conditioned on the outcome of the research

The research agreements contain no provisions on any outcomes of any study. However, as noted above, this could hypothetically be exercised through the termination provision. Thus, while we found no direct conditions pertaining to outcomes of the research, the effect of permissive termination provisions and recall of data provisions could indirectly have a 'chilling effect 'on researcher's work, influencing what researchers conclude. Past research has revealed that researchers do strive to maintain positive relations with Coca-Cola and produce results favourable to them [20].

Discussion

Our review of Coca-Cola's research agreements reveals that it uses terms in line with standard funding agreements seen with other corporate actors. Specifically, these contractual agreements contain no provisions granting the company absolute control over the studies it funds, but they could allow it to assert influence over studies and resultant publications. We found that Coca-Cola requires regular reports and input into projects, and maintains the ability to terminate agreements early and without reason. Of course, in some cases such early termination provisions are justifiable; for example, when there is improper behaviour like harassment or bullying, a failure to deliver work in accord with the contract or the other such examples, which tend to be given as reasons for termination. In contrast, the contractual terms for early termination without reasons are arguably beyond the legal scope needed to address such justifiable concerns, although they are not uncommon in commercial agreements generally and there is no evidence of their use in our batch. In light of past evidence of 'soft influence', whereby researchers sought to please funders in ways which, albeit not contractually specified, in practice operated to the same effect, the company's continued input and early termination provisions undermine its public assertions of researcher independence [20].

Before interpreting the implications of our study for research, policy and improving management of COIs, we must acknowledge several limitations. First, our case studies focused on Coca-Cola may not generalise to other segments of food and beverage industries. However, the contractual agreements appear to be commonly employed between private actors and public researchers. Second, several recipients of USRTK's FOI requests returned or did not respond to them, or, in some cases, they redacted material submitted. It is possible that we have been unable to detect contracts, which may have existed but were not obtainable through FOI, thus creating an omission bias in our analysis. The direction of such bias, however, would likely be to hide particularly egregious contracts. Third, despite a large document set, we only identified five research contracts. There may be heterogeneity in Coca-Cola's contracts with researchers given our observations that researchers could negotiate their terms. That said, there was relatively limited variation across the five agreements.

Our research reveals a need to improve reporting of COIs. Many declarations of funding and routinely employed COI statements fail to specify the true amount of input and influence Coca-Cola has (irrespective of whether it chooses to exercise it). While it is beyond the scope of our study to review all Coca-Cola funded research, we note that concerns have been raised elsewhere about the completeness of COIs in studies funded by Coca-Cola on topics of nutrition and physical inactivity [21]. Examples include publications arising from the Energy Balance grant at USC state "Supported by an unrestricted research grant from The Coca-Cola Company" [22]. Stephen Blair, one of the leads at USC, records that he has received funding from Coca-Cola, amongst others, in the preceding 5 years, as does co-author Gregory Hand. However, nowhere in the article is there a statement setting out the nature and amount of input Coca-Cola had, only that the funding was "unrestricted", which, as the email discussions between Coggins and Chandler indicate, was not how the grant was understood by USC. Coggins, as Director of Sponsored Award Management and Research Compliance at USC, makes clear the "the Energy Flux and Balance studies were conducted under the terms of Research Agreement with SCRF... [and] are not "un-restricted"..." [17]. Such attributions of funding are similarly made with regards to the results of Timothy Church's APEX study, and are a reflective example of the agreement provisions regarding funding statements across the agreements we received and resultant publications [23, 24].

Our research points to particular concerns about early termination provisions. The termination provisions in some of the agreements that allow Coca-Cola to discontinue the studies it funds if results are unfavourable, in contrast to the assurances it makes on its website about not being able to prevent publication, should be cause of concern. Although not all agreements we reviewed allow for full recall of research documents and materials, we identified several agreements that in effect allow Coca-Cola to terminate a study, if the findings are unfavourable to Coca-Cola. We observed push-back by researchers receiving unrestricted grants regarding restrictive provisions, revealing that the researchers were aware that there could be a problem. Coca-Cola was receptive to requested revision, but this may be due to the ongoing relationship the Company had with this particular researcher. Certainly, some of the agreements allow for unfavourable developments or findings to be quashed prior to publication. Future research will be needed to identify when and the extent to which funded studies were not published. This is but one source of potential 'publication bias', whereby only positive results are made publicly visible. Given the hidden nature of unpublished, funded studies, this is an extremely challenging area of research as there is no way for researchers to ascertain who produced the studies, why they remain unpublished and what their results may be.

We acknowledge that many provisions in Coca-Cola's research funding agreements are standard, including its early termination provisions. While recent termination of a non-industry-funded United Kingdom study due to findings of bullying by a primary investigator evidences how these provisions may be exercised to encourage positive research environments [25], we note that early termination may be used to discontinue studies in a less positive way. We found evidence that in at least one study Coca-Cola discontinued funding, seemingly without reason given to those involved, but found no evidence that this related to unfavourable findings or prospective publications. We did find evidence suggesting that Coca-Cola exerts influence on the design, conduct and write-up of studies, retaining rights to comment and have input throughout the research process.

Turning to implications for COIs, this study adds to a growing body of literature of their limited usefulness. Qualitative studies with researchers reveal diverse interpretations of what COIs and influence mean [26]. It is also easy for COIs to be inadequately reported. Most of what is detected comes to us through journalistic exposés [27]. Our study adds to these insights, showing that such general (and notably brief) declarations may fail to capture Coca-Cola's full involvement in the studies they fund, from design through to publication.

To remedy these weaknesses, we propose far more 'hard' information about funding, rather than relying on self-reports. Specifically, we call for journals to require authors receiving Coca-Cola or other industry financial support to provide more robust COI and funding statements, including declaring the specifics of input allowed in the study's research agreements. In addition, journals should require authors of funded research to upload the research agreements for studies as appendices to any peer-reviewed publication, allowing these to be published with ease and at little expense on the existing electronic platforms where supplemental information is commonly provided. A reader's appraisal of a study's scientific objectivity would best be supported by knowledge that Coca-Cola has input at various stages of the research and publication processes, an understanding facilitated by access to the research agreement governing the study.

For medical and public health professionals, the lack of robust information on the details of input by industry and on studies terminated before results enter the public realm makes it impossible to know how much of the research that enters the public realm reflects industry positions and content, as opposed to fully unbiased and uninfluenced research results. It is critical that professionals and scholars be able to appraise influence. We know that people trust studies with an industry partner less and approach these studies with greater suspicion about bias [28]. Greater information is needed to appraise influence.

Where studies are terminated without having been registered in advance, as should be the case with clinical trials, it may be that termination acts as suppression of critical health information. We therefore call for industry funders to publish complete lists of terminated studies as part of their commitment to act with integrity, and for clear declarations of involvement as standard publication practice.

Author contributions GR collected the data via Freedom of Information Requests. SS and DS analysed the data. All authors contributed to the writing and revision of the manuscript.

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Data availability All cited responses received to our Freedom of Information requests have been weblinked to allow the response to be read in full by all. The Freedom of Information responses are available online on the USRTK website and links have been provided to allow the individual FOI response referenced to be read in full. These are PDF copies of the documents we received in conjunction with the relevant state laws. There are no additional data to provide.

Compliance with ethical standards

Competing interests SS and MM have no competing interests to declare. DS is funded by a European Research Council Grant: 313590-HRES and the Wellcome Trust. GR is a co-director of U.S. Right to Know, a non-profit public interest, consumer advocacy and public health organisation. Since its founding in 2014, USRTK has received the following contributions from major donors (gifts of \$5000 or more): Organic Consumers Association \$554,500; Laura and John Arnold Foundation: \$198,800; Dr. Bronner's Family Foundation: \$183,000; CrossFit Foundation: \$50,000; Westreich Foundation: \$25,000; Panta Rhea Foundation: \$20,000; Community Foundation of Western North Carolina (Little Acorn Fund – M): \$5,000.

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