

# 'Third-party' threats to research integrity in public-private partnerships

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Submitted 1 October 2001;  
initial review completed 29 October 2001;  
final version accepted 28 January 2002

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## ABSTRACT

This paper examines threats to scientific integrity posed by possible conflicts of interests that can occur when commercial entities participate in publicly funded research partnerships. Particular attention is given to the activities of the International Life Sciences Institute (ILSI), which presents itself as a society of learned individuals and groups working in the public interest. In reality, ILSI's members largely consist of commercial companies and corporate conglomerates involved in the manufacture of foods, beverages, chemicals and pharmaceuticals. The main conclusion is that conflicts of interest arising from third-party involvement in research partnerships are a threat to scientific integrity. Urgent action is needed by the scientific community to find ways to safeguard against threats to scientific integrity due to undeclared involvement of commercial entities in seemingly independent research and scholarship.

**KEYWORDS** Alcohol, caffeine, commercial interests, ILSI, research integrity, smoking.

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## INTRODUCTION

It is believed widely that the sharing of intellectual and physical resources by way of public-private partnerships can create productive synergies in research. Moreover, although governments world-wide recognize the importance of public support for research conducted in the public interest, these same governments appear ever more committed to encouraging public-private partnerships as a means of limiting the burden of cost to the public. Notwithstanding possible benefits to the public, the 'private' partner of such arrangements is often a company for whom the partnership offers commercial advantage. It is self-evident that private commercial interest may at times conflict with public interest. Consequently, on the assumption that integrity in science is *always* in the public interest, it would seem appropriate that extra care be taken to ensure the scientific integrity of research conducted by public-private partnerships. A minimum safeguard is full disclosure of possible conflicts of interest.

Conflict of interest was the main theme of a recent editorial in which Edwards & Savva (2001) drew atten-

tion to limitations in disclosures made by the sponsor of a book about alcohol consumption and health (MacDonald 1999) that had been submitted to this journal for review. The book's sponsor, the International Life Sciences Institute (ILSI), had operated as a 'third party' with undisclosed links to the drinks industry. Edwards & Savva (2001) stated that conflict of interest, although 'not in itself wrongdoing... should and must be declared'. This invocation has long been a principle of codes governing ethical practice in research such as the Declaration of Helsinki and amendments (World Medical Association 2000) and the Farmington Consensus (1997). In the section dealing with publications, the Helsinki Declaration states that 'Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication'. Similarly, the Farmington Consensus (1997) requires authors to declare relationships 'with any type of funding source [that] might be fairly construed as exposing them to potential conflict of interest' (p. 1617). In this regard, the editorial by Edwards & Savva is important in drawing attention to the possible involvement of third parties in public-private research partnerships,

because third parties can give industry scope for concealing commercial interests in research outcomes. Closer examination of ILSI's activities serves to illustrate wider issues.

### **ILSI: FORMATION AND INITIAL ACTIVITIES**

Following passage by the United States Congress of new laws on foods and drugs in 1958, a list was compiled of some hundreds of additives, including caffeine, that were generally recognized as safe (GRAS). During the late 1970s, the Center for Science in the Public Interest, a US-based consumer-advocacy group, petitioned the United States Food and Drug Administration (FDA) to remove caffeine from the GRAS list. ILSI was founded during this period against a background of growing concern about possible adverse health implications of long-term consumption of caffeine (James 1994). Specifically, according to Pendergrast (1999), ILSI was founded in 1978 with funding from soft drink manufacturers. In 1980, in response to evidence of caffeine-induced teratogenic effects in rodents, the FDA issued a warning cautioning pregnant women against the use of coffee, and for a time caffeine's 'safe' status was in jeopardy. ILSI responded by initiating a wide-ranging review of the caffeine literature and submitted this work to the FDA in the form of an extensive report that was subsequently published as an edited book (Dews 1984). The book addressed the physiology, pharmacology and toxicology of caffeine, and much of its content was erudite and scholarly. However, in sections dealing with potentially adverse effects of caffeine, the available evidence appeared to be interpreted in the interests of the book's sponsors. Overall, caffeine was represented as being an essentially benign substance, when the evidence at the time of publication was open to alternative interpretations less favourable to the interests of caffeine manufacturers (James 1991).

Apart from scope for concealing possible conflicts of interest, an additional concern regarding the involvement of third parties in research partnerships is that industry influence may take subtle forms. By juxtaposing balanced works on basic science with less-balanced accounts of issues pertinent to health, the latter can be given greater credibility by association with the former. Indeed, the mere involvement of industry in research can be a form of manipulation, even if no attempt is made to influence results. This key tactic, pursued over several decades by the tobacco industry, was described early by one United States Senator as 'a stroke of ingenuity' (Neuberger 1963), because of the strategy's success in obfuscating the true impact of tobacco on health. For

decades, the act alone of supporting research gave credibility to industry claims of concern for the public interest. Moreover, by advertising its support for research, the tobacco industry succeeded in creating doubt in the general community about the severity of the hazards of smoking when no such doubts existed in the scientific community (Warner 1991).

### **ILSI: SUCCESSES OF THE THIRD-PARTY APPROACH**

Prior to the founding of ILSI, the threat to caffeine manufacturers was real. During the 20 years from 1962 to 1982, the average number of cups of coffee consumed per day in the United States declined 39% (Masterson 1983), and it is evident from caffeine-industry publications that manufacturers attributed much of this decline to increased public awareness of scientific concern about possible caffeine-induced harmful effects (James 1994). Around 1990, there was an arrest in the downward trend, and thereafter a reversal evidenced by substantially increased sales of coffee and tea. The improved commercial outlook for caffeine products has been largely attributed by industry representatives to the success of an industry campaign to counter adverse scientific findings (Heuman 1994; Richards 1994).

In its early years, ILSI declared itself to be 'a foundation developed primarily to permit companies to pool resources to support research programmes of common interest' (Dews 1984). In time, however, ILSI's role as a third-party representative of commercial interests evolved into a less openly stated operation, with the declaration that its central mission was 'to work toward a safer, healthier world' (<http://www.ilsi.org>). In less than a decade of its foundation ILSI had become a global organization, which now has regional offices in Africa, Asia, Australia, Europe, North America and South America. Today, ILSI adopts a public profile of independence and integrity in all its activities and operations. The name itself, 'International Life Sciences Institute', gives the impression of a learned society and all that this connotes.

Among ILSI's many subentities, its Research Foundation, created in 1984, 'recruits and engages internationally respected scientists to address scientific issues of public concern' (<http://europe.ilsil.org/index.cfm?pubentityid=12>). The Foundation has 'a Council of Scientific Advisors, whose members are drawn from the ranks of the world's top scientists [including] five Nobel laureates'. However, the Foundation is a subsidiary of ILSI, whose 'Assembly of Members' consists of hundreds of companies and corporate conglomerates. These commercial entities are involved in the manufac-

ture of foods, beverages, chemicals and pharmaceuticals, and include household corporate names such as Bayer, Coca Cola, Du Pont, Glaxo, Heinz, Hershey, Kellogg, Kraft, Lipton, Mars, Nabisco, Nestlé, Pepsi Cola, Procter & Gamble and Unilever, to name a few. Notwithstanding the credentials of the Research Foundation’s scientific advisors, ILSI’s Assembly of Members has commercial interests that are related directly to all of the Foundation’s research activities. ILSI does not advertise its commercial affiliations, but instead works at many levels in a manner which creates an impression of independence and public concern. At the level of the individual in society, through its literature and website (<http://www.ils.org>), ILSI solicits donations that are tax-deductible and offers the donor an opportunity to ‘make a difference’ to human happiness, health and wellbeing. ILSI also exerts influence by associating with public entities that are well known and highly esteemed. One such entity is the World Health Organization (WHO).

### WHO’S EXPERIENCE WITH THIRD PARTIES

In much of its literature, ILSI highlights its extensive collaboration with WHO, an affiliation which is now creating concern within the organizational structures of WHO (MacDonald 2001a). The Minnesota settlement of 1998, a result of lawsuits against the tobacco industry in the United States, resulted in millions of pages of confidential tobacco company documents being released into the public domain. While it comes as no surprise that tobacco companies have resisted proposals for tobacco control, the previously confidential documents reveal a scale and intensity of deception that was not known previously. In 2000, a WHO Committee of Experts on Tobacco Industry Documents reported that:

Tobacco companies have operated for many years with the deliberate purpose of subverting the efforts of WHO to address tobacco issues. The attempted subversion has been elaborate, well financed, sophisticated and usually invisible. (Zeltner *et al.* 2000; p. 18)

Zeltner *et al.* (2000) found that one method employed by the tobacco industry was to fund seemingly unbiased scientific groups (i.e. third parties) to influence political and scientific debate concerning tobacco and health. In 2001, the Tobacco Free Initiative (TFI), a WHO project, identified ILSI as one such group.

TFI reported that ILSI was in contact with the tobacco industry from 1983 to 1998, had been in receipt of tobacco industry funds, had engaged in actions on

behalf of the tobacco industry, and that ‘senior office bearers in ILSI were directly involved in these actions’ (<http://www.who.int/genevahearings/inquiry.html>). A summary account of TFI’s findings was published in the *British Medical Journal* (MacDonald 2001b), with a rebuttal from an ILSI Europe spokesperson (Murphy 2001). The gist of the rebuttal was that tobacco industry documents showed only that the industry was ‘interested in trying to use ILSI’, not that the companies were successful.

There are at least three reasons why Murphy’s (2001) argument should be seen as heightening concerns about ILSI’s operational tactics. First, ILSI’s long association with the tobacco industry, which included some funding from that industry, remained confidential until uncovered by others, and this happened only as a result of protracted legal proceedings against tobacco companies. Secondly, while Murphy (2001) acknowledged that some food and beverage companies that are subsidiaries of tobacco companies are ‘members of ILSI’, she claimed that ‘no tobacco companies are members of ILSI’ (p. 576). In fact, the Assembly of Members ([http://www.ils.org/misc/bmj\\_response/members.pdf](http://www.ils.org/misc/bmj_response/members.pdf)) lists Japan Tobacco, the fourth-largest tobacco company in the world, as a member. Finally, and crucially, Murphy’s rebuttal does not address the central issue of the fundamental obligation on all parties to declare possible conflicts of interest.

### THE EUROPEAN COMMISSION

Although essentially a third-party representative of commercial entities, ILSI has pursued a strategy of participating in publicly funded projects as if it were an independent non-commercial body. By way of illustration, ILSI is a partner in a large programmatic endeavour entitled ‘Food Safety in Europe: Risk Assessment of Chemicals in Food’ (FOSIE), funded by the Fifth Framework Programme of the European Commission. FOSIE is concerned with risks from chemical substances in the food chain (<http://www.ils.org/misc/fosie/index.html>). The findings of the project have direct implications for all of the categories of industry that form the membership of ILSI: namely, the food, beverage, chemical and pharmaceutical industries. There is representation of prominent industry names in the list of 60 partners, which also includes several universities, a European consumer umbrella group, the OECD and WHO. While the participation of an array of large and influential companies in publicly funded research raises questions about possible conflicts of interest when, as in this case, the names of the participants are in the public domain, the public is at least alerted. However, ILSI’s participation as a third party

presents difficulties of a different order. Specifically, ILSI's representation of itself as an independent body does not sit comfortably with the reality of its organisational structure.

Concerns about ILSI's role in research are especially serious in the case of FOSIE, because ILSI is not just a partner but actually *co-ordinates* the project. The named co-ordinator is Director of ILSI Europe, whose letter of reply to questions regarding possible conflict of interest surrounding the MacDonald (1999) book was described by Edwards & Savva (2001) as being of 'unconvincing content'. In addition, there is a FOSIE 'management team' consisting of the Director of ILSI Europe and two others, both ILSI Europe employees. There is also a 'steering committee', with a membership of 12, with majority representation comprising the same three ILSI Europe employees and representatives of companies, and minority representation comprising institutions whose primary interests are other than commercial. Thus, the management structure and control of FOSIE, a publicly funded project of great public interest, is substantially in the hands of commercial entities with vested interests in the project's outcomes.

## RESEARCH INTEGRITY AND PUBLIC-PRIVATE PARTNERSHIPS

Since merely declaring a possible conflict of interest would hardly seem sufficient in itself to ensure against undue influence, it is appropriate to ask what further steps should be taken to prevent a declared possible conflict of interest leading to actual influence? Also, what procedural protocols and institutional structures (other than the onus to declare possible conflicts of interest), should be established within research agencies (e.g. universities, institutes, scientific journals, granting bodies and industry) to safeguard against the special threats to scientific integrity posed by public-private partnerships? Many more such questions could be asked. To date, however, the research community does not appear to have been particularly successful in dealing with violations of the comparatively straightforward requirement to disclose possible conflicts of interest. As such, individual researchers and groups appear to be decidedly ill-prepared to address more complex problems that go beyond the circumscribed issue of conflict of interest.

For example, funding source is a key concern of codes governing ethical practice in research, including the Declaration of Helsinki and the Farmington Consensus. While funding source is likely to be important in drawing attention to possible conflicts of interest, it should not be regarded a necessary condition. Under the rules of the United States Internal Revenue Service, ILSI's Center

for Health Promotion qualifies as a public charity (<http://chp.ils.org/about/index.cfm?pubentityid=14>). Information previously, but no longer, available at ILSI's website stated that 'the centre's funding is designed to be separate from ILSI's', with the centre being encouraged to obtain funds from public sources. Moreover, while the current website states that governance of the centre is by a Board of Trustees comprised of scholars, an earlier ILSI web source stated that the centre's Board of Trustees is itself 'appointed by the ILSI Board'. As such, there is a real concern that the ILSI Board could exert ultimate control over the centre's activities, despite the centre's status as a financially independent charity and ILSI should be transparent in this regard.

## CONCLUSIONS

The main conclusion of this commentary is that third-party representation in research partnerships represents a threat to scientific integrity. In their analysis of tobacco industry efforts to undermine WHO activities, Zeltner *et al.* (2000) concluded that dealing effectively with problems of cigarette smoking, 'will be about overcoming a determined and powerful industry, many of whose most important counter-strategies are carried out in secret'. The same authors also suggested that the actions of tobacco companies in covertly opposing smoking controls puts smoking in a special category 'unlike other threats to health'. The present commentary suggests otherwise. Threats to research integrity having potentially harmful public health consequences are not restricted to the tobacco industry.

The health science community should take urgent action to find ways to safeguard against commercially related threats to scientific integrity. Ways must be found of ensuring exposure of possible conflicts of interest where they are not freely declared. Furthermore, when possible conflicts do exist, as seems inevitable in the context of some, if not all, public-private partnerships, ways must be found to safeguard against such conflicts undermining scientific integrity. The means for achieving such safeguards should include open and widespread discussion within the scientific community, followed by appropriate action in the form of new and more detailed research policies and protocols.

## ACKNOWLEDGEMENTS

The author gratefully acknowledges the comments of Dr Elizabeth Gregg and Drifa Hardardottir on an earlier draft of this paper, and support provided by the European Commission, Grant No. QLKI-CT-2000-00069.

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