

The alcohol industry and public interest science

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ABSTRACT

Aims This report argues that the growing involvement of the alcohol industry in scientific research needs to be acknowledged and addressed. It suggests a set of principles to guide ethical decision-making in the future. **Methods** We review relevant issues with regard to relationships between the alcohol industry and the international academic community, especially alcohol research scientists. The guiding principles proposed are modelled after expert committee statements, and describe the responsibilities of governmental agencies, the alcohol industry, journal editors and the academic community. These are followed by recommendations designed to inform individuals and institutions about current 'best practices' that are consistent with the principles. **Findings and conclusions** Growing evidence from the tobacco, pharmaceutical and medical fields suggests that financial interests of researchers may compromise their professional judgement and lead to research results that are biased in favour of commercial interests. It is recommended that the integrity of alcohol science is best served if all financial relationships with the alcoholic beverage industry are avoided. In cases where research funding, consulting, writing assignments and other activities are initiated, institutions, individuals and the alcoholic beverage industry itself are urged to follow appropriate guidelines that will increase the transparency and ethicality of such relationships.

Keywords Alcohol, alcohol beverage industry, alcohol research, conflict of interest, competing interests, ethics.

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Submitted 22 December 2008; initial review completed 6 April 2009; final version accepted 19 May 2009

INTRODUCTION

The alcohol industry is a powerful multi-national business complex that includes the producers of beer, wine and distilled spirits, as well as a large network of distributors, wholesalers and related organizations [1]. In addition to groups engaged directly in alcohol production and distribution, the industry includes trade associations, which are involved in information dissemination, collection of statistics, legislative advocacy, education programmes, media relations and scientific research, and 'social aspects' organizations, which manage sensitive issues that are relevant from the industry's viewpoint and often overlap with public health interests. Given the need for the alcoholic beverage industry to serve the interests of its stockholders, it is inevitable that the industry will at times be in conflict with the alcohol research community, which is defined here as individuals and organizations responsible for the production and interpretation of scientific information about the nature, causes and control of alcohol-related problems. The current world-wide

infrastructure of alcohol science includes numerous governmental research funding sources, more than 85 specialized scientific journals [2,3], scores of professional societies, more than 150 research centres and thousands of scientists investigating the genetic, biological, psychological and social aspects of alcohol use and misuse.

Traditional boundaries between alcohol scientists and for-profit organizations have been disappearing in many countries, as part of a general trend to make science more relevant to business applications and to provide revenues to academic institutions. One consequence of this has been the creation of conflicts of interest, particularly in the case of 'dangerous consumption' industries such as alcohol, tobacco and certain food products [4,5]. Studies have shown that conflicts of interests in health research are associated with biased research findings that favour commercial interests at the expense of patient health [6–11]. In this literature, bias has been associated with a wide variety of financial conflicts of interest, including acceptance of consulting fees, honorariums, gifts, grants, salary, stock options and contracts, which have been

given to scientists to prepare book chapters, edit books, draft journal articles, write letters to journal editors, speak at conferences and conduct research. In several integrative reviews of the evidence it has been argued that apparent conflicts of interest also decrease public trust in scientific research [12–14].

In the case of alcohol research, there has been increasing concern about the involvement of the alcoholic beverage industry in activities that impinge upon the public health and social welfare missions of research scientists and other professionals [15–17]. In one review of the literature [4], industry involvement in alcohol science was identified in seven areas: (i) sponsorship of research funding organizations; (ii) direct financing of university-based scientists and centres; (iii) studies conducted through contract research organizations; (iv) research conducted by trade organizations and social aspects/public relations organizations; (v) efforts to influence public perceptions of research, research findings and alcohol policies; (vi) publication of scientific documents and support of scientific journals; and (vii) sponsorship of scientific conferences and presentations at conferences. While industry involvement in research is increasing, it currently constitutes a rather small direct investment in the corpus of alcohol research. However, the industry's scientific activities often question or compete with public health views about alcohol problems and policy options, and question the need for population approaches to the prevention of alcohol problems [17]. Industry-supported research activities also give the industry an opportunity to demonstrate 'corporate responsibility' and thus gain political legitimacy and influence in the policy-making process [18]. The alcohol industry's involvement in alcohol research has been documented in several case studies where bias has been shown or suggested [19–23], and concerns have been raised in editorials and commentaries in the addiction speciality journals [24,25].

Within the context of the growing involvement of the alcohol industry in alcohol research, and its potential impact on the integrity of alcohol science, the aims of this article are: (i) to propose a set of voluntary standards that the alcohol research community could adopt to guide its relationships with the alcohol industry; (ii) to offer a set of 'ground rules' to the alcohol industry to govern their relationships with alcohol researchers and the broader academic community, including social policy and public health professionals; and (iii) to advise governments on how best to secure unbiased alcohol research.

CURRENT MODELS

A variety of frameworks have been proposed to guide the relationship between the alcohol industry and the alcohol research community: (i) partnership arrange-

ments; (ii) policy statements on conflicts of interest; (iii) ethical analyses, and (iv) blanket prohibitions.

Partnership arrangements

This approach encourages alcohol scientists to engage in dialogue with industry representatives, accept industry funding for their research, and participate as 'partners' in industry-funded scientific activities, such as the publication of books on alcohol-related problems and their prevention [26]. The most ambitious statement of this approach is the *Dublin Principles of Cooperation among the Beverage Alcohol Industry, Governments, Scientific Researchers, and the Public Health Community* [27], drafted by a group of individuals representing alcohol research, the alcohol industry, government, public health and non-governmental organizations, with financial support from the industry-sponsored International Center for Alcohol Policies (ICAP). The document proposes a constructive role for the industry as a player in alcohol control measures, including research; emphasizes the rights of researchers to work with the industry; and argues for the importance of an 'alternative truth' to that which focuses primarily upon alcohol as a risky product from a population perspective. As a model for the principles, Professor Hurst Hannum [28] refers to codes of conduct in marketing developed by the alcohol industry. However, the ICAP Dublin Principles are limited in their scope and do not properly address issues such as how to deal with conflict of interest, the prevention of research bias, the scientist's responsibility for the protection of research integrity and the relationship between the alcohol industry's support of alcohol research and its efforts to influence alcohol policy.

Conflict of interest policy (COI) statements

With increasing concerns about the potential for financial conflicts of interest to compromise research integrity, several organizations and self-appointed groups have developed consensus statements and voluntary guidelines to serve as a guide for research scientists and professional organizations. For example, the Federation of American Societies for Experimental Biology (FASEB) has issued a call to the scientific community to adopt more consistent policies and practices for disclosing and managing financial relationships between academia and industry in biomedical research [29]. The FASEB framework argues that investigators must conduct research activities objectively, operate with transparency and be accountable to all stakeholders. These principles are embodied in the *FASEB Toolkit and Guidelines* [29], which can be used by institutions, journal editors and scientific and professional societies to construct conflict of interest policies relevant to their own particular needs.

Another approach is described in the RESPECT Code of Practice [30]: a voluntary model code designed to protect researchers from unprofessional or unethical demands. The guidelines state that it is the duty of a responsible researcher to balance three different principles: scientific integrity; respect for the law; and the avoidance of social or personal harm. The document's recommendations are designed to uphold scientific standards, recognizing that it is impossible to lay down absolute rules that apply in all cases. Researchers are required to ensure factual accuracy and avoid misrepresentation, fabrication, suppression or misinterpretation of data; take account of the work of colleagues, including research that challenges their own results; use appropriate methodologies; and declare any conflict of interest that may arise in their research.

To promote uniform conflict of interest guidelines for scientific journals that publish alcohol research, the International Society of Addiction Journal Editors has issued a consensus statement [31] stating that all sources of funding and possible conflicts of interest should be declared when a scientific manuscript is submitted for editorial review. The consensus statement also requires that journal editors themselves declare any associations with the alcohol, tobacco and pharmaceutical industries. In an extension of the Farmington Consensus, the journal *Drug and Alcohol Review* [32] has developed a set of guidelines regarding conflict of interest that apply to all members of the editorial team, including the editors, staff and the editorial board.

Ethical analysis

Conflict-of-interest disclosure policies and exhortations to respect the highest ethical standards depend on voluntary adherence to external guidelines, with some attention given to the enforcement of these policies by professional organizations and journal editors. In contrast, the ethical analysis approach depends on the development of moral reasoning skills in the scientific community. One such approach that has been applied to conflict of interest situations in relation to 'dangerous consumption industries' is Peter Adams' moral jeopardy analysis [5]. Three kinds of risk are considered in Adams' proposal: (i) reputational risks, which refer to the negative perceptions of stakeholders when accepting industry funding; (ii) governance risks, where industry funding affects an organization's capacity to make choices about their future; and (iii) relationship risk, which is the potential damage done to an individual's or organization's working relationships over disagreements about industry funding. Instead of providing a binary approach to decision-making about industry relationships, Adams recommends that individuals and organizations engage

in a consciousness-raising exercise to consider all information relevant to an understanding of the degree of moral jeopardy involved in a particular choice.

Of particular relevance is the Purposes, Extent, Relevant, Identified and Link ethical risk analysis model he proposes. This can be conducted for the benefit of individual scientists, professionals, policy-makers and institutional officials who have the power to define appropriate funding sources, to make decisions and raise awareness. It is conducted by answering five questions: (i) to what extent do the *purposes* of the industry (e.g. return on investment, increased alcohol sales) differ from those of the scientist (e.g. to find out how best to prevent alcohol-related problems)? (ii) Is the *extent* or amount of research support offered sufficient to compromise the independence of an individual scientist or an academic institution? (iii) Is there *relevant* harm associated with continued marketing of the industry's products (for example, beer and alcopops are the beverages of choice for adolescent binge drinkers)? The greater the relevant harm, the greater the investigator's risk of being compromised by collaboration. (iv) Will the recipient of the funds be *identified* with the funder and will the industry-related organization derive a public relations benefit from its support of scientists? Could the scientists or their institutions eventually be exposed to reputational risk? (v) Finally, is the nature of the *link* between recipient and donor direct or indirect? If it is indirect, in some cases it may not involve a major conflict of interest.

Blanket prohibitions

In some cases universities have decided to prohibit all contacts with particular industries. For instance, the Stockholm University administration decided in January 2003 that no research funded by tobacco money should take place at the university (<http://www.su.se/pub/jsp/popopoly.jsp?d=1033&a=3086>), 'since it is not in accordance with the overall goals of the university. A not negligible risk is that the research funding agency in this case will use the name of the university to gain legitimacy both in society at large and in relation to other possible financing bodies. Research financed in this way could also by outsiders be used to cast doubt on the integrity of the researcher.' Other universities and professional groups have enacted similar policies, but we do not know of any such statements that have been developed with regard to the alcohol industry.

Summary

With options ranging from working collaboratively with the alcohol industry to blanket prohibitions of any financial conflicts of interest, there is obviously little consensus about how best to manage the relationship between the

alcohol research community and the alcohol industry. Although many of the conflict of interest approaches from other research fields seem relevant to alcohol industry issues, most have been developed to deal with the specific relationship between clinical scientists and the pharmaceutical industry. Another limitation is that they are often too general in scope to be helpful, or lack clarity, both of which may lead to confusion and non-compliance. The major elements of conflict of interest policies typically used by universities and other organizations (e.g. disclosure, conflict management) may be insufficient to control the more worrisome influences of financial conflicts of interest [33] with alcohol industry funding. Finally, many of the guidelines and codes may not be relevant to developing countries where industry funding is sometimes the only source of support for alcohol research.

Our proposal is therefore to develop a set of voluntary guidelines based on several of the models reviewed above [29,31], and to apply them to the major stakeholders in the alcohol field: government agencies, the alcohol industry, research scientists and their institutions. Below we offer a set of general principles along with recommendations derived from them.

GUIDING PRINCIPLES FOR RELATIONS BETWEEN THE ALCOHOL INDUSTRY AND SCIENTIFIC RESEARCH

Governmental agencies

Principles

Alcohol consumption is a potential threat to the health and welfare of a large part of the population in many countries of the world. Governments have a responsibility to protect the health and welfare of the population as a whole [34]. Using such tools as social policy, health law and legal enforcement, this responsibility makes the state distinct from other stakeholders, such as the alcohol industry or non-governmental organizations that represent specific interests that may conflict with public health and welfare. One task of the government is to ensure that policymakers and the general public receive accurate information about the health and social consequences of drinking, as well as evidence-informed policy assessments. A special case concerns government agencies which, themselves, are actors in the alcohol market. In many countries these agencies, such as state alcohol monopolies, were set up specifically to exclude private interests from parts of the market, and to operate in the interests of public health and order. In some cases these agencies have drifted over time into acting primarily as revenue-producing agencies. The field of gambling offers examples of government gambling agencies supporting

only those kinds of research that will not interfere with revenue maximization [35]. Where this appears to be true of a government alcohol agency, it should act in accordance with the principles laid out below for the alcohol industry.

Recommendations

Governments should:

- 1 Develop research funding policies that are designed to produce objective and relevant evidence for public health and social policy formulation.
- 2 Recognize the commercial imperative of industry. If industry funds research, measures should be taken to ensure that such research does not distort the totality of scientific evidence. In the case of public-private partnerships in research funding, government should consider excluding alcohol research partnerships with alcohol industry agencies, where an inherent conflict of interest may arise.
- 3 Provide the necessary resources to monitor systematically the research involvement and use of research of the industry and other stakeholders with specific interests. The pharmaceutical industry's registration of research could be a model. Monitoring may be particularly important in less developed countries with little publicly funded research.
- 4 Take action to channel industry support to research through publicly managed institutions.
- 5 Advise the general public and policy makers to analyse critically all sources of information about alcohol and alcohol-related problems.

The alcohol industry

Principles

The alcohol industry, including its trade associations and social aspect organizations, has an ethical responsibility to minimize the harm caused by its products at all stages of the production chain, including product design and marketing. The ethical responsibility of the industry for the harm caused by its products cannot be regarded solely as a national issue. A multi-national corporation has a responsibility for its behaviour world-wide [34]. This responsibility also concerns the relationship between the industry and research. In dealing with academic research, the industry has an ethical responsibility to respect the researcher and his/her intellectual ownership of the research results. In cases where the industry commissions or conducts research for commercial purposes, their proprietary interest in confidentiality and ownership should be recognized if it does not have relevance to public health (e.g. studies of agricultural productivity or wine quality).

Recommendations

The alcohol industry should:

- 1 Refrain from direct funding of biomedical and public health research because of the potential conflict of interest. If research funding is provided by the alcohol industry, it should be channelled through health or welfare authorities or independent research granting organizations, and not be specific to a particular topic, investigator or institution. All funding activities, including grants and contracts, should be disclosed in terms of the amount of money and type of project. Industry funding sources should give written assurances guaranteeing researchers complete freedom to publish findings, and funding sources should be disclosed in all publications.
- 2 The industry must respect the rules of science and the integrity of researchers and research organizations. They should quote and use the research in appropriate ways, and not use their sponsorship of scientific research for marketing or political lobbying purposes.
- 3 The alcohol industry, its trade associations and its social aspects/public relations organizations should refrain from scientific publishing through their own publishers. If they produce publications that claim to be scientific through other channels, they should follow rules of open scientific peer review and otherwise meet the standards of academic publishers.

The scientific community

Principles

The roles of those who produce knowledge in academia and those who have a financial interest in that knowledge should be kept separate and distinct [14]. Management of academic–industry relationships is a shared duty involving researchers, academic institutions and sponsors of research [29]. Financial interests and related research support from the industry have the potential to affect professional judgement, research integrity, the dissemination of research results and may strengthen the influence of private interests in the policy-making process. Accepting alcohol industry support may affect a scientist's reputation adversely and decrease public trust in research [29]. Scientists are well advised to take these reputational issues into consideration. They should keep in mind that the evolution of ethical thresholds and standards in recent decades has generally been towards more stringent standards, for instance in the case of tobacco.

There are differences between disciplines and according to research topics in the perceived threat to the reputation of a researcher from alcohol industry support. Many biomedical researchers and biomedically dominated research organizations do not see industry support

as problematic, whereas social science and public health researchers may be more sensitive to these issues, particularly if the research is of obvious policy relevance. To the extent that industry research funding initiatives are part of a larger corporate strategy to minimize the regulation of alcohol marketing, alcohol availability and taxation [18,36], biomedical scientists have, however, the same responsibility as behavioural and social scientists.

The scientific community has a fundamental responsibility to ensure that research is conducted objectively, transparently and in such a manner that researchers are accountable for the results to all stakeholders [29]. Research institutions have particular responsibility to protect the integrity of research. Research integrity means that researchers serve primarily scholarly and public interests. Scholarly, public or ethical considerations should not be compromised by economic gain or material advantage [30]. Research institutions also need to protect junior researchers from potential problems that can emanate from relations with the alcohol industry. Scientific journals, as part of the scientific community, have a special responsibility for the communication of objective, transparent and accountable research. Finally, research ethics committees also have a role to play in setting standards and policies regarding industry funding sources [37].

Recommendations

Strategies for dealing with individual conflicts of interest are the joint responsibility of individual investigators and the organizations where they work. Three main strategies should be used with regard to collaborations with the alcohol industry, depending on the extent of industry involvement, the nature of the conflict and other considerations [33]: (i) Disclosure is a first step and a general rule. Investigators should declare all sources of research funding and give full and regular internal (institutional) reporting and external disclosure of financial interests that could reasonably appear to affect the research [29]. (ii) Conflict management, with procedures to oversee and review conflicts of interest to prevent or minimize problems they might create, is a minimum requirement when research grants are awarded directly by industry sources to investigators. (iii) Prohibition to prevent or eliminate the conflict of interest is an option that should follow from proof of clear misbehaviour and breaches of the academic rules by an industry research sponsor.

Alcohol researchers should:

- 1 Follow the development of ethical issues related to industry funding of research and recommendations on how to handle these issues.
- 2 Pay particular attention to funding opportunities that are provided by organizations such as law firms,

consulting organizations and non-profit 'think tanks' to determine whether the research is actually being commissioned or supported by the alcoholic beverage industry or its social aspect organizations.

- 3 Conduct an ethical risk (e.g. PERIL) analysis before making any decision to accept industry funding for any activity connected with their expertise or research experience.
- 4 Be particularly attentive to requests to conduct studies or write review articles that are dictated by industry priorities, rather than investigator interests or expertise. If a research project is funded by the industry, the researcher must be ready at all times to demonstrate internally and externally that his or her research design, data collection and interpretation have not been influenced by the funding source.
- 5 Ensure that, if industry funding is provided for a research project, all obligations of the scientist and the industry source are defined in a detailed contract that is publicly available. In addition, industry-funded investigators, like those funded by governments and non-profit foundations, should have a research protocol that addresses the rationale, hypotheses and methods of the proposed research. These protocols should be subject to all appropriate human subjects protection procedures and should be publicly available.
- 6 Retain ownership of the data and publication rights [38].
- 7 Ensure that funding for a project should not be contingent on results [38].
- 8 Ensure that reimbursement for a study equals the direct and indirect costs of the work [38]. If full indirect costs are not covered, an explanation for the subsidization of the research should be provided. If indirect costs exceed the usual institutional rate, an explanation for this difference should also be provided.
- 9 Be prepared to defend publicly the results in academic debates and prevent his/her name from being used by commercial interests in a way that is not in accordance with the rules of objective science [29].
- 10 In deciding on whether to seek or use industry funding that will support doctoral studies or the work of other junior scientists, take into account the present and future reputational interests of the junior researcher.

Research organizations and academic institutions should:

- 1 Review all alcohol industry funding of its staff and assess whether the financial interest could affect the design, conduct or reporting of results or produce a real or perceived bias that will damage the credibility of the researcher or the institution [29].

- 2 Require continuous reports from projects with industry funding if institutional policy permits active management of obvious conflicts of interests.

- 3 Put particular emphasis on the protection of young researchers in industry-funded research and their possibilities to defend their scientific independence, adhere to reasonable time limits, publish their findings, and not be the object of suspicions of bias due to financial conflicts of interest

Scientific journals should:

- 1 Adhere to the Farmington Consensus [31] guidelines regarding their responsibilities to require conflict of interest declarations and to publish such declarations along with any research funded in whole or in part by the alcohol industry.

The scientific community should:

- 1 Ask the government(s) or an independent organization to monitor and report industry activities as they affect the integrity of science; develop case studies of industry activities that compromise scientific integrity; maintain a register of conflict of interest statements that is publicly available on the internet; and set up an international website to provide this information.
- 2 Based on the accumulated information, revise the guidelines continuously for relations between the alcohol industry and research.

CONCLUSION

Three approaches to the relationship between research and the alcohol industry have been discussed in this paper. One is a 'hands-off' position whereby members of the scientific community refuse to engage in communication or collaboration with industry representatives, based on the assumption that the industry's commercial interests are incompatible with the values and aims of social policy and public health in general and with health-related scientific research in particular [4]. The second approach is collaborative, where alcohol scientists are encouraged to engage in dialogue with industry representatives, accept industry funding for their research and participate as 'partners' in industry-funded scientific activities, such as the publication of books. The third approach argues that active collaboration with 'dangerous consumption' industries such as the alcoholic beverage industry contributes little to the advancement of science or health and welfare. This approach avoids categorical recommendations in favour of the application of risk analyses and guidelines that set forth conditions of cooperation between science and industry. Because this approach is more situational and individualized, it may be more appealing to the scientific community, but it should be recognized from the information reviewed in this paper that under most circumstances collaboration

with the alcoholic beverage industry is neither warranted nor advisable.

Acknowledgements

The authors would like to thank Robin Room for valuable comments to the manuscript.

Declarations of interest

Kerstin Stenius was employed as an editor of *Nordic Studies on Alcohol and Drugs* between 1983 and 1996 by the Finnish State Alcohol Monopoly. At that time the State monopoly had research departments under the Ministry of Social Affairs. In 1996 the journal and Stenius moved to the Finnish National Research and Development Board for Welfare and Health (Stakes). Thomas Babor has never received funding from the alcoholic beverage industry or its social aspects organizations.

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