

Report of the Working Group on the Alcohol Industry, Brief Interventions and INEBRIA

This report describes the recommendations of a Working Group appointed by the Coordinating Committee of INEBRIA to consider all issues relating to the alcohol industry (hereby referred to as the 'industry'), brief interventions and INEBRIA and to draft a concise position statement for consideration by the membership at the INEBRIA Annual General Meeting at the Annual Conference in Warsaw, Poland on 18-19 September, 2014. The following issues were presented in the remit to the Working Group:

1. Whether there is evidence that the alcohol industry supports brief interventions as a means of opposing effective population-level interventions to reduce alcohol problems, potentially undermining the credibility, influence, aims and objectives of INEBRIA;
2. How should INEBRIA view funding and other support by the alcohol industry for brief interventions, which appears to be increasing in recent times;
3. Whether industry funded research on brief interventions should be presented at INEBRIA conferences, or on the website;
4. Whether researchers in receipt of industry funding should be eligible for membership of INEBRIA and which timescales should apply to previous funding, i.e. how long a period of time should elapse from the end of funding before becoming eligible for membership;
5. Whether any distinctions should be made between direct funding by alcohol producers and retailers and indirect funding by Social Aspect/ Public Relations Organisations (SAPROs), dedicated research funding organisations and other front or third party groups;
6. Whether there are specific provisions necessary in respect of existing members with direct or indirect funding;
7. Whether any distinctions should be made between receiving research funding and working directly for the alcohol industry, or any industry-funded trade association or industry social aspects organisations;
8. Whether forms of financial support other than research funding, including directly for implementation purposes, also need to be considered;
9. How the alcohol industry and industry funding should be defined for these purposes.

Definitions and guidance

The '**ALCOHOL INDUSTRY**' is broadly defined to include producers, distributors, sellers and marketers of alcohol, including any company that derives significant revenues from producing, selling or marketing alcoholic products, or products necessary for the production of alcoholic beverages. The 'alcohol industry' also includes beer, wine and spirit trade associations and alcohol social aspect/ public relations organizations (SAPROs).

For the purposes of this report, **DIRECT FUNDING** is defined as funding received from the alcohol industry as described above. Funding from foundations, research institutions, university departments, etc. who receive over 5% of funding from the alcohol industry but have independent boards is considered

INDIRECT FUNDING. A list of some of these organizations can be found at <http://www.parint.org/isajewebsite/conflict3.htm>.

Working Group Membership

Volunteer participation in the working group was open to the entire membership of INEBRIA except those in receipt of industry funding within the last two years, for conflict of interest reasons. Members of the working group were asked to declare sources of funding, direct or indirect, and any connection with the tobacco or alcohol industries or any organisation/group substantially funded by them. This formulation was modelled on the requirements of the World Health Organisation. The WG was co-chaired by an ex-officio member who is an international expert in alcohol policy. A complete list of the Working Group membership is listed at the end of this report.

Methods of working

After the Working Group (WG) was established, a literature review and PERIL analyses were conducted, an initial response to the questions was prepared, and WG members edited the responses and reached consensus via email regarding the contents of this longer report as well as a shorter *Summary of Recommendations* that was also prepared. These documents were then submitted to the Coordinating Committee (CC) for consideration. Any related actions to be taken, including changes to the statutes, will be considered by the 2014 Annual General Meeting. Throughout this process the WG was assisted by Katherine Robaina, MPH, who helped with the initial draft and with the formulation of the PERIL Case Studies.

Responses to issues described in the WG remit

1. Is there any evidence that the alcohol industry supports brief interventions as a means of opposing effective population-level interventions to reduce alcohol problems, potentially undermining the credibility, influence, aims and objectives of INEBRIA?

NOTE: Some members of the WG found the wording of this question confusing. The meaning of the question was interpreted as follows: Is there any evidence that the alcohol industry supports brief interventions? If it does, is this done as a means of opposing effective population-level interventions to reduce alcohol problems? And does the industry have the potential to undermine the credibility, influence, aims and objectives of INEBRIA?

In response to the first part of this question, we reviewed industry-sponsored websites listing industry actions that pertain to screening and brief intervention (SBI). Most of these are summarised on a website (<http://initiatives.global-actions.org/>) which describes over 3500 'initiatives' undertaken by the alcohol industry in support of the World Health Organization's Global Strategy to Reduce Alcohol-related Harm (WHO, 2010). The site is maintained by the International Center for Alcohol Policies (ICAP), an industry-sponsored public relations organisation. Our review of industry sources identified 37 initiatives, or programs, in nine countries, including three with an "international" focus. Results were retrieved using the keywords 'screening' and/or 'brief intervention'. The industry-funded SBI activities identified tend to focus on high-risk drinking patterns rather than on volume of alcohol consumption.

Approximately half of the programs (17), which date from 2003, deal specifically with screening, brief intervention and referral to treatment. As indicated in Table 1, the programs are diverse, ranging from

Coors Brewers Limited's campaign in the UK to provide "the government's sensible drinking message and a logo to advertise against drinking during pregnancy," to the "BIG Initiative Clinician Training Program" in which Diageo USA is training Employee Assistance Program clinicians and counsellors to use SBI techniques in their work.

Seven research studies were identified (see projects in Table 1 with an asterisk (*) before their name), including a 2007/8 study funded by the European Foundation for Alcohol Research (ERAB) to examine if a workplace psychosocial intervention could reduce high-risk single session binge drinking among company employees. The Century Council, a large SAPRO in the US, funded two studies on the effectiveness of using text messages to reduce hazardous drinking (Diageo, 2013). And the Alcoholic Beverage Medical Research Foundation lists on their website fewer than 10 grant awards for brief intervention research made since 1983.

To the extent that the most recent SBI programs are part of a larger industry strategy coordinated by the alcohol industry, the second part of the question ("as a means of opposing effective population-level interventions") is more difficult to answer. Some critics of industry corporate social responsibility (CSR) activities (Babor and Robaina, 2013) have argued that these kinds of industry actions tend to be self-serving, focused on ineffective interventions with little or no evidence-base and are lacking in transparency. The promotion of SBI programs by the alcohol industry may qualify as support for particular evidence-based activities while failing to support the principle of evidence-based policy which does not permit such selectivity. In the case of SBI, in contrast to evidence-based supply-side policies (e.g., taxation), the effectiveness of the strategy can be easily undermined, even unintentionally, by poor implementation. The actual implementation and content of these programs have to be evaluated carefully to determine whether they are designed properly and are given appropriate logistical support. As part of its larger Corporate Social Responsibility strategy, industry activities such as SBI, drink-driving countermeasures and youth prevention programs seem to reflect the following industry goals (Babor and Robaina, 2013; Babor et al., 2013):

- Increase the social and psychological availability of alcohol
- Improve public perception and credibility of the industry, as they are working to ensure their products are used "responsibly".
- Narrow the focus on a small subset of the population (i.e., binge drinkers) and emphasise personal responsibility, while minimising industry responsibility – a common strategy used by the alcohol industry and very familiar to the tobacco industry.
- Highlight irresponsible drinkers as the problem, rather than alcohol itself.
- Promote the concept that moderate "healthy" drinking is beneficial (and therefore policies that infringe on moderate drinkers do not benefit public health). The industry has consistently exaggerated the claim that regular drinking is healthy.

Another way to evaluate whether the SBI actions are "a means of opposing effective population-level interventions" is to consider how such CSR activities are used in lobbying for industry-favourable policies, less regulation, or against evidence-based policies that have a wider population reach. The following examples, drawn from an unsystematic review of publicly-available industry documents and websites, suggest SBI is being used by the industry and related organisations to push a pro-industry agenda:

- Miller Beer, then owned by Philip Morris, explained the rationale for its responsible drinking campaigns as a means to defend its product from government interference. The strategy was to emphasise the alcohol industry's role as a 'responsible corporate citizen' and to "stress alcohol education programs and messages so as to develop public policy from a framework of education and responsible drinking, as opposed to one of control". It was a plan expressly designed to stave off effective government action. Miller vowed to "fight aggressively, with all available resources, against any attempt, from any quarter" public health efforts that would curb its ability to manufacture and market its product (Miller Brewing Company, 1992).
- In response to a consultation document issued by the Cabinet Office Strategy Unit and the Department of Health of the UK, the Portman Group (TPG) (2002) submitted, *The Alcohol Harm Reduction Strategy: a Response by The Portman Group* to the Department of Health of the UK. The document applauds the Cabinet for its decision to focus on reducing harm rather than on reducing consumption. It then recommends key principles to 'underpin' the strategy, including a strong emphasis on education and personal responsibility, stressing that the strategy should be targeted at harmful drinking rather than to "punish the majority." It also acknowledges "low-risk and beneficial drinking" (p2). TPG believes public health campaigns are more likely to succeed by focusing on the positive aspects of moderate drinking, in addition to "the negative aspect of alcohol misuse" (p5). The document suggests revisions to the UK Government's Sensible Drinking Limits, stating that the word "sensible" is both "negative and nannyish" and states that "it is not possible to define any specific amount of alcohol as inevitably harmful – whether short or long term" and that alcohol misuse is better determined by consequences rather than amount and frequency consumed (p6). These statements are not consistent with the epidemiological literature used by the World Health Organisation and expert groups in the design of SBI programs and allow the industry to promote "responsible drinking" without ever defining what it means.
- A memo by the Portman Group argues against evidenced-based population level interventions such as increased taxes, stating "alcohol policies to reduce the amount of alcohol that all drinkers consume in order to impact upon harmful drinking... penalises all drinkers alike", calling such policies "untargeted and unfair". Under the heading of 'Solutions', the memo focuses on the importance of social marketing—particularly the 'industry's own marketing platforms', "providing early advice and support to problem drinkers on a one-to-one basis through the medical profession and other public sector professionals", and "given accurate and full information, the vast majority of consumers will make healthier lifestyle choices." (The Portman Group, 2009).
- In Scotland, the Scotch Whisky Association lobbied policy makers to focus on education and responsible drinking campaigns rather than price (SHAAP, 2009; Gonall, 2014).

Although the number of SBI and referral activities supported by the alcohol industry has increased in recent years, the diverse nature of these programs and their limited scope suggests that they are not likely to have a significant impact on alcohol-related problems in the countries where they are implemented. Except for the BIG Initiative in the USA and midwife training initiatives in the UK (both funded by Diageo), the programs tend to be small and time-limited, and in some cases the fact that they tend to be branded with the company's logo or brand name means that industry-funded SBI activities

may have as well as a public relations benefit as well as a marketing potential, to the extent that SBI clients receive information provided by an alcohol producer.

Furthermore, some research shows (Heather, 2011) that brief interventions for alcohol are unlikely to achieve a noticeable population-level reduction in per capita consumption or alcohol-related harm unless accompanied by the introduction of more effective alcohol control measures. Therefore, it is possible that the industry promotes and funds SBI activities because it poses little threat to their profits.

Based on the evidence reviewed, we conclude that the alcohol industry's involvement in SBI activities to date has been small, with many programs being unlikely to have a significant effect on alcohol-related problems in the countries where they are implemented. In some cases the programs are not consistent with evidence-based interventions and in most cases they are not monitored or evaluated with sufficient rigor to estimate their likely effectiveness. We also identified a small number of research studies (see Table 1) funded by the industry or by industry-funded grant-making organizations (i.e., ABMRF, ERAB), in addition to ICAP's support for a conference symposium and the publication of its proceedings. Compared with the hundreds of research studies published on alcohol screening and brief interventions, the industry's support for SBI research is quite small.

2) How should INEBRIA view funding and other support by the alcohol industry for brief interventions, which appears to be increasing in recent times?

INEBRIA needs to consider recent developments in industry CSR activities in relation to the growing concerns among NGOs, and other organisations such as WHO about industry funding for prevention and treatment programs. Several arguments have been advanced against accepting industry funding for such programs. These arguments can be summarised within the context of Peter Adams' (2013) moral jeopardy framework, which is designed to assess a variety of risks involved with accepting funding from dangerous consumption industries.

Using terms of justification like "corporate social responsibility" and "partnerships with the public health community", the alcoholic beverage industry (mainly large producers, trade associations and "social aspects" organisations) has begun to support SBIRT activities as part of its CSR initiatives, as noted above. As an organisation established to support research and evidence-based practice, INEBRIA seems to have at least three choices:

- 1) Adopt a "hands-off" position where INEBRIA leadership and members of the network are advised not to engage in communication or collaboration with industry representatives, based on the assumption that the commercial interests are incompatible with the values and aims of health promotion, disease prevention and scientific research. For example, it has been argued that the main effect of the alcohol industry's cooperation with scientists and health professionals has been to improve their corporate image with the public and with government policymakers, rather than promote science (Statement of Concern, 2013; Stenius and Babor, 2010; Babor and Robaina, 2013; McCreanor, Casswell, & Hill, 2000; Munro, 2004).
- 2) The other end of the spectrum is to engage in dialogue with industry representatives, set conditions for the acceptance of industry funding for programs and research, and participate as "partners" in industry-funded scientific activities, such as SBIRT programs. This approach is based on the assumption that the industry is acting as a "good corporate citizen" and will spend

the money anyway. Government cuts to funding for public health campaigns have also been cited as a reason for partnerships with the industry.

3) A third approach is based on the growing number of case studies, ethical reviews and documentary information now available with respect to industries that have an important stake in products that affect public health (Brennan et al., 2006; Hirshhorn et al., 2001; Rampton&Stauber, 2002; Rundall, 1998). This approach avoids categorical recommendations to either allow or discourage relationships between the health community and industry in favor of guidelines that set forth conditions of cooperation or non-cooperation (Adams, 2007).

To assess these options, a PERIL analysis was completed based on Peter Adams' (2007) PERIL framework (Purpose, Extent, Relevant-harm, Identifiers, Link) which assesses a variety of risks based on a continuum of moral jeopardy, from minor involvements to major conflicts. The case study below illustrates the application of a PERIL analysis to evaluate whether INEBRIA and other nongovernmental organisations should accept funding from the alcohol industry for SBIRT programs. Depending on circumstances, each of the PERIL domains should be considered according to the amount of benefit and risk involved.

PURPOSE refers to the degree to which purposes between funder and recipient diverge. For example, if the primary purpose of the recipient (e.g., INEBRIA) is the advancement of public good, receiving funds directly from the alcohol industry conflicts with this purpose simply because the industry derives social capital (credibility and influence) from providing the funding. In some cases the risk may be mitigated partially if the funder has a clear public good role, such as a third party organisation that acts independently after it receives funding from the alcohol industry. For example, the provincial government of Ontario runs a state monopoly on liquor distribution, the profits from which they invest in a broad range of research (Adams, 2007).

EXTENT is the degree to which the recipient is reliant on this source of funding. As the proportion of income increases so it becomes more difficult to separate the organisation's independence from expectations associated with the funding source. For example, Scottish & Newcastle UK funded a hospital intervention program for which they were also a member of the project steering group.

RELEVANT HARM is the degree of harm associated with alcohol consumption. The burden of disease associated with alcohol consumption in many countries is enormous. There is increasing evidence that the alcohol industry's product design innovations, production capacity, and political influence may contribute to the amount of harm in a society (Babor and Robaina, 2013). For example, a company that produces quality wines to be consumed with meals may be associated with less harm than one that produces high alcohol content malt liquors that are targeted at young consumers, inner city alcoholics and women of child bearing age.

IDENTIFIERS is the PERIL domain that determines the extent to which the relationship can be observed by outsiders and whether this relationship has political or marketing benefits for the industry funder. Alcohol industry funders are unlikely to contribute anonymously because, for them, the point of the exercise is often to be identified, to form a visible association with public good activities for the purposes of positive branding. The extent of visible association can be reduced by moving away from high profile advertisements (such as logos) to more discrete acknowledgements on plaques or at the end of publications. However initiatives attempting to limit the visibility may be viewed as lacking transparency.

The final domain, **LINK**, assesses the risks posed by examining how the funding is obtained (i.e. direct or indirect) and ultimately discourages engaging in industry-supported research or program activities because it could damage the reputation of the recipient organisation. Direct funding by an alcohol producer (i.e. Diageo, SABMiller, Ab InBev) involves more negative exposure than receiving indirect funding via an 'independent' intermediary agency, such as a research foundation supported by industry (i.e. ABMRF/The Foundation for Alcohol Research, or ERAB). Separation reduces the likelihood that recipients will feel obligations -perhaps coercion - for their activities to comply with the interests of the donor as long as there are no major conflicts of interest for the intermediary agency. Further separation can occur when the funds are collected and distributed to an organization by an independent third-party, for example in Finland where the state and the Alko retail monopoly fund the Finnish Foundation for Alcohol Studies. The more direct the link, the stronger the influence and the more visible the association. Even the receipt of funding from a third party organization like ICAP, which is funded by the major alcohol producers, can pose reputational risks for INEBRIA and its members. For example, internal conflicts were precipitated when funding was provided to the International Council on Alcohol and Addictions and the International Harm Reduction Association. Eventually, both organisations severed their association with ICAP because of the reputational risk.

According to Adams, the overall extent of moral jeopardy varies from very high levels, as indicated by high ratings on all five domains (Diageo, ICAP), to very low levels (Finnish Foundation for Alcohol Studies) as indicated by consistently low ratings. Decisions regarding future industry relationships are made accordingly.

A key part of this kind of analysis is the aims and purposes of the two organisations. The aim of INEBRIA is to "provide global leadership in the development, evaluation and implementation of evidence-based practice in the area of early identification and brief intervention for hazardous and harmful substance use." In particular, INEBRIA seeks "to integrate the study of brief interventions within the wider context of measures to prevent and reduce alcohol-related harm."

As a scientific body, INEBRIA supports evidence-based approaches to reducing alcohol-related harm. While INEBRIA's focuses on the science of brief intervention, it recognizes the critical importance of countermeasures addressing price, physical availability, and promotion of alcohol, as evaluated in systematic reviews of independent research (e.g., Babor et al 2010). On the basis of the PERIL analysis described in the case study and the aims of INEBRIA, which are not restricted to BI but also support other approaches to reduce the harm caused by alcohol, the WG favors the 'hands-off' position and believes that INEBRIA should set an example by refusing to accept industry funding or other support for SBI activities. INEBRIA should ask NGOs, research institutions, universities and individual researchers to consider the harm caused to public health by alcohol and the damage to their reputation if they accept industry funds, while recognizing that the ultimate decision rests with said organization or university. INEBRIA should also applaud those organizations that already have a policy not to accept direct funding from the alcohol industry and encourage others to follow their lead, and/ or develop a clear Conflict of Interest (COI) declaration policy. INEBRIA could also take responsibility for informing organizations about the risks involved in accepting industry funding for SBI activities.

3) Whether industry funded research on brief interventions should be presented at INEBRIA conferences, or on the website.

There are growing concerns in the scientific community about the impact of alcohol industry funding on research and research integrity (Babor, 2009; Stenius and Babor, 2010; Miller et al., 2008; Adams, 2012;

Babor and Robaina, 2013). There are several areas to consider: research bias, agenda-setting, and COI. A more extensive bibliography of this literature has been prepared by the International Society of Addiction Journal Editors and is included in the appendix.

Evidence from other fields supports the claim that industry-funded research produces industry-favourable results. Drug research sponsored by the pharmaceutical industry is more likely to end up favouring the drug under consideration than studies sponsored by government grants or charitable organisations (Als-Nielsen et al., 2003). Similarly, nutrition research sponsored by the food industry is more likely to end up favoring the food under consideration than independently funded research (Lessor et al., 2007). Wallace (2009) reported that interpretative bias played a role in the research funded by the tobacco industry claiming a genetic predisposition to lung cancer, and that studies tended to over-estimate genetic risk. Barnes and Bero (1998) found that review articles funded by the tobacco industry are 88 times more likely than non-industry funded studies to conclude that passive smoke is not harmful to health. Recently, a systematic review and meta-analysis of studies examining the effects of alcohol on cardiovascular disease showed that studies possibly funded by the alcohol industry were more likely to find that alcohol consumption was protective against ischemic stroke than studies not funded by the alcohol industry (McCambridge & Hartwell 2014), although this association was not found for other areas of heart disease.

In addition to the potential for bias in the design, conduct and reporting of research, industry funding for a particular topic is not likely to be selected for scientific reasons, given the industry's lack of scientific expertise. To the extent that funding for a particular research question is dictated by commercial reasons, it is likely to alter the research agenda of the recipient organisation or an individual. Industry funding for tobacco and alcohol has been criticised because it often supports topics that are considered favorable to an industry's commercial interests (Babor, 2009).

On the other hand, it can be argued that industry funding for research may add to the literature and help to support needy scientists. Furthermore, science has some safeguards in place to catch instances of bias affecting research outcomes.

Regarding the issue of presentations of such research at INEBRIA meetings, it is generally accepted by clinical researchers, particularly those engaged in drug company trials, that industry funding should not disqualify a scientist from submitting, presenting and publishing his or her research, as long as the potential COI and the funding source are declared (Farmington Consensus, 1998; U.S. National Institutes of Health, Office of Research Integrity; Committee on Publication Ethics (COPE), 2001). In the case of tobacco, some professional organisations and journals have banned the reporting of research conducted by scientists funded by the industry, but such bans have not been applied to other industries that produce harmful products (e.g., alcohol). In the absence of systematic reviews demonstrating that industry-funded SBI research is biased, there is no compelling reason to ban presentations at the INEBRIA meeting, if they meet INEBRIA's standards. Nevertheless, any real, apparent or potential COI should be declared upon abstract submission and if accepted, a clear Conflict of Interest Declaration policy should be used to inform the audience about the sources of funding for a presentation which includes an explanation of the funding source (e.g., Diageo, a multinational alcohol beverages company) and whether there were guidelines attached to the funding or it was unrestricted. INEBRIA should also be aware that such research may be used by the industry to gain credibility and to improve their image when determining which submissions are appropriate for presentation or on the website.

4) Should researchers in receipt of industry funding be eligible for membership in INEBRIA and which timescales should apply to previous funding, i.e. how long a period of time should elapse from the end of funding before becoming eligible for membership.

As the purpose of INEBRIA is to support research, training and education, it is likely that these aims can be better achieved by adopting a “hands-off” position regarding prospective members who receive industry funding. If an applicant for membership works directly for the alcohol industry (as defined in #9), the conflict of interest may be sufficient to question the purpose of that person’s membership and its value to INEBRIA. The WG suggests that conditions for new membership will be (1) that applicants are not currently in receipt of direct industry funding and (2) that if they choose to apply for or accept industry funding in the future, they must first resign from INEBRIA. Regarding prospective members who are currently supported by research funding organizations such as ABMRF and ERAB that fund junior investigators through an independent peer review process, it seems counter-productive to deny membership for receipt of indirect funding. In such cases the CC should communicate its position that such funding represents reputational risks and ask prospective members to apply when their funding is ended.

In addition, a distinction should be made between membership in INEBRIA and participation in the network’s governance. It seems reasonable to adopt a policy where all candidates for organisational leadership should declare real, apparent, and potential Conflicts of Interest, and to deny individuals with a real or apparent COI from participation in the organisation’s governance.

Regarding cases where a candidate for membership or election to a leadership position is being considered, INEBRIA should develop a COI declaration procedure and ask all candidates to provide information about financial and non-financial conflicts. The International Society of Addiction Journal Editors (ISAJE), representing 35 journals in the addiction field, recently endorsed a general policy statement called the Common Standard (Goozner et al., 2009; Babor and Miller, 2014) and adopted a new procedure specifically designed to document COI information relevant to research on alcohol, tobacco, gambling, pharmaceuticals and a variety of other commercial and noncommercial sources. This statement has since been translated into a simple, four question declaration form and has been used by authors submitting manuscripts to *Addiction* over the past 2 years. This procedure is very specific about the types of competing interests that should be declared, especially with respect to third-party organisations supported by the alcohol and gambling industries. It also asks about personal conflicts, and uses a five-year look-back period to keep the focus on influences that are relatively contemporaneous with the research or other information being reported. This can serve as a model for INEBRIA.

5) Should distinctions should be made between direct funding by alcohol producers and retailers and indirect funding by social aspects and public relation organisations, dedicated research funding organisations and other front or third party groups.

SAPROs and trade associations receive monies directly from the industry, have boards composed of or appointed by the industry, and are used by the industry to help frame the public discourse on alcohol. This dialogue tends to focus on the benefits of alcohol and why [‘a small proportion of’] consumers, rather than the industry, are responsible for alcohol-related harms. These groups provide direct ways for the alcohol industry to gain credibility, promote themselves as responsible, build support for industry-favorable policy changes, and promote industry-favorable research (Miller et al., 2011). With non-profit classifications, deliberately confusing names such as the International Center for Alcohol

Policies and the Foundation for Advancing Alcohol Responsibility, and frequent name changes, it can be challenging to identify the underlying purpose of the organisation. SAPROs and front groups position themselves ingeniously and can confuse young researchers, media outlets, policy makers and the public, which often assume the information is coming from an independent, reliable source. Trade associations and SAPROs are defined as part of the 'industry' and their funding of research and programs should be considered as direct.

Indirect funding (as defined under *Definitions and Guidance*) through a research foundation which receives its monies directly from the industry but claims to have an independent board, or provides unrestricted grants, may involve the same reputational and ethical challenges as direct funding from an alcohol producer organisation simply because of perceived industry ties.

It is therefore suggested that a list of SAPROs, trade associations, and other organisations funded by the industry be provided on the INEBRIA website, and/ or be attached to the COI Declaration Form. A list is currently available on the ISAJE website (<http://www.parint.org/isajewebsite/conflict3.htm>). As names are frequently changing and new SAPROs are frequently being established, researchers should be strongly encouraged to carefully look into their funding mechanisms.

6) Are specific provisions necessary in respect of existing members with direct or indirect funding;

The WG suggests there be a grace period of 5 years, e.g., that if by 1 Jan 2020 existing members have not ceased to be in receipt of direct industry funding, their membership ceases.

7) Should any distinctions be made between receiving research funding and working directly for any of these organizations?

According to Adams, two main indicators of risk when assessing the moral jeopardy of industry funding include the directness of the funds and one's reliance on it. While both situations carry a significant amount of risk, directness and reliance carry an even higher risk for those working for an industry organisation than individuals receiving funding from one (Adams, 2012).

8) What forms of financial support other than research funding, including directly for implementation purposes, also need to be considered

A **CONFLICT OF INTEREST (COI)** is a situation in which financial or personal considerations have the potential to compromise or bias professional judgment and objectivity. A **REAL CONFLICT OF INTEREST** is broadly defined as any financial interest, e.g., anything of monetary value, including salary or payment for services, fees or honorariums, travel and accommodation expenses, writing or consulting fees, ownership in stocks or shares, paid advisory positions, and interests of close relatives.

An **APPARENT CONFLICT OF INTEREST** is one in which a reasonable person would think that the professional's judgment is likely to be compromised. These non-financial interests should also be considered. They include unpaid advisory positions. For example, some scientists serve as unpaid consultants or board members to organisations funded by the alcohol industry. These should be covered in any COI declaration forms.

A **POTENTIAL CONFLICT OF INTEREST** involves a situation that *may* develop into real conflict of interest. It is important to note that a COI is present whether or not judgments are affected by a personal interest and indicates only the potential for bias, not the likelihood. It is also important to note that a COI is not

considered misconduct in research, since misconduct is currently defined as fabrication, falsification, and plagiarism.

9) How the alcohol industry and industry funding should be defined for these purposes.

The alcohol industry should be broadly defined to include producers, distributors, sellers and marketers of alcohol, including any company that derives significant revenues from producing, selling or marketing alcoholic products, or products necessary for the production of alcoholic beverages. The 'alcohol industry' also includes beer, wine and spirit trade associations and alcohol SAPROs, such as ICAP.

Funding from foundations, grant making foundations such as ABMRF and ERAB, university departments, and other organizations that receive over 5% of funding directly from the alcohol industry such as the Ernest Gallo Clinic and Research Center at the University of California, San Francisco, should be considered sources indirect industry funding (Level I). Level II indirect funding can include organizations which receive industry money, but receive these funds through an independent third party, such as the case with the Finnish Foundation for Alcohol Studies or the Thai Health Foundation. As stated in #5, it is suggested that a list of SAPROs, trade associations, and other industry-funded organisations be provided on the INEBRIA website, and/ or be attached to the COI Declaration Form. A list is currently available on the ISAJE website, although names change and new organisations are established frequently (<http://www.parint.org/isajewebsite/conflict3.htm>).

10) Other issues and actions that INEBRIA should consider.

In the course of conducting our review of industry actions, the WG found claims of industry sponsorship that were false and one rightfully incensed organization, the Alcohol Education Research Council (AERC), demanded that they and the 6 initiatives associated with their name be removed from the ICAP website. Initiatives listed included the establishment of the Alcohol Academy, which provides training and support around evidenced-based interventions, and funding for research to examine whether community pharmacists could provide structured interventions to people who drink too much alcohol. As the independent charity had been established with government funds originally designated to compensate pub owners whose livelihood was affected by licensing law changes, but had never accepted industry funds, ICAP immediately complied with the demand that the organization be removed from the site. ICAP claimed the data had been pulled from an earlier database compiled by another SAPRO. It is unknown why this SAPRO included AERC, but this example illustrates that ICAP and other industry players seem to be eager to claim CSR credit for health-related activities, and more importantly, that their personnel cannot be trusted to provide accurate information. Moreover, in some cases individuals and organizations are at risk of being tainted by the industry's duplicity or incompetence. This provides support for the "hands-off" approach proposed in our report, to the extent that the inappropriate involvement of the alcohol industry in public health activities and research creates dissension within the field, has the potential to serve industry commercial interests, requires time-consuming monitoring, puts demands on professional organizations to create, implement and enforce policies, and does not contribute to either science or public health.

Given the increasing interest by the alcohol industry in harm reduction and clinical services, and the serious ethical and health questions that have been raised about industry involvement, INEBRIA should make a deliberate effort to educate its members and the broader public about the risks involved in accepting industry funding for research and clinical programs. We recommend that INEBRIA conduct PERIL analyses covering key ethical issues and broadly disseminate these case studies to its members. At the same time INEBRIA should adopt policy statements on the advisability of accepting such funding.

INEBRIA could also use its meetings and its website to disseminate information about questionable industry activities.

Conclusion

The practical and ethical challenges associated with the acceptance of funding for clinical services and research are becoming increasingly complex in a context where research plays a greater role in the regulation and marketing of potentially addictive products. Since the initiation of the WHO Global Strategy in 2010, the global alcohol producers have accelerated their “Corporate Social Responsibility” activities, which in many cases conflict with the research and policy initiatives advocated by public health authorities (Babor and Robaina, 2013).

The information reviewed in this background paper, and in the *Annotated Bibliography on Competing Interests* (Appendix 1), suggest that alcohol clinicians and scientists should be vigilant about the funding they accept from any source, particularly when there are restrictions on the design of a program, the research agenda, or the interpretation and publication of data. In particular, they should be very wary about accepting research funding directly from various dangerous consumption industries, their trade associations and public relations organisations.

Programmatic funding for SBI activities is complicated by the argument that the industry takes some responsibility for the damage caused by alcohol. However, the amount of financial support and the nature of the programs supported (e.g. time-limited, low-impact pilot programs) amounts to a trivial contribution to address the damage caused by alcohol products. To the extent that the industry is deriving political benefit and improved public perceptions through these generally minimal contributions, the risks seem to outweigh the benefits and any association should be avoided.

One alternative that could be promoted by INEBRIA is that used by the Government of Thailand, where tax revenues derived from the sale of tobacco and alcohol are used to fund treatment programs, research and evidence-based policy advocacy. As an alternative to merely opposing industry funding for SBI and research, INEBRIA could demand that the industry pay their fair share to an independent third party organisation, as is done with the Thai Health Foundation.

With regard to SBI research, indirect funding obtained from ‘independent’ research or nongovernmental organisations in the form of an unrestricted grant from a particular industry may be consistent with scientific and public health aims if the funding is obtained and distributed through an independent third party, and the grant review process is independent, transparent and peer reviewed. Nevertheless, alcohol scientists and clinicians need to be careful that their objectivity and independence are not compromised by fraternising with industry executives as well as accepting paid travel to meeting sites and consulting fees. Investigators in particular need to be attentive to the possibility that industry funding in many health areas is being contested on both ethical and scientific grounds. Finally, all funding sources should be subject to a PERIL analysis that allows the individual and his or her institution to review relevant information about the motives of the funding source and the uses of the research that will be conducted.

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Table 1. Examples of Alcohol Industry-funded Brief Intervention Programs and Research

Program Name (Year)	Producer/ Organization	Country	Partner(s)	About
American Medical Scholars Program (1996-?)	AB InBev	US	American Medical Scholars Program	Funding for a program which promotes optimal education in medical schools regarding the identification and care of people with alcohol use disorders and other substance-related problems.
*Research funding (2011 and 2012)	ABMRF	South Africa	University of Limpopo	Testing brief intervention intended to reduce the prevalence of alcohol use among HIV positive patients in a primary health care setting.
Screening and brief interventions (2010-2012)	Alcohol Beverages Committee	Russia	St. Petersburg Medical Academy of Postgraduate Studies	Curriculum was developed and integrated into Medical Academy regular classes. 919 patients screened and 366 brief interventions were delivered.
Alcohol Risk Assessment and Intervention (ARAI) Program (2011)	Brewers Association of Canada	Canada	College of Family Physicians of Canada and Health Canada	Training for physicians
Screening, Briefing Intervention and Referral Programme (SBIR) (2011)	Brewers Association of Canada, Canadian Vintners Association (CVA), and Spirits Canada.	Canada	Canadian Centre on Substance Abuse (CCSA) in partnership with the College of Family Physicians of Canada (CFPC)	Training for caregivers to identify patients who are at risk of developing health problems linked to alcohol misuse. Unlike the Alcohol Risk Assessment and Intervention Program (closed), participants include a wider range of health caregivers. Web-based resource also created.
*Research funding (2010)	Century Council (via Emergency Medicine Foundation)	US	University of Pittsburgh's Department of Emergency Medicine	3 year grant to University of Pittsburgh's Department of Emergency Medicine to research the effectiveness of text messaging in reducing hazardous drinking over 1 year
*Research funding (2010)	Century Council (via Emergency Medicine Foundation)	US	University of Pittsburgh's Department of Emergency Medicine	Grant to University of Pittsburgh's Department of Emergency Medicine to research the effectiveness of text messaging in reducing hazardous drinking over 12 weeks
Sensible Drinking Advice (2011)	Coors Brewers Limited's	UK		Support the UK government's Harm Reduction Strategy by displaying sensible drinking advice on its beers (sensible drinking message and a logo to advertise against drinking during pregnancy).
PräventionausLiebezum Kind (Prevention as Labour of Love for Children) (2010)	DeutscherBrauer-Bund e.V	Germany		Campaign using various measures including posters, postcards, and information brochures available at places where girls and women of child-bearing age get in direct contact, for example doctor's offices.

Ask Dave (2013)	Diageo	Western Europe		Drinks 'guru' who calculates how long it will take for alcohol to be processed by your body. Promoted on social media so as to facilitate discussion in a way that is not 'preachy', but instead, uses humor.
BASICS (Brief Alcohol Screening Intervention for College Students) (2010)	Diageo	US	Sacred Heart University	Following its 2009 launch through funding, in part, from the US Department of Education, the program risked premature closure but, with Diageo's grant of \$5,000, will be able to continue operating through the first half of 2011.
Diageo City Partnership Projects (2011)	Diageo	Europe	Government and civil society	Partnerships which bring together industry, government and civil society to reduce harm. Diageo contributes by using their marketing skills to support harm reduction interventions.
Online Military SBIRT Training Program	Diageo	US	NORC at University of Chicago	Grant to develop a training system that meshes with the Department of Defense/Army Alcohol Screening and Brief Intervention (ASBI)
Physicians Training Program	Diageo	US	Medical Society of the State of New York	Full funding provided through unrestricted grant
BIG Initiative (2011-current)	Diageo	US	NORC at the University of Chicago; American Society of Addiction Medicine (ASAM); American Academy of Addiction Psychiatry (AAP); and other professional associations	Training Employee Assistance Program clinicians/ counselors to use SBI; web and face-to-face SBI training materials developed
The Kenya Alcohol Screening and Brief Intervention Programme (2010)	Diageo	Kenya	Rural hospital and a National Public Referral Hospital	1.5 day training course organized for 10 participants.
Turning Point_pilot project (2007)	Diageo	UK	Queen Elizabeth Hospital; Turning Point	Funding for 2 year pilot project to conduct SBI in hospital accident and emergency departments
What do you tell a pregnant woman about alcohol? (2009-2013)	Diageo	UK	National Organisation for Foetal Alcohol Syndrome (NOFAS-UK)	Training for midwives to start conversations with mums-to-be about the risks of drinking during pregnancy.
Alcohol Education Center (AEC) (2011)	DISCUS	US	University of Florida	Creation of an education center for physicians to receive continuing medical education credits for alcohol-related issues (moderate consumption, metabolism)
Puis-je boire un verre à sa santé (Can I have a drink to his health?) (2006)	Entreprise&Prévention (E&P)	France	The National College of French Gynecologists and Obstetricians (CNGOF)	Campaign to promote dialogue between women and their medical practitioners about the risks associated with alcohol consumption during pregnancy

*Research funding (2007/8)	ERAB	UK		Is brief personalized feedback effective in reducing alcohol-related problems amongst University students in different European countries?
*Research funding (2007/8)	ERAB	UK		A psychosocial intervention to reduce high-risk single session alcohol (binge) drinking among company employees in a workplace setting in four European nations.
*Research funding (2005/6)	ERAB	UK		The e-UNICAL project: A feasibility and effectiveness study into delivering an Electronic feedback and social norms intervention designed to decrease UNiversity students' Consumption of ALCOhol
Community Based Alcohol Intervention Service (2009)	Heineken	UK		Fire Service referrals - delivering BIs and service referrals to individuals identified by the Fire Service when it is believed alcohol was a contributing factor to a fire; and Aged Care Services referrals - delivering BIs and service referrals to individuals identified by aged care services. Alcohol awareness training was conducted with the Tyne and Wear Fire Service to help them identify potential signs of alcohol misuse. By December 2009, 12 referrals were received and assessed through this route. Another 15 referrals were received via aged care services.
Responsibility Partnerships (2008)	Heineken	International		Partnerships with experts in the field of harm reduction in all top 25 business markets. The partnerships are either Heineken branded, branded by the local company or branded by the local brand. The issues addressed included excessive drinking.
Early Identification and Lifestyle Counselling for Problem Drinkers (1996)	ICAP	Chile	University of Chile, Thomas Jefferson University, and FarmaciasAhumada (a Chilean pharmacy chain)	Project to train pharmacists in screening and brief intervention.
Sensible Drinking Project (2002)	Industry Association for Responsible Alcohol Use (ARA)	South Africa	Western Cape Provincial Government's Department of Health	Health practitioners brief interventions training
Harm Reduction and its application to Alcohol Policy (2005, 2008)	International Center for Alcohol Policies (ICAP)	International		Sessions at the 16 th and 18 th International Conferences on the Reduction of Drug Related Harm (ICDRH), which provided insight into how harm-reduction can be integrated into alcohol policy.
Turning Point (2007-2009)	Scottish & Newcastle UK (Heineken)	UK	Queen Elizabeth Hospital; Turning Point	Full funding was provided for an Alcohol Intervention Worker and half funding for an Alcohol Case Worker to support highly

			dependent and repeat admissions to the Hospital. 553 patients were referred to the service. *HEINEKEN UK was a member of the project Steering Group.
Office Christmas Party Survey (2011)	The Portman Group	UK	Survey findings used to encourage party-goers to have a great party season without drinking to excess at office holiday parties.
Alcohol and You (2011)	Waitrose and Alcohol in Moderation (AIM)	UK	A guide on safe consumption of alcohol

CASE STUDY 1. PERIL analysis evaluating whether INEBRIA and similar NGOs, health authorities, hospitals, clinics, universities and other public service organizations should accept funding for SBIRT clinical programs from the alcohol industry or from organizations funded directly or indirectly by the alcohol industry or its surrogates?

	Context	Continuum of Risk Low —————> High		Risk-benefit ratio
Domain				
Purpose	The alcohol industry has a responsibility to their shareholders to increase profits by increasing sales and consumption of alcoholic beverages. The goal of SBI is to reduce consumption and reduce alcohol-related harms.	If funder is an independent 3 rd party, for example, an organization funded by a state retail alcohol monopoly, that does not engage in lobbying and whose its purpose is to promote and support research on alcohol and related-harms, there is little clash of purpose.	Strong clash of purpose with the alcohol industry whose goal is to increase sales, and therefore consumption. Additional clash of purpose with goals of SBI as industry has said it is not possible to define any specific amount of alcohol as harmful.	Support may signify that the alcohol industry is taking responsibility for the damage caused by the consumption of alcohol. Acceptance of funds may alter organizational purpose and put individual and organizational reputation at risk
Extent	The industry generally provides small amounts of support for pilot or time-limited programs dealing with a small subset of the population (i.e. binge drinkers or “hardcore drunk drivers”).	Varying degrees of risk based on proportion of funding derived from industry, and organization’s reliance on said funding.	High risk if organization is completely dependent on industry funds. Additional risk if the industry is involved in the design and dissemination of a program, training and/ or educational materials used for SBI.	Benefits include more money for programs, however small grants may not be worth the damage to reputation.
Relevant Harm	Alcohol contributes to 5.5% of disability adjusted life years (DALYs) lost globally, i.e. 136 million years of life lost through dying early or living with an alcohol-related disability.	Risk of harm is lessened if the funder does not produce alcoholic beverages, is not governed by industry representatives, and does not engage in lobbying.	Alcohol is the 3 rd leading cause of death and disability, making it one of the most harmful substances next to tobacco. Advertising, expansion to developing countries, and litigation and lobbying activities by the industry further contribute to alcohol-related harms. Additional risks present if intervention is designed or delivered	Extremely high risk due to the extent of harm caused by alcohol. Benefits may include improved health for moderate drinkers over age 45 (males) and post-menopausal women.

<i>Identifiers</i>	The industry generally takes credit for their funding in efforts to improve public perceptions and stave off regulations. The industry also broadcasts their partnerships with NGOs, universities, etc., to gain creditability.	Less risk posed if visible association is minimized (i.e. COI declaration on publication), however less visibility may also be viewed as lacking transparency.	by the industry, as SBI may be used as a means to inform public of the “benefits” of drinking and to normalize drinking. The alcohol industry will take credit for the funding of SBI programs. Allows industry to position itself as “socially responsible” and avoid liability or blame, bolster image as “good corporate citizen” and to promote SBI as an effective alternative to population-based interventions.	Funding may enhance prestige, but also may undermine the credibility/ integrity of recipient individual/ organization. May result in conflict with the public health community. Extremely high risk.
<i>Link</i>	Funders often have an influence over programs they are funding. The more direct the link, the stronger the influence and the more visible the association.	Less risk posed if link is indirect, for example the Finnish Foundation for Alcohol Studies, which is funded by the state retail alcohol monopoly, or if funding is received through an independent intermediary.	Funding received directly from a producer of alcoholic beverages poses great risks of bias and COI becomes difficult or impossible to manage. Funding from SAPROs should be considered direct.	Direct funding affords the industry with influence over research, design and/ or implementation. Direct funding is likely to be strongly opposed by public health community, thereby damaging reputation. May also cause disagreement within organizations and should be consider extremely high risk.

Appendix 1. Annotated Bibliography of Research on Competing Interests

This bibliography lists articles describing research on competing interests in science, medicine and addiction studies. It includes books, original studies, review articles, opinion pieces and news reports.

Adams, P. J., Buetow, S., & Rossen, F. (2010). Vested interests in addiction research and policy - poisonous partnerships: Health sector buy-in to arrangements with government and addictive consumption industries. *Addiction*, 105(4), 585-590.

- *Appraises relationship arrangements among three broadly conceived sectors: the government sector, the health sector (including researchers) and addictive consumption industries (particularly tobacco, alcohol and gambling) and concludes that health sector engagement in partnership arrangements entails too many risks.*

Adams, P. J. (2007). Assessing whether to receive funding support from tobacco, alcohol, gambling and other dangerous consumption industries. *Addiction*, 102(7), 1027-1033.

Als-Nielsen, B., Chen, W., Glud, C. and Kjaergard, L. Association of Funding and Conclusions in Randomized Drug Trials: A Reflection of Treatment Effect or Adverse Events? *JAMA*. 2003;290,921-928.

- *of 167 randomized drug trials concluded that industry funded trials may be more positive due to biased interpretation of trial results, rather than actual differences in treatment effect or adverse events between the experimental and comparison treatments.*

Angell, M. (2011). "The Epidemic of Mental Illness: Why?" The New York Review of Books. <http://www.nybooks.com/articles/archives/2011/jun/23/epidemic-mental-illness-why/?page=1>

Baker C. B., Johnsrud M. T., Crismon M. L., Rosenheck R. A., Woods S. W. (2003). Quantitative analysis of sponsorship bias in economic studies of antidepressants. *Br J Psychiatry*; 183: 498-506.

Barnes, D. E., & Bero, L. A. (1996). Industry-funded research and conflict of interest: An analysis of research sponsored by the tobacco industry through the center for indoor air research. *Journal of Health Politics, Policy and Law*; 21(3), X5-542.

Bekelman JE, Li Y, Gross CP. (2003). Scope and impact of financial conflicts of interest in biomedical research: a systematic review. *JAMA*;289(4): 454-465.

- *Found that industry funding greatly increased the chances of pro-industry results, with an odds ratio of 3.60 (95% confidence interval 2.63-4.91).*

Bell, C. M., Urbach, D. R., Ray, J. G., Bayoumi, A., Rosen, A. B., Greenberg, D., et al. (2006). Bias in published cost effectiveness studies: Systematic review. *BMJ*;332: 699-703.

Bero L, Oostvogel F, Bacchetti P, Lee K. (2007). Factors associated with findings of published trials of drug-drug comparisons: why some statins appear more efficacious than others. *PLoS Med*; 4(6): e184.

- *Reported that RCTs of head-to-head comparisons of statins with other drugs are more likely to report results and conclusions favoring the sponsor's product compared to the comparator drug and*

recommend that this bias in drug–drug comparison trials should be considered when making decisions regarding drug choice.

Bero LA, Rennie D. (1996). Influences on the quality of published drug studies. *Int J Technol Assess Health Care*; 12(2):209-237.

- *Provides examples of published drug studies that are defective, sometimes because pharmaceutical industry funding has affected their content and quality.*

Bhandari, M., Busse, J., Jackowski, D., Montori, V., Schünemann, H., Sprague, S., Mears, D., Schemitsch, E., Heels-Ansdell, D. and Devereaux, P. (2004). Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials. *Journal of Can. Med. Assoc*;170: 477 - 480.

Brennan, T. A., Rothman, D. J., Blank, L., Blumenthal, D., Chimonas, S. C., Cohen, J. J., et al. (2006). Health industry practices that create conflicts of interest: A policy proposal for academic medical centers. *Journal of the American Medical Association*, 295(4), 429-433.

Caplan, A. L. (2011). Is industry money the root of all conflicts of interest in biomedical research? *Annals of Emergency Medicine*.

Davidson RA.(1986). Source of funding and outcome of clinical trials. *J Gen Intern Med*1:155-158.

- *Found that studies sponsored by pharmaceutical companies were much less likely to favor traditional therapy over new drug treatment.*
 - *reviewed 107 RCTs in several general medical conditions and found a significant association between source of funding and outcome, with industry-funded studies favoring new therapies in comparison with non-industry-funded studies.*

DeAngelis CD, Fontanarosa PB. (2008). Impugning the integrity of medical science: the adverse effects of industry influence. *JAMA*;299(15):1833-1835.

Djulfbegovic, B., Lacevic, M., Cantor, A. Fields, K.K., Bennett, C.L. and Adams, J.R. et al., (2000). The uncertainty principle and industry-sponsored research. *Lancet*.

- *Compared outcomes of RCTs of multiple myeloma treatments by funding source and found that industry funded trials produce more favorable outcomes for newer treatments than do non-industry-funded trials ($p=0.004$).*

Etter, J.-F., Burri, M. and Stapleton, J. (2007). The impact of pharmaceutical company funding on results of randomized trials of nicotine replacement therapy for smoking cessation: a meta-analysis. *Addiction*102:815–822.

- *In reviewing all randomized controlled trials included in the Cochrane review, authors found that compared with independent trials, industry-supported trials were more likely to produce statistically significant results and larger odds ratios. These differences persisted after adjustment for basic trial characteristics.*

Finucane T. E., Boulton C. E. (2004). Association of funding and findings of pharmaceutical research at a meeting of a medical professional society. *Am J Med*; 117: 842–5.

Friedberg M, Saffran B, Stinson TJ, Nelson W, Bennett CL. (1999). Evaluation of conflict of interest in economic analyses of new drugs used in oncology. *JAMA*282:1453-1457.

- *Examined whether there was an association between industry-favored outcomes of cost-effectiveness studies for high-profile, expensive oncology drugs and corporate funding of the research. Authors found that studies funded by pharmaceutical companies were nearly 8 times less likely to reach unfavorable qualitative conclusions than similar studies funded by nonprofit organizations.*
- *Also found that industry-sponsored studies were more likely to contain qualitative overstatements of quantitative results.*

Friedman, L. S., & Richter, E. D. (2004). Relationship between conflicts of interest and research results. *Journal of General Internal Medicine*19, 51–56.

- *There was a strong association between those studies whose authors had COI and positive findings and that association persisted after controlling for sample size, study design, and country of primary authors.*

Fugh-Berman, A. (2005). The corporate coauthor. *Journal of General Internal Medicine*, 20(6), 546-548.

- *Discusses drug marketing techniques, including the sponsorship of articles signed by academic physicians or researchers and submitted to peer-reviewed medical journals, some of which are authored or coauthored by ghostwriters who work for pharmaceutical companies or medical education companies hired by pharmaceutical companies.*
- *“Conflicts of interest may be difficult to detect in the subset of articles and presentations sponsored by pharmaceutical companies that never mention the targeted drug, but focus on stimulating the perceived need for the targeted drug or highlighting problems with competing drugs.”*
- *Concludes that the current voluntary standards for declaring conflicts of interest to readers of medical journals and audiences at medical conferences are inadequate.*

Fugh-Berman, A. (2010). The haunting of medical journals: How ghostwriting sold “HRT”. *PLoS Medicine*7(9), e1000335.

Greenberg, D. S. (2003). Conference deplors corporate influence on academic science: Speakers argue that corporate funds should be separated from science to prevent undue influence. *Lancet*, 362(9380), 302-303.

- *At the conference title, *Conflicted science: corporate influence on scientific research and science-based policy*, 20 speakers—from academe, public-interest organisations, and journalism—who presented reports of corporate abuse of science in pursuit of profits. Their subjects ranged from the court-documented malfeasance of the tobacco, lead, and asbestos industries to retaliation against university-based researchers investigating the harmful health effects of industrial swine production.*

Harris G. and Berenson, A. 10 Voters on panel backing pain pills had industry ties. [The New York Times](#). February 25, 2005.

- *At the 2005 FDA advisory committee meeting on COX-2 inhibitors, 93% of advisors who had received fees from Merck or Pfizer voted in favor of COX-2 drugs, compared with 56% of other members of the committee.*

Hartmann, M., Knoth, H., Schulz, D., & Knoth, S. (2003). Industry-sponsored economic studies in oncology vs. studies sponsored by nonprofit organisations. *British Journal of Cancer*;89, 1405–1408.

Jagsi, R., Sheets, N., Jankovic, A., Motomura, A. R., Amarnath, S., & Ubel, P. A. (2009). Frequency, nature, effects, and correlates of conflicts of interest in published clinical cancer research. *Cancer*;115, 2783–2791.

- *In randomized oncology trials that looked at overall survival, those with COI were more likely to have positive findings.*

Jahiel, R. I. (2008). Corporation-induced diseases, upstream epidemiologic surveillance, and urban health. *Journal of Urban Health*, 85(4), 517-531.

Jorgensen AW, Hilden J, Gøtzsche PC. (2006). Cochrane reviews compared with industry supported metaanalyses and other meta-analyses of the same drugs: systematic review. *BMJ*.;333(7572):782.

Kassierer, J. (2005). *On the take: How medicine's complicity with big business can endanger your health*. New York: Oxford University Press.

Katz, D., Caplan, A. L., & Merz, J. F. (2003). All gifts large and small: Toward an understanding of the ethics of pharmaceutical industry gift-giving. *American Journal of Bioethics*;3, 39–46.

- *“When a gift or gesture of any size is bestowed, it imposes on the recipient a sense of indebtedness. The obligation to directly reciprocate, whether or not the recipient is conscious of it, tends to influence behavior”.*
 - *researchers may not necessarily have financial interest in the outcome of their research but subconsciously create conditions that yield the results most favorable to the company providing the resources to undertake the study.*
 - *gifts create strong dispositions or obligations to reciprocate (Mauss, 1967)*

Kesselheim, A. S., Lee, J. L., Avorn, J., Servi, A., Shrank, W. H. and Choudhry, N. K. (2011), Conflict of interest in oncology publications. *Cancer*.

- *Authors identified oncology journals and found that 88% requested that authors disclose conflicts of interest, whereas the remaining 12% did not.*
 - *Disclosure policies and the very definition of conflict of interest varied considerably among journals*
 - *Substantial proportion did not publish disclosure statements consistently, with deficiencies particularly among editorials and commentaries.*

Kjaergard, L. L., & Als-Nielsen, B. (2002). Association between competing interests and authors' conclusions: Epidemiological study of randomised clinical trials published in the BMJ. *BMJ*;325, 249.

- *Examined clinical RCTs published in the BMJ between 1997 and 2001. In publications where authors declared a financial COI, the conclusions that they reached were significantly more likely to be positive towards the experimental intervention than if COI was not present.*
 - *The association between financial COI and authors' conclusions was not explained by methodological quality, statistical power, type of experimental intervention, type of control intervention or medical specialty.*

Komesaroff, P. A. (2005). Ethical issues in the relationships with industry: An ongoing challenge. New guidelines open for public comment. *Journal of Paediatrics and Child Health*, 41(11), 558-560.

- *New guidelines established by the Royal Australasian Collage of Physicians which recommend that gifts should be rejected; that industry sponsorship to attend meetings should be restricted to cases where formal contributions are being made; that drug samples should not be accepted from*

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- *Investigated the impact on publication bias caused by multiple publication, selective publication, and selective reporting in studies sponsored by pharmaceutical companies and found that out of 42 studies, 21 contributed to at least two publications each, and three studies contributed to five publications; studies showing significant effects of drug were published as stand alone publications more often than studies with non-significant results; and that many publications ignored the results of intention to treat analyses and reported the more favourable per protocol analyses only.*

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- *Found that industry-supported trials produce more favorable outcomes for innovative treatment over standard therapies than do non-industry-supported studies (p=0.02).*

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- *Authors of industry-funded trials were still more likely to conclude that the medication was “safe” than were authors of trials without industry funding.*

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 - *Once statistical adjustment was made for three factors: industry funding, the Jadad score and the number of participants in the trial, the relationship between COI and positive outcomes was no longer significant.*
 - *In pharmaceutical company funded RCTs comparing psychiatric drugs to placebo the chance that the study would report a positive outcome was 8.4 times greater if one of the authors had a COI. In the absence of industry funding there was no association between author COI and positive outcomes.*

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Resnik, D. (2007). *The Price of Truth: How Money Affects the Norms of Science*. New York: Oxford University Press.

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Rochon, P. A., Gurwitz, J. H., Simms, R. W., Fortin, P. R., Felson, D. T., Minaker, K. L., et al. (1994). A study of manufacturer-supported trials of nonsteroidal anti-inflammatory drugs in the treatment of arthritis. *Archives of Internal Medicine* 154: 157–163.

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Shah R. V., Albert T. J., Bruegel-Sanchez V., Vaccaro A. R., Hilibrand A. S., Grauer J. N. (2005). Industry support and correlation to study outcome for papers published in *Spine*. *Spine*; 30: 1099–104.

- *Reported that industry funded studies demonstrated a statistically greater likelihood to report positive results than studies with other funding sources.*

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- *COI probably does not operate on a conscious level but rather the act of accepting funding from a pharmaceutical company creates a gift relationship between the investigator and the sponsor wherein the person receiving the "gift" feels an obligation to repay the present in some manner.*

Sismondo S. Pharmaceutical company funding and its consequences: a qualitative systematic review. (2008). *ContempClin Trials*;29(2):109-113.

- *Examined the evidence subsequent to the Lexchin article and found 17 additional articles that supported his conclusion with only 2 dissenting.*

Spielmanns, G. I., Biehn, T. L., & Sawrey, D. L. (2010). A case study of salami slicing: Pooled analyses of duloxetine for depression. *Psychotherapy and Psychosomatics*. 2010;79, 97–106.

Stelfox HT, Chua G, O'Rourke K, Detsky AS. (1998). Conflict of interest in the debate over calcium-channel antagonists. *N Engl J Med*;338:101-106.

- *Found that authors who had a financial association with manufacturers were much more likely than those who did not to have a favorable published position on the safety of calcium channel antagonists as a treatment for cardiovascular disorders.*
 - *Reported that 96% of the authors who were supportive of calcium channel antagonists had financial relationships with manufacturers compared with 60% who were neutral and 37% who were critical.*
 - *Only 2 of the 70 articles included in the study disclosed the authors' potential conflicts of interest. After reviewing these and other results, the editor of BMJ wrote, [these studies] "begin to build a solid case that conflict of interest has an impact on the conclusions reached by papers in medical journals."*

Tong, E., England, L., Glantz, S. (2005). Changing Conclusions on Secondhand Smoke in a Sudden Infant Death Syndrome Review Funded by the Tobacco Industry. *Pediatrics*;115:3.

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- *Also found that the involvement of a drug company employee had a much greater effect on study outcome than financial sponsorship alone.*

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Yank V, Rennie D, Bero LA. (2007). Financial ties and concordance between results and conclusions in meta-analyses: retrospective cohort study. *BMJ*;335(7631):1202-1205.

- *In analyzing meta-analyses of antihypertensives, authors found when controlling for other characteristics of the meta-analyses, the only factor associated with positive conclusions was if there was a relationship to industry.*

Yaphe J, Edman R, Knishkowsky B, Herman J. (2001). The association between funding by commercial interests and study outcome in randomized controlled drug trials. *Fam Pract*;18(6):565-568.

- *Found an association between the source of study support and the published outcome.*

