

CHAPTER 13

RELATIONSHIPS WITH THE ALCOHOLIC BEVERAGE INDUSTRY, PHARMACEUTICAL COMPANIES, AND OTHER FUNDING AGENCIES: HOLY GRAIL OR POISONED CHALICE?

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The ethical dimensions of the relationships between researchers, research organizations, journal editors and the various industries that profit from addictive substances and behaviours are complicated and extensive. They embrace the individual, institutional and societal dimensions of ethical reflection. In a way this chapter is a case study on a grand scale that calls for profound ethical analysis. The forces and interests involved are of necessity interwoven and researchers are dependent on many funding sources as a mainstay for their research. These will be covered in detail as the chapter unfolds. At the heart of the ethical conversation is an issue of trust for individuals and institutions. Ultimately, there are no simple guidelines to help an investigator decide which funding sources to accept or reject. However, it is vital that researchers go through an ethical assessment to consider the issues involved. In this chapter we will explore the ways in which different interest groups have influenced the research process before demonstrating the use of the PERIL analysis (Adams, 2007), an ethical decision-making framework developed specifically for this issue.

A high proportion of an active researcher's workload is spent applying for grant income. Successful receipt of grant monies is seen as an independent measure of a scientist's worth to the field. But the successful awarding of research money can occasionally be a "poisoned chalice" because of the problems engendered by an association with a funding agency. Such problems include having commercial or other vested interests set the research agenda, determine the way in which research is conducted, or define when and where research is published. Contracts that might seem reasonable when the cash is being waved under one's nose may prevent entire studies from being published or, worse, result in selective publication that does not portray the actual findings accurately. These types of experiences can devastate individual researchers, both personally and professionally. From the outset we want to emphasise that individual researchers cannot deal with these issues alone, but need support from senior colleagues, their institutions, professional associations and academic journals.

A GROWING CONCERN

In a climate of self-interest, often nurtured by a high regard for an exaggerated form of individualism (which is inimical to the common good), it is difficult to develop a consistent appreciation of the place of trust in research undertakings, as elsewhere in society.

(McGovern et al., 2004: 122)

Concerns about the integrity of the evidence base of addiction science have been raised in a number of forums recently (e.g. Adams, 2007; Hall, 2006a; Miller et al., 2006). Many of the authors expressing these concerns have reminded us that while safeguards such as ethical review committees and other regulatory agencies are in place, ensuring the integrity of the evidence is an ongoing task that requires an awareness of new players (e.g. the gambling industry) seeking to influence the evidence base, as well as new technologies for doing so (Hall, 2006a), such as paid contributions to edited books that look scholarly but often have a hidden political agenda .

Miller et al. (2006) highlighted the role that major funding bodies (such as pharmaceutical companies and government departments) can have in influencing research findings and the information dissemination process. This was considered important from two angles: 1) keeping true to the ideal of science and 2) adhering to the ethical principle of beneficence (see Chapter 12). Maintaining the ideal of science was seen as essential for the field, not only in terms of sustaining public trust (as mentioned above), but also in terms of ensuring that the field moves towards the most effective interventions available. Adhering to the ideal of beneficence (the obligation to maximise possible benefits and minimise possible harms) was viewed as equally important when considering whether research (which may be censored, be partially reported or go unpublished) could truly be said to be in the best interests of the research participants.

The recent debate within academic journals and subsequent commentaries has added substantially to our knowledge of how funding bodies influence research both directly and indirectly (Adams, 2007; Ashcroft, 2006; Babor, 2006; Hall, 2006a, 2006b; Hough & Turnbull, 2006; Khoshnood, 2006; Lenton & Midford, 2006). The observations collected from various authorities and presented in Box 13.1 highlight some of the main issues and point to the fact that influences on the research process go far beyond industry-related funding bodies alone.

Box 13.1 OBSERVATIONS ABOUT RESEARCH FUNDING FROM DIFFERENT COMMENTATORS

"Because ...research may adversely affect the reputations of governments and government departments, "project management" has become an increasingly central part of contractual arrangements between researchers and funders" (Hall, 2006b: 240).

"[I]n the current funding climate, universities and research centres have incentives not to adhere rigorously to these norms" (Ashcroft, 2006: 238).

"In recent years almost all [Australian] state and federal funded drug education research has been commissioned according to funder specifications, rather than being investigator driven" (Lenton & Midford, 2006: 244).

"Certainly, too, government departments set research agendas - and specify research methodologies to suit their own interests, rather than to contribute in a disinterested way to the body of knowledge that relates to policy issues. Government departments do not intentionally commission research that will embarrass their ministers" (Hough & Turnbull, 2006: 242).

"Senior academic researchers should be prepared to 'out' funding bodies for bad behaviour. Researchers with seniority and the protection afforded by tenure should be prepared to protect junior researchers and advocate for an unencumbered right to publish research results" (Hall, 2006b: 240).

TYPES OF ADVERSE INFLUENCE

Miller et al (2006) identified five major avenues through which funding bodies can regulate research in an adverse way: 1) direct censorship (where material is edited or dissemination is interfered with), 2) limiting access to data (either affecting some point or to be used as coercion for favourable interpretation), 3) ongoing funding insecurity (attaching conditions to subsequent funding if previous findings have been awkward or unwelcome), 4) using under-qualified or easily influenced researchers (which allows funders to control the quality of investigation being carried out, even before the research has commenced), and 5) setting research agendas or *dilution* (whereby decisions are based on the political, financial or ideological interests of the funder). For example, pharmaceutical companies oversubscribe to studies that examine the efficacy of pharmacotherapeutic solutions to drug-related problems, which could make the evidence base appear to be overly favourable for such an intervention (Wagner & Steinzor, 2007: 5). Other authors (e.g. Gruning et al., 2006: 26; Kassirer, 2004: 168) have provided similar, although slightly different, descriptions of the ways in which interest groups have influenced health policy and scientific research (see Box 13.2).

Box 13.2 THE TOBACCO INDUSTRY IN GERMANY

Gruning and colleagues (2006) identified five ways in which the tobacco industry in Germany distorted science:

Suppression, through actions such as closing the German Industry Research Institute (which it funded) when its head published results unfavourable to the industry, and having subsequent scientists in its employ guarantee that unfavourable results would not be published.

Dilution, through selective funding of research and the recruitment of scientists who had doubts about the adverse health effects of smoking or whose previous work had found no links, as well as funding research projects designed to find no association between smoking and disease (e.g., Wander & Malone, 2006).

Distraction, by selecting and supporting a large number of "confounder studies," which are research projects aimed to distract attention from smoking by investigating other potential causes of smoking related diseases.

Concealment, using "third party" scientists whose connection to the industry was hidden to increase the credibility and impact of the studies published.

Manipulation, the vetting of articles and presentations by the industry before publication or presentation.

Source: Gruning et al., 2006: 26.

THE TOBACCO INDUSTRY

The best known example of the way a funding body can act to undermine research integrity and muddy the waters surrounding a topic of interest is the concerted campaign by the tobacco industry first to deny the links between smoking and lung cancer and then more recently to support programmes which attribute responsibility to the individual smoker rather than the tobacco companies. Investigations into tobacco companies continue to identify new ways in which the industry seeks to encourage smoking and at the same time divest itself of responsibility for the subsequent health costs (Drope et al., 2004; Iida & Proctor, 2004; King, 2006; Muggli et al., 2004; Ong & Glantz, 2000). There are numerous examples of how tobacco companies have acted to undermine or adulterate health initiatives. The tobacco industry has been found to influence research using every one of the techniques discussed earlier (e.g. Hirshhorn et al., 2001; King, 2006). According to one authority, "perhaps research grants coming from tobacco companies should carry their own Surgeon General's warning. Caution: Tobacco industry sponsorship may be hazardous to the public's health" (Parascandola, 2005: 549).

THE ALCOHOL INDUSTRY

Using terms of justification like "corporate social responsibility" and "partnerships with the public health community," the alcohol beverage industry (mainly large producers, trade associations and "social aspects" organizations) funds a variety of "scientific" activities that involve or overlap with the work of independent scientists using techniques that range from efforts to influence public perceptions of research to the direct commissioning of research that is consistent with their public relations priorities.

There are at least three organizations funded predominantly by alcohol industry sources for the primary purpose of conducting scientific research on alcohol: the European Research Advisory Board (ERAB), the Alcoholic Beverage Medical Research Foundation (ABMRF) and the Institut de Recherches Scientifiques sur les Boissons (IREB). Although some consider the operations of these organizations as a model of

the way industry should contribute to alcohol science, questions have been raised about the way they operate and their influence on the scientific process (Babor, in press).

For example, IREB commissions its own studies in addition to funding investigator-initiated projects, thereby increasing the possibility that industry-favorable topics are promoted. It has also been suggested that a scientist's objectivity might be compromised by receipt of the honoraria and travel funds involved, and the opportunities to fraternize with industry executives at international meetings. Each of these organizations also funds research on industry-favorable topics like the health benefits of moderate drinking, which then are used as a part of the marketing strategies by the wine and beer industries, or as reasons why regulation and taxation should not be imposed on the alcohol industry.

In addition to indirect support of research through third party organizations, there have been several instances in which individual alcohol producers or industry-supported "social aspects/public relations" organizations (SAPROs) provide direct support to university based scientists engaged in alcohol research. The most notable examples include the Ernest Gallo Clinic and Research Center established by the Gallo Winery at the University of California to study basic neuroscience and the effects of alcohol on the brain, Anheuser-Busch's support of social norms research at seven U.S. universities, and a research center on youth binge drinking funded by Diageo Ireland, part of Diageo PLC, the world's largest producer and distributor of alcohol (Babor et al., 1996; Babor, 2006; Babor, in press).

Little is known about the internal marketing research conducted by the alcohol industry and contract research organizations because the information is not shared with the public, the scientific community, or public health professionals. In the case of tobacco, previously secret internal industry documents have revealed that independent analysis of research on sensory perception was used to inform product design for targeted segments of the cigarette market, including young adults (e.g. Carpenter et al., 2005), and there is evidence that the alcohol industry does similar research (Babor, in press). Contract research requires the services of social and behavioral scientists, so it may pose ethical problems to the extent that such research could facilitate the marketing of products (such as alcopops) that are misused by vulnerable populations.

These kinds of funding initiatives not only have the potential for conflict of interest, but they may also affect the objectivity of independent scientists and the integrity of science. At best, the scientific activities supported by the alcohol industry provide financial support and small consulting fees for basic and behavioral scientists engaged in alcohol research; at worst, they confuse public discussion of health issues and policy options, raise questions about the objectivity of industry-supported alcohol scientists, and provide industry with a convenient way to demonstrate "corporate responsibility" in its attempts to avoid taxation and regulation (see Box 13.3 for further examples of industry activities).

Box 13.3 THE RESEARCH PEDIGREE OF THE INTERNATIONAL CENTER FOR ALCOHOL POLICIES (ICAP)

ICAP is an industry-funded public relations "social aspect" organization located in Washington, D.C., USA. It defines its task as "changing the debate about alcohol's place in the world by shifting the discussion from the commodity to the behaviour," away from "the traditional focus of policy discussions [which] has been on the regulation of beverage alcohol" (Room, 2005: 1803). Despite ICAP's facade of science and objectivity and its claims to being a go-between that can bring together the different constituencies in the world of alcohol policy, ICAP's work has been identified as an ideological instrument on behalf of a set of political actors with deeply vested interests that "bastardises" the scientific process (Foxcroft, 2005). There is also evidence that ICAP-supported research is of poor quality and is biased in favour of industry positions supporting alcohol education over more effective alcohol policies (Babor and Xuan, 2004). ICAP also pays scientists to edit and write chapters for commissioned books that have been criticized for their bias toward industry-favourable positions on alcohol policy (Stimson, et al., 2006; Caetano, 2008).

THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry has become more interested in the discovery and evaluation of medications that can be used for the treatment of addiction, including opiate substitution therapies and nicotine replacement therapies. As such, pharmaceutical companies represent a different type of research funder from those who sell dangerous consumables, such as the tobacco industry. The pharmaceutical industry commissions and funds legitimate research that has genuine benefit for consumers. This has certainly been the case with pharmaceutical therapies for illicit drug use (such as buprenorphine for heroin dependence). However, pharmaceutical companies are as profit-driven as the tobacco and alcohol industries and have demonstrated a willingness to engage in such activities as *suppression*, through delayed or non-publication of null or negative findings, and *dilution*, through the selective funding of certain types of research (Kassirer, 2005). There is also evidence that some industry-supported research is biased (Kassirer, 2005; Singer, 2008; Brennan et al., 2006). In an interesting case study that combines pharmaceutical companies and tobacco, Etter, Burri and Stapleton (2007) assessed whether the source of funding affected the results of trials of nicotine replacement therapy (NRT) for smoking cessation. They found that compared with independent trials, industry-supported trials were more likely to produce statistically significant results and larger odds ratios.

In general, it has been found that researchers who report a financial conflict of interest are more likely to present positive findings (Friedman & Richter, 2004). Such behaviour has not been documented within the addictions field, although drugs used by many addicted patients for other complaints such as depression and anxiety have been the subject of controversial research practices.

Within the addictions field, it is likely that the most common way that pharmaceutical companies have distorted the evidence base is by creating a publication bias. For instance, pharmaceutical companies can oversubscribe to studies that examine the efficacy of pharmacotherapeutic solutions to drug-related problems, which will result in the evidence base appearing to be overly favourable to such an intervention.

THE GAMBLING INDUSTRY

Problem gambling has been strongly linked to a range of personal and social problems (Gupta & Derevensky, 1998). Previous research from North America highlights how young weekly gamblers' involvement with gambling outstrips their participation in smoking, drinking, and taking other drugs (Gupta & Derevensky, 1998; Shaffer & Kidman, 2003). The opportunities for addiction scientists to receive funding from gambling industry sources have increased significantly over the last decade, raising a number of ethical and organisational risks not unlike those associated with accepting such funding from other dangerous consumption industries (Adams, 2007).

As in the case of the tobacco and alcohol industries, relationships with SAPROs have been used to mitigate potential negative associations and to give the impression either that the activity leads to public good or that they have at least attempted to rectify potential harm (Adams & Rossen, 2006). In countries such as Australia and New Zealand, a government or quasi-governmental agency has been created to manage voluntary funds in a way that appears independent of the source. Adams and Rossen point out that the major problem with such arrangements "is the perception that donor organisations should still retain a significant say in how the money is used" (2006: 11). This culture leads to uncritical acceptance of gambling industry perspectives and misrepresents the industry's willingness to trade profits for public health. This has meant in the past that industry officials were "consistently instrumental in ensuring that activities that might threaten the consumption of gambling were unlikely to receive significant funding (this particularly applied to research, health advocacy, and public health initiatives)" (Adams & Rossen, 2006: 12). This may explain why there have been few studies of the role of the gambling industry in the promotion of gambling behaviour and pathological gambling.

It has been proposed that government-mandated contributions provide an alternative option to support research and provide a way to mollify criticism. In this arrangement governments enact legislation that requires gambling providers to allocate a portion of their net income to projects, including research, with a community purpose. The major difficulty with this arrangement is the risk of increasing financial dependency leading scientists to avoid criticising gambling interests (Adams & Rossen, 2006). Likewise, the responsibility of governments to regulate gambling and prevent gambling problems may be compromised by the possibility that governments have themselves become "addicted" to the tax revenues derived from gambling.

GOVERNMENT AGENCIES

Albert Einstein (1934) once said that the "pursuit of scientific truth, detached from the practical interests of everyday life, ought to be treated as sacred by every government, and it is in the highest interests of all that honest servants of truth should be left in peace." Einstein's plea, directed at the fascist government of Mussolini, has been honoured by most government funding agencies, but there are several cases in which it rings sadly true in the current funding environment. In a similar situation to pharmaceutical companies, national and international governmental bodies fund many valuable research studies. However, as seen in earlier examples, research has sometimes been used to achieve political or financial goals such as supporting current policies or undermining less popular alternative strategies. Miller et al. (2006) identified two examples in which government funders acted to distort research findings in Australia and the UK, particularly around more controversial activities such as needle and syringe programmes (NSPs). Small and Drucker (2006) also point to the difficulty in obtaining funding for research into the effectiveness of NSPs, and the way in which the US National Institute of Drug Abuse (NIDA) does not support research on some forms of harm reduction. They report senior scientists' beliefs that while evidence supports the efficacy of NSPs, the US government will not fund research into their effectiveness, or indeed the more important topic of how to improve their effectiveness on what actually constitutes models of best practice (Pollak, 2007).

OTHER FUNDING AGENCIES

Increasingly, charitable organizations such as the Robert Wood Johnson Foundation in the US, the Joseph Rowntree Foundation in the UK and the Millennium Trust in Australia have taken on agenda-setting roles that include funding research. While most do not have profit imperatives akin to those seen in the tobacco, alcohol and pharmaceutical industries, some nonetheless have their own agendas and only a worthy few employ transparent peer review. For example, the Wates Foundation in the UK only funds research that supports abstinence-only approaches. Furthermore, nepotism and personal conflicts of interest can come into play when trustees back projects supported by their friends or projects in which they are personally involved. This lack of peer review and external accountability means that such organisations may end up skewing the evidence base by only supporting research into certain types of intervention. While some of this might be balanced by different foundations having different interests, the reality is that these funders have the potential to at times favor ideologically and politically simple and popular interventions. For example, while a small number of trusts, such as the Soros Foundation, have funded research into harm reduction and drug policy reform, there are many more foundations that will only fund abstinence-based programmes or programmes aimed at abstinence, such as education programmes. While there are many reasons for this, most revolve around trustees not being knowledgeable about the available evidence and theory. In addition, many trustees and directors are politically aware individuals who are in the public spotlight. They may be reluctant to become associated with politically sensitive topics. All of this means that researchers should be aware of the possible consequences of applying for funding from such organisations because even limited research might contribute to the overall publication bias in the field.

OTHER INTEREST GROUPS

Funding bodies are not the only groups to control research findings. For instance, Hall (2006b) identified the possibility of drug user groups and socially conservative members of ethics committees prioritising their own interests at the expense of the integrity of the research. Members of ethics committees hold very powerful positions when it comes to rejecting, delaying or modifying research proposals. While most declare financial conflicts of interest, ideological positions are different and, indeed, many would not identify strongly held beliefs as being a conflict of interest. For example, individual members of ethics committees who are strongly attached to abstinence-only programmes may block or delay research into controlled drinking interventions in the belief that they cannot be morally justifiable.

There is also substantial room for conflict of interest inherent in the current peer review framework (Hall, 2006a). With increasing competition over scarce resources, individuals may thwart the publication of research papers that counter their own theories or the findings of their major competitors for funding. While some journals have begun to publish ethical statements for editors, similar statements for reviewers of articles and funding applications may soon be required. Similarly, we should not forget that most researchers have their own pet theories, which can result in skewed research findings, particularly when those theories align with the interests of others such as professional societies, governments or industry bodies. As noted in Chapter 11, these kinds of conflict are difficult to detect, but they should nevertheless be considered by authors when evaluating their own work.

Other social groups that might seek to influence research include professional associations, fellowship groups, religious organizations and even service providers. Professional associations (such as medical societies) have traditionally sought to maintain or increase their influence regarding any number of areas of knowledge and practice (Willis, 1989). Each discipline produces its own literature base. The size and complexity of this literature base helps to determine differential power structures within treatment settings. In the alcohol and drug sector, medicine (with the support of the pharmaceutical industry) dominates the literature base, resulting in the medical model (and pharmacotherapies) having the strongest evidence base. In a different type of influence, some fellowship groups may influence research findings through non-participation (e.g., Wilton and DeVerteuil, 2006).

Service providers are also not disinterested parties. Almost all (with a few notable exceptions) derive their income (and some of their *raison d'être*) from treating addiction. This has substantial implications for the politics of treatment and the vested interests many people bring to the research enterprise. The political and economic weight of mantras such as *treatment works* bear little relation to the complex evidence base and far more to the pragmatic needs of governments and service providers. While many service providers use the discourse of charitable objectives, they are invested both financially and existentially in the perceived success of the treatment they provide. This raises substantial ethical issues when conducting research in treatment settings, especially if the evaluation is funded by the service provider or its funding

body. Ethical considerations such as the true reporting of findings (even when negative), full editorial control of research projects, and the assurance of adequate dissemination should be negotiated before research commences. Such issues require that researchers, reviewers and journal editors within the field apply a strong critical gaze to research and encourage an ethos of independence, even when such independence may not be economically prudent.

FUNDING ISSUES IN THE DEVELOPING WORLD

All of the examples discussed thus far describe the situation in the developed world. However, the issues facing researchers in the developing world are likely to be even more complicated and are much less likely to be documented. Like their counterparts in the more developed parts of the world, researchers in developing countries face many challenges in their work. In both environments, success is tied to the availability of resources and the overall intellectual climate (Adair, 1995). Significant achievements as a scholar in a university or research institute require the ability to attract funding for research and also productivity in publishing research findings, preferably in journals of high repute. Though the expectations from employers and the public might be the same, both activities are not always easy to execute by scholars in poor countries where there are virtually no local resources for research.

When asked about the major problems encountered in their work, researchers and service providers affiliated with drug demand reduction organizations in Nigeria not surprisingly identified lack of funding as the leading challenge (Obot, 2004). Indeed it is a rare country in Africa and other low income parts of the world where one can find consistent and near-sufficient outlay for scientific research on any topic, including addiction and other public health issues. This is especially the case for researchers in countries that constitute the "bottom billion" (Collier, 2007) or countries often described as least developed. In addition, competing for scarce resources with colleagues in resource-rich countries is often an impossible challenge in their prevailing circumstances. For the enterprising researcher, therefore, the response to this dearth of local funding opportunities is to conduct self-sponsored research (with all the limitations that this entails) or seek support from less competitive external sources. This situation provides a good opportunity for organizations with ideological positions to propagate their interests and for others with economic interests to gain a foothold through financial support for research and training in these countries.

This is a potential source of growing danger for research in many developing countries and one that has not received sufficient attention. While there has been active discussion about unfair distribution of benefits of international research, especially coming from concerns about the ethical dimensions of clinical trials in developing countries (e.g., Bhutta, 2002), the exploitation that is implicit in some sources of funding for research in developing countries deserves greater scrutiny. Exploitation is more likely to occur in situations where there is little understanding of conflict of interest, low economic capacity, limited infrastructure, and lack of ethical oversight, all of which are conditions that characterize most low income countries.

In the field of alcohol research, developing countries are experiencing a growing interest by representatives of the alcoholic beverage industry masquerading as "social aspects" organizations and seeking partnerships with researchers and policy makers. Usually the amount of money involved is a fraction of what would be spent for similar efforts in western countries but it goes a long way for the scholar to whom such support is a lifeline, enabling research and the publication of a book with an international imprint. In Africa, for example, the International Center for Alcohol Policy (ICAP, see Box 13.3 above) has provided support for data collection, write-up and publication of work with the potential of influencing local alcohol policy (see, for example, Haworth & Simpson, 2004). For the funding organization, association with (usually) a high profile academic or policy expert in a developing country validates their professed selfless motives. This can be a particularly pernicious strategy because, unlike in western countries where there are many voices, the developing country scholar who has been co-opted by the alcohol, tobacco or pharmaceutical industry might be the same scholar on whom government depends for advice when needed.

Research is not the only mechanism used to gain entry into a country, and economic gain is not always the only motive. Conferences and workshops touting issues like "best practices" have become quite a popular way to make friends and influence scholars and policy makers, usually at the same time. Outside the addiction field, the most well-known current example of funding for service delivery with ideological strings attached is PEPFAR, the President's Emergency Plan for AIDS Relief, launched by President Bush in 2003 to combat HIV/AIDS in selected focus countries. PEPFAR supports programmes that promote abstinence and not condom use for young people. The focus of funded work is service delivery but some research is involved. Because PEPFAR is a major source of funding for HIV/AIDS work in countries in dire need, recipients are oblivious to the ideological implications of helping sustain public health interventions with little or no evidence of effectiveness (Epstein, 2007; *Lancet*, 2006).

It is not always lack of financial resources that drives the accommodation to untested imported theories and practices. Sometimes it is lack of knowledge, or even naïveté. A researcher in a developing country might find it difficult to suspect the motives of a funding agency that is acceptable to that country's government, and one that is supported or led by internationally recognized academics or professionals. In order to guard against establishing or sustaining relationships with funding agencies that might lead to bad science or bad policy, it is important for researchers in developing countries to be more skeptical of easy money by questioning its source and the motives of its providers. That is easier to do today than it might have been ten years ago because most of the time all the information that is needed to decide whether to take the money or not can be found on the Internet.

CONFLICT OF INTEREST: WHAT IT IS, WHY IT IS IMPORTANT

As suggested by the examples reviewed above, funding sources can influence scientific integrity in a variety of ways, ranging from subtle bias in the way research findings are presented to outright distortion of the research agenda or the scientific literature. One way to approach the ethical implications of many of the issues raised in this chapter is

through the concept of conflict of interest. Conflicts of interest can be financial, personal, ideological, political and academic. A conflict of interest does not in itself constitute wrongdoing; rather, it acknowledges that the researcher has an interest which may be put above the integrity of the research being conducted. It is only the failure to declare real or potential conflicts to an editor, one's co-authors, and the readers of a paper that constitutes scientific misconduct. Potential conflicts are very important when it comes to the ability of the reader to assess the validity of any piece of scientific work. As noted above and in Chapter 11, conflict of interest may take many forms. For example, recently the issue of ideological bias has been raised as a possible conflict in medical research. A series of articles and responses about prayer as medicine has raised substantial concerns about the interface between faith and science (Clarke, 2007; Jantos & Kiat, 2007). It has been suggested that "for the benefit of a secular readership, in articles concerning religion and medicine in the Journal, the Editor should require the authors' religious position to be stated under 'competing interests'" (Clarke, 2007: 422).

HOW TO AVOID CONFLICTS OF INTEREST AND OTHER THREATS TO SCIENTIFIC INTEGRITY AND ACADEMIC FREEDOM

Just as there are many forms of conflict of interest, so too are there many different ways to avoid or reduce undue influence, although many commentators believe that none of the possible options is entirely satisfactory or risk-free (Adams and Rossen, 2006). By far the most commonly proposed way to avoid or ameliorate conflict of interest is through communication with one's peers, particularly when done alongside ethical awareness exercises (e.g. White and Popovits, 2001). Adams (2007) recommends that individuals, organisations and others involved with interested parties engage in processes that raise ethical consciousness in conjunction with transparent regulatory frameworks that ensure accountability and independence from organisations, government and professional associations. This kind of communication and awareness-raising has begun to occur at a number of levels.

Recently, the institutions responsible for the production and dissemination of research (i.e., journals, professional societies and academic institutions) have taken some important initiatives.

Academic journals have increasingly begun to enact COI strategies including: a) requiring author statements that declare funding source, which are then published with the article; b) a positive statement that all authors had complete control over the research process; c) reviewer and editor statements similar to those of authors; and d) prior registration with the ICMJE-approved clinical trials register as a pre-requisite for publication. Journal editors have also begun to look at strategies for assessing publication bias within their journals and at a more general level. Some journals have used their editorial pages to name and shame parties that behave inappropriately (e.g. Edwards et al., 2005).

Professional associations have begun to draw up guidelines regarding the behaviour of acceptable funding bodies, conflicts of interest, and related issues. For example, the Federation of American Societies for Experimental Biology (FASEB, 2007) 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. The FASEB Toolkit (see <http://opa.faseb.org/pages/Advocacy/coi/Toolkit.htm>) consists of a set of model guidelines that speak specifically to institutions that develop and enforce policies for their investigators, editors who develop disclosure policies for authors, and scientific and professional societies that have a role in promoting professional ethics. Similarly, the RESPECT Code of Practice (Dench et al., 2004) is a voluntary code of practice regarding the conduct of socio-economic research. The proposed guidelines are a synthesis of several professional and ethical codes of practice designed to protect researchers from unprofessional or unethical demands.

Institutions such as universities and research centres have developed policies around acceptable funding bodies and some scrutinise research contracts for possible conflicts of interest. For example, a growing number of universities (e.g., Kings College London) have refused to accept funding from the tobacco industry, and some research centres have developed their own internal policies (see Box 13.4). There is also scope for institutional ethics review boards to assess the appropriateness of funder-researcher relationships. Such responses would support individual researchers in the decision-making process and provide more reliable and consistent approaches to this complex issue (Babor and McGovern, 2007; Miller et al., 2006).

Box 13.4 ONE RESEARCH INSTITUTION'S GUIDELINES ON ACCEPTABLE RESEARCH FUNDING

Dealing with possible conflicts of interest related to the financing of our research projects

The proportion of industry research funding within the financial budget of the institute has been very low since the foundation of the IFT in 1973. But caution is needed as this support is provided by organizations and companies which produce or distribute psychoactive substances (e.g. alcohol or pharmaceutical industry) or are active in the gambling business (including private lottery companies licensed or owned by the German States), and because of the internationally known incidents of scientific misconduct.

The IFT does not reject funding of research by commercial institutions in principle, but is aware of the particular responsibility in this area. In times of short or even declining public research funding and direct demands of the public to cooperate with industry and to expand commercial third-party funds for research, it is hardly possible to abandon such sources of funding in principle. The institute has in this context the following rules:

- Research requests (i. e., to conduct a study on a given research question) will only be accepted if (1) the question is formulated globally and is undirected (e.g., the extent of drug abuse in the population) and not biased (e.g., the study is expected to demonstrate that a certain behaviour bears no risk for the population), (2) the research question is scientifically relevant, and (3) the free and unrestricted further design of the study is guaranteed by the contract.
- A further precondition for accepting funding by industry sources is the guaranteed independent formulation of the research objectives, hypotheses and the study methodology, and the unrestricted statistical analysis, interpretation and publication of results. The funds have to be granted to the IFT as unrestricted educational grants or donations.
- Currently, we do not accept funding of research projects by the tobacco industry (reasons: evidence of long lasting one-sided and unacceptable manipulation of scientists and scientific results).
- A single funding source must not contribute to more than 10 % of the annual budget, and all industry funds should not exceed 20 %. It is notable that these limits have never been reached: The current contribution is about 2 %, and it has never exceeded 5 % in the past.
- All results will be published.
- Lectures given in the context of industry organisations are accessible via the website of the IFT.

Funding in the "grey area" between public and commercial organisations

Examples are charitable organizations, (non-profit) health insurance companies, industry associations. In most cases, these organizations are accountable to the public or the commercial sector. The IFT applies in each case the same rules as for commercial organisations.

Source: The German IFT (Institut für Therapieforschung) website - www.ift.de

However, resolving these issues remains in large part the responsibility of individual authors, many of whom have a limited ability to understand or act upon the complex ethical, political, clinical and scientific issues surrounding the initiatives coming from a particular funding source. Fortunately, most addiction scientists have chosen to eliminate themselves from participation in activities with obvious conflicts of interest, such as consulting arrangements with the tobacco and alcohol industries and restrictions from funding sources that prevent them from retaining ownership of data and the investigator's right to publish it (Babor & McGovern, 2004). Nevertheless, what is needed is a more systemic set of procedures that allow individuals to conduct a risk analysis of different funding opportunities.

DECISION-MAKING APPROACHES

Several approaches have been suggested to guide decision-making by independent scientists regarding collaboration with the alcohol beverage industry and other dangerous consumption industries (Babor, in press). Decisions regarding collaboration with bodies that may seek to influence research can range from a "hands-off" position to full collaboration. Adopting a "hands-off" position, in which members of the scientific community and their organizational sponsors refuse to engage in communication or collaboration with industry representatives, is based on the assumption that commercial interests are incompatible with the values and aims of public health in general and with health-related scientific research in particular. Some have argued that the main effect of industry's recent cooperation with scientists and public health professionals has been to improve their corporate image with the public and with government policymakers, rather than to promote science (Babor et al., 1996; Gmel et al., 2003; McCreanor et al., 2000; Munro, 2004).

The other end of the spectrum is to engage in dialogue with industry representatives, accept industry funding for research, and participate as "partners" in industry-funded scientific activities such as the publication of books (e.g. Stimson et al., 2006).

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 science and industry in favor of a more nuanced set of guidelines that outlines conditions of cooperation between science and industry (Adams, 2007).

PERIL

Peter Adams' (2007) PERIL framework (Purpose, Extent, Relevant harm, Identifiers, Link) provides a structured means of evaluating individual situations from an ethical perspective. Depending on circumstances, each of the five PERIL subcontinuums is influenced in varying ways by the different domains of risk.

Purpose refers to the degree to which purposes are divergent between funder and recipient. For example, if the primary purpose of the recipient is the advancement of public good, receiving funds from dangerous consumption industries such as tobacco, alcohol and gambling will probably conflict with this purpose. Similarly, the risk is mitigated partially if the funder has a clear public good role. 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 relies on this source of funding. As the proportion of income increases, it becomes more difficult to separate from expectations associated with the source. For example, a young investigator may find an award from an industry-sponsored organization is the sole source of salary support, which could

create pressure to obtain industry-favorable results to ensure the continuation of funding.

Relevant harm is the degree of harm associated with this form of consumption. The level of harm generated by different forms of consumption varies. Lower potency products, such as lottery tickets or low-alcohol beer, are on the whole less likely to lead to problems than more potent products, such as electronic gambling machines or extreme alcohol content beers.

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. This in turn can be used for political or commercial purposes. The extent of visible association can be reduced by moving away from high profile advertisements (such as media releases of findings) to more discrete acknowledgements on plaques or at the end of publications. Through reputational risk, this strategy indirectly discourages engaging in industry-supported research.

The more direct the *link* between funder and researcher, the stronger the influence and the more visible the association. For example, direct funding by a tobacco company involves more exposure than receiving the funding via an independent intermediary agency, such as a foundation or government funding body. As long as there are no major conflicts of interest for the intermediary agency, the separation reduces the likelihood that recipients will feel obligations, even coercion, for their activities to comply with the interests of the donor. The overall extent of moral jeopardy ranges from very high levels, as indicated by high ratings on all five subcontinuums, to very low levels, as indicated by consistently low ratings. Decisions regarding future industry relationships are made accordingly. Boxes 13.5 and 13.6 provide two case studies to illustrate how a PERIL analysis can be applied to specific funding opportunities.

Box 13.5 PERIL ANALYSIS OF A FUNDING OPPORTUNITY FROM PHILLIP MORRIS

A university-based School of Medicine distributes an email announcing to all faculty and staff the availability of a new research funding opportunity. The announcement reads: “Please see the link below for an available funding opportunity from the Philip Morris External Research Foundation (<http://resadm.uchc.edu/orsp/funding/opps/2007RFA.pdf>).” The website invites scientists to submit funding proposals to Philip Morris' independent, peer reviewed, external research programme, which is willing to support research on the disease mechanisms and health endpoints of tobacco smoking and smoke exposure. The programme's Scientific Advisory Board Members are listed on one of the pages of the Request for Applications (RFA), an impressive looking group of academics, including department chairs, distinguished professors, and even the President of the Hungarian Academy of Sciences. This announcement raises a number of questions about the moral hazards of industry sponsorship of scientific research.

Assume you are a tobacco researcher at a large academic medical center whose dissertation was recently completed on a topic related to the announcement. Should you apply for the funds? A PERIL analysis along the lines recommended in Adams' paper would require some independent research and a review of the literature on tobacco industry tactics.

PERIL analysis

Is the *purpose* of your academic institution (e.g., "excellent medical care through research and education") consistent with the stated purpose of Phillip Morris (i.e., to sell cigarettes to adults, without taking any responsibility for the millions of adolescents who become addicted before they can legally purchase tobacco products)? If your institution is in any way devoted to health, the answer is that the purposes are incompatible. In addition, some have pointed to the anti-scientific record of Phillip Morris. The reason Phillip Morris' research foundation is now called "external" is that the company was ordered to disband a prior organization that was found by a US court of law to be biased in the way it awarded grants to scientists.

What about the *extent* of the funding? Is it sufficient to compromise the independence of an academic medical center with a large portfolio of research grants and contracts? Probably not, but for individual investigators it could create a dependence on tobacco money when other sources of funding become more scarce.

Is there *relevant harm* associated with Phillip Morris's continued marketing of tobacco products? The evidence is incontrovertible.

Will the recipient of the funds be *identified* with the funder so that Phillip Morris might benefit from its support of university-based scientists? And could funded scientists eventually be exposed to reputational risk if their names were associated with Phillip Morris? The answer is a possible yes to both questions.

Finally, is the nature of the *link* between recipient and donor direct or indirect? In this case it is indirect, so it may not involve a major conflict of interest, and there are no limitations on publication imposed by the funder.

In summary, the analysis indicates that there are incompatible institutional interests, a potential for developing dependence on an industry funding source, relevant harms to the public if tobacco sales continue as more research is conducted, a potential for future reputational risk, and a possible political benefit for Phillip Morris.

Box 13.6 PERIL ANALYSIS OF A FUNDING OPPORTUNITY LIMITED BY CONDITIONS IMPOSED BY A COLLABORATING ORGANIZATION.

A residential rehabilitation charity approaches you to collaborate in an application to fund doctoral research into the long-term effectiveness of its project. The charity reports that it has been involved in research previously and has found it beneficial. The methodology is discussed and agreed. The application is designed to go to a government funding body which provides match funding for collaborations between community organisations and universities. The charity expresses concern about the confidentiality of its service users and requests that "We would, however, want the research findings to be kept confidential except in so far as they are needed to fulfill the requirements for the degree." Subsequent investigation shows that while the charity refers to a strong research pedigree, findings have only been published in non peer-reviewed trade magazines or internal reports.

PERIL analysis

Is the *purpose* of your academic institution (e.g., excellent medical care through research and education) consistent with the stated purpose of the charity? At first glance it would appear that the charity has the laudable goal of assessing its effectiveness through independent research. However, its desire to control dissemination (presumably in case of unfavourable findings) and its previous track record of publishing only in non peer-reviewed journals would suggest that its goal might not be excellence.

What about the *extent* of the funding? In this example this is unlikely to be a major factor as the amount involved would be comparatively small.

Is there *relevant harm*? There is a chance of some harm in this case if the findings are unfavourable and the charity chooses not to disseminate the report. In this situation, the charity is clearly providing ineffective treatment and using resources that might be better used elsewhere. In addition, it may be skewing the knowledge-base through omission of negative findings.

There is also a significant issue that the researchers and university will be *identified* with the evaluation. It is within the interest of the charity to point to the fact that the research was independently conducted.

Finally, is the nature of the *link* between recipient and donor direct or indirect? In this case it is indirect, so it may not involve a major conflict of interest, and there are no limitations on publication imposed by the funder. In this case, it would be possible for the researchers or the university to insist that the charity remove its right to control release of the data. If that were done, the PERIL analysis would suggest that the funding is worth pursuing.

SUMMARY

Every individual, discipline, and funding organization brings its own agenda to the research process. The practical and ethical conundrums associated with research funding are becoming increasingly complex in a context in which research plays a greater role in the regulation and marketing of potentially addictive products. The examples reviewed in this chapter suggest that addiction scientists should be vigilant about the funding they accept from any source, particularly when there are restrictions on the design, interpretation and publication of the resulting data. In particular, researchers should be very wary about accepting research funding directly from various dangerous consumption industries, their trade associations, and public relations organizations. Consulting arrangements wherein scientists are paid by parties with a clear conflict of interest to critique the work of other scientists can constitute a serious financial conflict of interest that is unlikely to benefit either science or the investigator. Acceptance of fees for writing book chapters, preparing background reports, attending industry-organized conferences and writing letters to the editor should be prefaced by careful consideration of the following questions:

1. To what extent is the scientific activity designed to promote the commercial interests of a particular industry?
2. Will the funding source be acknowledged?

Funding obtained from "independent" research organizations that are supported exclusively by a particular dangerous consumption industry may be consistent with scientific and public health aims if the grant review process is independent, transparent and peer reviewed, and the funding source does not impose rigid limits on the types of research to be conducted. But addiction scientists need to be careful that their objectivity and independence are not compromised by fraternizing with industry executives as well as 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 (Foxcroft, 2005; King, 2006; Babor, in press; Brennan et al., 2006). Finally, researchers should examine all funding sources using PERIL analysis, which allows the individual scientist 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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