

7 Tobacco industry manipulation of research

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This chapter differs in some ways from the others in Volume 2 of *Late lessons from early warnings*. The history of 'second hand', 'passive' or 'environmental tobacco smoke' (ETS), to which non-smokers are exposed overlaps with the history of active smoking. Those affected include the partners and children of smokers, and the bartenders and other workers who have to work in smoky environments.

The focus in this chapter is on the strategies used by the tobacco industry to deny, downplay, distort and dismiss the growing evidence that, like active smoking, ETS causes lung cancer and other effects in non-smokers. It does not address the history of scientific knowledge about tobacco and how it was used or not used to reduce lung cancer and other harmful effects of tobacco smoke. There is much literature on this ⁽²⁾ and a table at the end of the chapter summarises the main dates in the evolution of knowledge in this area.

The chapter concentrates on the 'argumentation' that was used to accept, or reject, the growing scientific evidence of harm. Who generated and financed the science used to refute data on adverse health effects? What were the motivations? What kind of science and information, tools and assumptions were used to refute data on the adverse health of tobacco?

The release of millions of internal tobacco industry documents due to law suits in the US has given insights into the inner workings of the tobacco industry and revealed their previously hidden involvement in manipulating research. However, this insight is not available for most corporate sectors. The chapter discusses the possibilities of 'full disclosure' of funding sources and special interests in research and risk assessment in order to secure independence and prevent bias towards particular viewpoints.

While smoking bans are now being introduced in more and more countries, other industries are drawing inspiration from tobacco company strategies, seeking to maintain doubt about harm in order to keep hazardous products in the marketplace.

The chapter also includes a summary of the tobacco industry's role in shaping risk assessment in the US and Europe to serve its own interests.

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⁽²⁾ For example, two contrasting yet complementary histories of cancer in general and smoking in particular are Davies (2007) and Keating (2009).

7.1 Introduction

This chapter describes the strategies that the tobacco industry has used to influence the design, conduct and publication of scientific research on second-hand smoke; and how the tobacco industry used this research in attempts to influence policy. It represents an expansion of an earlier article, 'Tobacco industry manipulation of research' by Bero (2005).

The primary motivation of the tobacco industry has been to generate controversy about the health risks of its products. The industry has used several strategies including:

1. funding and publishing research that supports its position;
2. suppressing and criticising research that does not support its position;
3. changing the standards for scientific research;
4. disseminating interest group data or interpretation of risks via the lay (non-academic) press and directly to policymakers.

The strategies used by the tobacco industry have remained remarkably constant since the early 1950s when the industry focused on refuting data on the harmful effects of active smoking, through to the 1990s, when the industry was more concerned with refuting data on the harmful effects of second-hand smoke. Tobacco industry lawyers and executives, rather than scientists, have controlled the design, conduct and dissemination of this research.

When data on risk appear to be controversial, users of the data should investigate the sources of controversy. This can be done only if interest group involvement in all steps of the risk determination process is transparent and fully disclosed. Since the tobacco industry's efforts to manipulate research are international endeavours and are shared by other corporate interests, individuals around the world should be aware of the strategies that the industry has used to influence data on risk.

Communicating accurate information on risk is essential to risk perception and risk management. Research findings, often from basic science, epidemiology and exposure or engineering research, provide the basis for information on risk. These research findings or 'facts' are, however, subject to interpretation and the social construction of the evidence (Krimsky, 1992). Research evidence

has a context. The roles of framing, problem definition and choice of language influence risk communication (Nelkin, 1985). Furthermore, scientific uncertainties allow for a wide range of interpretation of the same data. Since data do not 'speak for themselves' interest groups can play a critical role in generating and communicating the research evidence on risk.

An interest group is an organised group with a specific viewpoint that protects its position (Lowi, 1979). Interest groups are not exclusively business organisations; they can comprise all kinds of organisations that may attempt to influence governments (Walker, 1991; Truman, 1993). Therefore, interest groups can be expected to select and interpret the evidence about a health risk to support their predefined policy position (Jasanoff, 1996). For example, public health interest groups are likely to communicate risks in a way that emphasises harm and, therefore, encourages regulation or mitigation of risk (Wallack et al., 1993). Industry interest groups are likely to communicate risks in a way that minimises harm and reduces the chance that their product is regulated or restricted in any way. Disputes about whether a risk should be regulated or not are sometimes taken to the legal system for resolution (Jasanoff, 1995). Thus, interest groups often have two major goals: to influence policy-making and litigation.

Beginning in the 1970s, the tobacco industry influenced the collection, interpretation and dissemination of data on risks of exposure to second-hand smoke. The analysis below suggests that this was history repeating itself; in the 1950s, the tobacco industry had used similar strategies to manipulate information on the risks of smoking. Moreover, other corporate interest groups appear to use similar tactics (Special Issue, 2005; White et al., 2009).

Many of the strategies available to interest groups — for example sponsoring, publishing and criticising research — are costly. Industry might therefore be expected to dominate examples of such activities because corporate interest groups are more likely to have the resources to launch expensive, coordinated efforts. In contrast, public health groups, which tend to act independently, are less likely to command such resources (Montini and Bero, 2001).

Industry examples may also predominate because some interest group activities have come to light through the documents released during the 'discovery' process in law suits. For example, the asbestos and tobacco industries were required to release large amounts of internal correspondence

when they were sued by groups attempting to show that they were harmed by industry products.

7.2 Scientific community knowledge about the hazards of second-hand smoke exposure

Environmental tobacco smoke, or second-hand smoke, is a complex mixture of thousands of gases and fine particles emitted by burning tobacco products and from smoke exhaled by smokers, as well as smoke that escapes while the smoker inhales and some vapour-phase related compounds that diffuse from tobacco products. During the 1970s and 1980s, data on the harmful effects of exposure to second-hand smoke began to be published in the scientific literature. Seminal epidemiological studies in 1981 demonstrated that second-hand smoke exposure was associated with lung cancer (Hirayama, 1981). United States Surgeon General and National Academy of Sciences reports in 1986 concluded that second-hand smoke was a cause of disease (US DHHS, 1986; NRC, 1986).

A landmark European epidemiological study on lung cancer and second-hand smoke was initiated by the International Agency for Research on Cancer (IARC) in 1988 and published in 1998. The publication reported a 16 % increase in lung cancer risk for non-smoking spouses of smokers and a 17 % increase for non-smokers who were exposed in the workplace (IARC, 1998).

In 1992, the US Environmental Protection Agency (EPA) released a risk assessment classifying ETS as a Group A human carcinogen (US EPA, 1992). The tobacco industry criticised the methodology of the US EPA risk assessment for its study selection and statistical analysis. The industry also criticised the epidemiological design of the studies included in the risk assessment, the ways that these studies controlled for bias and confounding, and measured ETS exposure (Bero and Glantz, 1993). The EPA revised the report in response to valid criticisms and the report was approved by the Scientific Advisory Board. The report was improved but the sheer volume of tobacco industry comments that required consideration probably delayed its release. Although the science was valid, the tobacco industry successfully attacked the US EPA risk assessment in court on procedural grounds (*Flue-Cured Tobacco Co-op vs. US EPA*, 1998) and the tobacco industry had similar procedural objections to the report of Australia's National Health and Medical Research Council, 'The health effects of passive smoking' (NHMRC, 1997).

In 1997 the California EPA published the final report of a risk assessment entitled 'Health Effects of Exposure to Environmental Tobacco Smoke' (Cal-EPA, 1997). The California risk assessment was more comprehensive than the US EPA's assessment because it examined the association of second-hand smoke exposure, lung cancer and respiratory illness, as well as cardiovascular, developmental, reproductive and childhood respiratory effects. The California EPA risk assessment also addressed criticisms brought by the tobacco industry against the US EPA risk assessment. The California risk assessment was the result of a collaborative effort between the Office of Environmental Health Hazard Assessment (OEHHA) and the Air Resources Board (ARB), two of the six constituent organisations of the California EPA. The Scientific Review Panel that endorsed the report concluded that second-hand smoke is 'a toxic air contaminant' that 'has a major impact on public health' (Cal-EPA, 1997).

In June 2005 the California Scientific Review Panel approved an updated draft report on Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant (Cal-EPA, 2005). The report concluded that second-hand smoke exposure is causally associated with developmental effects (e.g. inhibited foetal growth, sudden infant death syndrome, pre-term delivery), respiratory effects (e.g. asthma, acute and chronic respiratory symptoms in children, middle ear infections in children), carcinogenic effects (e.g. lung cancer, nasal sinus cancer, breast cancer in younger, premenopausal women) and cardiovascular effects (e.g. heart disease mortality, acute and chronic heart disease, morbidity).

The growing evidence documenting the adverse health effects of second-hand smoke was clearly a threat to the tobacco industry as early as the 1970s. Restrictions on smoking could lead to reduced daily consumption of cigarettes and a decline in sales. The tobacco industry responded with its own science to the independently generated data on tobacco-related adverse health effects.

7.3 Tobacco industry strategies to subvert scientific knowledge

Policymaking is facilitated by consensus (Kingdon, 1984; Mazmanian and Sabatier, 1989; Sabatier, 1991). Scientific research, on the other hand, is characterised by uncertainty. The uncertainty that is familiar to scientists poses problems when decision-making occurs in a public forum. Thus, it is often to the benefit of corporate interest groups to generate controversy about evidence of a product's

health risks because such controversy is likely to slow or prevent regulation of that product. Similarly, scientific debate over the data and methods used in risk assessment, for example, can hinder the development of the risk assessment (Stayner, 1999).

The release of previously secret internal tobacco industry documents as a result of the Master Settlement Agreement in 1998 has given the public health community insights into the tobacco industry's motives, strategies, tactics and data (Bero, 2003). These documents show that for decades the industry has been motivated to generate controversy about the health risks of its products. They have also revealed that the industry was concerned about maintaining its credibility as it manipulated research on tobacco (Bero, 2003).

The strategies used by the tobacco industry have remained remarkably constant since the early 1950s. During the 1950s and 1960s, the tobacco industry focused on refuting data on the adverse effects of active smoking. The industry applied the same tools it developed during that period when it subsequently refuted data on the adverse effects of second-hand smoke exposure during the 1970s through the 1990s.

A 1978 report prepared by the Roper Organization for The Tobacco Institute noted that the industry's best strategy for countering public concern about passive smoking was to fund and disseminate scientific research that countered research produced by other sources:

'The strategic and long-run antidote to the passive smoking issue is, as we see it, developing and widely publicizing clear-cut, credible, medical evidence that passive smoking is not harmful to the non-smoker's health' (Roper Organization, 1978).

Philip Morris promoted international research related to passive smoking in order to stimulate controversy, as described in the notes of a meeting of the UK [Tobacco] Industry on Environmental Tobacco Smoke, London, 17 February 1988:

'In every major international area (USA, Europe, Australia, Far East, South America, Central America and Spain) we are proposing, in key countries, to set up a team of scientists organized by one national coordinating scientist and American lawyers, to review scientific literature or carry out work on ETS to **keep the controversy alive**' (emphasis added) (Boyse, 1988).

The tobacco industry organised teams of scientific consultants all over the world with the main goal of stimulating controversy about the adverse health effects of second-hand smoke (Barnoya and Glantz, 2006; Chapman, 1997; Muggli et al., 2001; Grüning et al., 2006; Assunta et al., 2004).

A variety of studies show that industry sponsorship of research is associated with outcomes that are favourable for the industry (Lexchin et al., 2003; Barnes and Bero, 1998; Barnes and Bero, 1997). One possible explanation for this bias in outcome is that industry-sponsored research is poorly designed or of worse 'methodological quality' than non-industry-sponsored research. However, there is no consistent association between industry sponsorship and methodological quality (Lexchin et al., 2003).

Factors other than study design can affect the outcome of research, including:

- the framing or social construction of the research question;
- the conduct of the study;
- the publication (or not) of the study findings.

The tobacco industry has manipulated these other factors in a variety of ways. First, by using its funding mechanisms to attempt to control the research agenda and types of questions asked about tobacco. Second, the industry's lawyers and executives have been involved in the design and conduct of industry-supported research. Third, the tobacco industry has sponsored publications of its own funded research, and suppressed research not favourable to the industry.

Box 7.1 summarises the range of strategies that the tobacco industry has used for decades to manipulate information on the risks of tobacco. These strategies are described in more detail in the remainder of this section.

7.3.1 *Strategy 1: fund research that supports the interest group's position*

The first element in the tobacco industry's strategy to influence data on risk has been to sponsor research designed to produce findings that are favourable to the industry.

Funding research can stimulate controversy in multiple ways. First, it can put the research agenda

Box 7.1 Tobacco industry strategies to manipulate data on risk

1. Fund research that supports the interest group position.
2. Hide industry involvement in research.
3. Publish research that supports the interest group position.
4. Suppress research that does not support the interest group position.
5. Criticise research that does not support the interest group position.
6. Change scientific standards.
7. Disseminate interest group data or interpretation of risk in the lay press.
8. Disseminate interest group data or interpretation of risk directly to policymakers.

in the control of the interest group. Second, it can produce data to refute research on risk conducted by others. In addition to stimulating controversy, funding research serves other useful purposes for the tobacco industry. The research can be disseminated directly to policymakers and the lay press. It can provide good public relations for the tobacco industry by establishing it as a philanthropic body that funds scientific research. Similarly, funding research can increase the industry's credibility. One of the criteria that the Philip Morris Worldwide Scientific Affairs Programme considered when deciding whether to fund a research application was whether the research would enhance the credibility of the company (Malone and Bero, 2003).

The US tobacco industry funded research through its trade association, The Tobacco Institute (Bero et al., 1995; Hanauer et al., 1995), internally (e.g. internal company research), externally (e.g. by supporting the research of scientific consultants) and through sponsored research organisations. Tobacco industry lawyers and executives were involved in selecting which research to fund. Most of the research did not undergo any form of independent scientific peer review but was funded on the basis of its potential to protect the interests of the companies.

Lawyer involvement in research

In the mid-1990s, internal tobacco industry documents were circulated by industry whistle-blowers. By 1998, the availability of tobacco industry documents increased exponentially as a result of the settlement of a suit by the State of Minnesota and Blue Cross/Blue Shield against the major tobacco companies. The Master Settlement Agreement between the attorneys general of 46 states and Brown & Williamson/British American Tobacco, Lorillard, Philip Morris, RJ Reynolds, the Council for Tobacco Research and The Tobacco Institute released millions of additional documents to the public. These documents provide an unprecedented

look at how tobacco industry lawyers were involved in the design, conduct and dissemination of tobacco industry-sponsored research (Bero, 2003). By involving lawyers in research, the tobacco industry protected their research activities from public discovery and kept their lawyers informed about science relevant to litigation.

The internal tobacco industry documents include descriptions of research that was funded directly by law firms. For example, the law firms of Covington and Burling, and Jacob and Medinger, both of which represent a number of tobacco company clients, funded research on tobacco (Bero et al., 1995). Lawyers selected which projects would be funded. The supported projects included reviews of the scientific literature on topics ranging from addiction to lung retention of particulate matter. The law firms also funded research on factors potential confounding the adverse health effects associated with smoking. For example, projects examined genetic factors associated with lung disease or the influence of stress and low-protein diets on health (Bero et al., 1995). Thus, some of the research funded by law firms served the purpose of deflecting attention away from tobacco as a health hazard and protecting the tobacco companies from litigation.

Other research was funded directly by the tobacco companies but lawyers were involved in selecting and disseminating these projects. For example, tobacco companies funded individuals to serve as consultants to prepare expert testimony for Congressional hearings, attend scientific meetings, review scientific literature or conduct research on the health effects of tobacco or second-hand smoke (Hanauer et al., 1995). At one tobacco company, Brown & Williamson, the legal department controlled the dissemination of internal scientific reports (Hanauer et al., 1995). The lawyers at Brown & Williamson developed methods for screening

scientific reports from their affiliated companies in order to ensure that scientific information related to tobacco and health would be protected from discovery by legal privileges. In a memo dated 17 February 1986, J. K. Wells, the Brown & Williamson corporate counsel, outlined one method for protecting industry produced research data:

'The only way BAT [British American Tobacco] can avoid having information useful to plaintiff found at B&W is to obtain good legal counsel and cease producing information in Canada, Germany, Brazil and other places that is helpful to plaintiffs' (Wells and Pepples, 1986).

Although tobacco industry public statements claimed that the tobacco companies were funding objective research to gather facts about the health effects of smoking, lawyer involvement in the research served to control the scientific debate on issues related to smoking and health and protect from discovery scientific documents that were potentially damaging to the industry.

Research organisations

The tobacco industry also formed research funding organisations, which gave the appearance that the research they supported was independent of influence from the industry.

The **Council for Tobacco Research (CTR)** was formed by United States tobacco companies in 1954 as the Tobacco Industry Research Committee (TIRC). The industry stated publicly that it was forming the TIRC to fund independent scientific research to determine whether there was a link between smoking and lung cancer. However, internal documents from Brown & Williamson Tobacco Company have shown that the TIRC was actually formed for public relations purposes, to convince the public that the hazards of smoking had not been proven (Glantz et al., 1996).

Research that is sponsored by federal organisations or large foundations is typically peer reviewed by other researchers before funding is approved. Although the Council for Tobacco Research had a Scientific Advisory Board consisting of well respected researchers, not all of the research funded by the CTR was peer reviewed by this board. Beginning in 1966, tobacco industry lawyers became directly responsible for many of the funding decisions of the CTR. Between 1972 and 1991, the CTR awarded at least USD 14 636 918 in special project funding (Bero et al., 1995). Lawyers were not only involved in selecting projects for funding but

also in designing the research and disseminating the results (Bero et al., 1995).

The research funded by CTR, although initially useful for public relations, became increasingly important for the tobacco industry's activities in legislative and legal settings. This evolution is described in a memo dated 4 April 1978 from Ernest Pepples, Brown & Williamson's vice president and general counsel, to J. E. Edens, chairman and CEO of Brown & Williamson Tobacco Company:

'Originally, CTR was organized as a public relations effort. ... The research of CTR also discharged a legal responsibility. ... There is another political need for research. Recently it has been suggested that CTR or industry research should enable us to give quick responses to new developments in the propaganda of the avid anti-smoking groups. ... Finally, the industry research effort has included special projects designed to find scientists and medical doctors who might serve as industry witnesses in lawsuits or in a legislative forum' (Pepples, 1978).

The Pepples memo gives insight into why lawyers became increasingly involved in the selection of research projects for CTR.

The **Center for Indoor Air Research (CIAR)** was formed by Philip Morris, R. J. Reynolds Tobacco Company and Lorillard Corporation in 1988 (CIAR, 1988). The founding companies were joined by Svenska Tobaks A.B., a Swedish domestic tobacco company in 1994 (CIAR, 1994). The stated mission of CIAR was 'to create a focal point organisation of the highest caliber to sponsor and foster quality, objective research in indoor air issues **including environmental tobacco smoke**, and to effectively communicate research findings to a broad scientific community' (CIAR, 1989). CIAR's mission statement was modified in 1992 to eliminate the words referring to environmental tobacco smoke (CIAR, 1992a; CIAR, 1992b). The elimination of research on second-hand smoke from the mission statement was followed by a shift in the research agenda of CIAR to one that would prevent it investigating the health effects of second-hand smoke.

Similar to the CTR, CIAR awarded 'peer-reviewed' projects, which were reviewed by a Science Advisory Board, and 'special-reviewed' projects, which reviewed by its Board of Directors consisting of tobacco company executives (Barnes and Bero, 1996). From 1989 to 1993, CIAR awarded USD 11 209 388 for peer-reviewed projects and USD 4 022 723 for

special-reviewed projects (Barnes and Bero, 1996). Seventy per cent of the peer-reviewed projects funded by CIAR examined indoor air pollutants other than tobacco smoke. Thus, the industry appeared to be financing peer-reviewed projects through CIAR to enhance its credibility, to provide good publicity and to divert attention away from second-hand smoke as an indoor air pollutant.

In contrast to the peer-reviewed projects, almost two-thirds of CIAR's special-reviewed projects were related to second-hand smoke (Barnes and Bero, 1996). In addition, most special-reviewed projects studied exposure rather than health effects. It is therefore possible that the tobacco industry was funding research through CIAR to develop data it could use to support its frequent claim that persons are not exposed to sufficient levels of passive smoke to cause any serious adverse health effects (Tobacco Institute, 1986).

The tobacco industry may have also been funding special-reviewed research through CIAR to develop scientific data that it could use in legislative and legal settings. Six CIAR-funded investigators have testified at government hearings. All of the statements submitted by them supported the tobacco industry position that second-hand smoke exposure is not harmful to health. Data from two of CIAR's special-reviewed projects were presented at hearings held by the United States Occupational Safety and Health Administration (OSHA) regarding its proposed indoor air quality regulation. Data from a third special-reviewed project was presented at a Congressional hearing related to a proposed ban on smoking on commercial aircrafts. One CIAR-funded study was investigated extensively by the United States Congressional Subcommittee on Health and the Environment after it was cited in testimony before numerous government agencies. The CIAR-funded study had concluded that, with good building ventilation, clean air could be maintained with moderate amounts of smoking (Turner et al., 1992) and was used to support testimony that indoor smoking restrictions are not necessary. However, the Congressional Subcommittee found that data for this study had been altered and fabricated. An earlier CIAR-funded study by the same organisation was also severely compromised because The Tobacco Institute selected the sites where passive smoking levels were measured for the study (Barnes and Bero, 1996).

The Center for Indoor Air Research was disbanded as part of the US Master Settlement Agreement in 1998. However, in 2000, Philip Morris re-created an external research programme called the 'Philip Morris

External Research Program' (PMERP) with a structure similar to that of CIAR. Like CIAR, PMERP's grant review panel consisted of a cohort of external peer reviewers, a science advisory board, and an internal, anonymous review and approval committee. Three of the six advisory board members had a previous affiliation with CIAR. The majority of the named reviewers also had previous affiliations with the tobacco industry (Hirschhorn et al., 2001).

Research is an international endeavour

The tobacco industry applied the strategy of covertly funding research on an international scale. In Latin America and Asia, tobacco companies, working through the law firm Covington and Burling, developed a network of physician and scientist consultants to prepare and present data to refute claims about the harms of second-hand smoke (Assunta et al., 2004; Barnoya and Glantz, 2002). In Germany, tobacco companies and the German Association of the Cigarette Industry developed a similar team of consultants and funded research through various foundations and research organisations (Grüning et al., 2006). In many cases, the industry employed the next strategy discussed below: hiding its support for the research.

In summary, funding research serves multiple purposes for the tobacco industry. The research that is directly related to tobacco has been used to refute scientific findings suggesting that the product is harmful and sustain controversy about adverse effects. Tobacco industry-supported research has been used to prepare the industry for litigation or legislative challenges. The industry may also have funded research not directly related to tobacco in order to generate good publicity, enhance industry credibility and to distract from tobacco products as a health problem.

7.3.2 Strategy 2: hide industry involvement in research

A defining characteristic of the tobacco industry's response to independent evidence of the harms of second-hand smoke has been attempts to hide its involvement in refuting this evidence. In both of the cases described below, tobacco companies were secretly involved in generating data to suggest that second-hand smoke was not harmful and suppressing data suggesting that it was.

Philip Morris European research programme on second-hand smoke

As early as 1968, executives at Philip Morris began planning a new biological research facility that

would focus on examining the effects, including carcinogenic effects, of second-hand smoke exposure in various animal species. In 1970, Philip Morris purchased a research facility in Germany, Institut für Industrielle und Biologische Forschung GmbH (INBIFO) (Diethelm et al., 2004). Philip Morris hired Ragnar Rylander, a Swedish university professor, as the coordinator of INBIFO. Rylander communicated INBIFO's research findings to Philip Morris executives in the United States, who would then decide whether to disseminate the research more widely or keep it secret. Research that remained unpublished included studies providing evidence that 'sidestream smoke' (which enters the air from a burning cigarette, cigar or pipe) is more toxic than 'mainstream smoke' (which is inhaled directly) (Diethelm et al., 2004). Published research included an epidemiological study suggesting an association between lung cancer and green tea, a finding that would be useful to the tobacco industry in distracting from the harms of second-hand smoke (Tewes et al., 1990).

One of the most striking features of the INBIFO programme was that its coordinator, Ragnar Rylander, had long-standing and secret links to the tobacco industry. Thus, he conferred a false sense of credibility to the programme. Professor Rylander's association with the tobacco industry was investigated by an official university committee, the Fact Finding Commission of the University of Geneva. The committee concluded that Rylander was acting as a sponsored agent of the tobacco industry, rather than as an independent researcher when he testified as a scientific expert, organised scientific congresses and directed research at INBIFO (Fact Finding Commission, 2004). An extensive analysis of internal tobacco industry documents found that Rylander took no initiatives 'in the area of [second-hand smoke research] without first consulting extensively with his contacts within the tobacco industry' (Fact Finding Commission, 2004).

Tobacco industry creation and dissemination of a study on second-hand smoke

The tobacco industry's development of the Japanese Spousal Smoking Study provides another example of industry involvement in designing, conducting and disseminating research, and its efforts to hide this involvement.

In 1981, Takeshi Hirayama published an influential study showing an association of second-hand smoke exposure and lung cancer (Hirayama, 1981). The Hirayama study has been voted the most influential

paper ever on second-hand smoke (Chapman, 2005) and was the most frequently cited study in regulatory hearings on smoking restrictions (Montini et al., 2002). In these hearings, tobacco industry representatives have argued that the Hirayama study is flawed due to misclassification bias (Bero and Glantz, 1993; Schotland and Bero, 2002). Furthermore, analysis of internal tobacco industry documents by Hong and Bero (2002) has shown how the tobacco industry hid its involvement in creating a study, the Japanese Spousal Smoking Study, to support its arguments about misclassification bias.

The tobacco industry documents reveal that although the Japanese Spousal Smoking Study was undertaken by named Japanese investigators, project management was conducted by Covington and Burling (a tobacco industry law firm), the research was supervised by a tobacco industry scientist and a tobacco industry consultant assisted in reviewing the study design and interpreting the data (Hong and Bero, 2002). The documents show that the tobacco companies that funded the study did not want any of these individuals named as co-authors on any of the resulting scientific publications. Although the tobacco companies considered using the Center for Indoor Air Research (CIAR) as 'a cover' to fund the study, three companies agreed to fund the study directly. Progress reports for the study were prepared on Covington and Burling stationery. When the study was prepared for publication, the tobacco industry consultant was the sole author (Lee, 1995). The publication acknowledged 'financial support from several companies of the tobacco industry' (Lee, 1995). This acknowledgement tells the reader little about who was actually involved in the design, conduct and publication of the study. The hidden roles of the tobacco company lawyers and scientist raise questions about who was accountable for the research (Hong and Bero, 2002).

The analysis of tobacco industry documents (Hong and Bero, 2002) was noticed by Dr E. Yano, one of the Japanese investigators who was originally involved in the Japanese Spousal Smoking study. Dr Yano had been unaware that Dr Lee had published the study. He had retained the original data from the study and has reported that Dr Lee's published analysis excluded data that did not support misclassification bias (Yano, 2005). Dr Yano demonstrated that using the full data from the Japanese Spousal Smoking Study changes the conclusion of Lee's published report. After 10 years, the scientific community was able to obtain data that had been suppressed by the tobacco industry.

7.3.3 *Strategy 3: publish research that supports the interest group position*

Research has little impact unless it can be cited. The tobacco industry has realised that funding research that supports its interests must be followed by the dissemination of such research in scientific literature. The tobacco industry uses several vehicles to publish the findings of its sponsored research, including funding the publication of symposia proceedings, books, journal articles and letters to the editors of medical journals. To suggest that the research it funds meets scientific standards and that there is substantial support for its position, the tobacco industry then cites its industry-funded, non-peer-reviewed publications in scientific and policy arenas.

Symposium proceedings

Scientific meetings or symposia often result in the publication of books or journal articles that summarise the research presented there. The pharmaceutical industry, for example, publishes reports of symposia containing poor quality and unbalanced articles favourable to particular drugs (Bero et al., 1992; Rochon, 1994). The tobacco industry has sponsored numerous symposia on second-hand smoke (Bero et al., 1994) and paid for scientific consultants to organise and attend these meetings (Barnoya and Glantz, 2002, 2006; Muggli et al., 2001).

Between 1965 and 1993, reports on 11 symposia on passive smoking were published. Six were published as special issues of medical journals, while five were published independently as books. None of the symposia was peer reviewed; six were sponsored by the tobacco industry or its affiliates such as the Center for Indoor Air Research, The Tobacco Institute and Fabriques de Tabac Reunies. Two of the six industry-sponsored symposia did not explicitly acknowledge industry sponsorship. The tobacco industry sometimes sponsored conferences through independent organisations so that their sponsorship would be hidden (Bero et al., 1995; Bero et al., 1994).

The symposia on passive smoking were attended by an international group of scientists and held across the world, including Europe, the United States, Canada, Japan and Argentina. One symposium report was published in Spanish. CTR special projects were often used to support scientists to prepare talks for conferences and to send scientists to conferences (Glantz et al., 1996).

On the surface, articles from symposia look like articles from peer-reviewed journals. To test the hypothesis that symposium articles on second-hand smoke differ in content from articles on second-hand

smoke appearing in scientific journals, Bero et al. (1994) compared the symposia articles to a random sample of articles on passive smoking from the scientific literature and to two consensus reports on the health effects of passive smoking (US DHHS, 1986; NRC, 1986). Of the symposium articles, 41 % (122/297) were reviews, compared with 10 % (10/100) of journal articles. Symposia articles were significantly more likely than journal articles to agree with the tobacco industry position that tobacco is not harmful (46 % compared to 20 %), less likely to assess the health effects of passive smoking (22 % compared to 49 %), less likely to disclose their source of funding (22 % compared to 60 %), and more likely to be written by tobacco industry-affiliated authors (35 % compared to 6 %). Symposium authors published a lower proportion of peer-reviewed articles than consensus report authors (71 % compared to 81 %) and were more likely to be affiliated with the tobacco industry (50 % compared to 0 %) (Bero et al., 1994).

Symposia proceedings can potentially influence policy because they are often cited as if they are peer-reviewed articles and balanced reviews of the scientific literature, with no disclosure of their industry sponsorship. For example, tobacco industry-sponsored symposia on second-hand smoke have been used to attempt to refute both peer-reviewed journal articles and risk assessments of second-hand smoke (Bero and Glantz, 1993; Schotland and Bero, 2002; Chapman et al., 1990). Symposia articles have also been cited in tobacco industry public relations materials and the press (e.g. Tobacco Institute, 1986); and as the consensus of a gathering 'of leading experts from around the world' who disagree with the published literature on passive smoking (Johnston and Sullum, 1994).

In summary, tobacco industry-sponsored symposia articles on second-hand smoke consist, in large part, of review articles that reach different conclusions about the health effects of passive smoking than peer-reviewed journal articles or consensus reports. Furthermore, symposia are more likely to publish research that discusses issues that distract from tobacco as a health problem. The tobacco industry affiliations of symposia authors suggest that industry control over publication and research funding is likely to influence the presentation of findings.

Quality of tobacco industry-funded symposium publications

When policymakers, judges, lawyers, journalists and scientists are presented with tobacco industry-sponsored symposium articles, they must decide whether to incorporate these publications into

their deliberations. Although the lack of balance and peer review suggests that tobacco industry-sponsored literature may lack scientific rigour, the issue of peer review and study quality is a contentious subject. Methodological quality is determined by the presence or absence of study design characteristics aimed at reducing bias, such as blinding, follow-up, controlling for confounding and controlling for selection bias.

Barnes and Bero (1997) assessed the methodological quality of the research presented at symposia. As articles from pharmaceutical industry sponsored symposia have been found to be of poor methodological quality (Rochon, 1994; Cho and Bero, 1996) it was hypothesised that articles from tobacco industry-sponsored symposia would be poorer in methodological quality than peer-reviewed journal articles. Other characteristics of articles were evaluated that might be associated with quality, such as disclosure of the source of research sponsorship and the study's conclusions, topics and design. Original research articles on the health effects of second-hand smoke published in peer-reviewed journals were compared to those published in non-peer-reviewed symposium proceedings from 1980 to 1994.

The study found that peer-reviewed articles were better quality than symposium articles independent of their source of funding, their conclusions on the health effects of second-hand smoke and the type of study design. Peer-reviewed articles received higher scores than symposium articles for most of the criteria evaluated by the quality assessment instrument.



Photo: © istockphoto/Richard Clark

Quality of tobacco industry-sponsored review articles

Policymakers and clinicians often rely on review articles to provide accurate and up-to-date overviews of a topic of interest (Montini and Bero, 2001). As already noted, a large proportion of symposium articles are reviews of the health effects of second-hand smoke (Bero et al., 1994) and are frequently cited in response to government requests for information (Bero and Glatz, 1993; Montini et al., 2002; Schotland and Bero, 2002). In view of their importance in guiding policy, it is somewhat disconcerting that published review articles often reach markedly different conclusions about the adverse health effects of second-hand smoke.

Barnes and Bero (1998) conducted a study to evaluate the quality of review articles on the health effects of passive smoking and to determine whether the conclusions of review articles are primarily associated with their quality or with other article characteristics. The *a priori* hypotheses were that review articles concluding that passive smoking is not harmful would tend to be poor in quality, published in non-peer-reviewed symposium proceedings and written by investigators with tobacco industry affiliations. The topic of the review and the year of publication were also reviewed as potential confounding factors.

In the sample of 106 review articles, the only factor associated with concluding that passive smoking is not harmful was whether the author of the review article was affiliated with the tobacco industry (Barnes and Bero, 1998). As shown in Table 7.1, review articles concluding that passive smoking is not harmful were about 90 times more likely to be funded by the tobacco industry than those concluding that second-hand smoke is harmful. Methodological quality, peer-review status, outcomes studied in the reviews, and year of publication were not associated with the conclusions of the articles. Thus, sponsorship of review articles by the tobacco industry appears to influence the conclusions of these articles, independent of methodological quality.

The tobacco industry has argued that independent reviews of second-hand smoke are flawed because studies with statistically significant results are more likely to be published than studies with statistically non-significant results (Dickersin et al., 1992; Shook, Hardy and Bacon, 1993). The industry argues that publication bias — the tendency to publish work with statistically significant results — prevents the identification of all relevant studies for reviews of the health effects of second-hand smoke (e.g. Armitage, 1993). Bero et al. (2004) conducted a preliminary

Table 7.1 Factors associated with review articles concluding that passive smoking is not harmful to health: multiple logistic regression analysis

Factor	Odds ratio (95 % CI)	P value
Quality score	1.5 (< 0.1–67.5)	0.83
Not peer reviewed v. peer reviewed	1.3 (0.3–5.4)	0.70
Tobacco industry sponsored v. not tobacco industry sponsored	88.4 (16.4–476.5)	< 0.001
Outcomes — lung cancer v. other clinical outcomes	1.6 (0.2–10.3)	0.63
Heart disease v. other clinical outcomes	1.6 (0.2–14.7)	0.67
Year of publication	1.1 (0.9–1.3)	0.45

Source: Barnes and Bero, 1998.

study of publication bias showing that statistically non-significant studies are published: approximately 20 % of the published peer-reviewed articles on passive smoking present statistically non-significant findings.

By interviewing investigators studying second-hand smoke and health effects, Misakian and Bero (1998) determined that studies with statistically non-significant results take about two years longer to be published than those with statistically significant results. For studies conducted in humans, only statistical significance was predictive of time to publication, not study design or sample size. Thus, the tobacco industry's argument that statistically non-significant results are not published is invalid.

Since statistically non-significant results are published but take longer to be published than statistically significant results, reviews of research should attempt to include unpublished data and be periodically updated. Reviews conducted by the Cochrane Collaboration, for example, attempt to identify unpublished studies and include them in reviews if they meet quality standards. Cochrane reviews, which are published online, are also regularly updated (Bero and Rennie, 1995).

7.3.4 *Strategy 4: suppress research that does not support the interest group position*

Interest groups are eager to fund and publish research that supports their position and hesitant to publicise research that does not. In some cases, tobacco industry lawyers and editors have edited their externally funded scientific research publications; in other cases they have prevented publication of the research (Hong and Bero, 2002; Muggli et al., 2001; Barnoya and Glantz, 2002). Editing has included attempts to obscure evidence on adverse health effects by using the code word 'zephyr' for 'cancer' in internal memos about health effects research (Glantz et al., 1996; BAT, 1956).

Research conducted internally by tobacco companies or through industry-controlled research organisations is likely to be suppressed if it is unfavourable to the industry. For example, the German tobacco industry-supported research organisation, INBIFO, did not publish its research showing that sidestream smoke is more toxic than mainstream smoke (Grüning et al., 2006).

Tobacco companies have also conducted internal research on the use of chemical additives to reduce, mask or otherwise alter the visibility, odour, irritation or emission of second-hand smoke. Some of these studies showed that the additives increased emissions of toxins such as carbon monoxide or the carcinogenic substances, N'-nitrosoniornicotine and benzo(a) pyrene (Conolly et al., 2000). Virtually none of this research has been published in scientific literature, however, and data on additives is not typically available to public health policymakers.

7.3.5 *Strategy 5: criticise research that does not support the interest group position*

Another strategy that the tobacco industry has used to stimulate controversy about research on risk has been to criticise research that is not favourable to its position. Science is improved by constructive criticism. However, the tobacco industry has misused legitimate means of scientific debate, such as letters to the editor of scientific journals and editorials. The tobacco industry has also used less legitimate methods to criticise research, including attacking the integrity of researchers or obtaining data through lawsuits and reanalysing it using inappropriate techniques (Barnes et al., 1995).

In order to get its views into public commentary on risk assessments (Bero and Glantz, 1993; Schotland and Bero, 2002) or the lay press (Chapman et al., 1990), the tobacco industry has frequently cited letters to the editor as if they were peer-reviewed

journal articles. Letter authors affiliated to the tobacco industry often fail to disclose their affiliation. These findings support the suggestions by a number of journal editors that letter writers should disclose potential conflicts of interest and that journals should peer review letters (Rennie, 1993).

As mentioned above, the tobacco industry has maintained large teams of international scientific consultants (Chapman, 1997; Muggli et al., 2001; Barnoya and Glantz, 2002). A major goal of the tobacco industry's scientific consultancy programme was to refute data about the harmful effects of tobacco. Industry consultants were paid to criticise independent research on tobacco and second-hand smoke via participation in scientific conferences; publications such as conference proceedings, journal articles and books; media appearances; testimony at tobacco litigation trials; forming a scientific society on indoor air; and preparing statements for government committees. The industry consultant programmes were international and were used to discredit research conducted by non-industry scientists around the world (Chapman, 1997; Muggli et al., 2001; Barnoya and Glantz, 2002).

7.3.6 Strategy 6: changing scientific standards

As described above, the tobacco industry has devoted enormous resources to attacking and refuting individual scientific studies. In addition, the industry has attempted to manipulate scientific methods and regulatory procedures for its benefit. The tobacco industry has influenced the debate around 'sound science' (Ong and Glantz, 2001), standards for risk assessment (Hirschhorn and Bialous, 2001), international standards for tobacco and tobacco products (Bialous and Yach, 2001) and laws related to data access and quality (Baba et al., 2005).

The tobacco industry has played a major role in developing ventilation standards for indoor air quality and in establishing international standards for tobacco and tobacco products. The International Organization for Standardization (ISO) develops international standards for tobacco and tobacco products, including the measurement of tar and nicotine yield. The tobacco industry, working through the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) gathered scientific evidence for ISO and suggested the standards that were adopted (Bialous and Yach, 2001). These standards incorrectly imply that there are health benefits from low-tar and low-nicotine products (Djordjevic et al., 1995). The tobacco industry has also been involved in developing ventilation

standards for over 20 years. The industry influenced the development of ventilation standards by the American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE) by generating data and presenting it to the committee (Bialous and Glantz, 2002). This resulted in a standard that ignores the health effects of second-hand smoke exposure, concentrating instead on a 'comfort' standard.

In the early 1990s, the tobacco industry launched a public relations campaign about 'sound science' and 'good epidemiological practices' (GEP) and used this rhetoric to criticise government reports, particularly on the harms of environmental tobacco smoke. All scientists agree that research should be rigorously conducted. But the 'sound science' and 'GEP' campaigns were public relations efforts controlled by industry executives and lawyers to promote unreasonably high standards of proof about the harm caused by the industry's products. For example, 'sound science' rhetoric argues that epidemiological studies can never establish evidence of harm because they cannot 'prove' causality. This approach ignores the fact that a comprehensive assessment of risk involves considering all the evidence related to a toxin, not just the epidemiology (Ong and Glantz, 2001).

The tobacco industry also developed a campaign to criticise the technique of risk assessment of low doses of a variety of toxins (Hirschhorn and Bialous, 2001). The tobacco industry worked with the chemical, petroleum, plastics and chlorine industries to develop its criticisms of risk assessment. In fact, the first version of GEP was drafted by the Chemical Manufacturers Association. After about ten years, by the late 1990s, the industry's 'sound science' public relations campaign ended. The tobacco industry then turned to advancing the 'sound science' concept through legislation (Baba et al., 2005).

One major goal of the tobacco industry has been to obtain data from independent studies and reanalyse it using 'sound science' criteria to reach different conclusions. Philip Morris, for example, used a three-step strategy to obtain data:

1. asking the researchers for the data directly;
2. litigation;
3. encouraging the enactment of policies that release data (Baba et al., 2005).

The industry's efforts resulted in 'sound science legislation': laws that influenced access to data and standards for data analysis.

In 1998, the United States Congress enacted a data access law as a rider to the Fiscal Year 1999 Omnibus Appropriations Act (US Congress, 1999). The law, for the first time, made all data produced under federally funded research studies available on request through the Freedom of Information Act (FOIA) (Zacaroli, 1998). Two years after the adoption of the data access provision, another amendment was added to the 2001 Omnibus Appropriations Act. The Data Quality Act (2000) requires the Office of Management and Budget to develop government-wide standards for data quality in the form of guidelines. Individual federal agencies must promulgate their own conforming guidelines based on OMB's model and adopt standards that 'ensure and maximise the quality, objectivity, utility and integrity of information disseminated' by federal agencies (OMB Watch, 2002). The standards to be adopted were created by the industry sponsors, not independent researchers.

While the public had an opportunity to comment on implementing the laws, these amendments were initially passed and adopted without a legislative hearing, committee review or debate (Renner, 2002). The scientific, academic research and public health communities voiced concerns during the public comment period about potential problems with confidentiality of medical information, discouragement of research subjects, misinterpretation of incomplete or prematurely released data sets, delay of research, protection of national security information, and administrative and financial burdens (AAAS, 1999). The research community was also concerned that these measures were supported by industry groups seeking to contest environmental and other regulations (Zacaroli, 1998).

Although the tobacco industry intended to hide its involvement in the data access and quality acts, internal industry documents reveal that these policies were driven by tobacco industry efforts to coordinate corporate interests. Tobacco industry strategies to advance sound science legislation included (Baba et al., 2005):

- demonstrating that the public cares about the issue by sponsoring a poll on issues of data access and rules of epidemiological studies that can be made public;
- leveraging allies and groups that have already taken a stand on the issue;
- using scientists and technical conferences to focus on the issue;

- encouraging a small group of members of Congress to take a stand on the issue;
- encouraging the Administration to take a stand for sound science;
- mobilising allied industries (i.e. fishing, utilities, waterworks) to lobby their local representatives;
- helping to organise coalitions for other epidemiological issues coming up soon (e.g. fishing industry, mercury, methylene chloride);
- educating and mobilising the business community on sound science v. junk science and the federal legislative/regulatory process;
- using states to generate action — conducting briefings in states on epidemiological studies and the need for uniform standards and encouraging the passage of state laws;
- developing broad bipartisan support for 'freedom of information' with regards to the data behind regulations and laws;
- leveraging lobbyists to contact key legislative members;
- briefing the media;
- briefing business coalitions on the need for data access;
- using the Congressional Science Committee to influence Congress.

Together, the data access and data quality acts provide a mechanism for challenging the scientific merit of data outside scientific journals and other channels of scientific review (McGarity, 2004; Kaiser, 1997). As scientists, legal experts and environmentalists have pointed out, however, the data access and data quality riders have the potential to block agencies from using emerging science from non-industry sources and to slow the regulatory process (Kaiser, 2003; Hornstein, 2003; Shapiro, 2004). The laws can be used to prevent future policies and to repeal existing policies that do not meet the data quality standards. The laws could shift the scientific standards of data used for policy purposes to favour standards promulgated by industry. Finally, access to data and quality standards are not applied equitably; they only apply to data generated with government funding, not industry funding.

Panel 7.1 Shaping risk assessment in the US and the EU: the role of the tobacco industry

Katherine Smith, Anna Gilmore and Gary Fooks

The interest of Philip Morris in shaping risk assessment was precipitated by the US EPA risk assessment of environmental tobacco smoke (ETS), which resulted in ETS being categorised as a class A human carcinogen (Hirschhorn and Bialous, 2001). Philip Morris challenged the assessment as part of its broader 'sound science' campaign (Ong and Glantz, 2001). This involved lobbying for laws requiring that:

- epidemiological studies meet a particular set of criteria or standards before they can officially inform policy decisions;
- epidemiological data used in publicly funded studies be made available through freedom of information requests.

Although the tobacco industry's campaign was ultimately unsuccessful in overturning the EPA's classification of ETS, it did manage to place 'a cloud over its validity' until 2002 (Muggli et al., 2004), leading to delays in subsequent introduction of protective legislation. Further, Philip Morris had some success in introducing data access laws and shaping the Data Quality Act (2000) (Baba et al., 2005).

Philip Morris believed that a similar campaign might be even more effective in Europe, where officials had not yet taken up the scientific threat of ETS to the same extent. From the mid-1990s onwards, therefore, it focused its campaign more heavily on Europe. Here, informed by what the Chemical Manufacturers Association had termed 'good epidemiological practice' (GEP), Philip Morris concentrated on lobbying for a mandatory set of criteria or standards that epidemiological studies would have to meet before they could be officially considered by policymakers in Europe (Ong and Glantz, 2001). The Philip Morris standards for 'good epidemiological practice' included a requirement for evidence relating to relative risks of less than 2.0 to be disregarded as too weak to warrant policy intervention.

As of late 2000 Ong and Glantz (2001) concluded that, despite the efforts of Philip Morris, 'no European Union resolution on GEP had been produced'. As far as we are aware, this remains the case.

British American Tobacco (BAT) managers studied the Philip Morris campaigns carefully and from 1995 onwards considered lobbying for a mandatory requirement for 'structured risk assessment' in EU policymaking because they believed it could be used to prevent the introduction of public smoking restrictions (Smith et al., 2010; BAT, 1995 and 1996). By this stage, the industry was well aware of the negative health impacts of second-hand smoke and was simultaneously trying to influence the evidence-base on this issue. BAT managers believed that 'a legislated demand for structured risk assessment', governed by strict 'rules for the assessment of epidemiological and animal data' would 'remove the possibility of introducing public smoking restrictions that are based on risk claims' (BAT, 1995).

Our analysis of BAT's internal documents has not yet established precisely what BAT managers meant when they used the term 'structured risk assessment'. All of the documents with titles indicating that they include detailed information on this issue have been redacted ⁽³⁾.

A 1995 BAT document makes it clear that the company's interpretation of 'risk assessment' involved a set of 'rules for the assessment of epidemiologic and animal data', which BAT managers believed would, if applied, make it 'apparent that ETS has not been proven to be a cause of disease in non-smokers' (BAT, 1995).

BAT managers wanted to use risk assessment as a way of limiting officials' discretion. For example, a document discussing the company's efforts to influence risk assessment says: 'The challenge will be to persuade government departments to subordinate policy or judgemental considerations in favour of scientific rigour in risk assessment' (Gretton, undated [circa 1995]).

⁽³⁾ See for example BAT (1991 and 1996). The Legacy Tobacco Documents Library website, which hosts these documents, states that the term 'redacted', 'Indicates whether the document contains words or sentences that were erased (redacted) by the tobacco company due to confidentiality issues (i.e. trade secrets, attorney/client privileges) before the document was publicly released' (University of California, 2011).

Panel 7.1 Shaping risk assessment in the US and the EU: the role of the tobacco industry (cont.)

In practice, this constituted a way of undermining the precautionary principle as a basis for policy decisions.

The key innovation of BAT's European campaign was the decision to focus on promoting risk assessment within a framework of 'cost-benefit analysis', a term that BAT used interchangeably with business impact assessment (see Smith et al., 2010). This had the additional effect of embedding economic considerations into the risk assessment process, which would also require interventions to protect the public against particular risks to be justified on the basis of economic costs (BAT, 1996; European Policy Centre, 1997).

BAT initially sought advice on how to shape risk assessment in the EU from the US advisers to Philip Morris, Covington and Burling (Covington and Burling, 1996). They advised BAT that although there was little interest in risk assessment within the European Commission at the time it might be possible to include 'structured risk assessment' in detailed guidance for business impact assessments, which had been flagged as a priority for the European Commission in 1996.

BAT was aware that a campaign for regulatory reform with known links to the tobacco industry was unlikely to succeed (Honour, 1996). It had been advised to work through a 'front group' and to recruit other companies with similar interests, such as other large firms in regulated sectors (MacKenzie-Reid, 1995). Following this advice, BAT approached the European Policy Centre (a prominent Brussels-based think tank with strong links to the Commission) to lobby for regulatory reforms on its behalf (Smith et al., 2010). BAT and the European Policy Centre then jointly set about recruiting other business interests to this campaign (Smith et al., 2010). These companies, which included large corporations from the oil, chemical and pharmaceuticals sectors, established an invitation-only sub-group within the European Policy Centre, known as the Risk Forum (Smith et al., 2010).

These efforts contributed to certain amendments to the Treaty on European Union (EU, 1997), placing a legal duty on the Commission to 'consult widely' and to minimise the potential 'burden' of policy changes on 'economic operators' and others (EU, 1997). BAT interpreted this to mean that business impact assessment and risk assessment were now mandatory within EU policymaking. The company perceived this as 'an important victory' (BAT, undated).

The guidelines for EU officials on how to undertake impact assessment have been revised several times since and now incorporate guidance on undertaking risk assessment (European Commission, 2009).

In 2006–2007, under pressure to open up to civil society organisations and other members of the European Policy Centre (which was under new leadership), the coalition of companies involved in the think tank's Risk Forum left and established a separate organisation called the European Risk Forum. This group describes itself as 'an expert led, not-for-profit think tank' (European Risk Forum, 2008a), despite solely representing corporate interests, virtually all of which are connected to the chemical and tobacco industries. This was confirmed via personal correspondence from the Forum's chair, Dirk Hudig, in February 2010. The European Risk Forum is now actively encouraging the European Commission to adopt a more structured approach to risk assessment and risk management (European Risk Forum, 2008b), although it remains unclear precisely what this involves.

Recent analyses suggest that these corporate efforts have been somewhat successful in redefining policymakers' understandings of and responses to risks, including those that limit use of the precautionary principle in the EU (Löfstedt, 2004) and the United Kingdom (Dodds, 2006). However, as risk assessment continues to be actively debated in Brussels, it is not yet possible to assess the success of the BAT or Philip Morris campaigns.

It is of course legitimate for corporate interests to contribute to discussions on assessing scientific evidence and weighing up risks. However, it is important to ensure that this influence is transparent, is not excessive in comparison to other stakeholders, and does not compromise public welfare.

7.3.7 *Strategy 7: disseminate interest group data or interpretation of risk in the lay press*

While the tobacco industry appears to have recognised the importance of publishing work that supports its position in the scientific literature, the industry also seems aware of the need to get research data directly into the hands of the public and policymakers. How, then, were the public and other stakeholders involved in generating, presenting, understanding, communicating and using science to refute data on the adverse health effects of tobacco?

The important role of the media in communicating risk has been extensively studied (Nelkin, 1985; Raymond, 1985). The tobacco industry has been active in stimulating controversy in lay print media about the health effects of second-hand smoke. In a cross-sectional sample of 180 North American newspaper and 95 magazine articles reporting on second-hand smoke research between 1981 and 1995, Kennedy and Bero (1999) found that 66 % of newspaper articles and 55 % of magazine articles left readers with the impression of continuing controversy about second-hand smoke research. However, the proportion of those articles concluding that the research was controversial remained relatively constant.

Although tobacco industry-sponsored research studies were not widely cited in lay press articles, tobacco industry affiliated individuals were often cited (Kennedy and Bero, 1999; Malone et al., 2001). Among the 180 newspaper articles examined by Kennedy and Bero (1999), 52 % cited tobacco industry officials, whereas 56 % cited government officials and 46 % cited independent scientists. This citation of tobacco industry officials as experts on scientific studies on second-hand smoke could have contributed to the emphasis on controversy.

7.3.8 *Strategy 8: present interest group data or interpretation of risk directly to policymakers*

The last strategy in the tobacco industry's effort to stimulate controversy about data on risk has been to get its funded research directly into the hands of individuals who are likely to influence policy. A series of in-depth case studies have been undertaken, examining the role of research evidence in the development of two risk assessments of second-hand smoke, two state indoor air regulations and two United States federal tobacco regulations (Schotland and Bero, 2002; Roth et al.,

2003, Bero et al., 2001; Bryan-Jones and Bero, 2003). Each study addressed the role of the tobacco industry in developing risk assessments and regulations by analysing archival data, including written commentary and hearing transcripts, and interviewing key policymakers.

In the United States, the processes for developing these risk assessments and regulations involves the appropriate government agency reviewing the relevant scientific literature, preparing a draft report, collecting written and oral public commentary, and revising the report based on that public commentary (Jasanoff, 1987 and 1996, Silbergeld, 1993). Public participation in the process is important for shaping the findings of the final risk assessment or regulation, and for public acceptability of the findings (Jasanoff, 1987). Furthermore, public commentary could help prevent the 'capture' of the risk assessment process by interest groups (Wilson, 1989).

Risk assessments of second-hand smoke

As noted earlier in this chapter, the US Environmental Protection Agency (EPA) published a risk assessment of environmental tobacco smoke (ETS) in 1992, which concluded that passive smoking is associated with lung cancer in adults and respiratory disease in children. The risk assessment's development was considerably delayed by the tobacco industry's criticisms of the report (US EPA, 1992). Sixty-four per cent (69/107) of submissions received by the EPA during the public commentary period claimed that the conclusions of the draft were invalid and, of these, 71 % (49/69) were submitted by tobacco industry-affiliated individuals (Bero and Glantz, 1993). The tobacco industry-affiliated reviewers supported their criticisms of the risk assessment by selectively citing non-peer-reviewed literature, especially articles from symposium proceedings (Bero and Glantz, 1993). Thus, tobacco industry-sponsored research that was not published in the peer-reviewed scientific literature was submitted directly to the EPA for review.

Schotland and Bero (2002) examined the development of the California risk assessment, revealing that participation in the public contribution process was not balanced among all interested parties, and was dominated by the tobacco industry. Critics and supporters of the risk assessment used different criteria to evaluate the science, suggesting that they were constructing the evidence to support their predefined positions. Similar to the US EPA risk assessment, the tobacco industry was able to use its funded research to support its arguments against the California risk assessment.

Indoor air regulation

During the 1990s, the Washington and Maryland Occupational Safety and Health Administrations each promulgated regulations restricting smoking in private workplaces. The US Occupational Safety and Health Administration also proposed a workplace smoking restriction but this failed. Internal tobacco industry documents show that one strategy the industry used to defeat the proposed federal regulation was to 'produce data to counter the findings about the adverse health effects of second-hand smoke' (Bryan-Jones and Bero, 2003). Despite the tobacco industry's use of this strategy and others to defeat the Maryland and Washington regulations, the state regulations were passed (Mangurian and Bero, 2000).

The two states' regulatory development processes required a public commentary period. Opposition to the regulation came primarily from the tobacco industry, small businesses, and business organisations and appeared to be coordinated (Bero et al., 2001). Much of the business group opposition was supported by the tobacco industry, although this support was not disclosed in the public commentary (Mangurian and Bero, 2000). Although arguments not related to science were more common than scientific arguments as a whole, arguments about science were used more often by opponents than supporters of the regulations (Bero et al., 2001). As in the other examples cited in this chapter, opponents of regulation, primarily the tobacco industry, cited industry-sponsored symposium proceedings or peer-reviewed journal articles of low methodological quality to support their criticisms of the science on which the regulations were based.

Apparent disagreement among experts during public testimony reinforces uncertainty about the data underpinning risk estimates or regulations. The studies of the Washington and Maryland regulations suggest, however, that the industry-supported experts used different criteria to evaluate the science, different bodies of evidence to support their claims and relied on arguments about specific studies rather than emphasising the body of evidence as a whole. In general, the involvement of tobacco industry lawyers and executives in the design, conduct and dissemination of research has an impact on how controversy can influence public opinion and policy decisions.

Box 7.2 describes how the tobacco industry worked to undermine tobacco control activities at the World Health Organization.

7.4 Lessons learned

The tobacco industry has had a long-standing strategy of funding research and disseminating it through their sponsored, non-peer-reviewed publications. These strategies have remained relatively consistent as the industry has evolved from refuting research on active smoking to refuting research on second-hand smoke. Despite the questionable conduct of much of this research, the tobacco industry has widely disseminated it to lay journalists and policymakers. In addition, the tobacco industry has a record of suppressing and criticising research that is unfavourable to its position. Tobacco industry lawyers and executives, rather than scientists, have been in control of the design, conduct and dissemination of this research, thereby protecting the research from public discovery. Since the tobacco industry's efforts to manipulate research are international endeavours, there is a need for global awareness of the strategies that the industry has used to influence data on risk.

When data on risk appear to be controversial, users of the data should investigate the sources of the controversy. Does the controversy exist only because the findings of interest group-funded research are contrary to data collected by others? Is the controversy supported primarily by evidence published in interest group-supported publications? Is the controversy supported primarily by research publications of low scientific quality? Is the controversy perpetuated in the lay press through citation of interest group-affiliated individuals? Are the data that suggests a controversy presented to policymakers only by the interest group?

Policymakers should apply these questions to all situations in which a company has an interest in creating controversy about the risks of its products. The tobacco industry differs substantially from other industries in the deadly nature of its products when used as directed, and the historical lack of regulation of tobacco products. However, the tobacco industry's methods for influencing the design, conduct and publication of research are similar to those of other corporate interests. For example, studies examining the association of pharmaceutical industry funding and research outcomes suggest that such funding produces studies with outcomes that are favourable to the sponsor (Lexchin et al., 2003; Cho and Bero, 1996; Bekelman et al., 2003). The reasons for this observed association of funding and outcome are not clear (Bero and Rennie, 1996). For example, the funding source does not appear to influence the methodological quality of the published research (Lexchin et al., 2003). Therefore, biased outcomes may

Box 7.2 Tobacco industry strategies to undermine tobacco control activities at the World Health Organization

'Tobacco industry documents reveal that, for many years, tobacco companies have deliberately subverted the efforts of the World Health Organization (WHO) to control tobacco use. The attempted subversion has been elaborate, well financed, sophisticated and usually invisible.

The release of millions of pages of confidential tobacco company documents as a result of lawsuits against the tobacco industry in the United States has exposed the activities of tobacco companies in resisting tobacco control efforts. That tobacco companies resist proposals for tobacco control comes as no surprise. What is now clear is the scale and intensity of their often deceptive strategies and tactics.

The tobacco companies' own documents show that they viewed the WHO, an international public health agency, as one of their foremost enemies. The documents show further that the tobacco companies instigated global strategies to discredit and impede the WHO's ability to carry out its mission. The tobacco companies' campaign against the WHO was rarely directed at the merits of the public health issues raised by tobacco use. Instead, the documents show that tobacco companies sought to divert attention from the public health issues, to reduce budgets for the scientific and policy activities carried out by the WHO, to pit other UN agencies against the WHO, to convince developing countries that the WHO's tobacco control programme was a 'first world' agenda carried out at the expense of the developing world, to distort the results of important scientific studies on tobacco and to discredit the WHO as an institution.

Although these strategies and tactics were frequently devised at the highest levels of tobacco companies, the role of tobacco industry officials in carrying out the strategies was often concealed. In their campaign against the WHO, the documents show that tobacco companies hid behind a variety of ostensibly independent quasi-academic, public policy and business organisations, whose tobacco industry funding was not disclosed. The documents also show that tobacco company strategies to undermine the WHO relied heavily on international and scientific experts with hidden financial ties to the industry. Perhaps most disturbing, the documents show that tobacco companies quietly influenced other UN agencies and representatives of developing countries to resist the WHO's tobacco control initiatives.

That top executives of tobacco companies sat together to design and set in motion elaborate strategies to subvert a public health organisation is unacceptable and must be condemned. The Committee of Experts believes that the tobacco companies' activities slowed and undermined effective tobacco control programmes around the world.

Given the magnitude of the devastation wrought by tobacco use, the Committee of Experts is convinced that, on the basis of the volume of attempted and successful acts of subversion identified in its limited search, it is reasonable to believe that the tobacco companies' subversion of the WHO's tobacco control activities has resulted in significant harm. Although the number of lives damaged or lost as a result of the tobacco companies' subversion of WHO may never be quantified, the importance of condemning the tobacco companies' conduct, and taking appropriate corrective action, is overriding'.

Source: Summary of a report of the WHO Committee of Experts on Tobacco Industry Documents (CETID, 2000).

be the results of how the research questions are asked, how the research is actually conducted and whether the results are published (or not published). Food industry funding for research has also been shown to produce outcomes favourable to the sponsor (Nestle, 2002; Levine et al., 2003).

A report by the Union of Concerned Scientists (2007) has documented how ExxonMobil has used the tactics of the tobacco industry to stimulate controversy about climate science. ExxonMobil has raised doubts about the evidence, hidden

involvement behind front groups, sponsored scientific spokespersons to criticise the science and attempted to shift the focus away from existing evidence to the need for 'sound science'.

The public health community must learn more about the internal behaviour of corporations other than the tobacco industry in order to make conclusions about similarities in corporate behaviour. The release of millions of internal tobacco industry documents has given the public health community insights into the inner workings of the tobacco industry and revealed

their previously hidden involvement in manipulating research (Bero, 2003). However, this insight is not available for most corporate sectors.

In some of the few other analyses of internal industry documents, Markowitz and Rosner describe how the chemical, asbestos and lead industries manipulated research about the harms of their products (Markowitz and Rosner, 1991, 2000, 2002). Their analysis reveals that these industries used the same tactics as tobacco companies to create controversy about the health effects of tetraethyl lead, asbestos, polyvinyl chloride and other chemicals. A recent issue of the *International Journal of Occupational and Environmental Health* relies heavily on internal company documents that the authors obtained by serving as expert witnesses in litigation (Special Issue, 2005). It describes how a variety of chemical companies and their trade organisations have used the strategies outlined in this article:

1. funding research that supports the interest group's position;
2. hiding industry involvement in research;
3. publishing research that supports the interest group's position;
4. suppressing research that does not support the interest group's position;
5. criticising research that does not support the interest group's position;
6. changing scientific standards;
7. disseminating interest group data or interpretation of risk in the lay press;
8. disseminating interest group data or interpretation of risk directly to policymakers.

The role of the sponsor in designing, conducting and disseminating research can be evaluated only if interest group involvement in all steps of the risk determination process is fully described. Thus, funding sources for all published research should be fully disclosed. Our analyses show, however, that disclosure of funding sources often provides incomplete information about the involvement of the sponsors in the research process. The tobacco industry has a long history of hiding the involvement of its lawyers and executives in the designing, conducting and disseminating research. If internal tobacco industry documents had not been made

available to the public, much of what is known about the industry's manipulation of research would have remained undiscovered.

Disclosures should not be limited to describing the roles of the research funders in all stages of the research process. Personal financial ties between investigators and corporate interests (such as consulting fees, stock ownership, honoraria etc.) should also be fully disclosed. Personal financial ties are increasing (Boyd and Bero, 2000) and are associated with favourable research outcomes for the corporate interest, even if the corporate interest is not funding the research (Lexchin et al., 2003). Experts who criticise research describing the harms of a company's product should also fully disclose their financial ties with the company. These complete and accurate disclosures should be found in scientific publications (including research articles, letters to the editor and editorials), citations in the lay press, and testimony in policy or legal settings.

Full disclosure of a sponsor's role in designing, conducting and publishing a study could also improve the peer-review process. Peer reviewers are typically limited by the information available in the article they are reviewing. The peer review process itself should be conducted by individuals with adequate expertise and be independent of industry sponsors.

The findings presented in this chapter also have implications for how experts should be selected to participate in the risk assessment process. As suggested by others, professional competence, diversity of political views, disciplines, opinions and attitudes are important (von Winterfeldt, 1992). However, consideration should also be given to affiliation or interest group bias and how this will affect risk assessment. Encouraging transparency regarding the roles of interest groups in developing and disseminating data on risk will not prevent their involvement in the process. However, such transparency will make it easier to determine which strategies, if any, an interest group has been using to influence the data.

Detailed and accurate financial disclosures of research funding and financial ties are necessary, but not sufficient, for safeguarding the integrity of the research record. One possible benefit of disclosure is that it might discourage scientists from entering into financial relationships that could detract from the perceived integrity of their research. Another possible benefit is that transparency might improve public trust in research (Cho, 1998). Krinsky

(2003), however, has described disclosure as a 'rationalisation for creating more serious conflicts'. He points out that disclosure is a 'public relations' response to dealing with corporate influence on research and not a way of potentially decreasing the effect of the corporate sponsor on research integrity.

Although greater transparency about industry involvement in research could facilitate evaluation of biases in the design, conduct and reporting that might be introduced by such sponsorship, it will not eliminate the biases. Furthermore, if researchers and institutions are concerned that the public views industry-sponsored research as less credible, regardless of any effect on bias, eliminating financial ties may be the best way to deal with the issue. A number of scholars have argued that there should be a total ban on clinical investigators' financial ties to companies that fund their research (Krimsky, 2003; Dana, 2003). These proposed bans eliminate the need for oversight committees to 'manage' the conflict of interest and protect against even the appearance of conflict.

Schafer (2003) supports the 'sequestration thesis', which would eliminate direct corporate sponsorship of research and financial ties of investigators. Sequestration could be achieved by forming an independent research institute, funded by companies, to support research. Shamoo and Resnik (2003) have noted, however, that eliminating financial ties and corporate funding may not be realistic today. Some investigators advocate 'self regulation': voluntary compliance with professional society guidelines, or adaptation of the federal conflict of interest policy to clinical trials funded by private sponsors (Boyd et al., 2003).

Support for banning corporate funding of research is most developed among academic institutions that have policies prohibiting researchers from accepting tobacco industry funding for research. For example, some academic institutions, particularly schools of medicine and public health, have developed bans on tobacco industry funding (Herman, 2002). Examples include Harvard University and the University of Sydney. Some funding agencies (e.g. Legacy Foundation) have developed policies that require such bans as a condition for receiving funding (Shield, 2001).

Bans on tobacco industry support for research are warranted in view of the industry's history of deception about its role in designing, conducting and disseminating industry-supported research. They are further justified by the tobacco industry's motives for funding research, which include distracting attention from tobacco's health risks, gaining credibility and using the research for public relations (Cohen, 2003).



Photo: © istockphoto/Gremlin

Table 7.2 Key dates relating to knowledge of harm from active and second-hand smoke

1604	King James I of England wrote 'A Counterblaste Against Tobacco' expressing his distaste for tobacco, particularly tobacco smoking. This was one of the earliest anti-tobacco publications
1903–1908	In the United Kingdom, the Boer War Recruits Health Report led, in 1908, to restrictions on the sale of tobacco to children under 16 and empowered police to confiscate cigarettes from children smoking in public places
1931	Argentinian oncologist Angel Roffo (1931) produced skin tumours in rabbits with tobacco tar, building on similar work on tars and skin cancer that began with Percival Pott's UK studies of scrotal cancer and chimney sweeps (1775)
1936	US physician Alton Ochsner (1973) sees nine cases of lung cancer in six months after not seeing one in 20 years. Noting that all the patients had begun smoking during World War I, he suggested that smoking was the cause
1938	US statistician Raymond Pearl (1938) uses insurance records to show increased death rates of smokers
1939	Franz Müller (1939) uses 86 cases of lung cancer compared to controls to show that heavy smokers had 16 times the lung cancer deaths than non-smokers: a 'one in a million chance' finding leading to the conclusion that tobacco was the 'single most important cause of the rise in lung cancer'
1930–1941	Schairer and Schöniger (2001) studied 195 lung cancer cases using two control groups (other cancers and no diseases), showing that only three lung cancer cases had not smoked and that a statistical association between tobacco and lung cancer was 'likely'
1942–1944	Seven dissertations were published on tobacco and health effects at the German National Scientific Institute for Research on Tobacco, Jena (Zimmermann et al., 2001)
1946	Percy Stocks (1947), UK chief medical statistician to the General Register Office, noted a 'startling' six-fold increase in male lung cancer between 1930 and 1944
1947	The UK Medical Research Council (MRC) met to discuss action and was attended by Bradford Hill, Alice Stewart, Ernest Kennaway and others. Several possible causes of lung cancer were discussed: tar from roads, urban air pollution, traffic fumes and smoking. These were all probably 'factors which prepare the soil rather than sow the seed' (Tudor Edwards, 1946; Keating, 2009)
1948	In an MRC study by Doll and Bradford Hill, preliminary results on 156 interviews with patients showed 'definite association' between lung cancer and smoking, although the lack of a link between inhaling and cancer was 'surprising' (Pollock, 1999). This was to provide the eminent statistician, Sir Ronald Fisher, with his denial of the association between smoking and lung cancer for many years
1950	Five papers were published showing the dangers of smoking. Wynder and Graham (1950) (concerning military veterans in the US), Doll and Bradford Hill (1950) (concerning hospital patients in the United Kingdom) concluded that smoking was 'an important factor' in the 'induction/production' of lung cancer. Of 647 cases in the Doll and Bradford Hill study only 0.3 % were non-smokers: a 'one in a million' chance finding. Heavy smokers had 16 times the lung cancer deaths than non-smokers. But this result was 'largely doubted and generally ignored' by the medical establishment (Keating, 2009)
1953	A UK Government Advisory Committee concluded that the 'association was causal' and 'young people should be warned' (Ministry of Health, 1953a, 1953b and 1954)
1954	Preliminary results were released from the study of Doll and Hill (1954) of 40 000 doctors which was to last 50 years. Data on 39 lung cancer cases out of 769 deaths confirmed their earlier findings and now revealed a dose/response effect and an association with heart disease. In the US, Hammond and Horn's (1954) study of 5 000 deaths showed similar results
1954	Publication of scientific studies documenting tobacco's role in cancer and other fatal illnesses together with subsequent media coverage and declining sales was referred to internally by the tobacco industry as the '1954 emergency'. The industry responded with a public relations campaign led by Hill and Knowlton to 'manufacture doubt' about the link between smoking and lung cancer, without actually denying it
1964	A US Surgeon General report, 'Smoking and Health', based on 29 studies, concluded that 'there is a causal relationship between excessive smoking and lung cancer' (US DHEW, 1964)
1970–1980s	The first studies were published showing that second-hand smoking is associated with lung cancer. A US Surgeon General report in 1986 concluded that the link is causal (US DHHS, 1986)
1993–1998	Tobacco industry subverts the WHO International Agency for Research on Cancer (IARC) study and evaluation of second-hand smoking as a human carcinogen

Source: EEA, based on Keating, 2009 and Ong and Glantz, 2000.

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