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TOBACCO INDUSTRY MANIPULATION OF RESEARCH

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Research findings provide the basis for estimates of risk. However, research findings or "facts" are subject to interpretation and to the social construction of the evidence.[1] Research evidence has a context. The roles of framing, problem definition, and choice of language influence risk communication.[2] Since data do not "speak for themselves," interest groups can play a critical role in creating and communicating the research evidence on risk.

An *interest group* is an organized group with a narrowly defined viewpoint, which protects its position or profits.[3] These groups are not exclusively business groups, but can include all kinds of organizations that may attempt to influence government.[4,5] Interest groups can be expected to construct the evidence about a health risk to support their predefined policy position.[6] For example, public health interest groups are likely to communicate risks in a way that emphasizes harm and, therefore, encourages regulation or mitigation of a risk.[7] Industry groups are likely to communicate risks in a way that minimizes harm and reduces the chance that their products are regulated or restricted in any way. Disputes about whether a risk should be regulated are sometimes taken to the legal system for resolution.[8] Thus, interest groups often have two major goals: to influence policy making and to influence litigation.

CREATING CONTROVERSY

Policy making is facilitated by consensus.[9–11] However, scientific research is characterized by uncertainty, which poses problems when decision-making moves to a public forum. It is often to the benefit of interest groups to generate controversy about data because the controversy is likely to slow or prevent regulation of a given product. For example, scientific debate over the data and methods used in a risk assessment can hinder the development of the risk assessment.[12]

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 to its benefit. The tobacco industry has played a role in influencing the debate around "sound science,"[13] standards for risk assessment,[14] and international standards for tobacco and tobacco products.[15] In the early 1990s, the tobacco industry launched a public relations campaign about "junk science" and "good epidemiological practices" and used this rhetoric to criticize government reports, particularly risk assessments of environmental tobacco smoke.[13] The industry also developed a campaign to criticize the technique of risk assessment of low doses of a variety of toxins,[14] working with the chemical, petroleum, plastics, and chlorine industries.

In this article, I describe the strategies used by the tobacco industry to manipulate information on the risks of tobacco (Figure). These strategies 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 tools it had developed during this time to refute data on the adverse effects of secondhand smoke exposure from the 1970s through the 1990s.

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 insight into the tobacco industry's motives, strategies, tactics, and data.[16] These documents show that for decades the industry has tried to generate controversy about the health risks of its products. The internal documents also reveal how the industry has been concerned about maintaining its credibility as it has manipulated research on tobacco.[16]

The tobacco industry has explicitly stated its goal of generating controversy about the health risks of tobacco. In 1969, Brown and Williamson executives prepared a document for their employees to aid them in responding to new research about the adverse effects of tobacco, which stated: "Doubt is our product since it is the best means of competing with the 'body of fact' that exists in the mind of the general public. It is also the means of establishing a controvery. . . . If we are successful in establishing a controversy at the public health level, then there is an opportunity to put across the real facts about smoking and health."[17] Eleven years later, the tobacco industry expressed the same goal regarding evidence on the risks of secondhand smoke. A report prepared by the Roper Organization for the Tobacco Institute in 1978 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."[18]

Philip Morris promoted international research related to passive smoking in order to stimulate controversy, as

Figure. Tobacco industry strategies to manipulate data on risk

1. Fund research that supports the interest group position.
2. Publish research that supports the interest group position.
3. Suppress research that does not support the interest group position.
4. Criticize research that does not support the interest group position.
5. Disseminate interest group data or interpretation of risk in the lay press.
6. Disseminate interest group data or interpretation of risk directly to policy makers.

described in the notes of a meeting of the UK [Tobacco] Industry on Environmental Tobacco Smoke, London, February 17, 1988: "[W]e 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 . . . to keep the controversy alive."[17] The tobacco industry organized teams of scientific consultants all over the world with the main goal of stimulating controversy about the adverse health effects of secondhand smoke.[19–21]

Studies show that industry sponsorship of research is associated with outcomes that are favorable for the sponsor.[22–24] One possible explanation is that industry-sponsored research is poorly designed or of worse methodological quality than non-industry-sponsored research. However, no consistent association has been found between industry sponsorship and methodological quality.[22] Factors other than study design can affect the outcome of research, including (*1*) the framing or social construction of the research question, (*2*) the conduct of the study, and (*3*) the publication (or not) of the study findings. In the following sections, I describe how the strategies that the tobacco industry uses to stimulate controversy about tobacco involve manipulating research at multiple stages. The tobacco industry, through its funding mechanisms, has attempted to control the research agenda and types of questions asked about tobacco. The industry's lawyers and executives have been involved in the design and conduct of industry-supported research as well as the suppression of research that has not been favorable to the industry.

STRATEGY 1: FUND RESEARCH THAT SUPPORTS THE INTEREST GROUP POSITION

The first prong in the tobacco industry's strategy to influence data on risk has been sponsorship of research designed to produce findings that are favorable to the industry. Direct funding of research serves several purposes for the tobacco industry. Industry-supported research can be disseminated directly to policy makers and the lay press. Support for research can provide good public relations for the tobacco industry by portraying it as philanthropic. Last, funding of research can increase the credibility of the industry. One of the criteria that Philip Morris' Worldwide Scientific Affairs Program considered during the 1990s when deciding whether to approve a given research application was whether the research would enhance the credibility of the company.[25]

The tobacco industry funded research through its trade association, the Tobacco Institute,[26,27] internally (e.g., internal company research), externally (e.g., by supporting the research of scientific consultants), and through sponsored research organizations. Tobacco industry lawyers and executives were involved in the selection of the research that was funded. Most of this research did not undergo any form of scientific peer review, but was funded on the basis of its potential to protect the interests of the companies.[26,27]

Lawyer involvement in research

Much of what is known about corporate interest group activities has been pieced together by studying internal industry documents that have been made available through the legal "discovery" process. In the mid-1990s, internal tobacco industry documents were circulated by industry whistleblowers. By 1998, 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, R.J. Reynolds, the Council for Tobacco Research, and the Tobacco Institute released millions of additional documents to the public. These documents provided an unprecedented look at how tobacco industry lawyers were involved in the design, conduct, and dissemination of tobacco industry–sponsored research.[16]

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 in the late 1970's through the early 1990's.[26] Lawyers selected which projects would be funded; including reviews of the scientific literature on topics ranging from addiction to lung retention of particulate matter. These law firms also funded research on potential confounding factors for the adverse health effects associated with smoking. For example, projects were funded that examined genetic factors associated with lung disease or the influence of stress and low-protein diets on health.[26] These deflected attention from tobacco as a health hazard and protecting tobacco companies from litigation.

In other research funded directly by the tobacco companies, lawyers were involved in the selection of projects and dissemination of findings. For example, tobacco companies funded individuals to serve as consultants to prepare expert testimony for Congressional hearings, attend scientific meetings, review the scientific literature, or conduct research on the health effects of tobacco or secondhand smoke.[27] At one tobacco company, Brown and Williamson, the legal department controlled the dissemination of internal scientific reports.[27] The lawyers at Brown and Williamson developed methods for screening scientific reports from affiliated companies to ensure that scientific information related to tobacco and health would be protected from the legal discovery process. In a memo dated February, 17, 1986, J. K. Wells, the Brown and Williamson corporate counsel, outlined one method for protecting industry-produced research data: "The only way BAT [British American Tobacco, parent company of Brown and Williamson] 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."[27]

Research organizations

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

Council for Tobacco Research. The Council for Tobacco Research (CTR) was formed by U.S. tobacco companies in 1954 as the Tobacco Industry Research Committee (TIRC).

Industry representatives stated publicly that the TIRC was formed to fund independent scientific research to determine whether there is a link between smoking and lung cancer. However, internal documents from Brown and 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.[17]

Research proposals to federal organizations or large foundations are typically reviewed by other researchers before funding is approved. Although the CTR had a Scientific Advisory Board consisting of well-respected researchers, not all of the research funded by CTR was peer-reviewed by this board. Beginning in 1966, tobacco industry lawyers became directly responsible for many of the funding decisions of CTR. From 1972 to 1991, CTR awarded at least $14.6 million in special project funding.[26] Lawyers were not only involved in selecting projects for funding, but also in designing the research and disseminating the results of the selected projects.[26]

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 an April 4, 1978, memo from Ernest Pepples, Brown and Williamson's Vice President and General Counsel, to J.E. Edens, the company's Chairman and CEO:

> 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.[17]

Center for Indoor Air Research. The Center for Indoor Air Research (CIAR) was formed by Philip Morris, R.J. Reynolds Tobacco Company, and Lorillard Corporation in 1988.[28] The founding companies were joined by Svenska Tobaks A.B., a Swedish domestic tobacco company in 1994.[28] The stated mission of CIAR was "to create a focal point organization 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."[29] CIAR's mission statement was modified in 1992 to eliminate the reference to environmental tobacco smoke.[30] The elimination of research on secondhand smoke from the mission statement was followed by a reduction in CIAR-funded research on health effects of secondhand smoke. Instead, CIAR emphasized research on other contaminants in indoor air, a shift in the research agenda of CIAR to prevent the answering of questions about the health effects of secondhand smoke.

CIAR awarded funding for "peer-reviewed" projects after review by a Science Advisory Board and for "special-reviewed" projects after review by a Board of Directors consisting of tobacco company executives.[28] From 1989 to 1993, CIAR awarded $11,209,388 for peer-reviewed projects and $4,022,723 for special-reviewed projects.[28] Seventy percent of the peer-reviewed projects funded by CIAR examined indoor air pollutants other than tobacco smoke, diverting attention from secondhand smoke as an indoor air pollutant.

In contrast, almost two-thirds of CIAR's special-reviewed projects were related to secondhand smoke.[28] In addition, most special-reviewed projects studied exposure rather than health effects. The tobacco industry may have been funding research through CIAR to develop data it could use to support its frequent claim that levels of exposure to secondhand smoke are not sufficient to cause disease.[31]

Six CIAR-funded investigators testified at government hearings in the 1990's. All of their statements supported the tobacco industry position that secondhand smoke exposure is not harmful to health. Data from two of CIAR's special-reviewed projects were presented at hearings held in 1994 by the Occupational Safety and Health Administration regarding its proposed indoor air quality regulation. Data from a third special-reviewed project was presented at a Congressional hearing in 1989 related to a proposed ban on smoking on commercial aircraft. One CIAR-funded study was investigated extensively by the Congressional Subcommittee on Health and the Environment after it was cited in testimony before numerous government agencies. The study concluded that, with good building ventilation, clean air could be maintained with moderate amounts of smoking[32] 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 research organization was also severely compromised because the Tobacco Institute selected the sites where passive smoking levels were measured for the study.[28]

The CIAR was disbanded as part of the Master Settlement Agreement in 1998. However, in 2000, Philip Morris created the Philip Morris External Research Program (PMERP) with a structure similar to that of CIAR. Grant applications were reviewed by a group of external peer reviewers, a science advisory board, or 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.[33]

STRATEGY 2: PUBLISH RESEARCH THAT SUPPORTS THE INTEREST GROUP POSITION

Research has little impact unless it can be cited. The tobacco industry has realized that the funding of research that supports its interests must be followed by the dissemination of this research in the scientific literature. The tobacco industry uses several vehicles to publish the findings of its sponsored research, including symposium proceedings, books, journal articles, and letters to the editor in 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, nonpeer-reviewed publications in scientific and policy arenas.

Symposium proceedings

The tobacco industry has sponsored numerous symposia on secondhand smoke[34] and paid for scientific consultants to organize and attend these meetings.[19,21,35] From 1965 to 1993, the proceedings of 11 symposia on secondhand smoke were published. Six were published as special issues of medical journals, while five were published independently as books. None of these publications were peer-reviewed. Six of the symposia were sponsored by the tobacco industry or its affiliates such as CIAR, the Tobacco Institute, or *Fabriques de Tabac Reunies*, Neuchatel, Switzerland. Two of the six industry-sponsored symposia did not explicitly acknowledge industry sponsorship. The tobacco industry has sometimes sponsored conferences through independent organizations so that its sponsorship would be hidden.[26,34]

The symposia on secondhand smoke were held across the world, including Europe, the United States, Canada, Japan, and Argentina. The proceedings of one symposium were published in Spanish. CTR special projects funds were often used to support scientists to prepare talks for conferences and to send scientists to conferences.[17]

On the surface, symposium presentations often look like peer-reviewed journal articles. To test the hypothesis that symposium articles on secondhand smoke differ in content from those appearing in scientific journals, two colleagues and I[34] compared the articles from symposia on secondhand smoke 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.[36,37] Of the symposium articles, 41% (122/297) were reviews, compared with 10% (10/100) of journal articles. Symposium articles were significantly more likely to agree with the tobacco industry position that tobacco is not harmful (46% vs. 20%), less likely to assess the health effects of passive smoking (22% vs. 49%), less likely to disclose their source of funding (22% vs. 60%), and more likely to be written by tobacco industry–affiliated authors (35% vs.6%) than journal articles. Symposium authors published a lower proportion of articles that were peer-reviewed (71% vs. 81%) and were more likely to be affiliated with the tobacco industry (50% vs. 0%) than the consensus report authors.[34] Symposium proceedings can potentially have a disproportionate influence on policy because they are often cited as if they are peer-reviewed articles, as if they are balanced reviews of the scientific literature, and with no disclosure of their industry sponsorship. For example, research presented at tobacco industry–sponsored symposia on secondhand smoke has been used to attempt to refute both peer-reviewed journal articles and risk assessments.[38–40] Symposia have been cited in tobacco industry public relations materials and the lay press.[31] Positions taken by symposium presenters were described as the consensus of a gathering "of leading experts from around the world"[41] who disagreed with the published literature on secondhand smoke.

Quality of tobacco industry–funded symposium publications

When policy makers, 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 lack of peer review suggest that tobacco industry–sponsored literature is not scientifically rigorous, the association of peer review and study quality is a contentious subject. Therefore, we assessed the methodological quality of the research presented in symposia. Articles from pharmaceutical industry–sponsored symposia have been found to be poor in quality.[42,43] Barnes and I hypothesized that articles from tobacco industry–sponsored symposia would be poorer in quality than peer-reviewed journal articles.[24] We evaluated characteristics of articles that we hypothesized might be associated with quality, such as the disclosure of the source of research sponsorship, article conclusion, article topic, and study design.

We compared original research articles on the health effects of secondhand smoke published in peer-reviewed journals to those published in non-peer-reviewed symposium proceedings from 1980 to 1994.[24] Peer-reviewed articles were of better quality than symposium articles independent of their source of funding, the conclusion drawn about the health effects of secondhand smoke, or the type of study design.[24] Peer-reviewed articles received higher scores than symposium articles for most of the criteria evaluated by our quality assessment instrument.

Quality of tobacco industry–sponsored review articles

Review articles are often relied upon by policy makers and clinicians to provide accurate and up-to-date overviews on a topic of interest.[44] Furthermore, reviews on the health effects of secondhand smoke comprise a large proportion of tobacco industry-sponsored symposium articles[34] and are frequently cited in response to government requests for information on tobacco regulations.[38,40,45] Therefore, it is somewhat disconcerting that published review articles often differ in the conclusions they reach about the adverse health effects of secondhand smoke.

Barnes and I evaluated review articles on the health effects of secondhand smoke to determine whether their conclusions were primarily associated with their quality or other article characteristics.[23] Our 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. We also examined the topic of the review and the year of publication as potential confounding factors.

In our 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.[23] Tobacco industry–funded reviews were about 90 times as likely as reviews funded by any other source to conclude that passive smoking was not harmful. 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 secondhand smoke are flawed because studies with statistically significant results are more likely to be published than studies with statistically nonsignificant results.[46] 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 health

effects of secondhand smoke.[47] Two colleagues and I conducted a preliminary study of publication bias; we found that approximately 20% of published peer-reviewed articles on passive smoking presented statistically nonsignificant findings.[48] Then, by interviewing investigators studying secondhand smoke and health effects, Misakian and I determined that studies with statistically nonsignificant results take about two years longer to be published than those with statistically significant results.[49] Thus, the tobacco industry's argument that statistically non-significant results are not published is invalid. Since statistically nonsignificant results are published, but take longer to be published than statistically significant results, reviews of research should attempt to include unpublished data and should be periodically updated. The Cochrane Collaboration, for example, attempts to identify unpublished studies and include them in reviews if they meet quality standards. Cochrane reviews, which are published online, are regularly updated.[50]

STRATEGY 3: SUPPRESS RESEARCH THAT DOES NOT SUPPORT THE INTEREST GROUP POSITION

While interest groups are eager to fund research and the publication of research that supports their position, they are hesitant to publicize research that does not support their position. Tobacco industry lawyers and executives have edited their externally funded scientific research publications and, in some cases, prevented publication of research.[21,35,51] 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.[17]

Another example of research suppression is shown in the contrast between what a tobacco company knew in 1963 and what it stated publicly in 1994. In 1963, Addison Yeaman, Vice President and General Counsel at Brown and Williamson, attended a meeting of tobacco industry researchers, executives, and lawyers, where he summarized the findings of some recent tobacco industry research: "[N]icotine is addictive. We are, then, in the business of selling nicotine, an addictive drug. . . ."[52] Yet Yeaman's summary and other findings from tobacco industry research on nicotine were not released to the public. In 1994, Thomas Sandefur, Chairman and CEO of Brown and Williamson, testifying before Congress about whether the Food and Drug Administration should regulate nicotine products, stated, "I do not believe that nicotine is addictive. . . . [It is] a very important constituent in the cigarette smoke for taste."[52]

For years, tobacco industry executives suppressed the dissemination of its internal research findings to the public and regulatory decision makers.

STRATEGY 4: CRITICIZE RESEARCH THAT DOES NOT SUPPORT THE INTEREST GROUP POSITION

To criticize research that is not favorable to its position, the tobacco industry has misused legitimate means of scientific debate, such as letters to the editor in scientific journals and editorials. The industry has also used less legitimate methods to criticize research, including attacking the integrity of researchers or using lawsuits to obtain data that are then reanalyzed.[53]

To get its views into public commentary on risk assessments[38,40] or into the lay press,[39] the tobacco industry has cited letters to the editor as if they were peer-reviewed journal articles. Tobacco industry–affiliated authors of letters often fail to disclose this affiliation.[54]

The tobacco industry maintains large international teams of scientific consultants.[20,21,35] A major goal of the industry's scientific consultancy program from the 1970s on has been to refute data about the harmful effects of tobacco. Industry consultants were paid to criticize independent research on tobacco and secondhand smoke in a variety of forums; these industry consultant programs were international and were used to discredit research conducted by non-industry scientists around the world.[20,21,35]

STRATEGY 5: DISSEMINATE INTEREST GROUP DATA OR INTERPRETATION OF RISK IN THE LAY PRESS

The important role of the media in risk communication has been extensively studied.[2,55] The tobacco industry has been active in stimulating controversy in the lay print media about the health effects of secondhand smoke. In a cross-sectional sample of 180 North American newspaper and 95 magazine articles reporting on secondhand smoke research from 1981 to 1995, 66% of newspaper articles and 55% of magazine articles left readers with the impression that there was continuing controversy about secondhand smoke research.[56] As scientific studies showing an association of secondhand smoke and adverse effects accumulated, the proportion of articles concluding that the research was controversial remained relatively constant.[56] Although tobacco industry–sponsored research studies were not widely cited in the lay press articles, tobacco industry–affiliated individuals were often cited.[56,57] Among 180 newspaper articles examined,[56] 52% cited tobacco industry officials, whereas 56% cited government officials and 46% cited independent scientists.

STRATEGY 6: PRESENT INTEREST GROUP DATA OR INTERPRETATION OF RISK DIRECTLY TO POLICY MAKERS

The last strategy in the tobacco industry's effort to stimulate controversy about data demonstrating risk is to get its funded research directly into the hands of individuals who are likely to influence policy. My colleagues and I conducted a series of in-depth case studies examining the role of research evidence in the development of two risk assessments of secondhand smoke, two state indoor air regulations, and two federal tobacco regulations.[38,58–60] In the United States, the processes for developing these risk assessments and regulations involves review of the relevant scientific literature by the appropriate government agency, preparation of a draft report, collection of written and oral public commentary, and revision of the report based on that public commentary.[8,61,62] Public participation in the process is important for shaping the findings of the final risk assessment or regulation as well as for public acceptability of the findings.[61]

Furthermore, public commentary could help prevent the "capture" of the risk assessment process by interest groups.[63] We studied the role of the tobacco industry in the process by analyzing archival data, including written commentary and hearing transcripts, and by interviewing key policy makers involved in each case study.[38,58–60]

Risk assessments of secondhand smoke

In 1992, the U.S. Environmental Protection Agency (EPA) published a risk assessment of environmental tobacco smoke, which concluded that passive smoking is associated with lung cancer in adults and respiratory disease in children.[64] The development of the risk assessment was considerably delayed by the tobacco industry's criticisms of the draft report.[40] Sixty-four percent (69/107) of submissions received by the EPA during the public commentary period claimed that the conclusions of the draft were invalid; of these, 71% (49/69) were submitted by tobacco industry–affiliated individuals.[40] The tobacco industry–affiliated reviewers supported their criticisms of the draft report by the selective citation of non-peer-reviewed literature, especially articles from symposium proceedings.[40] Thus, tobacco industry–sponsored research that was not published in the peer-reviewed scientific literature was submitted directly to the EPA for review.

In 1997, the California Environmental Protection Agency (Cal-EPA) published the final report of a risk assessment, titled *Health Effects of Exposure to Environmental Tobacco Smoke.*[65] The California risk assessment was more comprehensive than the U.S. EPA risk assessment of passive smoking because it examined the association of secondhand smoke exposure with lung cancer and respiratory illness as well as with cardiovascular, developmental, reproductive, and childhood respiratory effects. The Cal-EPA risk assessment also addressed criticisms brought by the tobacco industry against the U.S. EPA risk assessment.

In an examination of the development of the California risk assessment, Schotland and I found that participation in the public input process was not balanced among all interested parties and was dominated by the tobacco industry.[38] Critics and supporters of the risk assessment used different criteria to evaluate the science, which suggests that they were constructing the evidence to support their predefined positions. As was the case with the U.S. 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, Washington State and Maryland restricted smoking in private workplaces. The U.S. 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 secondhand smoke."[60] Although the tobacco industry used this strategy, among others, in an attempt to defeat the Maryland and Washington regulations, the state regulations were passed.[66]

Each of these states' regulatory development processes required a public commentary period. Opposition to the proposed regulations came primarily from the tobacco industry, small businesses, and business organizations—and appeared to be coordinated.[59] Much of the business group opposition was supported by the tobacco industry, although this support was not disclosed in the public commentary.[66] Although arguments not related to science were more common than scientific arguments on the whole, arguments about science were used more often by opponents than supporters of the regulations.[59] 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 regulation was based.[59]

Apparent disagreement among experts during public testimony reinforces the uncertainty of the data on which risk assessments or regulations are based. However, the findings from our case studies suggest 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 emphasizing the body of evidence as a whole. 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 or policy decisions.

A case example: Tobacco industry creation and dissemination of a study

The tobacco industry's creation of the Japanese Spousal Smoking Study illustrates the industry's hidden involvement in the design, conduct, and dissemination of research. In 1981, Takeshi Hirayama published an influential study showing an association between secondhand smoke exposure and lung cancer.[67] The Hirayama study has been the most frequently cited study in regulatory hearings on smoking restrictions.[45] In these hearings, tobacco industry representatives have argued that the Hirayama study is flawed due to misclassification bias.[38,40] Hong and I conducted an analysis of internal tobacco industry documents that showed how the tobacco industry hid its involvement in creating the Japanese Spousal Smoking Study to support its arguments about misclassification bias.[51]

Although the Japanese Spousal Smoking Study had 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.[51] 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. When the study was published, the tobacco industry consultant was the sole author. [68] The publication acknowledged "financial support from several companies of the tobacco industry."[68] 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 is accountable for the research.[51]

CONCLUSION

The tobacco industry has had a longstanding strategy of funding research and disseminating it through sponsored, non-peer-reviewed publications. These strategies have re-

mained relatively constant as the industry has progressed from refuting research on active smoking to refuting research on secondhand smoke. Tobacco industry lawyers and executives, rather than scientists, have been in control of the design, conduct, and dissemination of this research. Despite the questionable conduct of much of this research, the tobacco industry has widely disseminated it to lay journalists and policy makers. In addition, the tobacco industry has a record of suppressing and criticizing research that is unfavorable to its position.

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 suggest a controversy presented to policy makers only by the interest group? Policy makers should apply these questions to all situations in which a for-profit company has an interest in creating controversy about the risks of its products.

The tobacco industry's methods for influencing the design, conduct, and publication of research may be 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 favorable to the sponsor.[22,43,69] Reasons for this observed association of funding and outcome are not clear.[7] Therefore, biased outcomes may be the result 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 favorable to the sponsor.[71,72]

The release of millions of internal tobacco industry documents has given the public health community insight into the inner workings of the tobacco industry and revealed its previously hidden involvement in manipulating research.[16] However, analogous information is not available for most corporate interests. Among 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.[73–75] Their analysis reveals that these industries used many of the same strategies as the tobacco companies to create controversy about the health effects of tetraethyl lead, asbestos, polyvinyl chloride, and other chemicals.

Funding sources for all published research, as well as the roles of the sponsor, should be fully disclosed. The tobacco industry has a long history of hiding the involvement of its lawyers and executives in the design, conduct, and dissemination of 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 the roles of funders at all stages of the research process. Personal financial ties between investigators and corporate interests (such as consulting fees, stock ownership, and honoraria) should also be fully disclosed. Personal financial ties are increasing[76] and are associated with favorable research outcomes for the corporate interest, even if the corporate interest is not funding the research.[22] Experts who criticize 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.

Our findings also have implications for how experts should be selected to participate in the risk assessment process. As suggested by others, professional competence and diversity of political views, disciplines, opinions, and attitudes are important.[77] However, consideration should also be given to affiliation or interest group bias. Encouraging transparency regarding the roles of interest groups in developing and disseminating data on risk will not prevent their involvement in the process. However, 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. A 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 the industry-supported research.[78] Krimsky, however, has described disclosure as a "rationalization for creating more serious conflicts."[79] 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.

A number of scholars have argued that there should be a total ban on clinical investigators' financial ties to companies.[79,80] Such bans would eliminate the need for oversight committees to "manage" conflicts of interest and protect against even the appearance of conflict. Schafer supports the "sequestration thesis," which would eliminate direct corporate sponsorship of research and financial ties of investigators.[81] Sequestration could be achieved by forming independent research institutes that operate independently of the companies that provide funding for the research. Shamoo and Resnik, however, have noted that elimination of financial ties with industry and corporate funding may not be realistic in today's environment.[82] 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.[83]

Some academic institutions, particularly schools of medicine and public health, have instituted bans on tobacco industry funding (e.g., Harvard University, University of Sydney).[84] Some funding agencies (e.g., the Legacy Foundation) have developed policies that require such bans as a condition of receiving funding from an organization.[85] Prohibitions on tobacco industry funding for research are supported by the industry's history of deception about its role in the design, conduct, and dissemination of research. Such

prohibitions are further supported by the tobacco industry's motives for funding research: to distract from the issue of tobacco as a health problem, to gain credibility, and to use the research for public relations. purposes.[86]

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