Constructing “Sound Science” and “Good Epidemiology”: Tobacco, Lawyers, and Public Relations Firms

The tobacco industry has attacked "junk science" to discredit the evidence that secondhand smoke—among other environmental toxins—causes disease. Philip Morris used public relations firms and lawyers to develop a "sound science" program in the United States and Europe that involved recruiting other industries and issues to obscure the tobacco industry's role. The European "sound science" plan included a version of "good epidemiological practices" that would make it impossible to conclude that secondhand smoke—and thus other environmental toxins—caused diseases.

Public health professionals need to be aware that the "sound science" movement is not an independent effort from within the profession to improve the quality of scientific discourse, but reflects sophisticated public relations campaigns controlled by industry executives and lawyers whose aim is to manipulate the standards of scientific proof to serve the corporate interests of their clients.

THE TERMS "SOUND SCIENCE" and "junk science" have increasingly appeared in the media, medical literature, and litigation. Industries—those responsible for products ranging from silicone gel breast implants to hormone-treated beef to secondhand smoke—claim to be victimized by lawsuits and regulations based on "junk science," while the scientific public health, and regulatory communities claim their actions are based on "sound science." The tobacco industry has always contended the evidence that secondhand smoke endangers nonsmokers; during the last decade the Philip Morris (PM) tobacco company appropriated the "sound science" concept to attack studies on secondhand smoke. To deal with the tobacco industry's lack of credibility, it developed "sound science" coalitions involving other industries opposed to regulation to support its position, similar to smokers' rights and restaurant association front groups. PM also mounted a sophisticated public relations campaign to promote "good epidemiology practices" (GEP) to shape the standards of scientific proof to make it impossible to "prove" that secondhand smoke—among many other environmental toxins—is dangerous.

We analyzed tobacco industry documents made public as a result of litigation in the United States and available on the Internet in an online repository to which documents are continually added as additional and unrelated legal cases are resolved. The documents cited in the reference list were originally accessed between January 2000 and May 2001. Search terms included "IARC," "TASSC," "sound science," "junk science," "GEP," and the names of key players. We did not use documents from a related depository covering British American Tobacco in Guildford, England, because of the depository's practical inaccessibility to researchers. If we had used the Guildford documents, they probably would have contributed to a broader story.

PHILIP MORRIS'S "SOUND SCIENCE" ORGANIZATION IN THE UNITED STATES

PM began its "sound science" program in 1993 to stimulate criticism of the 1992 US Environmental Protection Agency (EPA) report, which identified secondhand smoke as a Group A human carcinogen. Ellen Merlo (vice president, PM Corporate Affairs) wrote to William Campbell (chairman, PM USA):

OBJECTIVES
Our overriding objective is to discredit the EPA report and to get the EPA to adopt a standard for risk assessment for all products.

Concurrent to this objective, we need to prevent states and cities, as well as businesses from passing smoking bans. And finally, where possible, we will proactively seek to pass accommodation legislation with preemption.

STRATEGIES
To form coalitions to help us educate the local media, legislators and the public about the dangers of "junk science" and to caution them from taking regulatory steps before fully understanding the costs in both economic and human terms.

In February 1993, PM and its public relations firm, APCO Associates, worked to launch a "sound science" coalition in the United States, with approximately $320,000 budgeted for the first 24 weeks. Three months later, The Advancement for Sound Science Coalition (TASSC) had been formed. TASSC described itself as "a not-for-profit coalition advocating the use of sound science in public policy decision making," even though APCO created it to help PM fight smoking restrictions. TASSC's public positioning and media campaign were designed to minimize its connections with the tobacco industry and to desensitize the public to the scientific evidence. A broad base of issues and members was necessary to provide credibility to the new organization. Charles Lister, a lawyer at the tobacco industry's Washington, DC, law firm, Covington & Burling, wrote, "No one would take seriously a meeting even partly sponsored by PM in which..."
EPA was more than one example among several. In any event, our points can be made more effectively and persuasively if EPA is discussed within a larger context. Lister suggested that “foods, plastics, chemicals, and packaging would be natural candidates” in broadening the scope of TASSC’s sponsors and issues beyond EPA and the tobacco industry.  

To develop TASSC into “a broad-based and diverse national coalition,” more than 20,000 recruitment letters were mailed, with 100 letters mailed to “key scientists,” signed by TASSC’s chairman Garrey Carruthers (former Republican governor of New Mexico). The leadership and members, which included prominent scientists and policymakers, plus representatives from corporations, would be provided PM’s secondhand smoke agenda suggestions through APCO but made to feel that the agenda was their own.  

PM hid its role so successfully that when longtime tobacco industry consultant Gary Huber, then a professor at the University of Texas Health Center, received the letter inviting him to join TASSC, he contacted Tony Andrade of the PM law firm Shook, Hardy & Bacon (SH&B) to inform him that the organization might be helpful to the tobacco industry. Andrade, also unaware of PM’s role with TASSC, forwarded the information to PM, which subsequently “fired him in on TASSC.”  

TASSC’s overall effectiveness in serving PM’s initial goal of discrediting the EPA report may not have met PM’s expectations; by April 1994, Merlo expressed concern that, despite its $880,000 cost in 1994, TASSC was not proving to be a “tool to affect legislative decisions” to stem smoking restrictions.  

Even so, by 1995, a TASSC Web site was being planned with PM to distribute scientific papers and polls to support PM’s position, TASSC and its Web site are now defunct, but its executive director Steve Milloy, an adjunct scholar at the Cato Institute (a libertarian think tank in Washington, DC, that has received funds from the tobacco industry), now produces a “junk science” Web site. Milloy’s Web site continues TASSC’s original work in criticizing and “debunking” the science behind public health and environmental issues, including secondhand smoke.  

THE EUROPEAN “SOUND SCIENCE” PROGRAM AND “GOOD EPIDEMIOLOGY PRACTICES”  

PM also developed a “sound science” program in Europe to counteract the impact of a large ongoing European epidemiologic study of passive smoking and lung cancer being conducted by the International Agency for Research on Cancer (IARC), which the tobacco industry feared would stimulate smoking restrictions in Europe. PM sought to “develop a program to generate support for junk science” and education on use and abuse of epidemiology, possibly through a coalition on bad science, which would provide a skeletal environment for interpreting the study’s results. PM used the public relations firm Burson-Marsteller and APCO to address the need that “science must be managed according to clear, scientifically based criteria, e.g., good epidemiology,” consistent with the industry’s interests.  

PM’s interest in promoting “good epidemiology” developed after the Chemical Manufacturers Association (CMA) published its “Good Epidemiology Practices” (GEP) in 1991 as a framework for “consumers of epidemiology” (policymakers and regulators) to determine the quality of a study and address poorly conducted studies. The CMA’s GEP promoted the “sound science” and “good epidemiology” concepts for each step in the conduct of an epidemiologic study.  

Covington & Burling lawyer Charles Lister distributed the CMA’s GEP to PM in February 1994:  

PM’s scientific personnel agreed that PM could adapt GEP to include secondhand smoke studies and that PM’s consultants, a network of scientists being financed by industry lawyers to contest the evidence that secondhand smoke caused disease, should use the GEP guideline to influence the science in a direction allowing a decision to be made without regard for scientific evidence.  

PM’s strategic plan to spread ‘junk epidemiology’ included the following:  

Objectives:  
  * Impede adverse legislation  
Strategy:  
  * Enforce failure by scientific world  
  * International gathering of world’s top epidemiologists (October)  
  * Task: GEP guidelines  
  * Expand debate to EU (European Union) political targets  
  * Political conference opportunities (DGV, STOA, EU Directors General for Eco-
PM wanted GEP guidelines to be endorsed by the scientific community, a GEP resolution to be passed through European legislation, and a GEP lobby with other industries facing regulation and a broad-based "sound science" lobby. As with the initial "sound science" efforts, the tobacco industry's role would be minimized. The industry sought broad support of numerous en- dorsers on a variety of issues to provide credibility for PM's GEP objective—to avert increased smoking restrictions.

With the help of its legal, public relations, and scientific re- sources, PM began drafting a GEP resolution that would be "authored" by a "sound science" coalition. In June 1994, APCO drafted a potential TASSC-sponsored list of "17 Guiding Scientific Principles," which PM found "too vague" and not supportive enough of its GEP plans. SHAB drafted GEP guidelines to be sponsored by an "Executive Committee of the Sound Science Coalition" (Table 1). SHAB's GEP resolution promoted the tobacco industry's position, subsequent- ly advocated publicly by SHAB, that odds ratios of 2 or less are highly questionable and that a statistically significant asso- ciation is not strong enough evidence for causation to warrant regulatory action. This concentration on odds ratios was not in the original CMA proposal.

PM consultant Roger Walk restructured the GEP resolution, re- lieving "neutrally on the content of the [SHAB] draft" to look more like a "scientist's version of guidelines," with the relative risk for lung cancer due to passive smoking at about 1.27,22,23,24,25,26 and the relative risk for heart disease about 1.37,24,25,26 this standard would prevent action to protect the public from lung cancer and heart disease caused by secondhand smoke.

To obtain scientific endorse- ment of PM's GEP, PM needed scientists to promote it to government bodies. In June 1994, PM sought scientists to participate in a GEP seminar in Germany and planned for a subsequent long-term coalition that would help criticize the IARC study. Burston-Marsteller identified scientists interested in "sound science" and "good epidemiology," but found that some scientists were concerned that corporate sponsorship—especially sponsorship by PM—would limit their scientific independence, even though Burston-Marsteller had not mentioned PM.

In August 1994, Cogovning & Burling created a list of potential epi- demiologists who might be approached for the GEP seminar, excluding "influential epidemiologists known to have strongly anti- tobacco views." The plan to use prescreened epidemiologists may have changed just as PM was ready to introduce GEP to them. An Oc- tober 1994 memo from Joanna SHAB

| TABLE 1—Sheek, Hardy & Bacon's Draft GEP Resolution for a "Sound Science" Coalition |

The Executive Committee recommends that the members of the Sound Science Coalition adopt and actively promote in the scientific community at large and within their individual disciplines, appropriate and specific professional standards for epidemiological research, to be carried out by accredited individuals and institutions, reflecting the following principles:

1. The study design should clearly define all objectives and hypotheses. Possible problems in design and data interpretation should be described and the intended method for addressing each fully set out. Every effort should be made to address possible confounders to avoid the need for subsequent adjustments.

2. In case-control studies, special attention should be given to how the control group will be selected and well-matching procedures will be utilized. Also, case selection should be explained with emphasis on efforts to ensure a high participation rate. A precalculation of required sample size should be carried out to ensure that the sample is sufficient to produce meaningful results.

3. Statements of study design should contain a description of statistical techniques. This should include underlying assumptions for distribution, variance, correction and regression procedures. The degree to which violations of these assumptions would invalidate the analysis should be specified whenever possible.

4. Adherence to the study protocol should be as close as possible. Any deviations (e.g., errors in randomization, low participation rate, suspected covariates, poor or infeasible analysis) should be documented.

5. Special care should be given to the training and monitoring of those administering questionnaires and surveys; all technical techniques are preferred.

6. After the study is conducted, the results should be analyzed as specified by the study protocol. Two-sided hypothesis tests are encouraged. If one-sided tests are employed, this should be noted and the rationale for using it provided. The presentation of confidence intervals for the estimate of risk gives more information than a single point value with an associated p-value. Generally, 95% confidence intervals are preferred.

7. An accurate description of the raw data should precede and complement formal statistical analysis. If the data are not supportive of the stated hypotheses, no further analysis is necessary. Subsequent treatment of the data should only be for hypothesis-generating purposes.

8. Odds ratios of 2 or less should be treated with caution, particularly if the confidence intervals are wide. There is a likelihood that the odds ratio is artificial and the result of problems with case or control selection, confounders or biases.

9. Meta-analysis and pooling techniques are best used for homogeneous data gathered under a uniform pool.

10. Observations that are inconsistent with the main body of the data should not be excluded from the analysis.

11. Journal articles and scientific conferences are the appropriate forums for the presentation of research results. Every effort should be made to publish and report on all completed research, regardless of outcomes. Only by such efforts can the entire sample of conducted research be made available to the scientific community and public debate be minimized.

12. Generally, hypothesis tests not specified by the study protocol should not be reported. When many hypothesis tests are applied to data from a single study, a number of positive results can be expected to arise by chance alone, creating serious problems of interpretation.

13. Recognizing that a statistically significant association does not in itself provide direct evidence of causal relationship between the variables concerned and that causation can only be established on nonstatistical grounds, particular care should be taken when comparing two variables that have changed over time. Such comparisons often produce apparent associations.

14. Graphic display of results and figures that show individual observations are to be encouraged. For example, when appropriate, fixed regression lines should be presented together with a scatter diagram of the raw data. Any complex statistical methods should be communicated in a manner that is comprehensible to the reader.

15. Rigorous scientific objectivity should be the standard when reporting on epidemiological results. Defects in study design, conduct and analysis should be frankly admitted. It is helpful for abstracts accurately to reflect any study deficiencies. Advocacy and objectivity rarely comfortably coexist.
Sullivan (PM Corporate Services Brussels) announced, "the GEP project would be halted as previously discussed because IARC Task Force agreed it could be counterproductive." PM's planned long-term "sound science" coalition is now likely to be the Cambridge-based European Science and Environment Forum, which sought funding from tobacco companies in addition to PM for its 1996 inception and has actively criticized the IARC study.47

PM still sought official European Union endorsement of GEP, which other industries were already seeking,60 and PM hoped it would contain "the necessary language to catch the IARC study."77 In July 1994, PM had a draft of a possible European Union GEP resolution,54 and Covington & Burling lawyer John Rupp drafted a European Council resolution about GEP for PM's consideration.84 In early 1995, PM was considering holding a GEP seminar in Germany and introducing PM's GEP at an October 1995 conference on the use of science in public health regulations to be funded by the European Union's Directorate General V (Employment, Industrial Relations and Social Affairs) and the nonferrous metal industry.85

In September 1995, Joanna Sullivan (PMCS Brussels) wrote to Richard Carchman (director, Scientific Affairs, PM USA) saying that the SH&B GEP guideline revision71 "should be given to Professor [Ernst] Wynder for passing onto Dr. [Henriette] Chamboullet of DGV of the European Commission."44 Wynder, whose early work linked smoking and cancer, had developed a financial relationship with the tobacco industry.51-52 PM described Wynder as "being in favor of the [GEP] project" and helping PM organize a GEP conference.80

It is unclear whether Wynder and Chamboullet did indeed meet, but by late 1995, the European Union Data Protection Directive was adopted, stating that "the Commission shall encourage the drawing-up of codes of conduct for studies involving the processing of medical data" and that "the Commission may ensure publicity for [approved] codes."62,62 This European Union directive led to a new GEP proposal, drafted in 1995, with limited distribution in 1997, by a group of European and American epidemiologists from industry and academia, in hopes of international review and subsequent European Union Working Group approval.63 Despite PM's efforts, no European Union resolution on GEP had been produced as of mid-2000.

WORLDWIDE SEMINARS ON GOOD EPIDEMIOLOGY PRACTICES

From 1994 to 2000, seemingly independent seminars on GEP have been conducted by several organizations in the United States, United Kingdom, European Union, and China. In fact, PM is connected to all these events.

Federal Focus, Inc., a nonprofit foundation based in Washington, DC, that engages in research and education pertaining to federal government policy issues, conducted a 2 seminar83 on epidemiology and risk assessment that appear to have been part of PM's GEP program. In 1994, Federal Focus convened a 19-member panel in the United States that advocated uniform epidemiology principles.61 In October 1998, a second 17-member panel in London, England, and drafted the "Principles for Evaluating Epidemiologic Data in Regulatory Risk Assessment," or "London Principles,"85 which pose a series of questions to guide a risk assessor about the overall quality of the data and its potential weight for a risk assessment. The panel comprised scientific representatives from academia and industry, including some who had received tobacco industry funding or served as tobacco industry consultants.67,68,69

The London Principles do not criticize relative risks of less than 2, but the Federal Focus leaders have, while working under contract with PM. Federal Focus received at least $200,000 from PM in 1993.87 Federal Focus' chairman, Jim Tozzi of Multinational Business Services, was under contract with PM for $40,000 a month in 1993 and up to $61,000 in 1994.88,89 Thorne Auchter, director of Federal Focus' Institute for Regulatory Policy, has testified to the US Occupational Safety and Health Administration Public Meeting on Standards Planning Process that "a determination needs to be made regarding the reliability of relative risks in the "weak association (RR <2.0-3.0) range."90 In 1993 and 1994, Tozzi was to work with PM to develop materials designed to intensify the debate on the need for scientific standards on meta-analysis and epidemiology such as electromagnetic fields, chlorinated water, and radon in water," with the purpose of "supporting legislative mandates on epidemiological standards" and "increasing debate on ETS risk assessment within EPA."83

PM, Covington & Burling, and Tozzi collaborated on the PM Criteria for Epidemiology, which "all guidelines for conducting epidemiological studies should incorporate consideration," including "if the relative risk fall into the realm of "weak association" (RR <2.0-3.0) relative to background."91 In July 1995, Tozzi sought PM to discuss the Federal Focus "EPI Principles from the "first conference" with NATO and IARC officials, as "EPA, through IARC and NATO, continues to market its indoor air quality program overseas."92

The Weinberg Group, a consultancy run by Myron Weinberg and includes tobacco industry consultant Ragnar Rylander99 (who has consulted for PM about GEP's utility.99,100 stated that relative risks of less than 2 have severe methodological problems,99 and advocated treating GEP at a 1996 scientific conference99 and the European Science and Environment Forum's executive director, Roger Bates.101 Government administrators were session moderators, which Weinberg described to PM as a "valuable concept" because they were "the target of the expert presentations."102 PM wanted to repeat a similar Weinberg seminar in Asia in 1998, to be endorsed by the Association of South East Asian Nations,103 which PM expected to establish guidelines for risk assessment.104 PM planned to commit $123,000 for a conference in Kuala Lumpur or Bangkok by
November 1998 and hoped for published journal articles or conference proceedings.

The tobacco industry’s Center for Indoor Air Research cohosted a July 1997 “International Workshop on Risk Assessment and Good Epidemiological Practices” in China with the Guangzhou Institute for Chemical Cardiogenus and the Chinese Epidemiological Association. The Center for Indoor Air Research financed projects “specially reviewed” by tobacco industry lawyers, as opposed to its peer-reviewed projects; the former are more likely to conclude that secondhand smoke does not cause disease. The China conference brought together 100 lung cancer specialists within China with a few scientists from outside China, including scientists funded by the tobacco industry.47,52This China GEP workshop was part of the tobacco industry’s “Asia-specific IARC preparation” and PM hoped to produce GEP resolutions by Chinese science organizations. An organizer of the conference coauthored a paper on GEP and the etiology of lung cancer with industry consultant Joseph Wu, who had been paid $235,000 in 1995 and 1996 to organize and conduct “Chinese projects” through SHIB. Wu authored an accompanying editorial on risk assessment and GEP in the Chinese Journal of Epidemiology that states that relative risks of less than 2 may be artificial for secondhand smoke studies, and that scientists need to examine other factors, such as pollution and diet, for lung cancer.

Several European epidemiologic societies have developed GEP guidelines, including the International Epidemiological Association (IEA), the Danish Society of Epidemiology, and the French-speaking Epidemiologists de Langue Française (ADELF). PM may have sought to participate in these processes; John Rupp, the lawyer from Covington & Burling who had drafted a European Council GEP resolution for PM, lobbied ADELF on GEP, as well as in Italy and Germany. The ADELF and IEA epidemiologists who headed the GEP efforts for their organizations stated that they had no idea what PM had such subversive intentions. The GEP guidelines developed by the epidemiologic societies do not discuss relative risks of less than 2, and the IEA guidelines emphasize the ethical conduct of epidemiologic studies.

CHANGES IN PHILIP MORRIS’S GOOD PRACTICE PROGRAM

By April 1998, PM began to scale back its GEP program. Ted Sanders (PM Worldwide Scientific Affairs), who was to inherit the GEP program, expressed concern about the GEP program’s value to Cathy Ellis (senior vice president of research and development, PM USA):

... the concept of GEP was discussed in considerable detail in PM. Corporate Affairs thought it was a wonderful idea, because at first they ... felt that part of a code for Good Epidemiological Practices would state that any relative risk of less than 2 would be ignored. This is of course not the case. No epidemiological organization would agree to this, and even Corporate Affairs realizes that now (emphasis added).

Sanders describes PM’s initial objective as to discredit epidemiologic results with relative risks of less than 2, but the company realized that no epidemiological organization would agree to such a standard. Sanders’ memo also suggests that if PM had succeeded in securing a GEP code as initially planned, there was a good chance PM would not be able to criticize future errors in epidemiologic studies, and a better alternative would be to continue developing GEP with other companies. PM seems to have followed Sanders’ advice; by July 20, 1998, “no further work was to be done on GEPs” by Rupp, who had continued his activities in France.

GEP has most recently been a focus for Toxicology Forum, a nonprofit organization that fosters interaction between scientists in academia, government, and industry. The 1999 Brussels conference included “Epidemiology in a Policy and Regulatory Context: Considering a Code of Good Epidemiology Practice,” and the May 2000 Brussels conference discussed “Determination and Structure of Guidelines of Epidemiological Practice.” (Note: When the referenced Web site was accessed on September 24, 2001, the title of the May 2000 conference had been changed to “Comparison of the Principles and Practice of Risk Assessment Performed at the Global and European Level,” and the list of pending participants had been removed.) The May 2000 session speaker list included tobacco industry consultants and PM, R.J. Reynolds, and the Tobacco Institute contributed $35,000 through Covington & Burling for a 1992 Toxicology Forum meeting that included the session “Weak Epidemiological Associations and the Limitations of Meta-Analysis.” The international discussion of GEP continues, although the tobacco industry’s interest in the 1999 and 2000 GEP Toxicology Forum conference remains unclear.

DISCUSSION

PM appropriated the “sound science” concept to shape the standards of epidemiology and to prevent increased smoking restrictions. The “sound science” coalition was viewed by PM and its public relations firms as a launching point to introduce the tobacco industry version of “good epidemiological practices” that would be accepted by the scientific community. The “sound science” coalition is similar to other tobacco industry front groups used as third-party spokesmen without disclosing the tobacco industry’s involvement. PM’s GEP was constructed by their lawyers and internal scientific resources. To gain support for its GEP programs and perspectives, PM capitalized on the concerns of other industries facing regulation and the good intentions of the scientific community, which sought to improve the conduct of epidemiology.

PM has gone beyond “creating doubt” and “controversy” about the scientific evidence that demonstrates that active and passive smoking cause disease; to attempting to change the scientific standards of proof. PM’s higher level of activity in Europe with GEP reflects the reason for this strategy shift. PM sought to establish a technologically advantageous scientific and policy-making environment before a scientific threat materialized in Europe, whereas in the United States, PM was reacting against an already damaging scientific government publication. The versions of GEP PM
These claims of inconsequential exposure are based on tobacco industry-funded studies of dubious accuracy that were carried out within the same construct as the GRP efforts and other efforts to subvert the scientific process. Indeed, the pilot studies for these exposure studies have been demonstrated in government proceedings to be unreliable.47

As greater understanding of the tobacco industry's subversive operations accumulates, scientists and policymakers face the question of whether or not to include the tobacco industry in their discourse. In 1954-1955, the tobacco industry was publicly reviled itself, while privately doing everything it could to protect itself from meaningful regulation and maximizing sales and profits, suggest that the WHO and other government and scientific bodies maintain an arm's-length relationship with the tobacco industry until it visibly reduces its aggressive efforts to promote tobacco use, whether to children or adults, worldwide.

Because the US Supreme Court is allowing judges more freedom to decide whether to admit or exclude scientific evidence,148,149 the question of what work constitutes "junk science" or "sound science" comes to the forefront in discussions of the health effects of industry products and activities. Discussions of how to improve epidemiology should be ongoing, although there is continued debate as to the necessity for epidemiologic guidelines.150,151 While every practicing scientist agrees that scientific work should be rigorously done, the scientific, public health, and regulatory communities need to be more aware that the "sound science" and "GEP" movement is not simply an effort from within the profession to improve the quality of scientific discourse. This movement reflects sophisticated public relations campaigns controlled by industry executives and lawyers to manipulate the scientific standards of proof for the corporate interests of their clients.12

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