



Legislating “Sound Science”: The Role of the Tobacco Industry

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In the late 1990s, in an effort to dispute the link between secondhand smoke and lung cancer, Philip Morris initiated a campaign to legislate “sound science.” The campaign involved enacting data access and data quality laws to obtain previously confidential research data in order to reanalyze it based on industry-generated data quality standards. Philip Morris worked with other corporate interests to form coalitions and workgroups, develop a “data integrity” outreach program, sponsor symposia on

“research integrity,” and draft language for the new acts.

The tobacco industry played a role in establishing laws that increase corporate influence on public health and regulatory policy decisions. (*Am J Public Health*. 2005;95:S20–S27. doi: 10.2105/AJPH.2004.050963)

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a data access law as a rider to the Fiscal Year 1999 Omnibus Appropriations Act.¹ The data access act required the Office of Management and Budget (OMB)

to revise its Circular A-110, which provides guidance to federal agencies for managing grants to higher education institutions, hospitals, and other nonprofit institutions.^{2,3} The law, for the first time, made all of the data produced under federally funded research studies available by requests through the Freedom of Information Act (Table 1).²

Two years after the adoption of the data access provision, another amendment was added to the 2001 Omnibus Appropriations Act. The data quality act

requires OMB 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 maximize the quality, objectivity, utility, and integrity of information disseminated” by federal agencies (as defined in Table 1).⁴ Although the public had an opportunity to comment on implementing the regulations, these amendments were



TABLE 1—Data Access and Data Quality: Before and After the Laws of 1998 and 2000

	Before Data Access/Data Quality Laws	After Data Access/Data Quality Laws
Data access standards	Final reports and grant proposals of federally funded projects available by Freedom of Information Act request. Reports are already in agency files.	All data from federally funded projects available by Freedom of Information Act request. Agency must obtain data from grantees.
Data quality standards	Scientific norms of excellence and integrity apply, e.g., research reports are published in scientific journals after peer review. No other formal definitions or procedures.	Any data disseminated by government must adhere to definition of quality set by the law. ³ Citizens can bring challenges and agencies must respond. “Influential data,” defined by Office of Management and Budget as “scientific, financial, or statistical information that will have or does have a clear and substantial impact on important public policies or private sector decisions,” must be reproducible upon reanalysis by “qualified third parties.”

³Office of Management and Budget’s definition for data quality standards is threefold: (1) objectivity of presentation (accurate, clear, complete, and unbiased) and objectivity of substance (accurate, reliable, and unbiased information using sound statistical and research methods); (2) utility, meaning usefulness of the information to the public; and (3) integrity, meaning information has been protected from unauthorized access or revision.⁴

initially passed and adopted without a legislative hearing, committee review, or debate.⁵ 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.⁶ The research community was also concerned that these measures were supported by industry groups seeking to contest environmental and other regulations.² Together, the data access and data quality acts provide a mechanism for challenging the scientific merit of data outside of scientific journals and other channels of scientific review.^{7,8}

Internal tobacco industry documents that have been made

available through litigation give us the opportunity to analyze one industry’s involvement in a broader industry strategy to secure enactment of the data access and data quality provisions. These documents provide unprecedented insight into the industry’s motives, strategies, and tactics⁹ to challenge the scientific basis for public health policies.¹⁰⁻¹² In the 1990s Philip Morris implemented a 10-year “sound science” public relations campaign to create controversy regarding evidence that environmental toxins cause disease.¹³ Our article describes the tobacco industry’s later campaign to advance the “sound science” concept via legislation.

METHODS

We searched tobacco industry document archives from the University of California Legacy Tobacco Documents Library (www.legacy.library.ucsf.edu) using combinations of words

including: “sound science,” “legislation,” “data access,” “data quality,” “omnibus appropriations act,” “treasury and general government appropriations act,” and “peer review.” We conducted snowball searches using the names of key organizations and individuals identified in relevant documents, project dates, and reference (Bates) numbers.

Initial searches yielded hundreds of documents including letters, memorandums, and reports. The documents were read, and all of those relevant to the data access and data quality acts were selected, yielding 100 documents. We assembled the documents chronologically, and the extent of tobacco industry association with “sound science” legislation emerged. For reliability of interpretation, the documents were read and analyzed separately by all four authors. The grouping of the documents in this report was discussed by all of the authors.

RESULTS

The Tobacco Industry’s Efforts to Obtain Data

Between 1996 and 2002 Philip Morris began to advance the concept of sound science by seeking legislation that would increase access to research data and mandate new data quality guidelines. As described below, Philip Morris used a three-step strategy: (1) asking the researchers for the data directly; (2) litigation; and (3) legislating policies that release data.

Asking researchers: “the scientific cultural method” of obtaining data. In its quest to discredit the Environmental Protection Agency risk assessment of secondhand smoke, Philip Morris made repeated requests to Dr Elizabeth Fontham for her research data.^{14,15} Fontham published studies in 1991 and 1994 demonstrating that exposure to secondhand smoke during adult life increases risk of lung cancer in lifetime nonsmokers.^{16,17}



In collaboration with Philip Morris, consultant Jim Tozzi wrote letters to Elizabeth Fontham asking her to release her data.^{14,18} According to Tozzi, “a complete reevaluation of the published Fontham data by [his firm] Multinational Business Services leads to the strong conclusion that the Fontham results are more likely to be the result of various analytical and statistical errors and bias rather than demonstrating a significant positive correlation. For this reason, we remain convinced of the importance of releasing the underlying Fontham data so that such data may be subject to objective scientific analysis.”¹⁹

Dr Fontham refused to comply with these requests, explaining that “the investigators of her study are concerned that these data be used solely for furthering science and that they not be distorted by the economic interests of other parties who analyze them.”²⁰ Philip Morris referred to the initial contact letter with Dr Fontham as the “first of a series of very graduated steps to obtain the so-called Fontham data by the scientific cultural method.”²¹ In other words, they hoped to rely on the norm among scientists of requesting data from each other.

The litigation strategy. Philip Morris then initiated discovery requests in ongoing lawsuits to gain access to the Fontham data through litigation.^{22,23} In May 1995, Philip Morris executives commented that “based on previous experiences in attempting to obtain raw data from federally funded epidemiology studies,

this will be a very difficult task.”²⁴ In a memo to Philip Morris executives, Tozzi expressed concerns that “the judicial fate of the Fontham data is questionable” and that a member of Congress “should ask the Secretary of Health and Human Services to release the data underlying Fontham.”²⁵ The litigation strategy met with limited success, as the courts often denied the requests, only limited pieces of the data were released, and papers based on the reanalysis of such data proved difficult to publish.^{26,27}

The legislative strategy: data access and data quality. Table 2 lists the key events in Philip Morris’ role in the data access and quality acts. A Philip Morris strategy meeting held on March 15, 1996, assigned to Richard Carchman, Director of Scientific Affairs for Philip Morris Incorporated, the task of “prepar[ing] model data disclosure language for the instances of contested interpretation of underlying data in published studies.”²⁸ The notes from a May 1996 meeting show that

Philip Morris executives discussed how “the acquisition of data is a major goal” for the company, developed a position statement on data sharing, and identified company executives to take the lead on a policy strategy for data disclosure.²⁹

A Philip Morris planning document explains that the debate about the Environmental Protection Agency’s new outdoor air regulations is “remarkably similar to the ETS [environmental tobacco smoke] issue where the tobacco industry has not been able to get the supporting data from the Fontham Study.”³⁰ “Because of the parallels between the ETS issue and the new clean air regulations, already established and existing political and business coalitions could be used to focus on meeting the objectives of the tobacco industry.”³⁰ These groups could promote “legislative solutions to ensure that public policy is based on sound science” and “require epidemiological studies to meet a minimum set of criteria and/or require researchers to make

public the underlying data before these studies can be used as a basis for regulations at the state or federal level.”³⁰

The document additionally explains that in order for this strategy to succeed, the tobacco industry needs to take the necessary precautions to remain in the background of the public debate and ultimately develop epidemiological criteria to evaluate the quality of research data.³⁰ Thus, this 1997 planning document also lays the groundwork for the data quality act.

As shown in Table 3, the Philip Morris planning document also shows “best and worst case scenarios” for the industry in the event that the data access and data quality acts pass. A 1997 Philip Morris document entitled “sound science project” also lists the industry’s dual objective as the following: (1) to gain passage of federal law on criteria/standards for epidemiological studies; and (2) to legislate public access to epidemiological data used in support of federal laws and regulations.³¹ The document explained

TABLE 2—Timeline of Philip Morris Data Access and Data Quality Strategy

Date	Key Event
March 1996	Philip Morris drafts data access legislation.
September 1996	Philip Morris requests E. Fontham’s data.
November 1997 – March 1998	Philip Morris drafts data access legislation and identifies supporting industries.
September 1998	Shelby’s data access amendment passed as budget rider.
December 1998	Philip Morris writes six-step work plan on data access and data quality.
February 1999 – September 1999	12,000 comments received on Circular A-110 revisions.
October 1999	Data access act implemented with final Circular A-110.
June 2000	Philip Morris executives agree on data quality act language.
September 2000	Emerson’s data quality act passed as budget rider.
February 2002	Final data quality guidelines released.



TABLE 3—Legislating Sound Science: Scenarios Described by the Tobacco Industry³⁰

Worst Case

The EPA regulations [outdoor air regulations] are promulgated or the situation is resolved without addressing either of our core objectives regarding epidemiological criteria and data sharing.

The epidemiological criteria legislation passes but is in a form that is too weak or does not apply to ETS. Once again ETS becomes the exception to the rules.

Data sharing passes and we get access to the Fontham data. However, without established criteria to evaluate our analysis of the data the EPA and other groups discredit our evaluation and our results are ignored.

We do the reanalysis of the Fontham data and an association remains.

Our interest in the EPA rule and our legislative objectives become public knowledge, which could prevent/diminish the effectiveness of the legislation.

Best Case

Federal legislation passes including both criteria for epidemiological studies and a requirement for data sharing. As a result, smoking ban efforts are either preempted or no longer passed. The Occupational Safety and Health Administration rule on indoor air quality no longer requires separate ventilation in order to accommodate smoking.

Federal legislation passes on data sharing only. We get the data from the Fontham study and prove it does not show any association between ETS and disease. These results prevent Occupational Safety and Health Administration from acting and stops/repeals smoking bans.

cies.³⁴ The document lists “players” who might potentially support or oppose a data disclosure policy. Philip Morris identified the American Petroleum Institute, the National Rifle Association, the American Iron and Steel Institute, the Statistical Assessment Service, and the Electric Power Research Institute as supporters of the data access provision.³⁴

In November 1997, Philip Morris executives held meetings with the Center for Regulatory Effectiveness (CRE) to discuss draft language for the data access act. CRE is an advocacy group established in 1996 that monitors the federal regulatory process. CRE prepared a document exploring the link between data integrity and data sharing, identifying legislative precedents on which to build the new policy

that “our plans must always include developing the right criteria that will favorably evaluate and be applicable to ETS.”³⁰

Achieving these dual objectives would allow the industry to “reopen” the secondhand smoke issue.³¹ A 1998 internal memo, titled “Sound Science Legislation,” from Thomas Borelli at Philip Morris to other company executives confirms that the goal of the data access act was to influence the regulatory process.³²

Implementing the Legislative Strategy—Data Access

The Philip Morris draft “sound science project” identifies team leaders who are assigned specific roles for carrying out the project’s objectives. Table 4 lists potential strategies for legislating data access and data quality provisions.^{31,33} Although Philip Morris planned for an active role, its documents emphasize that this

role should remain hidden from the public.³⁰

Tobacco industry documents suggest that Philip Morris implemented at least some of their

strategies. In an October 1997 document entitled “Questions for Data Disclosure,” Philip Morris outlined the initial steps to implement data access poli-

TABLE 4—Philip Morris’ Outline for Passing the Data Access and Data Quality Laws

Options for Objectives/Strategies/Tactics/Actions ³¹
Demonstrate the public cares about the issue—sponsor a poll on issues of data access and rules of epidemiological studies that can be made public.
Leverage allies/groups that have already taken a stand on the issue.
Use scientists and technical conferences to focus on issue.
Encourage a small group of Congressional members to take stand.
Encourage the Administration to take a stand for sound science.
Mobilize allied industries (i.e., fishing, utilities, and waterworks) to lobby their local representatives.
Help organize coalitions for other epidemiology issues coming up soon (e.g. fishing industry, mercury, and methylene chloride).
Educate/mobilize the business community on sound science vs. junk science and the federal legislative/regulatory process.
Use states for generating action: conduct briefings in states on epidemiological studies and the need for uniform standards; encourage passage of state laws.
Develop broad bipartisan support for “Freedom of Information” in regards to data behind regulations and laws. <ul style="list-style-type: none"> • Leverage lobbyists to contact key legislative members. • Brief the media. • Brief business coalitions on the need for data access. • Use the Congressional Science Committee to influence Congress.



and outlining criteria for assuring high quality data.³⁵

By March of 1998, a document in Philip Morris files marked “confidential” listed a summary of data disclosure messages that could be used to support data access laws.³⁶ The document identified potential supporters and opponents of data disclosure in the food, health, pharmaceutical, chemical, energy, transportation, insurance, and waste products industries.

The data access act was passed in September 1998 and implemented a year later, on October 8, 1999. During this year, Philip Morris hired Jim Tozzi to coordinate industry efforts to ensure that OMB implemented the new law consistently with industry interests.³⁷ A contract dated December 24, 1998, shows that Philip Morris Worldwide Regulatory Affairs hired Tozzi to “work with federal agencies to encourage implementation of the recently enacted data access and data quality provisions.” Philip Morris planned to compensate Jim Tozzi with a monthly retainer of \$65,000.^{38,39} Shortly after Congress enacted the data access act, Tozzi met with OMB to develop a strategy for implementing both data access and data quality provisions.^{40,41} In December 1998, 3 months after the data access act became law, he submitted a workplan on data access and data quality to Matt Winokur of Philip Morris. Winokur was director of Philip Morris Worldwide Regulatory Affairs and a member of the five-person “sound science issues team.”⁴² The workplan included

plans to do the following: (1) solicit views of federal agency officials and draft prototype regulations on data access and quality; (2) present and market draft regulations for data access and data quality to various federal agencies; (3) keep congressional committees (appropriations, science, commerce, etc.) updated on data access and data quality developments; (4) brief congressional committee members and staff on the proposed regulations and elicit support; (5) identify supportive states, brief these states on developments involving the law, and elicit support for the proposed regulations before OMB and the federal agencies; and (6) advance the proposed regulations by building a coalition on data access and data quality issues with the Center for Regulatory Effectiveness, trade associations, and interested stakeholder groups.^{43,44}

The CRE, with Jim Tozzi as the lead advisory board member, made plans to create a workgroup to address data access and data quality. In a memo to Matt Winokur, Tozzi commented that his firm had made recommendations for data access and data quality to OMB. His firm would be meeting with “approximately a dozen major industrial firms and trade associations to discuss the possibility of forming a work group under the auspices of the CRE to address this issue.”⁴⁵

Tozzi invited the Chemical Manufacturers Association to a meeting to discuss member participation in specific work groups targeting issues of interest to the

industry.⁴⁶ The work group’s goal was to “ensure that OMB meets its September 30, 1999 deadline for issuing guidance that will require agencies to: (a) provide the regulated community with access to ‘underlying’ or ‘raw’ data; and (b) ensure the accuracy of information used by agencies in decision-making.”⁴⁶ The memo explained that the work group would also “ensure that: (a) substantive provisions of importance to the Work Group are included in the final guidance document; and (b) key rulemaking agencies, such as EPA and FDA, issue agency-specific guidance implementing the OMB guidance.”⁴⁶

Another Tozzi-affiliated advocacy group, Federal Focus, Inc, worked with Philip Morris to implement the data access and data quality amendments. Federal Focus, Inc,⁴⁷ has a prior history of working on the Philip Morris “sound science” campaign.¹³ In an internal tobacco industry document, Federal Focus, Inc, discussed “current and planned activities which Federal Focus would undertake to advance and build popular support for data access/data integrity measures.”⁴⁸

Federal Focus drafted strategies for influencing data access and data quality guidelines⁴⁸ and planned to involve other business groups including the automotive, telecommunications, pulp and paper, financial, and food and beverage industries in this effort.⁴⁸ Federal Focus sponsored seminars, including a joint symposium with the American Association for the Advancement

of Science to encourage discussion of the data initiatives. A memo from Jim Tozzi to Matthew Winokur at Philip Morris states that “cooperation with AAAS [American Association for the Advancement of Science], as represented by the symposium will offer considerable credibility to our overall effort.”^{49,50} The symposium was held on February 26, 1999, with the briefings prepared by Federal Focus.⁵¹

Implementing the Legislative Strategy—Data Quality

Three months after the data access act was implemented, Jim Tozzi focused his efforts on getting OMB to promulgate data quality guidelines. In a letter dated January 17, 2000, Tozzi informed OMB official John Spotila that CRE had drafted a model Notice of Proposed Rulemaking on Data Quality (NPRM). Tozzi claimed that “Congress had already instructed OMB to promulgate a data quality regulation by the end of [the 1999] fiscal year.”⁵² According to Tozzi, since OMB had not yet complied with this mandate, CRE took the initiative in developing model data quality guidelines for OMB to follow.

Tozzi explained that CRE would publish the model data quality document on the internet as an “interactive public docket” where the public could submit comments regarding the new guidelines. CRE would then prepare a summary of the comments, make revisions to the model guidelines based on the comments, and transmit the finalized draft to OMB.⁵²



Shortly after sending this letter to OMB, Tozzi contacted Robert Elves of Philip Morris to tell him that CRE could “use an experienced hand as it proceeds down the data quality road” and that he looked “forward to Philip Morris’s continued involvement in this endeavor.”⁵³ In a later letter to Elves, Tozzi outlined a schedule of events on data quality for Philip Morris to review. This included plans for discussions with industry stakeholder groups on the draft OMB regulation for data quality, discussions on draft regulation with federal agencies and the administration, and presentation of the draft OMB regulation to the administration.⁵⁴ Furthermore, the outline specified that if OMB did not adopt the data quality regulations by July 1, 2001, CRE would initiate judicial action.⁵⁴

A series of memos between Philip Morris and CRE indicate that Philip Morris contributed to the content and language of the model data quality guidelines that Jim Tozzi sent to OMB.⁵⁵⁻⁵⁹ Philip Morris executives reached consensus on the language of the data quality act on April 14, 2000, and sent their final comments to CRE on June 26, 2000.^{56,60}

Congress enacted the data quality act shortly thereafter as a two-paragraph provision buried in the Fiscal Year 2001 Treasury and General Government Appropriation Act. It is similar to the model draft created by CRE and stipulates that OMB must develop guidelines to “provide policy and procedural guidance to federal agencies for ensuring and

maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies” (Table 1). The data quality act directs federal agencies to issue their own conforming data quality guidelines using OMB guidelines as a model.⁴ “Influential data” as defined in Table 1 must be reproducible upon reanalysis.⁴ This requirement only applies to federally funded and not privately sponsored research. The scientific community has typically relied on peer review, not government standards, to ensure data quality.

DISCUSSION

On the surface, sharing research data and results with the public is a worthy effort, and high quality information is an essential prerequisite to a fair and effective regulatory process. Senator Richard Shelby, author of the data access act, cites the advancement of better science as his impetus. The data quality act’s sponsor, Representative Joann Emerson, asserts that her motivation for the law was a desire to ensure that information dispersed via the Internet meets certain quality standards.⁵ Proponents of the data access and data quality rules argue that these laws promise greater government accountability and better decisionmaking.⁶¹

However, as scientists, legal experts, and environmentalists have pointed out, the data access and data quality riders have the potential to block agencies from using emerging science and slow the regulatory process.⁶²⁻⁶⁴ The

laws could shift the scientific standards of data used for policy purposes. Although the tobacco industry intended to hide its involvement in the data access and quality acts, our analysis of the internal industry documents reveals that these policies were driven by corporate interests.

Opponents of the data access and data quality acts predicted that industry groups would use the new procedures to delay dissemination of or retract information that can be used to regulate their industry. Corporate interests have initiated the vast majority of data quality act challenges. Corporate advocacy groups including the CRE, the Competitive Enterprise Institute, the US Chamber of Commerce, the Salt Institute, and others have filed petitions challenging the data upon which health-related regulations are based.⁶⁵⁻⁶⁹

More recently, OMB proposed new guidelines for peer review standards to be used by federal agencies as “part of an ongoing effort to improve the quality, objectivity, utility, and integrity of information disseminated by the federal government to the public.”⁷⁰ CRE submitted comments to OMB in support of the revisions and explained that the proposed changes in peer review are necessary in order for OMB to meet its legal responsibilities under the data quality act.⁷¹ Scientists, public health professionals, and health organizations have expressed concerns about the new requirements. They point out that the language politicizes science by giving the White House unregulated power to ex-

pedite or delay the release of scientific information.⁶⁴

Our analysis of the tobacco industry’s role in the data access and quality acts provides a window into the collaboration among corporate interests. The petitions challenging national public health studies and environmental risk assessments that followed demonstrate the potentially broad application of these policies. All of these challenges, if successful, would lead to weaker public health protections and less corporate oversight. The peer review revisions recently proposed are an indication of continued corporate involvement in public health research policies.

To combat corporate obstruction of public health policies, scientists can actively support regulatory agencies that are the targets of abusive data quality act challenges by filing critiques of such challenges with the relevant agencies. Agencies are required to consider such critiques. Finally, the scientific community should support efforts by public interest groups to induce companies to make privately sponsored health and safety testing data available to scientists for interpretation and analysis. The decision by several drug companies to register all company-sponsored studies on the Internet should be expanded to include the raw data underlying those studies.⁷² The scope of these efforts should be expanded to include all company data relevant to the health and safety of toxic chemicals that are released into workplaces and the environment. ■



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Contributors

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