

Tobacco Industry Opposition to Designating Environmental Tobacco Smoke Through E-codes

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ABSTRACT

This manuscript examines the public policy importance of 1993, United States Department of Health and Human Services actions to require doctors and hospitals to report a new external cause of injury code or E-code for environmental tobacco smoke related to causes of death such as lung cancer and severe heart disease. Methods included a qualitative archival analysis of all previously internal tobacco industry documents, pertinent newspaper and magazine articles, Americans for Nonsmokers' Rights database, and pertinent websites regarding environmental tobacco smoke and E-codes from 1993 to 1998. The E-code has continued to the present because of scientific and administrative recognition that environmental tobacco smoke is conclusively linked to illness and death. The industry argued that the E-code was unnecessary because of costs to business and no conclusive scientific evidence linking environmental tobacco smoke with pulmonary and cardiovascular deaths. This regulatory action based on current scientific evidence and medical decision-making contradicts the industry's claim that no deaths are conclusively associated with environmental tobacco smoke.

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INTRODUCTION

During the early 1990s, several United States federal agencies including the Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), and Department of Health and Human Services (HHS) initiated actions to classify and regulate environmental tobacco smoke as harmful to human health. Environmental tobacco smoke, which annually kills over 50,000

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Americans (1), is defined as "...exposure to secondhand tobacco smoke and side stream smoke released from the smoldering cigarette or other smoking device (cigar, pipe, bidi, etc.) and diluted with ambient air" (2).

In 1992, an EPA report deemed environmental tobacco smoke a Class A carcinogen that causes lung cancer and other respiratory diseases in humans (3-5). In 1994, OSHA proposed a rule prohibiting environmental tobacco smoke in all indoor workplaces, except for designated smoking rooms—separate and ventilated to outside the building (6). Owing to political pressure from the tobacco industry and conservatives in Congress, OSHA never issued the final rule (7,8).

In 1993, HHS began a third important regulatory effort—a proposal to include a new external code or "E-code" that physicians and hospitals would use to denote environmental tobacco smoke as an external cause of injury in conjunction with other direct causes of death such as lung cancer, chronic obstructive pulmonary disorder, and cardiovascular disease (9,10).

E-codes have existed since 1893 when the international Bertillon Classification system was ratified. It has been updated irregularly through the auspices of the World Health Organization (11,12). E-codes fulfill an important uniform statistical reporting function for morbidity factors that may also contribute to mortality. Most countries in the world currently document external causes of death in conjunction with primary causes of death recorded under the World Health Organization's International Classification of Disease (ICD-10) classification system (8-10,13-18). By international agreement, the ICD-10 classification system (ICD-9 from 1993 to 1998) for coding mortality types, including E-codes that classify morbidity, is updated periodically. In addition, a separate and similar classification system of E-codes under the ICD-9-CM (Clinical Modification) is used in the United States (19). The purpose of the international system, which includes E-codes, was international collaboration and uniformity in the collection of mortality and morbidity statistics (11).

For designating E-codes, the United States has a similar and separate classification system administered through HHS. E-codes record external causes of injury that may also contribute to death (8). E-code designations may name a condition that can be fatal (20). If a

person dies due to suicide, for instance, an E-code might be recorded as death due to a gun (8). E-codes entries by doctors and hospitals in the United States are not mandatory (8).

The change in E-codes posed an important public health policy issue. Was the proposed E-code scientifically and administratively warranted as a tool to report and document morbidity associated with mortality and to provide conclusive documentation of death attributed to environmental tobacco smoke?

From the early 1990s to the present, the tobacco industry has argued that, while a large body of public health and scientific evidence indicated a connection between environmental tobacco smoke and various pulmonary and cardiovascular diseases and death, the evidence was not conclusive (4,5). Affirmation of the new E-code would have rejected this claim of lack of scientific evidence. This paper examines the policy positions and political tactics of the tobacco industry in tandem with the actions of federal regulators from 1993 to 1997 to learn whether the claim by the tobacco industry that there was no conclusive scientific proof of adverse health hazards due to environmental tobacco smoke was valid (13–16).

In 1993, at its annual meeting, the HHS Coordination and Maintenance Committee considered whether “current and best available scientific evidence” justified including environmental tobacco smoke as a new E-code (10). The Committee’s administrative decision-making process for coding ordinarily draws no attention from outside interests (9). This time, however, the tobacco industry hired a lobbying organization, Multinational Business Services (MBS), to argue against the new E-code, and did not directly associate itself to efforts to block the proposal (21). Multinational Business Services and its political allies, such as the Associated Industries of Florida (AIF), a broad-based business lobbying organization in Florida, in a nearly invisible campaign, argued to HHS that the proposed E-code was unnecessary because no conclusive evidence linked environmental tobacco smoke with cardiovascular diseases and pulmonary diseases such as lung cancer. They also argued that such a classification would cause substantial legal liability and cost to business due to misapplication of the proposed E-code (14,21).

The HHS committee, in consultation with the Health Care Financing Administration (HCFA) and the National Center for Health Statistics (NCHS), rejected the tobacco industry's arguments and decided that current and "best available scientific evidence" (including the recent 1992 EPA report on second-hand smoke) allowed for a designation of the new E-code (8). The tobacco industry appealed this decision to the Office of Management and Budget (OMB), which asked that HHS justify the new E-code because the "practical utility" of the new E-code had not been proven (8). Despite OMB's request, the new E-code was adopted by HHS, citing the need for doctors and hospitals to document adverse health effects caused by environmental tobacco smoke (8).

Until the early 1990s, the tobacco industry claimed that the scientific evidence was inconclusive regarding a direct link between environmental tobacco smoke and adverse health problems. The new classification and regulatory action by HHS was a direct scientific repudiation of the industry's claim that there were no health dangers associated with environmental tobacco smoke. The industry had been able to dispute statistical estimates of deaths from tobacco use; but deaths attributed by individual doctors presented it with a new and significant legal, political, and public relations challenge.

METHODS

In 2004, to examine the designation of environmental tobacco smoke as an E-code, I used a qualitative and archival analysis of previously secret and internal tobacco industry documents from 1993 to 1998. More than 40 million pages of documents have been made public as part of the legal settlement of *State of Minnesota, et al. v. Philip Morris, Inc.*, No. CI-94-8565, 2nd District, Minnesota, and subsequent litigation against the tobacco industry.

Under the terms of the legal settlement, five tobacco companies, a tobacco trade association, and a tobacco company research association have established searchable websites for documents produced during litigation. I accessed this material on the Internet at <http://www.cdc.gov/tobacco/industrydocs/>. The search terms International Classification of Diseases, environmental tobacco smoke, ICD, E-code, National Center for Health Statistics, Multinational Business Services, Paperwork Reduction Act, OMB and ETS, and

Office of Management and Budget *and* ETS produced 2,344 hits and 45 relevant documents, available in pdf format. These search terms were selected because of their wide and general scope with respect to E-codes and environmental tobacco smoke so that the search engine would identify all available documents.

Although I searched all tobacco industry sites, most of the relevant documents appeared on the Philip Morris site. I wrote a composite and chronological analysis and a summary of each document. I also obtained all relevant newspaper reports from Nexus Lexus for 1993 to 1998, all relevant articles from the Americans for Nonsmokers' Rights database, located at <http://www.tidatabase.org/>, plus pertinent magazine articles and web pages. These documents were then chronologically intermixed with the tobacco documents to ascertain public policy with respect to E-codes from 1993 to 1998. I read the collection as a whole to learn about the overall story of E-codes and environmental tobacco smoke from 1993 to June 1998.

RESULTS

On December 2, 1993, the HHS–Coordination and Maintenance Committee held its annual meeting to consider, based on best current scientific evidence, whether to include environmental tobacco smoke as an external cause of injury or E-code for the International Classification of Disease-9 Clinical Modification (ICD-9-CM) (10). The proposal for the new E-code was in the category of “accidental poisoning by other gases and vapors” (19).

Campaign Against the Environmental Tobacco Smoke E-code

A previously secret and internal Philip Morris document, dated four days after the Committee held its first meeting in 1993, reviewed the industry's lobbying tactics options and policy positions against the proposed E-code, including:

- the E-code was too costly and time consuming in terms of listing individual substances such as environmental tobacco smoke;
- a determination to mobilize an effort with coder, doctor, and health groups to argue that the issue of second-hand tobacco smoke being linked to adverse health effects is inconclusive (19);
- do nothing and monitor the situation.

In addition, the Philip Morris document cautioned:

We should also consider ensuring that the ETS (environmental tobacco smoke) is not raised all by itself, which may raise flags, by identifying another issue raised, which was discussed in the meeting to ensure that federal agencies do not recognize it as a tobacco industry effort (19).

In a memo dated January 1994, Thorne Auchter, former head of OSHA during the Reagan Administration, now working for the tobacco industry along with five other lobbyists hired by MBS, noted that the impetus behind the effort to obtain the proposed E-code was that hospitals and doctors were not being reimbursed for services, particularly for Medicaid, for adverse health conditions due to environmental tobacco smoke (8,13).

In compliance with the official public comment period that ended in February 1994, MBS began an intensive, behind-the-scenes lobbying effort against the proposed E-code. It presented HHS officials with data indicating a lack of scientific evidence with respect to the link between illness and death and environmental tobacco smoke (14). In February 1994, in coordination with MBS' lobbying campaign, a retired director of toxicology at the Food and Drug Administration, Dr. Alexander Apostolou, argued to HHS officials that the science linking environmental tobacco smoke with illness and death in human beings was not conclusive (14). The AIF also wrote to HHS officials saying: "AIF is very interested in this issue because they feel that inclusion of this code would cause significant shock waves in the Workers' Compensation arena" (14).

After the close of the official comment period, MBS continued to lobby against the proposed E-code by contacting Ms. Pat Brooks, staff director for medical coding policy in the HHS Office of Coverage and Eligibility Policy; Ms. Amy Gruber, head of coding changes for ICD-9-CM; and Ms. Donna Honneman, an employee in the HCFA Office of Payment Policy who was in charge of determining "where in the HCFA billing code to place new ICD-9-CM inclusions" (14). Also, MBS later lobbied the directors of NCHS and HCFA to oppose the proposed E-code (15).

Despite this intense behind-the-scenes lobbying effort, HCFA and NCHS staff agreed on May 5, 1994, based on "best and current

scientific evidence”, that the proposed E-code should be included in the ICD-9-CM classification system (8,22,23). The proposed E-code was officially adopted through an announcement by HHS in the Federal Register later in May 1994 (14). The Federal Register announcement said the new E-code for environmental tobacco smoke would become effective on October 1, 1994 (8,12).

MBS contacted the Washington, DC law firm, Multinational Legal Services (MLS), to see if the new E-code constituted an “information collection request” subject to the jurisdiction of the Paperwork Reduction Act of 1995 and thus could be reviewed by the Office of Management and Budget (OMB) (24). MLS concluded in a legal analysis sent to MBS that, yes, new E-code designations under the ICD-9-CM do constitute an “information collection request” covered by the Paperwork Reduction Act and thus would be subject to prior approval by the OMB (24).

Multinational Business Services subsequently argued to OMB that the new E-code for environmental tobacco smoke was covered under the Paperwork Reduction Act (8). The HHS opposed this claim, arguing that the time to object to proposed E-codes was during the public review process and not after the fact (8). In June 1995, OMB ordered HHS and HCFA to create a plan to examine all E-codes and “identify which ones merit dissemination” (8). The OMB also instructed doctors not to use any E-code that had been created since 1994 (8). Both HHS and HCFA appealed this decision (8).

In December 1995, OMB initially denied the appeal and ordered HHS not to publish the new E-code designation for environmental tobacco smoke (8,24). The OMB also instructed doctors not to use E-codes that had been approved in the last two years (8) and indicated to HHS that it must submit a plan to separate E-codes that have “immediate practical utility” from those that are preliminary and may have significant statistical issues (24). In essence, the Clinton Administration’s OMB was questioning the scientific validity of linking environmental tobacco smoke to human illness and death (24). This, of course, was the official position of the tobacco industry.

Despite the OMB’s initial request, the new E-code for environmental tobacco smoke continued to be used by HHS and HCFA (25–30). In response, MBS and the tobacco industry continued to

lobby OMB and HHS to rescind the new E-code (8). This lobbying campaign included the production of two large reports entitled: E-code Confusion: The Problem of Attributing Causation to Remote, Non-Proximal Events or Sources and Inaccurate Health Statistics: An Emerging Threat to the Federal Budget (8,31). A previously secret and internal MBS memorandum showed how these reports were used for lobbying purposes:

Today we messengered/Federal Expressed [sic] a copy of our paper entitled, E-code Confusion: The Problem of Attributing Causation to Remote, Non Proximal Events or Sources to all members of the National Committee on Vital and Health Statistics, as well as to selected government officials (32).

This lobbying effort continued into 1998, when MBS called for the replacement of the United States Clinical Modification E-code system with the Nordic Medico-Statistical Committee (NOMESCO) classification system (33). MBS' argument for this new classification system was:

The NOMESCO system offers the potential to greatly improve the amount and quality of data surrounding injury events, data which would help fashion stronger and more effective injury prevention programs. As the validity and reliability of the chronic E Codes has not been demonstrated, adding new chronic E Codes to the current system only has the potential to exacerbate the uncertainties in this area and any associated problems. In order to ensure and preserve the validity of our existing data bases for health policy, data generated from such codes should not be used until their practical utility have been determined and NOMESCO system has been thoroughly examined (33).

Multinational Business Services followed through with this argument to replace the ICD system with the NOMESCO system by urging interested parties to write HCFA and OMB making the following argument:

The HCFA Form 1500 [used for Medicare reimbursements] should be issued for use only if (1) HCFA solicits public comment on the NOMESCO system, a procedure for coding injuries, as a substitute for the ICD-9-CM E-codes and (2)

during that comment period no new chronic E Codes be added or utilized beyond those currently approved (33).

Despite this continued lobbying effort, no changes to the system were ever publicly proposed or made by HHS's Coordination and Maintenance Committee (11,20,25-29,34). Instead, HHS and OMB quietly and behind-the-scenes rebuffed MBS and the tobacco industry's intensive campaign to stop the new E-code for environmental tobacco smoke. The environmental tobacco smoke E-code designation and the ICD system have remained in place until the present (16). Designation of environmental tobacco smoke as a cause of death in humans was and is a regulatory and scientific recognition (as was also noted in the 1992 EPA report on environmental tobacco smoke) that environmental tobacco smoke is directly linked to illness and death in human beings (3).

Despite this recognition of the environmental tobacco smoke E-code designation, coding and collection of data remain incomplete. The NCHS currently does not collect and report full and complete hospital discharge statistics for E-codes associated with environmental tobacco smoke (11,34). The reasons for incomplete E-code data collection and reporting include physicians not asking patients if they lived in a tobacco smoke environment (11). E-codes omit long-term and acute patients with diseases such as lung cancer or severe heart disease who had hospital stays of greater than 30 days and patients who had shorter hospital stays, aggregated to be more than 30 days, but temporally close to each other (34). Nor does NCHS collect E-code statistics for patients who were treated in various publicly funded medical institutions, including Veteran's Affairs facilities (34). As the NCHS web site states:

The NHDS [National Hospital Discharge Survey] collects data from a sample of approximately 270,000 inpatient records acquired from a national sample of about 500 hospitals. Only hospitals with an average length of stay of fewer than 30 days for all patients, general hospitals, or children's general hospitals are included in the survey. Federal, military, and Department of Veterans Affairs hospitals, as well as hospital units of institutions (such as prison hospitals), and hospitals with fewer than six beds staffed for patient use, are excluded (34).

DISCUSSION

Throughout the 1990s, the tobacco industry, in an effort to protect its sales, market, and profits, has attempted to create doubts about the link between environmental tobacco smoke and illness and death, which annually kills over 50,000 Americans (3-5,35-37). This campaign directed at agencies of the federal government included an unsuccessful attempt to discredit a 1992 EPA report linking environmental tobacco smoke with adverse health trends (4); a successful campaign to defeat a proposed 1994 national smoke-free workplace rule by OSHA (37); and an effort to discredit claims of adverse health effects due to environmental tobacco smoke during the HHS 1994 E-code designation process for environmental tobacco smoke.

In all cases, including the HHS E-code designation, the industry feared that the acceptance of this link between severe health effects and environmental tobacco smoke, introduced into regulatory programs, would contribute to greater and stricter regulations in a variety of public places (35,36). As early as 1978, the industry had been worried about environmental tobacco smoke being linked to illness and death (38). In an internal report for the Tobacco Institute, the Roper Organization, concluded:

The original Surgeon General's report, followed by the first "hazard" warning on cigarette packages, the subsequent "danger" warning on cigarette packages, the removal of cigarette advertising from television and the inclusion of the "danger" warning in cigarette advertising were all "blows" of sorts for the tobacco industry. They were, however, blows that the cigarette industry could successfully weather because they were all directed against the smoker himself. The anti-smoking forces' latest tack, however—on the passive smoking issue—is another matter. What the smoker does to himself may be his business, but what the smoker does to the non-smoker is quite a different matter.... Nearly six out of ten believe that smoking is hazardous to the non-smokers' health up sharply over the last four years. More than two-thirds of nonsmokers believe it; nearly half of all smokers believe it. This we see as the most dangerous development to the viability of the tobacco industry that has yet occurred (38).

Historically, the tobacco industry has used many tactics to counter the threat to its sales and profits posed by increased indoor air regulation of environmental tobacco smoke: employing and recruiting scientists and witnesses, public relations campaigns, and the establishment of third party front groups (4,35,36,39). Its campaign against the HHS E-code for environmental tobacco smoke used MBS as a front group to work on its behalf, and it recruited an expert witness to testify that there was no conclusive evidence on the health effects of environmental tobacco smoke.

While the industry had been able to dispute statistical estimate deaths, a more serious challenge to their position occurred when individual doctors diagnose causes of death contributed by an external injury due to environmental tobacco smoke (with the data adequately collected and reported to document these trends). Finally, MBS recruited AIF as a covert political ally to testify on the alleged economic harm caused by the proposed E-code designation.

Federal agency officials at HHS and OMB rejected this intensive lobbying effort by agreeing to designate environmental tobacco smoke as an E-code. Federal agencies with jurisdiction can advance or retard tobacco control, as is evident at EPA, OSHA, and HHS. The powerful tobacco industry understands this, and they lobbied many federal agencies in the 1990s to counter regulation of environmental tobacco smoke.

The tobacco industry's lack of success in opposing the environmental tobacco smoke E-code designation was an important victory for HHS, doctors and hospitals, and enhanced public health. The HHS secured this success by quietly and steadfastly refusing, through a usually non-controversial and quiet coding decision-making process, to succumb to industry lobbying pressures against the medical and scientific evidence about health dangers of environmental tobacco smoke. Current federal data collection and reporting of this E-code designation for environmental tobacco smoke, as noted above, remain inadequate.

The E-code designation helps health advocates because it provides another official and conclusive administrative and scientific recognition of the dangers of environmental tobacco smoke. As health advocates continue to urge stricter public indoor air laws and regulations, one further argument that they should make is that this designation adds a further and important reason for public officials

to adopt stricter public indoor regulations. Public health advocates should also vigorously point out that this is not just a question of what smokers do to themselves—but also what they are doing to other innocent members of the public. This designation provides another strong reason why vigorous regulation of indoor air by public officials is necessary despite tobacco industry claims that there is no link between environmental tobacco smoke and death.

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