

# The Power Of Paperwork: How Philip Morris Neutralized The Medical Code For Secondhand Smoke

The use of politics to influence science.

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**PROLOGUE:** The smoke-filled back room is an icon of political deal making of the past. Modern-day power sharing and deal making aren't conducted in back rooms at all. Political participation, regulatory influence, and even data collection are power games that are played out in plain view in the courts, in conference committees and legislative markups, and in the fine print of regulations. Money may still speak loudest, but, as the traveling salesman in *The Music Man* advised his fellow passengers, to guarantee success, "You gotta know the territory."

Philip Morris knows the territory. They hired the "big guns." Tobacco, once legal tender, has long been under siege. Researchers, typically sheltered from such engagements, may have been unaware of the stakes of the game, of the armament arrayed to obstruct their efforts at data gathering. The paper that follows tells the story of how perseverant, combative, unrelenting attention and effective interest-group mobilization rewarded an industry while undermining equally legitimate efforts to collect data. The result was a missed opportunity to document the incidence of external contributors to disease. Now that the smoke has cleared, researchers can expect future scrutiny by interest groups. Like the man said, "You gotta know the territory."

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**ABSTRACT:** A new medical diagnostic code for secondhand smoke exposure became available in 1994, but as of 2004 it remained an invalid entry on a common medical form. Soon after the code appeared, Philip Morris hired a Washington consultant to influence the governmental process for creating and using medical codes. Tobacco industry documents reveal that Philip Morris budgeted more than \$2 million for this “ICD-9 Project.” Tactics to prevent adoption of the new code included third-party lobbying, Paperwork Reduction Act challenges, and backing an alternative coding arrangement. Philip Morris’s reaction reveals the importance of policy decisions related to data collection and paperwork.

RECENTLY, THE BUSH ADMINISTRATION has been subject to charges of “abuse of science.”<sup>1</sup> Science is vulnerable to pressure from politicians and from private industry.<sup>2</sup> For example, decisions about data collection policy are often contested in the political arena by various interests.<sup>3</sup> According to a *Los Angeles Times* story in 1995, one controversial case has been the tobacco industry’s response to the collection of data on secondhand smoke.<sup>4</sup> In December 1993 the U.S. government adopted a medical code for secondhand smoke as an external cause of illness or injury, in response to requests from coders and also in light of the Environmental Protection Agency’s (EPA’s) 1992 risk assessment of secondhand smoke.<sup>5</sup> The tobacco industry responded swiftly.

To better understand the tobacco industry’s involvement with the code, we conducted a search of once-private internal tobacco industry documents. The industry succeeded in making the new code invalid for use on the national standard Medicare billing form, Form 1500. We describe Philip Morris’s three-stage strategy that invalidated this most common use of the code. These findings evoke a discussion of the consequences of paperwork policy and private industry participation in regulatory politics. Data collection launches the policy process by revealing and describing problems, and, moreover, paperwork imperatives can affect the clinical practice of medicine.<sup>6</sup> We argue that a medical code for secondhand smoke should be allowed on the Medicare form.

■ **Data sources and study methods.** We performed qualitative analysis on an archive of internal tobacco industry documents, which includes memoranda, budgets, strategic plans, and reports.<sup>7</sup> The documents were made public through litigation brought by the State of Minnesota and Minnesota Blue Cross/Blue Shield and the subsequent 1998 Master Settlement Agreement (MSA) with state attorneys general.<sup>8</sup> A search of nearly forty million pages of indexed tobacco industry documents, maintained electronically at the Legacy Tobacco Documents Library of the University of California, San Francisco (UCSF), was completed between 15 September 2003 and 1 March 2004.<sup>9</sup>

We used standard searching techniques; we began with keywords such as “ICD,” “E-code,” and “MBS,” which revealed other search terms such as key names and document identification (Bates) numbers.<sup>10</sup> Documents were independently evaluated by two of the study authors to determine any evidence of industry par-

ticipation in the federal process for creating and using *International Classification of Diseases*, Ninth Revision, Clinical Modification (ICD-9-CM) codes. Two study authors reviewed the searches and agreed on relevance by consensus. We found eighty-one relevant documents, and we organized and summarized these chronologically from 1993 to 1998. The data from these documents were supplemented with information from government agency Web sites and telephone conversations with government officials.

■ **Background on the secondhand smoke code.** Diagnostic medical codes are used in the United States on Medicare and other forms for billing and tracking purposes. The U.S. government adopts and modifies the World Health Organization's (WHO's) ICD mortality codes to create a coding scheme for the collection of data on morbidity known as the Clinical Modification (CM). The E-codes indicate external causes of injury or illness. According to the ICD-9-CM instruction manual, E-codes "are intended to provide data for injury research and evaluation of injury prevention strategies."<sup>11</sup> The data from E-codes have allowed public health researchers to assess the costs of injuries nationwide and to focus on costs of specific causes of injury.<sup>12</sup> About half of the states either require or voluntarily use E-codes upon hospital discharge.<sup>13</sup>

The National Center for Health Statistics (NCHS) has an ICD-9 Clinical Modification Coordinating Committee that meets regularly to approve new codes, usually without controversy. The NCHS is not required to give advance notice when considering new E-codes because they are not used in payments. The secondhand smoke code was officially published in October 1994.

### **The Philip Morris ICD-9 Project**

Through its Worldwide Regulatory Affairs office, Philip Morris began its ICD-9 Project in 1994. Internal Philip Morris documents contain copies of the ICD-9 Project budget for three years, which totaled approximately \$2.2 million: \$531,000 for 1994, \$1,017,750 for 1995, and \$690,000 for 1996.<sup>14</sup> James Tozzi and Multinational Business Services (MBS) were the recipients of most of these budget allocations. The Washington consulting firm Barrera Associates also billed Philip Morris for work on ICD-9 in 1994.<sup>15</sup> The 1996 Philip Morris budget preparation indicates that of the \$690,000 allocated, the company expected that \$600,000 would go to MBS and \$90,000 to the law firm Shook Hardy Bacon.<sup>16</sup> We found examples of monthly invoices from MBS for \$8,000 in February 1994, \$65,000 in July 1995, and \$65,000 in January 1996, specifically for work on ICD-9-CM.<sup>17</sup>

MBS was founded in 1983 by James Tozzi, who had been an official with the federal Office of Management and Budget (OMB) for nearly twenty years.<sup>18</sup> Tozzi helped write the Paperwork Reduction Act of 1980, which created the Office of Information and Regulatory Affairs (OIRA).<sup>19</sup> That law required that all government forms involving data collection receive approval from OIRA.<sup>20</sup> After retiring from government, Tozzi offered his regulatory expertise to private industry clients

such as Philip Morris and has worked to minimize business regulation.<sup>21</sup> He contributed, for example, to Philip Morris's "Good Epidemiology Practices" plan to counteract scientific evidence on secondhand smoke.<sup>22</sup>

Philip Morris sought to keep its relationship with MBS secret. The contract between Philip Morris and MBS, dated 1 January 1995, stipulates that if "contacted by a third party, including the media," MBS should not comment and should notify Philip Morris of the contact.<sup>23</sup>

The ICD-9 Project had three phases. First, Philip Morris and MBS tried to prevent the code's creation and adoption in 1993 and 1994. When that failed, they challenged the code's validity on a Medicare billing form in 1994 and 1995. They then advocated for a new alternative coding system in 1996 and beyond.

The documents reveal that Philip Morris feared several developments, including the "empowerment" of physicians to "arbitrarily" blame illness on secondhand smoke.<sup>24</sup> A report submitted to Philip Morris by MBS in October 1994 made clear that "by adding ETS [environmental tobacco smoke] to the E-Code, NCHS and HCFA [Health Care Financing Administration, now the Centers for Medicare and Medicaid Services, or CMS] have essentially authorized individual physicians to attribute illnesses and deaths to ETS, despite the lack of scientific evidence establishing that ETS could cause such harm."<sup>25</sup> Even though E-codes (used for tracking) are not used for billing, they are in close proximity to billing codes and the Medicare reimbursement system. A memo from MBS to Philip Morris argues that the secondhand smoke E-code "would provide an incentive for people to claim illnesses related to second-hand smoke," and, the memo adds, "it would directly link second-hand smoke to national health costs."<sup>26</sup>

■ **Phase 1: attempt to prevent the code's adoption.** Philip Morris, via MBS, tried to challenge the legitimacy and publication of the new secondhand smoke code. Their approach was threefold. First, they held private meetings with several officials, including one meeting with the NCHS director, the branch chief for morbidity classification, and the associate director of the Office of International Statistics.<sup>27</sup> MBS consultant Thorne Auchter reported on the content of this meeting to Philip Morris Worldwide Regulatory Affairs senior analyst Mayada Logue, informing her that the NCHS director suggested that MBS could submit guidelines that "would be used by doctors to ensure consistency in their decisions to list ETS as a causative agent."<sup>28</sup> In that memo MBS recommended that Philip Morris "draft guidelines which will make it very difficult to designate ETS as the cause of a disease."

Second, MBS arranged for letters objecting to the code to be sent from various interested parties to the NCHS: a toxicologist (retired government official Alexander Apostolou of Maryland), a state trade association (Associated Industries of Florida Service Corporation), and themselves as experts in the regulatory process.<sup>29</sup> MBS originally considered also finding a physician to write a letter objecting to the code, but this was never done (a handwritten note on the memo proposing this reads, "not a good idea").<sup>30</sup>

When the tobacco industry follows an issue, the document files often contain correspondence and papers from other parties working on the same issue. In this case, we found no evidence of attempts by other industries or other interested parties not mobilized by Philip Morris to influence the creation and implementation of a secondhand smoke code.

Third, MBS requested that the OMB review the new code for approval under the Paperwork Reduction Act on the grounds that the codebook acts as an appendix to federal forms, so that addition of new codes was a “change of schedule” for previously approved data collections.<sup>31</sup> This argument would be repeated later in a detailed legal analysis sent to the OMB during the process of approving a specific medical form. There is no evidence in the documents of a government response to this procedural-legal objection to the new code. The code was published as planned in October 1994. However, these questions about legitimacy raised by MBS might have contributed to the success with the OMB in what we call phase 2.

■ **Phase 2: invalidate the code’s principal use.** Philip Morris and MBS next challenged the use of E-codes as an entry on one of the most common billing forms, the Medicare Form 1500. This form, titled the Health Insurance Claim Form, is often used by other insurance plans and is the nationwide standard billing form. Coincidentally, OMB approval of this form expired 30 September 1994, around the time of the new secondhand smoke E-code’s release. Under the Paperwork Reduction Act, agencies collecting data must justify doing so to the OMB in order to receive approval for all forms. MBS sent a twenty-four-page report to the OMB about “inaccurate health statistics” in October 1994.<sup>32</sup> MBS claimed that agencies must show “practical utility” of data collection. Secondhand smoke is mentioned only once in the report as part of a list of E-codes; the report focused on those codes, describing what it calls “chronic” exposures. MBS used three major points to dispute the utility of the data collection. (1) E-codes could not be reliably used for statistical analysis because of the large number of nonresponses. They claimed that physicians do not always provide enough information to coders about possible external causation of illness. (2) MBS raised the prospect of third-party liability claims against the government for hazardous substances: “Unreliable and insupportable statistics will be used to impose substantive liability. In the case of putative chronic causes such as radio frequency emissions, such attribution would have a direct, deleterious economic impact on such Federal agencies as the Departments of Defense and Energy.” MBS had noted that silicone, PCBs, asbestos, latex, and dioxin were proposed as new E-codes in 1994, one year after the secondhand smoke code was approved.<sup>33</sup> (3) The E-codes are an undue diagnostic burden on physicians, who would have difficulty ascertaining external causes in many cases.

Another MBS argument in the same report was that E-codes describe acute rather than chronic causes, which suggests that the secondhand smoke code would be a major departure from established data collection policy. This argu-

ment was rebuffed by NCHS officials, who denied that existing E-codes were used exclusively for acute causes.<sup>34</sup> In fact, existing E-codes were used to link active smoking to disease. MBS requested with its report that the OMB strike all E-codes from Form 1500, or at least strike the chronic E-codes. The OMB did withhold its approval of Form 1500 in November 1994, because of lack of evidence of the codes' practical utility. A Philip Morris internal memo gave credit for this victory to the MBS report.<sup>35</sup>

The Public Health Service (PHS) formed a task force to respond to the OMB and appeal the decision on Form 1500. During this appeal process, MBS produced another paper, entitled "E-Code Confusion: The Problem of Attributing Causation to Remote, Non-Proximal Events or Sources." According to an internal memo from Tozzi to Philip Morris, this paper was sent to many government officials.<sup>36</sup> In June 1995 MBS attorneys also sent a detailed legal analysis to the NCHS and the OMB repeating the previous argument that the ICD-9-CM itself was a form of data collection and should be reviewed by the OMB independent of Form 1500.<sup>37</sup> The PHS task force appeal failed to prove the utility of E-codes in December 1995, and the E-codes were not approved for use on the form.<sup>38</sup>

■ **Phase 3: advocate an alternative coding system.** Philip Morris and MBS proposed that the government and medical coding community adopt a new coding system, the Nordic Medico Statistical Committee (NOMESCO) model. MBS suggested that the United States and the WHO use NOMESCO codes in place of ICD E-codes to (in their view) better describe injuries. To advocate the alternative codes, MBS convened the First Annual Conference on Improving Clinical Data Bases for Health Policy Development in the summer of 1996.<sup>39</sup> In November 1996 MBS wrote a letter to the NCHS and HCFA explaining the findings of the conference proceedings and urging the NCHS to adopt the NOMESCO injury codes in place of ICD E-codes.<sup>40</sup> This letter explains that NOMESCO avoids the "uncertainty" of the "new chronic E-codes."

MBS also drafted a "Dear Colleague" letter urging various interest groups to write to HCFA with the same information and the demand that Form 1500 be delayed until public comment was sought for NOMESCO codes.<sup>41</sup> The American Health Information Management Association, an association of medical data professionals, responded negatively to the letter with a press release supporting the E-codes and urging its constituents to write to the federal government to counteract the efforts of MBS.<sup>42</sup>

There is no evidence in the tobacco industry documents that the agency task force or the OMB considered NOMESCO proposals during its review of E-codes and Form 1500. Nevertheless, this advocacy for NOMESCO continued beyond 1996. A December 1998 MBS memo to Philip Morris suggested that the tobacco company continue promoting NOMESCO by publicizing its use in Europe and developing a "primer" on the system.<sup>43</sup> However, the ICD-10-CM is in development for U.S. use, and it will not include NOMESCO codes. Still, the NOMESCO codes

are the basis of International Classification of External Causes of Injuries (ICECI), a recent project of the WHO aimed at better injury classification.<sup>44</sup> It is not clear from the documents if the tobacco industry has been involved in influencing the adaptation of the NOMESCO coding system for the ICECI supplement to the ICD-10, but the tobacco industry has a history of trying to influence the WHO and other standard-setting bodies.<sup>45</sup>

### **Discussion: The Power Of Paperwork And Data Collection**

Using the Paperwork Reduction Act as a foundation, MBS used multiple arguments that enacting a secondhand smoke code would be costly and inappropriate. Yet the industry documents reveal the contradictions between MBS's public arguments and Philip Morris's true motivations. First, MBS argued that physicians do not provide enough information for assessing external causes of injury and would be a poor data collection source. However, removing E-codes from the CMS form prevents Medicare from documenting sources of injury and itself weakens the validity of E-codes as a data source.

Second, MBS argued that such coding would place an undue administrative burden on physicians. This burden at most would be asking the patient or his/her family about secondhand smoke exposure. In contrast, MBS's privately acknowledged fear was that physicians could document that secondhand smoke causes disease and would be mobilized on the issue of smoke-free environments.<sup>46</sup>

Third, MBS argued that E-codes were not appropriate for describing the causes of chronic conditions. The tobacco industry has previously used similar arguments in denying a causal link between active smoking and lung cancer or cardiovascular disease.<sup>47</sup> The E-codes could contribute to tracking multifactorial etiologies of chronic disease, and some acute medical problems such as asthma exacerbations can be easily attributable to secondhand smoke exposures.<sup>48</sup>

Finally, MBS argued that third-party liability claims would be a threat to the government. However, Philip Morris was concerned about the threat to the industry. The company actually faced litigation by the state governments at the time to recover Medicaid costs from smoking.<sup>49</sup> It expected that E-code data could play a role in those lawsuits.<sup>50</sup> With Medicare data on secondhand smoke exposure prevalence, the tobacco industry could face higher financial damages with additional estimates of health care costs stemming from secondhand smoke.<sup>51</sup> This strategy of distraction with multiple tactics is typical of the industry. For example, when faced with a secondhand smoke regulation from the Occupational Safety and Health Administration (OSHA) at the state or federal level, the industry produced numerous responses that distracted the agencies.<sup>52</sup>

The E-code controversy is an example of the importance of federal paperwork regulation. The U.S. government exercises considerable power when establishing classification schemes and requiring mandatory submission of documents such as medical claim forms.<sup>53</sup> Likewise, the statistics gathered by the government on

forms can be politically motivated and can evoke political responses.<sup>54</sup> Political insiders such as officeholders and organized interest groups will try to change the rules for their own future benefit, and business interests often enjoy policy victories on narrow and technical regulatory decisions.<sup>55</sup> This fact suggests that the private sector will try to influence the rules about data collection.

A study of several clinical care tools, forms, and protocols in practice found that data were often modified to fit imperfect categories and that data collection mandates can develop into clinical protocols.<sup>56</sup> Statistical data thus obtained could link exposure to environmental toxins, such as secondhand smoke, with disease and could support efforts to enact regulation by providing the data necessary to justify such intervention. The health dangers of secondhand smoke are increasingly well known; it is estimated that secondhand smoke increases the risk of heart disease by 30 percent and may account for 53,000 deaths annually in the United States.<sup>57</sup> The tobacco industry has continually fought to counteract scientific consensus that secondhand smoke causes disease.<sup>58</sup> The creation of an ICD-9-CM code for secondhand smoke had potentially serious consequences for the industry because it could be used to obtain data on the effects of secondhand smoke on the incidence and causes of diseases.

Executive-branch bureaucratic structures allow several points of access to policy making for organized interests. In addition, private industry can successfully use the federal Paperwork Reduction Act to challenge data collection. Philip Morris hired a former OMB official who took full advantage of laws and rules he had helped to create. Often these matters are managed by career bureaucrats, but the OMB has been under considerable (and increasing) political control from the White House.<sup>59</sup> An NCHS staff person present at the time confirmed that rarely, if ever, has the creation of new E-codes been challenged in this manner.<sup>60</sup> Relevant agency officials might have been unaware of the interest-group politics behind the procedural disputes.<sup>61</sup> In this case, Philip Morris prevailed on the second part of its three-part plan to shape the classification scheme and prevent data collection for more than ten years. The major health care reimbursement form in use today cannot solicit the E-code for secondhand smoke.

**T**HE CMS FORM 1500 EXPIRES 31 MARCH 2006 and will need OMB reapproval; this presents an opportunity to readdress the issue by allowing all E-codes, including secondhand smoke, back on the form.<sup>62</sup> Successful lobbying by MBS has had a wide impact for different industries in which chemical exposures or occupational hazards are not documented. The agency will presumably solicit public comment on any changes to the form. The public health sector should be prepared to respond and to be attentive to any challenge to the form from private industry. Meanwhile, the ICD-10-CM, when it comes into use, contains some major changes in medical coding.<sup>63</sup> The secondhand smoke exposure code will be found under Z58.83.<sup>64</sup>

The tobacco industry has thus far undermined the collection of data on second-hand smoke's relationship to illness. These findings exemplify the use of politics to influence science. The medical and public health communities need to be made aware of these different codes and the potential for tobacco industry interests to undermine their use.

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 This work was supported by the American Legacy Foundation; the California Tobacco-related Disease Research Program, Grant no. 9RT0193; the National Cancer Institute, Grant no. CA-87472; and a National Research Service Award, Grant no. 1-T32-HP 19025. All four authors take responsibility for the content of the paper. Neither the authors nor their employers stand to benefit from the public response to this paper. The authors thank the anonymous reviewers for their valuable comments.

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