Environmental Health Policy

IDENTIFYING CARCINOGENS: THE TOBACCO INDUSTRY AND REGULATORY POLITICS IN THE UNITED STATES

Daniel M. Cook and Lisa A. Bero

The process of identifying carcinogens for purposes of health and safety regulation has been contested internationally. The U.S. government produces a "Report on Carcinogens" every two years, which lists known and likely human carcinogenic substances. In the late 1990s the tobacco industry responded to the proposed listing of secondhand smoke with a multi-part strategy. Despite industry efforts to challenge both the substance of the report and the agency procedures, environmental tobacco smoke was declared by the agency in 2000 to be a known human carcinogen. A subsequent lawsuit, launched by chemical interests but linked to the tobacco industry, failed, but it produced a particular legal precedent of judicial review that is favorable to all regulated industries. The authors argue that, in this case, tobacco industry regulation contradicts academic expectations of business regulatory victories. However, the tobacco industry's participation in the regulatory process influenced the process in favor of all regulated industry.

Business interests play a critical role in the development of regulatory policy worldwide (1). Since the 1990s, regulation of health and environmental risk in the United States has lagged that in the European Union (2). This article specifically examines a public health program in the United States: the Report on Carcinogens (3). Identification of carcinogens for regulatory purposes has been contested by industry internationally, while cancer incidence worldwide escalates (4–6).

Given the tendency of interested parties to seek preferences in regulation, we expected that the tobacco industry, in response to a 1998 proposal to list secondhand smoke, or environmental tobacco smoke, as a known human carcinogen, would try to influence an agency decision using a three-part strategy: (*a*) extensively utilize the procedures for public comment, (*b*) attack the fairness of the regulatory process

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itself, and (*c*) challenge unfavorable regulatory decisions in court (7, 8). Our evidence supports this expectation and a broader thesis that business interests dominate the regulatory process and seek procedural changes in order to institutionalize future advantage. But this case also raises an interesting puzzle because industry interests lost, and secondhand smoke was listed as a carcinogen. Therefore, we explore reasons why business might lose in regulatory politics.

We argue that tobacco industry regulation belies expectations of previous policy models. We introduce the theoretical background that leads us to further study of business and regulatory politics, and present the tobacco industry's strategy to influence a regulatory decision, as revealed by internal tobacco industry documents. We discuss the implications of these findings for regulatory politics and policy access points, considering any systemic favoritism. In the conclusion we discuss the implications of an instance in which the industry position loses; the tobacco industry's policy preference lost in this case when direct and indirect tobacco smoking were listed by the U.S. Public Health Service as known human carcinogens.

THEORETICAL BACKGROUND

Previous academic work on business participation in the regulatory process informs this study, but does not accurately predict the findings. The literature on the privileged position of business in regulation is substantial (9–11). But first, how does business decide to enter the policy process at a specific time? According to Cathie Jo Martin's more recent work (12), business participates in policymaking under very particular conditions. Martin states that three factors influence a corporation's involvement in the policy process: the capacity of policy experts within the firm, participation in business groups, and past experience with "policy legacies" (12, p. 31). The tobacco industry can serve as a test of her argument, as previous studies have revealed information about many of the conditions for participation that she requires. The tobacco industry employs policy experts, joins business groups, and has extensive past policy experience both positive and negative (8, 13, 14).

Martin suggests conditions under which business will participate, and Mark Smith (15) considers when business will successfully influence regulation. Smith's work predicts that business will be most influential over more technical and detailed regulatory policy. He argues that the minutiae of administrative rulemaking escape public notice, which increases business influence. However, both Smith and Martin argue that the privileged position of business power is often mitigated by private sector fractionalism, and that on controversial issues that attract major public attention, business often fails to influence the outcome.

Yet even while tobacco control in the United States has been more successful since 1984 (16), the tobacco industry has responded to recent attempts at federal regulation with impressive force. Despite the increased public attention in the 1980s and 1990s on the public health problems associated with tobacco, the industry has continued to enjoy many policy victories. For example, when the Occupational

Safety and Health Administration (OSHA) was crafting a smoking-related indoor air quality rule from 1994 to 2001, the tobacco industry responded with a strategy of delays and scientific debates until the proposal was withdrawn (8). The industry also stopped potential regulation from the U.S. Food and Drug Administration (FDA) with a lawsuit (16). The industry is not always publicly united, however, as in the recent case of defeated FDA regulation proposals, when Philip Morris supported legislation opposed by the other tobacco companies (17).

Business interests do more than change policy: the very structures of policymaking are often changed, and these changes constrain future policy action (18). The path-dependent nature of regulatory politics is often overlooked by theorists. This study presents several examples of procedural and institutional developments that enhance the position of the regulated industry in future contests. In a recent article examining pharmaceutical company regulation, Daniel Carpenter (19) argues that the "systematic advantages" afforded certain businesses can derive not only from politics but also from bureaucratic behavior intending "neutrality." Carpenter finds that regulatory administration could never be neutral and will produce biased outcomes for various reasons, but he seemingly does not consider a broader view that bureaucratic decision-making procedures, even if in pursuit of neutral policy goals, are themselves creatures of the American political system of regulation that, since its creation, has produced an institutional legacy of privilege and benefits for business interests (20).

A previous case specifically instructs how the tobacco industry might respond to a government declaration on the carcinogenicity of its products. When the U.S. Environmental Protection Agency (EPA) published a risk assessment study that declared secondhand smoke caused lung cancer, the industry responded with overwhelming public comments (7), numerous procedural challenges, and lawsuits that were eventually successful in vacating the study (later reinstated) (21). Later, the industry responded similarly to the California Environmental Protection Agency risk assessment of 1997 (22). We would expect the industry to behave similarly in response to the second attempt by the federal government to declare the carcinogenicity of tobacco smoke for a report to be published in 2000.

Outside the United States, the tobacco and chemical industries have successfully influenced the evaluation process at another agency that makes lists of carcinogens, the International Agency for Research on Cancer (IARC) at the World Health Organization (23, 24). Many countries worldwide, including China, follow the IARC evaluations of carcinogenicity (25, 26). The Nordic countries have a separate identification process; environmental tobacco smoke is an "ongoing project" of the Nordic countries, while in Finland the tobacco industry tried but failed to keep tobacco off the carcinogen list (27–29). When the European Community proposed a new program in 2001 for registration, evaluation, and authorization of chemicals ("REACH") that would identify associated health risks using the "precautionary principle," industry protested vigorously and won a few concessions (2, 30, 31). Despite this challenge and

others, the REACH program continues to follow the precautionary principle and serves as a model of stronger regulation of industrial chemicals (2).

With notable exceptions, there is less analysis of when business loses in the regulatory process (32). The policy literature seemed to anticipate a tobacco industry victory on the secondhand smoke proposal, but we found the opposite. In fact, the historical pattern of tobacco industry regulation is arguably the opposite of Mark Smith's model: the more conspicuous regulatory proceedings have favored the industry, while the industry has lost on more narrow technical questions.

METHODS

We conducted qualitative analysis on archival tobacco industry documents made public through litigation to determine whether the tobacco industry acted as predicted by the literature on business participation in the regulatory process. The documents give us unique insight into the response from the tobacco industry to the National Toxicological Program (NTP) regulatory process (33). We searched the electronic Legacy Tobacco Documents Library of the University of California, San Francisco (http://legacy.library.ucsf.edu) between October 1, 2003, and March 1, 2004. We searched keywords such as "NTP," "Report on Carcinogens," and "RoC," which revealed other searchable names, keywords, and files. We identified 65 documents as relevant and analyzed them chronologically. To triangulate our data sources, we also examined government websites and other public records.

THE NATIONAL TOXICOLOGY PROGRAM AND THE REPORT ON CARCINOGENS

The National Toxicology Program was created in 1978 by the U.S. Department of Health and Human Services in response to Public Health Services Act requirements that the government provide information about toxicity of chemicals. The NTP's mission "is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology" (34). The program was created as the "first systematic evaluation of the universe of substances," and provides scientific evidence for government regulation (35). In her book on science advisors, Sheila Jasanoff (36) explains that the NTP quickly became "the primary institutional focus of federal efforts to forge stronger links between toxicological research and regulatory needs."

In fact, earlier research has revealed that the tobacco industry successfully influenced a particular NTP division. Operation of the NTP Center for Evaluation of Risks to Human Reproduction (CERHR) is contracted out to the group Sciences International, led by a scientist with tobacco industry ties (37). The CERHR has evaluated the teratogenic properties of nicotine, but has deferred making any recommendations (38, 39). The tobacco industry monitored these proceedings and provided scientific information on nicotine to the

CERHR (40). The same government inaction might easily have occurred regarding the carcinogenicity of secondhand smoke.

A principal function of the NTP is to issue the Report on Carcinogens (RoC), which currently lists 246 substances "known" or "reasonably anticipated to be" human carcinogens. The first report was issued in 1981, and the eleventh report was released in January 2005 (3). The process for listing or delisting a substance in the report consists of several steps (Figure 1). In all, each nomination is subject

Step 1: Nomination
- Lists or delists substances as known or reasonably anticipated to be human carcinogens
- Contains rationale for listing with supporting background and data
- Accepted or rejected by RG1 for further review
- If rejected by RG1, petitioner invited to revise and resubmit

Step 2: RG1 (Review Committee)
- Consists of NTP staff
- Accepts or rejects nominations to begin process
- Announces accepted nominations and solicits public comment
- Makes background document public
- Conducts scientific review, considers public comment
- Recommends listing or delisting in RoC

Step 3: RG2 (Interagency Working Group)
- All government regulatory agencies represented
- Considers all public comments and the nomination documents
- Recommends listing or delisting in RoC

Step 4: Board of Scientific Counselors RoC Subcomittee
- External peer review
- Open public meeting
- Solicits public comment
- Recommends listing or delisting in RoC

Step 5: Final Public Comment
- All recommendations published and public comment solicited

Step 6: Final Approval and Publication
- NTP executive committee reviews all above and recommends listing or delisting
- NTP director reviews all above and recommends list, delist, or no action
- Secretary of Health and Human Services approves director's recommendation, sends to Congress
- NTP publishes latest edition of RoC with new items indicated

Figure 1. Report on Carcinogens (RoC) listing/delisting process. *Source*: NTP (3, sect. V).

to three public comment periods and multiple reviews by different committees, including nongovernmental advisors. This extensive RoC process is only the first step in U.S. environmental health policy, as it represents the "hazard identification" stage of a complete quantitative risk analysis of substances (41).

The Report on Carcinogens influences the regulatory decisions of other agencies and government sectors. A listing as "known human carcinogen" can incite federal and state regulatory agencies to prevent exposures (41). Of the possible consequences from RoC listing, a pro-industry legal analysis exclaims, "none of them are good" (42). We derive the following list of consequences from that analysis. RoC status can trigger OSHA's requirements for how carcinogenic substances are handled in the workplace (43). There are also various disposal and hazardous waste restrictions, including Clean Water Act rules, that are influenced by the RoC. Listed substances have a good chance of making the California Proposition 65 list, which triggers "significant warning and labeling requirements" for carcinogenic substances (42). Various other programs and initiatives will follow NTP publication of a known human carcinogen. The regulatory lawyers raise the possibility of "the demise of entire product lines" (42).

Below we explain what the internal tobacco industry documents reveal about the RoC listing process for tobacco smoking and environmental tobacco smoke, and the actions taken by the industry to influence that process. We find, as expected, that the tobacco industry first challenged the substance of the decision, then challenged the procedures themselves, and finally brought litigation.

THE REPORT ON CARCINOGENS AND THE TOBACCO INDUSTRY

The tobacco industry has monitored the NTP Report on Carcinogens since at least 1982. The tobacco document archive contains a 1982 R.J. Reynolds memo reporting the latest data on benzene (which is found in cigarette smoke) and its regulation. The memo explains that benzene appeared in the Second Annual Report on Carcinogens of that year (44). The tobacco industry was naturally interested in the RoC when in 1997 the NTP proposed listing direct tobacco smoking in the Ninth Report. An unsigned December 17, 1997, memo marked "confidential, attorney work product," found in Scientific Affairs Vice President Richard Carchman's files at Philip Morris, recommends actions in response to the NTP process (45). This memo concedes that direct tobacco smoking will likely be listed and so recommends monitoring the process only. It suggests that for the future, "it is possible to file a petition to delist a substance" (45, p. 2). The memo also considers the possibility that environmental tobacco smoke (ETS) will be listed in the Report on Carcinogens, which NTP staff had indicated might be considered soon. The memo recommends watching the situation closely and preparing to submit comments if ETS is nominated to the list.

Soon, environmental tobacco smoke was indeed nominated to the Ninth Report for consideration in 1998. An unsigned memo written on January 23, 1998, from

someone at the law firm Shook Hardy & Bacon reports the newly proposed listing to Philip Morris after finding it on the NTP website (46). The nomination apparently derived from the review of direct tobacco smoking for the same report the previous year and put ETS under review of RG1, the second step in the listing process (see Figure 1) (47). The Shook Hardy & Bacon memo also suggests that opportunities for public comment will be many, and recommends continuing monitoring and submitting comments.

In addition to the clear implications of having tobacco smoking and environmental tobacco smoke declared as known human carcinogens, Philip Morris had a more immediate concern related to regulatory policy. As mentioned above, OSHA was developing workplace smoking regulations at the same time as the NTP listing process, but these regulations were eventually withdrawn in 2001 after the tobacco industry used multiple strategies over 10 years to defeat them (8). An attorney from Philip Morris's legal firm Shook Hardy & Bacon wrote a memo explaining the NTP's link to OSHA's pending regulation on secondhand smoke. On November 13, 1998, Leo Dreyer wrote to Philip Morris executives Asante, Berlind, Keane, Whidden, and Winokur that an OSHA representative sits on the NTP executive committee and that the evidence presented to that committee could influence OSHA's own work. He noted that this "could be a catalyst for OSHA to take specific action" (48). In fact, this NTP listing process was unfolding late in the OSHA process as the secondhand smoke rule was losing agency support, and new evidence from the NTP could have reinvigorated the OSHA rule.

The tobacco industry researched the backgrounds of the relevant members of NTP's board of scientific counselors. A memo from attorney Leo Dreyer addressed to five Philip Morris executives (Asante, Carchman, Koller, McAlpin, and Winokur) provides short biographical paragraphs of the members of the NTP Board of Scientific Counselors Report on Carcinogens subcommittee, who were scheduled to meet in December (49). One member of the subcommittee was toxicologist Carol J. Henry, Ph.D. Henry had a past relationship with the tobacco industry, as the Dreyer memo notes. In 1982 she was on the staff of Microbiological Associates when that group was finishing work on a $13 million, 10-year contract with the Council for Tobacco Research (50).

In his book on the tobacco industry, Richard Kluger (51) reports that the Henry study, involving smoke inhalation by thousands of mice, was scientifically flawed and yet was published by the Council for Tobacco Research "in a misleading and confusing way that was close to fraudulent." Henry explained in an affidavit in 1998 that the Council for Tobacco Research misrepresented some of her scientific findings from this research and cancelled the contract early, after some disagreements (52). According to Kluger, Henry was going to conclude that cigarette smoke was carcinogenic (51). After the Council's study, Henry was a consultant to Lorillard in 1986 (53). She participated in the discussion of listing ETS, raising a few questions about the preponderance of evidence of risk

presented to the committee. The committee voted unanimously to list ETS as a known human carcinogen in December 1998.

Challenging the Evidence

Before the vote, the tobacco industry tried all means of influence over the public proceedings of December 2 and 3, 1998. First, it coordinated the appearance of several speakers in opposition to the Report on Carcinogens listing (Table 1); ETS had by far the most speakers. A list of the scheduled "5 Minute Public Presentations" at the meeting shows 13 speakers for ETS, 4 for dioxin, 4 for diesel exhaust, 2 for alcoholic beverages, and others (54). According to the meeting transcript, 2 ETS speakers from the original schedule did not appear. Of the 11 speakers testifying on ETS, all except James Repace represented the industry view that the evidence linking ETS to cancer was deficient. An industry newsletter explains that "all but one of the presentations made by other groups were opposed to classification of ETS as a known human carcinogen" (55). The tobacco industry documents suggest that the industry coordinated these speakers. For example, an e-mail from epidemiologist Paul Levy of the University of Illinois at Chicago to NTP asking to make a presentation at the meeting on ETS appears in the document collection as a fax from Womble Carlyle, the R.J. Reynolds–affiliated law firm (56). In his message, Levy promised to address the meta-analysis findings of A. J. Wells that the NTP committee was considering, and to present his own analysis. Wells (57) had found an association between ETS exposure and lung cancer.

The tobacco industry was in communication with a multi-industry coalition that monitored the NTP Report on Carcinogens. The tobacco documents contain an agenda for an "NTP Discussion" held in September 1998 at the American Industrial Health Council, an industry coalition created 20 years previously to "counter the concept that a major cause of cancer is the increased manufacture of industrial chemicals." The agenda contains an argument that the process for listing butadiene (considered at the same time as direct tobacco smoking) was flawed (58). 1,3-Butadiene is "produced through the processing of petroleum" and is also found in cigarette smoke (59). The butadiene industry has fought classification of 1,3-butadiene as carcinogenic by OSHA and by several other government agencies worldwide (43).

In January 1999 the NTP published the decisions of RG1, RG2, and the NTP board for each substance, and announced the preliminary choice to list ETS and alcoholic beverage consumption as known human carcinogens (60). Diesel engine particulate matter was recommended as "reasonably anticipated to be a human carcinogen." Dioxin was also considered for the list at the same time as ETS. After the RG1 and RG2 panels unanimously recommended upgrading dioxin to known carcinogenic status, the advisory committee (step 4 in Figure 1) narrowly voted to keep dioxin listed as "reasonably anticipated" to be a human carcinogen (60). Dioxin is a by-product associated with incineration, bleaching, and other

Table 1

Public presentations, National Toxicology Program Board of Scientific Counselors: Report on Carcinogens subcommittee meeting, December 2–3, 1998, by order of appearance at the meeting

Hazardous substance	Name	Affiliation
2,3,7,8-TCDD (dioxin)	Jim Tozzi	Center for Regulatory Effectiveness
	Nathan Karch	Vinyl Inst.
	Raymond Greenberg	Chlorine Chemistry Council CMA
	Thomas Starr	American Forest & Paper Assn.
Isoprene	Philip Leber	Intl. Inst. of Synthetic Rubber Production
Alcoholic beverage consumption	William Waddell	Beverage Alcohol Industry
	Emanuel Rubin	Jefferson Medical College
Environmental tobacco smoke	Roger Jenkins	Center for Indoor Air Research
	Keith Phillips	Covance Labs
	Chris Coggins	Lorillard Tobacco
	Paul Levy	Univ. of Illinois, Chicago
	James Repace	Repace Associates
	Richard Carchman	Philip Morris USA
	William Butler	R.J. Reynolds Tobacco
	Gerhard Scherer	German Assn. of Cigarette Manuf.
	Gio Gori	Brown & Williamson Tobacco Co.
	Ronald Marks	Univ. of Florida
	Maurice LeVois	Tobacco Inst.
Silica, crystalline	Robert Glenn	Crystalline Silica Panel, CMA
	William Moll	Sorptive Minerals Inst.
	David Crawford	Clorox
Ethylene oxide	Julian Preston	Chemical Industry Inst. of Toxicology
	M. Jane Teta	Union Carbide
	Sara Schotland	Ethylene Oxide Industry Panel
	Ralph Gingell	Shell Chemical Co.
Diesel exhaust particulates	Jeff Terry	Engine Manufacturers Assn.
	Kathleen Nauss	Health Effects Inst.
	Joe Mauderly	Lovelace Respiratory Research
	Bill Bunn	Navistar
Methyl-tert-butyl ether	Susan Borghoff	Chemical Industry Inst. of Toxicology
	Larry Andrews	Oxygenated Fuels Assn.
Ethyl acrylate	Sandra Murphy	Basic Acrylic Monomer Manuf.
Nickel compounds	Adriana Oller	Nickel Producers Enviro Res. Assn.
Boot/shoe manufacture and repair	Ralph Mosely	Footware Industries of America

processes (61). In the end, NTP decided to list it as a "known" human carcinogen, in disagreement with the step 4 committee. Industries such as the chemical manufacturers, using some of the same consultants as tobacco, would eventually win a small but important legal victory over the procedures underlying the Ninth Report, as explained below. After the tobacco industry unsuccessfully challenged the data underlying the decision to list ETS, it next disputed the decision on procedural grounds.

Challenging the Procedures

The Ninth Report on Carcinogens sparked much controversy over NTP procedures, including a debate about the relative ease of delisting substances, but previous accounts have not discussed the role of the tobacco industry (41). After the December 1998 meeting of the NTP Board of Scientific Counselors, Philip Morris regulatory consultant Jim Tozzi wrote to the NTP challenging the listing procedures. He argued that under the Federal Advisory Committee Act all meeting materials should be made public, and they were not (62). As a remedy he asked to extend the public comment period.

Soon afterward, Tozzi prepared a "white paper" analysis entitled "Upholding Standards for Data Quality in Regulatory Decision Making: Procedural Violations in the National Toxicology Program's Report on Carcinogens Program." The first draft in the documents is dated January 4, 1999. The paper was then revised with the "comments of Robin Kinser [of Philip Morris Worldwide Scientific Affairs] and Shook Hardy Bacon [tobacco industry law firm]" (63). The final, slightly longer version is dated January 25. The final white paper argues that the NTP did not provide meeting materials, did not consider a recent and relevant IARC study (published during the listing process), did not demonstrate an accurate consideration of the literature, and relied too much on the EPA 1992 secondhand smoke risk assessment study, which had since been vacated by a judge (64). The objection to the EPA study is among the points added to the second draft of Tozzi's white paper.

The director of the NTP, Kenneth Olden, wrote back to Tozzi on February 25 (65). He replied that the NTP had fully considered the recent IARC study, that the federal EPA 1992 study was used as background but not considered, and that the NTP relied more on the California EPA risk assessment of 1997 (66). The tobacco industry had also fought the release of the Cal-EPA report, which was more comprehensive than the federal EPA risk assessment (22). Olden affirmed in the letter that the RoC policy was to include only peer-reviewed literature in its analysis. Olden closed the letter by stating that the NTP refused all of Tozzi's requests. During the final comment period that followed, Ted Sanders and Matt Winokur submitted Philip Morris's comments, including procedural and substantive points similar to the Tozzi white paper (67, 68). These comments also

included a lengthy rebuttal to James Repace's presentation at the December advisory committee meeting, which was the only one presenting data that favored listing ETS.

On March 18, 1999, the American Forest and Paper Association wrote a letter objecting to the listing of dioxin as a known human carcinogen (69). This set in motion a broad challenge to the NTP listing procedures that included Philip Morris consultant Jim Tozzi, who apparently also had clients interested in dioxin. On July 15, 1999, Tozzi wrote to Philip Morris about a Toxicology Forum meeting in Aspen in which a report written by his organization, the Center for Regulatory Effectiveness, was influential (70). Apparently, NTP director Olden was a participant at the meeting and according to this memo seemed to listen to the procedural criticisms (71). The NTP decided to review its RoC listing process in general at a public meeting on September 15, 1999.

The tobacco documents contain several examples of the public comments submitted to this September 15 meeting about RoC procedure. For example, a group led by the Chemical Manufacturers Association sent a letter signed by 10 people objecting to the process leading to the Ninth Report (72). The letter does not mention any specific chemical or substance. R.J. Reynolds also submitted public comments on the review process, with specific objections concerning the Ninth Report (73). At the meeting itself, Tozzi spoke about procedural violations and argued that the Ninth Report should be delayed until all interested parties had had enough time to receive meeting materials and submit more public comment (74). Carchman of Philip Morris also spoke at the meeting, echoing the same arguments (75). The NTP postponed the release of the Ninth Report until May 15, 2000, due to court proceedings in the case of *Tozzi v. HHS* (discussed below) (76). By July 5, 2000, the R.J. Reynolds law firm Womble Carlyle was circulating within the company a draft memo challenging the ETS listing as a carcinogen, but there is no evidence anything final was sent (77).

Time to Sue: Legal Challenges to the Decision

A court case on dioxin challenged the same Ninth Report on Carcinogens; the plaintiffs claimed that the NTP must rely on epidemiological studies establishing carcinogenicity (78). Epidemiology provides empirical evidence of disease in populations, but instead, the NTP may have relied on "mechanistic" studies of dioxin that demonstrate a process or mechanism by which a substance may cause cancer (79). Examples of mechanistic studies include enzyme analyses and in vitro experiments with animal cells. As noted above, Jim Tozzi was a consultant to Philip Morris and other industries (80). Tozzi-affiliated Multinational Legal Services filed suit in the District Court for the District of Columbia on May 14, 1999, on behalf of dioxin-related industries (81).

Beyond involving the same Washington consultant, the dioxin lawsuit was in fact related to tobacco industry interests. This lawsuit was part of a broad anti-regulatory strategy pursued by many regulated industries. An internal tobacco industry document from Tozzi's organization outlines a strategy of drafting a scientific meta-analysis for "dioxin, alcoholic beverages, and ETS (substances currently under NTP review)" (82). The tobacco industry would clearly benefit if the process for considering both dioxin and environmental tobacco smoke as cancer-causing were criticized by a judge. In 1998 the tobacco industry was temporarily successful in court when a judge invalidated the 1993 EPA secondhand smoke report (reinstated in 2002) (21).

The NTP procedural case later went to the U.S. Court of Appeals and a decision in *Tozzi v. HHS* was issued on November 23, 2001 (42). The court upheld the NTP's decision-making process, and dioxin was listed in the Ninth Report as a known human carcinogen. Nonetheless, the industry side claims some victory with this case, because it established "standing," meaning that NTP decisions are regulations subject to lawsuits and judicial review (83). An environmental law journal article explains that this decision "also provides needed leverage to stakeholders when engaged in advocacy with NTP" (42). The authors conclude with the suggestion that "this may help make NTP more receptive to heeding the comment, technical advice, and other advocacy offerings of business stakeholders in the NTP listing process." In fact, litigation is becoming a normal part of the regulatory process (84).

The NTP continues to review and reconsider its listing process, and convened a public meeting in January 2004 that generated 16 public-comment submissions both in advance and in person from industry and advocacy organizations (85). In addition, representatives from various regulated industries challenged the public dissemination by the NTP of information on its procedures in June 2004 (86, 87). This is another example of regulated industries using every available tool to stall the NTP process. Under the Information Quality Act of 2001, citizens may petition agencies to remove from public dissemination any information that does not meet certain quality standards. In fact, Philip Morris officials and consultants contributed to the drafting, passage, and implementation of the data quality law (88).

DISCUSSION

When Does Industry Lose?

We are left with the question we raised at the beginning: when does industry lose? The possible explanations are several. First, testimony from the public health sector could potentially overshadow the industry arguments. Yet there is little evidence of tobacco control or public health advocacy here. The one public health advocate present at the public hearing described the very surprised demeanor of the tobacco industry representatives when the panel voted unanimously against them (89). A second explanation may be that the scientific evidence was too

compelling. Compared with the EPA secondhand smoke risk assessment of 1992, the evidence of health risks and secondhand smoke was more comprehensive and of better quality during the NTP review. However, the tobacco industry continues to challenge the data on the health effects of secondhand smoke. For example, in March 2005 the industry challenged these data during hearings on a county-level indoor air regulation in St. Louis, Missouri.

Third, business interests can lose political contests because of pressure "from below," such as from mass social movements (90). The late-1990s' public agenda was predisposed to tobacco control, which had increasing public support at that time (16). But by the time of the RoC listing, the tobacco control movement was losing some steam, and in fact had never much engaged with technical-regulatory questions of implementation and enforcement (91). We found no evidence of participation by the tobacco control movement on this policy, other than the testimony of one activist expert.

A fourth and most likely possibility is political direction from above: perhaps the administration preferred the listing, or the relevant presidential (and secretarial) appointees made a difference. As explained above, we found that the NTP, at least in reviewing dioxin, made policy in disagreement with the recommendation of its advisory committee. Moreover, the sole testimony in favor of listing secondhand smoke was arranged by other public health officials within the government (89). The Clinton administration had attempted to regulate cigarettes under the Food and Drug Administration. These circumstances indicate leadership from above in this case. Our document research is limited to the public archival record and so cannot definitely attribute the outcome of this process to any combination of these causes.

Nonetheless, we find that Smith's argument (15) that business should win when the decision is technical and low-profile is not supported by the NTP case of environmental tobacco smoke. Tobacco regulation was attracting considerable attention around this time, perhaps suggesting that the policy question here was not exactly "low-profile" as described by the theory. But when added to the other examples of business victories on conspicuous regulatory proposals, this point deserves further consideration. In fact, much of the history of tobacco industry regulation seems contrary to the academic models. We maintain that these particular proceedings for listing carcinogenicity were narrow, technical, mostly unknown, and not publicly contentious or exceptionally notorious. For example, we searched for news accounts of the Ninth Report on Carcinogens and found only a few stories about the delisting of saccharin. The tobacco industry seems to win more often on conspicuous proposals but lose on lesser-known regulatory actions. Other research has found that policy proposals receiving greater public attention attract ideological and economic arguments that distract from the scientific evidence and public health claims, which may explain why, in the case of secondhand tobacco smoke, the evidence was heard in this less conspicuous policy process (22).

Imbalance of Public Comments

This article also addresses the role of public comment periods in regulation, because the NTP process includes public comments at several points. Public input is solicited three times before a substance is listed as carcinogenic (see Figure 1), and the public is also invited to give a short presentation at a meeting of advisors. In the case discussed here, these public presentations were dominated by the views of business interests. The public presentation section of the proceedings included only one person arguing that smoke is carcinogenic. Previous studies have found that during regulatory public comment periods, industry-friendly submissions far outweigh the anti-industry position (7, 8). This case from the NTP process corroborates that finding. Moreover, the apparent lack of public health input during the process may have put the determination of carcinogenicity at risk. The NTP policy may be challenged in the future, and evidence and testimony from the public health sector are missing from the record. Recall that one industry memo noted the future possibilities for delisting smoking. In fact, the ease with which substances in the U.S. may be delisted has been described as "alarming" (41). Public health involvement in these proceedings can be very effective; in Finland, the struggle over listing tobacco as carcinogenic was overcome in part because public health advocates made use of information on industry strategy as revealed by tobacco industry internal documents (29).

In addition, public comment periods delay regulation while the comments are obtained and processed. Delayed decision-making usually benefits the industry (1). And further, these comments are often used by regulated industries in future legal challenges; the agency then may preemptively adjust its decision in order to avoid the courts (92). The NTP process is now accessible for judicial review, as are many regulatory decisions. The transfer of stakeholder contests to the courts is a development anticipated by Martin Shapiro (93). While the U.S. political system is often more litigious than others, the tobacco industry has also taken regulation to court elsewhere, for example in the case of European Union advertising restrictions (94). Our data are specific to the United States, but the challenges to regulation described here could be similarly employed by the chemical and tobacco industries worldwide. Health policy makers should carefully consider the available choices for controlling "industrial technologies" when attempting to address cancer (95).

CONCLUSION

The role of business participation in regulatory politics continues to evolve. Clearly, business—in this case the tobacco and chemical industries—had terrific access to the multi-part regulatory policymaking process in the United States. When the government moved to build a legal foundation for public health challenges to harmful practices by defining new carcinogens, the stakeholder

industries mobilized to counteraction. The industry responded to the proposal just as the work of Mark Smith and Cathie Jo Martin would predict as it vigorously contested a specialized question; this demonstrated both the capacity of the tobacco industry and the narrow and technical scope of this policy problem. In this case the industry position (mostly) lost, which theorists might not have predicted. Yet the unbalanced pattern of public participation raises questions about the U.S. regulatory process, which includes many access points for industry that can become policy veto points. In this case the industry made the most of the steps in the process such as public comment periods and courtroom challenges, and won a new future veto point in judicial review. This finding is consistent with Eisner's discussion (20) of the important consequences of institutional evolution; the regulatory politics and structures described here, such as the expanded judicial review, will influence and constrain ensuing regulatory proceedings.

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Direct reprint requests to:

Dr. Lisa A. Bero
Department of Clinical Pharmacy
Institute for Health Policy Studies
University of California, San Francisco
Box 0613
3333 California Street, Suite 420
San Francisco, CA 94143

e-mail: berol@pharmacy.ucsf.edu