

UCSF

Postprints from the CTCRE

Title

Understanding Philip Morris's pursuit of US government regulation of tobacco

Permalink

<https://escholarship.org/uc/item/35p0r9x2>

Journal

Tobacco Control, 14

Authors

McDaniel, Patricia
Malone, Ruth E

Publication Date

2005

DOI

10.1136/tc.2004.009878

Peer reviewed

Understanding Philip Morris's Pursuit of U.S. Government Regulation of Tobacco

Patricia A. McDaniel, PhD and Ruth E. Malone, RN, PhD, FAAN

University of California, San Francisco

Patricia A. McDaniel, Ph.D.*
Center for Tobacco Control Research and Education
University of California, San Francisco
530 Parnassus Ave., Ste. 366
San Francisco, CA 94143-1390
pmdanie@itsa.ucsf.edu
(w) (415) 514-9342
(f) (415) 514-9345

Ruth E. Malone, R.N., Ph.D., F.A.A.N.
Department of Social and Behavioral Sciences, School of Nursing, University of
California, San Francisco

*Corresponding author

The Corresponding Author has the right to grant on behalf of all authors and does grant on behalf of all authors, an exclusive licence (or non exclusive for government employees) on a worldwide basis to the BMJ Publishing Group Ltd and its Licensees to permit this article (if accepted) to be published in Tobacco Control editions and any other BMJ PGL products to exploit all subsidiary rights, as set out in our licence (<http://tc.bmjournals.com/misc/ifora/licenceform.shtml>).

keywords: Philip Morris, FDA regulation, corporate image enhancement

Understanding Philip Morris's Pursuit of U.S. Government Regulation of Tobacco

Abstract

Objective: To investigate Philip Morris's support of U.S. Food and Drug Administration regulation of tobacco products and analyze its relationship to the company's image enhancement strategies.

Data sources: Internal Philip Morris documents released as part of the Master Settlement Agreement.

Methods: Searches of the Legacy Tobacco Documents Library (<http://legacy.library.ucsf.edu>) beginning with such terms as "FDA" and "regulatory strategy" and expanding to include relevant new terms.

Results: Philip Morris's support for government regulation of tobacco is part of a broader effort to address its negative public image, which has a damaging impact on the company's stock price, political influence, and employee morale. Through regulation, the company seeks to enhance its legitimacy, redefine itself as socially responsible and alter the litigation environment. Whereas health advocates frame tobacco use as a public health policy issue, Philip Morris's regulatory efforts focus on framing tobacco use as an individual choice by informed adults to use a risky product. This framing allows Philip Morris to portray itself as a reasonable and responsible manufacturer and marketer of risky products.

Conclusions: Philip Morris's ability to improve its image through support of FDA regulation may undermine tobacco control efforts aimed at delegitimizing the tobacco industry. It may also create the impression that Philip Morris's products are being made

safer and ultimately protect the company from litigation. While strong regulation of tobacco products and promotion remain critical public health goals, previous experiences with tobacco regulation show that caution may be warranted.

Understanding Philip Morris' Pursuit of U.S. Government Regulation of Tobacco

Since 2000, Philip Morris (PM), the largest tobacco company in the world, has been aggressively pursuing U.S. Food and Drug Administration (FDA) regulation of tobacco products. In 2004, the company came close to achieving its goal: the U.S. Senate, but not the House of Representatives, supported legislation granting FDA authority over tobacco products. Mike Syzmanczyk, PM's Chairman and CEO, called the failure to pass this legislation "a bitter disappointment",¹ but the company continues to pledge its support for FDA tobacco regulation.²

Why does PM, which was among a group of tobacco companies that sued to stop previous attempts at FDA regulation of tobacco, now seek such regulation? This study uses internal company documents to explore the development of PM's support for FDA regulation and its links to the company's decade-long efforts to remake its image. Although PM initially opposed FDA regulation, it came to regard "reasonable" regulation as a way to end its isolation and redefine the company as socially responsible. With that goal in mind, PM devoted enormous resources to achieving regulation on its terms. We investigate the type of regulation that PM regarded as reasonable, as well as the legislative and public relations strategies PM employed in relation to such regulation.

METHODS

Data for this study came from publicly available PM documents released as a result of the 1998 Master Settlement Agreement between the attorneys general of 46 states and the tobacco industry.^{3,4} Between June and August 2004, we accessed these documents through the Legacy Tobacco Documents Library

(<http://legacy.library.ucsf.edu>). PM initiated its internal discussions regarding a revised company policy toward regulation in October 1998,⁵⁻⁸ thus, we searched the PM collection of the Legacy Library for documents dated between October 1998 and December 2004 that contained the keywords “FDA”, “regulatory strategy”, and “societal alignment”. Using a snowball sampling strategy, we used the retrieved material to identify additional search terms (such as names of PM staff involved in FDA regulation). This produced over 18,000 documents; approximately 3,000 were relevant to our inquiry, with the majority dated between 2000 and 2001. (Although more documents may become available in the future, at the time of our search, the Legacy library contained only 115 Philip Morris documents dated in 2003 and 0 in 2004). We analyzed the relevant documents by assembling them into a chronologically constructed case study.^{9,10}

FINDINGS

Background

The modern FDA was established in 1906 with the passage of the Federal Food and Drugs Act;¹¹ it was given additional regulatory powers by the Food, Drug and Cosmetic Act of 1938.^{12, p. 173} Among them was control over the introduction of new drugs: before they could be marketed, manufacturers had to prove to FDA that they were safe.^{12, p. 173} In 1962, amendments to the Act stipulated that manufacturers also had to demonstrate that new drugs were effective for their intended use.^{12, p. 174} Until recent scandals,¹³ FDA had an international reputation as a vital source of consumer protection information regarding drug safety and efficacy.^{12, p. 174} PM’s own market research showed that, in 1999, the majority of Americans viewed FDA very favorably and approved of how the agency handled its responsibilities.¹⁴

Beginning in the late 1970s, public health groups (including Action on Smoking and Health and the Coalition on Smoking or Health) petitioned FDA to include cigarettes under its regulatory mandate.^{15, p. 53} FDA declined to do so until August 1996, when it claimed the authority to regulate tobacco products as medical devices and nicotine as a drug. The agency's tobacco regulations, most of which were set to take effect in one year, included restricting tobacco advertising to which children were exposed, and requiring cigarette and smokeless tobacco packages to carry the label "Nicotine-Delivery Device for Persons 18 or Over".^{15, p. 66} PM and four other American cigarette manufacturers filed suit in federal court arguing that FDA had no such statutory authority.^{15, p. 67} The case was fought all the way to the U.S. Supreme Court, which ruled in March 2000 that Congress never intended to give FDA the power to regulate tobacco products under the Federal Food, Drug and Cosmetic Act.^{16, p. 384}

Even before the case was decided, however, PM and the other major U.S. tobacco companies had agreed in 1997 to a "Proposed Resolution" with state attorneys general that would have granted the FDA limited authority to regulate tobacco.^{15, p. 244, 16, pp. 360-1} The agreement was contingent upon Congressional approval, which did not materialize; instead, in 1998, the Senate considered, but failed to pass a more restrictive bill that would have granted the FDA authority to take whatever steps it deemed necessary to protect the public from the risks of tobacco.^{15, pp. 121-2, 17} After the Supreme Court decision, Congressional efforts to pass some form of legislation granting FDA authority over tobacco multiplied: at least 8 bills were introduced between 2000 and 2001.¹⁸ Below, we discuss two that received PM's support.

Gaining legitimacy

Although the March 2000 Supreme Court ruling represented a victory for PM and the tobacco industry, PM began shortly thereafter to publicize its support for some form of tobacco regulation.¹⁹ In initial public statements, PM said that such regulation would be good for its business and its customers.²⁰ Several months later, in June 2000, the company offered the explanation that “the industry benefits from the increased predictability that comes with knowing what the rules are, and how to follow them”.²¹

Before it provided further public details about its position, PM commissioned 12 focus groups to assess the plausibility of various possible explanations for tobacco company support of FDA regulation.^{22,23} Focus group members considered messages about business benefits to be more plausible than those suggesting moral or ethical motives.^{22,23} Business benefits included creating a stable and predictable environment, avoiding litigation, generating good PR, and ensuring milder regulations.²⁴

A nationwide poll commissioned by PM in March 2001 confirmed these findings. It also found support for three positive messages explaining the company’s support of regulation: creating more informed consumers due to ingredient disclosures, creating more choices for smokers through the ability to develop and market a reduced risk cigarette, and ensuring that only adults smoke by strengthening laws limiting youth access.²⁵ An internal memo discussing PM’s research concluded that “[o]ur core messages will be the need for **stability, predictability and uniformity**, and that regulation is necessary to help **ensure that only informed adults make the choice to smoke**” (emphasis in original).²⁶

Within the company, PM explained its pursuit of FDA regulation somewhat differently. In a March 2001 speech to PM's board of directors, senior vice president of corporate affairs Steve Parrish explained that government regulation was part of PM USA's larger plan to be regarded as a normal, legitimate corporation, thereby ending its isolation and assuring its continued success.²⁷ This larger plan, first conceptualized in 1999, was named Societal Alignment, or "meeting society's expectations of us as a responsible manufacturer and marketer of all our products, especially those that carry risks".²⁸ Societal Alignment brought together a number of new and existing company strategies aimed at responding to and shaping its business environment in a way that would protect the company from criticism.^{28,29}

One of these strategies was image enhancement, a project that had been underway since at least 1989.³⁰ While the company has always been image conscious, these concerns were exacerbated in the late 1980s, as PM's public image plummeted, leading to new initiatives.³⁰ Image enhancement was the rationale behind the corporation's 2001 name change (to The Altria Group), as well as an advertising campaign touting PM's charitable contributions, and PM's youth smoking prevention initiatives.^{31,32} These actions were intended to position PM as a socially responsible, progressive, community-minded company that represented values shared by Americans.^{33,34} As Steve Parrish explained in a 1999 company presentation to stock analysts, the goal of enhancing the company's image was to "construct a platform of credibility so we can ...take our rightful place in the social, political, and economic mainstream".³⁵ PM's support of government regulation of tobacco was another means of building the company's image.²⁷ Indeed, PM's March 2001 polling data had found that knowledge that the company

supported FDA regulation substantially reduced the percentage of adults with an unfavorable image of the company, from 50% to 35%.²⁵

PM also explained both publicly and privately that it regarded some sort of regulation as inevitable.^{27,36} The company predicted that the Republican party-controlled Congress of 2001 was more likely to enact what it regarded as “reasonable” regulation than any Democratic party-controlled future Congress.²⁷ (Critics suggested that this was due, in part, to PM’s generous donations to the Republican party—\$8.1 million between 1992 and 2001, compared to \$1.4 million to Democrats).³⁷ PM argued that it was better to act now than to risk more onerous regulations.^{27,36}

“Tough” but “reasonable” regulation

In public statements in 2000, PM representatives did not provide many specifics regarding the type of regulation that the company was seeking. They argued that “it would be better for us to listen and to engage in dialogue rather than present specific proposals”.³⁸ The company, did, however, stress that it wanted “tough” but “reasonable” regulation.³⁹ It also outlined key goals of such regulation, including regulating cigarettes as cigarettes, rather than as medical devices; respecting adults’ right to smoke; addressing the public health information available to consumers; encouraging the introduction and marketing of less risky cigarettes; and avoiding the establishment of a black market.^{20,38}

In March 2001, PM posted on its website a white paper containing more details regarding the type of regulation it favored.⁴⁰ Even before releasing it, PM’s law firm Arnold and Porter had written several drafts of model legislation.⁴¹⁻⁴³ PM had also provided members of Congress with bill language.⁴⁴⁻⁴⁶ One of the company’s primary requirements (which was not mentioned in the white paper) was that any FDA legislation

preserve the preemption clause of the 1965 Federal Cigarette Labeling and Advertising Act (FCLAA).^{47,48} In addition to prohibiting state governments from requiring different warning labels on cigarette packs, the preemption clause has been interpreted by the courts as prohibiting certain types of state tort damage claims against the industry.⁴⁹ In early 2000, Tennessee Republican Senator Bill Frist's staff were drafting an FDA bill containing a provision to repeal FCLAA preemption. John Scruggs, PM's chief lobbyist, was in frequent contact with staff members regarding the language of this bill; upon learning of the preemption provision, he explained to his PM colleagues that "I took the opportunity to 'fall on my sword' and made it very clear that we would do everything in our power to kill this bill and any other bill that contains such a provision".⁴⁷

In its white paper, PM explained that it wanted limits placed on any performance standard that FDA might impose on cigarettes.⁴⁰ In establishing a performance standard, FDA might, for example, mandate changes in cigarette ingredients. PM did not want FDA to be empowered to force changes that would make cigarettes taste unappealing or that would eliminate nicotine entirely.⁴⁰ In June 2001, representatives of the American Cancer Society (ACS), American Heart Association (AHA), American Lung Association (ALA) and the Campaign for Tobacco-Free Kids (CTFK) argued that the palatability clause represented a significant loophole in a bill, similar to Frist's, that had recently been introduced in the House by Representative Tom Davis (Republican, Virginia).⁵⁰ They argued that tobacco companies could claim that a small reduction in smoking levels following FDA-mandated ingredient changes was evidence that cigarettes had been made unpalatable to smokers.⁵⁰ In response, PM tried to clarify this issue for Representative Henry Waxman's (Democrat, California) staff.⁵¹ The company argued that FDA could

order the removal of harmful components “so long as product taste is not significantly altered”; FDA could also impose limits on tar, nicotine or carbon monoxide, provided they did not “severely limit choice for adult smokers who do not enjoy low or ultra-low yielding products”.⁵²

PM sought limited FDA authority over product labeling. An internal list of PM’s priority FDA items included fixing the size of warnings at 25% of packs, and 20% of ads.⁵³ PM sought text-only warnings; it wanted to prevent the introduction of warning labels containing graphic images of tobacco-related disease (such as those enacted in Canada, which had recently proven effective in encouraging smokers to quit).^{54,55} In a press statement drafted to respond to a study confirming the utility of graphic warnings, PM stated that such warnings were inappropriate because they “humiliate adults for legal choices they make”.⁵⁶

PM’s white paper also advocated the continued use of product descriptors like “light” and “ultra light”.⁴⁰ In November 2001, the National Cancer Institute (NCI) released a comprehensive report showing that despite the tobacco industry’s marketing claims, light or low-tar cigarettes did not reduce health risks.⁵⁷ In response, the major health groups (ACS, AHA, ALA and CTFK) called on tobacco companies to eliminate these terms from cigarette packages and advertising.^{58,59} PM refused, asserting in a press release that, for smokers, such descriptors “serve as useful points of comparison for cigarette brands regarding strength of taste and reported tar yield”.⁶⁰

In terms of marketing restrictions, PM advocated codifying those contained in the Master Settlement Agreement, which limited tobacco advertising seen by children,⁴⁰ however, the company rejected restrictions on marketing seen predominately by adults.⁴⁰

The company wanted to continue communicating with what it termed “verified” adult smokers through direct mail, events in adult-only facilities, and over the internet.⁶¹

PM wanted reduced risk tobacco products to be regulated by FDA, but it did not support applying a public health standard to such products.⁴⁰ A public health standard would require FDA to withhold approval from reduced risk cigarettes if they led to an increase in the incidence of smoking among the population by causing fewer people to quit or causing quitters to resume smoking. Instead, PM preferred a standard that focused on the benefits of reduced risk products for individual adult smokers.⁴⁰ In internal discussions, PM also advocated that FDA distinguish between reduced *exposure* and reduced *risk* cigarettes.⁶² This would allow PM (and other tobacco companies) to market reduced exposure cigarettes based on an initial determination that they exposed smokers to fewer toxins; when long-term evidence that such cigarettes resulted in reduced harm was available, PM could then advertise them as reduced risk.⁶³

Legislative strategies

To achieve its goal of “tough” but “reasonable” regulation, PM employed a number of different strategies. First and foremost, company representatives worked with legislators, meeting with staff to explain PM’s views, helping to write legislation, and lobbying on behalf of legislation PM supported. Initially, company representatives worked most closely with Republicans, who PM saw as more inclined to produce acceptable legislation.²⁷ However, as PM lobbyist John Scruggs explained in a memo to Steve Parrish, Republicans could be difficult to enlist as allies because they were typically “philosophically opposed to government intervention and regulation”.⁶⁴ PM used polling data to convince them of the political value of supporting regulation. These

data showed that FDA regulation was an important issue to suburban swing voters, particularly women, who were key to maintaining the Republican majority.⁶⁵ According to PM's polling company, supporting FDA tobacco regulation could help "redefine the image of the [Republican party] as being reasonable in addressing a significant public health issue".⁶⁵

PM lobbyists also worked with Democrats, who, according to Scruggs, needed to be convinced that limited, rather than unfettered FDA regulation was the politically sensible course of action.⁶⁴ Peter Harris, of PM's public relations firm BSMG Worldwide (BSMG), urged PM lobbyists, in their private discussions with Democrats, to start by emphasizing how the company had changed in recent years, and to refer to polling data showing that voters supported a pragmatic solution.⁶⁶ Some of these data were obtained by first asking a sample of registered voters to make a choice between two extremes; for example, whether they agreed that no further regulation of the tobacco industry was necessary (53% agreed) or that the tobacco industry should be nearly regulated out of existence (41% agreed). Next, respondents were asked to indicate whether a compromise was acceptable, such as granting FDA the authority to help prevent youth smoking, to provide information on ingredients to smokers, and to define criteria for marketing reduced risk cigarettes (70% agreed).⁶⁷ Asked in this way, the majority of those surveyed supported the compromise solutions that reflected PM's approach to regulation.

PM regarded the political center as the key to success.⁶⁸ In 2001, the company supported the narrow Davis bill and the broader Frist bill. PM expected that, if the bills were passed and sent to conference committee (where differences between the two would

be worked out), the resultant bill would represent a moderate compromise.^{64,69} The company was aware, however, that there were no guarantees that it could achieve this result; PM representatives repeatedly expressed concern about the issue “spinning out of control” on the Senate or House floor through the addition of amendments that might prove unfavorable to PM.^{27,70} In June 2001, with Democrats holding a slim majority in the Senate, Scruggs concluded that Democratic Senator Edward Kennedy of Massachusetts was the key to success, and recommended negotiating with him to try to reach a compromise bill.⁶⁴ The advantages of working with him, as reportedly pointed out by a Kennedy staff member, were that he would assure the bill’s acceptance by the public health community and control Senate debate of the bill by opposing all Democrat initiated amendments.⁷¹

To avoid the impression that it was dictating terms to Congress, PM tried to hide its support for the Davis and Frist bills.⁷² In a June 2001 *Washington Post* article, Steve Parrish stated that PM had “‘significant problems’ with the [Davis] bill and did not back it”.³⁷ Yet the public relations firm BSMG, in consultation with PM, appears to have prepared a packet of materials for Representative Davis to use to garner support for his bill, including drafts of talking points, a letter to House colleagues seeking cosponsors, answers to journalists’ questions, an op-ed, and a letter to constituents critical of the bill.^{73,74} When PM lawyer Mark Berlind conceded in an August 2001 *FDA Week* article that the company preferred the Frist and Davis bills, BSMG executive Scott Williams asked him an e-mail if he had intended to do so.⁷⁵ Berlind answered that he had not endorsed any particular bill “but did concede the obvious...Frist/Davis is to us the better approach”.⁷⁶ Williams responded, arguing that “I thought we were ... not pegging our

support, at least on the record, to Frist/Davis ... unless we say something like ‘[T]hose bills are the best starting point, though we, PM, have problems with a, b, c, etc.’ ... I would still not concede the obvious”.⁷⁷ Though PM’s support of the bills was an open secret, the company was reluctant to go on the record as their primary backer.

Public relations strategies

PM also engaged in an extensive public relations campaign to advance its goal of “reasonable” regulation. PM executives and consultants wrote op-eds and letters to editors of both major and local newspapers, participated in editorial board meetings, gave interviews to journalists, and had speaking engagements at local community organizations such as Rotary and the Chicago Mexican American Chamber of Commerce.⁷⁸⁻⁸⁴ BSMG recommended developing Steve Parrish as the central voice of the national media campaign, in order to “humanize the effort, and leverage Steve’s skills as a reasonable spokesperson and executive”.⁸⁵ BSMG also recommended discussions with senior members of the public health community, in part by participating in proposed forums at the Mayo Clinic and the University of California Berkeley School of Public Health^{85,86} (Neither of these events took place.)⁸⁷ Between December 2000 and July 2001, PM’s media outreach resulted in the publication of 50 news, editorial or opinion pieces on PM’s pursuit of tobacco regulation, as well as the placement in 14 news outlets of PM’s FDA op-ed piece.⁸⁸

PM’s media campaign had a grassroots element as well. PM mobilized its field action teams, lobbyists and consultants in all 50 states whose job was to enlist supporters for a variety of PM causes.^{89,90} In a three-month period, team members met with representatives of 650 different organizations, including hospitality, beverage, grocery,

retail, and convenience store associations, wholesalers, chambers of commerce, and one health organization (the Utah Nurses Association).⁹¹⁻⁹³ At these meetings, team members briefed organization representatives on PM's position on FDA regulation and asked for an official show of support—by contacting members of Congress, writing letters to local newspapers, or asking the national organization to endorse FDA regulation of tobacco.^{94,95} A PM summary of these meetings indicated that 20% of the groups contacted supported PM's position on FDA regulation, 57% were uncommitted or neutral but open to further discussion, 3% were opposed, and 20% needed input from other organization members.⁹² (The Utah Nurses Association representative, according to a field action team report, personally supported PM's position, but thought that it would be difficult for her organization to do so, in light of American Medical Association support of broader FDA regulation.)^{96,97})

PM also communicated its views on FDA regulation of tobacco to key state legislators and governors (who were encouraged to support regulation as a way to preserve 1998 tobacco settlement funds), union leadership, retailers, wholesalers, business partners, and suppliers through individual letters, one-on-one and group meetings, and mass mailings.^{72,86,88,98-100} The mailings might include PM's white paper on FDA regulation, a question and answer document, a fact sheet on the Master Settlement Agreement, or copies of op-eds by PM executives.^{72,86,100} In June 2001, the company launched "Tobacco Connections", a newsletter devoted to tobacco policy issues of importance to tobacco growers. The inaugural issue, mailed to 130,000 farmers, was devoted to explaining PM's position on FDA regulation and how such regulation would benefit growers.^{101,102}

Underpinning much of this media and communications campaign was extensive market research to uncover the most effective messages for gaining public support for PM's positions.¹⁰³ Early on, PM found that the key to claiming the company-defined reasonable middle ground in the FDA debate was to pose the options as "complete, unfettered government control over tobacco" versus "informed adult choice", "a government power grab" versus "reasonable common sense".¹⁰⁴ Examples of government control over cigarettes that had a highly negative emotional impact on adults surveyed included requiring a prescription for cigarettes, and limiting cigarettes to a single government approved style.¹⁰³

In a further effort to claim the "reasonable" middle ground of the debate, PM portrayed opponents of what it regarded as moderate legislation as extremists or obstructionists. In an August 2001 interview in *The Wall Street Transcript*, PM lawyer Mark Berlind expressed surprise at some public health groups' opposition to the Frist and Davis bills.¹⁰⁵ He asserted that these groups, in supporting only "the most radical, extreme kind of medical product regulation" were working against the passage of reasonable and effective legislation.¹⁰⁵ PM's question and answer document on FDA regulation described other tobacco companies who opposed the Frist and Davis bills as obstructionists whose objective was to "preserve the status quo".^{106,107} Internally, however, PM recognized that vocal opposition from the rest of the industry made PM appear more reasonable.⁶⁸ It provided useful political cover for PM's Congressional allies: as a PM lawyer pointed out to a Representative, "it's actually a good thing for the other companies to be opposed – it will keep the effort from being construed as 'pro-tobacco'".¹⁰⁸

The Davis and Frist bills failed to become law. In 2004, as mentioned earlier, PM endorsed an FDA regulation bill, sponsored by Senators Kennedy and DeWine, that was the first to gain the support of both PM and a number of public health groups, including the Campaign for Tobacco-Free Kids, the American Heart Association, American Cancer Society, and American Lung Association. As Table 1 shows, many of the provisions of this bill differed from those of the Davis and Frist bills, yet PM publicly supported it. However, the FDA provisions did not survive the Senate-House conference committee created to finalize the bill;¹⁰⁹ given PM’s powerful connections in Congress, it seems likely they knew it would not.

Table 1. Key Provisions of FDA bills supported by Philip Morris

	Davis Bill (H.R. 2180) 107 th Congress, 2001	Frist Bill (S. 190) 107 th Congress, 2001	Kennedy-DeWine Bill (S. 2461) 108 th Congress, 2004
Cigarettes regulated as medical devices	No	No	No
Descriptors (i.e., “light,” “ultra light”)	Use of descriptors in advertisements requires inclusion of disclaimer “[Brand] not shown to be less hazardous than other [type of tobacco product]’.	No explicit provisions	Regulated; cigarettes using such descriptors must be registered and approved as modified risk
Performance standards	FDA can mandate reduction in nicotine & other constituents; only Congress can eliminate nicotine or ban cigarettes; FDA cannot render tobacco product unacceptable for adult consumption	FDA can mandate reduction in nicotine & other constituents; only Congress can eliminate nicotine or ban cigarettes; FDA cannot render tobacco product unacceptable for adult consumption	FDA can mandate reduction in nicotine & other constituents; only Congress can eliminate nicotine or ban cigarettes
FCLAA preemption	Preserved	Preserved	Preserved
Warning labels	25% of front and rear of pack; text-only	25% of front and rear of pack; text-only	At least 30% of front and rear of pack; may be increased to 50%. May require graphic warnings if they would promote greater public understanding of risks
Marketing restrictions	Prohibits targeting	FDA may impose	FDA may require

	youth through use of cartoons & advertising in youth-oriented publications	advertising restrictions if they would be appropriate for the prevention of, or decrease in, the use of tobacco products by youth	restrictions on advertising and promotion (in keeping with 1 st amendment) if appropriate for protection of public health.
Approval of modified risk products	FDA must consider risks and benefits to individual & population as a whole	FDA must consider risks and benefits to individual & population as a whole	FDA must consider risks and benefits to individual & population as a whole
Reduced exposure vs. reduced risk	Reduced risk products substantially reduce exposure to toxins or substantially reduce potential health risks	Reduced risk products substantially reduce exposure to toxins	Modified risk products reduce harm or the risk of tobacco-related disease or reduce exposure to 1 or more substances in tobacco smoke

Source: <http://thomas.loc.gov>

When more internal PM documents become available, future research may reveal the behind-the-scenes negotiations that led PM to shift some of its positions. Meanwhile, however, in at least one public meeting shortly after the last bill’s failure, a top PM executive showcasing the company’s social responsibility initiatives proclaimed that PM had “partnered” with the leading health organizations in support of the bill, suggesting that this image enhancement through associating the company with health groups may be as important for PM as actual passage of FDA legislation.¹¹⁰ The major health organizations, responding to reports about the event, subsequently sent a letter demanding that PM cease calling itself their “partner”.¹¹¹

DISCUSSION

Available company documents support the notion that Philip Morris’s support for FDA regulation is primarily grounded in its efforts to respond to its unfavorable public image. In the early 1990s, PM’s opinion research showed that Americans had a highly negative view of the company, giving it a favorability score no higher than 34 (on a scale

of 0 (least favorable) to 100 (most favorable));^{112,113} in 1997 and 1998, PM found that 45-49% of the American public viewed the company unfavorably.¹¹⁴ Negative public opinion, in turn, has damaging effects on stock price, political influence, and employee morale.³⁰

The company's (and the industry's) unfavorable image has been shaped by ongoing public health efforts to call attention to the deceptive practices of the industry through explicit or implicit industry delegitimization strategies, an effective part of comprehensive tobacco control efforts.^{115,116} To the degree that the largest tobacco company in the world succeeds in creating a more favorable image, it may also succeed in undermining tobacco control efforts in several important ways.

First, PM's idea of "reasonable" regulation reframes tobacco from a public health problem to an issue of individual choice. This strategy taps into American ideals of individual freedom, and in turn portrays public health advocates as extremists who support government intrusion into private decision-making. PM's framing suggests that the debate over tobacco regulation is a choice between two alternatives, one reasonable (freedom of choice), the other, excessive (government control). But it may not be reasonable or socially responsible to aggressively promote products that are known to cause debilitating disease and premature death in as many as half of all longtime users.^{117,118} Tobacco products kill an estimated 440,000 annually in the U.S. alone.¹¹⁹ By comparison, the FDA recently banned dietary supplements containing the botanical ephedra, after they were linked to the deaths of 155 people.¹²⁰

Second, if FDA regulation enhances PM's image as a reformed company, it may contribute to a belief among consumers that the company's products are being made

safer. Consumers are unlikely to be able to appreciate, for example, the differences between products that offer reduced exposure to certain ingredients and those that offer proven reduced risks of harm. Currently, no scientific base supports the notion that reducing certain cigarette ingredients results in harm reduction. PM's own market research found that 63% of Americans polled agreed that FDA regulation of cigarettes would lead people to believe that cigarettes can be safe.²⁵ This may be particularly true if tobacco companies are able to claim in packaging or advertisements that their products meet FDA standards, suggesting that cigarettes have a government seal of approval.

The image enhancement that PM stands to gain from "reasonable" FDA regulation may also provide it with protections from litigation. Ongoing litigation depresses stock prices and presents financial threats to the industry's stability. Enhancing its corporate image by embracing regulation may improve the company's credibility with potential jurors and with legislators. In shaping itself as a "responsible marketer of risky products", PM shifts responsibility for smoking away from its deceptive promotion of deadly products onto the shoulders of individuals who "choose" (ignoring the nature of addiction in shaping choice) to smoke despite knowledge of the risks. The challenge for litigants will be to draw attention to PM's unfortunate "choice" to continue to promote such products, arguments that may be unsuccessful given the high value Americans place on individualism.

While strong regulation of tobacco products and promotion remain critical public health goals, previous experiences with tobacco regulation show that caution may be warranted in anticipating the real-world effects of "reasonable" regulation. The Master Settlement Agreement (MSA), for example, was viewed as a windfall for public health;

in actual practice, most states have not devoted their MSA funds to tobacco control, and the agreement creates perverse incentives for the states to remain dependent on tobacco company funds to enhance their budgets. Would PM-supported FDA legislation really result in fewer tobacco-related deaths? Or could it result primarily in a public relations coup for the largest tobacco company in the world?

References

- ¹Lazarus D. Strange tobacco reaction. *San Francisco Chronicle*, 17 Oct 2004; Sect. J1.
- ²Philip Morris. 2004. PM USA's position on FDA & tobacco.
http://www.philipmorrisusa.com/en/policies_practices/legislation_regulation/fda_tobacco/pm_usa_position_on_fda_tobacco.asp. [accessed 22 Dec 2004].
- ³Malone RE, Balbach ED. 2000. Tobacco industry documents: Treasure trove or quagmire? *Tob Control* 9(3):334-338.
- ⁴Balbach ED, Gasior RJ, Barbeau EM. 2002. Tobacco industry documents: Comparing the Minnesota depository and internet access. *Tob Control* 11(1):68-72.
- ⁵Berlind M. 1998. Design, manufacturing and marketing of tobacco products: Towards a sensible regulatory framework. 17 Oct. Philip Morris. Bates No 2078343545/3571. <http://legacy.library.ucsf.edu/tid/gys17c00>.
- ⁶Berlind M. 1998. Design, manufacturing and marketing of tobacco products: Towards a sensible regulatory framework. 16 Oct. Philip Morris. Bates No 2072533639/3663. <http://legacy.library.ucsf.edu/tid/flj42a00>.
- ⁷Berlind M. 1998. Design, manufacturing and marketing of tobacco products: Towards a sensible regulatory framework. 1 Oct. Philip Morris. Bates No 2065346777/6799. <http://legacy.library.ucsf.edu/tid/lgs32a00>.
- ⁸Berlind M. 1998. Design, manufacturing and marketing of tobacco products: Towards a sensible regulatory framework. 15 Oct. Philip Morris. Bates No 2072533675/3698. <http://legacy.library.ucsf.edu/tid/hlj42a00>.
- ⁹Hill M. *Archival strategies and techniques*. Newbury Park, CA: Sage Publications, 1993.

- ¹⁰Yin R. *Case study research design and methods*. Thousand Oaks, CA: Sage Publications, 1994.
- ¹¹Swann JP. 1998. History of the FDA. U.S. Food and Drug Administration. <http://www.fda.gov/oc/history/historyoffda/default.htm>. [accessed 7 Jan 2005].
- ¹²Schweitzer SO. *Pharmaceutical economics and policy*. New York: Oxford University Press, 1997.
- ¹³Harris G. At FDA, strong drug ties and less monitoring. *New York Times*, 6 Dec 2004; Sect. A-1.
- ¹⁴American Viewpoint. 1999. FDA research. 20 Sep. Philip Morris. Bates No 2072013568/3608. <http://legacy.library.ucsf.edu/tid/xvn06c00>.
- ¹⁵Derthick MA. *Up in smoke: From legislation to litigation in tobacco politics*. Washington, DC: CQ Press, 2002.
- ¹⁶Kessler D. *A question of intent: A great American battle with a deadly industry*. New York: PublicAffairs, 2001.
- ¹⁷U.S. Senate. Universal tobacco settlement act. S. 1415.
- ¹⁸Thomas--legislative information on the internet. 2004. Library of Congress. <http://thomas.loc.gov/>. [accessed 16 Aug 2004].
- ¹⁹Egan C, Plitch P. Dow Jones News Service. 2000. Big tobacco wins at high court but still seeks regulation. 21 Mar. Philip Morris. Bates No 2078333266A/3267. <http://legacy.library.ucsf.edu/tid/sqd70c00>.
- ²⁰Philip Morris. 2000. Our position on federal regulation of cigarettes. 27 Mar. Bates No 2085289332/9333. <http://legacy.library.ucsf.edu/tid/uzm10c00>.

- ²¹Philip Morris. 2000. Philip Morris' support of meaningful tobacco regulation. 6 Jun. Bates No 2078876657/6661. <http://legacy.library.ucsf.edu/tid/lfr82c00>.
- ²²Singh R, Sosin J. KRC Research & Consulting. 2000. Focus group results. 22 Dec. Philip Morris. Bates No 2080375724/5740. <http://legacy.library.ucsf.edu/tid/dnc75c00>.
- ²³Frederick Polls. 2000. Summary of focus group findings FDA regulation. Dec. Philip Morris. Bates No 2080375701/5717. <http://legacy.library.ucsf.edu/tid/anc75c00>.
- ²⁴Sosin J, Frederick K. Frederick Polls. 2000. Focus group results -- consumer reactions to PM's support of FDA regulation. 28 Dec. Philip Morris. Bates No 2080375718/5722. <http://legacy.library.ucsf.edu/tid/bnc75c00>.
- ²⁵Frederick Polls. 2001. Nationwide poll on opinions toward FDA regulation. Mar. Philip Morris. Bates No 2085573103/3120. <http://legacy.library.ucsf.edu/tid/ntw21c00>.
- ²⁶Philip Morris. 2001. FDA campaign overview. Bates No 2085285653/5654. <http://legacy.library.ucsf.edu/tid/zhm10c00>.
- ²⁷Parrish S. 2001. Steven C. Parrish Sea Island 20010427. 19 Apr. Philip Morris. Bates No 2085077308/7336. <http://legacy.library.ucsf.edu/tid/yrq02c00>.
- ²⁸Philip Morris. 2000. Societal alignment. May. Philip Morris. Bates No 2505614860/4879. <http://legacy.library.ucsf.edu/tid/mso25c00>.
- ²⁹Philip Morris. 2000. CEMA 20000000 societal alignment research study. 10 May. Philip Morris. Bates No 2080985466/5471. <http://legacy.library.ucsf.edu/tid/kky65c00>.
- ³⁰Smith EA, Malone RE. 2003. Thinking the "unthinkable": Why Philip Morris considered quitting. *Tob Control* 12(2):208-13.

- ³¹Philip Morris. 2000. PM21 messages (as of 20000410, used in Chapel Hill, Raleigh, Durham). 10 Apr. Philip Morris. Bates No 2082023227/3228.
<http://legacy.library.ucsf.edu/tid/oai86c00>.
- ³²Smith EA, Malone RE. 2003. Altria means tobacco: Philip Morris's identity crisis. *Am J Public Health* 93(4):553-6.
- ³³Parrish S. 1999. Steven C. Parrish Kraft Foods North America operating company meeting 990203. 3 Feb. Philip Morris. Bates No 2076283646/3683.
<http://legacy.library.ucsf.edu/tid/kax45c00>.
- ³⁴Philip Morris. 1999. Philip Morris USA creative presentation. 20 Jul. Philip Morris. Bates No 2072536952/6974. <http://legacy.library.ucsf.edu/tid/rlx28d00>.
- ³⁵Philip Morris. 1999. "A powerful company, poised for growth". 28 Jun. Philip Morris. Bates No 2076613158/3207. <http://legacy.library.ucsf.edu/tid/vki85c00>.
- ³⁶Philip Morris. 2001. Trade magazine briefing. 13 Aug. Bates No 2085621967/1985.
<http://legacy.library.ucsf.edu/tid/def31c00>.
- ³⁷Hsu SS. Both sides criticize Davis's tobacco bill. *Washington Post*, 22 June 2001; Sect. B1.
- ³⁸Philip Morris. 2000. Our position on federal regulation of cigarettes. 7 Apr. Bates No 2077088807/8808. <http://legacy.library.ucsf.edu/tid/rbh62c00>.
- ³⁹Parrish S. 2000. Tobacco tussle. Online News Hour.
http://www.pbs.org/newshour/bb/law/jan-june00/tobacco_3-21.html. [accessed 17 December 2004].
- ⁴⁰Philip Morris. 2001. FDA & tobacco: Why Philip Morris USA supports passage of legislation in the 107th congress granting FDA regulatory authority over tobacco

- products. 4 Jun. Bates No 2080779683/9696.
<http://legacy.library.ucsf.edu/tid/jmo20c00>.
- ⁴¹Philip Morris. 2001. Proposed FDA (substantive) projects. 2 Jan. Philip Morris,. Bates No 2085288676/8679. <http://legacy.library.ucsf.edu/tid/uqm10c00>.
- ⁴²Berlind M. 2000. A&P legislative outline. 4 Jan. Philip Morris. Bates No 2078281608A. <http://legacy.library.ucsf.edu/tid/giy37c00>.
- ⁴³Levine A, Richman J. 1999. Draft FDA regulation bill. 9 Apr. Philip Morris. Bates No 2072533443. <http://legacy.library.ucsf.edu/tid/gia06c00>.
- ⁴⁴Scruggs J. 2000. Re: Hill visits. 12 Apr. Philip Morris. Bates No 2074106964A. <http://legacy.library.ucsf.edu/tid/wxo45c00>.
- ⁴⁵Desel P. 2000. Re: Hill visits. 11 Apr. Philip Morris. Bates No 2074106964B. <http://legacy.library.ucsf.edu/tid/xxo45c00>.
- ⁴⁶Berlind M. 2000. Re: Hill visits. 12 Apr. Philip Morris. Bates No 2074106964. <http://legacy.library.ucsf.edu/tid/vxo45c00>.
- ⁴⁷Scruggs J. 2000. Hill visits report. 25 Apr. Philip Morris. Bates No 2074106960/6961. <http://legacy.library.ucsf.edu/tid/sxo45c00>.
- ⁴⁸Philip Morris. 2001. [Items we will ask be completely taken off the table]. 19 Jul. Philip Morris. Bates No 2085234669. <http://legacy.library.ucsf.edu/tid/czx12c00>.
- ⁴⁹Douglas CE. 1998. Preemption of state and local tobacco control policies. The Advocacy Institute. <http://www.advocacy.org/publications/mtc/preemption.htm>. [accessed 2 Aug 2004].
- ⁵⁰Garrison J, Myers M, Sefferin J, et al. American Cancer Society, American Heart Assn, American Lung Assn, Campaign for Tobacco Free Kids. 2001. [We are writing to

- express our strong opposition]. 21 Jun. Philip Morris. Bates No 2085235623/5624. <http://legacy.library.ucsf.edu/tid/pby12c00>.
- ⁵¹McKittrick B. 2001. Meeting with Waxman staff. 18 Jun. Philip Morris. Bates No 2085775265C/5266. <http://legacy.library.ucsf.edu/tid/eaw41c00>.
- ⁵²Philip Morris. 2001. Possible interpretations of "consumer acceptability" limitation. 20 Jun. Bates No 2085233505/3506. <http://legacy.library.ucsf.edu/tid/iqx12c00>.
- ⁵³Berlind M. 2001. First conversation with JT. 7 Jun. Philip Morris. Bates No 2085234695. <http://legacy.library.ucsf.edu/tid/bzx12c00>.
- ⁵⁴Philip Morris. 2001. MCTV Philip Morris FDA 20010000. 14 Jun. Philip Morris. Bates No 2085575564. <http://legacy.library.ucsf.edu/tid/dqx21c00>.
- ⁵⁵French J. CNN. 2002. CNN: Canada study: Graphic cigarette warnings effective. 9 Jan. Philip Morris. Bates No 2085756068B/6070. <http://legacy.library.ucsf.edu/tid/fje41c00>.
- ⁵⁶Pfeil M. 2002. Re: Canada study: Graphic cigarette warnings effective. 9 Jan. Philip Morris. Bates No 2085221370. <http://legacy.library.ucsf.edu/tid/arv12c00>.
- ⁵⁷National Cancer Institute. Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine. Bethesda, MD US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute; 2001. Report No.: 13.
- ⁵⁸Merlo E. 2002. Draft letter from Ellen Merlo to CEO of ACS, et al. Jan. Philip Morris. Bates No 2085074583/4584. <http://legacy.library.ucsf.edu/tid/vsp02c00>.
- ⁵⁹Spivak J, Berman M. 2001. Joint statement of public health organizations reaction to new National Cancer Institute study on light and low tar cigarettes: Smokers

- should quit, not switch and government must grant FDA authority over tobacco products. 27 Nov. Philip Morris. Bates No 2085586510.
<http://legacy.library.ucsf.edu/tid/xjz21c00>.
- ⁶⁰Philip Morris. 2001. Philip Morris USA responds to National Cancer Institute report. 27 Nov. Philip Morris. Bates No 2085586492/6493.
<http://legacy.library.ucsf.edu/tid/kkz21c00>.
- ⁶¹Philip Morris. 2001. PM USA federal regulatory strategy potential business implications. 6 Jun. Bates No 2082721932/1949.
<http://legacy.library.ucsf.edu/tid/sef91c00>.
- ⁶²Philip Morris. 2001. Philip Morris USA and Philip Morris International perspective on the Institute of Medicine's eleven regulatory principles. 23 Apr. Philip Morris. Bates No 2080383943/3947. <http://legacy.library.ucsf.edu/tid/rtw14c00>.
- ⁶³Philip Morris. 2001. WSA scientific review of the 20010000 IOM report "clearing the smoke". 25 Apr. Philip Morris. Bates No 2082677876/7888.
<http://legacy.library.ucsf.edu/tid/hok92c00>.
- ⁶⁴Scruggs J. 2001. FDA tobacco regulation initiative status report. 5 Jun. Philip Morris. Bates No 2085285629/5632. <http://legacy.library.ucsf.edu/tid/fim10c00>.
- ⁶⁵American Viewpoint. 2001. National FDA regulation survey key highlights. 28 Mar. Philip Morris. Bates No 2081333047/3059.
<http://legacy.library.ucsf.edu/tid/epq81c00>.
- ⁶⁶Harris P. 2001. Messages for democrats on FDA legislation. 27 Apr. Philip Morris. Bates No 2085235968/5969. <http://legacy.library.ucsf.edu/tid/jky12c00>.

- ⁶⁷Penn Schoen & Berland Associates. 2001. Internal messaging survey: FDA regulation of tobacco. 25 Jun. Philip Morris. Bates No 2085238984/9021.
<http://legacy.library.ucsf.edu/tid/mdz12c00>.
- ⁶⁸Kessler R. 2001. Moderate strategy. 20 Jun. Philip Morris. Bates No 2085235688/5689.
<http://legacy.library.ucsf.edu/tid/cmy12c00>.
- ⁶⁹Scruggs J. 2000. Re: Bishop bill. 24 Apr. Philip Morris. Bates No 2074106740.
<http://legacy.library.ucsf.edu/tid/cxo45c00>.
- ⁷⁰Scruggs J. 2000. Hill meetings report Wednesday 000426. 26 Apr. Philip Morris. Bates No 2074106962. <http://legacy.library.ucsf.edu/tid/txo45c00>.
- ⁷¹Scruggs J. 2001. Teitz with Senator Kennedy. 25 Jan. Philip Morris. Bates No 2082724802A. <http://legacy.library.ucsf.edu/tid/bef91c00>.
- ⁷²Philip Morris. 2001. FDA communications plan. 26 Jan. Philip Morris. Bates No 2085632053/2072. <http://legacy.library.ucsf.edu/tid/nng31c00>.
- ⁷³Oilman B. BSMG Worldwide. 2001. Davis kit materials. 10 Jul. Philip Morris. Bates No 2085783774/3788. <http://legacy.library.ucsf.edu/tid/qse20c00>.
- ⁷⁴Williams S. BSMG Worldwide. 2001. Davis kit materials. 10 Jul. Philip Morris. Bates No 2085774820A. <http://legacy.library.ucsf.edu/tid/rvv41c00>.
- ⁷⁵Williams S. BSMG Worldwide. 2001. Re: FDA Week article -- Kennedy bill. 27 Aug. Philip Morris. Bates No 2085775475A.
<http://legacy.library.ucsf.edu/tid/skw41c00>.
- ⁷⁶Berlind M. 2001. Re: FDA Week article Kennedy bill. 27 Aug. Philip Morris. Bates No 2085775475. <http://legacy.library.ucsf.edu/tid/tkw41c00>.

- ⁷⁷Williams S. BSMG Worldwide. 2001. Re: FDA Week article -- Kennedy bill. 27 Aug. Philip Morris. Bates No 2085785657. <http://legacy.library.ucsf.edu/tid/xif20c00>.
- ⁷⁸Berlind M. 2001. Re: Business Week. 3 Jul. Philip Morris. Bates No 2085775291. <http://legacy.library.ucsf.edu/tid/cyv41c00>.
- ⁷⁹Hoel J. 2001. John Hoel director, state government affairs PMMC Oak Ridge Rotary club 20011018 Oak Ridge, TN. 18 Oct. Philip Morris. Bates No 2085257284/7290. <http://legacy.library.ucsf.edu/tid/uid22c00>.
- ⁸⁰Gomez F. 2001. Frank Gomez director, media relations Philip Morris Management Corp. Mexican American chamber of commerce Chicago, Illinois 20010726. 26 Jul. Philip Morris. Bates No 2085137381/7384. <http://legacy.library.ucsf.edu/tid/gsh12c00>.
- ⁸¹Parrish S. 2001. Federal regulation of cigarettes: An issue for Hispanics? Philip Morris. Bates No 2083407990. <http://legacy.library.ucsf.edu/tid/rnr92c00>.
- ⁸²Parrish S. 2001. Steve Parrish senior vice president Philip Morris management corporation editorial board meeting San Francisco Chronicle Wednesday, 20010711. 11 Jul. Philip Morris. Bates No 2085074801/4826. <http://legacy.library.ucsf.edu/tid/waq02c00>.
- ⁸³Pfeil M. 2001. The time is right for federal regulation of cigarettes. 2 Jul. Philip Morris. Bates No 2085075045/5046. <http://legacy.library.ucsf.edu/tid/sxp02c00>.
- ⁸⁴Oilman B. BSMG Worldwide. 2001. Editorial board visits. 19 Jul. Philip Morris. Bates No 2085575655. <http://legacy.library.ucsf.edu/tid/mpx21c00>.
- ⁸⁵BSMG Worldwide. 2000. FDA communications. 20 Sep. Philip Morris. Bates No 2085235197/5202. <http://legacy.library.ucsf.edu/tid/jgy12c00>.

- ⁸⁶BSMG Worldwide. 2001. FDA campaign revised communication plan. 16 Feb. Philip Morris. Bates No 2085249878/9885. <http://legacy.library.ucsf.edu/tid/fwb22c00>.
- ⁸⁷Telephone call with Michael Pfeil, vice president, community and public affairs, Philip Morris. Personal communication to McDaniel P. 6 January 2005.
- ⁸⁸Philip Morris. 2001. PMUSA corporate affairs department meeting. 11 Jul. Philip Morris. Bates No 2085581520/1591. <http://legacy.library.ucsf.edu/tid/gly21c00>.
- ⁸⁹Philip Morris. 2001. State government affairs districts - regions - public affairs network. 5 Apr. Bates No 2082656814/6822. <http://legacy.library.ucsf.edu/tid/oye91c00>.
- ⁹⁰Serrano MV. 2001. 2001 state coalition status report field action team. 12 Mar. Philip Morris. Bates No 2085257098/7152. <http://legacy.library.ucsf.edu/tid/hzc22c00>.
- ⁹¹Serrano M. 2001. Philip Morris field action team FDA education campaign stakeholder briefing report 20010524. 24 May. Philip Morris. Bates No 2085256882. <http://legacy.library.ucsf.edu/tid/jvc22c00>.
- ⁹²Philip Morris. 2001. PM field action team FDA education campaign stakeholder briefings summary 20010723. 23 Jul. Philip Morris. Bates No 2085074930. <http://legacy.library.ucsf.edu/tid/iaq02c00>.
- ⁹³Philip Morris. 2001. PM field action team FDA education campaign stakeholder briefings as of 20010515. 15 May. Bates No 2085247345/7348. <http://legacy.library.ucsf.edu/tid/cgb22c00>.
- ⁹⁴Philip Morris. 2001. The time is now for federal rules on tobacco. May. Philip Morris. Bates No 2085761541/1544. <http://legacy.library.ucsf.edu/tid/jhk41c00>.

- ⁹⁵Serrano M. 2001. FDA education campaign special report hospitality stakeholders. 4 Sep. Philip Morris. Bates No 2085232573.
<http://legacy.library.ucsf.edu/tid/vix12c00>.
- ⁹⁶Deem RA. American Medical Association. 2001. FDA regulation. 17 Apr. Philip Morris. Bates No 2085235447/5448. <http://legacy.library.ucsf.edu/tid/ody12c00>.
- ⁹⁷Philip Morris. 2001. Field action team ally meeting report FDA education campaign. 1 May. Bates No 2085257073. <http://legacy.library.ucsf.edu/tid/fad22c00>.
- ⁹⁸Wilson G. 2000. Re: FDA plan stakeholders. 6 Oct. Philip Morris. Bates No 2082716481D/6482. <http://legacy.library.ucsf.edu/tid/mel92c00>.
- ⁹⁹National conference of state legislatures assembly on federal issues. 2001. 11 May. Philip Morris. Bates No 2085761303/1306.
<http://legacy.library.ucsf.edu/tid/myj41c00>.
- ¹⁰⁰Philip Morris. 2001. FDA and tobacco FDA communications. 12 Jun. Philip Morris. Bates No 2085632027/2036. <http://legacy.library.ucsf.edu/tid/qng31c00>.
- ¹⁰¹Carnovale M. 2001. Re: B&W FDA press release. 7 Aug. Philip Morris. Bates No 2085263044. <http://legacy.library.ucsf.edu/tid/zfe22c00>.
- ¹⁰²Szymanczyk M. 2001. FDA regulation of cigarettes. 27 Jun. Philip Morris. Bates No 2085626863/6868. <http://legacy.library.ucsf.edu/tid/byf31c00>.
- ¹⁰³Sylvia D. 2000. Proposed FDA research plan. 11 Nov. Philip Morris. Bates No 2085235296/5299. <http://legacy.library.ucsf.edu/tid/jfy12c00>.
- ¹⁰⁴Carpenter R, Divall L, Frederick K. 2000. Focus group executive summary. 29 Mar. Philip Morris. Bates No 2085289499/9507.
<http://legacy.library.ucsf.edu/tid/xym10c00>.

- ¹⁰⁵Company interview: Philip Morris management corp. *Wall Street Transcript*, 27 Aug, 2001:109-112.
- ¹⁰⁶Philip Morris. 2002. [What is Philip Morris' current agenda?]. Jan. Philip Morris. Bates No 2085786117/6121. <http://legacy.library.ucsf.edu/tid/gnf20c00>.
- ¹⁰⁷Williams S. BSMG Worldwide. 2001. Re: B&W FDA press release. 6 Aug. Philip Morris. Bates No 2085263055. <http://legacy.library.ucsf.edu/tid/pfe22c00>.
- ¹⁰⁸McKittrick B. 2001. Meetings on FDA. 21 Mar. Philip Morris. Bates No 2085235084. <http://legacy.library.ucsf.edu/tid/ivx12c00>.
- ¹⁰⁹Morgan D, Dewar H. House blocks FDA oversight of tobacco. *Washington Post*, 12 Oct 2004; Sect. A.04.
- ¹¹⁰Greenburg D. From Marlboro to Velveeta: Can Altria become a model citizen? In: Speech at University of California, Berkeley Haas School of Business, Center for Responsible Business Lecture Series; 13 Oct 2004.
- ¹¹¹American Cancer Society, American Heart Association, Campaign for Tobacco-Free Kids, et al. [It has come to our attention]. Letter to Louis Camilleri; 19 Oct 2004.
- ¹¹²Wirthlin Group. 1993. Philip Morris companies a national opinion survey. Apr. Philip Morris. Bates No 2025415446/5466. <http://legacy.library.ucsf.edu/tid/emn85e00>.
- ¹¹³Richardson D. Wirthlin Group. 1994. Issues and image results. 18 Apr. Philip Morris. Bates No 2022890713/0715. <http://legacy.library.ucsf.edu/tid/uvc78e00>.
- ¹¹⁴Philip Morris. 1998. PM21 research brief. Bates No 2076283444/3450. <http://legacy.library.ucsf.edu/tid/bmx45c00>.
- ¹¹⁵Farrelly MC, Healton CG, Davis KC, et al. 2002. Getting to the truth: Evaluating national tobacco countermarketing campaigns. *Am J Public Health* 92(6):901-7.

- ¹¹⁶Niederdeppe J, Farrelly MC, Haviland ML. 2004. Confirming "truth": More evidence of a successful tobacco countermarketing campaign in Florida. *Am J Public Health* 94(2):255-7.
- ¹¹⁷Doll R, Peto R, Wheatley K, et al. 1994. Mortality in relation to smoking: 40 years' observations on male British doctors. *Br Med J* 309(6959):901-11.
- ¹¹⁸Kaufman D. Constituents of cigarette smoke and cardiovascular disease. In: Blum A, editor. *The cigarette underworld*. Secaucus, NJ, Lyle Stuart Inc., 1985:27-28.
- ¹¹⁹Centers for Disease Control and Prevention. 2002. Annual smoking attributable mortality, years of potential life lost, and economic costs--United States, 1995-1999. *Morbidity and Mortality Weekly Report* 51(14):300-303.
- ¹²⁰Anon. 2004. FDA finalizes ephedra ban. CNN.com.
<http://www.cnn.com/2004/HEALTH/diet.fitness/02/06/ephedra.ban.ap/>. [accessed 25 Aug 2004].

Competing interest statement:

The authors declare that they have no competing interests.