



Strategies of Influence: How Corporate Power Directs and Constrains the FDA

Citation

Strategies of Influence: How Corporate Power Directs and Constrains the FDA (2001 Third Year Paper)

Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8846804>

Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

Share Your Story

The Harvard community has made this article openly available.
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

Strategies of Influence: How Corporate Power Directs and Constrains the FDA

David Marc Solet
Peter Barton Hutt, Advisor
Harvard Law School
May 1, 2001

Table of Contents

Table of Contents.....	i
Introduction.....	1
The Role of the FDA	4
The Impregnable FDA.....	4
Shadow-Boxing With the Tobacco Industry	9
Using the Congress.....	11
The Role of Campaign Contributions: Paying the Piper, Calling the Tune	13
Tobacco Industry Support of Congressional Leadership, 1995-2000.....	16

Tobacco Industry Lobbying: Lend Me Your Ears.....	20
Inside Connections, Trustworthy Figures.....	23
The Shadow FDA.....	25
Flexing Tobacco’s Muscles: The Congressional Assault on Kessler’s FDA.....	27
Roll-Call Votes: Winning When it Counts.....	28
Congressional Committees and the Oversight Function.....	30
Attacking the FDA’s Integrity.....	32
Putting Words in the Mouths of Congress.....	34
High Pressure Letter Writing Campaigns	35
Friendly Governors.....	38
Threatening the FDA Budget.....	41
Aggressive Reform Plans: Eviscerating the FDA	43
The Outside Game: Shaping Public Opinion.....	46
Grassroots and Astroturf.....	47
Buying Legitimacy: A Patron of the Arts.....	51
A Patron of the Sciences.....	51

Discarding Evidence, Fabricating Data.....	53
The Council for Tobacco Research (CTR).....	54
The Tobacco Industry’s Scientists: The Whitecoat Project	56
The Center for Indoor Air Research (CIAR)	59
Using Third-Party Front Groups.....	66
Attacking Industry’s Opponents.....	70
Controlling Mass Media.....	72
Fox/NewsCorp.....	75
Forbes: Capitalist Tool.....	77
Tobacco Conclusion.....	79
A Case Study: Procter & Gamble and Olestra.....	80
Olestra: What It Cost Procter & Gamble.....	81
Concerns About Olestra.....	83
The FDA’s Decision.....	85
Behind the Scenes.....	86
Procter & Gamble’s Scientists.....	88

Peer-Reviewed Journals.....	90
Funding the Congress.....	91
Procter & Gamble Hard Money Contributions, 1997-2000.....	91
Using the Congress to Lobby the FDA.....	94
Lobbying for Olestra.....	96
Effects of Congressional Pressure.....	99
Attacking Olestra’s Enemies.....	101
Using Front Groups.....	102
Consumer Alert.....	105
Coordination From Above.....	108
Steven Milloy and “Junk Science”	109
Milloy, Tobacco, and Procter & Gamble.....	111
Suspicious Endorsements.....	114
The American Dietetic Association (ADA)	115
The American Council on Science and Health (ACSH).....	117
The National Consumers League (NCL)	120

The Shadow FDA: Part II.....	122
Conclusion.....	125

INTRODUCTION

This paper is about the Food and Drug Administration, and the tactics that regulated – and sometimes unregulated – industries use to influence that agency’s decision-making process. Many of these tactics are legal; others are illegal, but difficult to recognize and police. In virtually every case, the purpose of these tactics is to undermine the neutral and detached scientific processes to which the FDA aspires, in order to advance the financial interests of regulated industries. While some of the details recounted herein are gravely disturbing, even outrageous, the purpose of this paper is not to moralize, but to identify these tactics and assess them in a neutral fashion, in order that they may offer some lesson about the systemic structures that created them.

Concern about the interaction between the government and regulated industry is not a new development. In 1978, Richard Crout observed, with some disdain, that “It appeals to the biases of nearly everyone to view regulatory controversies as basically one-on-one contests between the virtuous and the untrustworthy.”¹ While this paper will explore in detail the sometimes unsavory methods by which industries regulated by the FDA seek to influence the regulatory process to their own advantage, it will attempt to heed Crout’s warning to avoid simplistic, Manichean analyses of what are, and should be treated as, complex systemic problems. Not every agreement or accommodation between the FDA and its constituent industries should be assumed to represent an abandonment of its statutory obligations; any agency that attempted to litigate

¹Richard J. Crout, “The Nature of Regulatory Choices,” 33 Food Drug Cosmetic Law Journal 413 (1978)

every potential violation would drown itself in the legal process, and frustrate the accomplishment of its mission. Likewise, it would be unfair to assume that every document request made by a member of Congress is part of a shadowy conspiracy; aggressive oversight by Congress is essential to the proper accountability and functioning of any regulatory agency.

What this paper does seek to explore, however, is the range of methods and techniques by which aggressive industry advocates have subtly shifted the balance of power away from the FDA and the consumer and toward regulated industries. The first part of the paper will deal primarily with the example offered by the tobacco industry, which has waged a protracted and ultimately successful campaign to avoid the regulation of its products by the FDA. I have chosen the tobacco industry (and not, for example, the pharmaceutical industry) for two reasons: first, because the tobacco industry has been resourceful, determined, and spectacularly creative in its efforts, pioneering many of the techniques that are now widely employed by more benign industries; and second, because the extended civil litigation surrounding the health effects of tobacco smoke has given the public unrivaled access to the internal deliberations and efforts of the industry.

The second part of this paper will focus on a far more benign product, a controversial food additive that has received little serious attention in the mainstream media: Procter & Gamble's "non-fat fat" olestra. Unlike the tobacco industry, the internal machinations of the Procter & Gamble Corporation remain largely shrouded in secrecy. There is enough evidence already available to the public, however, to interpolate and extrapolate from what we know to what we can surmise, and to compare and contrast the techniques employed by this giant of the food products industry to its counterparts in the world of tobacco.

What I hope to show is that the techniques that the tobacco industry perfected are not unique to that now

notorious industry, but are in fact routinely employed by a range of companies we often think of as harmless.² Evidence suggests that if we were given access to the inner workings of Procter & Gamble, or indeed of any large American corporation with a significant financial stake in a regulatory proceeding before the FDA, we would find strategies every bit as clever, methods every bit as calculating, as we find in the records of the tobacco industry giants. Perhaps it should come as no surprise that equivalently situated companies of the same scale, advised by the very same attorneys and guided by the very same public relations experts, will exploit every available opportunity to advance their agenda, and will pursue that agenda every bit as ruthlessly as the corporate leadership of Philip Morris or Brown & Williamson. Nevertheless, I think it *would* surprise most citizens that this is so – and the revelation that the techniques described herein are routine practice would fill them with shock and dismay. The purpose of this paper, however, is not to shock and dismay, but to stimulate thought and debate about structural reforms of the regulatory apparatus and the means by which interested parties seek to influence them.³

²If anything, the actions of the tobacco industry are strongly reflective of corporate norms. Evidence suggests it is unrealistic to imagine that industry will practice any more self-restraint than prudence demands. See Albert Z. Carr, “Is Business Bluffing Legal?” 46 Harv. Business Rev. 143 (1968). In that article, a Midwestern executive (who remains, by request, anonymous) says, “So long as a businessman complies with the laws of the land and avoids telling malicious lies, he’s ethical. If the law as written gives a man a wide-open chance to make a killing, he’d be a fool not to take advantage of it. If he doesn’t somebody else will. There’s no obligation on him to stop and consider who is going to get hurt. If the law says he can do it, that’s all the justification he needs. There’s nothing unethical about that. It’s just plain business sense.” While (at the behest of public relations consultants), most businessmen publicly deny that they see their own conduct in such Machiavellian terms, there is ample evidence that this is the dominant understanding in the corporate world. Indeed, adherence to a form of this creed is widely considered mandatory among corporate legal counsel.

³The primary purpose of this paper is descriptive, rather than prescriptive; it seeks to identify and explore the methods of industry influence on the FDA, but it is not a comprehensive plan to reform the federal campaign finance system, to regulate the lobbying industry, or to restructure our nation’s methods of funding scientific research.

THE ROLE OF THE FDA

In 1938, Congress enacted the Federal Food, Drug, and Cosmetics Act (FDCA) to protect consumers' health and welfare by preventing the introduction or receipt of misbranded or adulterated medicines, foods, or cosmetics.⁴ To give teeth to this goal, the FDCA conferred on the Secretary of Health, Education and Welfare (now Health and Human Services) the authority to issue regulations;⁵ the Secretary, in turn, delegated the authority to act under the FDCA to the Commissioner of the Food and Drug Administration (FDA).⁶ To fulfill its mission of protecting consumers, the FDA has been granted the "power to approve and regulate drugs, vaccines, over-the-counter remedies, food additives, medical devices, and animal medications; to inspect factories and set standards on food production; to sample marketed foods for impurities; and to regulate advertising for food, drugs, and cosmetics."⁷ Today the FDA is one of the most influential regulatory agencies in the nation, with jurisdiction over products that account for twenty-five cents of every consumer dollar – worth more than \$1 trillion annually.⁸

THE IMPREGNABLE FDA

With its vast responsibilities, and authority to make decisions with enormous financial ramifications, it should come as little surprise that industry forces have long sought to influence the FDA in its decision-making processes. What is surprising is the impressive record the FDA has achieved over most of the course of its existence of resisting the overtures of some of the nation's most powerful interest groups. Where other arms of the federal bureaucracy have been accused of being "captured" by the constituencies they are supposed

⁴See 21 U.S.C. §§ 301-395 (1994 & Supp. 1997); see also *United States v. Two Bags, Poppy Seeds*, 147 F.2d 123, 126-27 (6th Cir. 1945) (discussing the intent of the FDCA).

⁵See 21 U.S.C. § 371(a) (1994).

⁶See 21 C.F.R. § 5.10(a) (1997).

⁷"Perspectives: GOP Sets Its Sight on Food & Drug Administration," *Med. & Health*, Feb. 20, 1995

⁸Henry I. Miller, "The Wrong Choice For The FDA," *The Wall Street Journal*, June 26, 1998, p. A14.

to regulate (including, for instance, the Departments of Agriculture and Energy), the FDA has achieved a praiseworthy reputation for independence and scientific integrity.

To be sure, the FDA's record is not spotless. In 1987, the Agency suffered through one of its darkest hours, in what became known as the Generic Drug scandal. An FDA supervisor named Charles Chang had received expensive gifts (including a fur coat and a videocassette recorder) from drug company lobbyists, in exchange for arranging that their drugs received expedited Agency approval. Chang knew which of his subordinates were quick workers, and which were more methodical; by controlling the assignment of projects, he found he could manipulate the approval schedule. Chang's actions were a gross betrayal of the public trust, and a black eye for the Agency. By the end, Chang was in a federal prison, and forty-two other people and ten companies were convicted on charges of fraud and corruption.⁹

What made the Generic Drug scandal so newsworthy was not merely its tawdriness, but how out of place it was in the history of the Agency. For the most part, those who would exert undue influence over bureaucratic decision-making appear to have had far less success with the FDA than with other agencies of the federal government. Peter Barton Hutt and Richard Merrill, each a former general counsel to the FDA, offer a number of explanations for FDA's relative impregnability. First, they suggest, "the evident scientific basis for most of FDA's positions has helped insulate it from many of the customary forms of political pressure."¹⁰ Second, they cite the agency's public profile, which exceeds those of many Cabinet-level agencies: "the visibility of FDA's programs has given the agency, and thus the Commissioner, a public standing that frequently blunts pressure from within any incumbent administration."¹¹ Finally, Hutt and Merrill cite the composition of the rank-and-file personnel of the Agency, noting that because "few jobs have been

⁹David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.8

¹⁰Peter Barton Hutt and Richard A. Merrill, "Food and Drug Law: Cases and Materials, University Casebook Series, Foundation Press, Westbury, NY, 1991, p.16

¹¹Id.

subject to political appointment... for most of its existence FDA has operated with considerable decisional independence and enjoyed continuity in the service of employees who hold middle-management positions and staff its several field offices.”¹²

Certainly some of the factors Hutt and Merrill mention remain clearly present in the contemporary FDA; the esteem in which the public held former Commissioner David Kessler, and the constraints this put on President George H. W. Bush, nicely illustrate the Commissioner’s potential for “blunting pressure from within... the administration.” Indeed, in an era where the federal government, and especially the federal bureaucracy, have often been held up to public ridicule, the FDA remains an extremely popular agency, one which commands respect and admiration from citizens across the political spectrum. According to a 1997 nationwide poll of registered voters, the FDA rates among the federal agencies in which they have the greatest confidence.¹³ Eighty-seven percent of voters saw the FDA as “necessary,” and sixty-one percent described the FDA as “very necessary.”¹⁴ These favorable numbers remained despite the existence, at the time of the poll, of a concerted public relations effort to discredit the FDA. Despite the increasingly partisan nature of debate about the role of the federal government and of economic regulation, and the increasingly partisan battle lines between pro-tobacco Republicans and anti-tobacco Democrats, support for the FDA among the voters remained consistently strong across party lines: eighty-six percent of Republicans, eighty-eight percent of independents, and eighty-eight percent of Democrats felt the FDA was “necessary.”¹⁵ A plurality (forty-five percent) of those surveyed indicated their belief that the FDA does a better job than other government agencies, a figure that included forty-three percent of self-identified Republicans; only thirteen percent described the FDA as doing a worse job than other agencies.¹⁶

¹²Id.

¹³“America Supports FDA,” Human Rights Campaign, Press Release, April 16, 1997. Analysis based on results from a nationwide telephone survey of 1,000 registered voters by Lake Sosin Snell & Associates and the Tarrance Group, conducted April 8-10, 1997. The margin of error for the sample is +/-3.1 percent.

¹⁴Id.

¹⁵Id.

¹⁶Id.

But while FDA still commands the respect of the American public, many of the other factors that Hutt and Merrill cite as providing political insulation have been compromised or eliminated since 1991, the last edition of their text. Increasingly, industry representatives and their surrogates deride Agency scientists as risk-averse and unnecessarily paternalistic, and openly challenge the scientific bases of FDA decisions. Because the general public is largely incapable of choosing between conflicting positions on the scientific merits, “science” no longer serves as a trump for FDA. In addition, while the legacy of David Kessler has left the FDA Commissioner with arguably a greater public profile and moral authority than ever before, turnover among middle management has been greatly accelerated. It has now been nearly twenty-five years since the FDA launched Operation Hire, an initiative that expanded the agency by hundreds of people. As a result, 70% of all managers will be eligible for retirement between 1999 and 2001.¹⁷ Others are leaving because of the treatment FDA officials have received at the hands of an increasingly hostile Congress. “I decided it was no longer worth my time to take the psychological and verbal abuse from members of Congress or their staff,” said Curtis Scribner, deputy director of the FDA’s blood office until late 1997. “I wasn’t having fun any more.”¹⁸ Ralph Harkins, who spent more than a decade managing a major statistical division at the FDA, said, “I just decided I wasn’t getting the support I needed. I took my retirement and ran.”¹⁹ In Harkins’ division, 12 of 22 statisticians departed between 1998 and 1999. Working conditions were clearly a factor in the mass exodus; most of those who left had been working more than twelve hours a day to try to keep up with more demanding approval deadlines.²⁰ The hostility of the Congress and the budgetary constraints it has imposed risk creating a self-perpetuating cycle: congressional antagonism forces out the stabilizing core of middle managers, and the loss of their stability has left the FDA more vulnerable than ever to undue influence and bullying.

¹⁷Rochelle Sharpe, “FDA Tries to Find Right Balance on Drug Approvals,” *The Wall Street Journal*, April 20, 1999

¹⁸*Id.*

¹⁹*Id.*

²⁰*Id.*

The state of the FDA's independence remains hotly debated. Consumer advocates like Larry Sasich of Public Citizen argue that Commissioner Jane Henney "sold the farm" to win confirmation by a Republican Congress, and that the agency has been "completely co-opted by industry."²¹ Others reject the notion that FDA's integrity has been even remotely compromised by its struggles with hostile industries. Former Deputy Commissioner Carol Scheman, for instance, flatly rejects the suggestion that FDA officials would permit industry pressure to compromise their scientific judgement. "I don't think it's possible," she says. "These are among the most rigidly moral people I know."²²

If Larry Sasich perhaps overstates his case, Carol Scheman seems to ignore the practical realities of FDA's situation. The prophylactic protections of a "rigidly moral" staff are vital in avoiding the Watergate-style corruption that defined the Generic Drug scandal, but they are simply insufficient to resist the kind of systemic coercion to which the Agency is now legally subject. Because the methods by which industry players influence the FDA often go over and around, rather than through, the Food and Drug Administration, the integrity of FDA's officers has become a necessary, but not sufficient characteristic for effective FDA leadership. As the tobacco industry proved, it is possible to subvert the FDA without the Agency's assent.

SHADOW-BOXING WITH THE TOBACCO INDUSTRY

Industry actors who find themselves unable to influence the FDA directly have come to employ an array of other techniques. These include providing the political campaigns of sympathetic lawmakers with financial and organizational support, lobbying incumbent lawmakers to pursue an industry-supported agenda, supporting (and sometimes purchasing) scientific research likely to be favorable to industry, and organizing broad-based public relations campaigns, sometimes through third-party actors with independent credibility.

²¹Stephen Pomper, "The New Drug Pushers," *Shepherd Express Metro*, September 14, 2000

²²Stephen Pomper, "Drug Rush: Why the Prescription Drug Market is Unsafe at High Speeds," *Washington Monthly*, May, 2000

In its campaign to avoid FDA regulation, the tobacco industry used all of these techniques to brilliant effect. Since pre-colonial times, tobacco has been one of America's most profitable cash crops. It remains an agricultural staple; according to industry figures, the tobacco industry accounts for more than 680,000 jobs nationwide, and in many regions is the driving force behind the local economy.²³ Despite mounting evidence of tobacco's addictive properties and health risks from the 1950s onward, the Food and Drug Administration had never attempted to assert authority over cigarettes. For decades, the FDA acted under the assumption that it would need a specific grant of statutory authority to assert jurisdiction over tobacco products. In 1977, Commissioner Donald Kennedy, challenged by a member of the Senate to explain why the FDA had not regulated tobacco, responded, "Senator, I'll be glad to go to work on the cigarette ban as soon as you give me the authority to do so."²⁴ Commissioner David Kessler turned around the FDA's approach to tobacco, aggressively gathering evidence and building his case. On August 28, 1996, the Food and Drug Administration announced its controversial regulation of tobacco products, igniting a firestorm of political controversy.²⁵ The tobacco industry called on every weapon at its disposal - chief among them its carefully cultivated allies in the Congress.

USING THE CONGRESS

While in theory most of the FDA's decisions are made on the basis of independent scientific judgements, the

²³Hank Cox, "Feds and Smokers Fume Over the Right to Inhale," *The Washington Times*, Apr. 24, 1995, at 14 (citing to a 1992 Price Waterhouse Study).

²⁴David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," *PublicAffairs*, New York, 2001, p.27

²⁵See "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," 61 Fed. Reg. 44,396, 44,398 (1996)

Agency has always been closely scrutinized by members of Congress, and the degree of support or hostility the Congress demonstrates can have a powerful effect on internal FDA decision-making. Hutt and Merrill note in their seminal casebook:

The [FDA] is controversial. Its decisions are closely watched. Numerous congressional committees critique its performance, very often concluding that it has been reckless in approving new products or insufficiently vigorous in acting against old ones. The message conveyed by both the intensity and attitude of congressional oversight has had enormous influence on both the content of FDA's requirements and the thrust of its enforcement efforts.²⁶

While the statute under which the FDA operates has remained largely unchanged, the Congress controls the FDA's budget on a year-to-year basis, has broad oversight responsibilities, and has demonstrated a willingness to use that authority to control the FDA's regulatory agenda. The willingness of Congress to second-guess the FDA is hardly a new development; legislative micro-management has long been a concern of regulatory experts. Louis Rothschild wrote in 1978, "I am not criticizing the right of any segment of the population to take its troubles to Capitol Hill, for hearings to be held, or for members of Congress to express their views. However, I am disturbed by the threat of legislation to cut the ground out from under the FDA if it does not do what isolated Congressmen or a powerful Congressional subcommittee tell it to do, even though it may conflict with the Agency's stated policy or mandate."²⁷ This concern remains as vital and relevant in 2001 as when Rothschild voiced it in 1978.

What have changed are the source of congressional dissatisfaction, and the direction of its criticism. In 1974, FDA Commissioner Alex M. Schmidt wrote,

²⁶Peter Barton Hutt and Richard A. Merrill, "Food and Drug Law: Cases and Materials, University Casebook Series, Foundation Press, Westbury, NY, 1991, p.19

²⁷Louis Rothschild, "The Newest Regulatory Agency in Washington," 33 Food Drug Cosmetic Law Journal 86 (1978), as cited in Peter Barton Hutt and Richard A. Merrill, "Food and Drug Law: Cases and Materials, University Casebook Series, Foundation Press, Westbury, NY, 1991, p.1317

By far the greatest pressure that the Bureau of Drugs or the Food and Drug Administration receives with respect to the drug approval process is brought to bear through congressional hearings. In all of our history, we are unable to find one instance where a congressional hearing investigated the failure of FDA to approve a new drug. The occasions on which hearings have been held to criticize approval of a new drug have been so frequent in the past ten years that we have not even attempted to count them.... Until perspective is brought to the legislative oversight function, the pressure from Congress for FDA to disapprove new drugs will continue to be felt, and could be a major factor in health care in this country.²⁸

This sentiment would hardly be recognizable to contemporary observers of the Congress-FDA relationship. Since Schmidt's time, FDA-Congressional relations have undergone a profound shift.

Where FDA was once roundly criticized for insufficient oversight and an overly solicitous attitude toward the industries it regulates, contemporary Congressional criticism has lambasted FDA for being unnecessarily adversarial in its relations with industry, and for pursuing its regulatory mission with excessive zeal. This paradigm shift in Congressional attitudes reflects a number of larger changes: shifts in public attitudes toward government regulation, in the partisan composition of the Congress, in the mounting importance of fundraising to political success, and in events like the HIV/AIDS crisis, which required a more flexible and adaptable Food and Drug Administration. This change in congressional attitudes is also reflective, in no small degree, to an aggressive, resourceful campaign by the American tobacco industry to deter, or if necessary, prevent the FDA from regulating its products.

²⁸Statement of Alex M. Schmidt, M.D., Commissioner of Food and Drugs, "Regulation of New Drug R. & D. By the Food And Drug Administration," Joint Hearings Before the Subcomm. On Health of the Senate Comm. On Labor and Public Welfare and the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, 93d Congress, 2d Session (1974)

THE ROLE OF CAMPAIGN CONTRIBUTIONS: PAYING THE PIPER, CALLING THE TUNE

One of the principal means by which an industry can advance its political agenda is by supporting the electoral campaigns of ideologically friendly candidates. Running for elected office can be enormously expensive – candidates for the House of Representatives routinely spend over one million dollars on their campaigns, and candidates for the Senate frequently spend in the tens of millions. As the cost of political campaigns has accelerated, elected officials have found it necessary to raise ever-increasing amounts of money, and corporate interests have proven to be a reliable source of funding. Though corporations have been prohibited from making direct donations to candidates for federal election since 1907, when Congress passed the Tillman Act,²⁹ corporations still make their influence felt, through the personal donations of industry-affiliated individuals like executives and lobbyists, through industry-affiliated Political Action Committees (PACs), and, increasingly, through unregulated “soft money” contributions, which are ostensibly for “party-building” purposes and are donated directly to the national or state-level political parties.

Louise Overcracker wrote in her 1932 book, *Money in Elections*, “No party which is financially dependent upon the substantial business interests... would feel free to embark on an economic program which met with their hostility. Even a dog will not bite the hand that feeds it, and a political party will hardly ‘sell out’ the person whose money it accepts.”³⁰ Overcracker’s model is of course oversimplified; academics like Herbert Alexander and Frank Sorauf have contended that the popular model of politicians being “bought and sold” by campaign contributions is unsubstantiated by empirical evidence, and have emphasized the existence of stronger correlation of legislative voting to ideology, party or constituency interests than to contributions.³¹

²⁹ *Election Reform: Basic References* United States Senate, Select Committee on Presidential Campaign Activities Pursuant to S. Res. 60, 93rd Congress, 1st session, November, 1973

³⁰ Louise Overcracker, “Money in Elections,” New York: Macmillan, 1932, pp. 374-375

³¹ See Herbert Alexander, Brookings Institution Working Group on Campaign Finance Reform, 1996

What Alexander and Sorauf ignore, however, is that campaign contributions make the bulk of their impact in the campaigns themselves, by helping to determine *who is elected*, and consequently the ideology and party affiliation that most consistently determine voting behavior. And while elected representatives rarely deviate from their core positions, campaign donations can have a significant effect at the margins; among uncommitted representatives, on issues that have little salience with the public, financial support – or the threat of its withdrawal – can be a deciding factor for a legislator. Because the individual regulatory decisions of the FDA have little salience with the general public, but enormous financial consequences for interested parties, they are uniquely vulnerable to this kind of legislative influence.

One of the key elements of the tobacco industry's legislative strategy was to maintain a broad base of political support among the elected leaders of both parties in Congress. For many years, tobacco-producing Southern states like North Carolina, Kentucky and Virginia were firmly in Democratic hands, and the tobacco industry became a generous patron of Southern Democrats. As Southern states gradually gravitated toward the Republican Party, the tobacco industry slowly shifted its political allegiances. That shift was cemented by the 1994 change in party control of Congress, and escalated as David Kessler's FDA – with the public support of a Democratic President – made regulation of tobacco an Agency priority. Between 1989 and 1994, when Democrats controlled both Houses of Congress, tobacco PACs contributed nearly identical amounts of hard money – about \$3.3 million each – to Republican and Democratic candidates.³² But after the GOP assumed control in 1994, tobacco donations shifted strongly to the new party in power; once Republicans assumed control, the tobacco industry was intent on keeping them there. The alliance was in many ways a natural fit: the Republican Party was ascendant in tobacco states like North Carolina and Kentucky, ideologically

³²“Buying Influence, Selling Death: How Big Tobacco's Campaign Contributions Harm Public Health,” Common Cause, March 14, 2001

opposed to federal regulation and taxation, and strongly in favor of pro-business anti-tort legislation. Today, the tobacco industry's support is firmly behind the Republican Party, and has stayed there, even as the Republican advantage in the Congress has slipped with each successive election cycle. In the 2000 election cycle, the tobacco industry gave \$6.3 million, or eighty-three percent of its total contributions, to Republican candidates and committees.³³

Part of the tobacco industry's campaign finance strategy was to forge friendly relationships with the leadership of the major parties, those Members who set the legislative agenda in the Congress. The tobacco industry is one of the most generous supporters of the Republican leadership, and while tobacco donations to Democrats have tailed off, particularly in the Senate, Democratic leaders continue to attract disproportionate attention from tobacco PACs.

Tobacco Industry Support of Congressional Leadership, 1995-2000³⁴

Senate Republican Majority Leadership	Member	Tobacco PAC Donations, 01/01/95-11/27/00	
President <i>Pro Tem- pore of Sen- ate</i>	Strom Thur- mond (R- SC)	\$15,000	
Majority Leader	Trent Lott (R-MS)	\$4,500	
Majority Whip	Don Nick- les (R- OK)	\$15,166	

³³Id.

³⁴"Buying Influence, Selling Death: How Big Tobacco's Campaign Contributions Harm Public Health," Common Cause, March 14, 2001

Republican Conference, Chair	Rick Santorum (R-PA)	\$31,000
Republican Pol- icy Com- mit- tee, Chair	Larry Craig (R- ID)	\$23,000
Republican Senatorial Committee, Chair	Bill Frist (R-TN)	\$15,500

Senate Democratic Minority Leadership	Member	Tobacco PAC Donations, 01/01/95-11/27/00
Minority Leader	Tom Daschle (D- SD)	0
Minority Whip	Harry Reid (D-NV)	\$6,500
Democratic Con- fer- ence, Chair	Tom Daschle (D- SD)	0
Democratic Policy Committee, Chair	Byron Dorgan (D-ND)	0
Democratic Sen- a- to- rial Cam- paign Com- mit- tee, Chair	Patty Mur- ray (D- WA)	0

House Republican Majority Leadership	Member	Tobacco PAC Donations, 01/01/95-11/27/00

Speaker of the House	Dennis Hastert (R-IL)	\$9,000	
House Majority Leader	Dick Armey (R-TX)	\$35,500	
House Majority Whip	Tom DeLay (R-TX)	\$56,500	
House Republican Conference, Chair	JC Watts (R-OK)	\$17,500	
House Republican Policy Committee, Chair	Christopher Cox (R-CA)	\$14,500	
House Republican Congressional Committee, Chair	Tom Davis (R-VA)	\$1,000	

House Democratic Minority Leadership ³⁵	Member	Tobacco PAC Donations, 01/01/95-11/27/00	
House Minority Leader	Richard Gephardt (D-MO)	\$23,000	
House Minority Whip	David Bonior (D-MI)	\$8,000	
House Democratic Caucus, Chair	Martin Frost (D-TX)	\$32,500	

³⁵In the House of Representatives, Democratic leaders Gephardt, Bonior and Lowey have received no tobacco PAC money since January 1, 1997.

House Democratic Policy Committee, Chair	Richard Gephardt (D-MO)	See above
Democratic Congressional Campaign Committee, Chair	Nita Lowey (D-NY)	\$500

In addition to seducing the leadership of the major parties, the tobacco industry's campaign finance strategy aimed to cement friendly relations with a broad cross-section of the Congress, across regions and across party lines. While the industry's most loyal supporters in Congress hailed from tobacco-producing Southern states, the industry was careful to spread its largesse across the country. Between 1989 to 1994, 73 of the Senate's 100 Members accepted campaign contributions from the tobacco industry, as did 287 of the 435 Members in the House.³⁶ While the proportion of Members receiving tobacco contributions has declined in recent years, as the Democratic Party has taken an increasingly anti-tobacco stance, and as accepting tobacco money has become an increasing electoral liability, a considerable proportion of the Congress still receives support from the tobacco industry. Nearly sixty percent of current Members of Congress received contributions from tobacco industry PACs between 1995 and 2000.³⁷

While publicity considerations have led it to assume a low profile in political matters, the tobacco industry

³⁶Vicki Kemper, "The Inhalers: They May Not Smoke Tobacco Products, But Some In Congress Are Addicted to the Industry's Money," Common Cause Magazine, Jan./ Feb./ Mar. 1995.

³⁷"Buying Influence, Selling Death: How Big Tobacco's Campaign Contributions Harm Public Health," Common Cause, March 14, 2001

has demonstrated its willingness to target individual Members who have threatened the industry's financial interests. Rep. Mike Synar (D-OK), who had been one of the tobacco industry's most vociferous critics in the House, faced three opponents in a vicious Democratic primary in 1992, who were heavily funded by tobacco interests. His opponents posted billboards along the highways of his district that depicted his face alongside those of Adolf Hitler, Josef Stalin and Fidel Castro.³⁸ While Synar survived the challenge in 1992, he was weakened, and lost to another tobacco-financed primary challenger in 1994. This willingness on the part of the industry to lash out at troublemakers not only intimidates or eliminates an individual Member, it sends a message to others that the industry is best kept an ally.

Just as the targeting of specific members has an expressive, as well as a functional purpose, the timing of contributions is sometimes calculated to send a message. On February 24, 1998, the same day tobacco executives were called to Congress to discuss the nationwide antismoking proposal, Philip Morris contributed \$100,000 to the Republicans who control the House.³⁹ The donation was the largest the National Republican Congressional Committee took in during the first three months of 1998, according to documents filed with the Federal Election Commission.⁴⁰

Opponents of campaign finance regulation often argue that full disclosure of contributors should provide a sufficient deterrent incentive for politicians to avoid taking money from unsavory sources. But it can be notoriously difficult to track money to its source in industry, a fact that the following memo, a confidential inter-office correspondence, makes clear. At the time the memo was written, Pete Wilson was the Governor

³⁸David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.282

³⁹"Tobacco Firms Gave Big to GOP Leaders," Associated Press, April 18, 1998

⁴⁰Id.

of California, considered a rising star in the Republican Party and potential presidential timber. During the 1990 election, Wilson publicly declared he would not accept campaign funds from the tobacco industry, but later attended a Philip Morris-sponsored fundraiser that raised \$100,000 for the California Republican Party. After the fundraiser prompted an outcry, Wilson claimed he was unaware of the company's involvement. The following memo was circulated inside Philip Morris immediately after Wilson's disavowal.

To: Buffy

Date: 4/24/90

From: Jim

Subject: Pete Wilson

Wilson is only sending about 16K of the 100K he collected. This 16K includes checks he received from either a tobacco company or anyone working directly for a tobacco company, i.e. Hamish Maxwell, Mrs. Ehud, Bill Murray.⁴¹

Apparently, he has also done with other “controversial industries such as lumber, chemical and others. The decision to do this was Wilson’s alone, and in the [sic] response to a wave of negative campaigning in California that not only attacks the candidates, but those who give to them as well.

You will be pleased to know that Pete called Hamish to explain that he was doing this to protect Hamish as well as himself. You will also be pleased to know that Pete is still “pro-tobacco.”⁴²

In the years that followed, Governor Wilson proved his status as “pro-tobacco;” he repeatedly tried to divert funds from California’s highly successful anti-smoking campaign.

⁴¹Hamish Maxwell, former CEO of Philip Morris, is the chairman of the executive committee; Mrs. Ehud is the wife of Ehud Houminer, CEO of Philip Morris USA; Bill Murray is the former president of Philip Morris. The remaining \$84,000 mentioned in the memo remains unaccounted for.

⁴²Peter. H. Stone, “The Wilson Memo,” Mother Jones, May/June, 1996

TOBACCO INDUSTRY LOBBYING: LEND ME YOUR EARS

While the tobacco industry is one of the most generous political givers in the country, it is an equally prodigious lobbying influence. Brown & Williamson spent \$25 million dollars in 1998 to lobby Congress – successfully – to oppose the McCain tobacco legislation; Philip Morris spent \$23 million more. No other business, trade association, union or citizen’s group spent as much as either corporation, though other tobacco industry organizations spent an additional \$18 million. In all, the industry spent \$66 million lobbying the Congress in 1998.⁴³

The industry is also extremely sophisticated in its employment of lobbying techniques. Because members of Congress are frequently back home in their districts, Philip Morris actually hired friends of the legislators in particular states and congressional districts to “deliver the Philip Morris message informally.”⁴⁴ Sometimes lobbying efforts can be as unassuming as throwing a party in a Member’s honor. At the Republican National Convention in Philadelphia, U.S. Tobacco wined and dined delegates at a tribute to Senator Mitch McConnell (R-KY) and paid for an American Bandstand party honoring Senate Majority Leader Trent Lott (R-MS), complete with appearances by Dick Clark and the Shirelles.⁴⁵ Philip Morris and Brown & Williamson were among the sponsors of a “Mardi Gras Goes Hollywood” party honoring Senator John Breaux (D-LA) that was held on a Paramount Studios lot and featured Mardi Gras floats, zydeco bands, gumbo and jambalaya.⁴⁶ Not all politicians feel comfortable being publicly wooed the way Sens. Lott and Breaux do, particularly by as controversial an industry as the tobacco industry. To protect prospective allies from negative publicity, the tobacco industry has often used front groups to lavish favors on legislators. In 1997, Philip Morris sent

⁴³The tobacco industry spent another \$40 million running television and radio advertisements attacking the McCain bill. Senator Mitch McConnell (R-KY), a staunch supporter of the industry, promised his colleagues the advertisements would continue even after the bill was defeated, in order to provide political cover to those Senators who stood with the industry. See Jeffrey Taylor, “Is the Tobacco Industry Playing Politics With Issue Ads?” Wall Street Journal, September 1, 1998

⁴⁴Ernest Wittenberg and Elizabeth Wittenberg, “How to Win in Washington: Very Practical Advice About Lobbying, the Grassroots, and the Media.” 2nd Edition, Blackwell, Cambridge, MA, 1994. p.46

⁴⁵Al Cross, “Corporate America Gives the Red-Carpet Treatment,” The Louisville-Courier Journal 3 August 2000.

⁴⁶Bruce Alpert, “Despite Ban, Tobacco Filters into Parties, New Orleans Times-Picayune, 16 August 2000

twelve state legislators (among them Jeff Wells, the majority leader of Colorado's state Senate, who was then considering a run for state attorney general) on a six-day vacation in Costa Rica, where they stayed at a luxury resort with a casino and pool bar.⁴⁷ The trip was sponsored by the innocently named New York Society for International Affairs. While that group has a Manhattan telephone number and address, it is actually a front organization funded by Philip Morris. The president of the New York Society, Andrew Whist, is a vice president at Philip Morris; in a rare moment of candor, he bragged to the *Wall Street Journal* that the New York Society's office is "a chair in my apartment."⁴⁸ Tax records filed by the Society show that Philip Morris was nearly the exclusive donor to the non-profit organization between 1991 and 1995; during that time the tobacco giant was responsible for \$620,000, or 98% of the \$631,000 in total contributions received by the organization.⁴⁹

Lobbying is not all flattery and vacations. Lobbyists also play an essential role in connecting members of Congress with campaign donors. To raise money for their campaigns, members of Congress often need to woo lobbyists as much as lobbyists need to woo them. In the words of Tommy Boggs, one of Washington's most famous and powerful lobbyists, "The real abuse is the amount of time these guys [members of Congress] have to spend kissing my ass... It's ludicrous how much time these women and fellas have to spend raising money."⁵⁰

This co-dependence often translates into concrete action by members of Congress: they come to recognize that lobbyists and legislators have a symbiotic relationship, in which each can help the other succeed. "It's usually not put in the way of saying, 'See, we want your vote next week,'" said Cincinnati attorney and former congressman David Mann, a Democrat who served in the House of Representatives from 1992 to

⁴⁷Scott C. Yates, "The Marlboro Hombres," Westword.com, August 27, 1997. In 1998 Wells circulated petitions to qualify in the race for attorney general, but did not file them.

⁴⁸Tatiana S. Boncompagni and Jill Abramson, Tobacco- Funded Group Gives Legislators Free Trips, *The Wall Street Journal*, August 4, 1997, p. A20.

⁴⁹"Thompson Was Among VIPs Who Traveled Through Groups Backed By Firm," Steve Schultze and Daniel Bice, *Milwaukee Journal-Sentinel*, July 30, 1997

⁵⁰"The Buying of the Congress: Transcripts," Thomas Hale Boggs, Jr., Interviewed by Chuck Lewis, Center for Public Integrity, August 15, 1997

1994. “But you’re campaigning every two years and you’re under pressure to raise and spend money. Your votes are influenced by that if you’re a human being... How you vote on this may affect your ability to raise money,” Mann said. “It’s always on your mind. Anyone who says otherwise is not being truthful.”⁵¹

INSIDE CONNECTIONS, TRUSTWORTHY FIGURES

Lobbying is expensive because the most persuasive and well-connected lobbyists can command enormous fees. The tobacco industry has spent liberally to land the most credible and trustworthy figures that the Western world had to offer. Former British Prime Minister Margaret Thatcher became a consultant to Philip Morris after she left office.⁵² Senator Howard Baker, (R-TN), the former Minority Leader and Majority Leader of the Senate, and Chief of Staff to President Ronald Reagan, also became a paid advocate for Philip Morris.⁵³ Senator Zell Miller (D-GA) actually lobbied for Philip Morris between his service as Governor of Georgia and his ascension to the Senate.⁵⁴ In addition to the personal relationships they retain from their time in office, former members of Congress who become lobbyists retain certain advantages in their new incarnation; unlike other lobbyists, they are allowed on the House floor and in private dining rooms reserved for elected officials.⁵⁵

While its campaign donations have increasingly shifted toward the Republican Party, the tobacco industry’s lobbying efforts retained a heavily bipartisan flavor. In February of 1997, the five largest tobacco companies –

⁵¹Bill Straub, “Lobbyists Practice Art of Subtle Pressure,” *The Cincinnati Post*, July 15, 1998

⁵²“Ms. Thatcher would be available to consult with us for an initial three-year period.. [T]he fee we would pay for those services would consist of a \$250,000 annual payment to her and a \$250,000 annual contribution to the Margaret Thatcher Foundation... we are of like mind.” Michael A. Miles, PM memo July 20, 1992, PM ID 2022854068-69, at 68.

⁵³“Senator Baker’s attachment to this Company gives us an effective, high-level advocate of our policies...[I]f the Company needs to be publicly identified in a positive way with an issue, he can do it best.” Jame Dyer, PM memo to David Greenberg and Buffy Linehan, “Senator Howard Baker,” June 29, 1989, PM ID 2041252693-94).

⁵⁴Joshua Micah Marshall, “Zellout,” *The American Prospect*, Volume 12, Issue 8, May 1, 2001

⁵⁵Lobbyists without access to the House Floor must sometimes rely on other techniques of persuasion. Paula Parkinson, an agricultural lobbyist, claimed to have had sex with eight different members of Congress. See Ken Rudin, “Congressional Sex Scandals in History,” *The Washington Post*, 1998

Philip Morris, RJR Nabisco, Brown & Williamson, U.S. Tobacco, and Loews Corp. – hired Verner, Liipfert, a powerful Washington law firm with strong Democratic ties.⁵⁶ Among the Democratic luminaries who now lobby their former colleagues for Verner, Liipfert are former Senate Majority Leader George Mitchell (D-ME), former Gov. Ann Richards (D-TX), and former Treasury Secretary and Senator Lloyd Bentsen (D-TX). Both Mitchell and Richards were active in lobbying Democrats on behalf of the tobacco industry.⁵⁷ On the Republican side, the tobacco group hired Barbour, Griffith & Rogers, a lobbying shop that boasts as a name partner Haley Barbour, a former chairman of the Republican National Committee. More than a few Republican members of Congress owe their seats to Barbour’s fundraising prowess at the RNC.⁵⁸

THE SHADOW FDA

In addition to former members of Congress, the tobacco industry’s lobbyists include many attorneys previously employed in the highest legal positions at the FDA. These individuals have not only substantial knowledge about the internal politics and machinations of the Agency, but the credibility and prestige to publicly second-guess the decisions of the FDA.

This “Shadow FDA” includes Richard Merrill, former chief counsel during the Carter Administration and Peter Barton Hutt, former chief counsel during the Nixon Administration, both of whom are now partners at the Washington law firm of Covington & Burling, which has represented Philip Morris, Lorillard Tobacco and the Tobacco Institute;⁵⁹ Richard Cooper, a former associate chief counsel in the Carter Administration,

⁵⁶Omar Beer and Suzanne Herel, “Loan Officer for the Corporate Welfare State,” *Mother Jones*, April 23, 1997

⁵⁷*Id.*

⁵⁸Even in his time at the RNC, before he was a tobacco lobbyist, Barbour was accused of whipping votes for the tobacco industry; see p. 30.

⁵⁹David Kessler, “A Question of Intent: A Great American Battle With A Deadly Industry,” *PublicAffairs*, New York, 2001, p.337

now a partner at the Washington law firm of Williams & Connolly, which represents R.J. Reynolds; Thomas Scarlett, former chief counsel during the Reagan Administration; Gene Pfeifer, a former FDA lawyer, now a partner at King & Spalding, which represents Brown & Williamson; Arthur Levine, former deputy general counsel of litigation from 1978-91; and Donald Beers,⁶⁰ former associate chief counsel for enforcement from 1978-85. Levine and Beers both have represented Philip Morris as members of the law firm of Arnold & Porter.⁶¹ “It is astonishing. These lawyers are the experts in the field, and they know where everything is buried at FDA,” said one FDA official. “When they talk to their clients, they say, ‘Ask for this document,’ and they know about the document because they are the ones who wrote it.”⁶²

These lawyers not only have invaluable knowledge, they are often the unchallenged authorities in their field of expertise; Hutt and Merrill, for instance, literally wrote the book on Food and Drug Law.⁶³ But the impact of these officials goes beyond their legal acumen. Their past government service gives them unrivaled credibility, a quality which the tobacco industry is willing to pay for dearly. Charlie Edwards, a former commissioner of FDA, became a consultant for Philip Morris in 1994, in part because of the credibility that his stature and years of government service could lend to the industry’s message.⁶⁴ In testimony before the Senate Committee on Labor and Human Resources, Edwards attacked Commissioner David Kessler in starkly personal terms: “We have yet to ensure that those who are appointed as Commissioner have the necessary qualifications for the job. Far too often, the wrong person is in charge because it is easy but very wrong to assume that a medical degree or a prior post in academia is all that is needed to run this agency.”⁶⁵ Many of Edwards’ statements matched verbatim the remarks prepared by Philip Morris media

⁶⁰See Milo Geyelin, “Tobacco Industry Gets Help From Ex- FDA Lawyers,” *The Wall Street Journal*, January 16, 1995.

⁶¹David Kessler, “A Question of Intent: A Great American Battle With A Deadly Industry,” *PublicAffairs*, New York, 2001, p.143

⁶²Robert Dreyfuss, “Tobacco Enemy Number One,” *Mother Jones*, 1997

⁶³See Peter Barton Hutt and Richard A. Merrill, “Food and Drug Law: Cases and Materials, University Casebook Series, Foundation Press, Westbury, NY, 1991

⁶⁴Charles R. Wall, PM memo to Steve Parrish, “Retainer Fee for Dr. Charles Edwards,” May 20, 1994, PM ID 2047710586

⁶⁵Senate Committee on Labor and Human Resources, testimony of Charles C. Edwards, hearing, *The FDA and the Future of American Biomedical and Food Industries*, 104th Cong., 1st Sess., April 5 and 6, 1995

experts.⁶⁶ Edwards had been wooed by \$125,000 in consulting fees and by Philip Morris' proposal to build a scientific research center at Scripps Research Institute in La Jolla, California, where Edwards had served as president.⁶⁷

FLEXING TOBACCO'S MUSCLES: THE CONGRESSIONAL ASSAULT ON KESSLER'S FDA

It should come as no surprise that members of Congress who hail from tobacco-producing districts are vigorous supporters of the industry, who are willing, even enthusiastic about standing up for a valued corporate constituent. But supporting tobacco interests is politically risky for many members of Congress whose districts don't depend on tobacco for their vitality. In extreme cases, supporters of the tobacco industry have been called on to affirmatively cast votes to protect their patrons. This is, however, a last resort, as it exposes both the industry group and their allies in Congress to criticism. More often, recipients of tobacco industry funds earn their keep through simply maintaining the *status quo*. The activist FDA of Commissioner David Kessler, with its aggressive effort to bring the tobacco industry under FDA jurisdiction, made the *status quo* approach unsustainable; industry leaders felt forced to call in chits from the entire panoply of political allies in an all-out assault on Kessler and his Agency. The tobacco industry's campaign against the Food and Drug Administration encompassed not only roll-call votes to deny granting the Agency jurisdiction over tobacco, but also casting aspersions on the leadership of the FDA and on the agency itself. Congressional recipients of tobacco industry largesse acted to attack FDA's integrity, its physical plant, its budget, and its statutory mandate.

⁶⁶The documents that matched Edwards' testimony were PM ID 2044771450-54 and PM ID 2044771477-49. Edwards would admit only that he "ran it through" executives at Philip Morris.

⁶⁷David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.315

ROLL-CALL VOTES: WINNING WHEN IT COUNTS

When necessary, the tobacco industry has been able to muster enough support in the Congress to win roll-call votes, even when the industry's position is disfavored by the general public. National polls show that a substantial majority of registered voters support strong action to address youth smoking; three out of four voters support granting the FDA authority over the manufacture, marketing and sale of tobacco products, and support lawsuits against the industry.⁶⁸ Support for FDA regulation of tobacco crosses political and demographic lines, as overwhelming majorities of Democrats (eighty-one percent), Republicans (seventy-two percent) and independent voters (seventy-two percent) favored legislation that would grant the FDA authority to regulate tobacco products. Even a lopsided majority of smokers (sixty-seven percent) felt that Congress should pass a bill establishing FDA authority.⁶⁹

Nevertheless, in July of 1997, the House and Senate defeated efforts to fund enforcement of the Food and Drug Administration's initiative to prevent illegal tobacco sales to minors. On July 23, 52 senators voted against funding; they received, on average, nearly three times the tobacco PAC contributions in the two years before their last election as the 48 senators who supported the funding (\$14,884 vs. \$5,223). In the corresponding House vote on July 24, 248 Members voting against the funding; they had taken, on average, nearly five times as much tobacco PAC money in the previous cycle as the 177 Members who voted to fund the compliance checks (\$5,636 vs. \$1,142).⁷⁰

In June of 1998, allies of the tobacco industry in the U.S. Senate defeated the comprehensive tobacco legislation sponsored by Senator John McCain (R-AZ). The bill was defeated by filibuster on June 17, 1998, when supporters of the bill could muster only 57 of the 60 Senators needed to end debate and bring the bill

⁶⁸Market Facts' Tele Nation conducted a random national survey of 864 registered voters February 2 through February 4, 2001. The survey has a margin of error of +/- 3.5 percentage points.

⁶⁹Id.

⁷⁰"Buying Influence, Selling Death: How Big Tobacco's Campaign Contributions Harm Public Health," Common Cause, March 14, 2001

to a final vote. The 42 senators who voted to kill the McCain bill received, on average, \$17,902 in the two years before their last election; the 57 senators who supported the bill received an average of \$4,810.⁷¹

In 1999, Congress refused to appropriate the \$20 million requested by the Justice Department to fund the lawsuit. The Justice Department then sought funding through a provision of federal law allowing litigation assistance from other affected departments, including the Departments of Defense, Veterans Affairs and Health and Human Services. In June of 2000, the U.S. House of Representatives voted twice on whether to deny that alternative avenue of funding. On the first vote, on June 19, industry supporters carried the day, 207-197; the 207 industry allies had received, on average, five times as much tobacco PAC money in the previous two election cycles as the 197 who voted to continue funding (\$9,712 vs. \$1,750). On a subsequent vote, on June 23, supporters of the suit won a majority, 215-183. Members who voted to cut off funding had taken, on average, nearly seven times as much tobacco PAC money in the previous two cycles as the Members who supported funding for the lawsuit (\$10,715 vs. \$1,539).⁷² Efforts to kill the lawsuit also failed in the Senate, where the issue did not come to a floor vote.

When hard-money donations are an insufficient incentive, the role of soft-money donations to the political parties can also increase pressure on reluctant members of Congress to support party-line votes. In 1996, at the peak of the partisan rancor surrounding the FDA's role in tobacco regulation, the chairman of the Republican National Committee, Haley Barbour, was accused of exerting pressure on Republican members of Congress from Texas and Arizona to support industry-sponsored legislation. Barbour said he made the Arizona calls to check on the legislation but denied exerting pressure. "I'm not in the business of pressuring anybody, in Congress or anywhere else," he said.⁷³

⁷¹Id.

⁷²Id.

⁷³"Clinton: RNC Exerted Pro-Tobacco Pressure," Reuters News Service, July 5, 1996. These comments were made before he became a lobbyist for the tobacco industry, at which point his job became, literally, the business of pressuring members of Congress or anybody else.

CONGRESSIONAL COMMITTEES AND THE OVERSIGHT FUNCTION

Because of the structure of the committee system in Congress, some Congressmen are uniquely positioned to help – or hurt – a given industry. The Chairman of a Committee or Subcommittee can bottle-up legislation and keep it from reaching the Floor, or he can ensure that it has been neutered by the amendment process. As a result, even an industry that is unpopular with the general public can be effectively protected by a well-placed supporter in Congress. While it has proven its ability to muster a wide base of support in the Congress when necessary, the industry has preferred to make its influence felt through the discretion of strategically placed allies in the leadership. This low-visibility strategy preserves the industry’s political capital for when it is most crucial, and protects allies in the Congress from more criticism than is necessary.

For all these reasons, Rep. Thomas J. Bliley Jr., (R-VA) is the perfect ally for the tobacco industry. Chairman of the House Commerce Committee, which oversees the FDA, Bliley hails from a Richmond district that is home to a major Philip Morris plant; virtually no action he takes on behalf of the tobacco industry could threaten his base of political support in his district. Bliley has received so much tobacco money, and fought on behalf of the industry so vigorously, that he has earned the moniker “the congressman from Philip Morris.” Philip Morris agreed: in 1986, before Bliley assumed the chairmanship himself, an internal Philip Morris document referred to him as “our sentry” on the Health and the Environment subcommittee.⁷⁴ And that feeling was no secret: after Bliley replaced Rep. Henry Waxman (D-CA) as chairman, Philip Morris CEO Geoffrey Bible wrote a letter to shareholders in which he wrote that “new faces and new leadership on Capitol Hill [give us] tremendous opportunities to get new and unbiased hearings on the issues that concern

⁷⁴Gregory R. Scott, PM memo to Gene A. Knorr, “Rebuilding Our Relationship With Tobacco-State Congressmen,” August 25, 1986, PM ID 2025854686-89.

us most.”⁷⁵

In 1996, the RJ Reynolds Tobacco Company sponsored a reception in Bliley’s honor at the Republican Nominating Convention in San Diego. Asked to explain the attention, Bliley joked, “I guess they think I’m a great American.”⁷⁶ When he was pressed as to whether RJR was trying to influence him, Bliley denied that they would have to, replying proudly, “I’ve been a defender of the tobacco industry since being elected to Congress.”⁷⁷

Bliley used his chairmanship to aggressively pursue FDA Commissioner David Kessler, often making unreasonable, even impossible requests of FDA officials. One letter demanding documents, dated March 18, 1994, arrived at FDA headquarters March 21; the closing line of the letter read, “Please provide this information to my office no later than March 21, 1994.” The letter itself later proved to be a direct product of tobacco industry strategizing; internal Philip Morris documents from the time list a “letter to Kessler from Bliley” as a top priority.⁷⁸ Such document requests are often used by hostile Members to tie up the bureaucracy; Rep. Charlie Rose (D-NC) actually submitted document requests drafted by outside counsel to RJ Reynolds.⁷⁹ “Anytime there’s an enforcement action or any policy or regulation deemed controversial in the eyes of Republicans, they can slam the FDA with a massive document subpoena and hold hearings on it,” an anonymous FDA official said. “It’s an incredible waste of time.”⁸⁰

⁷⁵See Ken Silverstein, “Washington on \$10 Million a Day,” Common Courage Press, 1998, p.113

⁷⁶T. Whitley, “Tobacco Plays Host for Bliley Reception,” Richmond (Virginia) Times-Dispatch, August 12, 1996

⁷⁷Id.

⁷⁸Action Team, PM notes, March 16, 1994, PM ID 2022838682-83.

⁷⁹“This is what is being sent to Rep. Rose for his review and, hopefully, transmittal to the FDA.” Arnold & Porter, fax cover sheet with draft letter attached, June 7, 1994, RJR ID 515786099-107.

⁸⁰Richard Blow, “10 Ways the Republicans Will Change Your Life,” Mother Jones, 1995

ATTACKING THE FDA'S INTEGRITY

Bliley's public attacks on Commissioner Kessler were often scathing. As Kessler sat before the Subcommittee on Health and the Environment, Bliley launched into an *ad hominem* attack. "I was saddened by what took place in this room a couple of weeks ago," Bliley said. "I witnessed the Commissioner of the FDA, who is both a trained scientist and a lawyer, take threads of truth and weave them into whole cloth of rumor and innuendo."⁸¹ Bliley was sending a message: he would fight tooth and nail to protect the tobacco industry from regulation. A staffer for Rep. Charlie Rose (D-NC), a tobacco industry ally, privately warned Kessler that "[Bliley's] preparing to send investigators all over the Agency looking for dirt... [the t]obacco industry's goal is to dismantle FDA."⁸²

Bliley wasn't the only tobacco ally in the Congress to impugn the integrity of the FDA and its leadership, or even the most prominent. Speaker of the House Newt Gingrich labeled the FDA the "number one job-killer" in the country, and called David Kessler, "a bully and a thug."⁸³ Later Gingrich added, "I think the FDA is a bureaucracy that has overreached on a number of fronts. It is weakening American job creations, weakening the introduction of new medications."⁸⁴ During his campaign for the presidency, Senator Bob Dole (R-KS) aggressively criticized Kessler; at a GOP fundraiser in September of 1995, Dole actually promised an audience of pharmaceutical executives that Kessler would be out of a job if he were elected.⁸⁵

Rep. Joe Barton (R-TX), the Chairman of the Subcommittee on Oversight and Investigations, accused Mitch Zeller, Kessler's Deputy Associate Commissioner for Policy, of committing perjury.⁸⁶ Where Tom

⁸¹David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.171

⁸²Id. at 289

⁸³Nicholas Regush, "Migraine Killer," Mother Jones, 1995

⁸⁴See Jeanne Cummings, "Preventative Care Gains Support; But Gingrich Rejects Targeting Tobacco," Atlanta J. & Const., Sept. 26, 1996, at 12A

⁸⁵Sheila Kaplan, "Tobacco Dole," Mother Jones, May/June, 1996

⁸⁶David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.346. A tobacco executive later admitted the strategy behind the accusation to Kessler: "If you need to create a diversion because you don't want the agency [FDA] involved, attack the agency. Throw everything at the wall and something will stick."

Bliley openly admitted his advocacy for the industry, Barton denied that tobacco played any role in his hostile attitude toward the FDA and its staff. On national television, Barton pulled out a Bible and told ABC's Peter Jennings, "This is the Holy Bible. I'm a United Methodist. I swear on everything I hold dear to this country, and to my family and to my God, that my concern about FDA reform and my responsibilities and duties have nothing to do whatsoever with tobacco."⁸⁷ When pressed with the fact that he had received donations from RJR, Brown & Williamson, Philip Morris, U.S. Tobacco, the Tobacco Institute, and Nabisco, Barton declared, "I've never had anybody directly relating a tobacco issue in this office." Internal Philip Morris reports seem to contradict this statement; they show that tobacco lobbyists "secured scheduling" of two congressional hearings, one of which was Barton's.⁸⁸

PUTTING WORDS IN THE MOUTHS OF CONGRESS

Reps. Bliley and Barton were not alone in their willingness to carry out the industry's agenda. At times, the relationship between industry patrons and their "friends" in Congress is so close that the public relations staff of the corporations can literally put words into the mouths of Congress. At a June 21, 1994 hearing, Rep. Michael Bilirakis (R-FL), among others, peppered Commissioner David Kessler and his staff with elaborate hypotheticals, reading verbatim from a script provided by R.J. Reynolds.⁸⁹ Philip Morris actually wrote talking points for Reps. Martin Lancaster (D-NC) and James Clyburn (D-SC) to read into the congressional record on its behalf.⁹⁰ Shortly after Lancaster's testimony, Philip Morris sent around an internal e-mail to

⁸⁷ABC News Report with Peter Jennings, June 27, 1996.

⁸⁸See David Nicoli, Philip Morris memo, "Weekly Direct Report," October 20, 1995, PM ID 2047993169-72. This memo includes the notation "secured scheduling of two FDA oversight hearings at House O&I [Oversight and Investigations], in November, including one where Kessler will appear." Oversight and Investigations was Rep. Barton's Committee.

⁸⁹David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.249

⁹⁰Kathleen Linehan, PM memo to Robert Reese and Gregory Scott, "Waxman FDA hearing," March 17, 1994, PM ID 2023029473.

its executives, suggesting that they contribute to Lancaster’s campaign fund: “It is suggested that you give \$200-250 and that you send a letter with the check indicating that you are an executive of PM.”⁹¹

HIGH-PRESSURE LETTER-WRITING CAMPAIGNS

Not every elected official is as useful an ally as a Chairman Bliley. But even those elected officials who lack a strategic perch on an influential committee can still be valuable assets. Internal documents show how important Philip Morris felt it was to have public officials deliver their message directly to the FDA, to create the impression of massive resistance by political authorities. An internal Philip Morris e-mail dated from October, 1995, described a state-by-state “FDA project.” The message, from a Philip Morris executive to employees in the field, suggested, “... the objective is to submit at least 10 quality letters per state primarily from elected officials... you know your state assignments.”⁹² Shortly thereafter, three of the four top Republican leaders in the House of Representatives – Majority Whip Tom DeLay (R-TX), Majority Leader Dick Armey (R-TX) and House Republican Conference chairman John Boehner (R-OH) – signed a letter in December of 1995 opposing the FDA’s proposed regulation of tobacco. So did Senate Majority Leader Bob Dole. The letter was also signed by some prominent Democrats, including Senate Minority Leader Thomas A. Daschle (D-SD) and Sen. Sam Nunn (D-GA).⁹³

The same pattern occurred the next year, when 124 members of the House sent a sharply worded letter to the

⁹¹Ellen Merlo, PM memo to Fred Laux, et al., “Lancaster Contribution,” April 19, 1994, PM ID 2041166362.

⁹²Liam Pleven, “How Big Tobacco Courted Senator/Lobbyists Targeted Lack in FDA Fight,” *Newsday*, September 6, 1999

⁹³Peter H. Stone, “Blowing Smoke at its Critics,” *National Journal*, April 20, 1996

FDA, claiming the agency's tobacco proposal would put 10,000 jobs at risk and "trample First Amendment rights to advertise legal products to adults." Two weeks later, 32 senators signed a virtually identical letter.⁹⁴ Those senators who signed the letter had received an average of \$31,368 from tobacco, compared to \$11,819 for those senators who did not sign. The House signatories had received an average of \$19,446, almost three times the \$6,728 that non-signing members had received.⁹⁵

A similar effort took place at the state level. Though the threat from the FDA was in theory a federal problem, the tobacco industry has taken to heart the adage of former Speaker of the House Tip O'Neill that "all politics is local." Keenly aware that state-level officials provide the feeder system for members of Congress, industry representatives have carefully cultivated relationships with governors and state legislators. According to data compiled by the National Institute on Money in State Politics and by the Virginia Public Access Project, tobacco interests have given more than \$5.4 million to state candidates and political parties since 1995.⁹⁶

Tobacco interests are major donors to the American Legislative Exchange Council (ALEC), a group of about 3,000 conservative state legislators committed to fighting excise tax increases; Philip Morris and RJR actually sit on the Council's board of directors. Philip Morris gives the group about \$50,000 per year; RJR about \$25,000; and UST about \$15,000.⁹⁷ Philip Morris also contributes to the bipartisan National Conference of State Legislatures, a group of more than 7,000 state legislators. In 1995, Philip Morris gave \$150,000 for the group's annual meeting, doubling its 1994 contribution.⁹⁸ This largesse was well rewarded. An Oct. 4, 1995, newsletter cited with approval the view of the Smokeless Tobacco Council that FDA regulation would amount to an "agency power grab" that "flouts Congress's steadfast refusal to give FDA jurisdiction over tobacco." The newsletter urged ALEC members to write to the FDA to voice their opposition to proposed

⁹⁴Robert Dreyfuss, "Tobacco Enemy Number One," *Mother Jones*, 1997

⁹⁵*Id.*

⁹⁶See Campaign Finance Information Center, www.campaignfinance.org

⁹⁷Peter H. Stone, "Our Good Friend, the Governor," *Mother Jones*, May/June, 1996

⁹⁸*Id.*

regulation.⁹⁹

Philip Morris wasn't content to rely on the exhortations of ALEC; the company also organized state legislators on its own behalf to rally against the FDA's proposed regulation. One of company's targets was Sen. James Lack (R-East Northport), a New York State legislator who was president of the National Conference of State Legislatures, a nationwide organization.¹⁰⁰ Philip Morris courted both Lack and the NCSL, contributing to Lack's campaign, taking Lack and his aides to dinner, and sponsoring NCSL events in Milwaukee and Atlanta. In November of 1995, less than a month after Philip Morris's chief lobbyist in Albany treated Lack, his wife and two staff members to dinner, Lack wrote an impassioned letter to the FDA, drawing heavily on arguments contained in internal Philip Morris documents. Lack signed the letter in his dual capacity as both NCSL president and as a state senator, denouncing the FDA for overreaching its statutory mandate.¹⁰¹ State legislators in North Carolina were even more forceful in their protest. After David Kessler was invited to the University of North Carolina to speak about tobacco control issues, some state legislators actually threatened to cut off funding to the state's flagship university.¹⁰²

FRIENDLY GOVERNORS

The tobacco industry has made similar efforts to elect and support "friendly" governors, and to enlist their aid against the FDA. Both Philip Morris and R.J. Reynolds are members of the elite board of the Republican Governor's Association; each contributes approximately \$40,000 annually to the group.¹⁰³ On February 5, 1996, Geoffrey Bible, the CEO of Philip Morris, chaired a dinner for the Republican Governors

⁹⁹Peter H. Stone, "Blowing Smoke at its Critics," *National Journal*, April 20, 1996

¹⁰⁰Liam Pleven, "How Big Tobacco Courted Senator/Lobbyists Targeted Lack in FDA Fight," *Newsday*, September 6, 1999

¹⁰¹*Id.*

¹⁰²David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," *PublicAffairs*, New York, 2001, p.355

¹⁰³Peter H. Stone, "Our Good Friend, the Governor," *Mother Jones*, May/June, 1996

Association in Washington that raised a record-breaking \$2.6 million.¹⁰⁴ Philip Morris underwrote the event with a \$100,000 contribution, while Bible delivered a speech extolling the economic benefits of the tobacco industry.¹⁰⁵ Just eleven days after the dinner, Gov. Kirk Fordice (R-MS), made the unusual move of filing suit against his own state's attorney general. Fordice's suit alleged that Michael Moore, who in 1994 had been the first state attorney general in the country to file suit against the industry to recoup Medicaid costs, had exceeded his legal authority.¹⁰⁶

In November of 1995, at the annual Republican Governor's Association meeting in Nashua, New Hampshire, tobacco lobbyists pressured governors to lobby the FDA on their behalf.¹⁰⁷ Tobacco lobbyist Kerry Paulsen reminded one North Dakota official that his company, UST (formerly U.S. Tobacco), had long supported Gov. Edward Schafer (R-ND) and that 1996 was an election year. When asked if he was threatening to withhold his company's financial support, Paulsen said, "I'd never do that," but added, "You know we have PAC money, we like the governor, and we want him to be re-elected."¹⁰⁸ Governor Schafer heard the message loud and clear; like many other governors who attended the Nashua meeting, he ultimately signed and sent out under his own name a letter drafted by tobacco industry lawyers.

In addition to the North Dakota letter, the FDA received letters opposing tobacco regulation from governors or lieutenant governors in Kentucky, South Carolina, Connecticut, Montana, and Mississippi.¹⁰⁹ Many of these letters bear signs of having been adapted from the same source as the North Dakota letter: tobacco industry lawyers and lobbyists. In a letter to the FDA dated November 26, 1995, Lt. Gov. Eddie J. Briggs of Mississippi (R-MS) wrote:

In his August 10 speech, President Clinton stated that he was authorizing federal action against tobacco

¹⁰⁴Id.

¹⁰⁵Peter H. Stone, "Blowing Smoke at its Critics," National Journal, April 20, 1996. Fordice's suit was unsuccessful.

¹⁰⁶Id. The lawsuit ultimately failed.

¹⁰⁷Peter H. Stone, "Our Good Friend, the Governor," Mother Jones, May/June, 1996

¹⁰⁸Id.

¹⁰⁹Id.

products 'to protect the young people of the United States.' This insinuates that I and the other members of the Mississippi government cannot look out for the well-being of our children, and that we therefore must rely on the paternal hand of our federal government. I resent the implication that Mississippi is unable to care for its children.

A letter from Lt. Gov. Dennis Rehberg (R-MT), dated December 25, 1995, said much the same thing:

In authorizing this federal action, President Clinton said he did so ‘to protect young people of the United States.’ This statement implies that we here in Montana cannot look out for the well-being of our own children, and therefore must rely on assistance from the omnipresent federal government. Quite frankly, I resent this implication, and I firmly reject this unwarranted federal intrusion into our business.¹¹⁰

In another letter, dated January 2, 1996, Gov. David M. Beasley (R-SC) wrote:

First of all, I must be clear on one basic point. I do not recognize FDA authority to regulate tobacco products. The FDA repeatedly has declared that it lacks jurisdiction to regulate tobacco products as traditionally marketed. Now the FDA has reversed course and asserted jurisdiction where it has none.¹¹¹

This portion bears a striking resemblance to part of the letter from Lt. Gov. Briggs of Mississippi:

Before discussing the proposed regulations, I need to be clear about one basic point. Do not take my participation to mean that I recognize FDA authority to regulate the sale, distribution, marketing and advertising of tobacco products. I do not. For decades, the FDA has declared that it lacks jurisdiction to regulate tobacco products as traditionally marketed. Now, however, the FDA simply has reversed course. I cannot accept this display of federal arrogance. The regulations must be withdrawn.¹¹²

While an official who serves the governor of North Dakota admits his governor’s letter was written by a tobacco industry lawyer, the others continue to deny that they were influenced. “There’s no connection between my letter and the tobacco industry,” claims Montana Lt. Gov. Dennis R. Rehberg. “I stand on the principle of individual responsibility.”¹¹³ Rehberg has since been elected to the House of Representatives - with the aid of \$26,500 in contributions from the tobacco industry.¹¹⁴

¹¹⁰“A Case of Great Minds Thinking Alike?” Mother Jones, May/June, 1996

¹¹¹Id.

¹¹²Id.

¹¹³Id.

¹¹⁴See The Center for Responsive Politics, Dennis Rehberg, Top Industries, available at <http://www.opensecrets.org/politicians/indus/N00004645.htm>

THREATENING THE FDA BUDGET

When veiled threats and angry letters are insufficient, members of Congress have other tools with which to protect their industry patrons from the Food and Drug Administration. One of the most powerful of these is Congress' control over the purse strings of the federal government. Often the mere existence of this power is sufficient to deter cautious bureaucrats from offending the Congress. But as David Kessler's FDA moved forward with its plan to regulate tobacco, industry-friendly members of Congress made that threat a reality, punishing the Commissioner by attacking the FDA's budget.

In particular, tobacco-industry allies in Congress saw an opportunity to send the FDA's leadership a message by attacking a signature spending program. Kessler was intent on moving the FDA to a unified, more modern headquarters; for years it had been spread across forty-eight buildings in twenty different locations around Washington, D.C.¹¹⁵ The need for a new headquarters was clear.¹¹⁶ But while there had been a bipartisan consensus in favor of the appropriations in 1992, the FDA's challenge to the tobacco industry had created new opposition. The new headquarters became a symbol, and a rallying point for opposition to the FDA. Rep. John Duncan (R-TN) called the headquarters "a Taj Mahal," while others referred to the project as "Kessler's Castle."¹¹⁷

Testifying against the new headquarters, C. Boyden Gray, former White House Counsel to President George H. W. Bush and chairman of the conservative (and tobacco-funded) thinktank Citizens for a Sound Economy, actually suggested that the FDA might be best eliminated altogether:

¹¹⁵David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.313

¹¹⁶See "Officials Warn: FDA Infrastructure Could Be Hazardous to Its Work," The Washington Post, June 5, 1991, p.A17

¹¹⁷"FDA Consolidation Plan Hit as a 'Taj Mahal,'" The Washington Times, February 1, 1995, p.C6

The 104th Congress is currently in the process of identifying and eliminating federal agencies that have either outlived their usefulness, or whose mission can be best accomplished at the state level. Breaking ground on a government construction project of this magnitude is shortsighted – especially until the future of the FDA can be defined by the new Congress.¹¹⁸

Shortly thereafter, Rep. Duncan proposed an amendment to strike the funds for FDA construction from appropriations legislation; it carried by a vote of 278-146.¹¹⁹ As David Nicoli, a Philip Morris strategist, noted approvingly in an internal email, “tobacco was NOT mentioned” during the entire debate.¹²⁰

Some industry allies took their campaign even further. Rep. Jim Bunning (R-KY) actually proposed an amendment to strike *all* funding for the FDA altogether, crowing that the FDA “was a rogue agency and Congress needs to slap it down.”¹²¹ He was ultimately convinced to withdraw the amendment by embarrassed Republican colleagues. However ridiculous his behavior appeared to his peers, it did not hinder his political career in Kentucky, one of the nation’s largest tobacco-producing states. Bunning ascended to the Senate in 1998, with more funding from the tobacco industry than all but one other member of the Senate.¹²²

AGGRESSIVE “REFORM” PLANS: EVISCERATING THE FDA

¹¹⁸House Appropriations Committee, Treasury, Postal Service, and General Government Subcommittee, testimony of C. Boyden Gray, hearing, March 21, 1995.

¹¹⁹David Kessler, “A Question of Intent: A Great American Battle With A Deadly Industry,” PublicAffairs, New York, 2001, p.316

¹²⁰David Nicoli, Philip Morris e-mail to Murray Bring, et al., “Round Two on FDA Campus,” July 19, 1995, PM ID 2046620272B-73.

¹²¹U.S. Congress, House of Representatives, Congressman Bunning amendment and subsequent debate, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1996, July 20, 1995.

¹²²Jim Bunning received \$80,366 in tobacco industry PAC funds between January 1, 1995 and November 27, 2000. See “Buying Influence, Selling Death: How Big Tobacco’s Campaign Contributions Harm Public Health,” Common Cause, March 14, 2001

An alternate method of protecting the tobacco industry from the FDA is to change the structure of the regulatory process, constraining the powers of the agency under the guise of FDA “reform.” In the wake of Commissioner Kessler’s effort to regulate tobacco, numerous tobacco-supported thinktanks released plans to pare down FDA’s responsibilities and to reassign FDA functions to private actors in an effort to eviscerate the Agency. Ever-conscious of public relations ramifications, the tobacco industry’s front groups were careful to couch the “reform” plans in terms that emphasized life-saving medicines and devices, and neatly avoided the central role the tobacco industry played in the “reform” effort.

On February 7, 1996, the Progress & Freedom Foundation (PFF) released a report entitled “Advancing Medical Innovation: Health, Safety and the Role of Government in the 21st Century,” during a conference attended by Rep. Thomas Bliley (R-VA). Rep. Bliley endorsed the PFF report and promised that his committee would begin holding hearings on reforming FDA beginning in late February.¹²³ The Progress & Freedom Foundation’s plan would place responsibility for drug development, testing, and review in the hands of government-licensed “drug (or device) certifying bodies,” or DCBs, private firms hired by the drug companies themselves. According to the proposal, “competition between firms would inevitably produce a lower-cost, faster, and higher-quality development and approval process.”¹²⁴ While the FDA would still exist, and would theoretically retain a veto power over new products, the PFF plan would have created “a strong presumption that private certification decisions would not be overturned without substantial cause.” Further, the FDA would not be authorized to request additional testing or data, and it would “have to exercise its veto within a fixed time period (e.g., 90 days) after which the drug would automatically receive FDA approval.”¹²⁵ The result would be an almost irresistible pressure on the FDA.

The PFF’s call for FDA privatization was echoed by Henry Miller, a former director of the FDA’s Office

¹²³Legislative and Regulatory Overview, McKenna & Cuneo, L.L.P. Client Bulletin, March 1996

¹²⁴Nicholas Regush, “Migraine Killer,” Mother Jones, 1995

¹²⁵Id.

of Biotechnology, has been a persistent critic of the agency. Now a Senior Research Fellow at the Hoover Institution, a conservative public policy thinktank that receives funding from the tobacco industry, Miller is affiliated with a numerous anti-regulation organizations, including the American Council on Science and Health (ACSH). In *To America's Health: A Proposal to Reform the Food and Drug Administration*, Miller argues that "The current system of drug regulation is, literally, overkill and works against the public interest," and contends that "attempts at regulatory reform have been weak, undermined by the absence of any constituency that demands improvements in our regulatory system."¹²⁶ In Miller's conception, "The seminal change would be that day-to-day oversight of drug testing and review of the initial application for marketing approval would be performed by nongovernmental, FDA-certified entities."¹²⁷

The Heritage Foundation, which has long received substantial tobacco funding, came out with a similarly aggressive privatization approach. "Whenever a drug or medical device is kept off the market for extended periods of time, or the cost of a drug or medical device is artificially heightened by overregulation, Americans are dying or being forced to suffer the unintended consequences of excessive FDA regulation."¹²⁸

To the major players in the pharmaceutical industry, however, the FDA is not simply an adversary, but also an important seal of approval, one that reassures consumers and bolsters the public's faith in the safety of its products. They are far less enthusiastic than their tobacco industry colleagues about the prospecting of starving – much less eliminating – the FDA. Steve Berchem of the Pharmaceutical Research and Manufacturers of America (PhRMA) said that while some drug reviews can be handled by the private sector, it would be a mistake to weaken the FDA's authority over product approvals. "We need an FDA

¹²⁶"New Books from Hoover Fellows: *To America's Health: A Proposal to Reform the Food and Drug Administration*," *Business Wire*, September 14, 2000. The claim that "no constituency demands improvements" is absurd; numerous and powerful constituencies, including industry, consumer and patient groups, have brought vast resources and millions of dollars to bear on demanding improvements. Whether the FDA remains in need of further reform, and what kind of reform, remain open questions. But the allegation that no constituency demands improvement is absurd.

¹²⁷Henry L. Miller, "Don't Create a New Entitlement, Reform the FDA," *St. Louis Post-Dispatch*, July 17, 2000

¹²⁸Adam D. Thierer, "Balancing America's Budget: Ending the Era of Big Government," Section 554: *Restructure the Food and Drug Administration*, The Heritage Foundation, 1997

that maintains public confidence,” Berchem says.¹²⁹ Said one FDA official in 1997, “The drug companies are happier than they have been in 10 years.”¹³⁰ Tom Lenard, the Progress & Freedom Foundation’s director of regulatory studies, admitted as much: “The drug companies are not particularly radical. Our proposal is beyond where most of them seem to want to go.”¹³¹ Nor was the medical device industry calling for drastic structural changes. “The device industry doesn’t want to see the FDA go away or be weakened,” said Jim Benson, senior vice president of the Health Industry Manufacturers Association (HIMA).¹³² Who, then, was behind radical efforts to restructure the FDA, if not the pharmaceutical and medical device industries those plans claimed to benefit? “If you look at the people who are pushing for reform of the FDA,” says one FDA official, “behind the scenes you will see the tobacco industry.”¹³³

THE OUTSIDE GAME: SHAPING PUBLIC OPINION

All of these efforts – aggressive oversight efforts, threats to the budget, “reform” of the decision-making structure, bullying FDA staff – are “inside” strategies for constraining FDA. But industry strategists are savvy enough to realize that no matter how much lobbying they do, public opinion remains a significant check on the ability of any interest group to advance its agenda. Accordingly, the tobacco industry has aggressively pursued a campaign to shape public opinion outside the Capitol – an “outside” game to match its “inside” approach.

¹²⁹Nicholas Regush, “Migraine Killer,” *Mother Jones*, 1995

¹³⁰Robert Dreyfuss, “Tobacco Enemy Number One,” *Mother Jones*, 1997. Part of the explanation may be that under Commissioner David Kessler, the FDA made significant strides in reducing the time required for new drug approval. Changes instituted by Kessler cut approval time by 30 to 40 percent.

¹³¹*Id.*

¹³²*Id.*

¹³³Robert Dreyfuss, “Tobacco Enemy Number One,” *Mother Jones*, 1997

Some members of Congress, like former Rep. Mike Synar (D-OK) or Sen. Dick Durbin (D-IL) oppose the tobacco industry for ideological reasons; the only way to stifle their voices is to remove them from office. Tobacco industry loyalists like Sens. Mitch McConnell (R-KY) and Jesse Helms (R-NC) are equally unshakable in their support for the industry. Between these two polar positions lie the vast majority of the members of Congress. While they may have personal opinions on the subject, their position on tobacco regulation is shaped largely by political realities, by the risks and rewards offered by assuming one position over another. While many political decisions are the product of backroom deals and fundraising considerations, many others are determined in the home districts of the wavering Members, in the hearts and minds of their constituents. Public opinion remains a significant constraint on legislative action, and the tobacco industry, keenly aware of this fact, has positioned itself to take maximum advantage.

The tobacco industry has had two primary goals in pursuing this “Outside Game:” to create the illusion of scientific uncertainty surrounding the health effects of tobacco use, and to link in the minds of voters FDA regulation of tobacco (which most voters favor) with the expansion of an overbearing bureaucracy and free-spending federal government (which most voters oppose). To achieve these ends, the tobacco industry has pursued an unprecedented public relations campaign, using front groups, advertising, promotional schemes, and even direct dissemination of industry disinformation.

“GRASSROOTS” AND “ASTROTURF”

Professional lobbyists like George Mitchell and Haley Barbour may be personally persuasive, but to convince wavering members of Congress that a given position is politically viable, an industry must convince Members

that the voters in their district support – or at least will not oppose – the industry’s position. To do this, industry lobbyists have employed what they euphemistically call “grassroots” organizing, and what skeptics refer to as “Astroturf” – the effort to make a narrow corporate agenda appear to have broad-based support among voters. Using specially tailored mailing lists, field officers, telephone banks and the latest in information technology, public relations firms are able to generate hundreds of telephone calls and thousands of pieces of mail to elected officials, creating the impression of wide public support for their client’s position. In 1995, Bob Beckel, once the manager of Walter Mondale’s 1984 presidential campaign and now a Washington lobbyist, organized a “grassroots” lobbying campaign on behalf of large long-distance telephone companies that generated more than 500,000 telegrams to members of Congress. Ultimately as many as half proved to be faked; some had been sent on behalf of people who were dead.¹³⁴ *Campaign and Elections* magazine reported in mid-1995 that some \$790 million dollars had been spent on “grassroots” telemarketing campaigns over the previous two years – a jump of seventy percent.¹³⁵

One expert in creating grassroots support for corporations is John Davies, whose print advertisements features a picture of an old lady carrying a sign bearing the legend “Not in my backyard.” The caption below reads:

Don’t leave your future in her hands. Traditional lobbying is no longer enough. Today numbers count. To win in the hearing room, you must reach out to create grassroots support. To outnumber your opponents, call the leading grassroots public affairs communications specialists.¹³⁶

At a 1994 conference of public relations professionals entitled “Shaping Public Opinion: If You Don’t Do It, Someone Else Will,” Davies explained how his operation produced authentic-looking letters for “grassroots”

¹³⁴See Ken Silverstein, “Washington on \$10 Million a Day,” Common Courage Press, 1998, p.88

¹³⁵Id.

¹³⁶John Stauber and Sheldon Rampton, “Deforming Consent: The Public Relations Industry’s Secret War on activists,” *CovertAction Quarterly* 55, 1995/96, p. 18

campaigns:

We want to assist them with letter writing. We get them on the phone, and while we're on we say 'Will you write a letter?' 'Sure.' 'Do you have the time to write it?' 'Not really.' 'Could we write the letter for you? I could put you on the phone right now with someone who could help you write a letter. Just hold, we have a writer standing by.' We hand-write it on 'little kitty cat stationary' if its an old lady. If it's a business we take it over to be photocopied on someone's letterhead. [We] use different stamps, different envelopes.. Getting a pile of personalized letters that have a different look to them is what you want to strive for.¹³⁷

In this way, Davies proudly relates, he is able to create the impression of a "spontaneous explosion of community support for needy corporations."¹³⁸

The tobacco has industry used this method to great effect. As early as 1986, Philip Morris had assembled a database of almost three million customers that it used to generate phone calls and letters to elected officials.¹³⁹ Philip Morris launched the National Smokers Alliance (NSA) in 1993 with an estimated \$4 million in seed money, and contributed a total of \$42 million to the NSA between 1993 and 1996.¹⁴⁰ Publicly, the NSA claimed it sought to "empower" smokers. In private, industry strategists expressed concern that "empowerment" not go too far:

The issue of 'empowerment of smokers' was viewed as somewhat dangerous. We don't want to 'empower' them to the point that they'll quit.¹⁴¹

The tobacco industry's letter-writing campaign was highly effective: between the FDA's August 1995 decision to regulate tobacco as a drug and January 1996, when the official period for public comment on the plan

¹³⁷See Ken Silverstein, "Washington on \$10 Million a Day," Common Courage Press, 1998, p.91

¹³⁸John Stauber and Sheldon Rampton. "Deforming Consent: The Public Relations Industry's Secret War on activists," CovertAction Quarterly 55, 1995/96, p. 18

¹³⁹Allison Mitchell, "The Influence Industry: A New Form of Lobbying Puts Public Face on Private Interest," New York Times, September 30, 1998.

¹⁴⁰Andrew Tobias, "Those Lovable Tobacco Execs," February 16, 2000, <http://www.andrewtobias.com/bkoldcolumns/000216.html>
See also Myron Levin, "Smoker Group's Thick Wallet Raises Questions," The Los Angeles Times, March 29, 1998

¹⁴¹Document available at <http://www.prwatch.org/prwissues/2000Q3/empower.gif>

ended, the Agency received nearly 700,000 pieces of mail, most of them strongly condemning the FDA's action.¹⁴² "The tobacco companies think it will have some psychological effect on the FDA, on the courts, and on Congress," said Alan Morrison, an attorney with the consumer advocacy group Public Citizen. "These guys are used to sparing no expense. This is war."¹⁴³

In March of 1994, a hidden camera belonging to an ABC crew captured Elizabeth Gallagher, an RJR employee who organized "smokers' rights" groups around the country, explaining the industry strategy. "A politician will not listen to you if they think all you are is a mouthpiece for the tobacco companies. Your only prayer is being independent, appearing independent, and for that reason, we don't get directly involved with organizing you guys."¹⁴⁴ RJR actually obtained the itineraries of various members of Congress who supported or were considering supporting proposed tax increases - particularly a cigarette excise tax - so that industry-funded protesters could pursue them carrying placards with anti-tax slogans. The protests appeared to be spontaneous, but in at least one instance the placards for a choreographed demonstration were literally shipped by Federal Express directly from RJR headquarters in Winston-Salem, North Carolina.¹⁴⁵

BUYING LEGITIMACY: A PATRON OF THE ARTS

One of the challenges facing the tobacco industry was to create a positive corporate image. As in all their pursuits, the tobacco industry spared no expense. In New York, for instance, the tobacco industry became a major patron of the arts. In other parts of the country tobacco companies sponsored NASCAR events (the Winston Cup, for instance) and the Virginia Slims women's tennis tournaments. By its own estimate, Philip

¹⁴²Robert Dreyfuss, "Tobacco Enemy Number One," *Mother Jones*, 1997

¹⁴³*Id.*

¹⁴⁴"Tobacco Under Fire," *Mother Jones*, 1996. ABC Executive Vice President Paul Friedman called *Tobacco Under Fire* a boring rehash; the program never aired.

¹⁴⁵Ted Gup, "Fakin' It," *Mother Jones*, 1996

Morris spends over \$150 million a year on public relations efforts, including millions in charitable giving.¹⁴⁶ These investments don't create as readily recognizable financial returns as donations as to elected officials, or magazine advertising, but their purpose is every bit as calculated. Philip Morris actually spends more on promoting public awareness of its charitable giving than it does on charitable giving itself.¹⁴⁷

A PATRON OF THE SCIENCES

In the scientific field, the tobacco industry has had two primary goals: to forge friendly relationships with important institutions, and to produce plausible scientific studies which, if they could not demonstrate the truth of the industry's positions, could at least muddy the waters of scientific certainty and create doubt in the minds of jurors and the voting public. To achieve the first goal, the tobacco industry followed the same strategy it did in politics and in civil society: it gave away enormous amounts of money. It made grants to prestigious institutions like Johns Hopkins Medical School and Harvard Medical School (one industry insider noted that the importance of the Harvard grant "continues to be viewed by some as relating wholly to the name of Harvard,"¹⁴⁸). While the industry was largely unable to purchase endorsements of the industry's scientific positions from these institutions, it often succeeded in purchasing passivity and inaction. Just as generous campaign donations could persuade members of Congress not to make trouble, donations to scientific and medical institutions could at least purchase neutrality. In recounting donations made to UCLA Medical School, an internal industry document noted "The industry also funded a project at UCLA

¹⁴⁶Dan Harris, "Corporate Goodwill or Tainted Money," ABC World News Tonight, February 8, 2001.

¹⁴⁷Id.

¹⁴⁸Janet C. Brown, memo to Arnold Henson, "Industry Research Review Study Group," November 4, 1978, p.17, B&W ID 0012684784,

Medical School, but only after the Medical School reassured the industry that nothing damaging to the industry would be discovered.”¹⁴⁹

Perhaps the most cynical efforts by the industry were to associate itself with cancer research institutions. Philip Morris, R.J. Reynolds, the American Tobacco Company, Liggett & Myers, Lorillard, and Rothmans all contributed money to the Sloan-Kettering Institute for Cancer Research; Philip Morris alone contributed over \$200,000 before 1970.¹⁵⁰ Amazingly, the tobacco companies reaped more than merely positive publicity, winning the complicity of some of the nation’s most respected doctors. One Philip Morris memo noted with pleasure that Frank Horsfal, the director of Sloan-Kettering, had “publicly expressed his doubt that smoking is implicated in carcinoma causation. Dr. Horsfal’s opinion (coupled with his demonstrated liking for our Marlboro cigarettes) has been beneficial. As head of the nation’s principal cancer research organization, he has tremendous influence.”¹⁵¹ The contributions apparently helped to silence Ernst Wynder, a researcher at the Institute. According to an internal industry document, Horsfal and other Sloan-Kettering officials, conscious of the interests of their patrons, began “subjecting Wynder to more rigorous screening procedures before letting him speak in the name of the Institute. This has had a proper and pleasing effect... The [tax-] deductible contribution to Sloan-Kettering is probably the most effective of all health research contributions.”¹⁵² The irony of this statement is truly chilling; the contribution was “effective” because it prevented the truth from coming to light.

Even the American Medical Association was wooed by the tobacco industry’s largesse. In 1964 the six largest tobacco companies offered the AMA \$10 million dollars to fund research on smoking and health; two weeks

¹⁴⁹Jones, Day, Reavis & Pogue, draft report, “Corporate Activity Project,” B&W ID 681879254-715.

¹⁵⁰David Kessler, “A Question of Intent: A Great American Battle With A Deadly Industry,” PublicAffairs, New York, 2001, p.207

¹⁵¹C.H. Kibbee and J.C. Bowling, PM memo to Joseph F. Cullman III, “Sloan-Kettering Institute for Cancer Research,” 18 February 1970, PM ID 2024774530.

¹⁵²J.C. Bowling, PM memo to C.H. Kibbee, “Sloan-Kettering Contributions,” November 23, 1964, PM ID 1005038364.

after the AMA accepted the offer, Francis Blasingame, the AMA's executive vice-president, penned a letter to the Federal Trade Commission in which he opined that "with respect to cigarettes, cautionary labeling cannot be anticipated to serve the public interest with any degree of success."¹⁵³ Ultimately, the companies contributed \$15.005 million between 1964 and 1972.¹⁵⁴

DISCARDING EVIDENCE, FABRICATING DATA

To the general public, the tobacco industry presented itself as interested in scientific research, regardless of where it might lead. In a full page advertisement which ran in 448 leading newspapers, beneath the headline "A Frank Statement to Cigarette Smokers," one tobacco ad read: "We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business. We always have and always will cooperate closely with those whose task it is to safeguard the public health."¹⁵⁵ The advertisement announced an initiative to fund research into tobacco use and its health implications – an effort that culminated in the creation of the Council for Tobacco Research. The research effort, however, proved to be anything but altruistic.

¹⁵³David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.207

¹⁵⁴Shook, Hardy & Bacon, "Brown & Williamson – American Medical Association Issues Notebook," January 1990, B&W 682623623-788.

¹⁵⁵David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.200

THE COUNCIL FOR TOBACCO RESEARCH

The Tobacco Industry Research Committee, later renamed the Council for Tobacco Research (CTR), was headed by a man of impeccable credentials. Clarence Cook Little was a Harvard-educated cancer researcher and former university president who had been active at both the National Cancer Institute and the American Cancer Society. His stature in the scientific community provided the essential element of credibility the industry needed. Though CTR was a grant-making organization that claimed to be dedicated to the cause of scientific health research, applications for grants from the CTR's Special Projects division were vetted by tobacco industry lawyers rather than scientists. Their explicit purpose was to develop scientific data that could be used to defend the tobacco companies in court.¹⁵⁶ One internal memorandum from Philip Morris noted, “[I]f CTR [the Center for Tobacco Research] is to be useful, ways must be found to bolster its reputation so it can be useful to ‘launder’ industry money.”¹⁵⁷ Another internal document was even more frank:

[CTR] was set up as an industry shield.... CTR has helped our legal counsel by giving advice and technical information, which was needed in court trials. CTR has provided spokesmen for the industry at Congressional hearings... On these projects, CTR has acted as a front.¹⁵⁸

At a 1979 meeting of American Tobacco officials, tobacco industry officials agreed that “CTR Special Projects should continue under CTR to give investigators an aura of independence.”¹⁵⁹ That aura was a deception.

Wrote a Lorillard official, “CTR is NOT independent – because of what we have asked them not to do.”¹⁶⁰

¹⁵⁶“Environmental Tobacco Smoke: The Brown and Williamson Documents,” Journal of the American Medical Association, Special Communication, July 19, 1995, available at <http://www.ama-assn.org/sci-pubs/journals/archive/jama/vol.274/no.3/sc5045.htm>

¹⁵⁷Philip Morris notes, New York meeting, November 15, 1978.

¹⁵⁸See *Haines v. Liggett Group*, 140 F.R.D. 681 (E.D.N.J. 1992)

¹⁵⁹American Tobacco meeting notes, May 7, 1979. AT ID MNATPRIV00034812-13.

¹⁶⁰James Bowling, PM notes, quoting Alexander Spears at meeting of Industry Research Study Committee, April 19, 1979, cited in William L. Alinder (Shook, Hardy & Bacon), letter to K.F. Bixenstein (Jones, Day), October 22, 1992, PM ID 2048925020.

Tobacco companies did more than tailor the direction of their research; they were so dominated by the threat of litigation that they willfully avoided recognizing data that contradicted the industry's litigation positions. In one memo, an official of Brown & Williamson suggested that certain kinds of information from British American Tobacco (BAT), Brown & Williamson's parent company, were better left uncommunicated: "[I]f the reports include discussions of pharmacological effects of nicotine, the information will not be interesting and would be helpful to the plaintiff." The company ultimately decided to receive the reports, but remained ready "to inform BAT to cease sending the data to B&W if the science is not interesting."¹⁶¹ "Interesting" in this context is an industry euphemism meaning "favorable for our litigation defense strategy."

When such "uninteresting" research was produced, the industry was more than willing to destroy or suppress it. Another memo, from RJR, makes this willingness explicit:

We do not foresee any difficulty in the event a decision is reached to remove certain reports from Research files. Once it becomes clear that such action is necessary for the successful defense of our present and future suits, we will promptly remove all such reports from our files. As a rule, we invalidate about 15 reports each year for various reasons... [W]e can cite misinterpretation of data as reason for invalidation.... As an alternative to invalidation, we can have the authors rewrite those sections of the reports which appear objectionable.¹⁶²

What is clear from these documents is that the tobacco industry was intent not merely on averting its eyes from potentially harmful discoveries, but on making scientific claims it knew to be untrue.

¹⁶¹J.K. Wells III, B&W memo to E. Pepples, "BAT Science," February 17, 1986, B&W ID 682419469-70

¹⁶²M. Senkus, RJR memo to Max Crohn, "Invalidation of Some Reports in the Research Dept.," December 18, 1969, RJR ID 500284499.

THE TOBACCO INDUSTRY’S SCIENTISTS: THE WHITECOAT PROJECT

While they knew that giving to recognized institutions like Harvard and Sloan-Kettering would win the industry praise (and perhaps even some breathing room), tobacco industry lawyers recognized that they would need scientific evidence to support the industry’s positions. To protect themselves from regulation and litigation, the tobacco companies needed scientists who were willing to go on the record.

In 1967, Rosser Reeves, a public relations expert employed by the tobacco industry, proposed to enlist “janis-saries” to challenge the conventional wisdom on smoking and health, with the knowledge that those people would come to “depend on it for their livelihood and whose zeal, consequently, often runs well ahead of their facts.”¹⁶³ In short, Reeves sought to create a class of advocates who could be expected to play fast and loose with science, while maintaining plausible deniability for the industry.

The effort was code-named “The Whitecoat Project,” after the white lab coats worn by scientists. The project had four primary goals:

-

-

-

¹⁶³Rosser Reeves, Tiderock Corp. memo to Anne Hetfield et al., “The Study of a Propaganda Phenomenon,” July 18, 1967, PM ID 1003059283-85.

-

Records of correspondences between industry officials and Whitecoat Project scientists sometimes resemble negotiations between businessmen, explicit in their recognition of a *quid pro quo*: A 1965 RJR memorandum describes such an exchange:

Dr. Sprunt wants something more than the hope they will approve his grant application before he takes further public position on our behalf... Dr. Sprunt's present attitude is that he is prepared to testify in Washington (including an adequate statement by accepting our help in preparing the final form...) but feels that before he does so, we should adopt a more positive attitude towards his situation.¹⁶⁵

While it is written in euphemisms, the meaning of the conversation is clear: Dr. Sprunt is willing to testify to industry-friendly conclusions ("adequate statement"), even sign his name to a document drafted by industry lawyers ("accepting our help in preparing the final form") but only in exchange for more money that he has previously been offered ("a more positive attitude toward his situation").

The American Medical Association and the American Public Health Association have had policies for years urging researchers not to accept tobacco industry money, but nearly all universities have continued to allow professors to accept such support, citing the importance of academic freedom.¹⁶⁶ The tobacco industry had its own reasons for funding research, which had little to do with academic freedom. In 1993, after the Environmental Protection Agency ruled that environmental tobacco smoke (ETS) was a Class A carcinogen

¹⁶⁵Edwin Jacob (of Cabell, Medinger, Forsyth & Decker), letter to H.H. Ramm (of R.J. Reynolds), January 25, 1965, RJR ID 500887112-13.

¹⁶⁶Scott Shane, "Tobacco Deal Would Disband Controversial Research Center," Baltimore Sun, November 14, 1998

and a health hazard, the tobacco industry paid thousands of dollars to scientists to voice their objection to the finding in letters to medical and scientific journals.¹⁶⁷ Dr. Gio Gori was one of thirteen scientists who accepted large sums of money from the Tobacco Institute to write letters to the editor attacking the EPA's report. Records show that Gori was paid \$20,137 for two letters to the *Wall Street Journal*, one letter to the British medical publication *The Lancet*, one letter to the *NCI Journal*, and one opinion piece for the *Wall Street Journal*. Dr. Gori, a former scientist at the National Cancer Institute, is now a consultant to the tobacco industry.¹⁶⁸ Said Clive Bates, director of the antismoking organization Action on Smoking and Health, "No matter how strict you are about conflicts of interest, there is not much you can do if scientists conceal who they are paid by."¹⁶⁹

THE CENTER FOR INDOOR AIR RESEARCH

Concealing the existence of financial relationships between scientists and industry figures became a critical component of the tobacco industry's research strategy. As late as the 1980s, some industry groups were maintaining their campaign through openly tobacco-affiliated groups. While the results invariably favored the industry's position, the subterfuge involved was so transparent that the studies lacked credibility. A 1987 Tobacco Institute memo lamented:

Yesterday morning, the Texas Association of Wholesale Distributors and the Tobacco Institute held a news conference in Dallas to release the results of an environmental smoke study...The highly favorable results of the study were reviewed at our meeting last week....Questioning at the conference was skeptical but not

¹⁶⁷David Hanners, "Scientists Were Paid to Write Letters – Tobacco Industry Sought to Discredit EPA Report," Pioneer Planet/St.Paul Press, August 4, 1998. See also Philip Morris Report, "IAQ Goals," January 25, 1993, Philip Morris ID 2023206195/6198.

¹⁶⁸David Hanners, "Scientists Paid to Write on Tobacco: Letters Aimed to Discredit Report on Secondhand Smoke's Effects," Saint Paul Pioneer Press, August 14, 1998

¹⁶⁹Clare Dyer, "Tobacco Company Set Up Network of Sympathetic Scientists," British Medical Journal, May 23, 1998

hostile. The Institute's open sponsorship of the study affected the credibility of the results...¹⁷⁰

Because industry allies lacked credibility, and most independent scientists (particularly in medicine) were unwilling to associate themselves with such a disreputable industry, cigarette companies created a front group called the Center for Indoor Air Research (CIAR). Formed in late 1987, and funded by a coalition that included Lorillard, Philip Morris and R.J. Reynolds, the purpose and origins of the organization had to be carefully concealed if it was to fulfill its mission of legitimizing industry propaganda.¹⁷¹ As a result, many of the documents about hiring staff and recruiting scientists for it were stamped "confidential," and much of the work to form CIAR was labeled "Attorney Work Product" by Covington & Burling, the Tobacco Institute's legal counsel.

The minutes of a secret meeting in London makes the purpose of funding CIAR clear:

Philip Morris presented to the UK industry their global strategy on environmental tobacco smoke [ETS]. In every major international area (USA, Europe, Australia, Far East, South America, Central America and Spain) they are proposing, in key countries, to set up a team of scientists organized by one national coordinating scientist and American lawyers, to review scientific literature or carry out work on ETS to keep the controversy alive.¹⁷²

While tobacco industry executives were conscious of the deceptive nature of their enterprise, their chief concern was how this might hinder their ability to recruit scientists:

The excessive involvement of external lawyers at this very basic scientific level is questionable and, in Europe at least, is likely to frighten off a number of scientists who might otherwise be prepared to talk to the industry.¹⁷³

¹⁷⁰Document available at <http://www.pmdocs.com/getallimg.asp?DOCID=2025855771/5772>

¹⁷¹"The Tobacco Institute's Center for Indoor Air Research (CIAR)," <http://www.tobaccofreedom.org/issues/documents/ets/cia.center/>
See <http://www.tobaccoinstitute.com/getallimg.asp?DOCID=TIMN0014390/4393> for minutes and participants of that December 10, 1987 meeting.

¹⁷²"Note On a Special Meeting of the U.K. Industry on Environmental Tobacco Smoke," London, February 17th, 1988, document available at <http://www.tobaccofreedom.org/issues/documents/landman/conspiracy/401247331a.pdf>

¹⁷³Id.

This concern was well-founded; the industry's sometimes manic effort to recruit scientists had already created a number of embarrassing, awkward situations, as the Philip Morris memorandum below indicates.

MEMO¹⁷⁴

To: J.P. Rupp, Attorney [A partner at Covington & Burling]
From: Helmut Gaisch [Philip Morris, Europe]
Date: November 16, 1987

Dear John,

I had a surprise phone call earlier today from Dr. Bieva in Brussels. He was rather amazed that a certain Dr. Weimberg in Washington should call, asking him exactly the questions that we had already asked him and also offering him a contract. It made him uneasy that so much attention was suddenly focussed upon him from America (we had already introduced him to Shook Hardy).¹⁷⁵ We really should not be seen falling over each other when contacting independent scientists.

When I gave you the other day – in confidence – our list of “whitecoats”, it was precisely with the purpose in mind of avoiding double approaches....May I suggest that we agree as quickly as possible amongst ourselves on who contacts whom....

Kind regards,

Helmut

According to a memo from industry law firm Covington & Burling, which emerged during the discovery phase of litigation in Minnesota, the company's consultants included “an editor” of the *Lancet*, an adviser to a select committee of the British House of Commons, and members of working groups of the International Agency for Research in Cancer.¹⁷⁶

One of our consultants is an editor of this very influential British medical journal, and is continuing to publish numerous reviews, editorials, and comments on environmental tobacco smoke and other issues.¹⁷⁷

¹⁷⁴Document available at <http://www.tobaccofreedom.org/issues/documents/landman/whitecoats/p1.gif>

¹⁷⁵Shook, Hardy & Bacon is a national law firm that represented both Philip Morris and R.J. Reynolds.

¹⁷⁶Clare Dyer, “Tobacco Company Set Up Network of Sympathetic Scientists,” *British Medical Journal*, May 23, 1998

¹⁷⁷Id. The Philip Morris memo can be found at <http://www.bmj.com/misc/philipmemo.shtml>

These scientists were “asked to cover all substantial scientific conferences where they can usefully influence scientific and public opinion,” and were “not paid unless and until they actually perform work,” according to the Covington and Burling memo.¹⁷⁸

Because deniability was a cornerstone of the industry effort, the CIAR’s scientific recruits were carefully picked to avoid any detectable evidence of bias:

The consultants should, ideally, according to Philip Morris, be European scientists who have had no previous connection with tobacco companies and who have no previous record on the primary issue which might, according to Remes,¹⁷⁹ lead to problems of attribution.¹⁸⁰

The memorandum, however, leaves little doubt that biased research was the explicit goal of the project:

Philip Morris then expect [sic] the group of scientists to operate within the confines of decisions taken by PM scientists to determine the general direction of research, which apparently would then be ‘filtered’ by lawyers to eliminate areas of sensitivity.¹⁸¹

CIAR acknowledged no connection with the tobacco industry.¹⁸² Its annual budget of about \$5 million, however, came almost exclusively from the four largest U.S. tobacco companies.¹⁸³ Though they worked assiduously to create the perception of independence, the financial powers behind CIAR were not shy about ensuring that the research the Center produced was favorable. The authors of a 1996 study on CIAR-funded

¹⁷⁸Id.

¹⁷⁹David Remes was and is a partner at Covington & Burling.

¹⁸⁰‘Note On a Special Meeting of the U.K. Industry on Environmental Tobacco Smoke,’ London, February 17th, 1988, document available at <http://www.pprc.org/pprc/rfp/archives/indoora.html>

¹⁸¹Id.

¹⁸²According to a CIAR grant advertisement, “The Center for Indoor Air Research was established in 1988, as an independent, non-profit corporation. Its primary purpose is to sponsor scientific and technical research on the sources, transformation, and fate of constituents affecting indoor air quality; on factors governing human exposure to and retention of those constituents; on the effects of those constituents on health, including exposure-response relationships; and on methods of preventing or abating indoor air contaminant concentrations. The research program is supplemented by periodic conference workshops and commissioned monographs.” This description is available on the web page of the Pacific Northwest Pollution Prevention Resource Center, which itself appears to be an industry front, at <http://www.pprc.org/pprc/rfp/archives/indoora.html>

¹⁸³Scott Shane, “Tobacco Deal Would Disband Controversial Research Center,” Baltimore Sun, November 14, 1998

projects found that “. . . one recipient of an applied project, Roger A. Jenkins (1995), of Oak Ridge National Laboratory, testified at length regarding the funding process for his project. He stated that CIAR had approached him with a proposal for his project, and that he and his colleagues had developed the study methodology with input from CIAR, R.J. Reynolds, and Bellomy Research (a marketing research firm).” CIAR tax records show that the Oak Ridge lab received \$797,892 in 1993 for Jenkins to conduct a study titled “Determination of Human Exposure to Environmental Tobacco Smoke.”¹⁸⁴

Another project related to ETS was conducted by ACVA Atlantic, a small firm that was paid \$13,800 in 1985 to conduct a study of air quality in homes.¹⁸⁵ Although the president of ACVA Atlantic, Gray Robertson,¹⁸⁶ has since characterized his organization as “an independent consulting firm specializing in solving indoor air problems such as sick building syndrome,” his research proposal stated – before even preliminary tests were conducted - that the results of his study could demonstrate that ETS has a relatively insignificant effect on indoor air quality.¹⁸⁷ In addition, the methodology for the study stated the following:

Twelve homes will be selected in three discrete areas of the country giving a total of 36 homes, the selection will be by the Tobacco Institute who will provide the names, addresses, phone numbers and contact at each of the homes chosen to [sic] ACVA.¹⁸⁸

As the Journal of the American Medical Association later noted, “It is highly unusual for an ‘independent’ company to allow an organization such as the Tobacco Institute, which clearly has a strong interest in the outcome of a study, to select the sites for the study.”¹⁸⁹

¹⁸⁴D.E. Barnes and L.A. Bero, Industry-funded research and conflict of interest: an analysis of research sponsored by the tobacco industry through the Center for Indoor Air Research, *Journal of Health Politics*, Fall 1996, pp. 515-542, 515-542,

¹⁸⁵ACVA Atlantic Inc and Robertson G. Residential Inspection–Indoor Air Pollution. Quotation, May 2, 1985.

¹⁸⁶Robertson G, Healthy Buildings International Inc. Testimony before the House Subcommittee on Health and the Environment, Committee on Energy and Commerce, US House of Representatives; March 17, 1994. Washington, DC: US Government Printing Office serial No. 103-127.

¹⁸⁷ACVA Atlantic Inc and G. Robertson. Residential Inspection–Indoor Air Pollution. Proposal, May 2, 1985.

¹⁸⁸Id.

¹⁸⁹“Environmental Tobacco Smoke: The Brown and Williamson Documents,” *Journal of the American Medical Association*, Special Communication, July 19, 1995, available at <http://www.ama-assn.org/sci-pubs/journals/archive/jama/vol.274/no.3/sc5045.htm>

Perhaps to avoid association with its previous work for the tobacco industry, ACVA Atlantic later changed its name to Healthy Buildings International (HBI). In practice, however, it remained the same organization, faithfully carrying out the same industry-supported agenda. A 1994 staff report prepared by the House Subcommittee on Health and the Environment suggested that a study conducted by HBI to measure levels of ETS in typical office environments contained fabricated and falsified data.¹⁹⁰ The HBI study, like the ACVA Atlantic study before it, had been funded as a special project by the Center for Indoor Air Research, and concluded that “with good ventilation, acceptable air quality can be maintained with moderate amounts of smoking.”¹⁹¹ HBI employees stated that their field notes had been routinely altered so that the levels of ETS reported were lower than those that had actually been measured.¹⁹² Alfred H. Lowrey, a research chemist at the Naval Research Laboratory who reviewed the HBI data, concluded that “the data is so marred by unsubstantiated data entries, discrepancies, and misclassifications that it raises serious questions of scientific fraud.”¹⁹³ Though the revelation of the falsified data brought HBI’s usefulness to an end, the organization had already served its purpose well. Between August, 1985, and September, 1994, employees of HBI/ACVA Atlantic testified on at least 129 occasions before federal, state, or local government agencies concerning ETS. HBI’s standard statement was that, according to their analyses, moderate levels of smoking could be tolerated indoors with adequate ventilation. In many cases, they did not acknowledge tobacco industry funding.¹⁹⁴

One of the main goals of CIAR was to “mainstream” industry-friendly research, to create the (false) im-

¹⁹⁰House Subcommittee on Health and the Environment. Oversight Hearing on Tobacco Product Regulation. Washington, DC: Committee on Energy and Commerce, US House of Representatives; 1994. House Subcommittee on Health and the Environment. Environmental Tobacco Smoke Investigation: Exhibits. Washington, DC: Subcommittee on Health and the Environment, Committee on Energy and Commerce, US House of Representatives; 1994.

¹⁹¹Turner S, Cyr L, Gross A. “The Measurement of Environmental Tobacco Smoke in 585 Office Environments,” *Environ Int.* 1992;18:19-28.

¹⁹²House Subcommittee on Health and the Environment, Oversight Hearing on Tobacco Product Regulation. Washington, DC: Committee on Energy and Commerce, US House of Representatives; 1994. House Subcommittee on Health and the Environment. Environmental Tobacco Smoke Investigation: Exhibits. Washington, DC: Subcommittee on Health and the Environment, Committee on Energy and Commerce, US House of Representatives; 1994.

¹⁹³*Id.*

¹⁹⁴See M. Levin, “Who’s Behind the Building Doctor?” *The Nation*, August 9, 1993; D. Levy, “Smoking Data Tampered With, Researchers Say,” *USA Today*, November 2, 1994

pression that scientific opinion was divided on issues surrounding Environmental Tobacco Smoke. In this, they were largely successful. Publications of the Center for Indoor Air Research are to this day included alongside legitimate scientific publications, in the University of Washington library, for instance, and at many other sites.¹⁹⁵ As late as 1998, the CIAR was still offering fellowships through the website of The American Thoracic Society - the medical section of the American Lung Association.¹⁹⁶

USING THIRD-PARTY FRONT GROUPS

Just as the tobacco industry learned in the 1970s to conceal the source of its scientific claims, it also learned to mask its efforts in the political and commercial realms. Because tobacco money has attracted negative attention from the press, tobacco interests often use front groups with benign-sounding names, a tactic that enables corporations to take part in public debates and government hearings behind a cover of community concern or scientific independence.¹⁹⁷ Merrill Rose, executive vice president of the public relations firm Porter/Novelli, advises her clients: “Put your words in someone else’s mouth... There will be times when the position you advocate, no matter how well framed and supported, will not be accepted by the public simply because you are who you are. Any institution with a vested commercial interest in the outcome of an issue has a natural credibility barrier to overcome with the public, and often, with the media.”¹⁹⁸

The tobacco industry has taken Rose’s words to heart. Said a Philip Morris official at a 1984 workshop on cultivating relationships with third-party organizations,

The whole question of getting third-party assistance and enlisting this whole third-party concept in our defense structure is to give us clout, to give us power, to give us credibility, to give us leverage, to give us access where we don’t ordinarily have access ourselves. Those are the kinds of things we are looking for.

¹⁹⁵For example, the University of Washington’s library shows CIAR publications alongside legitimate scientific works. See <http://staff.washington.edu/ehlib/outlinks/bibls/iaqbibl.html>

¹⁹⁶A copy of the fellowship offer is available at <http://www.thoracic.org/news/atsnews/news0998/story19.html>

¹⁹⁷This has become a common, although still highly effective practice for supporters of unpopular causes. The Seniors Coalition and United Seniors, for instance, are actually anti-Medicare groups.

¹⁹⁸Merrill Rose, “Activism in the 90s: Changing Roles for Public Relations,” *Public Relations Quarterly*, Vol. 36, No. 3 (1991)

And to make them useful, we have to cultivate them, we have to build them, we have to stay with them... what we're doing is nothing new because the company has been doing this all along. Every time we have an issue, we always reach out to third parties wherever we can.¹⁹⁹

In 1994, as part of the coordinated campaign against the FDA, Philip Morris strategists proposed to their board of directors a series of “Allied attacks, where friendly third parties are engaged on our side but without direct or obvious connection to the industry.”²⁰⁰ In one report, Philip Morris identified twenty-five third-party ally organizations:

Action Institute for the Study of Religion and Liberty
Alexis DeToqueville Institution
Americans for Tax Reform
Cato Institute
Center for the Study of American Business
Citizens for a Sound Economy
Citizens for Tax Justice/Institute on Taxation and Economic Policy
Claremont Institute for the Study of Statesmanship and Political Philosophy
Consumer Alert
Grocery Manufacturers of America
Heartland Institute
Heritage Foundation
Hoover Institution on War, Revolution and Peace
Institute for Research on the Economics of Taxation
Mackinac Center for Public Policy
Manhattan Institute
National Association of Manufacturers
National Center for Policy Analysis
National Empowerment Television
National Journalism Center
National Policy Forum
Pacific Research Institute for Public Policy
Tax Foundation
Texas Republic
Washington Legal Foundation²⁰¹

¹⁹⁹Workshop: Dealing with the Issues Indirectly: Constituencies, Philip Morris 1984 Corporate Affairs World Conference, September 13, 1984, Philip Morris ID 2025421934/2000

²⁰⁰Steven Parrish, PM draft presentation to the PM board of directors, Sea Island, Georgia, April 11, 1994, PM ID 2048310347.

²⁰¹Philip Morris strategy report, “Tobacco Strategy,” March 1994, PM ID 2045741542-48.

Some of the above organizations are simply ideological peers of the tobacco industry, dedicated to unregulated markets, but otherwise generally independent. In many other cases, however, these third-party groups took their marching orders directly from the tobacco industry. One internal Philip Morris memo suggested of the Washington Legal Foundation, “*have them publish* an article.”[emphasis added]²⁰² When a Philip Morris executive learned that *Roll Call*, the Capitol Hill newspaper, was running a special issue on the Food and Drug Administration, he dashed off an e-mail that ordered “Contact CSE [Citizens for a Sound Economy] about running an ad.”²⁰³

The tobacco industry was a major contributor to most, if not all, of the listed groups, including the American Enterprise Institute, the Cato Institute, the Competitive Enterprise Institute, Citizens for a Sound Economy, the Heritage Foundation, and the Washington Legal Foundation.²⁰⁴ These “thinktanks” and public policy organizations serve multiple purposes for the industries that support them. They provide an illusion of independence and scholarship, and they provide a resource for cultivating industry-friendly “experts.”²⁰⁵ They also serve as a clearinghouse for data; in the words of lobbyist Tommy Boggs, “information... became something that special interests learned they could develop quicker, better, faster, and more accurately than the government could.”²⁰⁶

²⁰²Craig L. Fuller, PM memo to Michael A. Miles, “February Monthly Report,” March 17, 1994, PM ID 2023439346-51.

²⁰³David Nicoli, Philip Morris e-mail to Ellen Merlo et al. “*Roll Call*/FDA-October 9,” September 26, 1995, PM ID 2037027442B.

²⁰⁴“A Million For Your Thoughts: The Industry-Funded Campaign Against the FDA by Conservative Think Tanks,” Public Citizen, July 24, 1996

²⁰⁵For instance, Alan Slobodin, a lawyer at the Washington Legal Foundation before the Republican takeover in 1994, became counsel to the Commerce Committee’s Subcommittee on Oversight and Investigations, which has jurisdiction over the FDA. In his new post, Slobodin continued an aggressively campaign against the agency, draining resources with constant hearings and demands for documents. “Slobodin is constantly saying, ‘Give us all your documents on this or that,’” said one attorney close to the FDA. “And then all of a sudden these papers show up in the hands of the Washington Legal Foundation.” See Robert Dreyfuss, “Tobacco Enemy Number One,” Mother Jones, 1997

²⁰⁶“The Buying of the Congress: Transcripts,” Thomas Hale Boggs, Jr., Interviewed by Chuck Lewis, Center for Public Integrity, August 15, 1997

The relationship between the tobacco industry and the Cato Institute is typical. The Cato Institute, one of the most frequently quoted policy institutions in Washington, has received hundreds of thousands of dollars of support from Philip Morris and R.J. Reynolds. In return, Cato has produced industry friendly reports, conferences, and articles. One policy forum was entitled, “The New Prohibition? Freedom & Tobacco Under Siege by the FDA.”²⁰⁷ Cato published an article in *Regulation*, its quarterly journal, entitled “Lies, Damned Lies, & 400,000 Smoking-Related Deaths,” which challenged the validity of data from the Centers for Disease Control and Prevention (CDC). If the same study had been written by the Tobacco Institute, it would have been immediately dismissed by serious journalists (particularly if it had borne the same title). But because Cato’s status as a “legitimate” conservative thinktank is secure, its contentions were not viewed with the same skepticism. As a result, the article provoked positive commentary that appeared in newspapers around the country, including in *The Boston Globe*.²⁰⁸

ATTACKING INDUSTRY’S OPPONENTS

Most industry players remain unwilling to attack the FDA in public, either for fear of retaliation or, more likely, for fear that openly attacking an agency charged with protecting health and safety could create a political backlash. As a result, one of the most important roles of the tobacco industry’s third-party front groups was to engage in the hand-to-hand combat of the public relations business – a role that large companies are constrained from playing themselves. The public relations firm Hill & Knowlton outlined a strategy for dealing with the tobacco industry’s scientific critics:

²⁰⁷Public Citizen Congress Watch, “A Million for Your Thoughts: The Industry-funded Campaign Against the FDA by Conservative Think Tanks,” pp. 29-32 Washington, D.C., 1996

²⁰⁸See e.g. Jeff Jacoby, “Big Lies About Tobacco,” *The Boston Globe*, May 10, 1999

-
-
-
-

Examples of “smearing and belittling” by third-party groups abound. The Washington Legal Foundation, which received generous support from the tobacco industry, and appeared in Philip Morris’ list of third party allies (see pp.67-68), produced advertisements that showed two gravestones accompanied by the headline “If a Murderer Kills You, It’s Homicide. If a Drunk Driver Kills You, It’s Manslaughter. If the FDA Kills You, It’s Just Being Cautious.”²¹⁰ These advertisements ran in *The New York Times*, *USA Today*, *The Wall Street Journal*, *The National Journal*, and *Roll Call*.²¹¹ Citizens for a Sound Economy (which also appears on Philip Morris’ list of allies) sponsored ads that claimed, “A better quality of life—even life itself—is being denied to too many Americans because of the FDA’s misplaced priorities.”²¹² The group received about \$250,000 a year in the early 1990s from Philip Morris to help launch its state affiliates in New Jersey, New York and four other states.²¹³ CSE spent some \$2 million on anti-F.D.A. advertising, organizing and lobbying between 1995 and 1996.²¹⁴

²¹⁰Robert Dreyfuss, “Tobacco Enemy Number One,” *Mother Jones*, 1997

²¹¹William Castagnoli, “What is the WLF and Why is it Challenging the FDA?” *Med. Marketing & Media*, April, 1995

²¹²Robert Dreyfuss, “Tobacco Enemy Number One,” *Mother Jones*, 1997

²¹³Peter H. Stone, “Blowing Smoke at its Critics,” *National Journal*, April 20, 1996

²¹⁴“A Million For Your Thoughts: The Industry-Funded Campaign Against the FDA by Conservative Think Tanks,” *Public Citizen*, July 24, 1996

Like industry allies in Congress, third-party allies of the tobacco industry showed a willingness to engage the FDA's leadership on a personal level. The National Legal and Policy Center, for instance, made more than 850 FOIA requests in an attempt to find damaging information about David Kessler. It found \$850 worth of taxi cab receipts over a six-year period, which industry allies in Congress seized upon in an effort to impugn Kessler's integrity and divert attention from the tobacco debate.²¹⁵

CONTROLLING MASS MEDIA

One of the most important components of the tobacco industry's "outside game" has been attention to the mass media. Just as the industry has leveraged its financial resources to forge relationships with political leaders, scientists and social organizations, so it has used its vast resources to win influence in the mass media. Sometimes this influence is used to quell a specific crisis. In order to defuse potential criticism over the marketing of tobacco products to minority neighborhoods, the tobacco industry provided direct financial support to the National Association of Hispanic Publishers, the National Newspaper Publishers Association, California Hispanic Publishers, West Coast Black Publishers, and the National Federation of Hispanic-Owned Newspapers.²¹⁶ In 1993, the West Coast Black Publishers Association actually passed a resolution endorsing the right of the tobacco industry to market to the black community, and penned a letter to Senator Ted Kennedy (D-MA) explaining their support for the industry.²¹⁷

The increasing consolidation of media corporations has helped to facilitate the forging of alliances between industry and media. In an internal memo from 1985, former Philip Morris chief executive Hamish Maxwell outlined a strategy to shape public opinion in the company's favor by directly influencing the content of the

²¹⁵David Kessler, "A Question of Intent: A Great American Battle With A Deadly Industry," PublicAffairs, New York, 2001, p.344. See also "Kessler Travel Investigation Called A Smear," USA Today, February 21, 1996, p.1D

²¹⁶Id. at 206

²¹⁷Id. at 211

television and print media:

The sixth point I want to make is that we are not using our considerable clout with the media. A number of media proprietors that I have spoken to are sympathetic to our position – Rupert Murdoch and Malcom Forbes are two good examples. The media likes the money they make from our advertisements and they are an ally that we can and should exploit.²¹⁸

An appendix to the memo, written by another Philip Morris employee, notes approvingly

As regards the media, we plan to build similar relationships to those we now have with Murdoch's News Limited with other newspaper proprietors. Murdoch's papers rarely publish anti-smoking articles these days.²¹⁹

This concern with directly influencing media was still alive and well in 1990, by which point the project had been dubbed "Operation Rainmaker." As the memo below makes clear, Philip Morris had become convinced that merely influencing the media would be insufficient for its purposes, and had concluded that purchasing major media conglomerates offered the potential for reliably disseminating industry propaganda.

TOP SECRET: Philip Morris – Operation Rainmaker

TOP SECRET Internal Report

Date: March 20, 1990

What are we trying to accomplish? Prevent further deterioration of overall social, legislative and regulatory climate, and ultimately, actually improve the climate for the marketing and use of tobacco products.²²⁰

²¹⁸ "The Perspective of PM International on Smoking and Health Issues: Text of the discussion document used at the meeting of top management," Internal Memorandum, Philip Morris, 1985, available at <http://www.media-awareness.ca/eng/news/news/two/rupsmoke.htm>

²¹⁹ Internal Memorandum, Philip Morris, 1985, available at <http://www.media-awareness.ca/eng/news/news/two/rupsmoke.htm>

²²⁰ "Operation Rainmaker," Internal Memorandum, Philip Morris, March 20, 1990, <http://www.tobaccofreedom.org/issues/documents/landman/rainmaker/p1.gif>

ACTION

... ACQUISITION - if we are to truly influence the public policy agenda and the information flow to the populace we must be the media, we must be part of it. The only way to do this is to own a major media outlet. If we are not willing to take this step, then we are not serious about really wanting to change the atmosphere.

Organizations that should be very seriously considered include:

- Knight Ridder
- Zuckerman's group
- the Copley News Service
- United Press International
- or a major city daily that has access to – and from – all of the major wire services.²²¹

The significance of the last portion of the memo – “that has access to – and from – all of the major wire services” – should not be overlooked. A media organization with access to the major wire services could arrange that its stories be picked up by the thousands of smaller local papers around the country, a unique vantage point from which to legitimize and disseminate the industry's point of view. Philip Morris seriously considered proposals to buy UPI,²²² but ultimately declined; the extent to which the plans outlined in the “Operation Rainmaker” memorandum were ever put into effect is unclear. But it is apparent that the tobacco industry has made significant inroads into major media organizations, among them those of Rupert

²²¹Id.

²²²David Kessler, “A Question of Intent: A Great American Battle With A Deadly Industry,” PublicAffairs, New York, 2001, p.211. UPI was purchased in May, 2000 by New World Communications, Inc., the publisher of *The Washington Times*, the arch-conservative newspaper affiliated with the Rev. Sun Myung Moon's Unification Church. The transfer of ownership sparked the resignation of veteran White House correspondent Helen Thomas and International editor Lee Michael Katz. See The New York Times, May 16, 2000.

Murdoch and Malcom Forbes, mentioned in Hamish Maxwell's 1985 memorandum.

FOX/NEWS CORP.

Some of the most obvious connections between Rupert Murdoch's media conglomerate and the tobacco industry are at the very top of the corporate structure. Philip Morris CEO Geoffrey Bible joined News Corp.'s Board of Directors on June 23, 1998; News Corp. owns the Fox Network. Bible effectively replaced Hamish Maxwell, the former chief executive of Philip Morris, who served on the News Corp. Board of Directors until early in 1998. Rupert Murdoch, CEO of News Corp., has sat on Philip Morris' corporate board since 1989. As a result, each is intimately familiar with the business of the other, and the two have offered one another public support. Murdoch himself has defended the tobacco industry in public; he told 240 executives attending the *Forbes* CEO Forum that Philip Morris and the tobacco industry in general were "victims of a classic media feeding frenzy."²²³

The Fox News Channel shows a pronounced conservative bias in its staffing (anchorman Tony Snow is a former aide to Vice President Dan Quayle), and is also known for being particularly heavy-handed in its top-down control of content. "I've been at editorial meetings," said one Fox News Channel employee. "Certain stories fly and certain stories don't. I'm not blind and neither are my colleagues. Everyone is aware that something is at work. There's a reason that there's a perception that Fox leans to the right."²²⁴

One of those reasons is Roger Ailes, the Chairman and Chief Executive Officer of the Fox News Channel.²²⁵ Ailes is the former executive producer of the right-wing "Rush Limbaugh Show."²²⁶ Ailes also has tobacco connections of his own. An internal R.J. Reynolds memo from 1988 details how Ailes was the media director

²²³ Jeffrey Klein, "Where There's Smoke," *Mother Jones*, September/October, 1998

²²⁴ Daphne Eviatar, "Murdoch's Fox News," *The Nation*, March 12, 2001

²²⁵ See <http://www.newscorp.com/management/foxnews.html>

²²⁶ Limbaugh, a proud cigar smoker, is also an outspoken defender of tobacco products. It has not been proven that nicotine is addictive, the same with cigarettes causing emphysema [and other diseases]." See *The Rush Limbaugh Show*, April 24, 1994, as cited by EXTRA!, <http://www.fair.org/press-releases/limbaugh-debates-reality.html#nicotine-addictiveness>

for the California Tax Initiative Campaign, an effort by tobacco companies “organized and directed to deal with Proposition 99.”²²⁷ The memo notes that “Roger Ailes, a nationally recognized candidate and issue media professional, has replaced Hal Larsen as media director,” and notes confidently that “in addition to working with the tobacco industry, Ailes is director of Bush for President media operations.”²²⁸

Ailes’ Fox News exhibits more than a generalized conservative bent; it is sometimes stridently anti-regulatory. The Fox News website, www.foxnews.com, is filled with attacks on the EPA²²⁹ and FDA,²³⁰ many written by Steven Milloy, a Cato Institute “scholar” with ties to the tobacco industry’s public relations arm (see pp. 109-114). Milloy refers to FDA warnings as “yet another example of a government agency terrorizing the public... for political gain.” Fox News applies a similar skepticism to anti-smoking activism: the channel recently declined to air an anti-smoking advertisement produced by the American Legacy Foundation. The advertisement, “Body Bag,” depicts corpses wrapped in body bags being pulled from a truck in front of Philip Morris headquarters. Fox officials said the decision not to air the ad was based on content, not board relationships.²³¹ But from the network which popularized such programs as “When Animals Attack” and “World’s Greatest Police Chases, ” the explanation seems incomplete.

FORBES: CAPITALIST TOOL

In 1994, Philip Morris began a nationwide counterattack on second-hand smoke, purchasing full-page advertisements in forty newspapers, including the *New York Times*, *Washington Post*, *Los Angeles Times*,

²²⁷Proposition 99 was an antismoking ballot initiative passed in 1988 by the voters of California.

²²⁸Memorandum from Roger Mozingo to Dolph W. von Arx, W.G. Champion Mitchell, and Gene Ainsworth dated July 7, 1988, re California Tobacco Initiative meeting July 6, 1988, Tobacco Institute Board Room, Washington, D.C. Copy available at <http://www.library.ucsf.edu/tobacco/calminnesota/html/3425/001/>

²²⁹“Adjusting Science to Fit Policy,” available at <http://foxnews.com/views/junkscience/030201.sml>

²³⁰“FDA’s Mercurial Fish Story,” available at <http://foxnews.com/views/junkscience/010119.sml>

²³¹Wendy Melillo, “Fox, CBS Nix ‘Morbid’ Anti-smoking Ads,” *Ad Week*, February 14, 2000

Chicago Tribune, *Miami Herald*, *Boston Globe*, and *Baltimore Sun*. The ads consisted of an article reprinted from *Forbes MediaCritic* that questioned the notion that second-hand smoke causes cancer in non-smokers, and appeared under the headline, “If We Said It, You Might Not Believe It.”²³²

You probably shouldn’t believe it anyway. The *Forbes* article was written by Jacob Sullum, then managing editor of *Reason* magazine, who called the Environmental Protection Agency’s 1993 report on second-hand smoke “one-sided, credulous and superficial,” and argued that journalists “missed an important story about the corruption of science by the political crusade against smoking.”²³³ What neither the original article nor the advertisements mentioned was that Sullum himself received tobacco industry funding, that *Reason* magazine received tobacco funding, or that Sullum’s key sources for the article, Gary Huber of the University of Texas Health Science Center²³⁴ and Alvin Feinstein, described as “an epidemiologist at Yale University,”²³⁵ also received tobacco industry support.

Sullum wasn’t the only voice at *Forbes* to come to the defense of the tobacco industry. *Forbes* editor Peter Brimelow, a former staffer of Senator Orrin Hatch (R-UT), actually wrote an article citing the supposed health benefits of smoking. In another, Brimelow attacked David Kessler in starkly personal terms, calling him “the quintessential D.C. chameleon... with an intense desire to control,”²³⁶ describing his career path as one that would be “sniffed at by doctors concerned with professional standards,”²³⁷ and characterizing his willingness to stay on under President Clinton as “a stunning act of treachery.”²³⁸ The cover of that issue

²³²Sheldon Rampton and John Stauber, “Tobacco’s Second-hand Science of Smoke-Filled Rooms,” *PR Watch*, Volume 7, No. 3, Third Quarter, 2000

²³³Jim Naureckas, “Smoke Screens,” *Extra!*, September/October 1994

²³⁴Huber’s research on secondhand smoke at Harvard was funded in part by a grant “from the major tobacco cigarette manufacturers in the United States.” He left the University of Kentucky’s Tobacco and Health Research Institute after evidence surfaced of further payments from R.J. Reynolds, Brown and Williamson, and the Tobacco Institute. Over the years, Huber received more than \$7 million in tobacco industry research funding. For Huber’s own perspective, see *Frontline*, “Inside the Tobacco Deal: Interviews,” Gary Huber, 1998, available at <http://www.pbs.org/wgbh/pages/frontline/shows/settlement/interviews/huber.html>.

²³⁵Between 1985 and 1990, according to confidential documents that leaked from Brown and Williamson, Feinstein received at least \$700,000 for basic epidemiological research from the special projects fund of the industry’s Center for Tobacco Research. See Jim Naureckas, “Smoke Screens,” *Extra!*, September/October 1994

²³⁶Peter Brimelow and Leslie Spencer, “Just Call Me ‘Doc,’” *Forbes*, November 22, 1993, pp. 108-110

²³⁷*Id.*

²³⁸*Id.*

of *Forbes* caricatured Kessler dressed as Napoleon Bonaparte.²³⁹

Speaking at a conference sponsored by the Pacific Research Institute for Public Policy, a pro-business 501(c)(3) organization dedicated to “principles of individual freedom and personal responsibility” (which also appears on Philip Morris’ secret list of allied third-party organizations, see p.68), Brimelow spoke in terms more befitting a political consultant than a journalist: “What we need in science policy is countervailing stereotypes to hand to the troops so they know which way to fire.” Said Brimelow, “The FDA is slowing arrival of new drugs on the market and people are dying. It’s a simple stereotype now being accepted, largely because of the AIDS crisis... The question of cost is another stereotype. You can express a stereotype in one sentence. It’s commission or omission. They are not letting the drugs through.”²⁴⁰

TOBACCO CONCLUSION

It is difficult to read a recounting of the misdeeds of the tobacco industry – the deception, the manipulation, the perversion of science and of the democratic process – without experiencing frustration, even anger. And it is surely a natural response to seek individuals to hold accountable; indeed, many have condemned the industry itself. While this is an understandable response, it is woefully, even dangerously incomplete. In fact, it may well be the conclusion that many of the *performers* in the tobacco industry drama would prefer, because such a conclusion has a clinical neatness to it, and compartmentalizes the infection to the tobacco industry alone. To conclude that the *individuals* who led the tobacco industry are simply depraved is to risk obscuring the institutional structures that enabled, and perhaps even determined the tobacco industry’s

²³⁹See *Forbes*, November 22, 1993

²⁴⁰“Junk Science: A Hazard to Your Health,” Conference of the Pacific Research Institute for Public Policy, June 25-28, 1998. Summary available at <http://www.pacificresearch.org/events/jscience.html>

actions.

As the following section of this paper aims to demonstrate, the tobacco industry's behavior is not primarily the fault of any exceptional failure of corporate morality, because the tobacco industry's moral compass is not exceptional. When confronted with a similar situation, working with similar constraints – and similar choices - Procter & Gamble followed the tobacco industry's battle-tested game plan precisely. While a similar demonstration could be made with virtually any other industry that faces FDA regulation, for purposes of simplicity the following section focuses on the FDA's consideration of the food additive olestra.

A CASE STUDY: PROCTER & GAMBLE AND OLESTRA

Not every industry player is as destructive as the tobacco industry; the tobacco industry is relatively rare among legal industries in that its products are both addictive and lethal. But the strategies that the tobacco industry pioneered have an enduring usefulness beyond the campaign to evade tobacco regulation; the range of techniques employed by the tobacco industry and their legal and public relations arms can be neatly adapted to other campaigns to manipulate the regulatory process. Procter & Gamble's campaign to promote the approval and sale of olestra, its controversial “non-fat fat,” serves to illustrate this larger point.

What emerges from a thorough comparison of the campaign to oppose the FDA's tobacco rules and the campaign to secure the FDA's approval of olestra is that the proper locus of debate is not one which anthropomorphizes the corporate form, and which defines misbehavior as a sign of personal deviancy, but one which assesses systemic pressures and seeks systemic remedies. Whatever one thinks of the tobacco industry, there is little reason to believe that Procter & Gamble is a “rogue corporation;” in fact, there is every reason to believe it is not (for example, P&G has been hailed as a good corporate citizen in its home state of Ohio, where it has stood behind politically risky tax hikes to support education).²⁴¹ Yet Procter &

²⁴¹See, e.g., Randy Ludlow, “Voinovich, P&G Lead School Tax Fight,” *The Cincinnati Post*, February 17, 1998

Gamble's tactics are startlingly reminiscent of the tobacco industry's.

Just as it is beyond the scope of this paper to opine upon the legal and scientific legitimacy of the FDA's claim of authority over tobacco, it is beyond the scope of this paper to debate the scientific merits of the FDA's approval of olestra; limitations of space and technical expertise demand this concession. The goal of this section is not to show that the approval of olestra was a mistake, but to show that the approval did not occur in a vacuum – that the activities of olestra's sponsor had the clear potential to influence the FDA's decision in ways that threaten the integrity of the process. Regardless of whether olestra is actually dangerous, one can fairly conclude that factors irrelevant to the scientific merits play a significant role in the approval process, and in matters of health and safety, and this is cause for concern.

OLESTRA: WHAT IT COST PROCTER & GAMBLE

Procter & Gamble, a multinational company with some \$35 billion in annual sales, spent nearly 25 years and more than \$200 million developing olestra, a chemical which tastes and cooks like fat but passes through the body undigested.²⁴² In addition to the research and testing, Procter & Gamble made significant capital investments; P&G constructed, with the help of equity partner Frito Lay, a \$200 million olestra-making plant in Cincinnati.²⁴³ In addition to the sunk financial costs, by the mid-1990s olestra had become a kind of test of corporate will. As P&G finally began marketing the product, P&G Chairman and Chief Executive Officer John Pepper said proudly, "This is one of a handful of events... that they will look back to and help define what this company is at its best. It's been torturous and at moments a source of some anxiety, but

²⁴²Art Levine, "Food Fight in Indianapolis," U.S. News, May 5, 1997

²⁴³Jeff Harrington, "Olestra Snacks Ready for Market," The Cincinnati Enquirer, February 10, 1998

our people have stayed with it.”²⁴⁴ It was also the defining event of Pepper’s tenure as CEO. For all of these reasons, Procter & Gamble was deeply committed to securing olestra’s approval.

Procter & Gamble had an enormous financial incentive to secure – and retain - FDA approval for their product. The market for a non-fat fat is potentially enormous; Americans spend close to \$2.4 billion on diet-related foods each year, and \$15 billion annually on snack foods.²⁴⁵ Given the rising rates of obesity among Americans, and the increased emphasis on diet, olestra has the potential to be a dynamic revenue generator. Financial analysts at Drexel Burnham Lambert predicted that olestra could generate \$1.5 billion annually in sales – which would make it the most profitable product in Procter & Gamble’s impressive corporate history.²⁴⁶

In June of 1995, a House subcommittee held hearings that focused on the FDA’s long delays in completing its reviews of food-additive petitions. Many of the industry witnesses who appeared before the subcommittee used olestra as an example of a beneficial food additive that was languishing on the desks of FDA reviewers. Members of Congress voiced their agreement. Under attack from all sides, FDA got the message.

CONCERNS ABOUT OLESTRA

In October of 1995, an FDA advisory committee of 22 scientists met to review the application and determine their recommendation. Two issues dominated their discussion: the risk of so-called “fecal urgency,” and the danger that olestra would “wash out” beneficial nutrients from a consumer’s body.

In 1995 FDA medical officer Karl Klontz reviewed a P&G study entitled “Measurement of Selected Fecal Parameters in Subjects Consuming Increasing Levels of Olestra.”²⁴⁷ For seven days, fifteen volunteers who

²⁴⁴Id.

²⁴⁵Art Levine, “Food Fight in Indianapolis,” U.S. News, May 5, 1997

²⁴⁶Ken Silverstein, “Procter & Gamble’s Academic ‘White Hats,’” *Multinational Monitor*, November, 1997, Volume 18, Number 11

²⁴⁷Michael Jacobson and Leila Corcoran, “Snack Attack: Olestra,” *The Center for Science in the Public Interest*, March, 1998

had previously reacted to the fake fat were fed meals with zero, ten, or twenty grams a day of hidden olestra. “There was a steady increase in the number of subjects who reported diarrhea with increasing dose of olestra consumed,” Klontz reported. The same was true of “severe” diarrhea as well as “loose stools.” The study showed that severe diarrhea only showed up when the volunteers ate olestra.²⁴⁸ In another P&G study from 1993 - the most complete available on olestra and gastrointestinal symptoms - fully one-third of the volunteers reported suffering diarrhea at least once when they ate twenty grams of olestra a day. Only one out of seventeen people who ate no olestra reported diarrhea.²⁴⁹ Except in extreme cases - for seriously ill people or young children - diarrhea is not a serious health risk. But it could be commercially lethal for a consumer product. Procter & Gamble was terrified that negative publicity about this side effect could threaten its investment.

The more serious medical concern was the risk of “washing out” nutrients - particularly carotenoids like lycopene.²⁵⁰ In two 1993 P&G studies, thirty-nine people who ate eight grams a day of olestra (the equivalent of sixteen chips - about one serving size) with meals for eight weeks had a fifty percent drop in their total blood carotenoids.²⁵¹ Much of the debate within the Advisory Committee centered on the questions surrounding carotenoids themselves. Some argued that carotenoids play a crucial health role. “There are dozens of studies indicating that carotenoids protect against cancer, heart disease, and macular degeneration,

²⁴⁸ “Final Report: Assessment of the Dose-Response Effect of Olestra on the Status of Fat-Soluble Vitamins and Other Marker Nutrients in Humans,” submitted by P&G to the FDA on January 29, 1993. See also “An Eight-Week Vitamin Restoration Study in Humans Consuming Olestra,” submitted by P&G to the FDA on June 2, 1993.

²⁴⁹ Michael Jacobson and Leila Corcoran, “Snack Attack: Olestra,” *The Center for Science in the Public Interest*, March, 1998

²⁵⁰ In human beings, carotenoids can serve several important functions. The most widely studied and well-understood nutritional role for carotenoids is their provitamin A activity. Deficiency of vitamin A is a major cause of premature death in developing nations, particularly among children. Vitamin A, which has many vital systemic functions in humans, can be produced within the body from certain carotenoids, notably beta-carotene. Carotenoids also play an important potential role in human health by acting as biological antioxidants, protecting cells and tissues from the damaging effects of free radicals and singlet oxygen. Lycopene, the hydrocarbon carotenoid that gives tomatoes their red color, is particularly effective at quenching the destructive potential of singlet oxygen. See Britton, G. (1995). Structure and properties of carotenoids in relation to function. *FASEB J.*, 9:1551-1558; Di Mascio, P., Kaiser, S., and Sies, H. (1989) Lycopene as the most efficient biological carotenoid singlet oxygen quencher. *Arch. Biochem. Biophys.*, 274:532-538.

²⁵¹ “Final Report: Assessment of the Dose-Response Effect of Olestra on the Status of Fat-Soluble Vitamins and Other Marker Nutrients in Humans,” submitted by P&G to the FDA on January 29, 1993. See also “An Eight-Week Vitamin Restoration Study in Humans Consuming Olestra,” submitted by P&G to the FDA on June 2, 1993.

the most common form of blindness that strikes the elderly,” said Walter Willett, head of the nutrition department at the Harvard School of Public Health.²⁵² The United States’ own Dietary Guidelines for Americans cite carotenoids “potentially beneficial role in reducing the risk for cancer and certain other chronic diseases.”²⁵³ Others, including Procter & Gamble, contended that evidence was inconclusive.

THE FDA’S DECISION

Despite a heated debate, the FDA’s Food Advisory Committee recommended approval after just four days of meetings in November 1995. Ultimately, seventeen members of the committee endorsed olestra for approval and five opposed it.

The panel didn’t include a single expert on carotenoids. The Center for Science in the Public Interest, a watchdog group, contended that “At least nine of the seventeen ‘yea’ votes came from food industry consultants,” and concluded that the panel had been “stacked in favor of P&G.”²⁵⁴ This may give P&G too much credit; there is no publicly available evidence that Procter & Gamble influenced the composition of the Advisory Committee. Given the relationship between scientific experts and industry, it may no longer be possible to assemble a group of academic nutrition experts that are both qualified to assess the scientific merits of a product like olestra and have never consulted for the food industry. Even if P&G played no role in their selection, however, the dual role clearly implicates conflict of interest concerns. Despite criticism of the panel’s composition, the FDA said it would try to issue a decision within two months.

²⁵² “Snack Attack: Olestra,” Michael Jacobson and Leila Corcoran, The Center for Science in the Public Interest, March, 1998

²⁵³ See “USDA-NCC Carotenoid Database for U.S. Foods – 1998,” U.S. Department of Agriculture, Nutrient Data Laboratory, 1998. Document available at <http://www.nal.usda.gov/fnic/foodcomp/Data/car98/car98.html>

²⁵⁴ Michael Jacobson and Leila Corcoran, “Snack Attack: Olestra,” The Center for Science in the Public Interest, March, 1998

In the intervening period, a number of distinguished scientists lobbied the FDA to deny olestra's petition for approval. One week before the FDA made its determination, Walter Willett, head of the department of nutrition at the Harvard School of Public Health, and Harvard colleague Meir Stampfer wrote a letter to then-FDA commissioner David Kessler cautioning him that olestra's widespread use in snack foods could cause hundreds of cases of blindness and thousands of deaths each year from heart disease and prostate and lung cancer. "Avoid submitting the U.S. population, including children and pregnant women, to a massive uncontrolled experiment with potentially disastrous consequences," they asked.²⁵⁵

Despite the outcry from many scientists, in January 24, 1996, the FDA approved olestra for use in savory snacks such as chips, crackers, and tortilla chips. There were conditions: though olestra had been determined to be safe, all snacks containing olestra would have to carry a label that stated:

This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.

A second condition of FDA approval was a requirement that Procter & Gamble, which makes the fat, and Frito-Lay, which manufactures and sells the chips, report on any adverse health effects.²⁵⁶

BEHIND THE SCENES

The FDA's decision to approve olestra did not end the debate. Shortly after its approval, Henry Blackburn of the University of Minnesota School of Public Health, one of the five FDA panel members who voted against olestra's approval, wrote a scathing criticism of the approval process in the prestigious *New England Journal of Medicine*. "The FDA did not conduct a disinterested peer review," he charged. "The FDA staff worked closely with P&G and acted as proponents of the company's petition."²⁵⁷ At another point he wrote,

²⁵⁵Id.

²⁵⁶Paul Recer, "Advisers Consider Label Change for Chips Made With Phony Fat," *Associated Press*, June 17, 1998

²⁵⁷Ken Silverstein, "How the Chips Fell," *Mother Jones*, May/June 1997

“The olestra meetings carried the sense of a *fait accompli*, or at least a juggernaut moving inevitably toward FDA approval,” he wrote.²⁵⁸ Blackburn concluded that by the time of the meeting, “FDA staff members had already concluded that olestra was safe and were acting as proponents of the petition for approval.”²⁵⁹ He complained bitterly about both the lack of available scientific research, noting that “there is almost no relevant scientific literature on [olestra’s] potential health effects, except for studies by Procter & Gamble.”²⁶⁰

Blackburn also echoed CSPI’s concern that the panel was disproportionately composed of industry-friendly scientists. Blackburn alleged that the committee that reviewed olestra “was weighed heavily with entrepreneurs, animal scientists, clinical scientists, and there was little representation of people with public health and consumer interest.”²⁶¹ Of the seventeen FDA panelists voted to approve olestra, nine had links to companies that could benefit from its approval, including Bruce Chassy of the University of Illinois, whose department’s research has been funded by Nestlé and Dean Foods; John Doull of the University of Kansas Medical Center, who has worked for Pillsbury and Best Foods; and David Lineback, a consultant whose client list has included P&G.²⁶²

Blackburn and Willett were not alone in their concern. Dr. John Bertram of the Cancer Research Center of Hawaii called olestra “a public health time bomb,” while Dr. Herbert Needleman of the University of Pittsburgh Medical School said “it would be clear folly to introduce this product into the diet of children.”²⁶³ “Olestra has the potential to do significant harm,” said Ernst Schaefer of the Jean Mayer U.S. Department of Agriculture Human Nutrition Research Center on Aging at Tufts University in Boston.²⁶⁴ “I don’t think the adverse health effects of olestra were given a reasonable public hearing, said Ian Greaves of the University

²⁵⁸Henry Blackburn, M.D., N Engl J Med 1996;334:984-986

²⁵⁹“FDA Panel Member Voice [sic] Olestra Concerns,” USA Today, April 11, 1996

²⁶⁰Id.

²⁶¹Id.

²⁶²Ken Silverstein, “How the Chips Fell,” Mother Jones, May/June 1997

²⁶³See Ken Silverstein, “Washington on \$10 Million a Day,” Common Courage Press, 1998, p.58

²⁶⁴Michael Jacobson and Leila Corcoran, “Snack Attack: Olestra,” The Center for Science in the Public Interest, March, 1998

of Minnesota School of Public Health. “It was a triumph of marketing over health concerns. The marketing people out-shouted the health people.”²⁶⁵

FDA spokesman Jim O’Hara defended the FDA’s review process, describing them as a “very open and public debate” about olestra. He also attempted to defuse criticism of the panel’s composition. “The advisory committee’s recommendations are just that: they are advisory. It is the agency that made its decision.”²⁶⁶

O’Hara’s comments left unanswered a larger, more important question: even if it was the Agency that made the decision, was the decision made for the right reasons? The FDA’s decision did not occur in a vacuum. Procter & Gamble conducted an intensive political and public relations campaign to shape the debate and influence the decision-making process.

PROCTER & GAMBLE’S SCIENTISTS

Just as the tobacco industry paid scientists to write to the EPA,²⁶⁷ Procter & Gamble engineered a massive effort to recruit scientists as advocates for their product. In the brief period between the committee’s adjournment on November 19 and the December 1 deadline for public comments, the FDA received nearly 800 letters concerning olestra. Most were from health professionals recommending that the product not be approved. But many others were the product of a Procter & Gamble-sponsored letter-writing drive. To ensure that it conveyed the appearance of at least some support from the scientific and medical communities,

²⁶⁵Id.

²⁶⁶“FDA Panel Member Voice [sic] Olestra Concerns,” USA Today, April 11, 1996

²⁶⁷D. Hanners, “Scientists Were Paid to Write Letters – Tobacco Industry Sought to Discredit EPA Report,” Pioneer Planet/St.Paul Press, August 4, 1998. See also Philip Morris Report, “IAQ Goals,” January 25, 1993, Philip Morris ID 2023206195/6198.

P&G wrote to dozens of scientists, asking that they write letters to the FDA on its behalf during an extended period for public comments. Many of the 26 scientists who complied had been paid consultants to P&G. Procter & Gamble denies that its financial generosity toward scientists and academics is any cause for concern. “These are known academics and health researchers who have built reputations for sound science over their careers,” said P&G spokeswoman Jacqui d’Eon. “They are not going to be bought.”²⁶⁸ If they are not going to be bought, however, that doesn’t seem to have prevented Procter & Gamble from trying. Certainly the example of the tobacco industry should serve as a note of caution of the dangers of scientific conflict of interest. And not all observers feel P&G’s scientist selection process is neutral. John Stauber, editor of *PR Watch*, a newsletter which covers the public relations industry, says that P&G hires people “who appear to have some distance from the company, but they are carefully selected and can be counted on to promote the official line. There’s nothing objective or independent about them.”²⁶⁹

Marion Nestle of New York University’s nutrition department was one of the many scientists who turned down Procter & Gamble’s overtures. She declined an offer of \$1,000 from P&G, for which she was to fly to New Orleans, give a short speech and eat products made with olestra to demonstrate her confidence in its safety. Dozens of other academics accepted P&G’s money and went to New Orleans, a favorite tourist destination. “It’s too crude or imprecise to say people are bought off,” Nestle told a reporter from the *Boston Phoenix*. “But I just know if somebody is giving my department money, then I would think twice before saying something mean about that particular industry.”²⁷⁰

²⁶⁸Ken Silverstein, “How the Chips Fell,” *Mother Jones*, May/June 1997

²⁶⁹Ken Silverstein, “Procter & Gamble’s Academic ‘White Hats,’” *Multinational Monitor*, November, 1997, Volume 18, Number 11

²⁷⁰*Id.*

PEER-REVIEWED JOURNALS

Like the tobacco industry, Procter & Gamble has made a concerted effort to place industry-friendly research in peer-reviewed scientific journals. Procter & Gamble's financial clout has clearly facilitated this goal. For instance, in October of 1996 the International Life Sciences Institute (ILSI) held a conference on fat and sugar substitutes held in Arlington, Virginia. Panelists at the conference included P&G scientist John Peters, and P&G consultants Penny Kris-Etherton of Penn State and John Foreyt of the Baylor College of Medicine, as well as representatives from food industry giants like Kraft Foods and Nabisco, both of which stood to reap financial benefits from olestra's approval. The attendance of P&G scientists at this particular conference was not coincidental; P&G sits on the Institute's Board of Directors, is a major financial supporter of the ILSI, and helped to underwrite for the conference.²⁷¹ The proceedings of the conference were later published as a bound volume in the Annals of the New York Academy of Science, which are distributed to more than 700 libraries and, according to the Academy, "are among the oldest and most frequently cited sources of scientific research."²⁷² As a result, studies on P&G products which were produced by paid P&G consultants and received by a P&G-funded organization at a P&G-funded conference have now been entered, mostly anonymously, into the ranks of peer-reviewed scientific literature.

FUNDING THE CONGRESS

Though less visible than the tobacco industry, Procter & Gamble is a prodigious political force in Washington, with a full-time lobbying staff and a governmental relations arm which vigilantly guards its interests on Capitol Hill. P&G's political action committee contributes hundreds of thousands of dollars to candidates

²⁷¹George Hardy, ILSI's executive director, would not reveal the amount of P&G's contribution.

²⁷²Ken Silverstein, "Procter & Gamble's Academic 'White Hats,'" *Multinational Monitor*, November, 1997, Volume 18, Number 11

each election cycle, and its executives, lawyers and lobbyists contribute thousands more. During the 1997-1998 election cycle, P&G gave \$25,000 in soft money donations,²⁷³ part of the \$161,700 it gave overall.²⁷⁴

Like the tobacco industry, P&G focused its contributions on the leadership of the two parties.

PROCTER & GAMBLE HARD MONEY DONATIONS, 1997-2000²⁷⁵

Senate Republican Majority Leadership	Member	P&G Donations
President <i>Pro</i> <i>Tempore</i> of Senate	Strom Thurmond (R- SC)	0
Majority Leader	Trent Lott (R-MS)	\$2,000
Majority Whip	Don Nickles (R- OK)	\$2,000
Republican Conference, Chair	Rick Santorum (R-PA)	\$1,000
Republican Policy Committee, Chair	Larry Craig (R- ID)	0
Republican Senatorial Committee, Chair	Bill Frist (R-TN)	\$5,000

²⁷³Federal Election Commission data, see [www.tray.com/fecinfo/98lbt/oh_\\$\\$.htm](http://www.tray.com/fecinfo/98lbt/oh_$$.htm)

²⁷⁴The Center for Responsive Politics, see <http://www.opensecrets.org/states/contribs98/OH.asp>

²⁷⁵The Center for Responsive Politics, see <http://www.opensecrets.org/pacs/pacgot/1998/00257329.htm>

Senate Democratic Minority Leadership	Member	P&G Donations
Minority Leader	Tom Daschle (D-SD)	\$2,000
Minority Whip	Harry Reid (D-NV)	0
Democratic Conference, Chair	Tom Daschle (D-SD)	\$2,000
Democratic Policy Committee, Chair	Byron Dorgan (D-ND)	0
Democratic Senatorial Campaign Committee, Chair	Patty Murray (D-WA)	0

House Republican Majority Leadership	Member	P&G Donations
Speaker of the House	Dennis Hastert (R-IL)	\$3,000
House Majority Leader	Dick Armey (R-TX)	\$1,000
House Majority Whip	Tom DeLay (R-TX)	\$1,000
House Republican Conference, Chair	JC Watts (R-OK)	0

House Re- pub- li- can Pol- icy Com- mit- tee, Chair	Christopher Cox (R- CA)	\$500	
House Republican Congressional Committee, Chair	Tom Davis (R-VA)	0	

House Democratic Minority Leadership	Member	P&G Donations	
House Mi- nor- ity Leader	Richard Gephardt (D- MO)	\$3000	
House Minority Whip	David Bonior (D-MI)	0	
House Demo- cratic Cau- cus, Chair	Martin Frost (D- TX)	0	
House Democratic Policy Committee, Chair	Richard Gephardt (D-MO)	\$3,000	
Democratic Con- gres- sional Cam- paign Com- mit- tee, Chair	Nita Lowey (D- NY)	\$500	

Procter & Gamble's pattern of corporate giving is more opportunistic than it is ideological. Because it was unclear to political oddsmakers which party would control the Congress after the 2000 elections, Procter & Gamble gave generously to the potential Speakers of the House (Reps. Gephardt and Hastert) from both parties. Likewise, in the 2000 cycle alone, P&G's PAC gave \$5000, the legal maximum, to Rep. Charles Rangel (D-NY), a liberal African-American from Harlem. Rangel is stood to be Chairman of the powerful Ways and Means Committee if the Democrats reclaimed the House.

Like its counterparts in the tobacco industry, P&G made a dramatic shift in its giving patterns when the Congress changed hands in 1994. Where before the company had expressed a mild preference for Republican candidates (explained perhaps in part by P&G's home state in Republican-leaning Ohio), after the Republican sweep of 1994, P&G's giving became heavily weighted toward the GOP.

Procter & Gamble Federal Campaign Contributions by Election Cycle:

Year	P&G Contributions	% Given to Republicans
1992	\$124,850	54%
1994	\$187,075	54%
1996	\$221,384	81%
1998	\$199,750	84%
2000	\$272,140	79%

Procter & Gamble is also a major contributor to state-level politicians and political organizations, giving both under its own name and through other groups. For instance, Procter & Gamble is a major supporter (along with DuPont, Dow, Eastman Kodak, General Electric Plastics, and Exxon) of the American Chemistry Council (ACC), a trade association that provides additional financial support to a number of groups P&G

supports on its own – including Consumer Alert and the American Legislative Exchange Council.²⁷⁶

USING THE CONGRESS TO LOBBY THE FDA

Just as the tobacco industry’s most loyal supporters, like Mitch McConnell (R-KY) and Jim Bunning (R-KY) hail from tobacco-producing states, Cincinnati-based Procter & Gamble has received some of its strongest support from Ohio’s congressional delegation. Like the tobacco industry, Procter & Gamble has cemented that relationship by generously supporting the officials of its home state.

Procter & Gamble Campaign Contributions to the Ohio Congressional Delegation:

Member	P&G Donations, 1997-2000
Boehner, John A (R- OH)	\$4,500
Chabot, Steve (R-OH)	\$10,000
DeWine, Mike (R- OH)	\$6,000
Gillmor, Paul E (R-OH)	\$2,000
Hall, Tony P (D- OH)	\$1,500
Hobson, David L (R-OH)	\$3,500

²⁷⁶“American Chemistry Council,” The Environmental Working Group, Washington D.C., January 10, 2001

Hollister, Nancy (R-OH)	\$5,000
Kasich, John R (R-OH)	\$2,500
LaTourette, Steven C (R-OH)	\$1,000
Ney, Bob (R-OH)	\$500
Oxley, Michael G (R-OH)	\$2,000
Pryce, Deborah (R-OH)	\$4,000
Sawyer, Tom (D-OH)	\$2,500
Tiberi, Pat (R-OH)	\$1,500
Voinovich, George V (R-OH)	\$11,000

Like the tobacco industry, Procter & Gamble benefited from the spirited advocacy of its favored legislators – especially in its dealings with the FDA. In February of 1995, Sens. John Glenn (D-OH) and Michael DeWine (R-OH), and Reps. John Boehner (R-OH)²⁷⁷, Steve Chabot (R-OH) (all of whom received money from P&G’s political action committee), and Rob Portman (R-OH) (who doesn’t accept PAC money but took contributions from P&G executives) wrote a joint letter to Health and Human Services Secretary Donna Shalala.²⁷⁸ In it they argued that olestra was safe and that the FDA approval should be expedited. The Ohio delegation’s letter made the obligatory concession that the public health was more important than profits, but noted that olestra’s approval would mean \$17.8 billion to Ohio over the next thirteen years.²⁷⁹ Observers might think it natural, even desirable, that Ohio legislators would act as advocates for one of the largest employers in their state. But evidence strongly suggests that Procter & Gamble expects a *quid pro quo* for its campaign contributions. When home-state legislators refuse to carry water for Procter & Gamble, the company has proved its willingness to strong-arm members of Congress. In 1998, Rep. Bob Ney (R-OH) reported that R. Scott Miller, who heads Procter & Gamble’s political action arm, had threatened to cut off campaign contributions in retaliation for Ney’s votes on international trade. In a letter to Procter &

²⁷⁷Rep. John Boehner (R-OH) is another of the repeat players in the tobacco and olestra stories. Boehner actually distributed checks from tobacco giant Brown & Williamson to Members on the floor of the House of Representatives, a violation of House rules for which he was disciplined. See “Boehner’s Blunder: Handing Out PAC Money Makes a Poor Floor Show, Leader Learns,” Cincinnati Enquirer, May 23, 1996, p. A18

²⁷⁸Ken Silverstein, “How the Chips Fell,” Mother Jones, May/June 1997

²⁷⁹See Ken Silverstein, “Washington on \$10 Million a Day,” Common Courage Press, 1998, p.59

Gamble CEO John Pepper, Rep. Ney wrote that Miller “told a member of my staff, in no uncertain terms, that contributions to my campaign were directly reduced because of my stance against Fast Track [trade legislation] and future contributions have been completely put in jeopardy due to my decision to vote against Most Favored Nation status for China.”²⁸⁰

Bill Dobson, Procter & Gamble’s vice president of international public affairs, said there was “absolutely no intent” to suggest financial contributions were tied to how Ney voted on specific legislation, and attributed the exchange to a “simple misunderstanding.”²⁸¹ Ney bristled at that suggestion. “This is the most blatant correlation of campaign contributions and votes,” he said. “If [Miller] said we won’t support you, that’s fine. This was a definite statement: ‘You should notice your contributions have dwindled, future contributions are in jeopardy.’”²⁸²

There is little public evidence to suggest that P&G employed such heavy-handed tactics in 1995, when olestra was facing its FDA review. In fact, Frank Cremeans, (R-OH), one of the only members of Congress to publicly comment on being subjected to P&G’s olestra lobbying campaigns, was effusive in his praise. “I knew very little about it, I’m not a chemist,” he said. “They came in and explained it to me, how it worked and it was very helpful.”²⁸³ Cremeans, however, seems to have been an easy sale for P&G. Perhaps the rest of Ohio’s delegation was as easy to convince. For more reluctant members, the process may have borne more resemblance to Rep. Ney’s experience with P&G than to Rep. Cremeans’.

²⁸⁰“Congressman Complains of Extortion By Contributor,” Associated Press, July 13, 1998, available at http://www.publiccampaign.org/news/news7_13_98.html

²⁸¹Bill Straub, “Lobbyists Practice Art of Subtle Pressure,” The Cincinnati Post, July 15, 1998

²⁸²“Congressman Complains of Extortion By Contributor,” Associated Press, July 13, 1998, available at http://www.publiccampaign.org/news/news7_13_98.html

²⁸³Bill Straub, “Lobbyists Practice Art of Subtle Pressure,” The Cincinnati Post, July 15, 1998

LOBBYING FOR OLESTRA

Procter & Gamble spent enormous sums on lobbying on average more than \$3,000,000 each year between 1997 and 1999.²⁸⁴ While P&G maintains a full-time lobbying staff in Washington (among them R. Scott Miller), it recognized that lobbying for olestra would be especially delicate. To carry its olestra campaign to Capitol Hill, P&G retained Carol Tucker Foreman, a former Assistant Secretary of Agriculture in the Carter administration and the founder of the Safe Food Coalition.²⁸⁵ Carol Tucker Foreman's Democratic Party credentials were impeccable, particularly in the Clinton era; her brother, Jim Guy Tucker, was Lieutenant Governor of Arkansas under Clinton, and moved to the governor's mansion after Clinton won the presidency. Her status as founder of the Safe Food Coalition only enhanced her credibility in endorsing olestra's safety. Foreman's Safe Food Coalition is not a front group; it has actually been a strong voice for consumers, speaking out on salmonella poisoning, for instance.²⁸⁶ But like many in the Washington lobbying community, Foreman wears more than one mask. In 1994, it emerged that Foreman had been discreetly lobbying on behalf of Monsanto and its controversial recombinant bovine growth hormone.²⁸⁷ Foreman also lobbied for Philip Morris.²⁸⁸ As a lobbyist for olestra, she seemed a perfect fit: she had personal connections with the Democratic Party and the White House, and credibility on food safety with the media, but was not so moralistic in her approach toward clients that she couldn't be trusted.

Because Procter & Gamble had already secured a hearing before the FDA, there was no need for P&G to rally all of the company's supporters in Congress. Foreman's task was more focused: she had merely to convince those members of Congress who had concerns about the product that the FDA was capable of making

²⁸⁴ "Addicting Congress: Drug Companies' Campaign Cash & Lobbying Expenses," Public Citizen, July 2000, Appendix B

²⁸⁵ "Procter & Gamble's Academic 'White Hats,'" Ken Silverstein, *Multinational Monitor*, November, 1997, Volume 18, Number 11

²⁸⁶ "Safe Food Coalition Charges USDA Proposal to Allow Retained Water in Poultry is an Attempt to Cover Economic Adulteration in a Cloak of Faux Food Safety," Safe Food Coalition, Press Release, January 14, 1999. Available at <http://www.consumersunion.org/food/0114sfcdc399.htm>

²⁸⁷ See "The 1995 Lobbying Hall of Shame," *Multinational Monitor*, January/February 1996

²⁸⁸ "Will CFA Save GM Foods?" *PR Watch*, Volume 7, No. 2, Second Quarter, 2000

all the proper determinations. Of particular concern for Procter & Gamble was first-term Congresswoman Julia Carson (D-IN), who P&G targeted for intensive lobbying. Carson's Indiana district includes much of Indianapolis, one of olestra's original test markets. After receiving numerous complaints about olestra from her constituents, many of whom experienced intense gastrointestinal problems, Rep. Carson threatened to introduce legislation strengthening the warning label.²⁸⁹ "We need to do a new, complete and independent review of olestra and its side effects," she declared.²⁹⁰ Carson also called for more prominent warning labels on products made with olestra; a more conscious effort by the snack industry to take care in the marketing of olestra-based snacks, especially with children; and a public awareness campaign warned potential consumers of snacks made with olestra to the potential side effects of the product.²⁹¹ "It is apparent to me and other residents of Indianapolis that olestra can do serious harm. My duty to my constituents is to assure that their public health is not at risk," Carson said in a prepared statement to the press. "The implications for using olestra on a nationwide basis is [sic] also at stake. The effects of olestra on the citizens of Indianapolis need to be examined thoroughly before expanding the use of this product to other communities across America."²⁹² The potential for negative publicity – even Congressional hearings – posed a tremendous threat to the olestra's profitability. P&G sent lobbyists to her office to get her to stop and even hired former Secretary of Health and Human Services Louis Sullivan to call her. Sullivan called an old friend, Rep. Carson's personal physician in Indianapolis, to help arrange a meeting. Though Carson's doctor convinced her to meet with Sullivan and listen to his arguments on olestra, Sullivan had little success. Instead, Carson attacked P&G in public for trying to muffle her. "It's irresponsible for P&G to try to impede my investigation," said Carson, "and my support of constituents who have had stomach cramps."²⁹³ P&G, of course, denied trying to impede her investigation. Rep. Carson failed to convince any other Members to join her call for hearings,

²⁸⁹ "Rep. Carson Calls For Action on Olestra," Press Release, Congresswoman Julia Carson, July 15, 1997

²⁹⁰ *Id.*

²⁹¹ *Id.*

²⁹² *Id.*

²⁹³ George Srait, "Fight Over a Fat Substitute," ABCNEWS.com, June 10, 1998

and her fight died a quiet death.²⁹⁴

EFFECTS OF CONGRESSIONAL PRESSURE

The letter from the Ohio delegation and the intensive lobbying on Capitol Hill had the desired effect: pressure from the Congress and from the Department of Health and Human Services was felt acutely by the FDA panelists that reviewed olestra's application. "They were under intense pressure from Congress to get off the backs of industry," said Dr. Walter Willett, head of the department of nutrition at the Harvard School of Public Health.²⁹⁵ In recent years this pressure has come not only from Procter & Gamble, but from regulated industries generally. In an anonymous September 1998 survey conducted by Public Citizen, FDA Medical Officers were asked how they would compare the current standards of FDA review for safety and efficacy to those in existence prior to 1995. Seventeen Medical Officers described the current standards as "lower" or "much lower," while thirteen described them as "about the same" and six described them as "higher." None described the standards as "much higher."²⁹⁶

Nineteen Medical Officers stated that the pressure on them to approve a greater proportion of new drugs was "somewhat greater" or "much greater" compared to the

period prior to 1995.²⁹⁷ One Medical Officer reported, "In the last 2 years, I recommended that two drugs not be approved. They were both approved without consulting me. This never happened before. In one

²⁹⁴Rep. Carson did face a bruising battle for reelection, in which she was attacked with vicious negative advertisements. Republican Gary Hofmeister ran a series of attack ads against Carson, including a 30-second ad that featured the face of Representative Carson (who is black) morphing into images of prison doors and hypodermic needles. It is unclear, however, if Carson's role as an olestra antagonist was responsible for her well-funded opponents. See Joshua Micah Marshall, "The Firewall Next Time," *The American Prospect*, January 31, 2000

²⁹⁵George Srait, "Fight Over a Fat Substitute," *ABCNEWS.com*, June 10, 1998

²⁹⁶Statement by Sidney M. Wolfe, M.D., Director, Public Citizen's Health Research Group, FDA Science Forum on Biotechnology, December 9, 1998

²⁹⁷*Id.*

case, the drug did not meet the standards set up by the division, so they nullified the standards.”²⁹⁸

With the implicit support of a hostile Republican Congress, direct industry lobbying of FDA officials has increased: nine Medical Officers reported a total of 23 inappropriate phone calls regarding a drug they were reviewing, usually from the sponsor.²⁹⁹ And senior officials in the FDA have contributed to the pressure on their subordinates. Eight Medical Officers reported instances in which they had been instructed, usually by the Office Director, not to present their own opinion or data to an FDA Advisory Committee when to do so might have reduced the likelihood that a drug would be approved.³⁰⁰

One Medical Officer stated: “My feeling after more than 20 years at FDA is that unless drugs can be shown to kill patients outright then they will be approved with revised labeling and box warning.”³⁰¹ Evidence suggests that this attitude played at least some role in the decision to approve olestra and the way in which that approval was granted.

ATTACKING OLESTRA’S ENEMIES

The most prominent critic of olestra and the process by which it was approved was the Center for Science in the Public Interest (CSPI). Under its director, Michael Jacobson, CSPI had earned an impressive reputation as a public health watchdog, making headlines for its exposes on fast food restaurants and junk food. While Procter & Gamble sought to reassure a wary public, Jacobson and his organization opened up telephone hotlines for sufferers of olestra-related “anal leakage” and “fecal urgency,” and held press conferences where they voiced their concerns.

²⁹⁸Id.

²⁹⁹Id.

³⁰⁰Id.

³⁰¹Id.

Despite the FDA's approval of olestra, high-ranking Agency officials made little effort to hide their sympathy for CSPI's battle against olestra. FDA deputy commissioner William Schultz said that CSPI staff "were the only ones there raising the right questions."³⁰² CSPI's scientific credibility was further underscored in 1996 when FDA Commissioner David Kessler honored Michael Jacobson with the agency's highest award, the Commissioner's Special Citation. The citation read, "For helping government, industry, and the public understand the relationship between diet and health, and, in doing so, accomplishing one of the great public health advances of the century."³⁰³ Procter & Gamble was keenly aware of the danger that an outspoken campaign against olestra – particularly one which focused on its embarrassing side effects - could pose. Even after initial FDA approval was secured, CSPI posed a serious threat to the profitability of olestra. In a worst-case scenario, if sufficient public outcry were raised, the FDA might even reconsider its approval, or add further conditions.

Like the tobacco industry, Procter & Gamble's first impulse was to move against CSPI on their own. Greg Allgood, a senior P&G scientist, called the statements of CSPI President Michael Jacobson "ridiculous." "It's not supported by any scientific facts," Allgood told United Press International. "What he's saying is false. He has a passion to limit food options for people. That's his track record. He goes after all kinds of foods. I would think people are getting tired of hearing about Michael Jacobson's press conferences."³⁰⁴ P&G spokesman Don Tassone distilled the message into an even simpler formula: "CSPI is obviously interested in sound bites, not sound science."³⁰⁵

³⁰²Center for Science in the Public Interest, Letter to the Editor of *The New Republic*, January 8, 1997, <http://www.cspinet.org/new/newrepb.html>

³⁰³*Id.*

³⁰⁴United Press International, October 23, 1996

³⁰⁵"Congresswoman Wants Olestra Review," *Cincinnati Enquirer*, July 16, 1997

These comments telegraphed Procter & Gamble's public relations strategy: rather than argue the scientific merits of the debate, they would attempt to discredit CSPI, depicting the organization as ideologically driven and extreme. To manage their "perception" problem, Procter & Gamble called on Hill & Knowlton, the same Washington D.C. public relations firm that created the "smearing and belittling" plan for the tobacco industry (see p.71).³⁰⁶ Shortly thereafter a coordinated strategy emerged.

USING FRONT GROUPS

At a conference of public relations experts in November of 1996, Jeff Prince, formerly of the National Restaurant Association, identified the Center for Science in the Public Interest as a threat to the profitability of the food industry. Prince urged CSPI's foes to "put out the money" needed for a campaign that would undermine the Center's credibility.³⁰⁷ Just as Philip Morris had coordinated a campaign of "allied attacks, where friendly third parties are engaged on our side but without direct or obvious connection to the industry,"³⁰⁸ Prince urged an offensive that employed industry front groups: "The companies and industries that wish to undermine [CSPI's] credibility can best do so working together to make a case that is partially removed from their own immediate interests," said Prince.³⁰⁹ Prince's reasoning followed Philip Morris' to a tee: "If it is the National Restaurant Association and Procter & Gamble out there making the case, nobody is going to believe them. Their ox has been gored."³¹⁰

And just as Philip Morris CEO Hamish Maxwell stressed cooperation with major media outlets ("The sixth point I want to make is that we are not using our considerable clout with the media. A number of media

³⁰⁶Art Levine, "Food Fight in Indianapolis," U.S. News, May 5, 1997

³⁰⁷Joel Bleifuss, "Food Flacks Say: Skip the Science," PR Watch, Volume 3, No.4, Third Quarter, 1996

³⁰⁸Steven Parrish, PM draft presentation to the PM board of directors, Sea Island, Georgia, April 11, 1994, PM ID 2048310347.

³⁰⁹Joel Bleifuss, "Food Flacks Say: Skip the Science," PR Watch, Volume 3, No.4, Third Quarter, 1996

³¹⁰Id.

proprietors that I have spoken to are sympathetic to our position,”³¹¹), Prince suggested that media would be receptive to attacks on consumer advocates: “The whole project would... require considerable skill in media management and almost infinite tact, but through a concerted effort I think it could be done, because the press no longer wants to believe CSPI. They would like to find an excuse not to carry those stories, but we haven’t given it to them yet. It may well be a job for some currently underfunded organization, or perhaps for some new organization, but it seems to me the food industry ought to get together and get this job done soon.”³¹²

The food industry – and particularly Procter & Gamble – was listening. Almost immediately after Prince’s lecture, a well-organized and well-funded coalition against CSPI coalesced. P&G had a ready supply of potential allies; it had long been a supporter of numerous industry front groups,³¹³ and a range of surrogates moved to take up the defense of olestra – and a series of withering attacks on olestra’s critics.

The Hoover Institution’s Henry Miller, who had proposed the effective dismantling of the FDA during its battle with the tobacco industry, leapt to the defense of olestra. Miller wrote a blistering op-ed attack on CSPI that ran in *The Wall Street Journal*, and was subsequently republished by the *Washington Times*³¹⁴ and *The Cincinnati Inquirer*. Miller lauded the FDA for approving olestra and called the fat substitute “perhaps the most tested food in history.”³¹⁵ Another puff piece was entitled “Yes, There is Free Lunch –

³¹¹“The Perspective of PM International on Smoking and Health Issues: Text of the discussion document used at the meeting of top management,” Internal Memorandum, Philip Morris, 1985, available at <http://www.media-awareness.ca/eng/news/news/two/rupsmoke.htm>

³¹²Joel Bleifuss, “Food Flacks Say: Skip the Science,” PR Watch, Volume 3, No.4, Third Quarter, 1996

³¹³Mark Megalli and Andy Friedman, *Masks of Deception: Corporate Front Groups in America: Essential Information*, 1991), p. 4; Richard Stapleton, ‘Green vs. green’, *National Parks* (November/December 1992), pp.184-185. Other Procter & Gamble front groups include The Keep America Beautiful Campaign, an organization that focuses on anti-litter campaigns and downplays the potential of recycling legislation and changes to packaging. The Keep America Beautiful Campaign receives approximately \$2 million per year from “some 200 companies that manufacture and distribute the aluminum cans, paper products, glass bottles and plastics that account for about a third of the material in US landfills.” In addition to Procter & Gamble, the Campaign’s board of directors include representatives of Philip Morris, Mobil Chemical and Procter and Gamble and PR giant Burson-Marsteller. See Michael Parenti, “Inventing Reality: The Politics of the Mass Media,” (New York: St Martin’s Press, 1986) , p. 731.

³¹⁴Henry Miller, *The Washington Times*, July 25, 1996

³¹⁵Miller didn’t mention that P&G’s tests of olestra were conducted almost exclusively on healthy people between the ages of 18 and 44, hardly a representative sample, or that the longest consecutive testing period for children was one week, with children consuming less than the equivalent of one ounce of potato chips per day.

Fat Free.”³¹⁶ Miller ran another similar article in the *Washington Times* in 1998, writing, “As a solution to Americans’ constantly-expanding waistlines and fat consumption, olestra is the closest thing to a free lunch.”³¹⁷ In none of the articles did Miller note that Procter & Gamble was a generous financial supporter of the Hoover Institution.

Norman Ornstein joined the attack on CSPI with a column that appeared in *USA Today*.³¹⁸ Ornstein belittled concerns about olestra, noting that while the fat substitute can cause diarrhea, “beans can cause gas and... hot peppers and Tabasco sauce can give me heartburn.”³¹⁹ Once again, P&G’s surrogate followed a consistent message, which ignored the health debate and instead focused on the efforts of a self-appointed elite to constrain “consumer choice.” Ornstein asserted that CSPI had attempted to “intimidate” the FDA into blocking olestra, and accused the Center of trying to be a “national nanny.”³²⁰ Ornstein’s byline revealed that he is a Fellow at the American Enterprise Institute (AEI), but failed to note that AEI receives about \$125,000 annually from P&G’s foundation,³²¹ or that P&G’s Chief Executive Officer, John Pepper, sits on AEI’s Board of Directors.³²²

CONSUMER ALERT

Another eager combatant in the campaign against CSPI was Consumer Alert. Consumer Alert’s name and

³¹⁶Henry Miller, Yes, There Is a Free Lunch–Fat-Free, San Jose Mercury News, Nov. 15, 1995

³¹⁷Henry I. Miller, “The Cutting Edge of Cutting Calories,” The Washington Times, April 16, 1998

³¹⁸Norman Ornstein, USA Today, August 1, 1996

³¹⁹Id.

³²⁰Id.

³²¹“From Leather Boots to Velvet Gloves,” Corporate Watch, Issue 11, Summer 2000

³²²Ken Silverstein, “Corporate Enemies, Corporate Friends,” EXTRA! May, 1997

self-description (it calls itself a “free market consumer group,” that “has members in all 50 states,”³²³) are benign enough that it is frequently quoted by unsuspecting journalists as an independent voice on consumer health. On its website, www.consumeralert.org, the ubiquitous Dr. Henry Miller of the Hoover Institution boldly proclaims that “Consumer Alert is everything that most other self-styled consumerist organizations are not: scholarly, scientific, honest, and motivated not by self-interest, but by the public interest.”³²⁴

The endorsement Henry Miller may provide some indication about the true loyalties of Consumer Alert. In fact, Consumer Alert is funded by some decidedly self-interested parties – including Pfizer Pharmaceuticals, Philip Morris, American Cyanamid, Eli Lilly, Monsanto, Upjohn, the Chemical Manufacturers Association, and Ciba-Geigy.³²⁵ It serves as an industry counterweight to genuine consumer groups like Consumers Union. Consumer Alert (a noted friend of the tobacco industry; see pp. 67-68) eagerly joined the attack on CSPI, blast-faxing press releases and writing op-ed pieces. One press release was entitled (appropriately enough) “CSPI Throws Consumer Choice Down the Toilet.”³²⁶ In another variation on the CSPI-as-paternalist theme, Consumer Alert’s John Berlau wrote, “In a free society, consumers should have the right to decide if olestra is right for them, and the self-appointed ‘Food Police’ should not be allowed to throw consumer choice down the toilet.”³²⁷

In December of 1996, Consumer Alert’s Sarah Durkin and James Plummer wrote an article in the *Detroit News* that again referred to CSPI as the “food police,” and argued that CSPI “aggressively ignores the

³²³See <http://www.consumeralert.org/>

³²⁴See <http://www.consumeralert.org/>

³²⁵John Stauber, “Trust Us, We’re Experts! How Industry Manipulates Science and Gambles With Your Future,” Tracher/Putnam, 2001.

³²⁶“CSPI Throws Consumer Choice Down the Toilet,” Consumer Alert press release, Washington, D.C.: Consumer Alert, July 1, 1996

³²⁷John Berlau, “Cursing the Cure for Fatty Food,” Consumer Alert, available at <http://www.consumeralert.org/issues/food/berestra.htm>. This follows almost exactly the game plan set out by Jeff Prince, the public relations consultant. “The second thing the restaurants have pushed, of course, is the ‘food police’ line, and they push that as far as possible,” Prince said. “The idea is simply that people... don’t need a third party interfering and making those choices for them especially when this third party seems inhuman, inflexible, puritanical, rigid.” See Joel Bleifuss, “Food Flacks Say: Skip the Science,” PR Watch, Volume 3, No.4, Third Quarter, 1996

ability of consumers to weigh the pros and cons of eating various foods without the uninvited opinion of nutrition activists.”³²⁸ At one point they went so far as to declare “It is clear that the center has a nutrition mission that lacks any effort to educate the public about what a truly healthy diet is. Rather than offer examples of how much fat is necessary to maintain good health, and how to make food choices to avoid eating too much fat, the center chooses to push an aggressive agenda designed to scare the public into a predominantly vegetarian and granola diet.”³²⁹

The *Detroit News* piece was little more than an *ad hominem* attack; CSPI has never endorsed a granola diet. The clear purpose of the article was to paint CSPI as a radical group, without addressing the scientific merits of the issues they raised. Consumer Alert’s website echoed the same core message, counseling consumers to “Decide for yourself if they taste as good as the real thing. But don’t let Luddite busybodies decide for you.”³³⁰ The goal is clear: to shift the focus of the debate from Procter & Gamble’s product to the motivations of its critics, by enlisting a kind of crude populism.

Durkin and Plummer identified themselves as “policy analyst[s] at Consumer Alert, a Washington-based consumer group,” and admitted no affiliation with Procter & Gamble. Indeed, there is as yet no hard evidence (leaked internal memoranda, for instance) that Consumer Alert’s campaign was conducted at the behest of Procter & Gamble. Their timing, however, was suspiciously well-coordinated, and their argument, was strikingly similar to Jeff Prince’s advice that industry, through third parties, assert that “people... don’t need a third party interfering and making those choices for them.”³³¹

³²⁸Ken Silverstein, “Corporate Enemies, Corporate Friends,” EXTRA! May, 1997

³²⁹Sarah Durkin and James Plummer, “Guess Who’s Not Coming to Dinner?” The Detroit News, December 1, 1996

³³⁰“Who are the Food Police?” See <http://detnews.com/1996/menu/stories/77247.htm>

³³¹Ken Silverstein, “Corporate Enemies, Corporate Friends,” EXTRA! May, 1997

COORDINATION FROM ABOVE

There is other evidence to suggest that Procter & Gamble's surrogates did not hit on the same themes and develop the same strategy by coincidence. Like the letters to the FDA that were penned by tobacco lobbyists and signed by Republican governors (see pp. 40-41), the texts produced by Procter & Gamble's allies show suspicious signs of having been coordinated from above by a single source. Henry Miller's *Wall Street Journal* op-ed, the Consumer Alert piece in the *Detroit News*, and an article by Stephen Glass in *The New Republic* all contain virtually identical phrases and diction.³³² Either media attention to CSPI has been marked by rampant plagiarism, or the pieces seem to have been written from the same set of talking points.³³³

³³²For direct comparisons of the language, see <http://www.cspinet.org/new/reeks.html>

³³³In the case of Stephen Glass, plagiarism seems to have been at least part of the story. His career was destroyed amid the revelation that he had plagiarized and fabricated numerous stories in the course of his work as a freelance writer. For more on his plagiarism, see <http://www.interlog.com/~rmcginn/Glassindex.htm>

Henry Miller, <i>The Wall Street Journal</i>, July 11, 1996	Stephen Glass, “Hazardous to Your Mental Health,” <i>The New Republic</i>, December 30, 1996
“[CSPI’s] budget is funded mostly by \$24-a-year subscriptions to its Nutrition Action Healthletter, a newsletter that has seen its circulation triple since 1991 to 800,000. Keeping that circulation up requires a lot of hype.”	“In a drive to boost the newsletter subscriptions that are its primary source of revenue, the center has increasingly tended to abandon the scientific method in favor of media hype... Since 1991, the newsletter’s circulation has tripled. At \$24 per year... Now about three-quarters of CSPI’s funding comes from the publication.”
“Mr. Jacobson was quoted in a <i>Los Angeles Times Magazine</i> article last year as telling one of his newsletter writers ‘to be more direct by removing “weasel words” – qualifiers such as “suggests” and “maybe.”	“According to a report, Jacobson instructed CSPI’s nutrition director ‘to be more direct by removing “weasel words” – qualifiers such as “suggests” and “maybe” from the newsletter.”

<i>The Detroit News</i>, December 1, 1996, by Consumer Alert	Stephen Glass, “Hazardous to Your Mental Health,” <i>The New Republic</i>, December 30, 1996
---	---

<p>“The Center’s <i>Nutrition Action Health-letter</i> uses Quarter Pounders and Big Macs as yardsticks of death to measure other foods by.”</p>	<p>“Instead of measuring fat content of food items in grams, it [Nutrition Action Health-letter] began using the Big Mac or the Quarter Pounder as a yardstick.”</p>
<p>“Given the puritanical nature of the center’s fat denunciations... “</p>	<p>“Less respect for good science also allows CSPI to push more easily a puritanical agenda.. “</p>

<p>“... one would have thought it would wel- come the po- ten- tial of Proc- ter & Gam- ble’s new non- caloric fat sub- sti- tute, olestra, to the Amer- i- can diet.”</p>	<p>“Knowing how much CSPI hates fat, Proc- ter & Gam- ble might have ex- pected the group to em- brace olestra, their new fake fat, which has no calo- ries.. “</p>
<p>“Certainly an occasional ‘splurge’ is no cause for self-loathing or even fear of clogged arteries.”</p>	<p>“... what they regularly eat – rather than the occasional splurge – is far more important.”</p>

STEVEN MILLOY AND “JUNK SCIENCE”

Not all the attacks from industry front groups were directed at CSPI. Procter & Gamble's public relations campaign also directed its efforts at Dr. Henry Blackburn, one of the most vehement dissenters on the FDA review committee, and a man whose scientific reputation and outspokenness about olestra made him a potential threat to long-term profitability – and far more difficult to ridicule and belittle than Michael Jacobson and CSPI.

Steven Milloy, however, was up to the task. The operator of junkscience.com, a website dedicated to exposing practitioners of “junk science” and debunking their claims, Milloy attacked both Blackburn's science and his integrity. Addressing the olestra controversy and Dr. Blackburn's New England Journal of Medicine article, Milloy wrote:

Apparently, one of Blackburn's public health concerns is that Olestra [sic] may leach certain vitamins from the body, including vitamins A, D, E, and K. At least some of the concern with this leaching is that these antioxidant vitamins are thought to play a role in preventing cancer. News flash to Blackburn....Beta Carotene and Vitamin A Cause Lung Cancer in Major Study! [J Natl Cancer Inst 1996;88:145- 6]. I think it's fairly safe to conclude that no one really knows the true association (one way or the other) between vitamin intake and cancer.³³⁴

No serious scientists would endorse the positions that Milloy takes in the above paragraph; these are specious and irresponsible claims. But Milloy is not acting in any official capacity as a P&G spokesman, and any scientific errors or misrepresentations he makes are his alone. This is not an accident. Like Rosser Reeves suggested to the tobacco companies in 1967, Procter & Gamble has assembled a roster of “janissaries” – Milloy among them – who can make materially false scientific claims for the company's benefit without any risk of P&G being held responsible.

Though the premise behind the Junkscience.com website is the “debunking” of fraudulent and overblown

³³⁴See <http://www.junkscience.com/news/olestra.html>

scientific claims, Milloy's essays contain little in the way of serious scientific argument, and are instead geared toward attacking Blackburn personally. Just as Consumer Alert did in its attacks on CSPI, Milloy seeks to ridicule and lampoon Blackburn as a radical. At one point Milloy writes, "It appears that Blackburn's standard of proof is so high that it could never be met. Blackburn would prevent virtually any new product from ever coming on the market."³³⁵ Later, Milloy asks rhetorically, "Is Blackburn really concerned about public health? Or, is his protestation against olestra a facade covering anti-technology sentiment? Could it be that he has taken a page from the Unabomber's manifesto and applied it to public health?"³³⁶ Ridicule has long been a weapon of Milloy's; after yet another researcher published a study linking secondhand smoke to cancer, Milloy wrote in 1997 that she "must have pictures of journal editors in compromising positions with farm animals. How else can you explain her studies seeing the light of day?"³³⁷

MILLOY, TOBACCO, AND PROCTER & GAMBLE

Steven Milloy is not merely an independent operator; he is a professional, and a figure whose role in both the tobacco industry effort and P&G's olestra campaign helps to explain the similarities between the two. Milloy was previously employed by a number of professional public relations and lobbying companies, including Multinational Business Services, which was Phillip Morris's primary lobbyist on the environmental tobacco smoke issue in late 1992, when Milloy worked there. In addition to being an "adjunct fellow" at the Cato Institute (which has a history of advocacy on behalf of the tobacco industry; see pp.68-70), and apparently the only member of an organization called "Citizens For The Integrity of Science" (its registered address is that of Milloy's home in Potomac, Maryland),³³⁸ Milloy is also the Executive Director of The Advancement

³³⁵Id.

³³⁶Id.

³³⁷Sheldon Rampton and John Stauber, "How Big Tobacco Helped Create "the Junkman," PR Watch, Volume 7, No.3, Third Quarter 2000

³³⁸Stewart Fist, "Milloy and the Art of Spin-Doctoring," available at <http://www.electric-words.com/junk/milloy/milloy2.html>

of Sound Science Coalition (TASSC).³³⁹

TASSC began as a front group for the tobacco industry, much like Healthy Building International (HBI) or the Center for Indoor Air Research (CIAR), built on the recognition that explicit connections to the industry or a single-minded focus on smoking issues would ruin the credibility of the organization and its usefulness as a front group.³⁴⁰ TASSC was originally created and controlled by APCO Associates, an international public relations and lobbying company. APCO had been founded in 1984 by Arnold & Porter (the 'AP' in the APCO name) which was then the primary legal counsel to Philip Morris.³⁴¹ If the connections seem tenuous and hard to follow, there is a reason: they were designed to be.

TASSC aimed to redefine the rules of proof and standards of epidemiology and toxicology, to a level that would frustrate efforts by government agencies like the EPA, FDA and OSHA to ever regulate tobacco smoke in a way that was based on the precautionary principle.³⁴² To this end, TASSC's web site offered examples of "junk science," alongside a host of entries defending bovine growth hormone, genetically engineered foodstuffs, dioxin, electromagnetic fields and endocrine disrupting chemicals.

Milloy joined TASSC in 1997 as its Executive Director, when responsibility for administering TASSC shifted from APCO to the EOP Group, where Milloy had worked as a lobbyist. The shift had been necessitated by a minor scandal; in much the same way that Andrew Whist let slip to the *Wall Street Journal* that the New York Society for International Affairs was "a chair in my apartment,"³⁴³ Neal Cohen, an APCO lobbyist, had bragged about TASSC's status as an industry front group at a meeting of public relations

³³⁹TASSC was originally dubbed the Restoring Integrity to Science Coalition; but was renamed to resemble the venerable American Association for the Advancement of Science, a legitimate scientific organization.

³⁴⁰Stanton Glantz and Elisa Ong, "Tobacco Industry Efforts Subverting International Agency for Research on Cancer's Second-Hand Smoke Study," *The Lancet*, April 8, 2000

³⁴¹Stewart Fist, "Milloy and the Art of Spin-Doctoring," available at <http://www.electric-words.com/junk/milloy/milloy2.html>

³⁴²*Id.*

³⁴³Tatiana S. Boncompagni and Jill Abramson, Tobacco- Funded Group Gives Legislators Free Trips, *The Wall Street Journal*, August 4, 1997, p. A20.

experts, and was quoted in the *New York Times*.³⁴⁴ Since its inception, TASSC has expanded beyond simply defending the tobacco industry – it also defends other industries whose products are of dubious safety. It was no coincidence, then, that Milloy came to the defense of olestra - Procter & Gamble is a major financial supporter of TASSC.³⁴⁵

Through years of trial and error, the public relations industry has learned that credibility is best achieved by creating a mixture of truth and falsehood, with legitimate information blended carefully with industry propaganda. The greatest testimony to the success of Milloy's "junk science" subterfuge is the acclaim it has received in the mainstream press. The *Denver Post* has called TASSC an organization "that provides a much needed balance to the public debate that often surrounds disputed areas of science,"³⁴⁶ while Milloy's work on the Junk Science Home Page has garnered numerous awards, including being named "One of the 50 Best Web Sites of 1998" by *Popular Science*; and designation as a "Hot Pick" by *Science*. The site has also been recommended by the *New York Times*, *Los Angeles Times*, *Times of London*, *Financial Times*, *Forbes* and *MSNBC*.³⁴⁷ Outlets that publish Milloy's work have made little effort to probe his background, or the source of his contrarian scientific positions. Beneath one of his op-ed pieces, the *Chicago Sun-Times* described Milloy simply as "a Washington-based business writer specializing in science" who "holds advanced degrees in health sciences from Johns Hopkins University and a law degree from Georgetown University."³⁴⁸

³⁴⁴Sheldon Rampton and John Stauber, "How Big Tobacco Helped Create "the Junkman," PR Watch, Volume 7, No.3, Third Quarter 2000

³⁴⁵Stewart Fist, "Milloy and the Art of Spin-Doctoring," available at <http://www.electric-words.com/junk/milloy/milloy2.html>
TASSC's other supporters include Amoco, Chevron, Dow Chemical, Exxon, General Motors, Lorillard Tobacco, Louisiana Chemical Association, National Pest Control Association, Occidental Petroleum, Philip Morris Companies, Santa Fe Pacific Gold, and W.R. Grace.

³⁴⁶See Ken Silverstein, "Washington on \$10 Million a Day," Common Courage Press, 1998, p.103

³⁴⁷While the *New York Times*, for example, was almost certainly duped when it made its recommendation, Forbes has shown tobacco sympathies before. See pp.77-78.

³⁴⁸Milloy's "advanced degrees in health sciences" actually consist of a bachelor's degree in natural sciences and a master's degree in biostatistics.

SUSPICIOUS ENDORSEMENTS

One measure of the scope of Procter & Gamble's olestra campaign is the range of organizations and individuals whose testimony they offer. Virtually every party to publicly endorse olestra can be traced to P&G's campaign and P&G's financial support. Like the tobacco industry, Procter & Gamble has found that it's easy to make friends if you have money to spread around. Take, for instance, the organizations and personalities whose endorsements grace the wowchips.com website – a promotional tool for Wow! Chips, a brand of snack chips that contain olestra. Organizational links on the site include the American Council on Science and Health (ACSH), the American Dietetic Association (ADA), and the Journal of the American Medical Association (JAMA).³⁴⁹ Providing endorsements on the site are former Secretary of HHS Louis Sullivan and the National Consumer's League. The Journal of the American Medical Association has never endorsed olestra; its presence on the wowchips.com website is simply an act of corporate name-dropping, one that suggests the JAMA's approval without going so far as to be actionable.³⁵⁰ The other links tell a more interesting story.

³⁴⁹See <http://www.wowchips.com/wowcrowd/links/indexmap.html>

³⁵⁰This formula is a favorite public relations tactic. Henry Miller writes, "Widespread use of olestra could enable more Americans to adhere to the American Heart Association's recommendation to consume less than 30 percent of total calories from fat." This formulation implies that the American Heart Association supports olestra's use, when, in fact, it has taken no such position. See Henry I. Miller, "The Cutting Edge of Cutting Calories," *The Washington Times*, April 16, 1998. Procter & Gamble also employ this technique at their olean.com website: "Leading health organizations—including the American Heart Association, the American Dietetic Association and the American Cancer Society—urge people to cut excess fat and calories as a key step toward good health." See "One Tool for a Healthier Lifestyle," Procter & Gamble, 1998, at <http://www.olean.com/media/media3.html>

THE AMERICAN DIETETIC ASSOCIATION

On the wowchips.com website, the American Dietetic Association offers a glowing review of olestra: “Fat replacers make it possible for Americans to eat a wide variety of foods without increasing their fat intake, which may already be too high. These products can help consumers achieve a lower-fat diet while still enjoying their favorite foods.”³⁵¹ The enthusiastic tone (“favorite foods”) – and the willingness of a nutrition organization to endorse a nutritionally suspect product – seem out of place. This may be because the remarks were prepared not by an officer of the ADA, but by Procter & Gamble’s own public relations staff.

As part of its olestra marketing campaign, P&G distributed a pro-olestra “fact sheet” from the American Dietetic Association³⁵² that was virtually identical to P&G’s own handouts – a fact which should come as little surprise, since P&G (which provides significant annual funding to the ADA) also underwrote the fact sheet in its entirety.³⁵³ In addition to its use at P&G promotional events, the fact sheet was mailed to each of the 70,000 nutritionists and dietitians who make up the ADA membership – presumably to encourage them to recommend olestra to their clients. Both P&G and the American Dietetic Association defend the funding concept. “It’s done fairly frequently,” P&G’s Jacqui d’Eon says, “as a way to get information to professionals about research that has been done, so they can answer questions they’re getting from their clients.”³⁵⁴ Nancy Schwartz, director of the ADA’s National Center for Nutrition and Dietetics, explains, “We have a couple such fact sheets a month, and it’s something we’ve been doing for several years. Companies, even companies with ties to the product, always fund them. It’s how we finance things.”³⁵⁵ Schwartz insists that P&G’s involvement in no way influenced the positive tone of the fact sheet: “Absolutely not. If it were bad news, or

³⁵¹See <http://www.wowchips.com/what/expert/text.html#ADA>

³⁵²The American Dietetic Association. “Nutrition Fact Sheet: What is olestra?” 1998.

³⁵³Ken Silverstein, “How the Chips Fell,” *Mother Jones*, May/June 1997

³⁵⁴Jim Knippenberg, “P&G-funded brochure chews fat on olestra,” *The Cincinnati Enquirer*, November 17, 1996

³⁵⁵*Id.*

if there were negative issues involved, yes, certainly we'd communicate it no matter who was funding it.”³⁵⁶

Apparently, in the opinion of the ADA, there was simply no bad news about olestra.

THE AMERICAN COUNCIL ON SCIENCE AND HEALTH

Another group which offers its endorsement on the Wow! Chips website is the American Council on Science and Health (ACSH). While its name suggests a public interest organization, the ACSH is in fact funded almost exclusively by chemical and food industry interests, and serves primarily as a front group for disseminating industry public relations material. Dr. Elizabeth Whelan, the ACSH's executive director, has claimed that the US government spends far too much on unproven health risks such as dioxin and pesticides because of the public's "unfounded fears of man-made chemicals and their perception of these chemicals as carcinogens.”³⁵⁷ She has made such outlandish statements as “There is no such thing as junk food,” and “There is insufficient evidence of a relationship between diet and any disease.”³⁵⁸ Dr. Whelan is not incompetent; she is simply available for rent. The ACSH receives funding from chemical, oil and pharmaceutical companies like Monsanto, Dow USA, Exxon, and Union Carbide, as well as from food and beverage interest like Burger King, Coca-Cola, PepsiCo, NutraSweet, Nestle USA – and Procter & Gamble.³⁵⁹

Any doubt that might have existed that the ACSH sees its role as that of industry advocate, rather than merely an “honest broker” of sound science, was erased with the revelation of an internal 1992 memo. In that document, Dr. Whelen bemoaned the loss of funding from the Shell Oil Company Foundation: “When

³⁵⁶Id.

³⁵⁷Joel Bleifuss, “Science in the Private Interest: Hiring Flacks to Attack the Facts,” PR Watch, Vol. 2, No. 1, 1995 , p. 11; “Public Interest Pretenders,” Consumer Reports, Vol. 59, No. 5, 1994 , p. 319; “Misguided Health Priorities Could Affect Economy,” International Insurance Monitor, Vol. 41, No. 6, 1987; “Dr. Blasts US Health care Priorities,” Cash Flow, Vol. 91, No. 47, 1987

³⁵⁸PR Watch, Volume 5, Number 4, available at <http://www.prwatch.org/prwv5n4.pdf>

³⁵⁹Id.

one of the largest international petrochemical companies will not support ACSH, the great defender of petrochemical companies, one wonders who will.”³⁶⁰ In 1991, when the “the great defender of the petrochemical companies” last made its sources of funding available to the public, some forty percent of its \$1.5 million annual budget was supplied directly by industry, including a long list of food, drug and chemical companies.³⁶¹ Since 1991, the ACSH has refused to disclose the sources or amounts of its funding. In a 1997 interview, Whelan explained that since she was already being called a “paid liar for industry,” she had decided to abandon restraints on corporate funding altogether.³⁶²

A survey of the Council’s board of directors provides some additional perspective on its mission. The board includes scientists with an avowedly anti-regulatory bent, such as chairman A. Alan Moghissi, a former EPA official who in 1990 served on a panel to challenge the EPA’s policy requiring asbestos removal from schools and other public buildings;³⁶³ Henry Miller, a former FDA official now at the Hoover Institution (who participated in the pro-olestra campaign on his own behalf as well as through ACSH); corporate public relations professionals Albert Nickel of the firm Lyons Lavey Nickel Swift (their motto: “We change perceptions”), and Lorraine Thelian, a senior partner at Ketchum Communications, which handles “environmental PR work” for Dow Chemical, the Aspirin Foundation of America, Bristol Myers Squibb, and the National Pharmaceutical Council.³⁶⁴

Procter & Gamble got its money’s worth from Dr. Whelan and the ACSH.

Dr. Whelan took her spirited brand of advocacy to the newspapers, and made little effort at balanced

³⁶⁰Sidney Wolf, “DRKOOP.CON? America’s Family Doctor and His Conflicts of Interest: The Doctor in Need of Doctoring,” TomPaine.com, 2001

³⁶¹Sheldon Rampton and John Stauber, “In Industry’s Hip Pocket? The American Council on Science and Health (ACSH),” TomPaine.com, 2001

³⁶²Id.

³⁶³Id.

³⁶⁴Id.

analysis. In an article that appeared in the *Washington Times*, Dr. Whelan wrote, “Within months we will be able to buy a variety of delectable zero-fat snacks — a real-life case of getting something for (almost) nothing.”³⁶⁵ At another point, Dr. Whelan hailed olestra’s approval by the FDA, writing “Dr. Kessler’s decision represents a triumph of sound science and common sense over scaremongering — with the American consumer the clear winner.”³⁶⁶ Whelan parroted Procter & Gamble’s line on CSPI almost word for word, implying that Jacobson and his cohort were untrustworthy and unscientific: “Since everyone these days seems to be anti-fat, one might be forgiven for assuming that olestra would be welcomed by everyone. But this has not been the case: The ‘usual suspects’ who routinely condemn products of food technology declared war on olestra — and so did a few respected scientists.”³⁶⁷ Nowhere in the article did Whelan mention that her group receives funding from P&G — at least \$12,500 in 1995 and \$10,000 in 1996.³⁶⁸ When questioned, Whelan would say only that P&G’s support represents less than one percent of her group’s total budget, and refused to comment further.³⁶⁹

The ACSH also acted as a stand-in for P&G on television. Dr. Whelan appeared on both NBC’s *Today* show and CNN’s *CNN Live* to debate CSPI’s Dr. Michael Jacobson, as well as on CNBC’s *Business Insiders* to debate CSPI’s Mira Karstadt. According to the ACSH’s newsletter, “ACSH was called upon to offer a mainstream scientific perspective.”³⁷⁰ The letter does not make clear who exactly “called on” the ACSH. But the money — and Dr. Whelan’s words — leave little doubt. According to the same newsletter, “On all three programs, Dr. Whelan emphasized how fat-free foods containing olestra will offer weight-conscious Americans more alternatives in their diet and refuted the fallacious and exaggerated claims of those who

³⁶⁵Elizabeth Whelan, “The New Skinny on Snack Foods,” *The Washington Times*, January 28, 1996

³⁶⁶*Id.*

³⁶⁷*Id.*

³⁶⁸Ken Silverstein, “Washington on \$10 Million a Day,” *Common Courage Press*, 1998, p.63

³⁶⁹Ken Silverstein, “How the Chips Fell,” *Mother Jones*, May/June 1997

³⁷⁰ACSH Newsletter, available at <http://www.acsh.org/publications/newsletter/>

have attempted to describe olestra as nutritionally harmful.”³⁷¹

THE NATIONAL CONSUMERS LEAGUE

The same website that bears the enthusiastic endorsement of the ACSH also bears the cautious pseudo-endorsement of the National Consumers League: “The National Consumers League (NCL) is fully confident in the thorough review of this product by the FDA.”³⁷² That the NCL feels the need to endorse the FDA’s process, rather than the product itself, is suspicious; it scarcely seems like the endorsement of a front group. There is a good reason for this: unlike the ACSH, the NCL was at least at one time a legitimate watchdog group. Founded by labor and consumer activists at the turn of the century, the NCL calls itself “America’s oldest consumer organization.”³⁷³ Today, the original consumer focus of the NCL has been heavily diluted; while it continues some activism in the field of child labor, the National Consumers League has come to rely on corporate interests for a significant portion of its budget. Though they refuse to give specific numbers detailing how much money each particular corporation or industry association has contributed, League officials admit that thirty-nine percent of the group’s 1997 budget of \$1.3 million came from corporations and industry associations.³⁷⁴ Asked why a consumer group would take any money at all from corporations that invest so heavily in opposing consumer interests, NCL spokesperson Cleo Manuel says mournfully, “I wish we didn’t have to.”³⁷⁵

It’s easy to understand why Manuel feels that way; the influx of corporate funding appears to have had a dramatic effect on the substantive content of the NCL’s work. A survey of the publications produced by the

³⁷¹Id.

³⁷²See <http://www.wowchips.com/what/expert/text.html#NCL>

³⁷³See <http://www.natlconsumersleague.org/>

³⁷⁴Russell Mokhiber, “Corporate Consumer Group,” *The Multinational Monitor*, April, 1998, Volume 18, Number 4

³⁷⁵Id.

National Consumer's League – and who paid for them - is illustrative:

- NCL's "Consumer Guide to Choosing Your Telephone Service" was paid for by Ameritech.
- NCL's "Consumer Credit Series" of reports was paid for by Fleet Finance Inc, a subsidiary of Fleet Financial Group.
- A brochure entitled "Making Sense of Your New Communications Choices" was paid for by GTE.
- A pamphlet bearing the legend "Take Care with Over the Counter Asthma Medicine" was paid for by Syntex, a pharmaceutical company.
- A newsletter, "Community Credit Link," was paid for by Visa USA.³⁷⁶

Of course, all manner of valuable products are produced by corporations for the benefit of their customers. What is far less likely is that any of the above publications contain information that threatens the financial interests of the sponsoring industries. In abandoning that function, one of the most important roles of the National Consumers League has been quietly subverted.

The NCL has one other, more attenuated relationship to P&G's olestra campaign. In 1996, at the annual "NCL Trumpeter Award Reception and Dinner," which brings in about forty percent of the League's annual budget, the NCL honored Carol Tucker Foreman, a noted food safety advocate - who was also Procter & Gamble's primary lobbyist on the olestra issue.³⁷⁷ Foreman's Safe Food Coalition is a legitimate organization; but given NCL's increasing advocacy for corporate causes, and its support for the FDA's olestra approval, it appears at least possible that Procter & Gamble convinced the National Consumers League to enhance the pro-consumer reputation of P&G's corporate lobbyist.

³⁷⁶Id.

³⁷⁷Id. See also, "NCL Honors Carol Tucker Foreman With Trumpeter Award," National Consumers League, Press Release, October 8, 1997. Available at <http://www.natlconsumersleague.org/trmpctf.htm>

THE SHADOW FDA – PART II

When the tobacco industry came under attack from FDA Commissioner David Kessler, the tobacco industry called on its roster of lawyers and consultants who served the FDA in the past – what I have called “the Shadow FDA.” The tobacco industry used former Commissioner Charlie Edwards not so much for what he had to say, but for what it meant for him to say it. Those who leave public service carry with them a credibility and reputation that would be unattainable in the private sector, and where food safety is at stake, and profitability depends on gaining the trust of wary consumers, credibility is paramount. Conscious of the questions that surrounded olestra, and aware that they needed credible figure to stand behind their product, Procter & Gamble called on two former Secretaries of Health and Human Services: Louis Sullivan and Otis Bowen.

Louis Sullivan, a Secretary of HHS during the administration of George H. W. Bush, not only lobbied members of Congress like Julia Carson; he also played a major role in Procter & Gamble’s promotional campaign, addressing press conferences and writing letters to newspaper editors on behalf of olestra. Only rarely did these papers note that Sullivan was a paid P&G consultant. In one letter to the *New York Times*, Sullivan - identified only as the president of the Morehouse School of Medicine – wrote unequivocally, Americans can feel confident in the safety of snacks made with olestra.”³⁷⁸ Sullivan also promoted olestra in a 10-minute video P&G sent to local groups, such as Parent-Teacher Associations, as part of its marketing effort in Columbus, Ohio.³⁷⁹

Many press outlets uncritically accepted the representations of Sullivan and Bowen as unbiased, and repro-

³⁷⁸Ken Silverstein, “How the Chips Fell,” *Mother Jones*, May/June 1997

³⁷⁹*Id.*

duced them verbatim. A story by the Associated Press was typical. Written under the headline, “Experts Say Fake Fat Helps In Weight Control,” the story read like a Procter & Gamble press release:

Former HHS Secretary Dr. Otis Bowen said he surveyed emergency rooms and physicians in Indiana and found no evidence of olestra causing medical problems. “The product causes no significant health risks, said Bowen. I eat the chips and so do my grandchildren.” Dr. Louis Sullivan, another former HHS secretary, said too many Americans are obese and olestra gives them “another tool to improve their lifestyle and overall health.”³⁸⁰

Though it emphasized their status as former Cabinet members, the article makes no mention of the fact that both were employed at the time by Procter & Gamble.

At another point, Bowen, a medical doctor, former two-time Indiana governor, and Secretary of Health and Human Services under President Reagan, reassured journalists at a “press availability” that the concern over olestra’s gastrointestinal side effects was unnecessary. “On average,” Bowen told members of the press, “all people have gastrointestinal upsets every three months or so; the number of cases that have been called in is probably an incidental thing.”³⁸¹

Like the tobacco industry’s “Shadow FDA,” that used its credibility to attack the FDA of David Kessler, Louis Sullivan explicitly underlines his former government post when doing promotional work for Procter & Gamble. On the wowchips.com website, Sullivan says

All Americans can feel confident in the safety of snacks made with olestra. As a former Secretary of Health and Human Services, I am aware of the intense scrutiny new food ingredients like olestra are subject to before they are approved by the FDA. The FDA with input from the many respected experts including the National Cancer Institute carefully reviewed more than 25 years of research supporting olestra’s safety. - Louis Sullivan, M.D. President, Morehouse School of Medicine³⁸²

³⁸⁰Paul Recer, “Experts Say Fake Fat Helps In Weight Control,” Associated Press, 1998

³⁸¹Art Levine, “Food Fight in Indianapolis,” U.S. News, May 5, 1997

³⁸²See <http://www.wowchips.com/what/expert/text.html#Sullivan>

Like the Associated Press story, the Sullivan quote mentions nothing of his conflict of interest. It also implies – incorrectly – that the National Cancer Institute has lent its name to olestra’s approval. It has not.

CONCLUSION

What I hope this paper has shown is that the sins of the tobacco industry are not unique or personal to that industry, but a natural and predictable outgrowth of the adversarial process that puts the Food and Drug Administration between regulated industry and enormous profit. Because of the scope and nature of the tobacco industry’s long campaign of deception, it is tempting to see tobacco as a mad dog among industries, the corporate equivalent of a “rogue state” that flagrantly defies behavioral norms. This paper has sought to expose that reasoning as naïve and unrealistic, and to suggest that, far from being unique, the actions of the tobacco industry in fact adhere quite closely to corporate norms. As this paper has tracked the tobacco industry’s campaign against the FDA, and Procter & Gamble’s campaign to secure olestra’s approval and market share, consistent parallels have emerged:

- Each industry gave generously to members of Congress, concentrating on the leadership of the two major parties and the chairmen of important committees, each shifting their support with the changing of political tides.
- Each relied on the loyalty of their home-state delegations to pressure the FDA with letters and with hostile hearings.
- Each enlisted well-connected lobbyists to smooth over dissenters, and employed “Astroturf” campaigns to generate pressure on reluctant legislators.

- Each poured resources into scientific research and scientists, in order to produce a steady stream of favorable data and friendly witnesses. Each proved willing to pick and choose among studies to find those that fit the industry's agenda.
- Each was ruthless in attacking potential threats, lampooning and slandering opponents, often through unaccountable third parties.
- Each used their vast corporate resources to purchase the support of credible organizations.
- Each employed a cast of former public servants – especially veterans of the FDA and HHS – to provide a public counterweight to government.

There is a difference between the actions of Philip Morris and the actions of Procter & Gamble, and it is an important one – there is no reason to believe that olestra is addictive, that it has been marketed to children, or that it will kill millions. But when it comes to their approach to the regulatory process, that difference is only one of degree. I cannot say whether the FDA's approval of olestra was a mistake - I am unqualified to judge the arguments on their scientific merits. But I hope this paper has demonstrated that the process that preceded olestra's approval was dangerously tainted — that institutional concerns unrelated to the public health appear to have played a significant role in securing its safe passage through the regulatory process. The continuing danger to the American public is not so much in olestra itself as in the increasing porosity of the regulatory structure. This paper could equally have focused its attention on pharmaceuticals, on blood products, or on medical devices, and demonstrated the same consistent industry strategies and the same systemic failures of our political and regulatory process. Eventually, such lax procedures will cause unnecessary harm to the American public, a public that barely questions the safety of the products it consumes because it believes in the FDA.

The relationship between the FDA and its regulated industries is by necessity adversarial, and will be so long as there is profit to be made in the sale of food and medicine. For practical, if not for moral purposes, we must come to grips with that fact. But this recognition need not lead to resignation. If the tobacco industry blazed a trail that other industries learned to follow – as I believe it did – it also left a blueprint for reform. What follows is merely a thumbnail sketch of prophylactic steps that could re-empower the FDA to protect the public health:

- The federal campaign finance structure has warped the loyalties of the Congress. The cost of campaigning continues to climb with each election cycle, but because only a fraction of one percent of the voting public donates money to elected officials, legislators face a “double constituency” problem: they must answer not only to the voters, but to their financial supporters. Too often, the financial supporters carry the day. So long as Members are beholden to wealthy individuals and corporations to win reelection, special interests will be able to use the Congress as a weapon against the FDA. While banning unregulated “soft money” is a good first step, it is insufficient; it would be a simple enough matter to redirect soft money into hard money donations, particularly if the Congress raises the hard money cap (as it is currently considering). Attempting to contain private expenditures is not only unfeasible, but potentially unconstitutional. Instead, the Congress should adopt a strong system of voluntary public financing for federal elections – a solution which eliminates the dependence of candidates on private wealth, but respects constitutional guarantees.
- The lobbying system has a clear public value: it enables legislators and regulators to hear persuasive arguments and gain access to valuable information. Lobbying is not a problem in itself. It becomes a problem, however, when lobbying is bound up with campaign donations, and where it perpetuates a revolving door between public service and the private sector. The revolving door process not only introduces personal relationships to what should be neutral policy determinations, it also offers a dangerous incentive for public

servants to satisfy private masters, in the hope of future employment.

President Clinton instituted waiting periods between the time someone left his administration and the time they could return to lobby it, but repealed them when his own administration left office – just in time for his loyalists to capitalize. Those prophylactic measures should be restored and enforced. Legislators should also be required to keep and make publicly available a record of the time they spend with registered lobbyists – another simple step toward achieving a transparent process.

- One of the most odious acts of the tobacco industry was its submission of fraudulent scientific testimony to government agencies. While there is no public evidence of Procter & Gamble engaging in such conduct, the FDA's approval of olestra was based almost entirely on industry-sponsored research – a situation that leaves open the possibility of fraud. There must be severe penalties for organizations that knowingly submit false or incomplete information to the FDA, including significant fines for corporations and criminal sanctions for executive officers. Unlike most criminal sanctions, there is reason to believe that such penalties – if vigorously enforced – could have a significant deterrent effect. The corporate context is one of the few scenarios in which the rational calculations inherent in deterrent theory actually take place.

- Other measures must address the dangers of tainted scientific research, increase awareness of front groups like HBI and the ACSH, and protect the public market for information from the emerging monopoly structure of the mass media.

These are but a few suggestions, a jumping-off point for what must be a comprehensive series of systemic reforms.

The American public cannot afford to assure itself that the corporate malfeasance of the tobacco industry is unique to that industry and that product. It is not. The problems described in this paper are systemic problems, endemic within the adversarial structure that defines the FDA-industry relationship, and if they are to be successfully addressed they must be met with systemic solutions.

