Chapter 2

Health Policy and Corporate Influences

The Impact of Corporate Practices on Health: Implications for Health Policy

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Introduction

Recently, policy makers, the media, advocates, and the public have called attention to the impact of corporate activities on health and disease in the United States. High-profile cases that have galvanized public discourse include the tobacco settlement that was designed to provide compensation to states for tobacco-related illness, widespread debate over the responsibility of the food and beverage industry for the current epidemic of obesity, and discussions about drug company profits and harmful product side effects. Criminal prosecutions of corporate executives have posed new questions about corporate responsibility. Controversy about corporations and corporate practices has reignited a perennial American conflict regarding appropriate roles for government and markets in political life and in public health.

Within public health, some have urged health professionals to engage corporations to improve health (1). Few public health commentators, however, have systematically examined corporate practices as social determinants of health or assessed their implications for health policy. While researchers have examined the occupational and environmental health consequences of corporate policies (2), very little work has focused on the cumulative impact of consumer exposures to corporate policies. Current interest in the role of

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social determinants in shaping illness and health has focused on structural characteristics such as poverty, inequality, and racism (3–5). The research that has considered the impact of corporate activity on health has usually examined the health consequences of a single product or a corporate practice rather than the patterns of behavior by corporations and governments across a variety of industries.

In our view, a systematic investigation of the impact of corporate decisions on health may yield insights that can guide prevention policy. In this review, we consider how fundamental factors such as the current relationship between markets and government influence corporate policies and in turn how these policies influence health behavior. Our primary interest is in *corporate practices*, defined as the business and political activities of corporations. These practices result from companies' decisions about the production, pricing, distribution, and promotion of their products and from their political efforts to create an environment favorable for their businesses. Our goals are to assess the role of corporate practices in determining health, examine their implications for health policy, and suggest directions for policy and research. More broadly, we hope to widen the discussion on social determinants to include corporate practices as a modifiable influence on population health.

Recent literature on social and policy determinants of health (6–11) and the authors' ongoing research (12) informs this inquiry. Corporate practices can both benefit and harm health. Changes in food production and marketing in the first part of the 20th century eliminated most malnutrition in the United States and products developed by the pharmaceutical industry have saved millions of lives, as two examples. A better understanding of what leads a company or an industry to choose health-promoting vs. health-damaging practices may help to identify new opportunities for policies that encourage primary prevention.

TRANS FATS, VIOXX, AND SPORTS UTILITY VEHICLES: THE IMPACT OF CORPORATE PRACTICES ON HEALTH

To understand how corporate practices influence population health, we consider three products that have attracted recent media attention.

Trans Fats

In 1994, the Center for Science in the Public Interest, a national advocacy organization, petitioned the Food and Drug Administration (FDA) to

require that food manufacturers label the *trans* fatty acid (*trans* fat) content of their food products. The petition was based on research showing that replacing *trans* fat with healthier oils could prevent 30,000–100,000 premature cardiovascular deaths in the United States each year (13,14). Some researchers have suggested that replacing *trans* fatty acids with healthier alternatives could reduce the incidence of Type 2 diabetes in the US by as much as 40% (15,16).

Artificial *trans* fats are used to enhance the crispness, stability, and flavor of many processed foods (17). By the late 1990s, 40% of US supermarket products contained *trans* fats. When evidence of harmful effects began to emerge in the early 1990s, sectors of the food industry chose different responses. Some producers rejected the claim that *trans* fats were harmful and sought to delay any regulatory action by calling for further research (18). Throughout the 1990s, food industry groups opposed new FDA regulations on *trans* fats (19). Other companies, however, accepted the call for labeling and looked for ways to reduce the amount of *trans* fats so that their labels might show lower levels.

In 1999, the FDA claimed that strengthening food labeling was likely to yield significant health and economic benefits, saving as many as 5,600 lives and $8 billion a year (20). Three years later, the US Institute of Medicine could not determine a healthful limit of *trans* fat and urged action to reduce its presence in the American diet (21). In January 2006, the FDA rule requiring *trans* fats content on food labels went into effect, but the FDA turned down requests to ban the additive altogether. More recently, several cities and states have banned *trans* fats in restaurant food.

Vioxx

Merck Pharmaceuticals obtained FDA approval to market the painkiller Vioxx (generic name, rofecoxib) in 1999. Merck marketing promised that Vioxx would bring pain relief to people with arthritis without the gastrointestinal side effects associated with other medications. Five years later, after more than $10 billion in sales, Merck withdrew Vioxx from the market because a study showed that it doubled the risk of heart attacks and strokes in long-term users (22). By then, more than 20 million people had taken the drug and thousands may have experienced adverse events, including deaths, attributable to Vioxx (23).

Why did so many people take a drug that turned out to be unsafe? First, Merck benefited from a drug-testing system that relied heavily on industry

studies rather than independent review – a testing regime developed at the behest of a politically powerful industry (22,23). Second, Merck invested hundreds of millions of dollars in promoting Vioxx. In 1997, after a decade of pressure by the drug industry, the FDA issued guidelines that relaxed restrictions on advertising prescription drugs directly to consumers (24). By 2001, spending by pharmaceuticals on direct-to-consumer advertising had more than doubled (24). In 6 years, Merck spent more than $500 million advertising Vioxx to consumers (23) and in 2003 alone, more than $500 million on Vioxx ads for physicians (25).

The company also developed an aggressive training program for its sales force. A training video told its sales representatives that the drug did not cause heart attacks and encouraged them to avoid questions on that topic (26). Merck's promotional campaigns and advertisements led many consumers and physicians to believe that Vioxx and other COX-2 inhibitors (the class of drugs that includes Vioxx) were superior pain-killers to much less expensive but equally effective over-the-counter alternatives (25).

Faced with mounting evidence regarding the dangers of Vioxx, the FDA adopted a policy of watchful waiting (23), despite the fact that one FDA scientist estimated that Vioxx was associated with more than 27,000 heart attacks or deaths linked to cardiac problems (27).

Finally, Merck ignored warning signs about cardiovascular side effects. Prior to FDA approval, for example, researchers discovered that COX-2 inhibitors interfere with enzymes that prevent cardiovascular disease (22). Another study in 2000 found that people taking Vioxx had three times as many cardiovascular events as those taking Naproxen, another pain reliever. Merck attributed these results to the heart-protective effects of Naproxen rather than the harmful effects of Vioxx (22). After another study showed serious cardiovascular problems in those who had taken Vioxx for more than 18 months (27), Merck pulled the drug from the market.

Sports Utility Vehicles

From the early 1990s to 2005, sports utility vehicles (SUVs) were the best-selling and most profitable vehicles made by the US auto industry. SUVs, together with pick-up trucks and minivans, are considered "light trucks," a category that has separate safety and fuel efficiency standards than passenger cars—an opportunity created by an exemption from new fuel efficiency standards, won by automakers in 1975. Since then, the auto industry has used its

influence in Washington to oppose changes in fuel standards for SUVs and light trucks, despite the existence of technologies that could improve their efficiency (28).

SUVs pose several health and environmental problems. First, because of their high center of gravity, they are three times more likely to roll over and the rate of occupant fatalities in these rollovers is almost three times higher than for passenger cars (29). Second, because of their weight and design, SUVs are more likely than sedans to kill the occupants of cars and pedestrians they hit. An analysis of US traffic fatalities from 1995 to 2001 found that each SUV occupant fatality averted because of the greater weight comes at a cost of 4.3 additional crashes that involve deaths of car occupants, pedestrians, bicyclists, or motor cyclists (30). Third, SUVs are harder to steer, take longer to stop, and give their drivers a false sense of security that leads to riskier driving (31). Fourth, because of high fuel needs, SUVs produce more pollution than passenger cars, contributing to respiratory disease, cancer, and other conditions. SUVs also release up to 47% more CO2 than sedans (32), thus contributing to global warming (33).

Based on a review of scientific and government reports, Bradsher estimated that SUVs account for roughly 3,000 annual excess deaths in the United States (31). Recent improvements in SUVs have reduced some hazards, although as older vehicles move into the second-hand market, characterized by riskier drivers and poorer maintenance, the SUV death toll may increase (34).

SUVs and pick-ups were the most profitable auto industry products because of trade protection against imported SUVs. The auto industry, the nation's largest advertiser, also promoted SUVs heavily, spending more than $9 billion on SUV ads between 1990 and 2001—ads wrongly suggesting that SUVs were safer than passenger cars (35). Once again, profitability trumped health, although in this case some analysts argue that US auto makers' short-term focus on profits actually harmed long-term profitability as changing economic conditions reduced the demand for SUVs (35).

HOW CORPORATE PRACTICES INFLUENCE HEALTH

These stories illustrate the ways in which specific corporate practices intended to achieve industry goals can result in actions that affect population health. Corporate managers have made decisions that have contributed to tens of thousands of preventable deaths, injuries, and illnesses. But in each case, advocacy, government regulation, and market forces ultimately reduced

the threat to population health. We suggest that the systematic investigation of how companies make decisions that affect health can help identify earlier opportunities for primary prevention, thus avoiding preventable deaths.

In each case, industries conducted extensive public relations and lobbying campaigns, and went to court to defeat or delay government regulation, extending both the period of profitability and adverse health impacts. Finally, Ford, General Motors, Merck, and major food companies paid scientists to conduct research to support their positions, contributing to doubt about the evidence that many public health experts believed justified regulation to protect health.

Recent scientific and popular work suggest that corporations regularly make decisions that adversely affect health and that their practices have a substantial impact on US mortality and morbidity (21,31,36–40). For example, the tobacco and alcohol industries target advertising at young people and heavy users, increasing the harm to health (41,42). The food industry modifies its products by increasing portion size (43) and adding sweeteners and fats, (44,45) contributing to obesity and diabetes. The tobacco, automobile, and firearm industries make campaign contributions, lobby, and go to court to prevent the government from passing stricter safety standards for their products (28,46,47).

In the political sphere, as a result of increased lobbying and campaign contributions, many areas of public health oversight have been deregulated and the staff available to monitor industry practices has been reduced (48–50). At the behest of lobbyists, 22 states have banned obesity-related liability lawsuits against fast food restaurants (51), and in its first term, the Bush Administration dropped 31 of 85 proposed auto safety rules from the National Highway and Auto Safety Administration's agenda (50).

In the personal sphere, increased advertising has doubled the number of television commercials viewed each year by the average American child, from about 20,000 in 1970 to 40,000 in 2000 (52). Advertisements for obesogenic processed foods are the most common television ads aimed at children (53).

CORPORATE PRACTICES AND THE SOCIAL PRODUCTION OF POPULATION HEALTH

In past decades, health researchers have disagreed about the most important causes of morbidity and mortality and therefore about prevention priorities. The dominant view in the United States is that individual behavior and lifestyle are the primary malleable determinants of health (54,55), suggesting

that the goal of policy is to change harmful behaviors. Some US and European researchers, however, argue that social structures and the distribution of wealth and power are the fundamental causes of disease, and that changes in these factors are needed to achieve improvement in population health (10,11,56,57).

In our view, a focus on corporate behavior provides common ground for these two approaches. It suggests a policy paradigm that aims to encourage corporate practices that promote healthy behavior. As corporate practices result from specific decisions, they may be more readily changed than underlying social and economic structures in which they are embedded. They offer more immediate opportunities for health promotion than those available to change more entrenched structures. While it is true that corporations, like individuals, make decisions constrained by the social and economic context, identifying policies that make it easier for corporations to choose health should be a public health priority.

Choices are made in a marketplace that produces and advertises certain options and suppresses others and within a political system where certain stakeholders hold more power and influence than others. In order to increase opportunities for primary prevention, two changes are needed: a re-conceptualization of "lifestyle" and a focused policy agenda that makes it easier for corporate managers to choose health-promoting practices.

BEYOND LIFESTYLE

Historically, health researchers have regarded lifestyle as the sum of behavioral choices in multiple arenas (e.g., diet, tobacco, physical activity), influenced by underlying personal characteristics (e.g., orientation to risk, self-efficacy) (58,59). However, sociologists from Weber on have seen lifestyle as a socially determined pattern of consumption or marker of status (60,61). By regarding lifestyle as the consequence of socially constructed choices, it is possible to identify policies that will facilitate healthier lifestyle options.

Free market proponents argue that individuals should have the right to choose what they consume without interference from a "nanny state" (62), suggesting that lifestyle choices are made in a vacuum. In fact, lifestyle choices are often the direct result of corporate decisions. No consumer ever entered a restaurant demanding a portion of *trans* fats. Rather, food companies constrain consumer options through decisions made primarily to increase profits. By exposing corporations as the real "nannies" who persuade children to eat to obesity, drivers to find their inner id behind the

wheel, or patients to solve their social problems with a new drug, health professionals can reframe the discussion about who can be trusted to look after the public's health.

Traditional market proponents have accepted that government has some right to intervene in markets: for example, to ensure that consumers have information to make informed choices, to protect vulnerable groups such as children, or to return unintended costs of a product ("externalities") from tax payers to producers. Recently, however, more ardent-free market advocates have challenged even these roles, a position some label "market fundamentalism" (63). By encouraging more discussion on these issues, health professionals may be able to reframe policy debates to lead to decisions that better protect health.

A POLICY AGENDA FOR HEALTH PROMOTING CORPORATE PRACTICES

Public health advocates have for the most part sought reforms governing corporate practices one product, company, or industry at a time. They have advocated strategies, including public education, to enable individual consumers to make more informed choices (64) and legal mandates to label products truthfully (65,66), on the premise that consumers have a right to know (67); and taxation of tobacco, alcohol, and high-calorie, low-nutrient foods (68–71) in order to make them less available. Others have suggested banning products like flavored cigarettes, designed to appeal to young people (72), or food advertisements for children (73) or requiring higher fuel and safety standards for SUVs in order to reduce their harmful impact (74).

Some advocates have switched from legislative to litigation strategies. Beginning with the lawsuits against Big Tobacco in the 1970s, a cadre of lawyers has emerged and shared lessons from their battles against alcohol, automobile, food, gun, pharmaceutical, and tobacco industries (75–77). Public health litigators assert that courts are an important arena in which to seek justice, educate the public, win resources for health promotion, and force companies to change corporate practices by returning externalized costs to their balance sheets.

In the long run, this piecemeal approach seems inadequate to the task of promoting population health and realizing opportunities for primary prevention. A broader agenda could serve to unify many disparate strands of current advocacy, bring together a more cohesive and powerful coalition to advocate in the political arena, and help reframe public debate in more favorable terms. Such an agenda would use language and concepts that

appeal to many Americans (78,79) and provide links to other major public issues such as campaign finance and electoral reform, reduction of corporate crime, health care coverage, and consumer protection.

While the specifics of such a policy agenda can only be forged by key stakeholders—policy makers, public health professionals, advocacy organizations, and citizens—we suggest one approach in order to stimulate discussion.

1. Provide consumers with a right to know the health consequences of legal products and companies with a duty to disclose such information.
2. Protect children and other vulnerable populations against targeted advertising that promotes unhealthy behavior.
3. Support measures to level the political playing field (meaningful campaign finance reform, higher ethical standards for elected officials, more stringent oversight of lobbying, and stronger voter rights).
4. Increase sanctions for deliberate distortions of science designed to protect corporate interests.

CONCLUSION

In summary, we argue that corporate practices are an important determinant of health, and those policies that alter damaging corporate practices are likely to improve population health. In recent years, public health advocates have developed strategies to bring about policy changes, efforts often opposed by industry and its supporters. A systematic study of both these domains will inform more effective public health policy and practice. In the current political climate, these proposals may seem idealistic, even naive. In a society that seeks to protect public health, they are common sense.

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Marketing Prescription Drugs to Consumers in the Twentieth Century

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Direct-to-consumer (DTC) advertising of prescription drugs has mushroomed from a few isolated and relatively sensational cases in the early 1980s to an omnipresent feature of American consumer society, powered in 2005 by $4.2 billion in promotional dollars.[1] This explosive growth—most intense in the past decade—has inverted the role of physician as learned intermediary in the flow of information about prescription drugs and replaced it with what is, in theory, a more egalitarian consumerist model of health information.

Considerable controversy persists, however, about the impact of DTC advertising on American public health and the doctor–patient relationship.[2] Whereas some argue that advertising has indeed democratized access to important new medications,[3] others decry the coarsening of medical discourse, the diminution of physicians' authority, and the risks of overprescription and inappropriate prescription by the manipulation of consumer awareness and consequent pressure on prescribers.[4]

The lively debate among scholars and policymakers about consumer-oriented pharmaceutical promotion has, for the most part, focused on the explicit regulation of prescription drug advertisements in print and broadcast media,[5] following a series of Food and Drug Administration (FDA) guidances in 1985, 1997, and 1999. However, explicitly regulated promotional practices such as advertisements and sales visits have long been flanked by such unregulated, implicit forms of promotion as the ghostwriting of scientific articles and control of the content of continuing medical education.[6]

We present new historical evidence to demonstrate that such "shadow" marketing has also been employed in the DTC promotion of prescription

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drugs for over a half century. These proto-DTC campaigns flourished at the boundaries of acceptable self-regulation by the pharmaceutical industry as it negotiated attempts at external regulation by the medical profession and the regulatory state. The vitality and persistence of DTC pharmaceutical promotion in the twentieth century suggest that contemporary DTC advertising is not merely a recent aberration that can be fixed by returning to an earlier and better time, and that attempts to wrestle with the consequences of popular marketing would do best to focus on managing, not eradicating, this longstanding element of public life.

ETHICAL MARKETING AND INSTITUTIONAL ADVERTISING

In the late nineteenth century, a number of drug and chemical firms in Europe and North America denounced the raucous commercial market for patent medicine producers and restyled themselves as "ethical" houses devoted to professional therapeutics. Whereas patent medicine makers hid the contents of their nostrums and touted expansive therapeutic claims to consumers via popular advertisements in magazines, newspapers, and traveling medicine shows,[7] ethical drug firms sold standardized preparations of the *materia medica* as designated in the United States Pharmacopoeia and marketed their wares only to the medical profession in keeping with the American Medical Association's (AMA) Code of Ethics.[8]

Aside from the voluntary decision to follow the AMA Code of Ethics, no formal regulation defined the "ethical" drug industry in the nineteenth century. This regulatory void began to close in 1906 with the passage of the Pure Food and Drugs Act. The act created the FDA, which was given the authority to ensure that drug labeling reflected standards of strength, quality, and purity, and, after the Sherley Amendment of 1912, to prohibit fraudulent therapeutic claims on drug labels.

When the Federal Trade Commission (FTC) was created in 1914 to regulate interstate advertising, journal advertising to physicians was exempted in deference to the unique expertise that medical professionals were understood to bring to the interpretation of pharmaceutical promotion. This created a favorable legal framework for what had been a matter of corporate culture. Ethical houses, unlike patent medicine companies, continued to enjoy few restrictions on their marketing as long as it remained restricted to medical journals, direct mail to physicians, and office- and hospital-based "detailing" of physicians by sales representatives. The professional regulation of ethical marketing to physicians was mediated through the Council on Pharmacy

and Chemistry of the AMA, whose "Seal of Acceptance" program governed access to the pages of the *Journal of the American Medical Association* and other reputable journals.

Distinctions between professional and popular drug marketing became more complicated in the first half of the twentieth century. Although in principle all drugs could be divided between patent and ethical, many pharmaceutical companies produced both classes of drugs. Many ethical firms began to diversify their product lines to include "household items" (such as topical disinfectants and milk of magnesia) that would now be lumped into the category of over-the-counter medications.

As they diversified, companies began to explore the possibility of marketing to consumers by promoting the institutional brand of the ethical firm as a whole. Examples of such institutional advertising can be seen in two storied ethical firms, E. R. Squibb & Sons and Parke, Davis & Company. In the 1920s, as both firms diversified into "household items," each developed widespread, highly visible institutional advertising campaigns in popular magazines such as the *Saturday Evening Post* and *Ladies Home Journal*. These ads mentioned no specific products or therapeutic indications. Instead, they praised the achievements of modern medical science, lauded the heroic figure of the modern physician, and testified to the high standards and quality of modern pharmaceuticals.

These DTC advertisements stood in sharp contrast to product-specific pharmaceutical advertisements appearing in the medical journals of the time. But with their "See Your Doctor" message and their decorous refusal to name specific drugs, they also sought to distinguish themselves from the crass commercialism of the patent medicine market. Institutional advertising, in other words, advertised the concept of ethical pharmaceuticals, and thus—ironically—reinforced rather than undercut the edifice of ethical marketing.

By the middle of the twentieth century, at the height of ethical marketing, DTC advertising by pharmaceutical companies had become standard fare. And yet these campaigns actually worked to strengthen the cultural and regulatory boundaries separating ethical drug marketing from the rest of America's intensifying commercial culture. By promoting ethical firms as producers of high-quality, innovative therapeutics while simultaneously insisting on the priority of the physician in selecting and prescribing pharmaceutical agents, these advertisements reinforced both the scientific legitimacy of the ethical pharmaceutical industry and the role of the physician as learned intermediary in ethical drug use.

PUBLIC RELATIONS AND THE PRESCRIPTION DRUG CONSUMER

The market for prescription drugs grew rapidly in the second half of the twentieth century along with a postwar boom in novel synthetic pharmaceutical products, a general rise in the consumption of health care, and new federal regulations that required a prescription for the sale of ethical pharmaceuticals. As brand-name drugs became increasingly important to physicians' practices and to pharmaceutical company profits, competition between firms heightened.[9] The resultant increase in journal advertising budgets created a financial incentive for the AMA, in 1955, to discontinue its Seal of Acceptance Program and open up the pages of the *Journal of the American Medical Association* to a less-discriminating but higher-volume advertising policy.[10] Looking for ways to improve their market position, a growing number of pharmaceutical companies looked beyond "institutional" advertising to a variety of creative means to communicate their own brand names to physicians and to the general public. By the mid-1950s, the popular promotion of brand-name prescription drugs through public relations and new-generation institutional advertisements had become a thriving and unregulated gray area of DTC marketing.

The 1950s were a propitious time for the new pharmaceutical advertisers. The popular promise of "miracle drugs" elicited general admiration of the industry by physicians and the consumer public, which gave companies a margin for error that they had not always had. The 1950s also saw a boom in industrial public relations, as corporations took the lead in selling the "free market system" to the public and the federal government.[11] The pharmaceutical industry had traditionally used public relations to attract investors and maintain institutional visibility; now it became their preferred vehicle for new marketing campaigns. In 1953, the Pharmaceutical Manufacturers Association urged all pharmaceutical firms to develop their own public relations offices and developed a primer in public relations for the industry.[12] By 1956, the heads of all major American pharmaceutical companies had pooled together to create an industry-wide public relations office, the Health News Institute, with Chet Shaw, the former executive editor of *Newsweek*, hired as the first director.[13]

Formally, public relations was distinguished from advertising in that it promoted the name of the firm or the interest of the industry as a whole instead of a single branded product.[14] Beginning in the 1950s, however, new popular advertisements began to promote the company's own innovative drugs, especially in the growing field of prescription antihistamines. One

1960 advertisement in the popular magazine *Today's Health*, titled "This Is What We Work For at Parke, Davis," featured a formerly allergy-ridden family enjoying a campfire together. "Fortunately," the text ran, "a new group of drugs, developed in research laboratories of pharmaceutical houses such as Parke, Davis & Company, goes a long way in relieving the agonies of allergies."

Another creative attempt to indirectly advertise a brand-name prescription drug to the general consumer came to public attention during a 1964 Senate investigation of the pharmaceutical industry. The previous year, Roche Pharmaceuticals had placed advertisements for the tranquilizer Librium in special copies of *Time* magazine that were mailed to doctors for use in their waiting rooms. Although Roche was censured by Congress and the offending issues of *Time* disappeared, Parke, Davis continued to advertise the benefits of antihistamines well into the mid-1960s.[15]

These efforts at what might be called "indirect-to-consumer advertising" were accompanied in the 1950s and 1960s by an energetic exploration of nonadvertising marketing through newsreels, article placements, event planning, and other domains of public relations. Companies also attracted popular media coverage by adding attention-grabbing gimmicks to their medical marketing. Carter Products pursued this strategy with their blockbuster tranquilizer Miltown (meprobamate) in 1958 by commissioning a sculpture from Salvador Dali for their exhibit at that year's AMA meeting.[16]

Such publicity stunts were coordinated with longitudinal public relations campaigns run by the Health News Institute and sister public relations outfit the Medical and Pharmaceutical Information Bureau (MPIB). Companies issued press releases based on clinical studies, mailed entire press release packages to newspapers, provided favored science writers early access to clinical materials, and made experts available for interviews or educational programs.[17] One favored MPIB strategy was to offer newspapers small boxes of text called "short shorts" to fill small spaces between stories, and to provide radio and television stations with small broadcast news items called "featurettes" for filling dead air time.

Perhaps the highest form of industry-ghostwritten media coverage was an omnipresent form of reportage called the "backgrounder." Backgrounders were seemingly legitimate news articles about new pharmaceutical developments that ran in popular magazines. Written by journalists who appeared to be neutral, they had actually been commissioned by the MPIB working through a stable of regular science writers. When they reported on miracle drugs (which they almost invariably did), they highlighted specific

brand-name medicines—but left them uncapitalized so that they looked like chemical or generic names, thus avoiding the appearance of impropriety. Some of them went so far as to "launch" a new class of medicines by listing all the competing brands along with the manufacturer and salient marketing claims.[18]

At the height of the ethical era in American pharmaceuticals, then, an increasingly competitive and increasingly profitable industry vigorously explored a range of shadow marketing techniques designed to work like DTC advertising without technically crossing the Rubicon and abandoning the ethical label. Aided by muckraking exposés of the industry by Congress and investigative journalists in the 1960s and 1970s, these ubiquitous and almost entirely unregulated marketing campaigns subtly altered the "ethical" label, anchoring it more on its new prescription-only status than on its older claim of forgoing popular advertising.

FORMAL DIRECT-TO-CONSUMER ADVERTISING

By the early 1980s, at least some pharmaceutical companies, chafing at the limits of informal and indirect marketing, were ready to test the waters of explicit advertising. This had been a surprisingly gray area marked by a complex interplay of industrial, professional, and regulatory developments since the original Pure Food and Drugs Act of 1906. One key development ushered in by the Congressional Food and Drug Act and its amendments in 1938 and 1951 was the establishment of a formal, legal category of drugs that could be used only under the supervision of a licensed physician—that is, prescription-only drugs.[19] The new category created ambiguity about which federal agency (the FTC or FDA) was responsible for overseeing pharmaceutical promotion to the general consumer. Not until the Kefauver-Harris Amendments of 1962 did the FDA receive explicit regulatory authority over advertisements for prescription only drugs, which was subsequently interpreted to encompass broader forms of promotional messages which endorsed a drug product and were sponsored by a manufacturer, such as press releases.[20] Subsequent FDA regulations imposed two major criteria on prescription drug advertisements: (1) a "brief summary," which required a presentation of all side effects, contraindications, warnings, and indications for use, and (2) "fair balance," which entailed an even presentation of risks and benefits in any given piece of advertising.

These two requirements effectively limited full product-specific DTC advertising to print media, where fair balance of drug risks could be

presented in small type. The cost of purchasing time for description of side effects would be prohibitive in broadcast media. Thus, DTC advertising in the broadcast media tended toward health-seeking campaigns, which emphasized a disease or medical condition but not a specific drug, or reminder campaigns, which promoted a drug name in the explicit absence of any therapeutic claims.[21]

Concerned that consumers were confused by the choppy nature of broadcast DTC advertising, the FDA convened a 1995 hearing on the putative risks and benefits of easing its regulation. In 1997, the FDA issued a draft guidance on DTC advertising, followed by a final guidance in 1999 that redefined "adequate provision" of risks and benefits to include reference to a toll-free number or Web site. This opened the door for federally regulated DTC advertising over broadcast media, and the industry responded quickly. Total DTC advertising in 1989 was estimated at $12 million; it reached $340 million in 1995, tripled to $1.1 billion in 1998, the year after the FDA's draft guidance, and doubled again to $2.24 billion by 1999, the year of the FDA's final regulatory decision on broadcast DTC advertising. It has doubled again in the decade since then.[22]

Federal regulation of other forms of promotion to consumers, however, has followed a less straightforward path. The explicit regulation of press releases has captured only a fraction of the nonadvertising forms of pharmaceutical promotion that have since been aimed at American consumers. Indeed, in an era of intersecting digital media, one might ask who needs press releases when consumers continually encounter celebrity endorsements, "astroturfing" (planned and industry-funded "grassroots" disease awareness programs), friendly (or for-hire) science writers, and the like? Although the Federal Physician Payments Sunshine Act, proposed in 2009, would increase the transparency of covert pharmaceutical promotion to researchers and physicians, it would do little to expose the covert marketing of pharmaceuticals to the general public. We are left in the same strange situation that has prevailed for much of the twentieth century: explicit forms of advertising are carefully monitored and regulated but widely decried, while informal or indirect promotions still flourish with virtually no oversight.

OVERT AND COVERT DIRECT-TO-CONSUMER MARKETING

We employed original archival research and a narrative review of clinical, policy, and trade literatures to reveal how recent forms of DTC advertising fit within a longstanding twentieth-century lineage of popular pharmaceutical

promotion. This brief review has limitations: it cannot claim to be a complete study of the subject because of the spottiness of archival records, a poorly indexed trade literature, and the general difficulty of documenting a process that has historically sought to obscure itself. Moreover, like most histories, it cannot answer the most pressing (but misleading) question of whether DTC advertising helps or harms the public health. It does, however, definitively document the popular promotion of prescription drugs throughout most of the twentieth century—a history with real significance for current efforts to understand and grapple with current forms of DTC advertising.

There are at least two broad lessons to be gleaned from this history. The first relates to the complexity of the flow of information about medicines. As this article has shown, federal regulatory categories have been inadequate to capture the bewildering profusion of marketing techniques employed by the pharmaceutical industry. "Ethical," "advertising," "labeling," "education," "public relations": each of these has meaning, technically, but they are of limited value when companies routinely pursue broader marketing strategies that synergistically combine all of these, often in the same campaign. A historical assessment of the promotion of prescription drugs to consumers helps to provide a more complete taxonomy of these efforts, supplementing named and formal channels of information with prominent, persistent, and well-used informal pathways. Only by knowing this informational landscape—by considering it holistically in terms of the packaging and circulation of ideas, rather than by defining particular kinds of marketing to focus on—can observers hope to evaluate and ultimately regulate its many traffickers.

Those "many traffickers" constitute a second, related point: the great diversity of invested parties involved in marketing campaigns. Pharmaceutical promotion does not only involve manufacturers, advertisers, and consumers. Rather, the social networks involved in pharmaceutical promotion are broad and employ artists, journalists, gossip columnists, science writers, editors, filmmakers, physicians, public relations firms, researchers, medical educators, and many others in popular and professional spheres. In many cases it has benefited all parties in these networks to obscure or even deny that marketing is taking place. Taking careful stock of this hidden economy of pharmaceutical promoters gives a more complete picture of how the system works and which actors need to be considered in any political or regulatory efforts.

Both of these taxonomic points are important because of a third, most central historical fact: the surprising continuity of drug marketing over time. It is hardly surprising that the form and content of pharmaceutical

promotion has changed over the twentieth century. Beneath this evolution, however, one finds a surprising consistency in the range of techniques by which companies delivered information about their products to the general public. But throughout, ordinary Americans still encountered paid advertising touting the importance, effectiveness, and scientific credentials of ethical and prescription-only drugs.

The popular promotion of pharmaceuticals, in short, needs to be understood as a longstanding—if often covert—dimension of prescription drug marketing, not merely as a recent aberration. This should come as little surprise given the industry's location within a resolutely commercial—and consumerist—medical system. In such a system, there will always be ways for information about products to flow to people who may want to use them. There is no golden age to return to by stamping out promotion. Instead, history suggests that reasonable goals would be to make the system transparent and efficiently regulated so that risks as well as benefits are communicated to consumers,[23] and to manage the system so that it has the ability to aggressively respond to unreliable information.

As anyone involved with consumer advocacy knows, this is no easy task. Its difficulty is compounded by the disproportionate size of the DTC marketing budget for the pharmaceutical industry, which is nearly twice the budget for the entire FDA, let alone the office in charge of the regulation of DTC advertising.[24] Nonetheless, for good and for ill, durable forms of popular pharmaceutical promotion—and a focus on the provision of drug-related information to consumers—have been a persistent part of the pharmaceutical marketplace for most of the twentieth century. By acknowledging this reality, and by adding informal and nonadvertising forms of drug promotion to a strengthened regulatory portfolio, we could at least take a step closer to the democratic world of medical information that drug advertisers claim to be helping to create.

ENDNOTES

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[2]J. M. Donohue, "Direct to Consumer Advertising of Prescription Drugs: Does It Add to the Overuse and Inappropriate Use of Prescription Drugs or Alleviate Underuse?" *International Journal of Pharmaceutical Medicine* 20, no. 1 (2006): 17–24. DTC advertising of prescription drugs is, for the most part, a unique feature of American public health policy; although the European Union is currently

debating a motion that would allow drug manufacturers to provide pamphlets of "nonpromotional" materials directly to consumers, apart from New Zealand, the United States remains the only country that explicitly permits the DTC promotion of pharmaceuticals. "Public Consultation (MLX 358): The European Commission Proposals on Information to Patients for Prescription Medicines," available at http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON046657 (accessed July 26, 2009).

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[6]D. Healy, "Shaping the Intimate: Influences on the Experience of Everyday Nerves," *Social Studies of Science* 34 (2004): 219–245; C. Elliott, "Pharma Goes to the Laundry: Public Relations and the Business of Medical Education," *Hastings Center Report* 34 (2004): 18–23; B. Moffatt and C. Elliott, "Ghost Marketing: Pharmaceutical Companies and Ghostwritten Journal Articles," *Perspectives in Biology and Medicine* 50 (2007): 18–31; S. Podolsky and J. Greene, "Pharmaceutical Promotion and Physician Education in Historical Perspective," *Journal of the American Medical Association* 300, no. 7 (2008): 831–833; D. Herzberg, *Happy Pills in America: From Miltown to Prozac* (Baltimore: Johns Hopkins University Press, 2009).

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[8]J. Liebenau, *Medical Science and Medical Industry: The Formation of the American Pharmaceutical Industry* (Baltimore: Johns Hopkins University Press, 1987).

[9]J. A. Greene, "Pharmaceutical Marketing Research and the Prescribing Physician," *Annals of Internal Medicine* 146, no. 10 (2007): 742–748.

[10]J. A. Greene and S. H. Podolsky, "Keeping Modern in Medicine: Pharmaceutical Promotion and Physician Education in Postwar America," *Bulletin of the History of Medicine* 83, no. 2 (2009): 331–377.

[11]Dominique Tobbell, "Allied Against Reform: Pharmaceutical Industry-Academic Physician Relations in the United States, 1945–1970," *Bulletin of the History of Medicine* 82, no. 4 (2008): 878–912; E. A. Fones-Wolf, *Selling Free Enterprise: The Business Assault on Labor and Liberalism* (Champaign: University of Illinois Press, 1994).

[12]*Public Relations Primer for the Drug Industry* (Washington, DC: American Pharmaceutical Manufacturers Association, 1953)

[13]M. Woodward, "The Facts Behind the Story: Pharmaceutical Public Relations," *Bulletin of the Medical Library Association* 46, no. 1 (1958): 53–59.

[14]The Health News Institute (HNI) defined public relations as "the management function which evaluates public attitudes, identifies the policies and procedures of an individual or an organization with the public interest and executes a program of action to earn public understanding and acceptance." In M. Woodward, "The Facts Behind the Story: Pharmaceutical Public Relations," *Bulletin of the Medical Library Association* 46, no. 1 (1958): 53–59. The assistant executive director of the HNI described his job as being to "present a friendly and true picture" of a "high type industry and a high type profession" (p. 55). When faced with someone "a little hot under the collar about a problem," he said, his firm "transpose[s] that problem so that it doesn't sound quite as bad or look quite as bad . . . by the time it gets to the other party or parties concerned, it isn't a problem anymore" (p. 56). "The press," he noted, "is becoming more and more cooperative with us all the time" (p. 58). This activity served multiple audiences: in addition to addressing the special concerns of physicians and pharmacists, and of consumers of prescription and nonprescription pharmacy products, it also served as an arena for the industry to lobby against perceived political threats. As Mickey Smith explained in his 1968 textbook of pharmaceutical marketing, public relations occupied a distinct sphere from product promotion, "much involved with 'image' creation and in the drug industry, it must be admitted, most of these activities have been defensive in nature—aimed at combating bad publicity or answering the charges of a Congressional Investigation." See M. C. Smith, *Pharmaceutical Marketing* (Philadelphia, PA: Lea & Febiger, 1968), 315.

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[20]Palumbo and Mullins, "Development of Direct-to-Consumer Prescription Drug Advertising Regulation," 428.

[21]L. R. Bradley and J. M. Zito, "Direct to Consumer Prescription Drug Advertising," *Medical Care* 35, no. 1 (1997): 86–92.

[22]Palumbo and Mullins, "Development of Direct-to-Consumer Prescription Drug Advertising Regulation," 423.

[23]For example, see L. M. Schwartz, S. Woloshin, and H. G. Welch, "Communicating Drug Benefits and Harms With a Drug Facts Box: Two Randomized Trials," *Annals of Internal Medicine* 150, no. 8 (2009): 563–564; J. Avorn and W. H. Shrank, "Communicating Drug Benefits and Risks Effectively: There Must Be a Better Way," *Annals of Internal Medicine* 150, no. 8 (2009): 563–564.

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The Role of Corporate Credibility in Legitimizing Disease Promotion

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

Increasingly, a strand of public health discourse has diverged from traditional "risk" discourse, which tends to draw attention to individual or community-level behavior, to explicitly highlight the roles played by the "supply side": corporations whose activities create or contribute to ill health.[1–4] Numerous industries have been identified as "antihealth" because of the effects of their products or activities, including the alcohol, chemical, firearms, food, oil, automobile, and tobacco industries.[5–10] Their continued operation depends, in part, on achieving and maintaining corporate "credibility"; without it, companies may face regulatory constraints, political disadvantage, and public disgrace. If credibility problems are severe, a corporation might ultimately lose its license to operate.

Researchers have examined how various industries attempt to build credibility by, for example, creating image-building campaigns or imposing self-regulation.[6,9,11,12] However, no previous studies have analyzed how any particular industry conceptualizes corporate credibility, how it relates to other concepts such as "responsibility," and whether the public shares corporate interpretations of credibility. We addressed this gap by examining the tobacco industry's conceptualizations of credibility across time and across companies. Our analysis has implications for public health efforts to challenge other industries' health-damaging practices.

METHODS

Litigation against the tobacco industry has resulted in the release of internal industry documents.[13,14] An electronic repository at the University of California, San Francisco, houses scanned PDF versions of more than 8 million documents[15]; full-text searches of word combinations can be con-

Source: McDaniel, P. A., & Malone, R. E. (2009). The role of corporate credibility in legitimizing disease promotion. *American Journal of Public Health, 99*(3), 452–461.

ducted. We used a snowball approach in our searches, beginning with the term *credibility*, which resulted in more than 44000 hits, many of which were unrelated to our topic of interest. We used Boolean operators (i.e., "credibility AND tobacco industry," "credibility NOT marketing") to narrow our search. We used retrieved documents to identify more specific search terms, including names of credibility projects (e.g., "Project Breakthrough"), names of employees associated with credibility projects, and file locations. This iterative process resulted in 850 documents, which we narrowed to 486, spanning 1958 to 2002.

To develop this interpretive account, P.A.M. reviewed all documents, and both authors reviewed selected key documents. Together, we compared and contrasted concepts of credibility across time and across companies. We took detailed notes and asked the following kinds of questions: (1) What types of language or related concepts do tobacco companies use to talk about credibility? (2) What assumptions about the concept of credibility are evident in industry credibility projects? (3) Do others outside of the industry use the same language or make the same assumptions about credibility? (4) Why do tobacco companies regard credibility as important, and are there particular events that stimulate credibility "crises"? We relied on iterative reviews of the documents and our notes to identify and evaluate common themes and "dusters of meaning."[16]

RESULTS

Since at least 1967, tobacco manufacturers have noted that they lacked credibility with the American public, largely because of their position that cigarettes had not been proven to cause disease.[17,18] Starting in the 1970s, surveys consistently showed that most Americans believed that the industry knew smoking was dangerous but would not admit it.[19] Tobacco companies considered their lack of credibility a threat to nearly every aspect of their business, including public acceptance of their right to exist.

Despite the nearly 45-year time span of documents reviewed, we found little variation in tobacco companies' conceptualizations of credibility until the late 1990s. We also found little variation across companies, most likely because credibility was an industry-wide problem often managed by the industry's lobbying organization, the Tobacco Institute.

Credibility as Perception

Credibility is formally defined as "being worthy of belief or confidence."[20] By contrast, the US tobacco industry regarded credibility as largely a matter of *inspiring* belief or confidence.[21] This process was linked to perception or, more specifically, to changing perception. For example, RJ Reynolds' Richard Kampe observed in 1989: "[c]redibility is perception, and we can change the way we are perceived."[22] Altering public perception of the tobacco industry and tobacco issues, rather than fundamentally changing industry behavior, appeared to be the implicit goal of many industry credibility-building projects.

One way of altering public perception was to claim public *misperception* about the industry. In 1990, RJ Reynolds and other companies altered their official views on smoking and disease, acknowledging that smoking was a "risk factor" in (but not a cause of) certain (unspecified) diseases.[23] RJ Reynolds framed its new position as long-held, suggesting that the public had misperceived the company's views.[24] Brown and Williamson took a similar approach in 2001, arguing that its position on the causal relation between smoking and disease had been misinterpreted as denial.[25]

A related strategy was to challenge public perception of the industry through "shock" tactics. A 1996 Philip Morris manual advised public speakers that increasing credibility depended on using "mind openers," saying the opposite of what an audience expected, such as "[c]hildren should not smoke."[26] The audience would thus "be more willing to listen to your other message points."[26]

Tobacco manufacturers explored public postures that would enhance their efforts to alter perceptions of the industry. These included demonstrations of "caring/empathy"[27] and the appearance of sincerity (convincing the public that "the industry sincerely believes the primary issue [whether smoking caused disease] is an open question").[28] The appearance of change also was important. The Tobacco Institute determined from a social science literature review: "[i]f it appears that a low credibility source has changed its ways and is acting differently than in the past, then credibility may be enhanced."[21]

Credibility Versus Truth

A review of rejected credibility-building projects proposed by tobacco industry consultants suggests that truth did not play a central role in tobacco industry conceptualizations of credibility. In 1980, Compton

Advertising recommended that the industry appoint outside experts to commission a panel of independent scientists to examine all smoking and disease research and publicize and agree to be guided by the findings.[29] Instead, the Tobacco Institute hired another firm whose credibility-building recommendations—associating with credible spokespeople, relating the industry's good deeds, and attacking industry critics' credibility—were more consistent with the goal of enhancing the public's perception of tobacco industry credibility.[30,31]

A 1996 credibility-building strategy proposed by Philip Morris consultant Smith Worldwide also emphasized impartiality and truth over perception.[32] The plan called for Philip Morris to "move beyond lip service" by funding a youth smoking prevention program over which it had no control or input. Philip Morris did fund a youth smoking prevention program developed by the national 4-H club, but Philip Morris retained control, with company representatives serving on the program's design committee.[33,34]

Credibility, Responsibility, and Reasonableness

Tobacco companies frequently invoked the concept of *responsibility* when discussing credibility. Sometimes, they regarded demonstrations of corporate responsibility (e.g., corporate philanthropy) as a route to credibility, primarily by publicizing these good deeds.[35–41] In other instances, being perceived as responsible and credible were dual goals.[42,24,43,44]

However defined, the goal of being regarded as responsible was to dispel the view of tobacco companies and their employees as "conscienceless killers" who placed profits before public welfare.[45] One of Philip Morris's long-term goals was "normalization"—convincing the public that it was "just another Fortune 500 Co[mpany]."[46,47]

American tobacco companies linked credibility and responsibility to *reasonableness*. The Tobacco Institute's William Kloepfer commented: "We have made a point of saying things in a moderate, *reasonable* way [italics added]."[48] The desired outcomes of voluntary initiatives Philip Morris considered in 1994 were "added credibility with opinion leaders and recognition of Philip Morris as a company with *reasonable* solutions to end the hysteria [italics added]."[49] As the last part of the quote suggests, one aspect of adopting the label "reasonable" was to suggest that the industry's opponents (or their ideas) were "unreasonable," "extreme," or "emotional."[50,51]

In recent years, Philip Morris has incorporated "reasonable" and "responsible" into its Philip Morris in the 21st Century (PM21) credibility

and image-building campaign.[12,52,53] The company advocated various "reasonable" tobacco policies, including US Food and Drug Administration (FDA) regulation of tobacco.[54] PM21 also involved repositioning critics as "extremists"[55] to "build an audience in the middle, a constituency for reason, that will create the political and social environment for policies that give us the freedom to prosper."[56,57]

Credibility as Leverage

In the view of American tobacco companies, credibility gained in relation to one issue could be leveraged against others.[58,59,60] Credibility projects typically did not address the main source of the tobacco industry's credibility problem: its position on smoking and disease. Instead, according to the Tobacco Institute, industry programs such as "Responsible Living for Teens," a youth smoking prevention initiative, "sow[ed] seeds for the credibility we so badly need."[44] Ideally, once obtained, credibility would function as a "platform" supporting industry statements regarding smoking and disease,[61,62] a more positive industry image,[63] or an industry reputation as a "credible participant" in tobacco policy discussions.[58]

The view of credibility as leverage also was evident in tobacco companies' estimation of the utility of third-party allies.[33] Enlisting third-party allies was a common theme of tobacco industry credibility-building efforts. Previous research has established the particular importance of scientists, firefighters, educators, African American organizations, and business owners as tobacco industry allies, helping convince policymakers and the public that the industry's perspective on various tobacco issues was valid or sensible (or not motivated solely by self-interest).[64,33,65–69]

Accordingly, tobacco company credibility-building projects typically targeted the media, opinion leaders, or scientists. The media were the conduit through which industry views reached the public,[70] whereas opinion leaders—business and community leaders, government employees, and other politically active adults[71,72]—helped enlist legislator support for industry positions.[73] Scientists were key to preserving industry access to scientific consultants, journals, and academic institutions and influence over regulatory proceedings.[74,75]

The "Public's Truth"

One element of tobacco companies' credibility approach appeared to change in the late 1990s—credibility as truth. Tobacco industry credibility was at

an all-time low because of waves of negative publicity, including the FDA's intention to regulate nicotine as a drug and cigarettes as drug-delivery devices, state lawsuits against tobacco companies to recover Medicaid costs, and releases of damaging internal industry documents.[76,77]

During 1997 to 2003, major US tobacco companies finally told a version of the "public's truth," acknowledging on corporate Web sites (with carefully parsed language) that smoking caused disease.[78] Perhaps a "tipping point"[79] had been reached in the companies' quest for credibility, such that truth, or some semblance of it, was thought to be required. A Florida jury's award of $145 billion in punitive damages against major US tobacco companies in 2000 (overturned on appeal) was likely a key factor.[12,80,81]

But tobacco companies' belated acknowledgment of this truth about their products did not result in greater credibility. National polls conducted in 2003 to 2005 found that only 3% to 4% of Americans regarded tobacco companies as honest and trustworthy.[82] Public skepticism appears well-founded because what tobacco companies admit on their Web sites has not reflected comprehensive corporate changes: in court, tobacco company representatives continue to deny that smoking causes disease.[80,78,83(p1635)] A recent federal ruling against tobacco company defendants determined that many of their Web site statements about smoking and health were "false and misleading."[83(p886)] These findings suggest that the tobacco industry's apparent acknowledgment of the "public's truth" about smoking and disease does not represent an authentic break with its traditional conceptualization of credibility as perception.

The public, however, may be unaware of the nuances of tobacco companies' litigation strategies or Web site admissions. Instead, public skepticism might be explained, in part, by tobacco

companies' long history of denials, which, according to Philip Morris's public relations firm, made it difficult for Americans to believe that "tobacco companies are suddenly not lying anymore."[84] The public also does not conceptualize credibility in the same manner as do tobacco companies: for the public, an admission of guilt is a key means of building trust.

Moreover, the public does not regard responsibility in the same manner as do tobacco companies. Instead of viewing responsibility as reasonableness, market research showed that participants regarded responsibility on the part of tobacco companies as a combination of acting responsibly (by, for example, reducing advertising or creating less harmful products) and accepting responsibility (telling the truth about and apologizing for past behavior, making amends somehow, or getting out of the tobacco business

altogether).[85–87] Some rejected the idea that tobacco companies could ever be considered responsible, because they manufactured harmful products.[84,85,86]

In addition, the public does not link responsibility and credibility. Instead, the public is willing to regard tobacco companies as acting responsibly in certain respects, while continuing to view them as untrustworthy. Philip Morris, for example, found that "People can hold two beliefs about P[hilip] M[orris] C[ompanies] simultaneously; that they contribute to communities and that they are a deceitful manufacturer of tobacco products."[88] A similar principle seemed to be operating among focus group participants who assured Philip Morris's market researchers in 2000 that a company that was deemed neither "good" nor "admired" could still be seen as acting responsibly.[86]

Philip Morris, like other tobacco companies, chose not to explicitly acknowledge or apologize for its history of deception. Instead, as part of PM21, Philip Morris representatives hinted at unspecified errors (e.g., "past confrontations with government and antismoking advocates").[89] Philip Morris speakers alluded to (but did not apologize for) the industry's history of deception, describing Philip Morris as now "more open and honest," a statement implying that Philip Morris had always been somewhat open and honest rather than fundamentally dishonest.[90,91] The goal, according to PM21 planners, was to improve public perception of Philip Morris by "being *seen* as 'coming clean' on tobacco issues [italics added]."[40]

However, building a solid foundation of credibility was challenging. In 2001, after 4 years of PM21, Philip Morris's credibility was damaged when news stories reported that it had spent $150 million to advertise philanthropy projects of $115 million; it was also hurt by a story indicating that "light" cigarettes were no safer than ordinary cigarettes and that the industry had long known this.[92,93] Consumer research determined that these "attacks" resulted in a significant decline in Philip Morris's credibility and responsibility ratings, indicating that "the foundation of the PM21 campaign . . . does not hold up against attacks on the company's credibility."[88,92]

DISCUSSION

Our study had limitations. The size of the archive means that we may not have retrieved every relevant document. Some may have been destroyed or concealed by tobacco companies[94]; others may never have been obtained through litigation. However, as the first study of how a corporate entity understands and open rationalizes credibility, this research shows the multidimensional nature of the concept.

As public health explores more explicitly how to address corporate influences on health in an era when transnational corporations have unprecedented power, this study suggests that continuing to undermine corporate credibility is strategically important. The tobacco industry's credibility-building efforts failed repeatedly, including its belated acknowledgment that smoking causes disease. Industry delegitimization campaigns, such as the California Tobacco Control Program's media efforts and the American Legacy Foundation's "truth" campaign, may have "inoculated" the public against industry attempts to build credibility.[95–97] These types of delegitimization efforts have several other notable effects, including reductions in tobacco use[98–101] and greater smoker support for government regulation of the industry.[102] Chapman and Freeman[103] have argued that tobacco control programs should monitor attitudes toward the tobacco industry, noting that negativity toward smoking and the tobacco industry contributes to a climate supportive of tobacco control policies and programs. These findings suggest that public health strategies to reduce the credibility of disease-promoting corporations can be effective in promoting cultural change.

Another reason for the failure of the tobacco industry's credibility-building efforts was the fundamental mismatch between public and tobacco industry conceptualizations of credibility. By calling corporations to account for behavior that defies public expectations about truth telling and responsibility, public health advocates can address structural, supply-side dynamics of corporate disease promotion and undermine the implicit social contract that allows corporations to continue profiting from these activities.[9]

Another topic for public discussion is the introduction of stronger disincentives for profiting from disease-producing products. Under current US law, corporate entities must maximize profits for shareholders, who, aside from a small but dogged shareholder activist movement, have largely been indifferent to the fate of consumers harmed by products such as tobacco.[69,104–106] Structural reform, such as converting disease-promoting industries to a nonprofit model, has been proposed for the tobacco industry.[107,108] Although such notions may sound politically infeasible in the current climate, now-commonplace public health policies, such as smoke-free workplaces, were once considered similarly impossible to achieve. Such reform could remove perverse incentives in the existing situation and allow tobacco companies to be authentically credible entities by providing incentives for reducing rather than increasing consumption.[107,108]

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Life and Health Insurance Industry Investments in Fast Food

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Life and health insurance firms profess to support health and wellness, but their choice of financial investments has raised doubts. We recently noted their investments in the tobacco industry,[1] but few data on insurance company investments in other potentially unhealthy products exist. We investigated the insurance industry's investments in fast food.

Unlike tobacco, which is inarguably harmful and addictive, fast food can be consumed responsibly. However, most fast food has high energy density and low nutritional value.[2] Indeed, fast food consumption is linked to obesity and cardiovascular disease, 2 leading causes of preventable death.[3–5] The industry markets heavily to children and often builds restaurants within walking distance of schools.[6,7] Children who live near fast food restaurants consume fewer servings of fruits and vegetables, drink more high-calorie soft drinks, and are more likely to be overweight.[7,8] In addition, fast food restaurants are more prevalent in Black and low-income neighborhoods, likely contributing to the burden of obesity among these groups.[9] And, finally, the fast food industry exacts a heavy environmental toll.[2]

In 2009 Americans were expected to spend $185 billion on fast food, and consumers globally were expected to spend $481 billion.[10] In addition, there has been a greater than 5-fold increase in fast food consumption by children and adolescents aged 2 to 18 years between 1977 and 1995.[7]

In response, many municipalities in the United States have moved to control fast food. In 2008 Los Angeles restricted the construction of new fast food restaurants and several other cities have used zoning restrictions

Source: Mohan et al. (2010). Life and health insurance industry investments in fast food. *American Journal of Public Health, 100*(6), 1029–1030.

to similar effect. In addition, San Francisco and New York have passed laws that require restaurants to visibly post the nutritional content of foods.[11–14]

Given the potential disconnect between insurers' financial investments and their professed missions, we sought to determine the extent to which insurance companies own stock in the fast food industry.

METHODS

We used shareholder data from the Icarus database, which draws upon Securities and Exchange Commission filings and reports from news agencies, to assess health and life insurance firms' shareholdings in the 5 leading publicly traded fast food companies. Our data reflect the most up-to-date information available. We obtained stock prices and market capitalization data from Yahoo! Finance (http://finance.yahoo.com). All data were accessed June 11, 2009.

RESULTS

Major insurers own $1.88 billion of stock in the 5 leading fast-food companies, representing 2.2% of total market capitalization of these companies on June 11, 2009 (**Table 2-1**). United States-based Prudential Financial, an investment firm that also provides life insurance and long-term disability coverage, has fast food holdings of $355.5 million, including $197.2 million in McDonald's, $43.7 million in Burger King, and $34.1 million in Jack in the Box. United Kingdom-based Prudential PLC offers life, health, disability, and long-term care insurance and owns $80.5 million in stock of Yum! Brands, owner of KFC, Pizza Hut, Taco Bell, and others. Standard Life, also based in the United Kingdom, offers both life and health insurance and owns $63 million of Burger King stock.

Canada-based Sun Life and Manulife offer life, health, disability, and long-term care insurance. Sun Life owns almost $27 million of Yum! Brands stock, and Manulife owns $146.1 million in fast food stock, including a $89.1 million stake in McDonald's. Holland-based ING, an investment firm that also offers life and disability insurance, owns $12.3 million in Jack in the Box, $311 million in McDonald's, and $82.1 million in Yum! Brands stock.

Guardian Life, MetLife, New York Life offer life, health, disability, and long-term care insurance. Northwestern Mutual and Massachusetts Mutual Life Insurance Company offer life, disability, and long-term care insurance. All of these companies are invested in the fast food industry to varying degrees. Northwestern Mutual's stake is the biggest, with its total investments

Table 2-1 Health and Life Insurance Industry Holdings in the Fast Food Industry, by Fast Food Company: United States, June 11, 2009

Insurance Company	*Jack in the Box Holdings, Millions $*	*McDonald's Holdings, Millions $*	*Burger King Holdings, Millions $*	*Yum! Brandsa Holdings, Millions $*	*Wendy's/ Arby's Group Holdings, Millions $*	*Total Holdings, Millions $*
Prudential PLC				80.5		80.5
Prudential Financial	34.1	197.2	43.7	80.5		355.5
Massachusetts Mutual	23.1	267.2	58.8	17.4		366.5
New York Life	2.4					2.4
Northwestern Mutual	40.9	318.1		63.2		422.2
Sun Life				26.8		26.8
Standard Life			63.0			63.0
ING	12.3	311.7		82.1		406.1
Manulife		89.1		53.7	3.3	146.1
Guardian Life	7.2				9.5	16.7
MetLife					2.2	2.2
Total	120.0	1183.3	165.5	404.2	15.0	1888.0

in excess of $422 million, including $318.1 million in McDonald's alone. Massachusetts Mutual owns more than $366 million of fast food stock, with its single biggest investment being $267 million in McDonald's.

DISCUSSION

Our data show that life and health insurers are substantial investors in the fast food industry. Although fast food can be consumed responsibly, the marketing and sale of products by fast food companies is done in a manner that undermines the public's health. Though investing in companies whose products undermine health while selling life or health insurance may seem inconsistent, there are several potential explanations. The first is that the practice has net profitability: the return on investment in fast food companies more than offsets the potential financial liability associated with their policyholders consuming fast food. A second possible explanation is that insurers are unaware of the social impact of their investments because there

has been little attention paid to the issue historically. A third possible explanation is that because insurers tend to be large organizations, one division (e.g., claims and underwriting) may be unaware of the activities in another (e.g., investments). And, finally, some of the larger investment companies have subsidiaries whose investments are made in the name of the parent company, even though the parent company might have little actual oversight of its subsidiaries' investments.

From our perspective, insurance companies have 2 ethical options. The first is to divest themselves of holdings in fast food companies as well as other industries that have a clearly negative public health impact. Socially responsible investment funds have shown that profits are not incompatible with social good.

A second option is that insurers could mitigate the harms of fast food by leveraging their positions as owners of fast food companies to force the adoption of practices consistent with widely accepted public health principles. Such moves could include encouraging companies to improve the nutritional quality of their products, reduce calorie density, serve smaller portions, and change marketing practices. To maximize their impact, insurers might turn over their proxy votes to an independent nonprofit organization that could pool votes in a way that effects meaningful change.

Health reforms in the United States would likely expand the reach of the insurance industry. Canada and Britain are also considering further privatization of health insurance. Our article highlights the tension between profit maximization and the public good these countries face in expanding the role of private health insurers. If insurers are to play a greater part in the health care delivery system they ought to be held to a higher standard of corporate responsibility. This responsibility includes aligning all of their resources—including financial investments—in ways that improve health or, at the very least, do not harm it.

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Food Safety and Food Security: A Matter of Public Health

Marion Nestle

We know how to produce safe food. In the United States, for example, standard food safety procedures are known as Hazard Analysis and Critical Control Point with Pathogen Reduction (HACCP). They were designed for the space agency to make sure that astronauts did not become ill under conditions of zero gravity. HACCP is difficult to pronounce and remember but its principles are simple: identify places in the chain of food production where hazards can occur, take steps to prevent the hazards, monitor to make sure the steps were taken, and test for pathogens to make sure the system is working properly. That HACCP rules are not required or followed by everyone involved in food production and service, from farm to table, is a result of politics and resistance to intervention by food producers. When they are not followed, foods cause more illness and death than is necessary.

In the United States, food safety regulation is largely divided between two agencies: the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA). The USDA is in charge of meat and poultry safety, and shares regulation of egg safety with the FDA. The primary responsibility of the USDA is to promote American agricultural production and its ties to agribusiness are historically strong and deep; this agency receives 80% of government funding for food safety oversight even though it regulates only about 20% of the food supply. In contrast, the FDA is in charge of 80% of the food supply but receives 20% of the funding. Since the mid-1990s, the

Source: Reprinted with permission from Marion Nestle, Paulette Goddard Professor of Nutrition, Food Studies, and Public Health at New York University (www.foodpolitics.com). This commentary is based on the concluding chapter of Marion Nestle's *Safe Food: Bacteria, Biotechnology, and Bioterrorism* (2003). It originally appeared in the quarterly newsletter, *BIJA: The Seed* (2007, Volume 45, pp. 34–37), which is published in India by the Research Foundation for Science, Technology, and Ecology (RFSTE) and its program Navdanya. *BIJA* is edited by the renowned environmentalist and founder of RFSTE/Navdanya, Dr. Vandana Shiva. For information about the work of Navdanya, visit the website at www.navdanya.org.

USDA has required HACCP for meat and poultry, beginning at the slaughterhouse; no rules apply to farm production. The FDA requires HACCP only for fruit juices, sprouts, and shell eggs. Indeed, eggs are the only American food produced under HACCP rules, from farm to table. Everything else is voluntary. The result is a food safety system with many gaps that leave the food system vulnerable to accidental and deliberate contamination.

The terrorist attacks of September 2001 (what the United States calls 9/11) had profound effects on issues related to food safety and food security. They shifted the common use of the term food security—protection against hunger and food insufficiency—to mean protection of the food supply against bioterrorism. They raised alarms about the ways food and biotechnology could be used as biological weapons. They encouraged more forceful calls for reorganizing the current system of food safety regulation—widely agreed to be fragmented and inadequate—into a single oversight agency that combines the functions of USDA and FDA. Finally, they focused attention on the need for a national public health system capable of responding to emerging problems in food safety and security.

FOOD SECURITY AS SAFETY FROM BIOTERRORISM

Prior to 9/11, food security in the United States had a relatively narrow meaning—reliable access to adequate food—that derived from criteria for deciding whether people were eligible to receive welfare and food assistance. The international definition is broader, however. Based on the United Nations' 1948 Universal Declaration on Human Rights, it encompasses the right to a standard of living adequate for health and well-being, including food security. This right implies reliable access to food that is not only adequate in quantity and quality, but also readily available, culturally appropriate, and safe. With respect to safety, the Geneva Convention of August 1949, an international agreement on the protection of civilians during armed conflict, expressly prohibited deliberate destruction or pollution of agriculture or of supplies of food and water. These broader meanings derived from work in international development, where it was necessary to distinguish the physical sensation of hunger (which can be temporary or voluntary), from the chronic, involuntary lack of food that results from economic inequities, resource constraints, or political disruption.

After 9/11, the meaning of food security changed to indicate protection of the food supply against bioterrorists. Officials soon identified safe food and water as key components of a new Department of Homeland Security,

which oversees the work of numerous federal bureaucracies established to protect the nation's borders, nuclear power plants, and public facilities; fight bioterrorism; obtain intelligence; and protect food and water supplies.

FOOD AS A BIOLOGICAL WEAPON

After 9/11, Americans became aware of the possibility that terrorists might try to poison food and water supplies. Prevention of such actions is exceptionally difficult because so many agents can be used as biological weapons and can be delivered in so many ways and in so many places. The increasing consolidation and centralization of the American food supply only increases vulnerability to inadvertent or deliberate contamination. This was amply demonstrated in 2006 by spinach accidentally contaminated with a deadly form of *E. coli* and in 2007 by adulteration of Chinese wheat gluten used in pet foods. The low rate of inspection of imported foods is an especially weak link in the chain of protection. Prior to 9/11, the FDA inspected roughly 2% of imported food shipments. As a result of political pressures on the FDA to regulate foods less forcefully, the agency now inspects 1% or less of such shipments.

One particular concern is the role of biotechnology in developing weapons of bioterrorism. The research methods used to transmit desired genes into plants could easily be adapted for nefarious purposes: creating pathogenic bacteria resistant to multiple antibiotics or able to synthesize lethal toxins, or superweeds resistant to herbicides. As more than half of the soybeans grown in the United States are bioengineered to resist the herbicide Roundup, genetic mischief could do a great deal of damage.

Public health experts concerned about such possibilities cite precedents, ancient and modern, for the use of poisoned food and drink to achieve political ends. These date back to the time when the Athenians forced Socrates to drink hemlock. There are plenty of modern examples as well, mainly concerning deliberate sabotage by dissatisfied factory workers. A 2001 review of these and international episodes described the deliberate poisoning of water at German prisoner-of-war camps with arsenic, of Israeli citrus fruit with mercury, and of Chilean grapes with cyanide, suggesting that no food or drink is invulnerable to such contamination.

In the United States, the single known case of food poisoning designed to achieve political goals occurred in 1984. It involved the deliberate sprinkling of *Salmonella* onto restaurant salads and cream pitchers by followers of the Indian guru Bhagwan Shree Rajneesh. The Rajneesh group had established

communal headquarters in a small rural town in Oregon but came into conflict with neighbors over issues related to land use and building permits. To keep local residents from electing county officials who might enforce zoning laws, members of the group tried to make people ill with *Salmonella*. They succeeded in sickening at least 750 people. This incident demonstrated that biological agents were easy to use and to obtain: the commune clinic had simply ordered them from a biological supply house. It also revealed the difficulties of investigating such incidents. Investigators, unable to discern a rationale for deliberate poisoning, were only able to identify the perpetrators when one confessed.

Experts disagree about the degree of danger posed by food bioterrorism and the extent to which countries should devote resources to guard against it. Some believe that food supplies are too diffuse to permit terrorists to do much harm and that water supplies are relatively invulnerable for reasons of dilution, chlorination, sunlight, and filtration. They greatly prefer a public health approach, which means identifying the most important risks and determining how they can best be addressed. They emphasize the greater degree of harm caused by foodborne microbes, tobacco, and inappropriate use of antibiotics in animal agriculture than by bioterrorism, and suggest that it makes more sense to apply limited resources to existing problems rather than to a much smaller—although perhaps more frightening—risk. For those who share this view, national preparedness against food bioterrorism inappropriately diverts resources from dealing with more compelling food safety problems.

UNIFYING THE FOOD SAFETY SYSTEM

One repeated suggestion to improve food safety oversight has been to combine the safety functions of the USDA and FDA into a single unit dealing with all foods, from farm to table. Soon after 9/11, officials throughout government agencies called on Congress to fund improvements in food safety and public health systems, especially those involving disease surveillance, food production quality control, food security (in the anti-bioterrorism sense), and inspection of imported foods. Many thought that one positive result would be increased funding for food safety surveillance and, indeed, Congress doubled the FDA's inspection capacity over imported food—from 1% to 2% of the total entering the country—but these improvements did not last. Although the FDA asked for authority to issue recalls, to require food companies to take steps to prevent sabotage, and to demonstrate the

traceability of ingredients and products, it was granted only limited authority to do so. Food companies strongly opposed such measures. Instead, the FDA and USDA issued voluntary guidelines. The many food safety problems surfacing in 2006 and 2007 indicate the unreliability of voluntary efforts.

FOOD SECURITY AS A PUBLIC HEALTH ISSUE

One additional reason why the United States is especially vulnerable to bioterrorism is its neglect of public health "infrastructure"—the systems and personnel needed to track and prevent disease. The focus on homeland security may be politically necessary, but it diverts attention and resources away from basic public health needs. Neither domestic or international actions are aimed at addressing "root causes"—the underlying social, cultural, economic, or environmental influences that might encourage people to become engaged in terrorist activities. From the perspective of public health, bioterrorism may never entirely disappear, but it seems less likely to be used as a political weapon by people who have ready access to education, health care, and food, and who trust their governments to help improve their lot in life. If, as many believe, terrorism reflects frustration resulting from political and social inequities, it is most likely to thrive in countries that fail to provide access to basic needs, or that give lesser rights to ethnic, religious, or other minority groups. In such situations, public health can be a useful means to strengthen society as well as to avert terrorism.

Because a healthy population is an essential factor in economic development, the health effects of globalization—positive and negative—become important concerns in considerations of food safety and security. Globalization has improved the social, dietary, and material resources of many populations, but it has also heightened economic and health inequities. Globalization brings safe drinking water and antibiotics, but it also brings pressures to reduce food safety standards, protect the intellectual property rights of corporate patent owners, and accept the marketing of high-profit "junk" foods. With these ideas in mind, it makes sense to engage in short- and long-term strategies to prevent terrorism and its adverse health consequences: address poverty, social injustice, and disparities; provide humanitarian assistance; strengthen the ability of public health systems to respond to terrorism; protect the environment and food and water supplies; and advocate for control and eventual elimination of biological, chemical, and nuclear weapons. It makes sense for societies to ensure safe and secure food for all citizens for humanitarian as well as political reasons.

ENSURING SAFE FOOD

Because food safety is a political problem inextricably linked to matters of commerce, trade, and international relations, ensuring food safety requires political action. Everyone involved in food production, distribution, preparation, and service—individuals, producers, food companies, governments—needs to take responsibility for food safety and food security. Individuals must learn to handle and cook foods properly. Food companies should institute and follow HACCP rules, disclose production practices, take responsibility for lapses in safety, and tell the truth about matters of public interest. The government should require food companies to follow food safety procedures and could invest more in public health. On the international level, governments should support treaties that promote food safety, environmental protection, and the right to food, as well as agreements to stop producing biological weapons, genetically modified or otherwise. Overall, they should be actively involved in international policies to promote health and food security as human rights for everyone, everywhere. Food safety and food security are nothing less than indicators of the integrity of democratic institutions. They are well worth the political commitment of individuals, societies, and governments.