

## CEASE-AND-DESIST REGULATION AND REINTEGRATIVE SHAMING: THE CASE OF THE DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS

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### ABSTRACT

Adopting aspects of John Braithwaite's "reintegrative shaming" theoretical framework, the authors evaluate the effectiveness of the Food and Drug Administration's (FDA's) "cease-and-desist" regulation of the Direct-to-Consumer Advertising (DTCA) of prescription drugs in the United States. This is accomplished in two ways: First, the authors examine the legislative record concerning drug marketing in the United States, drawing attention to how the inception of the FDA and the mode of "cease-and-desist" regulation predict many of the agency's problems in regulating DTCA. Second, the authors analyze the regulatory practices of the Division of Drug Marketing and Communications (DDMAC)—the division of the FDA that is responsible for DTCA oversight. Drawing attention to the ways in which pharmaceutical companies repeatedly violate FDA policy, the authors conclude that "cease-and-desist" regulation severely limits DDMAC's ability to enforce compliance. Indeed, the examples of repeated violations of FDA policy may imply that such violations are an expected part of DTCA campaigns. The authors conclude with a model that outlines how reintegrative shaming may be applied to DTCA regulation.

### INTRODUCTION

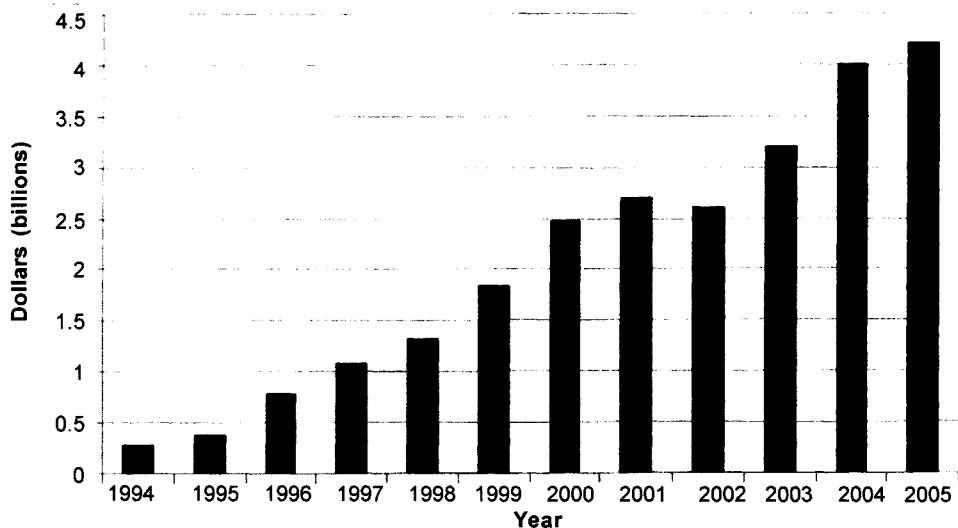
In his analysis of how firms respond to regulatory measures in the marketplace, John Braithwaite (2002 19) states: "The hard question is how do we decide when to punish and when to persuade." To understand how truly daunting this question is, one may look to the current regulation of broadcast advertising in the United States—a regulation structure that has been described as "industry-friendly" (Batra, Myers, & Aaker 1996). Commercial interests in the marketplace have consistently been favored over consumer interests through the successful legal defense of First Amendment rights (Beales & Muris 1993; Gartner 1989). This is exemplified by the U.S. government's 1997 allowance of the Direct-to-Consumer Advertising (DTCA) of prescription medications. Policy discussions have shifted from the feasibility of DTCA to how the Food and Drug Administration (FDA) can control DTCA content. In short, the FDA asserts this control by responding to DTCA violations that have been discovered in the marketplace with a "cease-and-desist" order to a pharmaceutical company. A few scholars have argued that "cease-and-desist" regulation has limited effectiveness. Gilmore (1991) argues that much of the FDA's authority over direct-to-consumer marketers is illusory, and the U.S. General Accounting Office (GAO) (2002) concludes that the FDA's regulatory power is weakened by a variety of organizational shortcomings.

Adopting a "reintegrative shaming" frame-

work (Braithwaite 1989, 2000, 2002), we evaluate the effectiveness of the FDA's regulation of DTCA content. There are two principles of reintegrative shaming that are integral to our analysis: 1) the effective communication of shame between a regulatory body and an offender; and 2) the proscription for methods by which the offender can reintegrate into social life and "make amends" to those who have been harmed. In order to show the many social problems associated with DTCA we explore its history in the United States and then list several examples of how pharmaceutical companies subvert federal DTCA guidelines. First, we investigate key aspects of the legislative record concerning drug marketing in the United States, highlighting how the federal government conceded to the interests of the drug industry. We draw particular attention to the inception of the FDA and how its mode of "cease-and-desist" regulation predicts many of the agency's current regulatory shortcomings. In the second section, we focus on the Division of Drug Marketing and Communications (DDMAC)—the division of the FDA that is responsible for the oversight of DTCA. Through examining how pharmaceutical companies violate federal drug advertising policy and the ways in which DDMAC responds to such violations, we argue for the employment of the above reintegrative shaming concepts into the DTCA regulation process.

In order to illustrate the importance of analyzing the regulation of DTCA, it is crucial to

Figure 1: Direct-to-Consumer Advertising Expenditures for Prescription Drugs, 1994-2005



**Notes:** DTCA expenditures from 1994-1997 primarily include print advertisements, as the initial Draft Guidance allowing broadcast media to provide adequate provision for the brief summary requirement was not released until August 1997.

**Sources:** Henry J. Kaiser Family Foundation and the Sonderegger Research Center, 2002. "Trends and indicators in the changing health care marketplace, 2002." Menlo Park, CA.

Kalorama Information, Inc. 2005. "Direct-to-consumer pharmaceutical marketing 2005: controversies continue." April. 114 pps. (<http://www.kaloramainformation.com>)

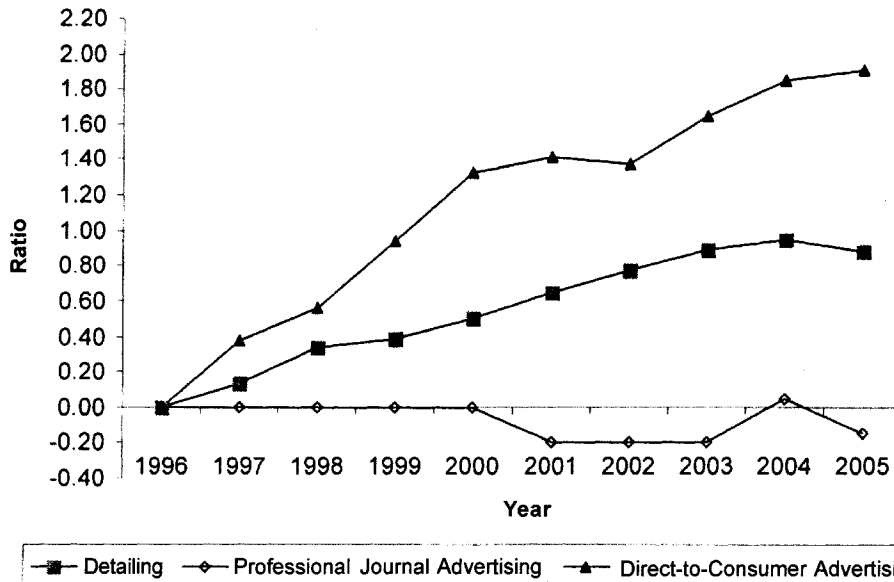
first discuss the prevalence of DTCA in the United States since 1997.

#### DIRECT-TO-CONSUMER ADVERTISING

The United States is one of only two countries<sup>1</sup> in the world to allow DTCA. As it has become a multi-billion dollar annual expenditure for the pharmaceutical industry, it is largely believed that DTCA will remain a permanent fixture in American life. Since the early 1980s, pharmaceutical companies have been keenly interested in advertising prescription drugs through television, radio, and telecommunications. Up until 1997, FDA regulations had made such broadcast marketing infeasible. Though the FDA did not specifically outlaw the direct-to-consumer marketing of prescription drugs, the administration's guidelines required such stringent disclosure of risk information that expenditures on broadcast advertising were financially impossible. This changed in 1997 when the FDA lessened its standards of risk disclosure, making broadcast DTCA a legitimate marketing option for the pharmaceutical industry. Relaxing its restrictions on drug information disclosure, the FDA issued the

Draft Guidance for Industry in August of 1997, which provided a preliminary federal statement about the parameters within which pharmaceutical companies could conduct DTCA through broadcast media. The Draft Guidance was revised slightly in August 1999 into a Final Guidance for Industry and remains the FDA's regulatory framework for DTCA. The relaxation of federal guidelines for DTCA as described in the Final Guidance has been a catalyst for a new era in how prescription drugs are advertised in the United States and has greatly affected doctor/patient relationships.

Prior to the 1997 Draft Guidance, DTCA comprised only a small percentage of prescription drug advertising and was done primarily through print advertisements, where costs were marginal in comparison to broadcast media. As it provided an unprecedented marketing opportunity for the pharmaceutical industry, the publication of the Draft Guidance had an immediate impact on drug advertising expenditures. Figure 1 illustrates how annual DTCA advertising expenditures jumped 1600 percent from \$266 million in 1994 to \$4.25 billion in 2005 (Levitt 2001;

**Figure 2: Proportional Change in Prescription Drug Expenditures by Promotion Type, 1996-2005**

**Sources:** Henry J. Kaiser Family Foundation and the Sonderegger Research Center, 2002. "Trends and indicators in the changing health care marketplace, 2002." Menlo Park, CA.  
 IMS Health, Integrated Promotional Services and CMR. 2004. "Top-Line Industry Data." (<http://www.imshealth.com>).

NIHCM Foundation 2002; Kalorama Information 2005).

In the early 1990s, DTCA represented less than 5 percent of total drug company promotional spending in the United States, but represented 31.8 percent of such expenditures in 2003 (Toop et al 2003). As Figure 2 illustrates, DTCA is the fastest growing promotional expenditure category for the pharmaceutical industry. Five of the top 50 corporations with the highest advertising expenditures for 2004 are pharmaceutical corporations (TNS Media Intelligence 2004). For example, GlaxoSmithKline, which spent slightly more than \$825 million on advertising in 2004, had advertising expenditures larger than AT&T (\$291 million), Campbell's Soup Company (\$274 million), and Coca Cola (\$254 million) combined. In 2002, the German pharmaceutical corporation, Merck and Co., spent \$160 million advertising its now recalled anti-inflammatory drug, Vioxx®—an expenditure that was \$35 million more than PepsiCo spent advertising its namesake soft drink, and more than double what Nike Corporation spent marketing its range of top end shoes (NIHCM

Foundation 2002; TNS Media Intelligence 2004).

Recent studies demonstrate that the expansion of DTCA has had a profound impact upon consumer behavior and doctor/patient relationships. A 1993 consumer awareness survey suggested that 39 percent of Americans had "seen or heard" an ad for prescription medication (Alperstein & Peyrot 1993). By 2000, that number had skyrocketed to ninety-one percent (Henry J. Kaiser Family Foundation and Harvard School of Public Health 2000). Illustrating how increased consumer awareness of prescription drugs impacts interactions between physicians and their patients, Gottlieb (2002) argues that DTCA explains why one-fifth of Americans now ask their doctor about medications they had specifically seen advertised on television. A study by Zachry et al (2002) concludes that the amount of prescriptions written for the antihistamine, Claritin®, and the cholesterol drug, Zocor®—drugs with DTCA expenditures that ranked 3<sup>rd</sup> and 5<sup>th</sup> respectively in 2001—was positively related to these drugs' advertising expenditures. Such conclusions support the assertion that DTCA, as it pro-

Table 1: DDMAC Letter Correspondence to Companies Violating DTCA Regulations

Year	Advertisement Type			Letter Type		Total Letters
	Broadcast	Print	Print & Broadcast	Regulatory	Warning	
1997	9	5	0	13	1	14
1998	9	11	4	24	0	24
1999	5	7	1	11	2	13
2000	12	7	1	19	1	20
2001	7	4	3	13	1	14
2002	5	2	2	9	0	9
2003	3	3	2	6	2	8
2004	5	4	0	7	2	9
2005	2	4	2	5	3	8

Source: U.S. Food and Drug Administration, Center for Drug Evaluation and Research (2005). "Index of Notices of Violation and Warning Letters to Pharmaceutical Companies." (Available at <http://www.fda.gov/cder/warn/>).

motes the awareness of certain illnesses, increases the market for drugs that are designed to treat such ailments. As Conrad and Leiter (2004) discuss, Viagra®, which is used for the treatment of "Erectile Dysfunction," and Paxil®, which is primarily marketed for the treatment of "Social Anxiety Disorder," are two drugs that have become synonymous with the ailments they are marketed to treat.

Interpreting whether or not the impact of DTCA constitutes a burgeoning social problem clearly depends upon perspective. For those sympathetic to the pharmaceutical industry, DTCA is an "opportunity" for consumers to know more about certain drugs and make more informed choices about the medications they take. A 1999 industry "Market Profile" of DTCA, for example, contends that a

survey of consumer attitudes reveals that people appreciate the ability to make their own informed choices, rather than leaving all decision making to institutions and professionals. (Magazine Publishers of America 1999 20)

While confirming that, indeed, DTCA has increased consumer awareness of prescription drugs and their uses, other studies argue that such awareness adversely affects how and what types of drugs physicians prescribe (Perri, Shinde, & Banavali 1999; Steinman 2000). This debate regarding the impact of DTCA upon consumers and the doctor/patient relationship is perhaps best summarized by a February 2002 issue of the *New England Journal of Medicine* which of-

fers two opposing editorials on the subject. The first, written by a member of the Public Citizen Health Research Group contends that

The education of patients—or physicians—is too important to be left to the pharmaceutical industry, with its pseudoeducational campaigns designed, first and foremost, to promote drugs. (Wolfe 2002 526)

Whereas the second, written by a representative of the pharmaceutical industry, argues that

Direct-to-consumer advertising does not replace the physician—patient relationship; its purpose is rather to encourage an informed discussion between patient and physician. (Holmer 2002 528)

While there has been considerable discussion about how DTCA raises, for better or worse, the awareness consumers have about prescription drugs, little has been said about how the federal guidelines for DTCA are enforced.

## THEORY AND METHOD

This study uses two data sources. First, using the historical record of DTCA as data, we chronicle the development of FDA advertising guidelines. Second, in order to supplement our examination of the many ways in which pharmaceutical companies violate DTCA guidelines in the United States, we sample the correspondence (in the form of regulatory letters) between DDMAC and phar-

Table 2: Ranking of Top Violators of DTCA Regulations, 1997-2005

Ranking	Pharmaceutical Company	Number of Letters Sent
1	GlaxoSmithKline	17
2	Schering Corporation	9
3	Pfizer Pharmaceuticals	8
4	Zeneca Pharmaceuticals	7
5	Bristol-Myers Squibb Company	6
6	Eli Lilly Company	5
7	Novartis	4
	Johnson & Johnson Consumer Companies	4
	Hoffman-La Roche Inc.	4
8	Merck & Co.	3
	G.D. Searle & Co.	3
	Vivus, Inc.	3
	Alza Corp.	3
	Boehringer Ingelheim Pharmaceuticals, Inc.	3

Source: U.S. Food and Drug Administration, Center for Drug Evaluation and Research, 2005. "Index of Notices of Violation and Warning Letters to Pharmaceutical Companies." Available at <http://www.fda.gov/cder/warn/>.

maceutical companies who have violated Final Guidance recommendations. Our approach to this study is detailed below.

Understanding public institutions such as the FDA benefit greatly from placing such institutions' history within a contemporary context (Aminzade 1992; Mahoney 2000). A comprehensive understanding of an institution's behavior must include a historical account that reveals an institution's impact upon the greater social world over time (Lieberman 2001; Rueschemeyer & Stephens 1997; Skocpol & Somers 1980). This impact may best be understood as a process of interaction between an institution's social organizations and events the institution is designed to oversee (Hironaka 2002). We believe that a sociological understanding of the federal regulation of DTCA must begin at the historical level. As the development of formal public institutions emanates from legislative processes, we treat the legislative record with respect to the regulation of DTCA as a significant data source. Our examination of this record begins with an analysis of *The Pure Food and Drugs Act* (better known as *The Wiley Act*) of 1906 up to the publication of the FDA's Final Guidance to Industry in 1999.

Our second data source will be used to investigate how the federal government communicates with industry violators. Black (2002, 2003) argues that government regulation is a "communicative process" which demonstrates protocol effectiveness. Here we examine the regulatory correspondence

between DDMAC and pharmaceutical companies whose advertisements are found to violate the Final Guidance. Two types of correspondence are sent by DDMAC: Notices of Violation that are sent to companies for lesser DTCA regulation offenses and Warning Letters that address more serious violations. These letters are indexed at the Food and Drug Administration's Freedom of Information Office (<http://www.fda.gov/cder/warn/>). We consulted this index by first counting the number and types of letters that were sent to industry violators between 1997 and 2005 (see Table 1) and second, by ranking the corporations who received the most letters and therefore violated DDMAC policy most frequently (see Table 2).

Table 1 provides a 9-year summary of DDMAC's regulatory correspondence with DTCA violators, whereas Table 2 illustrates corporate behavior. The frequency with which corporations violate DTCA policy will be used, in part, to evaluate DDMAC's regulatory effectiveness.

Our discussion of these data sources illustrates the use-value of a reintegrative shaming framework (Braithwaite 1989, 2000, 2002). As evidenced by the work of Ayers and Braithwaite (1992) and the legal analyses of Ayers (1990), this perspective has been usefully adopted in the analysis of micro- and macro-economic behavior, especially those exhibited in the marketplace. We try to explain the shortcomings of DTCA regulation by analyzing what aspects of reintegrative

shaming are missing from the FDA's stance toward this type of advertising. To this aim, we argue that the regulation of pharmaceutical advertising has never been equipped with an effective "shame mechanism" that would make industry accountable for the information they provide to consumers. Concomitant with the absence of this shame mechanism, we argue that the FDA and DDMAC provide no specific ways in which pharmaceutical companies can acknowledge their transgressions to consumers, and effectively "reintegrate" into a non-violator status. To set up this analysis we will now discuss the historical development of DTCA in the United States.

### THE LEGISLATIVE HISTORY OF "CEASE-AND-DESIST" REGULATION

The history of the federal regulation of food and drug production and marketing illustrates the antagonism between public-centered and industry-centered policy advocates. Central to this antagonism is the issue of government intrusion into the marketplace. Although politicians repeatedly expressed an unwavering commitment to consumers, the consumer protections that were enacted since the late 19<sup>th</sup> century demonstrated marked compromises between public interests and those of big business (Palumbo & Mullins 2002). Since the inception of the FDA in 1906, the passing of the *Wheeler-Lea Act* in 1938, and the current era of DTCA, the federal government has had the burden of monitoring the marketplace in order to prove corporate negligence. Since the issue of mass marketing drugs came to the political forefront in the 1930s, drug companies have never needed government pre-approval for the contents of their advertisements. Regulatory agencies such as the FDA mandate that drug companies comply with federal standards only after a negligent advertisement is discovered.

#### The Wiley Act of 1906

In the late 19<sup>th</sup> century Harvey Wiley, head of the U.S. Department of Agriculture, sought to regulate domestic food and drug industries by revamping the *Drug Importation Act* of 1848 (Young 1961, 1989). Wiley's efforts were met with stern opposition from drug manufacturers and their political backers (FDA 1981). Despite industry opposition, Wiley's efforts were bolstered in two ways:

first, by the publication of Upton Sinclair's *The Jungle* (1906)—a damning critique of the meat packing industry which was widely read by policy makers and the general public (Kantor 1976) and second, by the policy ambitions of President Theodore Roosevelt, who had read *The Jungle* and was seeking to increase industry accountability (Young 1961). The public's explosive response to *The Jungle* combined with the support of President Roosevelt meant success for food and drug law proponents. The *Pure Food and Drugs Act*, or *Wiley Act*, became law on June 30<sup>th</sup>, 1906. Primarily targeting the information on product labels, the *Wiley Act* prohibited any false statements about the ingredients in a particular medication. This and other provisions would be enforced through the development of a new regulatory body: the Food and Drug Administration.

Consumer rights advocates appeared to achieve a victory with the *Wiley Act* and the inception of the FDA. However, outside of its product labeling requirements, *Wiley* had little regulatory impact. In fact, industry representatives supported the passage of *Wiley*, which had far weaker standards than were initially proposed. Trade magazines that strongly opposed food and drug regulation such as the *National Druggist* acknowledged the drug industry's role in ensuring the passage of a weakened version of *Wiley*:

[it is] not such a terrible thing after all. But let it not be supposed that the law would have been enacted in its present rather innocuous form but for hard, intelligent and most tactful work on the part of the representatives of the interests it is intended to regulate. (Young 1961 8)

The shortcomings of the *Wiley Act* were visible immediately. Of particular concern was the enforcement capability of the FDA, which was designed to monitor for and respond to violations it found in the marketplace. Because the FDA's mode of regulation was reactive rather than proactive, consumer rights groups claimed that the act failed to prevent drug misbranding. Furthermore, drug manufacturers were particularly relieved by the *Wiley Act's* failure to ban false therapeutic claims (Miller 1999). The Sherley Amendment of 1912 remedied this by disallowing false therapeutic claims of any kind; however, the burden again lay on the federal

government to not only detect false claims, but to verify whether or not such claims were intentionally deceptive (Miller 1999). Drug manufacturers could no longer legally make misleading claims about their products' effectiveness, but the regulatory power of the federal government remained weakened by the "cease-and-desist" capacity of its agencies.

### Passing the Wheeler-Lea Act of 1938

The shortcomings of the *Wiley Act* were exacerbated by the increasing role of advertising in the development of medication markets. Along with organizations pressing for uncompromising, public-centered legislation to control food and drug advertising practices was Assistant Secretary of Agriculture Rexford G. Tugwell, who in 1933, gained President Franklin D. Roosevelt's support for his proposed Congressional bill, S. 1944 (Palambo & Mullins 2002; Stole 2000). Among the implications of S. 1944 (known as the Tugwell Bill) for the drug industry were broader definitions of the terms "drug" and "adulteration," more detailed ingredient disclosure on the product label, and removal of the requirement that the government must prove a drug maker intended to deceive the public in making false product claims (Young 1961). The bill also proposed that the FDA be granted authority to take legal action against drug manufacturers as well as media outlets (i.e.-magazines, radio, trade journals, etc.) for false advertising. In support of the Tugwell Bill, in early 1933 the FDA displayed to U.S. Senators the "Chamber of Horrors," an exhibit of hazardous medicines, fraudulent labels, and quack devices. The exhibit, which was supported by the Roosevelt administration, attempted to expose Congress and the public to a new era of drug industry fraud.

The Tugwell Bill remained in committee for almost four years until the Elixir Sulfanilamide tragedy of 1937. In an effort to tap into the children's market for the Sulfanilamide, chemists at S.E. Massengill Co. discovered that the drug, a popular anti-bacterial, could be dispensed in liquid form if combined with diethylene glycol (DEG). As a precursor to antifreeze, DEG is highly toxic and at least one-hundred-seven deaths (mostly children) were attributed to it (Young 2003). Fearing that a consumer-friendly version of the Tugwell Bill would be passed in response to

this tragedy, industry lobbyists worked vehemently to see that no new legislation would be passed without the inclusion of several industry-friendly amendments (Pines 1999). Industry representatives were particularly concerned that the FDA's "cease-and-desist" powers might be revamped (Pines 1999). The years following the 1937 tragedy saw revisions of the Tugwell Bill that presented a veneer of consumer concern, but gave significant concessions to big business. By the end of 1937 the Tugwell Bill was practically unrecognizable in its revised form, S. 1077.

After the Sulfanilamide tragedy politicians hurried S. 1077 to the House Interstate and Foreign Commerce Committee. In this committee hearing Representative Virgil Chapman of Kentucky questioned the potential of S. 1077 to thwart deceptive advertising through the use of "cease-and-desist" orders:

By the time a cease-and-desist order...becomes effective the advertiser, as a matter of course, will change his copy. He can continue this process indefinitely without running any risk whatever of penalty, and when he has run the gamut of all the claims he can plausibly make for his product, he can then change its composition, as patent-medicine manufacturers have so frequently done, and repeat the process over and over again. (*Congressional Record* 1938)

However, despite lawmaker concerns and the sensationalism of the "Chamber of Horrors," S. 1077 was passed as the *Wheeler-Lea Act* on March 21<sup>st</sup>, 1938. Inserted into *Wheeler-Lea* was amendment S. 5 that removed Tugwell's requirements for full ingredient disclosure and strictly held advertisers, not media outlets, responsible for false advertisements. As with previous legislation governing the food and drug industries, the government was held responsible for detecting advertising infractions and taking action against violators: "cease-and-desist" remained policy (Richards 1998).

### Parameters of DTCA Regulation

In 1979, the FDA responded to the pharmaceutical industry's increasing interest in the use of popular media for the expansion of professional (i.e.-researcher, pharmacist, clinician) markets by creating two requirements that all advertisements must meet: a

"brief summary" of side effects, contraindications, and effectiveness (21 U.S.C. § 352(n) (1979)) and the "fair balance" doctrine, which states that a drug's risk information be presented in a fashion comparable to statements of the drug's effectiveness (21 C.F.R. § 202.1(e) (1979)). These new FDA standards were first tested on a consumer audience in 1982 when Boots Pharmaceuticals released a series of print and television broadcast advertisements promoting its brand of ibuprofen, Rufen® (Snedden 2002). Concerned that it would be unprepared to monitor an onslaught of consumer-directed advertisements, the FDA issued a voluntary moratorium on all DTCA in September of 1982. In 1985 the FDA deemed DTCA acceptable, concluding that the current drug advertising standards for professional markets were also appropriate for consumers. Because meeting the "brief summary" and "fair balance" requirements through broadcast media were onerous and financially infeasible for pharmaceutical companies, DTCA did not immediately grow after the moratorium was lifted (Desselle 2004; Pines 1999). However, pharmaceutical companies quickly implemented marketing strategies that avoided FDA requirements.

In August 1995 the FDA responded to a steady increase in direct-to-consumer advertisements that subverted "brief summary" and "fair balance" requirements. Such advertisements described disease symptoms and urged viewers to seek their doctor's advice, but never mentioned a specific drug. Because such advertisements were not formally defined, the FDA created a typology of three types of prescription drug advertisements: reminder advertisements, help-seeking advertisements, and product claim advertisements. Reminder advertisements only call attention to the name of the drug product, while help-seeking advertisements encourage viewers to refer to a health professional for treatment options for particular symptoms. Only product-claim advertisements, that is those naming a drug and making claims about its effectiveness to treat specific diseases, must meet the FDA "brief summary" and "fair balance" standards (Palumbo & Mullins 2002).

In October 1995 the FDA held a public hearing to discuss the issue of DTCA with pharmaceutical industry representatives, clinicians, researchers, and drug consumer ad-

vocates (Nordenberg 1998). In August 1997 the FDA took formal regulatory action by releasing the "Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements" which was slightly revised in August 1999 as the "Final Guidance for Industry: Consumer-Directed Broadcast Advertisements" (Intra-Agency Group on Advertising & Promotion 1999). Swayed by industry representatives who felt that DTCA would provide much needed information to consumers, the FDA added an "adequate provision" clause to the guidance. In order to meet "adequate provision" requirements, consumer-directed advertisements must provide: 1) a toll-free telephone number that consumers can call to listen to a reading of the brief summary; 2) a web page address where product information can be accessed; and 3) a statement that encourages consumers to consult a healthcare professional for more information, or refers them to an "alternative mechanism," such as a print resource, to access the brief summary of the drug product (Intra-Agency Group on Advertising & Promotion 1999).

Today, the FDA regulates DTCA through the Division of Drug Marketing, Advertising, and Communications (DDMAC)—a subdivision of the FDA's Center for Drug Evaluation and Research. Following the same regulatory approach established in 1906, DDMAC detects non-compliant advertisements by monitoring print materials and broadcast media, and dispenses either Notices of Violation or Warning Letters, both of which call for an ad's alteration or cessation. The mode of cease-and-desist has been preserved in the FDA's "postmarketing reporting" requirements (21 C.F.R. § 314.81(b)(3)(i) (2003)) which require that pharmaceutical companies submit their consumer-directed advertisements at the time that such ads are broadcast. Such reporting has been at the root of a host of DTCA guideline violations.

Current Department of Health and Human Services (HHS)—the department that oversees the FDA and DDMAC) policy supports the notion that violating the Final Guidance benefits pharmaceutical companies and, indeed, may be a common part of DTCA campaigns. In January 2002 the Bush administration mandated that all NOV and Warning Letters be sent to the HHS's Office of the Chief Counsel (OCC) for "legal review" prior to being sent to industry. In what may be



construed as a federal giveaway to the pharmaceutical industry, this policy entitles the OCC to take up to 45 working days—slightly more than two months—to review regulatory correspondence before they are approved for dissemination. As the GAO (U.S. General Accounting Office 2002) points out, about one-third of DTCA campaigns remain on the air for less than two months. By the time OCC approval has been given, DDMAC's admonitions may be irrelevant because a new advertising campaign has already begun. We recall here the prophetic concerns of Kentucky Congressman Virgil Chapman. This new policy may partially explain the decrease in regulatory letters sent by DDMAC since 2001 (see Table 1). As DDMAC is now required to legally review every piece of regulatory correspondence it sends to industry, the burden of demonstrating non-compliance has shifted even more toward the FDA. As non-compliant advertisements can be ran for extended periods of time, it is clear that DDMAC's "cease-and-desist" admonishments are less effective today than ever before.

#### Media Outlet Immunity

The elimination of the Tugwell Bill's provision that media outlets (i.e. magazines, newspapers, professional journals, radio stations) be held legally responsible for fraudulent drug ads was a significant blow to federal authority. Since the passage of *Wheeler-Lea* media outlets can take in advertising revenues for virtually any product regardless of its use value. Media outlets can profit from misleading or blatantly fraudulent claims of their advertisers, but cannot be held accountable for them. DDMAC is limited to the monitoring of DTCA content, evaluating its compliance, and redressing complaints with the companies that fund such advertisements.

Part of DDMAC's approach to monitoring DTCA involves the use of a commercial service that monitors six cable television networks<sup>2</sup> and "the New York City affiliates of the four major networks and PBS" (U.S. General Accounting Office 2002 22). Smaller affiliates—which comprise up to 50 percent of the media for consumer marketing campaigns (Hoskins 2004)—are ignored in this monitoring process, effectively making many drug ads undetectable. There is evidence that local broadcasts of prescription drug

campaigns have become part of a marketing strategy for the drug industry. In 1999, for example, a misleading ad was broadcast in Puerto Rico for two years before the FDA became aware of it (Wilkes, Bell, & Kravitz 2000).

In addition to this routine surveillance, DDMAC relies heavily upon the pharmaceutical industry itself to draw attention to advertisements that may not be FDA compliant. Indeed, the bulk of complaints that DDMAC receives about non-compliant ads do not come from government officials or consumer awareness groups, but from pharmaceutical companies who are concerned about rival advertising campaigns (Bureau of Consumer Protection, Bureau of Economics, & Office of Policy Planning of the Federal Trade Commission 2003).

Relying heavily upon industry self-regulation, DDMAC's organizational structure does not anticipate changes in pharmaceutical company advertising expenditures. Despite the fact that DTCA is the fastest growing expenditure priority for the drug industry, DDMAC remains grossly understaffed to adequately monitor direct-to-consumer drug campaigns. At the time of this writing, DDMAC dedicated only four of their 39 staff members to monitoring direct-to-consumer advertisements with their remaining staff assigned to survey those advertisements that are directed at physicians (conversation with DDMAC's director of DTCA affairs, April, 2005). It is a matter of course that four staff, regardless of competence or dedication, who are assigned to monitor a multi-market, \$4.25 billion per year advertising strategy are going to be overwhelmed.

Despite DDMAC's monitoring process, pharmaceutical companies are still able to subvert Final Guidance requirements through the use of "help-seeking" and "reminder" advertisements, neither of which are required to follow "adequate provision" guidelines. Help-seeking advertisements, also known as "disease awareness campaigns," remind the viewer about a particular illness and implore medical consultation. One of the most famous of these campaigns was created in the 1980s by Upjohn Inc. (manufacturer of Rogaine) which sparked a tremendous amount of public awareness about male pattern baldness. Reminder advertisements, on the other hand, promote public awareness of a pharmaceutical company

and avoid mentioning any specific illness or medication. Bristol-Meyers, for example, has run numerous campaigns that tout the company's research prowess and corporate citizenship. One of their recent advertisements offers a cameo appearance by world-class cyclist and cancer survivor, Lance Armstrong, but omits any direct mention of Bristol-Meyers' cancer medications.

Though both of these types of advertisements are designed to cultivate a market for prescription drugs, neither is defined as direct-to-consumer advertising according to DDMAC. Pharmaceutical companies quickly learned that complimentary help-seeking and reminder advertisements could have the same effect as a DTCA campaign, but would not have to abide by Final Guidance regulations. For example, in an effort to promote its obesity medication Xenical®, Roche Pharmaceuticals began a national campaign in which a 30-second help-seeking add about obesity was broadcast almost immediately before a 30-second reminder advertisement. Between these two advertisements was a minute-long spot for an unrelated product. Within a two-minute period Roche had promoted awareness of a health condition and linked its company name to its treatment—all without mentioning a specific drug or abiding by federal guidelines (Adams 2001). DDMAC issued a "cease-and-desist" order to Roche, but not until the campaign had been nationally broadcast for over two months.

#### THE LIMITED EFFECTIVENESS OF NOTICES OF VIOLATION AND WARNING LETTERS

The *Wheeler-Lea Act* provided no protocols for regulatory action beyond "cease-and-desist"—a shortcoming that is preserved in DDMAC's Notices of Violation (NOVs) and Warning Letters. As the modern form of "cease-and-desist" regulation, NOVs and Warning Letters may implore companies to cease advertisements that violate the Final Guidance, but current marketing strategies greatly lessen such letters' impact.

DDMAC threatens enforcement of the Final Guidance by sending either NOVs or Warning Letters to non-compliant corporations. However, neither HHS nor FDA operating procedures clearly specify which violations warrant the sending of an NOV or a Warning Letter.

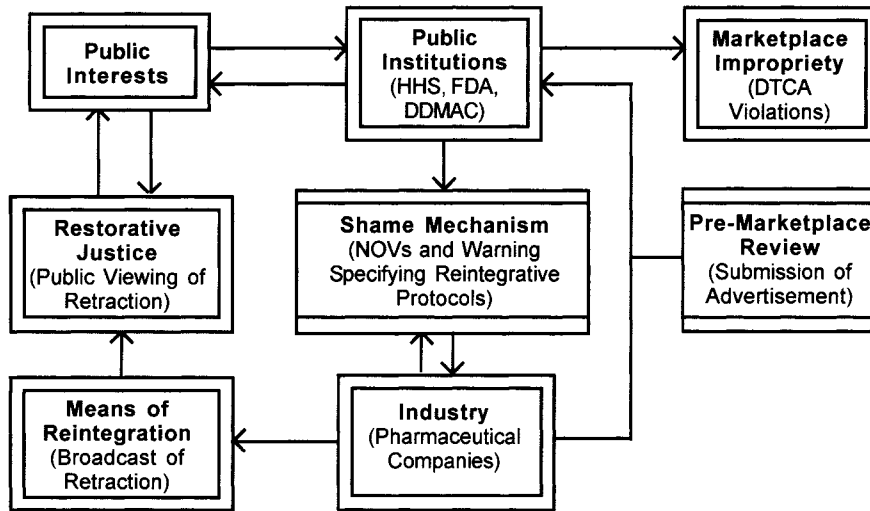
What is striking is that HHS does not out-

line any specific penalties that can be levied against industry beyond the message of "cease-and-desist." Although HHS may act on the FDA's behalf and file federal lawsuits against non-compliant pharmaceutical companies, this has *never* happened since the Draft Guidance of 1997.<sup>3</sup> Further, there are no protocols in the Final Guidance that specify the leveling of fines for industry violators, nor are there any provisions that suspend a company's DTCA privileges. Although the language of NOVs and Warning Letters appears very stern, and implores a company to cease its violations, such language never precedes regulatory action. Beyond these written warnings, there are no protocols determining what steps must be taken against repeat violators. The behavior of Schering Corporation and GlaxoSmithKline serves as two important examples.

Between 1997 and 2000, Schering Corporation received six NOVs for its marketing of Claritin®, the world's top-selling allergy medication. These NOVs explained that Schering had violated numerous Draft Guidance and Final Guidance recommendations. The letters (faxed between August 19, 1997 and August 18, 2000) demonstrate how Schering violated DTCA regulations in myriad ways and with impunity. In 1997, for example, Schering failed to insert a fair balance statement into their television promotion of Claritin® Tablets, fraudulently asked customers who called the mandatory "1-800-CLARITIN" number to respond to a marketing survey, and sent out a telephone script advertisement for the drug that touted the benefits of Claritin®, but failed to insert "adequate provision" or mention any of the drug's major side-effects. Schering's pattern of behavior continued with subsequent marketing of Claritin®, typified by a 1998 print advertisement that lacked both "fair balance" and "brief summary" requirements, and two television ads for the drug: one, a false "reminder ad" that specifically talked about the benefits of Claritin®, the other, back-to-back "reminder" and "help-seeking" ads similar to the previous example of Roche's Xenical® campaign.

GlaxoSmithKline has been served with almost double the amount of NOVs and Warning Letters of any other pharmaceutical company (see Table 2). Similar to Schering Corporation, many of the company's repeated violations occurred through the direct-to-consumer marketing of only one drug,

Figure 3: Model for Reintegrative Shaming and Direct-to-Consumer Advertising



the nasal spray Flonase®. Beginning in September 1997, DDMAC sent GlaxoSmithKline several NOVs for its marketing of Flonase®. The first concerned the company's failure to send consumers warning information about Flonase® in a timely manner (letter faxed on September 1997). In August 1999 DDMAC sent GlaxoSmithKline a Warning Letter regarding an advertisement that the company did not submit to the FDA at the time of its broadcast (in violation of the requirements for "postmarketing reporting") that had "misleading and incomplete" information about Flonase®. The Warning Letter sternly admonishes GlaxoSmithKline to

assure the FDA that similar advertisements are not being disseminated anywhere in the United States or its territories and possessions.

Such admonishment apparently had little effect. GlaxoSmithKline would receive three more NOVs for violations regarding the marketing of Flonase. These included: 1) a television advertisement that misrepresented the overall effectiveness of the nasal spray (letter faxed on September 1999) (DDMAC 1999); 2) misrepresenting doctors' favorable opinions about Flonase® in a newspaper advertisement (DDMAC 2000); and 3) a television advertisement that claimed Flonase® relieved post nasal drip, but provided no clinical

evidence for this. Between September 1997 and March 2000, DDMAC sent a total of five notices (including one Warning Letter) to GlaxoSmithKline about its direct-to-consumer marketing of Flonase®, but no action was ever taken against the company. Due to a lack of protocols for legal action against repeat violators (especially where such repeat violations are for the marketing of only one drug), corporations such as GlaxoSmithKline apparently violate with impunity.

## DISCUSSION

The legislative history of DTCA and the current environment of this form of advertising demonstrate a repeated pattern of federal concession to industry at the expense of consumer interests. As institutions that represent a public voice, HHS, the FDA, and DDMAC are supposed to function in ways that protect consumers from misinformation and from advertising campaigns that run counter to the public good. It should be expected, then, that such institutions transmit the voice of the public but also, mediate the conversation between public and industry interests. Borrowing from Braithwaite (1989, 2000, 2002), the public voice in this conversation may be best seen through a process of shaming noncompliant corporations, letting corporations know, just like any offender, that their behavior is as visible as it is unacceptable.

### The Absence of, and Necessity for, Reintegrative Shaming

As the current regulatory shortcomings and repeated violation of DTCA guidelines illustrate, there is no adequate "shaming mechanism" (Braithwaite 1989, 2000, 2002) in place that forces corporations to "listen to" the public. Indeed, the current mode of "cease-and-desist" regulation impedes a dialogue between industry and the public. Below, we outline three ways that the federal regulation of DTCA lacks both an adequate shaming mechanism and an appropriate means by which violating companies may acknowledge their transgressions and "re-integrate" into mainstream society. Figure 3 is a proposed model for the inclusion of reintegrative shaming mechanisms into the regulation of DTCA.

First, as an offender's awareness of public sentiment may be one of the most crucial aspects of reintegrative shaming, it is important that such sentiment be made clear through the regulatory process. Acting as monitors of the marketplace, DDMAC fails to protect the public from the presence of misinformation in DTCA campaigns. By only requiring that companies remove ads once they have proven to violate federal standards, DDMAC operates from an entirely reactive stance, which transmits no gesture of public concern. A more proactive stance, by contrast, would make public expectations known to corporations before they use media vehicles to economically benefit from the dissemination of ads in the marketplace. Such public expectations could be made clearer by hastening or removing HHS's legal review process for each advertisement, and/or reviewing each DTCA advertisement *before* it is broadcast or printed. Rapidly responding to DTCA violators and making them produce ads that are compliant before being disseminated would reduce much of the "gamesmanship" that currently plagues DTCA regulation.

Second, effective shaming is daunted unless the actions of an offender are acknowledged on a more accessible, public stage. The fact that NOV's and Warning letters are indexed on the Worldwide Web and made available to the public demonstrates a limited commitment to shame, but this is not the kind of conversation that makes shame truly effective. Anyone with access to this record could indeed view those corporations that

violate DDMAC policy. However, indexing DDMAC's admonishments within the recesses of an obscure government website hardly constitutes transparency when it comes to the public understanding of DTCA. The dialogue between industry and public institutions may be made more publicly-visible in a variety of ways—for example, broadcasting the presence of DTCA violations to a national audience, or directing people to a website that is *specifically* designed to list these violations and the companies who committed them.

Third, as Braithwaite (1989) implies, public scorn without some form of substantive penalty weakens the impact of shame. Specific disciplinary protocols for DTCA violations, of which there are currently none, may be established in order to make the shame process effective. As the current regulatory structure allows a tremendous amount of "self-regulation" from the pharmaceutical industry, there are few incentives (outside the vacant threat of more government intervention) for corporations to abide by federal guidelines. Whatever shame may be instilled through NOV's or Warning Letters is trumped by the larger goals of marketing.

Though the specifics of these disciplinary protocols may vary widely, they must allow for the violating company to play their part in "restorative justice" (Braithwaite 2000 292), which may be summarized as the process by which an offender reestablishes basic trust with the public. In the same way that newspapers print retractions when their facts are wrong—a gesture of credibility and public service—it makes sense that corporations who violate DTCA guidelines should also be compelled to broadcast a retraction to the public that acknowledges their transgressions. Both the damage to public relations and the expense of producing and broadcasting such a retraction may be an especially effective way of making the resolution of shame unpalatable and, hence, a deterrent. As exemplified by the broadcasting of mandatory retractions, this mechanism of restorative justice performs two major tasks that are highly relevant to the regulation of DTCA. First, by complying with a publicly-mandated protocol to acknowledge an offense, the needs of the public are given a necessary credibility. Second, the embarrassment associated with going through the "restoration process" acts as a strong deter-

rent to future violations. For U.S. corporations, which are held civilly, rather than criminally negligent, this embarrassment translates to a loss of revenue.

### CONCLUSION

The process of reintegrative shaming is not, in our opinion, just for the cessation of unlawful behavior and the reduction of recidivism. It is also a way of empowering the public to feel as though the dialogue between them and corporations is productive and effective. The public good, as expressed through federal government authority, is threatened by the current DTCA regulatory structure.

Illustrated by DDMAC's reliance upon the self-regulation of the pharmaceutical industry and sub-contracting to the private sector for the monitoring of DTCA content, regulatory authority does not emanate from one central, state-sponsored location but rather, from multiple locations. The allowance of self-determination by organizations that are subject to government sanctions illustrates the power of the marketplace in shaping federal regulation policy. As policy has become a product of compromises between government agencies and free-market interests, regulation adopts a negotiable form. The passage of the *Wheeler-Lea Act* in 1938 exemplifies a victory for this mode of regulation.

The weakening of the Tugwell Bill and the consequent passage of *Wheeler-Lea* demonstrates the point at which the federal government adopted a reactive rather proactive stance toward fraudulent advertising. *Wheeler-Lea* necessitated that the federal government react to conditions already present in the marketplace, rather than place the burden of proving compliance upon industry before advertisements were disseminated to the public. Such a cease-and-desist policy places regulatory bodies in an unavoidable dialogue with industry, where the marketplace has become a "proving ground" for industry compliance. Rather than telling industry which advertising practices are acceptable, the federal government must "listen" to industry by monitoring the marketplace and then either respond with approving silence or disapproving admonishment.

The establishment of the "adequate provision" clause in 1999 and the lessening of "brief summary" and "fair balance" standards drastically reduced how prescription drug

consumers were protected. Part of this public exposure involves the lack of an effective reintegrative shaming strategy. Rather than change its mode of regulation—for example, by requiring that drug companies gain pre-approval of their advertising campaigns and establish a set of protocols through which DTCA violators must publicly-acknowledge their transgressions—the FDA has effectively stated that it sees no difference between prescription drugs and other consumer items. Instead of doing away with "cease-and-desist" in cases of DTCA, the FDA adopted a policy of sending regulatory correspondence to companies who violate "adequate provision" requirements. NOV's and Warning Letters would have more regulatory impact if they were backed by appropriate reintegrative shaming protocols. As FDA policy currently stands, the difference between an NOV and a Warning Letter is subjective, and there is no provision of specific punishments for industry violators. It is also clear that the 45-day "legal review" delay in sending an NOV or Warning Letter further weakens the "cease-and-desist" approach. Unless DDMAC can support NOV's and Warning Letters with specific reintegrative shaming measures, its authority will remain symbolic.

### END NOTES

1. New Zealand is the only other country that currently allows DTCA.
2. These networks are CNBC, CNN, CSPAN, CSPAN2, MSNBC, and CNNFN. We find it interesting that CSPAN and CSPAN2 are on that list as commercials on those networks are extremely limited. Other cable networks, such as Disney, ESPN, Nickelodeon, Discovery, and so on, are conspicuously absent from this list.
3. This information comes from a phone conversation with DDMAC's director of DTCA affairs, April, 2005

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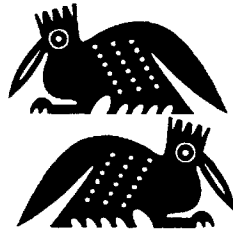
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