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Food for Thought

An Investigation of Food and Drug Administration Reporting Practices, 1995-1999

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ABSTRACT

Criminologists and criminal justice researchers have neglected the behavior of regulatory agencies. Furthering the goal of focusing on the behavior of regulatory agencies, this article analyzes the reporting practices of the Food and Drug Administration (FDA) on its activities as found in two publications produced by that agency: *FDA Enforcement Report*, its official data report, and *FDA Consumer*, a public information magazine. Results suggest that the FDA uses these mediums to construct different images of its activities. The authors examine reasons why the FDA engages in image management and the differences across different FDA publications. The authors also introduce the idea of public health justice to identify the social control concerns of agencies ostensibly charged with protecting the public's health.

ARTICLE

The majority of research performed in the fields of criminology and criminal justice focuses on laws that are primarily applied to people of lower socioeconomic status. Despite periodic calls for greater attention to the crimes of the powerful and the laws, regulations, and forms of justice that apply to these behaviors, little empirical research on these issues is found in criminological and criminal justice literature. There has been a particular lack of attention to research regarding regulatory responses to violations of law (for a review, see Friedrichs, 2004, pp. 247-259). There is even less emphasis on the behavior of specific regulatory agencies assigned the duty of policing corporate crime within the literature on regulatory agencies produced by criminologists (e.g., see Jamieson, 1994, on the Federal Trade Commission; Burns & Lynch, 2004; Szasz, 1986, on the Environmental Protection Agency [EPA]). This neglect is telling and speaks to the criminological penchant for focusing on the behavior and control of the powerless as opposed to the powerful (Reiman, 2004). This ten-

gency remains strong in criminology despite (a) widely accepted evidence that corporate criminality is more costly and more violent than ordinary crime (e.g., Frank & Lynch, 1992; Hills, 1987; Reiman, 2004; Simon, 1995; Sutherland, 1949) and (b) criticism pointing toward the continued neglect of corporate criminality and its processing (Burns & Lynch, 2002; Jamieson, 1994; Reiman, 2004; Simon, 1995; Sutherland, 1949).

As with other regulatory agencies of social control that deal with powerful actors, there has been little analysis of the Food and Drug Administration (FDA) by criminologists (see Braithwaite, 1984; Clinard & Yeager, 1980). Furthermore, when the FDA is discussed in the corporate crime literature, it is usually scrutinized only in relation to its drug approval procedures or the issue of deregulation (Quirk, 1980) and not as an agency of social control that plays an important role in defining and controlling behaviors that could be considered crimes. However, a considerable body of literature has developed exploring how various social issues become identified as social problems. The present study contributes to the growing body of constructionist research literature by examining the FDA's reporting practices about its regulatory activities. Given the tenuous position of regulatory agencies such as the FDA, exploring how such agencies report their behavior to various audiences may provide insight into how they respond to the challenges of regulation.

The FDA

Originally recognized as the "Division of Chemistry" and the "Food, Drug, and Insecticide Administration," the FDA added regulatory functions to its scientific mission in 1906 with passage of the Federal Food and Drugs Act. The agency was originally housed under the Department of Agriculture, although it is currently located in the Department of Health and Human Services (Swann, 1998). The FDA employs about 9,000 workers who are spread throughout approximately 170 sites maintained by the FDA. The agency is relatively small and lacks resources compared to other federal regulatory agencies. Its annual budget of roughly \$1.3 billion requires FDA administrators to creatively identify a means to use such relatively few resources to address an increasingly wide array of responsibilities (Hilts, 2003). According to Hilts (2003), despite a wide scope of responsibilities, limited resources, and recent calls to dismantle the agency, the FDA

has . . . proved itself an essential part of modern society. Its history demonstrates that regulatory agencies can not only establish effective protections but make high scientific standards the starting point for industry and the basis of modern government policy as well. (p. xvi)

Hilts (2003) highlights the extensive nature and broad scope of the FDA in noting that "[i]t is required to keep tabs on the products of about 95,000 businesses, amounting to about \$1 trillion worth of goods a year, about a quarter of the American economy" (p. xvi). The FDA annually catalogs over "200,000 reports of harmful effects from prescription drugs and medical devices each year" (p. xvi) and fields an immense number of consumer questions and information requests. Thus, the FDA is a complex agency responsible for a wide array of tasks and issues. For instance, the FDA is responsible for ensuring safety and effectiveness with regard to food products, veterinary and human drugs, biological products, medical devices, cosmetics, and electronic products that emit radiation. Hilts (2003) adds that the FDA, the most scrutinized regulatory agency, has retained extremely high standards as the first agency in the world to attempt to scientifically evaluate drugs and food. In addition to regulating food and drugs, the FDA created the "scientific base for industry—defining what is safe and what works or does not" (Hilts, 2003, p. xiv).

The complexity and wide-ranging scope of the FDA result in the agency constantly facing pressure from, and trying to maintain positive relations with, various interest groups. Hawthorne (2005) asserts that even though the FDA staffs “a corps of dedicated, careful scientists,” the agency “is, and always has been, buffeted by the conflicting demands of scientific accuracy and public pressure, of industry and consumers, and by the contradictions between two types of public need” (p. 27). With reference to the latter, the FDA faces often contradictory forms of consumer activism: Those citizens who feel the FDA impedes progress and should more quickly allow potentially helpful products become publicly available and those who believe the FDA too easily permits potentially harmful products to become available (Hawthorne, 2005). In other words, some consumers wish to have access to as many treatments as possible, whereas others remain concerned about harmful products reaching the general public. The former group is often identified as representing the voice of industry, whereas the latter is frequently supported by consumer advocate groups and public health organizations (Hawthorne, 2005).

Hawthorne (2005) describes the pressures faced by the FDA from various industries such as pharmaceutical companies that frequently characterize the FDA as

the all-powerful, arbitrary, nitpicky naysayer that keeps their desperately needed medicines off the market until they run a zillion unnecessary tests to prove things they already proved. The agency is unreliable, one week saying it wants to help manufacturers get their products out to patients quickly, then the next week panicking after too many reports of dangerous side effects. It is mysterious; there is no way of knowing just what a company must do to move its product past the regulatory box-checkers. At best, the FDA is a bunch of bureaucrats who mean well but are scared to be the first to approve something new. Most of all, the agency must be obeyed. It is almost impossible to get through a 10-minute interview with a pharmaceutical executive without hearing at least one complaint or fear about the FDA. (p. x)

An example of the conflict faced by the FDA in regulating industry without seeming overbearing is found in a 2002 appearance by FDA Deputy Commissioner Lester Crawford on Capitol Hill. Crawford faced questions from politicians who wished to know why the agency referred to regulated drug companies as “clients” and “customers” and why the FDA was “bragging” about how it had helped the U.S. drug industry’s global market share (Dickinson, 2002, p. 16). Crawford responded that the FDA “treads a tight wire of remaining correct but aloof in terms of its enforcement in its consideration of industry. Referring to the industry as a ‘client’ or ‘customer’ is sort of the new emphasis on stakeholder investment” (Dickinson, 2002, p. 18). Among other things, the agency’s ties and responsiveness to government pressures are affected by the pharmaceutical industry’s close ties to government (the industry is the “most powerful lobbying force in Washington, DC,” and is always among the most prominent donors to political campaigns [Hawthorne, 2005]) and the notable influence of those in the food industry.

That the head of the FDA was facing questions from politicians is not surprising given the relationship between the agency and government officials. Hawthorne (2005) noted that

it would be bad enough if the only political pressures that the FDA had to withstand were from powerful drug and food companies with multimillion-dollar lobbying budgets, consumer groups that pounce every time a drug shows serious side effects, and consumer groups that want drugs for their disease approved *now*. But there is more. As a federal agency, run by a commissioner who must be confirmed by the Senate, who must go to Congress every year for money, and who must report to another political appointee (the secretary of Health and Human Services),

the FDA also has to live in the hardcore world of Democrats and Republicans, Congress and the White House—the world of pure politics. (p. 209)

The FDA is a government agency whose budget is set by government officials. The president appoints the FDA commissioner, and agency decisions are vetted by the Department of Health and Human Resources (Hawthorne, 2005). Although it is hoped that the agency's decisions are based purely on science, industry, political, and consumer pressures likely result in FDA actions being affected by a range of variables and not just science.

Despite constantly facing pressures from many directions, the FDA, first and foremost, is a regulatory agency charged with responding to and protecting the public. The agency serves the general public primarily through regulating food and drug products, although information dissemination is also an important part of the FDA's charge. The FDA keeps the public (and others) informed through information-based publications such as *FDA Consumer*, providing a wealth of information about the agency on its Web site, maintaining a staff of public affairs specialists (who have been deemed “walking encyclopedias” [Adams & Henkel, 1995, p. 22]) and other means.

Of particular significance to the present work, the FDA is charged with ensuring that information pertaining to products in these areas is accurately, honestly, and informatively presented to various groups. The FDA accomplishes its information dissemination mission through the publication of two different reporting mechanisms: *FDA Enforcement Report* (hereafter *Report*) and *FDA Consumer* (hereafter *Consumer*). These outlets, which are described more completely in the Data and Method section, contain information that reflects actions taken by the FDA. The data and descriptions found in each outlet, however, are filtered or constructed by discretionary actions on behalf of FDA officials charged with determining how a case is classified and by the reporting format itself. In other words, the data and descriptions found in these reporting mediums may reflect organizational efforts to construct a particular image of FDA practices. To examine this possibility, we compared the information reported in each FDA information outlet within the theoretical context of social constructionism.

Constructing and Managing Image

The issue of image construction is typically examined from a constructionist perspective (e.g., Berger & Luckman, 1966; Best, 1989, 1991; Gale, 1994; Jenkins, 1992; Schneider, 1985; Schneider & Kituse, 1984; Spector & Kituse, 1977). There are several variations of contemporary social constructionist research, including new symbolic interactionism (e.g., Katovich & Reese, 1993; Musolf, 1992; Reynolds, 1978), the British School of Cultural Studies (Hall, 1985; Sholle, 1988), and the strict and the contextual versions of the sociology of social problems (Best, 1995; Holcomb, 1997). Although there are meaningful differences between these intellectual orientations (Holcomb, 1997), a central tenet of all constructionist thought is that reality is given meaning by the efforts of various parties to define aspects of the physical and social world in particular ways. The end result is that explanations of reality are evaluated as a social construction rather than some objective fact (see Berger & Luckman, 1966).

Within recent criminal justice research, social constructionist thought is most evident in research on moral panics (e.g., Burns & Crawford, 1999; Cohen, 1972; Jenkins, 1992) and

news making criminology (e.g., Barak, 1994). News making criminology, in particular, provides a useful framework for the present study, as it is designed to aid in the analysis of constructed images through comparing images to other sources of information (Barak, 1994). In the present research, we are interested in what the FDA reports about its activities to two different audiences. By comparing FDA official statistics and the FDA's reporting of its behavior in a public consumer format, we assess the consistency across reporting outlets and comment on possible discrepancies. The news making approach is well suited to this task, first because it constitutes a model for challenging constructed images and social conditions and second because it allows researchers to consciously participate in portraying a more accurate and representative picture of actual conditions (Barak, 1994; Chermak, 1994; Surette, 1994).

Previous research has employed a social constructionist framework to examine the treatment of crimes of the powerful by the media and agencies charged with enforcing laws regarding such behavior. Simon (1995) and Reiman (2004) emphasized how those with the most resources and power in society are able to construct and maintain an ideology that protects and reinforces that status. Others examined how the negative consequences of corporate behavior were reconstructed in an attempt to divert responsibility from corporations (e.g., Cullen, Maakkestad, & Cavender, 1987; Lynch, Nalla, & Miller, 1989; Wright, Cullen, & Blankenship, 1995).

Our research follows in the latter tradition by examining how the FDA reports its activities in protecting the American public from unsafe products. The FDA's precarious position between the public and business means it must manage its image in ways that appear favorable to both sides. Given the FDA's potential need to manage its image, the process by which images are constructed becomes relevant. The tenuous position occupied by the FDA likely requires not only that it construct an image as public protector but also that it also fosters a "less obvious" image consistent with corporate concerns and interests. This latter image minimizes the perception of the FDA as "overregulating" or infringing on the market system. The present study examines the extent to which this image construction takes place and how messages are conveyed to different audiences.

Data and Method

Generally, the FDA regulates industry behavior through one of four mechanisms: recalls, injunctions, seizures, or criminal action (which includes prosecution, indictment, information, and disposition). The definitions and responsibilities associated with these actions are provided in Table 1.

We collected two different sets of data concerning the FDA's regulatory behavior to examine the FDA's reporting behavior and image management. The data were drawn from *Report* and *Consumer Report*. *Report* is a weekly publication of the FDA that, in theory, includes information on all cases that come to the attention of the FDA. *Report* can be considered official data,

Table 1
FDA Classification and Definitions of Violations
as Recorded in *FDA Enforcement Report*

	Definition	Responsibility
1. Recalls and field corrections	An action taken by a firm to remove a product from the market or to conduct a field correction	FDA request, FDA order, or firm initiative
2. Injunction	A civil action taken against an individual or firm, which seeks to stop continued production or distribution of a violative product	FDA
3. Seizure	Action taken to remove a product from commerce because it is in violation of law	FDA; the FDA initiates a seizure by filing a complaint with the U.S. District Court; the U.S. Marshall is then directed by the court to seize the product until the matter is resolved
4. Criminal action	A criminal action taken against a company or individual	FDA

Note: FDA = Food and Drug Administration.

containing information on charges, prosecutions, violations, convictions, and recalls. Specifically, as stated in each edition of the *Report*, “the FDA Enforcement Report is published weekly by the FDA, U.S. Public Health Service, Department of Health and Human Services. It contains information on actions taken in connection with agency regulatory activities.” The FDA is mandated to report its actions in this way by the regulations that define FDA responsibilities. Analyzing the content found in *Report* involved limited subjectivity because of the direct presentation of information provided. For each edition of *Report*, we coded the frequency of each type of regulatory action (i.e., “recalls and field corrections,” “injunctions,” “seizures,” and “criminal actions”) reported and the seriousness class (i.e., Class I, II, or III) assigned to that action.

In addition, we extend our analysis of the FDA’s behavior by examining the stories the FDA publishes about its own activities in its official magazine, *Consumer*. The stories concern the FDA’s involvement in specific incidents that the FDA chooses to highlight in this popular magazine format. *Consumer* is best viewed as a general information magazine sponsored by the FDA; it does not contain information on all cases brought to the attention of the FDA. Rather, *Consumer* contains materials on only those cases the FDA chooses to highlight or publicize in this specific format. The majority of *Consumer*’s featured articles are designed to make consumers (more) aware of defective products and/or various safety tips.

After reviewing several dozen editions, it was decided that two sections or “departments” of each *Consumer* publication would be used for the analyses: the “Investigators’ Reports” and “Summary of Court Actions.” As noted in each edition of *Consumer*, the “Investigators’ Report” contains “selected cases illustrating regulatory and administrative actions—such as inspections, recalls, seizures, and court proceedings—by FDA’s regional and district offices across the country.” Summary accounts (in each edition of *Consumer*) describe “cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure

proceedings are civil actions taken against *goods* alleged to be in violation, and criminal and injunction proceedings are against *firms* or *individuals* charged to be responsible for violations.” Because of their focus on FDA enforcement actions, the information found in these departments of *Consumer* were selected as representative of how the FDA presents itself to consumers and thus deemed worthy of comparison to the information found in *Report*.

Perhaps the most subjective aspect of the study, latent content analysis was used to assess the essence of each article found in these reports. The process involved reading each article and determining its main focus as related to the four categories of FDA regulation (recalls, seizures, injunctions, and criminal actions). In general, determining the main focus of each article was quite simple. Given the fact that the articles are written for the general public, the authors are typically straightforward in presenting the details. Some articles ($n = 15$; 11.3%) found in the “Investigators’ Reports,” however, did not specifically relate to an enforcement action and thus were categorized as “other.”

All editions of both *Report* and *Consumer* published during the years 1995 to 1999 were analyzed to assess the reported enforcement behaviors of the FDA. Two hundred sixty editions of *Report* were used in the present study and were accessed through the FDA Web site (www.fda.gov). Thirty-nine editions of *Consumer* were included in the analyses and were found in publicly available print format. The 39 *Consumer* editions constitute all that were published during the 1995-1999 time period. Specifically, 10 editions of *Consumer* were published annually during 1995 and 1996 (two editions were bimonthly). In 1997, the publication became bimonthly, with a total of seven editions published during that year. Six editions were published during both 1998 and 1999.

Findings

Presentation of the findings is divided into three areas: (a) *Consumer* (including results from “Investigators’ Reports” and “Summary of Court Actions” departments), (b) *Report*, and (c) the FDA’s recall practices.

Consumer

As seen in Table 2, there were 133 articles found in the 5 years of “Investigators’ Reports” examined. There was an average of 3.4 articles per edition, the majority of which involved criminal actions. A sampling of titles from selected editions of *Consumer* suggests that the FDA used this outlet to demonstrate its punitive approach to regulating private industry. For example, headlines such as “Drug Firm President and Other Officials Sentenced” (*Consumer*, March 1995) and “Illegal Use of Vet Drug Results in Fines, Probation” (*Consumer*, April 1996) suggest that the FDA strongly punishes industry misbehavior. The “Investigators’ Reports” section had lead stories related to criminal actions in 31 of the 39 editions (79.5%) of *Consumer*. Analysis of the content of *Report* provided below lends support to the notion that the agency appears to employ *Consumer* as a public forum for image construction. The next most frequent article category in *Consumer* involved injunctions and seizures. These articles typically addressed the FDA practice of restricting certain “troubling” businesses behaviors (e.g., “Drug Manufacturer Enjoined,” *Consumer*, April 1995) or the FDA’s power to physically seize and destroy illegal goods (e.g., “Unapproved Drugs End Up at Hazardous Waste Site,” *Consumer*, September-October 1997). Finally, we discovered that only a

Table 2
Distribution of Articles in “Investigators’ Reports” Section
of *FDA Consumer*, 1995-1999

Type of Action	<i>n</i>	%
Recall/field correction	2	1.5
Injunction	25	18.8
Seizure	23	17.3
Criminal	68	51.1
Other	15	11.3
Total	133	100.0

Note: FDA = Food and Drug Administration.

Table 3
Distribution of Articles Found in the “Summary of Court Action” Section of *FDA Consumer*, 1995-1999

Type of Action	<i>n</i>	%
Injunction	47	13.2
Seizure	275	77.2
Criminal	34	9.6
Total	356	100.0

Note: FDA = Food and Drug Administration.

small percentage of articles in *Consumer* had recalls as the main focus. This finding, which is inconsistent with the results from our analyses of *Report*, is discussed more fully at a later point in this work.

The information provided in the “Summary of Court Actions” section of *Consumer* relates specifically to injunctions, seizures, and prosecutions (i.e., no information pertaining to recalls and field corrections can be found in these accounts) is displayed in Table 3. Through the 356 accounts of court-related actions, representing approximately 71 actions annually, one gets the impression that the FDA strongly uses the courts while regulating industry. From the information presented in Table 3, it is clear that the FDA presents information regarding seizures far more often (77.2%) than any other court action. Injunctions represented 13.2% of the stories, and criminal actions accounted for 9.6% of the accounts. Possible explanations for these findings are discussed later.

Report

According to the FDA, “the FDA Enforcement Report . . . contains information on actions taken in connection with agency regulatory activities” (FDAWeb site). That stated, much of what appears in these reports concerns recalls, with few mentions of criminal actions or

Table 4
Distribution of Articles Found in FDA Enforcement Report, 1995-1999

Type of Action	n	%
Recalls/field corrections	7,924	99.1
Alerts	39	0.5
Seizures	36	0.5
Total	7,999	100.1

Note: FDA = Food and Drug Administration.

injunctions. In addition to information on recalls, criminal actions, and injunctions, *Report* also includes data on “Alerts.” Specifically, alerts are

any communication issued by a manufacturer, distributor, or other responsible party or FDA to inform health professionals or other appropriate persons or firms of a risk of substantial harm from a medical device in commercial use. Notifications are issued at the request of FDA. Safety Alerts are voluntarily issued. (FDA Web site)

Table 4 presents findings summarizing the distribution of FDA actions noted in *Report*.

As noted, most FDA activity listed in *Report* involved “recalls and field corrections.” Of the total number of 7,999 FDA “agency regulatory activities” that were recorded during the time period under study, only a small portion (1%) involve anything besides recalls and field corrections. Seizures and alerts appear infrequently in this publication, suggesting that the agency primarily uses recalls to regulate industry. Comparing the results from *Report* and *Consumer*, a discrepancy in the number of serious cases reported seems evident. Specifically, in the “Investigators’ Reports” section of *Consumer*, more than 100 articles examining criminal cases, injunctions, and seizure were noted. In *Report*, fewer than 40 such cases are evident. The reason this occurs is that several articles may be written about the same case in *Consumer*, and in fact, specific cases may be followed over time and appear on numerous occasions. For example, an individual case may be discussed as a seizure and later as a criminal case both at the stage of charging and initial investigation and still later, after the penalty in the case has been determined. Thus, the discrepancy between the two sources is not a recording error but one that reflects the additional emphasis placed on depictions of criminal cases in *Consumer*.

FDA Recall Practices

Clearly, the vast majority of FDA actions (99%) involve recall and field correction activity. To further investigate the agency’s use of recalls, the first step was to analyze the seriousness of all recalls found in *Report*. To do so, we used the FDA’s own seriousness rating system (Class I, Class II, and Class III). Each edition of *Report* defines the seriousness of various recalls as follows:

A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Table 5
Distribution of Recalls and Field Corrections by Seriousness
as Reported in FDA Enforcement Report, 1995-1999

Seriousness Classification	n	%
Class I (most serious)	484	6.1
Class II	4,705	59.4
Class III	2,735	34.5
Total	7,924	100.0

Note: FDA = Food and Drug Administration.

A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

These definitions are reasonably clear; the seriousness of an offense is to be judged by the outcomes associated with the use of the product in question. Table 5 depicts the findings regarding the noted FDA recalls.

As indicated in Table 5, of the 7,924 total FDA recalls, only 6.1% were judged to be very serious (Class I) or as conditions in which a “reasonable probability” of adverse health consequences exists. Roughly 60% (59.4%) of cases were recorded as Class II recalls or involved products that could result in temporary or medically reversible adverse health consequence. The final 34.5% of the cases were Class III recalls or represented conditions that are not likely to lead to adverse health consequences. In general, it appears that the majority of FDA recalls are “less serious” in nature, involving Class II and III recalls. These findings are addressed below.

Discussion

Our findings indicate that when *Consumer* was employed to determine the nature of the regulatory work performed by the FDA, it appeared that more than 81% of cases were serious in nature and involved criminal charges or outcomes, seizures, and injunctions. Furthermore, recalls appeared to be insignificant and to compose a very small fraction of the work of the FDA. In contrast, when *Report* was employed to assess the type of regulatory activity in which the FDA engages, a completely different picture emerges in which recalls and field corrections compose 99% of FDA activity. Why would the image of the FDA that emerges from these two data sources be so different?

From a constructionist framework, such actions appear to be a logical response given the demands and constraints placed on a large bureaucracy operating within a complex social and political environment. The FDA’s precarious position between the public and the business world seemingly require that it manipulate its image in an effort to appeal to different constituencies. With respect to the public, the FDA desires to appear to be a strong advocate of public health as an agency that fulfills its mission by taking a strong stance against offenders who threaten public health. Meanwhile, the FDA cannot afford to present such an image

to all audiences because doing so would generate energetic responses from the business community. Such actions might include enhanced efforts to undermine the FDA's credibility, expanded lobbying, and an expansion of the argument that the FDA stifles free market incentives and operations. In other words, given its mission and the need to present very different images to potentially conflicting audiences, it would not be unusual to discover that an agency such as the FDA might engage in image management. Indeed, this is what the data we have reviewed suggest. Although such a practice is not uncommon in popular culture (e.g., *Playboy* and *Sports Illustrated* target males; *Playgirl* and *Redbook* target females), a problem occurs when we remove ourselves from popular culture and focus on a regulatory agency responsible for protecting and reporting about human safety. Targeting information to particular groups does not necessarily infer that the FDA is neglecting its responsibilities. Constructing an image through presenting select information, however, does present problems. If the FDA alters its reporting practices as part of its image-making efforts, where does this leave the consumer? More personally, where does this leave researchers?

In general, information reported in *Consumer* portrays the image that the FDA takes a punitive approach toward industry misbehavior. The titles of *Consumer* magazine sections (e.g., "Summary of Court Actions"), the omission of reports on recalls (an activity that constitutes the majority of FDA actions), and its focus on a small number of criminal actions in the "Investigators' Reports" all provide evidence of how the FDA attempts to manage its public image. The image portrayed in *Consumer* is in stark contrast to the information reported in *Report*, which indicated that the majority of the FDA efforts are classified by the agency itself as being of a less serious nature.

According to the information contained in *Report*, for example, 99% of the cases handled by the FDA during the time period investigated involved "Recalls and Field Corrections." Of those cases, only 6.1% are classified as "life threatening" or "medically irreversible" incidents (i.e., reported as Class I recalls). This is a surprising finding in many respects. For instance, given the nature of the literature on corporate violence, we expected to see many more serious violations of law in these FDA data, and at a minimum, we certainly expected to record a larger percentage of recalls defined as being more serious than reported in these data. Data collected from *Report* seem to suggest that researchers who are touting the violent nature of corporate violations may be overstating these concerns.

On further investigation, it appears that FDA data in *Report* are at times misleading with respect to case severity. Although definitions of the various classes of recall are not ambiguous, the manner in which the FDA coded many of its recalls did not appear to be consistent with its own classification system. After reading through numerous recall cases, a recurring pattern appeared to be a process of downward classification of the seriousness of offenses. For instance, some of the recall cases we investigated involved AIDS-tainted blood for transfusions or blood that tested positive for hepatitis B. These are serious situations that may have life-threatening implications and are not medically reversible. Given these conditions, it would seem that these cases ought to be recorded as Class I recalls. We were surprised to find, however, that these cases were coded by the FDA as Class II recalls; in effect, cases where the use of or exposure to the product may cause temporary or medically reversible adverse health consequences (see earlier discussion of FDA class recall definitions). In fact, we also found that several hepatitis recalls were classified as Class III recalls, indicating that the use or exposure to a violative product is not likely to cause adverse health consequences. Clearly, such classification is not consistent with the known health consequences associated with hepatitis B nor with the FDA's own definitions of harm. Other examples of misclassified recalls evident in our sample included the following:

1. oxygenation machines used in surgery which failed to displace carbon dioxide from patient's blood, leading to "possible death" of patients during surgery;
2. ventilators that failed during surgery, requiring manual "bagging" of patient, with the "possibility of death for some patients";
3. food (macaroni and cheese) contaminated with metal shavings, which cause "internal injuries," such as bleeding, which may be life threatening to persons with complicating medical conditions;
4. the distal tips of venous cannulae units used during cardiopulmonary surgery, which could detach and migrate through the venous system during bypass surgery and which "could result in death for patients"; and
5. ventricular assist devices that collapsed during surgery causing inadequate blood flow excessive blood pressure, which would "impede life support."

According to the FDA's own criteria, each of these events should have been classified as a Class I recall, as a situation in which a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death. However, none of these cases was recorded as such. In fact, each was recorded as involving the least serious possible outcome, or as a Class III recall.

Why would these kinds of cases be classified in a downward direction? There are a number of plausible explanations that could be offered. Prominent among the explanations is the misclassification of recalls in response to various pressures, whether originating internally or externally to the agency. In other words, various internal and external factors may influence FDA recall classification and reporting practices. Further research could more clearly identify these sources and the influences they have, although such classifications clearly benefit business interests. In addition, it is also plausible that downward classifications result from a form of plea bargaining the FDA might employ to speed up recalls and protect public health. Regardless of why downward classification occurs, these findings suggest that relying on the FDA's reporting practices, it would be difficult to assess the actual role and impact of the FDA in protecting the public health.

In addition to the problem of downward classification, the data examined for this study present quite different pictures with respect to describing the focus of the FDA. Clearly, the most reasonable conclusion is that the FDA presents two different sets of information for two different audiences: one for the public (*Consumer*) and the other for the agency itself and industry and governmental watch groups (*Report*). Why, however, is the information contained in each publication so different? A reasonable explanation is offered by Burkholz (1994), who discusses the balancing act that the FDA must engage in between various interested parties, most notably industry and consumer groups. *Report* presents a picture of a nonintrusive agency that deals primarily with relatively minor infractions. In contrast, the FDA presents a much stronger image as a defender of public health in *Consumer* by highlighting its successes in the relatively few serious cases that it apparently handles.

It is only by contrasting these two data sources that we came to realize that the FDA uses these sources to construct an image that the agency serves and protects the public while, at the same time, not impinging too greatly on the market. In light of these findings, further discussion of the FDA's role in regulating food and drugs sheds light on the reasons underlying the conflicting images portrayed by the agency.

Compliance and Regulation

The FDA, like many other regulatory agencies (e.g., Environmental Protection Agency, Occupational Safety and Health Administration, Consumer Product Safety Commission), is charged with protecting the public's health. This is a difficult task, especially where foods and drugs are concerned because of the large number of products and companies involved. This task is made more difficult in an environment where the regulated industries object to FDA regulatory procedures and attempt to influence public opinion and sentiment in various ways.

For example, private industry often claims it is capable of policing itself and that in a free market economy, only those companies that provide healthy, safe, and useful products can/would succeed. From this view, the invisible hand of the free market and consumers' abilities to freely choose among competing products act as market restraints or mechanisms of social control. In addition, the food and drug industry argues that unneeded and burdensome FDA regulations and regulatory responses cost companies and consumers millions of dollars annually. Specific industries have brought special interest claims to light that have influenced public opinion (Claybrook, 1984). For example, the pharmaceutical industry has claimed on numerous occasions that FDA drug approval processes cost companies millions of dollars and untold number of years in developing new drugs. Such claims intensified the public's fears that the FDA was a bureaucratic nightmare that kept major medical breakthroughs from the marketplace and that rather than protecting public health and well-being, the FDA is a hindrance to public health (Burkholz, 1994).

Industry arguments similar to those noted above often cause public relations and political problems for the FDA (Burkholz, 1994). These problems are similar to those that criminal law enforcement agencies face when their procedures and efficiency are publicly challenged. The FDA, however, is faced with a number of unique challenges. Of particular importance to the FDA is its role as a regulator of the marketplace. In this role, the FDA, like the EPA (Burns & Lynch, 2004), finds itself in the unique situation of having to balance its law enforcement charges and efforts with the conflicting demands of the general public's call for protection and the private sector's plea for diminished scrutiny. The FDA must accomplish its public health and regulatory mission in an environment where it is assaulted by a constant barrage of criticism from private industry, consumer advocates, and other governmental agencies and agents that point toward FDA flaws. In this environment, replete with its numerous conflicting demands, the FDA often finds itself in a no-win situation: When it protects the public's interests and health, it is more than likely violating some set of business ideals; when the FDA promotes business interests, it seems to step on demands for public health justice (Burkholz, 1994).

Adding to its difficulties, the FDA must accomplish its mission by applying the law in a flexible manner within the limitations of restricted resources. The extensive scrutiny of the FDA by other governmental agencies and frequent Senate and Congressional hearings probing FDA activities create considerable constraints and conflicts for the FDA. The responsibility of protecting the public's health by regulating foods and drugs is enormous. Given the scope of this task, the expectation that one agency can effectively regulate the safety of foods and drugs seems unreasonable.

Although the FDA, like any other agency, is far from perfect, it does manage to identify unsafe foods and drugs using reasonable standards and provides a margin of safety for consumers

that did not exist prior to the creation of this agency. In some sense, the FDA is an “unappreciated” agency that is constantly serving as the “whipping boy” for the public, private sector, or government. Given these circumstances, it is not hard to imagine that the FDA would undertake some attempt to control, change, or manage its public image as an agency. Furthermore, because the FDA serves several competing interests, it is likely that it would attempt to manage its image on more than one front. In other words, it would appear to be in the FDA’s best interest to engage in some form of social image construction and to do so on more than one level.

Toward Recognizing Public Health Justice and Crimes

During our study, we also paused to consider the broader theoretical implications of our research. In recent years, there has been a growing recognition of the wide variety of crimes committed by powerful people and their agents (e.g., corporations), the diverse characteristics of the victims of these crimes, and the considerable damage caused by these offenses (Burns & Lynch, 2004; Frank & Lynch, 1992; Reiman, 2004; Simon, 1995; Wright et al., 1995). As more and newer activities and a broader range of victims are added to discussions of corporate crimes, innovative terminology used to identify these new areas of concern have also emerged. In recent years, terms such as *green crime*, which identifies crimes against animals, plants, and the environment (see, Frank & Lynch, 1992; Lynch, 1990; Lynch & Stretesky, 2003; see also *Theoretical Criminology*’s special issues on green crime, 1998); *crimes against health and safety* (Frank, 1985); *occupational health crimes* (Frank, 1993); and *technocrimes* (Friedrichs, 2004), which deal specifically with the use of computer technology in the commission of corporate and white-collar crime, have been introduced by various scholars.

In contrast to definitions of corporate and white-collar crime provided during earlier periods in the development of criminological thought, these new terms have increasingly focused on the physical violence associated with corporate crime (with the exception of technocrimes). The introduction of each of these ideas is to be applauded. Most, however, suffer from a rather one-sided discussion of the behavior of criminals and omit any consideration of the social justice issues connected to the identification of these new forms of criminal behavior (for an exception, see research on green crimes noted above). In other words, although these terms call attention to the detrimental behavior of the powerful, they continue to neglect discussions of the methods and procedures designed to contain corporate crime. Furthermore, this neglect is far reaching and entails avoiding discussion of methods for controlling corporate crime (for an exception, see Braithwaite, 1984). In short, this observation implies a need to address broad questions of social justice alongside issues of administrative and criminal control (for excellent examples, see the last chapter in Simon, 1995; see also Reiman, 2004).

We have adopted the term *public health justice* to identify the focus of our study and an area of research emphasizing the investigation of those agencies and policies affecting the public’s health and safety. By *public health justice*, we mean a system of justice that protects citizens from the preventable and controllable health harms that result from detrimental corporate behavior. These harms include those associated with industrial byproducts, such as pollution and hazardous waste, as well as harms associated with the production and marketing of harmful consumer goods and extend to unsafe working conditions. Ultimately, the aim of a system of public health justice is to provide equal protection to all citizens, regardless of

race, gender, political, or class characteristics (for an alternative use of this term, see Burkholz, 1994). Given this definition, we consider public health crimes as noxious behaviors that endanger public health through ordinary means of industrial production that involve unsafe working conditions, the sale of unsafe goods and commodities, or the unsafe disposal of the byproducts of industrial production. Public health crimes are, in short, a specific, easily identifiable type of purposeful criminal activity, fraud, or malfeasance that affects the health and well-being of the general public. These acts violate social justice norms of fair and equitable distribution of “bads” and “goods” across the entire population. Currently, there is no existing term that applies to this specific form of criminal behavior within the criminological tradition.

According to our definition, there are few, if any, current mechanisms of social control that could be identified as providing public health justice in the strictest sense—that is, a system that controls corporate crime while taking account of the social justice concerns defined above. In theory, however, there are governmental agencies that are designed to fulfill this function, including the FDA.

Conclusion

Several limitations of this work should be noted. Although pressures faced by the FDA from outside sources are noted, the purpose of the present work was not to explain FDA behavior and the influence of specific interest groups in particular cases (see, e.g., Burkholz, 1994; Hilts, 2003). Future research in this area could more closely examine the relationship between the FDA, other governmental agencies, business groups, and consumers groups to observe the influences these groups have on the FDA. Research of this nature might include additional data sources, such as press releases and agency testimony at congressional hearings on specific activities.

Another limitation of the work involves the limited ability to conclusively pinpoint the motivations behind FDA image construction practices in particular cases. At the aggregate level, we offered possible explanations for our findings and identified the variety of interests to which the FDA typically must respond. The FDA likely engages in a context-specific manner at the individual case level. However, a pattern emerges from these responses that apparently reflect attempts to characterize the FDA’s activities in a different manner to different audiences.

Our analyses were informed by the belief that the activities of regulatory agencies have been largely ignored by criminologists. This neglect creates a misleading image of crime control, the role of power in defining and responding to crime, and definitions of those responsible for the crime problem in the United States. To facilitate further discussions of regulatory justice by criminologists, we decided to undertake a study of one well-known agency ignored by criminological researchers. We also focused on the FDA to discuss a new means of defining and conceptualizing crimes that victimize the public by threatening its health, which we call public health justice.

Originally at issue was a question of how the FDA processed cases that come to its attention. We quickly discovered that the FDA maintained two publications that recorded its official behavior. We wondered why there might be two such publications and decided to examine these publications to determine if each presented a different image of FDA activity and, if

so, what these differences were. Our analysis reveals that these publications present dramatically different images of what the FDA actually does. *Report* is constructed to be circulated to industries, government policy analysts, and watchdog groups, whereas the stories and records contained in *Consumer* report on a small sample of all FDA activities to a public audience. Although it is unclear the direct role that FDA administrators have in the selection and preparation of materials published in *Consumer*, the agency is clearly accountable to a variety of conflicting interest groups. Such pressures certainly dictate that public relations efforts and information dissemination receive careful consideration, and the present findings demonstrate that the information provided in FDA outlets is not randomly selected.

Furthermore, our findings suggest that the public is presented with an image of the FDA as an energetic and vocal advocate for public health justice. However, it appears that the dramatic activities reported in the public magazine are not representative of the typical, regulatory behavior as reported in its publication for government and industry. The situation we have uncovered is of a contextually embedded agency that is charged with serving as an advocate of public health, a watchdog over an industry, and a mediator of public-industry conflicts. ² As noted, this may occur because the FDA needs industry's cooperation to carry out its assigned task of protecting public health. Beyond this, however, the situational context must also be understood in relation to broader political and economic constraints that define and limit the relationship between the actors involved in the construction of the FDA's image and the FDA's ability to provide an environment in which public health justice can flourish. Most certainly, the FDA's image as a fetter on the free market (industry and some government view) and as an ineffective mechanism for protecting public health (public and some government view) is something the FDA would like to alter.

We believe that research into the nature and organization of agencies charged with regulating corporations and policing corporate crime must become more central to criminology. The public howls at the ineffectiveness of the criminal justice system in detecting, catching, prosecuting, and punishing crime and criminals. The situation that currently exists relative to the social control of deviant corporations and businesses, however, makes the criminal justice system appear very efficient in comparison. Many of those most concerned with street crime, such as the middle class, are much more likely to be harmed by crimes of the powerful compared to crimes of the powerless. The image of crime as the work of the powerless, without proper recognition of the crimes of the powerful, is often reinforced in traditional criminology and criminal justice textbooks (Lynch, McGurrin, & Fenwick, 2004).

Finally, if, as we are told in a contemporary advertisement, "image is everything," then the construction of multiple images is certainly useful for an agency operating in an environment as challenging and conflicted as the FDA. Although the existence of the FDA may deter some from marketing unsafe and harmful products—and most assuredly, the FDA has kept harmful products from reaching the market—the effect of such a deterrent is limited by an image of FDA incompetence and ineffectiveness. However, the FDA needs to be concerned with more than just its image of ineffectiveness and how the data it keeps affect that image; it needs to be concerned with its actual behavior. The problems the FDA has encountered are not entirely of its own making, nor are they confined to image management. Extremely limited budgets, lingering cutbacks from the Reagan-Bush years, and continual corporate challenges make the FDA tasks of protecting public much more difficult. Greater criminological interest in the political and economic climate surrounding the FDA, as well as the activities, tasks, and enforcement practices of the agency, may help produce enhanced understanding not only of this agency but also of the federal regulatory process more generally and stimulate criminological interest in the laws and practices governing agencies that police corporate and other

powerful offenders.

Notes

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1. There is ample evidence that industry's claim is an inaccurate representation of how corporations and businesses actually engage in unregulated environments, as the history of regulation (see Meier, 1985) aptly demonstrates. Business and corporate regulation emerged because business had in fact failed to protect the public from harm and produced unsafe products in an environment where these practices seemed to be spreading via competition rather than being controlled by competition.

2. As further evidence of the controversial nature of FDA rulings and procedures, see the literature on the health impacts of the diet drug Fen-Phen (Abenheim et al., 1996; Brenot et al., 1993; Cannistra, Davis, & Bauman, 1997; Connolly et al., 1997; Curfman, 1997; Graham & Green, 1997; Mark, Patalas, Chang, Evans, & Kessler, 1997).

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