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# Regulatory Exposure of Deceptive Marketing and Its Impact on Firm Value

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## ABSTRACT

Research linking marketing to financial performance has predominantly focused on how marketing assets and actions add value. We argue that it is equally important to understand how marketing decisions can destroy firm value. Prior research has indicated that negative events vary greatly in their indirect costs to the firm. Based on established theory and in-depth interviews with practitioners, we identify a set of factors that can explain the heterogeneity in the magnitude of indirect costs associated with negative marketing-related events. Specifically, we address how shareholder value is impacted by the regulatory exposure of deceptive marketing, which carries no direct cost to the firm. Using an event study, our analysis shows that incidents of exposed deceptive marketing are associated with significant negative abnormal returns amounting to a drop of 1%, which translates into an $86M wealth loss for the median-sized firm in our sample. In explaining the variation in magnitude of the impact between events, we find that event characteristics are generally more significant than firm and brand characteristics. When deception is highly egregious or directed at vulnerable populations, firm value is more negatively impacted than when the potential to mislead and harm is not readily verifiable. Furthermore, when the cited product has substantial brand market share, the levels of egregiousness and target audience explain substantially more of the variation in event impact than when brand market share is low. The results are robust to alternative stock portfolio-based measures of abnormal returns, model specification, heteroskedasticity, and examination of risk. Our framework and analysis have implications for Wall Street executives, Main Street managers, academic researchers, and public policy.

## INTRODUCTION

Following the challenge outlined by Srivastava, Shervani, and Fahey (1998) and subsequent criticism by Rust et al. (2004), a growing number of empirical studies have examined the marketing-finance interface. Studies have explored the financial market impact of brand asset perceptions (Mizik and Jacobson 2008), product quality (e.g., Tellis and Johnson 2007), corporate reputation (Roberts and Dowling 2002), and product innovation (Srinivasan et al. 2009). Researchers in this area have predominantly focused on how marketing assets and actions add to financial performance and shareholder value. We argue, however, that it is equally important to understand how marketing decisions can reduce firm value. It has been well-established that negative information and events often have a greater salience than positive ones (e.g. Mahajan, Muller, and Kerin 1984; Van Heerde, Helsen and DeKimpe 2007; Lei, Dawar and Lemmik 2008), and we contend that understanding this effect requires the consideration of a different set of factors than those considered in value-building studies.

Researchers have found that negative events, such as product recalls (Davidson and Worrell 1992) and drug withdrawals (Ahmed, Gardella, and Nanda 2002) can influence stock market value. However, little is understood regarding the indirect costs associated with these negative events. Jarrell and Peltzman (1985) and Karpoff, Lee, and Martin (2008), among others, find that the financial impact of negative events can be far greater than the direct costs (e.g., fines, restocking fees) associated with the event. Additionally, the indirect costs associated with the event can vary greatly between events. Prior researchers have been unable to determine what factors account for the variation in indirect costs. Understanding these costs is critical because indirect costs of negative events can amount to a significant proportion of a firm's market valuation. Furthermore, many negative marketing-related events, such as when a firm is exposed for using deceptive marketing, have no immediate impact on cash flows but garner a quick investor response. Investors adjust their valuation of a stock based on expected cash flows to the firm (Srivastava, Shervani, and Fahey 1998).

This study examines what indirect costs of negative events prompt investors to change their cash flow expectation for the firm.

In particular, the subject of our analysis is the investor reaction to the exposure of deceptive marketing. Deceptive marketing has received surprisingly little consideration from academic researchers despite the frequency of its use and the intensity of attention it receives from regulatory agencies and the popular press (Darke, Ashworth, and Ritchie 2008). Behavioral studies have found that deception engenders distrust (Darke and Ritchie 2007) and leads to avoidance of the perpetrator (Wang, Galinsky, and Murnighan 2009. However, the effect on firm valuation has not been measured. This is important because maximizing shareholder value is a principal concern of public firms (Srivastava, Shervani, and Fahey 1998) and understating the value impact of such actions would inform managers of the potential downsides of such actions.

Prior studies concerning value-reducing events have concentrated on firm and environmental characteristics and have not explained a significant proportion of the variation in indirect cost between events. We take a different approach by considering the characteristics of the events. In fact, in research examining value-creating activities, it is not uncommon for researchers to consider characteristics of the action when explaining the magnitude of change in market capitalization (e.g., Tellis and Johnson 2007). In the context of deceptive marketing, the event characteristics that vary between occurrences are the type of violation, the severity of the deceptive information, the target audience, and the marketing communication medium.

In developing a theoretical framework for understanding the impact of these factors, we rely on established theory and in-depth interviews with market analysts. Our theory begins with the expectation that following the exposure of deceptive marketing, subsequent trading will quickly change the market capitalization of the firm to reflect the change in cash flows to the firm expected as a result of this event (Srivasan and Hanssens 2009). Investors consider how public awareness of a firm's deceptive activity will lower cash flows

through increasing costs and decreasing revenues. As one market analyst explained, "When we find out about safety issues, we immediately (within 3-24 hours) issue a research report and reduce our revenue forecast from X to X minus something." This estimate is based on how the event will alter the behavior of relevant stakeholders (i.e., physicians, past and present consumers, competitors, state and federal governments, and shareholders) and the resulting implications for the firm's future cash flow.

To measure the aggregate financial impact of these events, we used an event study to calculate abnormal stock market returns, which, according to the efficient market hypotheses, provides an unbiased estimate of changes to future cash flow that can be attributed to a single event (Fama 1970).This analysis shows that, overall, incidents of exposed deceptive marketing are associated with significant negative abnormal returns.[1] In the second part of our analysis, we look at the factors that explain the variation in abnormal returns between events. We find that event characteristics are critical in understanding the heterogeneity of the financial market reaction and the resultant shareholder impact. Activities with high aggregate stakeholder costs (i.e., promotions directed at consumers, and highly egregious, unsubstantiated effectiveness claims) are associated with negative abnormal returns, while deceptive activities with lower total costs, namely unsubstantiated superiority claims and direct-to-consumer print advertising, are not. We also find moderating effects for brand market share and advertising spending that are consistent with our theory of stakeholder cost. Our framework and analysis have implications for Wall Street executives and Main Street managers, academic researchers and public policy.

## CONCEPTUAL BACKGROUND

### Deceptive Marketing In The Pharmaceutical Industry

Several factors make the pharmaceutical industry especially conducive and relevant to marketing

[1] The focus of the study is on heterogeneity in the financial market impact of regulatory exposure of deceptive marketing. We do not assess the overall impact of deceptive marketing (i.e. from its initiation to the exposure period).

research. An absence of blockbuster drugs has shifted the focus of the industry from research to marketing (Angell 2004). The drug industry association, PhRMA, argues that spending on R&D still outpaces promotional spending (Egan 2004). However, critics, including academic researchers and members of Congress, contend that standard measures of promotion, such as IMS data, exclude significant costs and rely on surveys of the pharmaceutical firms themselves, which have incentives to underestimate marketing spending (Gagnon and Lexchin 2008). Some researchers estimate pharmaceutical firms spend significantly more on marketing promotions than R&D (Angell 2004). Yet, even the conservative, self-reported measures show pharmaceutical promotion totaling $29.9 billion in 2005 and growing at an average annual rate of 10.6% since 1996 (Donohue, Cevasco, and Rosenthal 2007). Since the FDA loosened regulations governing direct-to-consumer (DTC) marketing in 1997, pharmaceuticals have increased DTC expenditures at an average rate of 14.3%. Merck's DTC promotional spending on Vioxx in 2000, for example, even exceeded that spent by Budweiser and Pepsi (Macilwain 2005).

Instances of deceptive marketing continue among drug companies, despite the fact that the pharmaceutical industry has arguably the strongest guidelines concerning marketing practices of any industry. Pharmaceutical marketing is regulated by the FDA's Division of Drug Marketing and Communications (DDMAC). Firms found to mislead consumers or physicians in their drug promotions are issued citation letters that cite firms for one or more of three major violations: unsubstantiated effectiveness claims, omitting risk information, and unsubstantiated superiority claims. Tables 1 and the appendix provide, respectively, technical definitions and measures of egregiousness related to the violations.

*[Table 1 About Here]*

The FDA letters are made publicly available on its website. They frequently receive abundant attention from the media, including high-circulation newspapers such as *The Wall Street Journal* and *The Los Angeles Times* (Darke, Ashworth, and Ritchie 2008). Additionally, the cited violations have received attention from

many popular consumer interest groups, such as the Consumers Union and the United States Public Interest Research Group (PIRG), as well as many of the individual state PIRGs. As a result of the negative publicity, many stakeholders (e.g. physicians, market analysts) are aware of these violations (Darke, Ashworth, and Ritchie 2008; Tyebjee 1982). The significance of this public awareness to investors (and thus to firms) is discussed in the following section.

**Theoretical Framework**

Previous research on the reduction of firm value has involved events with large direct costs to the firm. In business, psychology and economics literature, researchers have examined the overall financial impact of events such as financial misrepresentation (Karpoff, Lee and Martin 2008) and restatement announcements (Palmrose, Richardson, and Scholz 2004). The empirical research indicates that a sizable gap usually exists between estimates of direct costs and the magnitude of the capital losses due to recalls. Jarrell and Peltzman (1985) attribute these losses to a general and unspecified decline in goodwill surrounding the firm. For citations of deceptive marketing, the event carries no direct costs such as fines or corrective advertising requirements. Therefore, to begin a comprehensive analysis of the impact of deceptive marketing on stock return, we look at what makes up the previously undefined "loss of goodwill."

Based on in-depth interviews of market analysts[2], these citations do, in fact, change earnings estimates. The citations are described as "stirring up a lot of anxiety" due to the new information they provide, and they may be followed by an immediate change in revenue and cost forecasts. As one analyst explained, "we continuously track the FDA warnings and continuously update the impact of the warnings on the firm itself and on competitors. This is reflected in our quarterly reports." To add additional support for this argument, we conducted some exploratory analysis of analyst reaction to FDA warning letters. Using the Institutional

[2] We conducted in-depth interviews with six senior financial analysts, four of whom belonged to large Wall Street firms and two who belonged to boutique firms. In addition we also conducted in-depth interviews with two senior pharmaceutical firm executives. Each interview lasted between 25-40 minutes.

Brokers' Estimate System (I/B/E/S) database we examined if analysts changed their earnings estimates within five days of the posting of the FDA warning letter. The average percentage reduction in forecasted earnings was significantly different from the average increase in forecasted earnings ($p<0.05$). While not conclusive, this finding provides further preliminary evidence that financial analysts do react to the FDA warning letters.

With any marketing action, investors outlook is influenced by how the action will increase or decrease cash flows (Srinivasan et al. 2009). In the case of citations for deceptive marketing, firm valuation may be impacted by investor estimates of subsequent increased costs (through greater legal liability and lower marketing elasticity[3]) and decreased revenue (through fewer prescriptions and sales). Relying on the assumption of market efficiency, we argue that these unanticipated changes to the firm's future cash flows are reflected in abnormal stock market returns (Fama 1970).

Prior theory and interviews with market analysts indicate that the impact of the characteristics will vary according to the severity or egregiousness of the act. In the marketing literature, an action's egregiousness is determined by the degree of deception involved and how critical the information concealed is considered (Klein, Smith, and John 2004). In their study of consumer response to negative publicity, Ahluwalia, Burnkrant, and Unnava (2000) explain that their analysis is limited in not considering extreme or life-threatening consequences. They call attention to research indicating that, generally, more severe consequences are weighted more heavily in the evaluation of information (Fiske 1980; Fich and Shivdasani 2007).

The FDA citations distinguish between three major types of violations: omitted risk information, unsubstantiated effectiveness claims, and unsubstantiated superiority claims. The letters also contain information on the audience and type of media used. For each characteristic of the deceptive act, we identify the cost and revenue implications that are considered by analysts and investors when calculating changes to

[3] Marketing elasticity refers to the percent change in sales with respect to percent change in spending on marketing activities.

future cash flows.

## HYPOTHESES

### Omitted Risk Information

For violations involving omissions of risk information, the perceived egregiousness of the act is quite different when the false information concerns the possibility of nausea than when it relates to the drug's possibly fatal side-effects. When severe risk information is omitted, stakeholders may assume that the level of risk does not outweigh the benefits of the drug. In other words, consumers may suffer fatal or life-altering side effects as a result of a treatment they would not have pursued if aware of the true risks. The case of Merck's arthritis drug, Vioxx, is one of the most prominent examples of egregious omission of risk information. The FDA sent Merck multiple letters concerning the omission of life-threatening cardiovascular risks in its Vioxx promotions. While many safer treatments to arthritis existed, thousands of consumers took a potentially dangerous drug under questionable pretenses (Topol 2004). This is not surprising, since experimental research finds that pharmaceutical marketing leads to a boomerang effect (i.e., undermining the patients' intentions to engage in health-protective behavior (Bolton et al. 2008)). The outrage following the exposure of Merck's omission of risk information spurred a multitude of class action lawsuits and hundreds of articles calling for a review of pharmaceutical marketing.

Highly egregious acts impact several groups of stakeholders. The aggregate impact of changes in behavior by these groups is figured into calculations of the financial impact of the event.

Physicians: When risk information is omitted in a promotion, physicians must worry about protecting themselves against malpractice suits in addition to suboptimal patient treatment. According to the Learned Intermediary Rule, physicians are responsible for warning consumers of the dangers associated with the drug regardless of the information conveyed in DTC advertising (Hill 2005). Therefore, when the deception involves highly egregious omissions of risk information, the potential for patient harm is higher and more physicians will

seek alternative treatments to minimize their own liability. Fewer prescriptions will decrease the firm's expected revenue from sales of the drug.

In addition to impairing future revenues, exposure of deceptive marketing that involves severe risk consequences will negatively impact the response or returns to the marketing actions (i.e., marketing elasticity) of the firms. Highly egregious violations will command the attention of physicians because of the potential risk of malpractice suits, and deception will engender distrust (Darke and Ritchie 2007). Physicians will be less receptive to future attempts at persuasion when they distrust the firm (Ortmann and Hertwig 2002). Cited pharmaceuticals will subsequently have lower returns on their marketing efforts. In addition to difficulty regarding promotional efforts, physicians will be more wary of information originating from the firm and will tend to distrust the clinical trials conducted by the offending firm. As a result, firms will have to spend more on marketing activities to achieve the same returns as before the event. In summary, subsequent to the exposure of deceptive marketing, costs to physicians will induce behavior that adversely affects the firm's future cash flow by both decreasing revenue and increasing future marketing and sales costs.

Past Consumers: Consumers who were misled by the cited pharmaceutical firm may take legal action against it if the omitted risk information led to severe harm. If the consequences to consumers of using the firm's product are minimal, most consumers will not be able to make a strong legal case. Omissions of risk information judged to be at the lowest levels of egregiousness involve a lack of fair balance. The FDA does not give a clear definition of fair balance, and, as a result, these claims are difficult to prove in court. However, if the total physical or financial harm caused by the deception is high, the potential litigation from misleading consumers could translate into enormous financial burdens for the firm. According to one analyst, "Any time it could be a safety issue it is a problem. Litigation based on safety concerns seems to hit traction with juries." Misleading marketing practices have previously resulted in multi-million dollar fines and class action lawsuit settlements. In 2008, as a result of concealing information about fatal side effects associated with its arthritis

drug Vioxx, Merck was ordered to pay claimants $4.85 billion, the largest settlement in pharmaceutical history.

Potential Customers: Patients are no longer limited in their power to choose not to refill a prescription but can also control the brands they are prescribed. As articulated by the American College of Physicians, "the current wave of direct-to-consumer advertising is putting patients in the diagnostic driver's seat" (Maguire 1999). As a result, consumers can reduce firm revenues by changing their physicians' prescribing behavior as well as their own purchasing patterns. When a cited marketing action for a drug involves highly egregious omitted risk information, potential customers will seek alternative treatments out of fear for their health. While the benefit-to-risk ratio may still objectively be favorable, consumers have a tendency to overweigh negative information, especially when they mistrust the firm (Sorescu and Gelb 2000). Therefore, citations for highly egregious acts of deception will impair drug revenues.

Furthermore, as with physicians, consumers will be less receptive to future attempts at persuasion following the exposure of deceptive marketing. Consistent with this expectation, a recent case study using a VAR approach of a product-harm crisis (salmonella poisoning of peanut butter) found that it led to quadruple jeopardy of a loss of baseline sales, reduced own price increased cross-price elasticities, and reduced marketing instrument effectiveness (Van Heerde, Helsen and Dekimpe 2007). The cited firms will thus need to engage in more costly marketing activities to achieve the same returns as those prior to the violation.

Competitors: Any statement that makes a drug appear to be better than it is or better than its substitutes may draw sales from its direct competitors. Under the Lanham Act, firms can sue competitors for deceptive advertising. However, the plaintiff must be able to prove that the claims are false and that consumers were deceived by the information. According to the courts, implied falsity, which is analogous to lack of fair balance or low egregiousness, must be proved via consumer survey which is not often a viable option (Manning and McKenna 2002). Therefore, an outright omission of risk information with clear and egregious consequences is easier to prove and more likely to be taken to court. The Lanham Act allows for

monetary damages to be recovered from the misleading firm and thus negatively affect its future cash flows.

Government: State and federal agencies also heavily penalize firms to fund consumer protection education programs and to cover the increasing costs of treating harmed consumers.

In summary, following an FDA citation, highly egregious omissions of risk information will translate into reduced estimates of cash flows due to decreasing future sales and increasing marketing costs and legal liability. In accordance with the efficient market hypothesis, a decrease in estimates of future cash flows will be reflected in negative abnormal stock returns (Brown and Warner 1985). Therefore, we hypothesize:

$H_1$: The egregiousness of the omitted risk information cited will be negatively associated with abnormal stock returns.

**Unsubstantiated Effectiveness claims**

Similar to omitted risk information, highly egregious unsubstantiated effectiveness claims can lead to suboptimal prescribing decisions as consumers may take on high levels of risk for little benefit or for less benefit than would be gained from an alternate treatment.The potential negative word-of-mouth from disappointed patients in the current environment of blogs and online forums is likely to be significant. The subsequent negative stock market reaction in the airline industry illustrates the impact of negative voice (Luo 2007). Since patients are likely to be more involved with pharmaceutical products than airlines, negative voice should lead to a significant reduction in future cash streams for firms that are cited for the use of unsubstantiated efficacy claims. Investors are also concerned with the reaction of physicians: "When there are marketing malpractices in the area of use of the drug that is for a particular indication, and if the ads suggest that it could be for other indications, physicians will definitely react." In the case of Schering Plough and Merck (the JV partners that make Vyotorin and Zetia), prescriptions fell dramatically and shares plunged 46% and 35% respectively following the exposure of their unsupported claims (Rubenstein and Winslow 2008).

Additionally, unsubstantiated effectiveness claims leave firms vulnerable to legal action by government agencies seeking reimbursement for unnecessary or ineffective medications paid for by programs such as

Medicaid. Following false statements regarding the effectiveness of Synthroid, Knoll Pharmaceuticals signed a $41.8 million settlement (Department of Justice 1999). More recently, Pfizer agreed to pay $430 million to federal and state agencies for off-label marketing tactics (Harris 2004). Given the totality of the impact of egregious unsubstantiated effectiveness claims on cash flow, we hypothesize:

$H_2$: The egregiousness of the unsubstantiated effectiveness claims/broadening of indications cited will be negatively associated with abnormal stock returns.

**Unsubstantiated Superiority Claims**

Unsubstantiated superiority claims make unproven claims about the inferiority or unpopularity of competing drugs. Since it is usually prohibitively costly and complicated for firms or regulatory agencies to conduct comparative brand studies, stakeholders are unable to assess whether these violations actually lead to harm or suboptimal prescribing decisions (Gottlieb 2007). Thus, we argue that violations of unsubstantiated superiority claims are unlikely to lead to litigation or changes in prescribing behavior. The exposure of this type of deception could still lead to a reduction in marketing elasticity. However, the lack of severity in the violation is not likely to draw enough attention to significantly alter behavior and cash flows. Therefore, we hypothesize:

$H_3$: Unsubstantiated superiority claims will be associated with abnormal stock returns. The direction of the effect is an empirical issue.

**Target Audience**

Another factor of the FDA violations, the intended audience of the advertisement, also affects the costs stemming from the event. Whether the campaign is directed at consumers or health care professionals influences the probability that the act will cause harm (i.e., the egregiousness of the act). Reasoning that health care professionals are better able to detect deceptive claims and avoid being misled by vague language than consumers are, DTC advertising will be more likely to result in deception (Mizik and Jacobson 2004).

While physicians make the ultimate prescription decision, patients increasingly pressure their physicians to prescribe specific drugs (Aikin 2003; Menon et al. 2004), and physicians have strong financial

incentives to respond to their requests or else risk losing them as patients (Gönül, Carter, and Wind 2000). The published physician surveys and secondary data studies offer inconclusive evidence about the extent of patient influence on prescribing, but experimental evidence shows patients have a powerful effect on physicians' prescribing practices (Gellad and Lyles 2007). In an experiment conducted by Kravitz et al. (2005), stealth patients making unannounced visits to physicians were prescribed drugs far more often when they requested them, even when the indications were questionable. Therefore, because DTC violations may mislead more of the individuals involved in the prescription choice decision, more total harm will result from violations and thus increase the possibility of future legal actions against the firm.

In a few jurisdictions, courts have begun expanding the liability of drug manufacturers concerning DTC advertising. Based on state consumer protection statutes, some courts have agreed that DTC advertising empowers consumers and nullifies the protection afforded to drug manufacturers via the Learned Intermediary Doctrine (Graham and Vest 2005). The penalties under these state consumer protection statutes are substantially higher than the common law claims to which they were subject previously. The costs to the manufacturer from state consumer protection statutes also lead us to hypothesize:

$H_4$: Citations for direct-to-consumer marketing will be more negatively associated with abnormal stock returns than when the cited marketing is directed towards physicians.

**Media Type**

Previous research has specified that the types of media used can influence the effectiveness of advertising and moral judgments (Morris et al. 1986). Although we do not provide a directional hypothesis for print, we expect that the use of television will be negatively associated with abnormal stock returns. The difference in effect can be attributed to the ability of advertisements in these media channels to mislead consumers, the number of consumers exposed to the message, and the vulnerability of those exposed.

Researchers have found that consumers are more likely to miscomprehend televised drug advertisements than those from other media sources (Morris et al. 1986). The finding may be due to the

different guidelines for broadcast drug advertising set forth by the FDA. The rules for broadcast media advertising are appreciably more lenient than for other forms of communications and allow firms to simplify their messages (Coleman, Hartley, and Kennamer 2006). Often benefits are put in lay terms or portrayed visually, while competing sounds and visuals may be displayed during the disclosure of risk information. These factors have been shown to increase brand recall and positive associations (Callcott and Phillips 1996). Additionally, some critics argue that emotional appeals, which are more frequently used in television than in print, target the populations most vulnerable to persuasion (Macias, Pashupati, and Lewis 2007).

Because televised ads are likely to mislead viewers and thus lead to suboptimal health care, the firm has a greater chance of being the target of costly class action and government lawsuits. Therefore, we expect shareholders to pull out of their positions in the cited firm and abnormal returns of the stock to follow.

$H_{5A}$: Citations for television communications will be negatively associated with abnormal stock returns.

Print advertising covers a broad range of communication including brochures, magazine spreads, and tradeshow displays. Print communications are required by the FDA to include a brief summary of all risk and side effects as opposed to only the major risks required of broadcast ads. We do not argue a directional hypothesis for print communication as competing arguments exist about the persuasiveness of this medium.

Print is generally considered to be more informative and credible than other forms of advertising (e.g., Macias, Pashupati and Lewis 2007). Moreover, print media has been found to have a stronger transformative impact on affect and product attitudes than television (Bronner and Neijens 2006). Accordingly, it could be argued that misleading information in print advertisements is likely to be believed and lead to suboptimal patient care or harm. As a result, stakeholders will change their behavior in ways that will reduce future cash flows (e.g., filing law suits or prescribing the drug less often).

However, the technical language of these advertisements may make them ineffective. A recent study finds that the great majority of Americans are unable to understand the risk and benefit language of print

advertisements for drugs, and frustrated consumers ignore the information in such advertisements altogether (Sheehan 2007) As for physicians, the print medium allows them to process the information at an optimal pace. According to Darley and Smith (1993), print reduces agreement to non-credible messages because an expert audience is able to consider the difficult points and elaborate at will. If print advertising is ineffective and unable to deceive consumers or physicians, resulting harm will be minimal and estimates of future cash flow will not be affected. Given these competing arguments:

$H_{5b}$: Citations for print communications will be associated with abnormal stock returns. The direction of the hypothesis is an empirical issue.

The remaining media category, labeled "other media," includes primarily campaigns using mixed media, as well as, radio and detailing promotions. Because this category included a diverse group of promotion types, we did not put forth a hypothesis for these alternative types of communication.

**Brand Market Share**

The brand's market share does not impact stakeholders in any way not anticipated by investors and should not have a direct impact on abnormal stock returns following the exposure of deception. However, the level of brand market share will affect the relationship between the issue-contingent factors and market valuation. We argue that low brand market share of a cited product will reduce the impact on cash flow of the event characteristics. When market share of the brand is low, the majority of investors do not have prior knowledge of the brand or the extent to which stakeholders are likely to change their purchasing behavior or take legal actions. Therefore, we argue that investors are unlikely to have different estimates of future cash flow based on the egregiousness of the act or the target audience when brand share is low. On the other hand, when the brand market share of the cited product is high, the brand is salient and investors are better able to distinguish between the impact of different types of deception. Therefore, we hypothesize:

$H_{6A}$: Egregiousness of omitted risk information will have a stronger negative association with abnormal stock returns when brand market share is high than when brand market share is low.

$H_{6B}$: Egregiousness of unsubstantiated effectiveness claims will have a stronger negative association with abnormal stock returns when brand market share is high than when brand market share is low.

$H_{6C}$: Target audience will have a more negative association with abnormal stock returns when brand market share is high than when brand market share is low.

**Controls and Moderators**

We control for previous firm citations, market dependence, brand sales and advertising spending, each of which may affect negative abnormal returns. Previous citations sent to the firm may dull the negative impact of subsequent FDA citations. When a firm has been cited numerous times for marketing violations, its inclination towards illegal or deceptive activities will be taken into account in the firm value. Davidson and Worrell (1992) found that recalls in the automotive industry occur so often that the impact of a specific announcement has little or no effect. It can be argued that reductions in cash flow related to deceptive marketing will already be included in the stock evaluation. Brand sales of firms have been found to explain a significant amount of variance in the ability of firms to react to costly events (Moorman, Du, and Mela 2005; Tellis and Johnson 2007) Advertising spending is included as a control in the main model because it is well established that the level of advertising spending has a significant positive impact on estimates of future cash flows and shareholder value (e.g., Bharadwaj, Bharadwaj, and Konsynski 1999; Osinga et al. 2008). Advertising spending is positively correlated with both perceived and objective quality (Moorthy and Zhao 2000). Because advertising creates positive associations about a brand, investors may be more surprised by negative information about a brand with high advertising spending, and its stock price may fall. On the other hand, when positive associations are held about a brand, Ahluwalia, Burnkrant, and Unnava (2000) found the impact of negative information on attitudes is minimized, but, when a brand is unfamiliar, negative information is perceived as more diagnostic for the brand.

## METHODOLOGY AND DATA

**Research Methodology**

The impact on the financial market of the deceptive marketing detailed in the FDA warning letters is assessed using an event study methodology. This approach has a long history in finance and accounting of capturing the impact of mergers and acquisitions, earnings, stock splits, and other changes. Marketing researchers exploring the link between marketing actions and financial market impact have increasingly adopted this method (Srinivasan and Bharadwaj 2004). While common in finance, studies examining the impact of negative events using the event study method are far less prevalent in marketing.

The approach we have adopted follows theory and guidelines in the event study methodology literature (e.g., Brown and Warner 1985). This method assumes that changes in stock prices reflect information made newly available to investors. In this instance, the publicly available information about the FDA deceptive marketing violations is immediately incorporated to assess the impact of the FDA violations on either or both revenues and costs and, therefore, the future cash flow of the firm.

To assess the event's impact on the firm's shareholder value, we use the Fama-French-momentum four-factor model, which is also referred to as the Carhart model, to assess the change in the stock's price or the abnormal return (Fama and French 1996; Carhart 1997). The traditional market model estimates abnormal returns as the actual *ex post* return of the stock over the event window minus the expected normal return of the firm over the event window if the event did not take place. For each firm *i* and event date *t:*

$$\varepsilon_{it}^{*} = R_{it} - E[R_{it} \mid X_t] \quad (1)$$

where $\varepsilon_{it}^{*}$, $R_{it}$ and $E(R_{it})$ are the abnormal, actual, and normal returns, respectively, for the time period *t*. $X_t$ is the conditioning information for the normal performance model for the stock. The Carhart approach incorporates four additional factors that can contribute to differences in stock returns: the size of the firm, the market-to-book ratio, the firm's risk class, and its momentum (Carhart 1997):

$$\varepsilon_{it} = (R_{it} - R_{rf,t}) - \alpha_i - \beta_i (R_{mt} - R_{rf,t}) - s_i SMB_t - h_i HML_t - u_i UMD_t \quad (2)$$

where, for firm *i* at time period *t*, $\varepsilon_{it}$ is abnormal returns; $R_{it}$ is actual returns; $R_{mt}$ is returns for portfolio m; $R_{rf,t}$ is

risk free returns; $SMB_t$ , $HML_t$, $UMD_t$ control for differences in return due to size, tangible assets, and momentum, respectively.

As reported later, we use three broad-based indexes (S&P 500, NYSE, Nasdaq) and a pharmaceutical industry stock portfolio to proxy the market portfolio. Removing the portion of the stock's return that is related to variations in the market's return decreases the variance of the abnormal return resulting in an increased ability to detect the effect of the event on the stock's returns.

The market model was estimated with data from 250 trading days to 6 trading days prior to the event day. The event day was the day the FDA warning letter was posted on the FDA website, thus becoming public information. A two-day window was chosen to calculate the cumulative abnormal returns (CAR) since some of the letters may have been posted late in the day on the FDA website, and, consequently, the financial market impact may occur only on the following trading day. Moreover, the two-day window calculating CARs is long enough to capture the significant impact of the event and also short enough to exclude confounding events. The cumulative abnormal return is calculated as follows:

(3) $$CAR_i[t_1, t_2] = \sum_{t_1=0}^{t_{2=1}} \varepsilon_{it}^*$$

**Data**

Regulatory letters have been the subject of event studies across many disciplines. Statistically significant abnormal returns have recently been found for such events as automotive recalls (Davidson and Worrell 1992) and the announcement of drug withdrawals (Ahmed, Gardella and Nanda 2002). There is no reason to suppose that investors would be not anticipate these events while anticipating the publishing of the FDA letters. Pharmaceutical firms spend over $3 billion dollars a year on promotional activities. The varied and abundant promotion performed by pharmaceuticals make these activities as difficult or more difficult for investors to monitor than the activities of the firms in the cited studies. Therefore, we expect that deceptive marketing is not taken into account in security prices before the release of the FDA letter.

The population for our study is composed of all citation letters posted on the FDA website from the DDMAC. Our final sample was drawn using the following considerations. First, because the data is analyzed using the event study methodology, letters are included only if they are addressed to a publicly-traded pharmaceutical firm. Second, letters became available on the FDA website beginning in 1997, when pharmaceutical marketing regulations were loosened and DTC spending mushroomed (Huh and Langteau 2007). However, the great majority of the letters from 1997 and 1998 were released on the same day as other letters. Multiple events occurring on the same day could have had confounding effects (Geyskens, Gielens, and Dekimpe 2002), so we excluded all observations from these years. Third, we also excluded letters if multiple brands were cited in one citation because many of the explanatory variables are specific to a single brand. Fourth, the event date used is the date the letter was made public, which is the day that it was posted on the FDA's website. We conducted a thorough search of *The Wall Street Journal Index* to identify whether information about the letter was leaked prior to the posted release date or if other firm-related events were reported at or around the time of the event (Lane and Jacobson 1995). If evidence of either issue was found, the event was excluded. Data on the other independent variables of interest was available for only 170 letters, which became our effective sample size.

**Measurement**

*Dependent Variable*

The dependent variable, the financial impact of the deceptive marketing practices, was measured using the net present value (NPV) of the event for the following reason. Since CARs vary with firm size, larger firms tend to have smaller abnormal returns and smaller firms tend to have much larger abnormal returns (Anand and Khanna 2000). Net present value captures the total gains or losses of these events and alleviates the scaling problem faced otherwise (Kalaignanam, Shankar, and Varadarajan 2007). We computed the financial impact as the product of the CARs in the two day event window (0,+1) and the market capitalization of

the firm twenty days before the event (Chan et al 1997). We use the shortest significant window to minimize confounding effects. Stock market data were collected from CRSP, and factors particular to the Fama-French and Carhart approaches were collected from Professor Kenneth French's website.[4]

*Independent Variables*

The letters from the FDA may concern multiple promotional materials and multiple violations of varying degrees of severity. Either in the introductory paragraph or by subtitle, the letters identify clearly the violation(s) for which the firm is cited. Because unsubstantiated superiority claims do not vary in egregiousness, they were treated as a dummy variable, where "1" denotes that the violation was mentioned one or more times, and "0" indicates that no unsubstantiated superiority claims were made.

The other two violations were coded according to their severity on a scale from zero to three, where zero indicates no violation. The egregiousness of unsubstantiated effectiveness claims and omission of risk information is determined by the level of deception and the criticality of the information concealed (see appendix). Characterizing drugs along these two dimensions is common in medical journals and business literature on deception (e.g., Andrews, Netemeyer, and Burton 1998; Markovitch, Steckel, and Yeung 2005). The level of deception refers to whether the violation involves a false statement versus a misleading implication. Ads containing only misleading implications include all of the required information but may present it unclearly or in such a way as to emphasize benefits over risk (Schwartz et al. 2009). The promotions that involve implicitly false claims are less likely impact future cash flows for two reasons. First, these types of violations are difficult to prove and are often rejected by courts as a basis of liability suits (Giliberti 2003). Second, without extrinsic evidence supporting the actual interpretation of the representation by viewers, stakeholders usually cannot determine whether the ad will cause harm (Yao and Vecchi 1992). Therefore, when the violation involves a misleading implication, the event is coded as "1" regardless of the criticality of the

[4] http://mba.tuck.dartmouth.edu/pages/faculty/ken.french/data_library.html

information concealed.

When the violation involves a false statement, it is considered more egregious, and the event is coded as "2" or "3" depending on the type of information concealed. According to the FDA, a serious adverse drug event is one that results in death, a birth defect, a disability, or a hospitalization. When a false claim relates to these types of serious harm, the event is considered extremely egregious and is coded "3".

One author and a research assistant independently coded the egregiousness of each unsubstantiated effectiveness claim and omitted risk violation. The reliability of the severity measures was assessed using the proportional reduction in loss (PRL) approach (Rust and Cooil 1994). This approach is identical to Perreault and Leigh's measure when two judges are used (Perreault and Leigh 1989). The PRL level for severity of unsubstantiated effectiveness and omission of risk information is .94 and .93, respectively. These PRL levels fall well above the generally accepted minimum level of .90 (Rust and Cooil 1994).

The letter also identifies the intended audience. The DTC measure was treated as a dummy that takes the value "1" when all or part of the cited marketing efforts were directed at consumers and "0" when directed only at medical professionals. The type of media was treated as three dummy variables: print, where "1" indicates only print; television, where "1" indicates only broadcasts; and other media, where "1" indicates a combination of media or alternative promotions. In our sample, print accounts for roughly 65% of citations, while television and mixed/other accounts for about 17% each.

*Control Variables*

Previous violations were measured simply as a sum of all prior citations posted online, which includes all citations from March 1997 forward. To control for firm size, advertising spending was treated as a percentage of firm sales. Brand market share was calculated as the percentage of prescriptions within the treatment category. Annual measures of U.S. advertising spending and market share were obtained from Verispan, a market research firm that tracks marketing activity in the pharmaceutical industry. Data for firm

sales was collected from COMPUSTAT. We include the measures corresponding to each year of the violation.

## RESULTS

Table 2 presents the average abnormal returns for all letters in our sample posted on the FDA website on the event day as well as for several windows around the event. The results indicate that, on average, for the two day window (day "0" to "1"), firms that are cited on the FDA website for deceptive marketing practices experience a 1% drop in excess returns. The loss of 1% in excess returns translates into a wealth loss of $86 million for the median firm in the sample. In contrast, marketing events with positive news average gains of 0.42% across announcements of new product introductions (Chaney, Devinney, and Winer 1991), brand extensions (Lane and Jacobson 1995), celebrity endorsements (Agrawal and Kamakura 1995), product preannouncements (Sorescu, Shankar, and Kushwaha 2007), and new internet channel additions (Geyskens, Gielens, and Dekimpe 2002). The lack of significant abnormal returns before the event window suggests that there is no leakage or anticipation of information about the FDA warning letters (McWilliams and Siegel 1997). The cumulative average abnormal returns (CAAR) for longer windows after the event CAAR [1 to 5], CAAR[1 to 20] and CAAR[1, 100] are not significant. Following Gielens et al. (2008), we ran a pooled regression of the CARs against the time since the event date. This analysis indicates no drift in the results ($p<0.10$). The short event window and the insignificance of the subsequent drift are consistent with the efficient market assumption that is implicit in the method used in the study.

*[Table 2 About Here]*

### Explaining the Heterogeneity in Abnormal Returns

While the market generally views the FDA warning letters as a negative signal and delivers negative stock returns overall, there is still significant heterogeneity around the returns. Table 3 provides the results of the cross-sectional explanation of the variation in the observed stock-price reactions.

*[Table 3 About Here]*

Omission of risk information has the anticipated negative effect (b=-0.26, p<0.001). Therefore, H1 is supported. H2 also finds support, since the effect of unsubstantiated effectiveness claims is also negative (b=-0.20, p<0.05). While we had not developed a directional hypothesis for the effect of superiority claims, this violation has a positive but not significant association with abnormal returns (H3: p>0.05). Consistent with expectations, H4 is supported as DTC advertising has a significant negative effect (b=-0.27, p<0.001).

Model 2 provides the results for hypotheses H5A and H5B. For this analysis, we replaced the DTC variable with more specific measures that examine the effects of media type used. H5A is not supported (p>0.05), but the parameter estimate for TV is in the expected direction (b=-0.06). Print DTC advertising, on the other hand, has a positive and significant effect on the net present value (b=0.13, p<0.05). Thus, H5B is supported. While we do not posit a directional hypothesis, other media has a negative and significant impact on net present value (b=-0.65, p<0.001).

To test the moderator hypotheses, the sample was split on the median level of brand market share into two groups. A z-test was used to assess the difference of coefficients between the two samples. For two coefficients $\beta_i$ and $\beta_j$,

(4) $$z = (\hat{\beta}_i - \hat{\beta}_j)/[s^2(\hat{\beta}_i) + s^2(\hat{\beta}_j)]^{1/2}$$

where the null hypothesis of equality of the coefficients follows a standard unit normal (Clogg, Petkova, and Haritou 1995). Under the assumption that the samples are independent, the standard error of the difference is equal to the square root of the sum of the two squared standard errors. Support is found for H6A-C since the negative effects of the omission of risk information, unsubstantiated efficacy claims, and DTC advertising are larger when the brand market share is high than when the brand market share is low (all p<0.05). In fact, these results are conservative since we use sub-samples to test the hypotheses rather than creating continuous variable interactions with the full sample. Furthermore, using split samples reduces the likelihood of

multicollinearity, a common problem when interaction variables are used in regression models. In fact, the VIFs do support this expectation and multicollinearity is not an issue (maximum VIF=2.32). As shown later, creating continuous variable interactions in the full sample proved consistent with the sub-sample analysis.

In summary, the results indicate that the financial marketplace takes a bleak view of the regulatory exposure of egregiousness acts of deception and those aimed at consumers. The results also indicate that these relationships are more negative for firms with high brand market share. Among the controls, age of drug, therapeutic category, and year are not found to be significant. The results for the main effects of advertising, market share, and previous citations are also not significant in all models.

**Robustness Checks**

The results discussed so far are robust to alternative models of stock returns, alternative stock portfolio-based measures of abnormal returns, time and age effects, heteroskedasticity, and examination of risk. We used two other popular models to estimate the abnormal stock returns: CAPM and Fama-French 3-factor. The CAPM approach is equivalent to the one-factor market model described above, and the Fama-French 3-factor is similar to the Carhart 4-factor model without the inclusion of momentum. In both cases the results were not significantly changed (see Table 4). The omitted variables in the CAPM, however, weakened the power of some of our results.

*[Table 4 About Here]*

We used three alternative benchmark portfolios to calculate the market and abnormal returns: a portfolio of firms trading in NASDAQ, a portfolio of firms trading in NYSE, and a portfolio consisting only of pharmaceutical firms. We also calculated equally-weighted and value-weighted versions of abnormal returns. The cross-sectional regression analysis, based on these six measures (3 portfolios X 2 types of abnormal return calculation), yields results that did not materially change.

We also regressed the explanatory variables against the two-day CAR. Table 5 shows that the results

remain robust to the operationalization of the dependent variable.

*[Table 5 About Here]*

In all of these models, we controlled for effects due to time, therapeutic category, and age of the drug. We conducted this analysis by including year dummies, therapeutic category dummies, and a continuous measure of the time since each drug's approval for marketing. Inclusion of these controls did not alter the results for the key variables in any significant fashion.

To examine if the results were driven by a reduction in the returns or an increase in the risk, we explored each firm's stock return volatility $\sigma^2_i$ over two different windows: the pre-event window (-250,-1) and the post event window (0, 250), where "0" represents the event date. Market volatility $\sigma^2_m$ was also estimated over the same window. Following standard practice in finance (e.g., Schwert 1989), we calculated a volatility ratio, defined as, $\lambda$ = square root of ($\sigma^2_i / \sigma^2_m$). A comparison of the volatility ratio $\lambda$ over the pre-event and post-event windows serves as an estimate of the effect of the event on firm volatility. The ratio $\lambda = 0.99$ indicates that the volatilities, relative to the market, were not different before or after the event. Thus, the event's impact was not on the firm's stock return volatility[5].

## DISCUSSION

### Contributions to Research

Linking marketing actions to financial performance has been named a capital research priority of the Marketing Science Institute. The empirical work in marketing on this issue has typically examined the financial impact of positive marketing events. Our study extends the limited extant research on the financial value of

[5] We also examined if the firm's credit ratings (which have been used as a proxy for a firm's default risk) changed as a result of the FDA citations (Avramov et al. 2009; Anderson and Mansi 2009). Firm credit ratings are determined by rating agencies using assessments of probability distributions of future cash flows to bondholders. The data was drawn from S&P Long-Term Domestic Issuer Credit rating. The ratings range from a triple AAA rating to a D rating. We used the transformed numerical rating ranging from 1 for AAA and 22 for a D-rating. We examined the average credit rating the month before the event (posting of the FDA citation letter) and compared it to average credit ratings for the firm the month after the event. Simple t-tests indicate no significant change in the credit ratings after the event. Taken together, these results suggest that all the effect appears to be on the returns rather than risk.

negative events by examining deceptive marketing, a phenomenon pervasive in pharmaceuticals as well as in other industries. In addition to quantifying the financial market impact of deception, this study identifies a set of factors that comprise a substantial proportion of the variation in negative events.

While it has been thoroughly established that product harm crises and product withdrawals significantly impact firm value, the cost of the regulatory exposure of deceptive marketing has not been researched. Using the event study methodology, we find that the exposure of certain forms of deceptive marketing practices can lead to a significant reduction of firm value. Overall, our analysis shows a noteworthy loss of wealth by investors. The average change in excess returns following an FDA citation was 1%. For Pfizer, whose market capitalization was $97.91 billion on June 7, 2009, this translates into a wealth loss of almost a billion dollars. Compared to positive events, which have typically been explored in the marketing literature, the exposure of deceptive marketing has a significantly larger impact. Moreover, our analysis finds that firms can be financially punished even for negative marketing events that involve no direct costs to the firm.

The primary goal of this research was to deconstruct these events in order to understand what factors can explain the variance in market reaction to exposed acts of deception. Studies in finance and marketing involving negative abnormal returns have primarily considered events with high direct costs, such as automobile recalls, and have not been able to explain a substantial proportion of the often large indirect costs. The few past studies on value-reducing events that have considered the variation in shareholder value between events have only included firm characteristics, which are largely found to be insignificant. Our analysis has shown that characteristics of the event explain much of the heterogeneity of the impact of negative events.

We found that regulatory exposure of some acts of deception had no impact on firm value and a few even boosted share prices. For instance, the net present value of Pfizer saw an increase of $4 million when, in

2004, the FDA issued a letter regarding the omission of risk information on the website for its drug Zyrtec. However, under certain conditions, we are able to conclude that the cited firms do incur a significant financial penalty. In the main effects model, egregiousness of the violation and vulnerability of the target audience had significant and negative impacts on market value. As predicted, violations at levels of low egregiousness or unconfirmed egregiousness (i.e. unsubstantiated superiority claims) did not reduce estimates of future cash flows. As explained by one analyst, "Superiority claims are just about which drug you should buy. . . It makes people angry to pay more, but safety concerns carry greater weight."

The target audience of the misleading marketing is also critical to the impact of its exposure. The results indicate that firms are penalized far more severely when deception is directed at consumers than physicians. These results lend support for our argument that firm value is negatively impacted the most by acts of deception that target those most vulnerable to deception and that may lead to severe harm.

The results for type of media are slightly more difficult to interpret. Print media was positively related to abnormal returns which may be explained by the low likelihood of these ads to persuade or deceive given the highly technical language (Sheehan 2007). Broadcast media was not significantly related to abnormal returns. Despite the ability of the emotional appeals commonly used in these advertisements to persuade (Perrone 2007), the likelihood of deception may be dampened by the perceived untrustworthiness of the medium (Macias, Pashupati, and Lewis 2007). The negative results for "other media" are consistent with those of Narayannan, Desiraju, and Chintagunta (2004), who find synergies among various marketing investments lead to increased ability of a mixed media campaign to persuade.

Less intuitive, and perhaps the greatest contribution of our study, are the findings regarding the moderating effect of brand market share. As expected, brand market share did not have a direct impact on abnormal returns. In other words, firms using deceptive advertising for larger share brands were not punished overall more than firms using misleading claims for smaller share brands. However, brand market share made

a considerable difference in the relationship between the event characteristics and abnormal returns. For brands with large market share, egregiousness of violation and target audience explained a large proportion (over 40%) of the variation in abnormal returns following a citation. Yet, for brands with low market share, these factors explained almost none of the variation. Hence, we can conclude that firms cited for deception related to brands with high brand market share are punished more for highly egregious acts or deception aimed at vulnerable populations than for acts of deception that are less severe or physician-directed. However, firms cited for deception related to brands with low brand market share experience no significant difference in impact for acts of high or low egregiousness or by target audience.

**Implications for Managers**

The results of our research will enable Main Street managers and Wall Street executives to make more informed decisions about the financial risk of potentially destructive marketing strategies. Our findings indicate that Main Street managers need to consider both the target audience and the potential harm when communicating with outside stakeholders. Managers will also want to consider how these factors will interact with brand market share and advertising spending.

Although we did not have any ex ante expectations about the impact of advertising spending, a post-hoc analysis of its moderating role suggests that advertising spending also impacts the relationship between some of the event characteristics and abnormal returns (see columns 6 and 7 of Table 3). While the findings are more difficult to interpret than those concerning the moderating impact of brand market share, a few interesting observations can be made. Brands with high advertising spending (i.e., on average, more visible brands) lose more when cited for marketing directed at consumer or claims involving omitted risk information, whereas, these characteristics do not influence the relationship between the citation and abnormal stock market returns when the brand advertising spending is below the industry average.

With healthcare and highly technical products, Main Street managers may not be able to guard

against misinterpretations that could lead to public harm and, consequently, reduced cash flows for the firm. The possibility of such outcomes along with widespread criticism of pharmaceutical advertising has been attributed as the motivation for recent announcements by several major pharmaceutical firms, including GlaxoSmithKline and Pfizer, that spending on DTC advertising will be reduced significantly (Whalen 2009). On the other hand, while managers have to view this result as preliminary evidence, it still seems to imply that such acts of deceptive marketing do not put the firm in a double-jeopardy by negatively impacting return and risk.

**Implications for Public Policy**

For policymakers who consider how to effectively dissuade firms from utilizing misleading claims, our study offers some important insights. We are able to quantify the average financial penalty of different types of misleading claims following an FDA citation. Citations for certain acts, such as unsubstantiated superiority claims and for the use of print media, may actually boost firm value under some circumstances. In these cases, the citations may be encouraging the use of misleading tactics.

Under other conditions, the financial market heavily penalizes firms for garnering FDA citations. Several factors may contribute to the continued prevalence of deceptive practices given the potential for high financial losses. One potential cause may be that firms are not aware of the factors associated with high penalties and are willing to gamble with deceptive marketing actions. Another reason may be that managers believe that they will not be exposed, thus leading to moral hazard. Spending on drug promotion in the U.S. is rapidly rising, while the number of citations has been decreasing, the size of the DDMAC staff has stayed relatively constant, and the DDMAC budget has been shrinking (Domestic Social Policy Division 2005)(see Figures 1 and 2). Additionally, the process of issuing citations has increased in difficulty and length (from a few days up to 78 days) (Domestic Social Policy Division 2005). As a result of these factors

and despite assurances from the FDA that all pharmaceutical communications are reviewed, firms may believe that detection is not certain.

*[FIGURES 1 and 2 About Here]*

Finally, policymakers need to consider whether the loss of firm value following the publication of a citation outweighs the positive boost in sales associated with the misleading message. While calculating the overall payoff of using deceptive marketing is beyond the scope of this study, this analysis provides a set of factors that should be considered when evaluating the violations that may require additional fines to offset gains in sales.

**Limitations and Further Research**

Our study was restricted to a single industry with specific characteristics that make it necessary to use caution when generalizing these findings. Although we do not expect that the overall drop in market value will be as high for many other industries, we argue the relative degree of impact will be influenced by the factors identified in this study. Nevertheless, the magnitude of sales and advertising spending in the pharmaceutical industry make the analysis significant in itself. The drugs included in the study represent $95 billion in annual sales and $13 billion in advertising spending for the year of their respective citations. The letters were sent to firms regarding drugs that, on average, had $426 million in annual sales and represented almost one third of all prescriptions in its treatment category.

Since the focus of our study was the regulatory exposure of deceptive marketing, we cannot claim to have examined the full impact of deception. The financial impact of deception also includes any positive gains to the firm stemming from the misleading claim from the time it was initially communicated. We did not have access to appropriate data nor was this question the focus of our research. However, the issue posses an interesting question for future researchers.

Another limitation of this study is that the sample only included publicly traded firms. Accordingly, we

can say nothing about the impact of deceptive actions for privately held firms.

While we did rule out the impact of the FDA citations on the short-term risk of the firm (and attributed all value reduction to the stock returns), our analysis was rather preliminary. Future research should look at alternative risk metrics (e.g., the market, idiosyncratic and aggregate volatility risks faced by firms).

Our theoretical model considered the estimated impact of future behavior by multiple groups of stakeholders, but the method that we used could not separate the value placed on each. An experimental study needs to be conducted to distinguish the weight placed by analysts and investors on each group of stakeholders and on each type of action (e.g. litigation, lost sales, etc.).

Our analysis is also limited to the impact on the cited firm, but prior research indicates that advertising can have spillover effects on competitors. An analysis of the impact of regulatory exposure of deception on competitors' firm value, prescription share, and revenue would illuminate what managers can expect in the wake of their competitors' marketing missteps.

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**Table 1**
**Definitions and Examples of Promotional Violations Cited by the FDA**

| Violation | Definition | Example |
|---|---|---|
| Unsubstantiated Effectiveness Claims | (a) Representation of a drug as more effective than has been demonstrated by substantial evidence or clinical experience<br>(b) Representation of a drug as useful in a broader range of patients or conditions than has been demonstrated by substantial evidence or clinical experience | "You present the claim, 'It's not just for end stage cancer anymore!' This claim suggests that Duragesic can be used for any type of pain management. . . [this claim] is contradictory to the boxed warning in the PI. Specifically the PI states, 'Because serious or life-threatening hypoventilation could occur , Duragesic is contraindicated: in the management of acute or post-operative pain' . . . Therefore, [this claim] is misleading" (FDA 2000) |
| Omitted Risk Information | (a) Failure to reveal facts material to consequences that may result from proper use of the drug<br>(b) Failure to present information on side effects and contraindications of a drug with a prominence and readability reasonably comparable with the presentation of effectiveness information | "We are concerned about the section of your ad entitled, 'The FDA has confidence in the safety and efficacy of Crestor,' in that it misleading suggests that the Agency does not believe that Crestor poses safety concerns. . . There is, however, no statement on the website by FDA concluding that 'the concerns [about Crestor] that have been raised have no medical or scientific basis.' In fact, recent public statements made by the Agency contradict that conclusion" (FDA 2004) |
| Unsubstantiated Superiority Claims | Representation of a drug as more effective or safer than another drug when this has not been established by substantial evidence or clinical experience | "The [cited] ad features a picture of two people seated on an airplane. A man is sneezing and the text next to his picture states: 'In the right seat. On the wrong allergy medicine.' The woman in the seat next to him, who is not sneezing, is looking at him. The text next to her picture states: 'On top of things. On Zyrtec.' The prominent callout headline below the picture states 'Tired of your allergy medicine not working? Good thing there's Zyrtec'. . . The overwhelming message from the text and the visuals of these ads is the comparative claim that Zyrtec is more effective in treating allergies in general, or certain types of allergies, than some other allergy products. . . FDA is not aware of substantial evidence or substantial clinical experience demonstrating that Zyrtec is clinically superior to any other available OTC and prescription oral allergy medicine" (FDA 2005) |

Note: Definitions paraphrased from the Federal Food, Drug and Cosmetic Act

**Table 2**
**Abnormal Returns for Windows Surrounding the FDA Website Posting**

| Time Window with Day=0 as the Event Date | Mean Abnormal Return (%) Based on Carhart Four-Factor Model | T-Statistic |
|---|---|---|
| -5 | 0.18 | 0.95 |
| -4 | --0.18 | -0.98 |
| -3 | 0.06 | 0.35 |
| -2 | -0.22 | -1.17 |
| -1 | 0.21 | 1.11 |
| 0 | -0.60 | -1.97** |
| 1 | --0.41 | -1.68* |
| 2 | -0.20 | -1.00 |
| 3 | -0.11 | -0.61 |
| 4 | -0.26 | -1.40 |
| 5 | -0.17 | -0.40 |

**significant at p<0.05 *significant at p<0.10

**Table 3**
**Results with Net Present Value as Dependent Variable Based on Carhart Four-Factor Model**

| **Parameters** | **Standardized Estimate (Robust standard error)** | | | | | |
|---|---|---|---|---|---|---|
| | Model 1 | Media Type | Low Market Share | High Market Share | Low Ad Spending | High Ad Spending |
| Egregiousness of Omitted Risk Information | -0.26(0.13)*** | -0.33 (0.11)*** | 0.05 (0.12) | -0.35 (0.25)*** | -0.19(0.15)* | -0.52(0.24)*** |
| Egregiousness of Unsubstantiated Effectiveness Claims | -0.20 (0.16)** | -0.12 (0.15)* | -0.05 (0.17) | -0.40 (0.37)*** | -0.11(0.17) | -0.12(0.24) |
| Unsubstantiated Superiority Claims | -0.06 (0.27) | 0.14 (0.26)** | -0.08 (0.30) | -0.32 (0.46)*** | 0.15(0.30) | 0.06(0.55) |
| DTC | -0.27 (0.28)*** | | 0.17 (0.36) | -0.19 (0.51)** | 0.07(0.49) | -0.22(0.52)** |
| DTC (Print) | | 0.13 (0.39)** | | | | |
| DTC(Other) | | -0.65 (0.38)*** | | | | |
| DTC(TV) | | -0.06 (0.50) | | | | |
| **Controls:** | | | | | | |
| Brand Advertising/Sales Ratio | 0.13 (0.68) | 0.18 (0.60)** | -0.02 (0.53) | 0.10 (7.69) | | |
| Market share | 0.19 (0.003)** | -0.07(0.004) | | | 0.09(0.004) | 0.15(0.01) |
| Firm Letters | 0.07 (0.02) | 0.30(0.02)*** | -0.10 (0.02) | 0.37 (0.03)*** | 0.24 (0.03) | -0.19(0.04) |
| F-value (p-level) | 4.54 (0.0001) | 9.31(0.0001) | 0.26 (0.95) | 9.18 (0.0001) | 2.06 (0.005) | 4.34(0.0005) |
| $R^2$ ($R^2$ adj) | 0.17 (0.13) | 0.35 (0.31) | 0.02 (0.01) | 0.44 (0.39) | 0.15 (0.08) | 0.30(0.23) |
| Maximum VIF | 1.52 | 1.83 | 1.88 | 1.71 | 2.32 | 1.71 |

***p<0.001; **p<0.05 (one-tailed test)
Note: In addition, the models included twelve category dummies and seven year dummies. They are not shown in the table to save space.

**Table 4**
**Assessing Robustness of Results with Net Present Value as Dependent Variable Based on Alternative Models**

| | Fama-French 3-Factor Model DV: Net Present Value | | CAPM Model DV: Net Present Value | |
|---|---|---|---|---|
| | Model 1 | Model 2: With Media Types | Model 1 | Model 2: With Media Types |
| | Standardized estimate (Robust standard error) | Standardized estimate (Robust standard error) | Standardized estimate (Robust standard error) | Standardized estimate (Robust standard error) |
| Egregiousness of Omitted Risk Information | -0.25(0.13)*** | -0.32 (0.12)*** | -0.10 (0.11)* | -0.17 (0.11)*** |
| Egregiousness of Unsubstantiated Effectiveness Claims | -0.17 (0.16)** | -0.12 (0.15)* | -0.11 (0.15)* | -0.09 (0.14) |
| Unsubstantiated Superiority Claims | -0.05 (0.29) | 0.13 (0.28)* | 0.12 (0.27)* | 0.24 (0.30)** |
| DTC | -0.25 (0.28)*** | | -0.13 (0.25)** | |
| DTC (Print) | | 0.11 (0.42)* | | 0.08 (0.39) |
| DTC(Other) | | -0.55 (0.38)*** | | -0.32 90.42)*** |
| DTC(TV) | | -0.06 (0.49) | | -0.10 (0.50)* |
| **Controls:** | | | | |
| Brand Advertising/Sales Ratio | 0.09 (0.65) | 0.15 (0.60)** | -0.03 (0.60) | 0.08 (0.60) |
| Market share | 0.19 (0.004)** | -0.02(0.004) | 0.11(0.003) | -0.02 (0.004) |
| Firm Letters | -0.05 (0.02) | 0.14(0.02) | 0.02 (0.02) | 0.13 (0.02) |
| Age of the Drug | 0.11(0.09) | 0.06 (0.09) | 0.09 (0.13) | 0.13 (0.14) |
| F-value (p-level) | 3.75 (0.0001) | 5.32(0.0001) | 9.64 (0.0001) | 10.02 (0.0001) |
| $R^2$ ($R^2$ adj) | 0.41 (0.30) | 0.52 (0.42) | 0.64 (0.58) | 0.67 (0.60) |

***p<0.001; **p<0.05 (one-tailed test)
Note: In addition, the models included twelve category dummies and seven year dummies. They are not shown in the table to save space.

**Table 5**
**Assessing Robustness of Results with Two Day CARs as Dependent Variable Based on Alternative Models**

| **Parameters** | **Standardized estimate (Robust standard error)** | | | | | |
|---|---|---|---|---|---|---|
| | CAPM Model | CAPM Model | Fama-French 3-Factor Model | | Carhart 4-Factor Model | |
| | Model 1 | Model 1 | Model 1 | Model 2: With Media Types | Model 1 | Model 2: With Media Types |
| Egregiousness of Omitted Risk Information | -0.21 (0.002)** | -0.30(0.002)** | -0.14 (0.002)* | -0.18 (0.002)** | -0.16(0.002)* | -0.20 (0.002)** |
| Egregiousness of Unsubstantiated Effectiveness Claims | -0.26(0.003)** | -0.22 (0.003)** | -0.29 (0.002)** | -0.24 (0.002)*** | -0.27 (0.002)*** | -0.22 (0.002)** |
| Unsubstantiated Superiority Claims | -0.08 (0.17) | -0.10 (0.17) | -0.15 (0.005) | -0.05 (0.005) | -0.14(0.005) | -0.03 (0.005) |
| DTC | -0.29 (0.04)*** | | -0.21 (0.004)*** | | -0.22 (0.004)*** | |
| DTC (Print) | | 0.08 (0.007) | | 0.002 (0.008) | | 0.003 (0.009) |
| DTC(Other) | | -0.46 (0.006)*** | | -0.36 (0.007)*** | | -0.38 (0.007)*** |
| DTC(TV) | | -0.19 (0.007)* | | -0.06 (0.008) | | -0.05 (0.008) |
| **Controls:** | | | | | | |
| Brand Advertising/Sales | 0.21 (0.01)** | 0.25 (0.01)* | 0.13 (0.01) | 0.16 (0.01)* | 0.11(0.01) | 0.14 (0.01) |
| Market share | 0.27(0.001)** | 0.14 (0.001) | 0.29 (0.001)** | 0.19 (0.001) | 0.30 (0.00)*** | 0.18 (0.001) |
| Firm Letters | 0.11 (0.003) | 0.25 (0.003)* | -0.04 (0.001) | 0.08(0.001) | -0.04 (0.004) | 0.09 (0.001) |
| Age of the Drug | 0.06 (0.002) | 0.03 (0.001) | 0.04 (0.002) | 0.01 (0.001) | 0.04 (0.001) | 0.01 (0.002) |
| F-value (p-level) | 3.56 (0.0001) | 3.98 (0.0001) | 2.38 (0.0001) | 2.41(0.0005) | 2.45 (0.0005) | 2.52 (0.0003) |
| $R^2$ ($R^2$ adj) | 0.43 (0.31) | 0.48 (0.36) | 0.33 (0.19) | 0.35 (0.21) | 0.34 (0.20) | 0.36 (0.22) |

***p<0.001; **p<0.05 (one-tailed test)

Note: In addition the models included twelve category dummies and seven year dummies. They are not shown in the table to save space.

**Figure 1**

**Percentage Change in DDMAC Citations Issued and Advertising Spending by Pharmaceutical Firms**

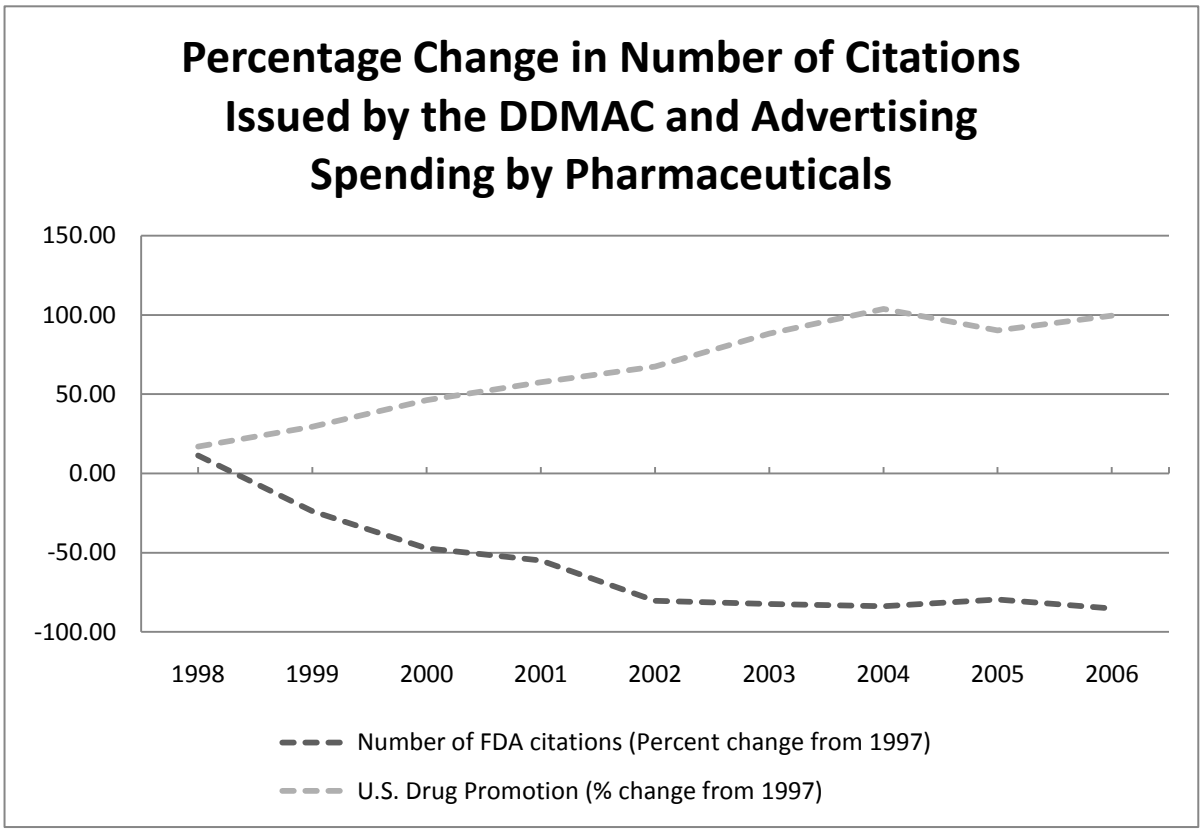
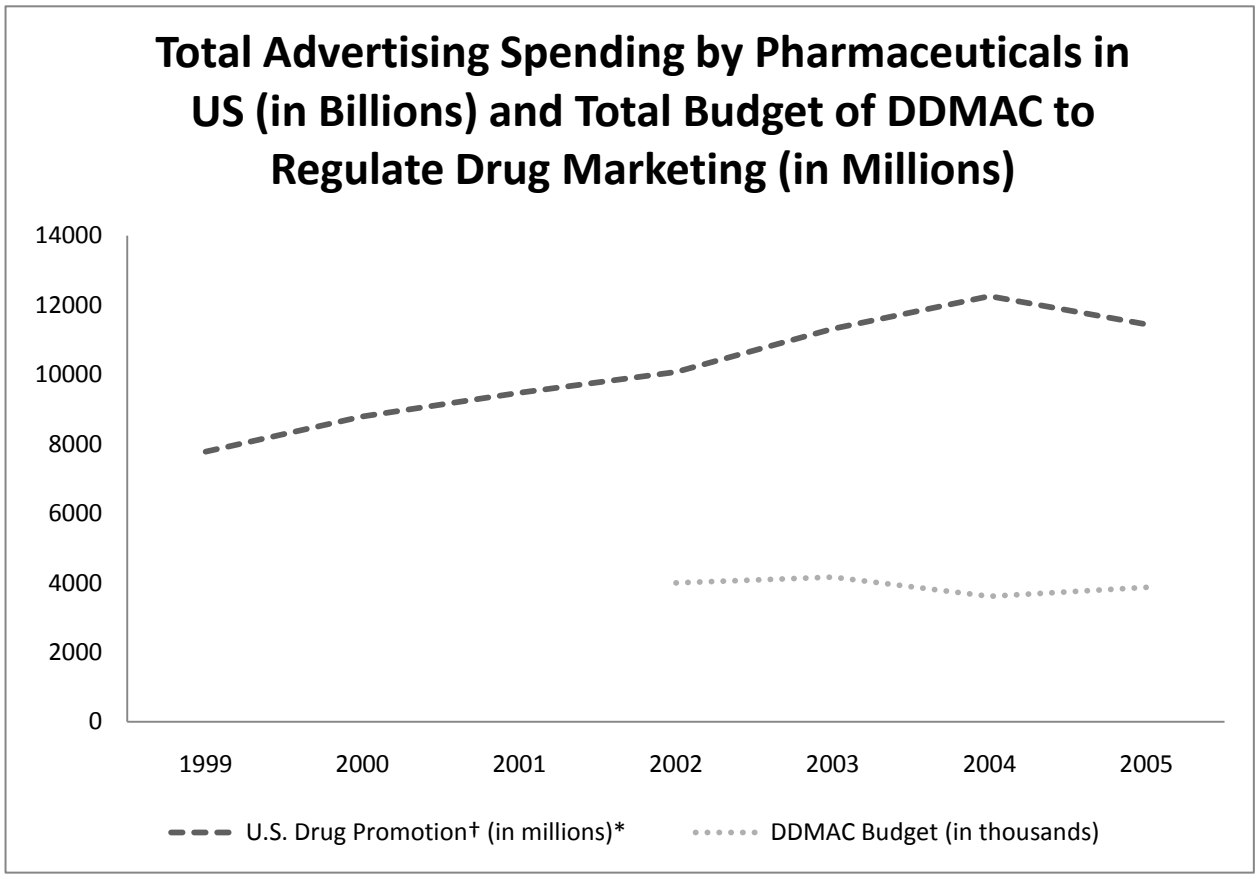


**Figure 2**

**Total Advertising Spending by Pharmaceutical Firms (in Billions) and Total DDMAC Budget to Regulate Drug Marketing (in Millions)**



## APPENDIX

### Criteria for Coding Egregiousness of Violations

**Egregiousness of Violations Concerning Unsubstantiated Effectiveness Claims**

Egregiousness is coded on a scale of 0 to 3 according to the extent of the unsubstantiated claim and the potential harm to public safety and health. If more than one promotional material contains a violation in this category, the level of egregiousness corresponds to the most severe violation cited.

- **0:** No citations
- **1:** When the efficacy/indication is stated, but not clearly. Thus, the promotion implies unapproved claims .
- **2:** When claims are directly made that are unsupported or false BUT the claims do not have life threatening or altering consequences
- **3:** When claims are directly made that are unsupported or false AND the claims have life threatening or altering consequences

**Egregiousness of Violations Concerning Omission of Risk Information**

Egregiousness is coded on a scale of 0 to 3 according to the extent of the risk information omitted and the potential harm to public safety and health. If more than one promotional material contains a violation in this category, the level of egregiousness corresponds to the most severe violation cited.

- **0:** No citations
- **1:** The risk information is fully divulged, but in an inadequate or unclear manor.
- **2:** All or a portion of the risk information is omitted in the promotional material BUT the claims do not have life threatening or altering consequences
- **3:** All or a portion of the risk information is omitted in the promotional material AND the claims have life threatening or altering consequences (“serious” or “significant”)