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Essays on Deceptive Marketing Strategies

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Doctor of Philosophy

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Essays on Deceptive Marketing Strategies

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B.A., Williams College, 2001

Advisor: Sundar Bharadwaj, Ph.D.

An abstract of
A dissertation submitted to the Faculty of the Graduate School of Emory University
in partial fulfillment of the requirements for the degree of
Doctor of Philosophy
in Business
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Abstract

Essays on Deceptive Marketing Strategies
By Martha Myslinski Tipton

This set of studies focuses on the antecedents and consequences of deceptive marketing. The first essay explores how marketing actions can destroy value by examining the stock market reaction to the exposure of deceptive marketing practices by pharmaceutical firms. Prior research has indicated that negative events vary greatly in their indirect costs to the firm. This study identifies a set of factors that explain a significant portion of the heterogeneity in the magnitude of indirect costs associated with negative marketing-related events. Specifically, the results indicate 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 variations in event impact than when brand market share is low. The second essay concentrates on the relationship between innovation and marketing strategy. The relationship between these concepts is relatively uncharted despite the criticality of innovation to firm health. Drawing mainly from the principals of prospect theory, I argue that current and potential innovation levels impact the likelihood of deceptive marketing. The analysis supports a relationship between use of deception and the strength of the innovation pipeline of a focal firm and its competitors. Together, these essays contribute to the literature on destructive marketing strategies and inform practitioners about the consequences and antecedents of unlawful marketing practices.

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TABLE OF CONTENTS

TABLES

ESSAY 1: THE REGULATORY EXPOSURE OF DECEPTIVE MARKETING AND ITS IMPACT ON FIRM VALUE

INTRODUCTION

Following the challenge outlined by Srivastava, Shervani, and Fahey (1998, 2) and subsequent criticism by Rust et al. (2004, 83), 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, 29), product quality (Tellis and Johnson 2007, 758), corporate reputation (Roberts and Dowling 2002, 1090), and product innovation (Srinivasan et al. 2009, 41). Researchers in this area have predominantly focused on how marketing assets and actions add to financial performance and shareholder value. I argue, however, that it is equally important to understand how marketing decisions can destroy firm value. It has been well-established that negative information and events often have a greater salience than positive ones (Mahajan, Muller, and Kerin 1984, 1389-1394; Lei, Dawar, and Lemmink 2008, 122), and I contend that understanding this effect requires the consideration of a different set of factors than those considered in value-building studies.

A handful of studies have found that negative production-related events, such as product recalls and drug withdrawals, produce significant negative abnormal stock returns (Ahmed, Gardella, and Nanda 2002, 21-25). In marketing, researchers have explored such phenomena as the impact of consumer negative voice (Luo 2007, 75-88), destructive acts in marketing channel relationships (Hibbard, Kumar, and Stern 2001, 55-58), endorsers involvement in undesirable events (Louie, Kulik, and Jacobson 2001, 13-23), and boycotting behavior (Klein, Smith, and John 2004, 92-108). Despite these

advances in understanding the destruction of firm value, many significant issues have not been addressed.

This study adds to this line of research by exploring the financial impact of the exposure of deceptive marketing. In contrast to previous research, I isolate the impact on shareholder value of a single type of destructive marketing action with no direct cost to the firm. As a result, I am able to quantify the financial impact of deceptive marketing and, more importantly, to identify a set of factors that explain a significant proportion of the variation in the indirect costs of negative events.

I conduct this analysis in the context of the U.S. pharmaceutical industry. Instances of deceptive marketing continue among these firms despite the fact that the pharmaceutical industry has arguably the strongest guidelines concerning marketing practices of any industry. Many physicians and consumer advocates reflect concern that the persistence of misleading claims is due to inadequate punishment by the U.S. Food and Drug Administration (FDA), which regulates all pharmaceutical communications with the public (Lyles 2002, 73-75). As maximizing shareholder value is a critical concern of public firms (Srivastava, Shervani, and Fahey 1998, 14-16), I address this concern by focusing on the relationship between the FDA's citations for deceptive marketing practices and stock market returns.

The response of the stock market to regulation by the FDA has been difficult to predict. For example, the FDA sent what superficially appeared to be similar citations for misleading risk claims to GlaxoSmithKline and Pfizer for televised advertisements. Despite the similarities, upon publication of the letters GSK's stock immediately dipped, but no significant abnormal excess returns followed the release of the letter sent to Pfizer.

Prior studies concerning value-destroying events have concentrated on firm and environmental characteristics and have not explained a significant proportion of the

variation in indirect cost between events. I take a different approach by considering the characteristics of the events. In fact, in research examining value-creating activities, it is common for researchers to consider characteristics of the action when explaining the magnitude of change in market capitalization (Tellis and Johnson 2007, 760). In the context of deceptive marketing, the event characteristics that vary between occurrences are the type of violation, the egregiousness of the violation, the target audience, and the marketing communication medium.

The primary expectation of this paper is that market analysts and shareholders anticipate how the event will impact future cash flows to the firm. 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 thus alter the firm's future cash flow. I argue that event characteristics that raise the cost of the event for stakeholders will motivate actions that will punish the firm and decrease future cash flows to the firm.

To measure the aggregate financial impact of these events, I use an event study to calculate abnormal stock market returns, which, according to the efficient market hypotheses, provide an unbiased estimate of changes to future cash flow that can be attributed to a single event (Fama 1970, 383). This analysis shows that, overall, incidents of exposed deceptive marketing are associated with significant negative abnormal returns. Unlike previous event studies, these incidents do not include any direct recall or withdrawal costs to the firm. In the second part of the analysis, I look at the factors that explain the variation in abnormal returns between events. I 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 vulnerable populations and those involving severe consequences)

are associated with negative abnormal returns. Conversely, deceptive activities with lower total costs, namely unsubstantiated superiority claims and direct-to-consumer print advertising, are not. I also find moderating effects for brand market share and advertising spending that are consistent with the notion of stakeholder cost. The developed framework and analysis have implications for financial analysts, corporate managers, academic researchers, and public policy.

CONCEPTUAL BACKGROUND

The Pharmaceutical Industry and Deceptive Marketing

Several factors make the pharmaceutical industry especially conducive and relevant to marketing research. Over the past two decades, pharmaceutical firms have been shifting their focus away expensive, newly discovered molecules and toward the marketing and development of new formula variations of existing drugs and new uses for existing drugs (Angell 2005, 24). The drug industry association, PhRMA, argues that spending on research and development (R&D) still outpaces promotional spending (Egan 2004). However, critics, including academic researchers and members of Congress, contend that standard measures of promotion exclude significant costs and rely on surveys of the pharmaceutical firms, which have incentives to underestimate marketing spending (Gagnon and Lexchin 2008, e1). Some researchers estimate that many major pharmaceutical firms spend more on marketing promotions than R&D (Angell 2004, 1451). 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, 675). 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, 910-911).

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, omitted risk information, and unsubstantiated superiority claims. Table 1.1 and the appendix provide technical definitions and measures of egregiousness related to the violations, respectively.

A significant proportion of stakeholders are aware of these citations. 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.* 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.

Theoretical Framework

Previous research on the destruction 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 financial misrepresentation (Karpoff, Lee, and Martin 2008, 589-594), restatement announcements (Palmrose, Richardson, and

Scholz 2004, 75). The empirical research indicates that a sizable gap usually exists between

Table 1.1. 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 (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" (U.S. Food and Drug Administration 2000)
Omitted risk information	(a) Failure to reveal facts material to consequences that may result from proper use of the drug (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	"I 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" (U.S. Food and Drug Administration 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" U.S. Food and Drug Administration 2005)

estimates of direct costs and the magnitude of the capital losses due to recalls. Jarrell and Peltzman attribute these losses to a general and unspecified decline in goodwill surrounding the firm (1985, 524). 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, I look at what makes up the previously undefined "loss of goodwill."

To assess whether analysts change estimates following citations, I conducted exploratory analysis of analyst reaction. Using the Institutional Brokers' Estimate System (I/B/E/S) database I 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 preliminary evidence that financial analysts do react to the FDA citations.

Citations for deceptive marketing may increase the probability of litigation being brought against the firm, decrease sales, and harm marketing elasticity. The degree to which these changes are anticipated depends on the estimated costs to relevant stakeholders. The costs considered by stakeholders can be divided into "private" and "public" costs (Innes 2006, 360). Private costs are those with direct economic consequences for the stakeholder (e.g., lost customers or increased medical costs). In other words, private costs reflect the monetary motives consistent with traditional economic concepts of rational behavior. Stakeholders also take into consideration the perceived fairness or ethical nature of the firm's action. In the economics literature, the value placed on these considerations is referred to as "public cost" whereas the term "moral cost" is more commonly used in the ethics literature. In general terms, these public costs include all nonmaterial costs. Recent studies have shown that a significant

proportion of rational people are driven by moral considerations (Fehr, Klein, and Schmidt 2007, 121; Trudel and Cotte 2009, 62). While not all people are similarly concerned with social ethics, some people are willing to change their behavior and endure private costs to punish those who have committed unethical or unfair acts (Tyran and Engelmann 2005, 13; John and Klein 2003, 1203-1207; Kahneman, Knetsch, and Thaler 1986, 729).

When calculating future cash flows, analysts and investors consider the totality of the cost of FDA citations to all stakeholders (i.e., physicians, past and present consumers, competitors, state and federal governments, and shareholders). When the aggregate public and private costs are high, stakeholders will take actions to punish the firm and protect their own interests. This idea that a threshold of arousal is necessary to change the behavior of individuals or firms is consistent with theories of fear-appeals. The underlying assumption of this concept is that marketing messages need to generate a certain level of fear in order to be effective (Kavadas, Katsanis, and LeBel 2007, 172-173). Similarly, studies of consumer negative voice (Luo 2007, 75-76), destructive acts in marketing channel relationships (Hibbard, Kumar, and Stern 2001, 46), and boycotting behavior (Klein, Smith, and John 2004, 93) suggest that a certain level of arousal is necessary to generate action. Initial empirical evidence shows support for a positive relationship between serious harmful consequences of a firm action and moral outrage, while modest consequences have not been shown to alter behavior, presumably because they do not generate the appropriate level of arousal (e.g., Klein, Smith, and John 2004, 93; Fiske 1980, 903-904).The threshold of arousal is generally considered to vary between individuals or organizations based on personal and environmental characteristics, so analysts estimate the aggregate change in stakeholder behavior given the severity or egregiousness of the act.

In sum, I argue that when the costs to stakeholders are perceived as significant, their aggregate changes in behavior will produce unanticipated changes to the firm's future cash flows through changes to legal liability, marketing elasticity, and sales. Relying on the assumption of market efficiency, I argue that these unanticipated changes to the firm's future cash flows are reflected in abnormal stock market returns (Fama 1970, 390-405).

HYPOTHESES

Both private and public costs will be associated with characteristics of the deceptive act. 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, I identify the costs to each group of stakeholders that may be considered by analysts and investors when calculating changes to future cash flows.

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, 96). In their study of consumer response to negative publicity, Ahluwalia, Burnkrant, and Unnava explain that their analysis is limited in not considering extreme or life-threatening consequences (2000, 212). They call attention to research indicating that, generally, more severe consequences are weighted more heavily in the evaluation of information (Fiske 1980, 903-904; Fich and Shivdasani 2007, 324).

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 they, or their healthcare provider, were aware of the true risks. The case of Merck's arthritis drug, Vioxx, is the most prominent example 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, 1707). 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, 723). 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 analysts' 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. While manufacturers can no longer rely on the Learned Intermediary Rule to escape all civil liability, physicians still hold a significant malpractice burden (Hill 2005, 371-372). Therefore, when the deception involves highly egregious omissions of risk information, it can be argued that 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 impact the marketing elasticity of the firms. Highly egregious violations will command the attention of physicians because of the potential risk of malpractice suits. Furthermore, deception will engender distrust (Darke and Ritchie 2007, 124-126). Physicians will be less receptive to future attempts at persuasion when they distrust the firm (Ortmann and Hertwig 2002, 120-125). 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 clinic 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 the offending firm if the omitted risk information led to severe harm. If the consequences to consumers of the offending 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 may be difficult to prove in court (Giliberti 2002, 43). 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. 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 (Tesoriero 2007).

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, 26). Therefore, citations for highly egregious acts of deception can be expected to 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 Value-at-Risk (VaR) approach found that a product-harm crisis lowered baseline sales, reduced own price, increased cross-price elasticities, and reduced marketing instrument effectiveness (Van Heerde, Helsen, and Dekimpe 2007, 240-244). Thus, cited firms will need to engage in more costly marketing activities to achieve the same returns as those achieved prior to the violation.

Competitors and Government Agencies

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 condemned by the legal system. Thus, the Lanham Act allows competing firms to negatively impact cash flows of an offending firm following an FDA citation. Furthermore, state and

federal agencies also heavily penalize deceptive 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 subsequent decreases in future sales and increases in 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, 25-27). Therefore, I hypothesize,

Hypothesis 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 may 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. This category also includes violations related to expanding the boundaries of treatment or "disease mongering."

The exposure of these acts will also lead to reduced prescriptions and increased risks of litigation by government organizations and of class action lawsuits. For instance, following the recent criticism of the DTC campaign for Vyotorin and Zetia that efficacy claims were unsupported by data, prescriptions plunged (Rubenstein and Winslow 2008). The potential negative word-of-mouth from disappointed patients in the current

environment of blogs and online forums is also likely to be significant. The negative stock market reaction in the airline industry following negative online reviews illustrates the impact of negative voice (Luo 2007, 82). 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. In the case of Schering Plough and Merck (the JV partners that make Vyotorin and Zetia), 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 state and federal governments 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 (Oregon Department of Justice 1999). More recently, Pfizer agreed to pay $430 million to federal and state agencies for off-label marketing tactics (Harris 2004).

The total stakeholder costs associated with egregious unsubstantiated effectiveness claims will lead many stakeholders to penalize cited firms. As a result, cash flows to the firm will suffer and negative abnormal stock returns will ensue. Thus, I hypothesize,

> *Hypothesis 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 popularity 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). Based on this evidence, it appears that violations of unsubstantiated superiority claims are unlikely to lead to litigation or changes in prescribing behavior. Furthermore, superiority claims may have a positive impact in that they have been found to build firm value by increasing brand awareness and by signaling higher levels of trust among prescribing doctors (Grewal et al. 1997, 12-13; Mitra, Swasy, and Aikin 2006, 381-387). On the other hand, some states have won major Medicaid and Medicare suits filed for overpaying for drugs with cheaper equivalents. Therefore, the change in future cash flows and resulting abnormal returns is unclear. Hence, I do not argue a direction hypothesis for unsubstantiated superiority claims. I hypothesize,

> *Hypothesis 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, 1705). Studies in healthcare have found that DTC advertising leads to consumer requests for particular drugs, which often lead to doctors writing prescriptions for the drugs (Mintzes et al. 2003, 411). While physicians make the ultimate prescription decision, patients increasingly pressure their physicians to prescribe specific drugs (Menon et al. 2004, 101-103), and physicians have strong financial incentives to respond to requests or risk losing patients (Gönül, Carter, and Wind 2000, 216-225). 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, 475-479). In an experiment conducted by Kravitz et al., stealth patients making unannounced visits to physicians were prescribed drugs far more often when they requested the drug, even when the indications were questionable (2005, 1995-2001). 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.

Furthermore, 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, 380-386). The penalties under these state consumer

protection statutes are substantially higher than the common law claims to which the pharmaceutical firms were subject previously. Though most of these claims have failed thus far, the potential for higher penalties must be considered by analysts and shareholders when calculating future cash flows. The direct costs to the manufacturer from state consumer protection statutes gives further reason to hypothesize,

> *Hypothesis 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, 110). Although I do not a directional hypothesis for print, I 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 the exposed populations.

Researchers have found that consumers are more likely to "miscomprehend" televised drug advertisements than of those from other media sources (Morris et al. 1986, 110). The finding may be due partially 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, 546). Often benefits are

put in lay terms or portrayed visually, while competing sounds and visuals may be displayed during the disclosure of risk informatio. These factors have been shown to increase brand recall and positive associations (Callcott and Phillips 1996, 76-77). 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. 241-246).

Because televised DTC ads are likely to mislead viewers, the total costs to stakeholders will increase when this type of media is used in the cited campaign. The costs discussed previously will be heightened as more potential and current patients are deceived about the characteristics of the cited drug. The higher total cost and resulting actions by stakeholders will be accounted for by shareholders in their calculation of future cash flows to the firm. Therefore, I expect shareholders to pull out of their positions in the cited firm and abnormal returns of the stock to follow.

Hypothesis 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. I 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 (Macias, Pashupati, and Lewis 2007, 241-252). Moreover, print media has

been found to have a stronger transformative impact on affect and product attitudes than television (Bronner and Neijens 2006, 92). 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). It can therefore be argued that print advertising will be associated with negative abnormal returns.

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 (Sheehan 2006, 14-15). Frustrated consumers then often choose to ignore the information in these advertisements altogether. As for physicians, the print medium allows them to process the information at an optimal pace. According to Darley and Smith, print reduces agreement to non-credible messages because an expert audience is able to consider the difficult points and elaborate at will (1993, 108-112). If print advertising is ineffective and unable to deceive consumers, resulting harm will be minimal and estimates of future cash flow will not be affected. Given these competing arguments, I hypothesize,

> *Hypothesis 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, I did not put forth a hypothesis for these alternative types of communication.

Brand Market Share

Additionally, I propose that the market share of the brand will moderate the relationship between abnormal stock returns and different types of violation as well as various intended audiences. The brand's market share is not moral in nature and does not impact stakeholders in any way unanticipated by shareholders. Thus, brand market share 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 number of consumers deceived, the number of stakeholders close to someone harmed by the act, and the attractiveness of the firm as a target for class action suits. When market share of the brand is low, even highly egregious violations can only affect a small number of victims and the level of total harm is unlikely to be large. Therefore, the cost of each issue-contingent factor will not be high enough to ultimately affect the firm's cash flows. When brand market share is high, even acts with low levels of egregiousness (e.g., unsubstantiated superiority claims) will translate into high total harm. A brand with a large market share will be a much more lucrative target for liability claims than a brand that can barely recoup R&D costs. Additionally, stakeholders will be more likely to reach a level of moral outrage when they feel close to a "victim" (Jones 1991, 376-377). When brand market shares are large, more patients are likely to have tried the drug. Consequently, the network of this large group of users is likely to be larger. On the other

hand, smaller volume brands are likely to have been tried by far fewer consumers (Ehrenberg, Goodhardt, and Barwise 1990, 87-89). Therefore, only when brand market share is high will the total cost of the act be sufficient to change stakeholder behavior and translate into reduced cash flows.

> *Hypothesis 6*: (a)The egregiousness of omitted risk information claims is more negatively associated with abnormal returns for citations of drugs with larger brand market share than for drugs with smaller brand market share; (b) the egregiousness of unsubstantiated effectiveness claims is more negatively associated with abnormal returns for citations of drugs with larger brand market share than for drugs with smaller brand market share; (c) unsubstantiated superiority claims are more negatively associated with abnormal returns for citations of drugs with larger brand market share than for drugs with smaller brand market share; (d) DTC is more negatively associated with abnormal returns for citations of drugs with larger brand market share than for drugs with smaller brand market share.

Controls and Moderators

I control for previous firm citations, firm market share, market dependence, 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 found that recalls in the automotive industry occur so often that the impact of a specific announcement has little or no effect (1992, 469-472). Brand equity and corporate reputation will already be sufficiently low that additional announcements will not be unexpected. In addition, the risk of future litigation related to deceptive marketing will already be included in the stock evaluation.

Market share of firms has been found to explain a significant amount of variance in the ability of firms to react to costly events. Moorman, Du, and Mela find that large share firms are more resilient to regulatory changes than small-share firms in part due to their greater resources to effectively react to shocks and absorb costs (2005, 270-271). Accordingly, I would expect market share to be positively correlated with abnormal returns. However, Borenstein finds market share and reputation are positively correlated (1991, 1260). Shareholders will thus have positive prior expectations for larger share firms. Therefore, when a large share firm receives a citation, investors are more likely to be negatively surprised, and share value will fall (Tellis and Johnson 2007, 766-768).

Advertising spending is included as a control in the main model because it is well established that advertising impacts stock price. The level of advertising spending has a significant positive impact on estimates of future cash flows and shareholder value (Bharadwaj, Bharadwaj, and Konsynski 1999, 1016; Srinivasan and Hanssens 2009, 305). Furthermore, advertising lowers systematic market risk (McAlister, Srinivasan, and Kim 2007, 36). As for the expected relationship with abnormal returns following a citation, I do not hypothesize a direction. Because advertising builds brand equity (Srinivastava, Shervani, and Fahey 1998, 2-18; Keller 1993, 1-2), firms with high advertising could be less affected by a negative event (Blattberg, Briesch, and Fox 1995, G122-G125). On the other hand, highly advertised brands are more visible, and citations

issued to such brands may garner more attention. Whether high advertising will protect brands or bring more focus to a negative firm event is unclear.

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, 9-28). For example, event studies have been used to explore the impact of brand extension announcements (Lane and Jacobson 1995, 63), new channels (Geyskens, Gielens, and Dekimpe 2002, 112-113), and new product preannouncements (Sorescu, Shankar, and Kushwaha 2007, 468). While common in finance, studies examining the impact of negative events using the event study method are far less prevalent in marketing.

The approach I have adopted follows theory and guidelines in the event study methodology literature (Brown and Warner 1985, 3-31). This method assumes that changes in stock prices reflect information made newly available to investors. In the context of this study, the publicly available information about the FDA deceptive marketing violations is assumed to be immediately incorporated in the stock price. This allows for the assessment of the impact of the violations on future cash flow of the firm.

In essence, the change in stock price following the posting of the citation provides an unbiased estimate of the change in future long-term earnings due to the FDA violation.

To assess the event's impact (i.e., the impact of the posting of the citation on the FDA website) on the firm's shareholder value, I use the Fama-French four-factor model, which is also referred to as the Carhart model, to calculate the change in the stock's price or the abnormal return (Fama and French 1996, 55-56; Carhart 1997, 61). 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,*

$$\varepsilon_{it}^{*} = R_{it} - E[R_{it}|X_t]$$

where ε_{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 Fama-French approach incorporates four additional factors that can contribute to differences in stock returns (Fama and French 1996, 55-57; Carhart 1997, 61). The four-factor explanatory model includes the size of the firm, the market-to-book ratio, the firm's risk class, and its momentum (Srinivasan and Hanssens 2009, 301).

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

where, for firm *i* at time period *t*, ε_{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, I use three broad-based indexes (i.e., S&P 500, NYSE, and NASDAQ) or 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 citation 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, I believe that the two-day window calculating cumulative abnormal returns is long enough to capture the significant impact of the event and also short enough to exclude confounding events. As demonstrated in the results section, there is no evidence of leakage of information and the event window chosen seems to be appropriate. The cumulative abnormal return (CAR) is calculated as follows:

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

Data

Regulatory letters have been the subject of event studies across many disciplines. Statistically significant abnormal returns have recently been found for internet channel additions (Geyskens, Gielens, and Dekimpe 2002, 112-113), automotive recalls (Davidson and Worrell 1992, 470-472), and the announcement of drug withdrawals (Ahmed, Gardella, and Nanda 2002, 29). There is no reason to believe that investors

would be less likely to anticipate these announcements than the publishing of the FDA letters. Pharmaceutical firms spend over three billion dollars a year on promotional activities, a significant proportion of which is only viewable to physicians. The varied and abundant promotion performed by pharmaceuticals would make these activities as difficult or more difficult for investors to monitor than the activities of the firms in the cited studies. Therefore, I expect that deceptive marketing is not taken into account in security prices before the release of the FDA letter.

The population for the study is all citations issued by the DDMAC and posted on the FDA website. The 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, 151). However, the great majority of the letters from 1997 and 1998 were released in large groups. Multiple events occurring on the same day could have had confounding effects, so the observations from these years were excluded (Geyskens, Gielens, and Dekimpe 2002, 111). Third, I also excluded letters if multiple brands were cited since many of the explanatory variables are specific to a single brand. Fourth, the event date used was the date the letter appeared on the website (i.e., what is labeled as the date "posted"). I 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, 69). 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 the effective sample size.

Measurement

Dependent Variable

The dependent variable was the financial impact of the deceptive marketing practices measured using the net present value (NPV) of the event. The choice of NPV over CARs was made 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, 305). Net present value captures the total gains or losses of these events and alleviates the scaling problem faced otherwise (Kalaignanam, Shankar, and Varadarajan 2007, 363). I computed the financial impact as CARs in the two day event window (0,+1) and the market capitalization of the firm 20 days before the event (Chan et al. 1997, 211). I used the shortest significant window to minimize confounding effects. Stock market data to calculate the dependent variable were collected from CRSP. The factors particular to the Fama-French and Carhart approaches were collected from the Kenneth R. French website.

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 (see table 1.1 for a description of the three major violations). Because unsubstantiated superiority claims were determined not to have a moral component, they were treated as a dummy variable, where “1” denoted that the violation was mentioned one or more times and “0” indicated that no unsubstantiated superiority claims were made.

The other two violations were coded according to their severity on a scale from "0" to "3," where "0" 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). Examining the characteristics of disclosures has previously been found to influence the probability of individuals being misled by advertising claims (Andrews, Netemeyer, and Burton 1998, 68-70). 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. These promotions that involve implicitly false claims are less likely to 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 2002, 43). 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, 2-4). Therefore, when the violation involves a misleading implication, the event is coded as "1" regardless of the criticality of the 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."

A research assistant and myself 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, 3-4). This approach is identical to Perrault and Leigh's measure when two judges are used (1989, 140-141). The PRL level for severity of unsubstantiated effectiveness and omission of risk information were .94 and .93, respectively. These PRL levels fall well above the generally accepted minimum level of .90 (Rust and Cooil 1994, 9).

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

Control Variables

Previous violations were simply a sum of all prior citations posted online, which includes all citations from January 1, 1999 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. Measures of advertising spending and market share were also obtained from Verispan, a market research firm that tracks marketing activity in the pharmaceutical industry. The observations are for the entire U.S. market on a yearly basis. Data for firm sales was collected from COMPUSTAT. I include the measures corresponding to each year of the violation.

RESULTS

Table 1.2 presents the average abnormal returns for all letters in the 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. In contrast, marketing events with positive news average gains of 0.42% across announcements of new product introductions (Chaney, DeVinney and Winer 1991, 690), brand extensions (Lane and Jacobson 1995, 72-74), celebrity endorsements (Agrawal and Kamakura 1995, 58), product preannouncements (Sorescu, Shankar, and Kushwaha 2007, 477), and new internet channel additions (Geyskens, Gielens, and Dekimpe 2002, 112-114). The loss of excess returns of 1% is, clearly, much more significant and translates into a wealth loss of $86M for the median firm in the sample. The lack of significant abnormal returns before the event window suggests that there is no leakage or anticipation of information about the FDA warning letters. The cumulative average abnormal returns (CAAR) for longer windows after the event CAAR (1 to 5), CAAR (1 to 20) and CAAR (1, 100) are not significant. Following Gielens et al., I ran a pooled regression of the CARs against the time since the event date and found no significant drift ($p<0.10$) (2008, 525). 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 1.2 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

* p<.10 ** p<.05

Explaining the Heterogeneity in Abnormal Returns

While the market views the FDA warning letters as a negative signal and on average delivers negative stock returns, there is still significant heterogeneity around the returns. Table 1.3 provides the results of the cross-sectional explanation of the variation in the observed stock-price reactions.

As shown in the second column of table 1.3, omission of risk information has the anticipated negative effect (b=-0.26, p<.001). Therefore, H1 is supported. H2 also finds support, since the effect of unsubstantiated effectiveness claims is also negative (b=-0.20, p<.05). While I had not developed a directional hypothesis for the effect of superiority claims, this variable has a positive effect but is not significant (H3: p>.05). Consistent with expectations, H4 is supported as DTC advertising has a significant negative effect (b=-0.27, p<.001). Model 2 provides the results for hypotheses H5A and H5B. Here I replace the DTC variable with more specific measures that examine the effects of media type used in the DTC advertising. H5a is not supported (p>.05), but the parameter

estimate for TV is in the expected direction (b=-.06). Print DTC advertising, on the other hand, has a positive and significant effect on the net present value (b=0.13, p<.05). Thus, H5b is supported. While I do not posit a directional hypothesis, other media has a negative and significant impact on net present value (b=-0.65, p<.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 (Clogg et al. 1995, 1261-1293). For two coefficients β_i and β_j,

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

The null hypothesis of equality of the coefficients follows a standard unit normal. 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-d, since the negative effects of the omission of risk information, unsubstantiated efficacy claims, unsubstantiated superiority claims, and DTC advertising are larger when the brand market share is high than when the brand market share is low (all p<.05). In fact, these results are conservative since I 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 variance inflation factors (VIFs) do support this expectation and multicollinearity is not an issue as maximum VIF is 2.32. As shown later in the robustness checks section, creating continuous variable interactions in the full sample proved consistent with the sub-sample analysis.

Table 1.3. Results with NPV as DV based on Carhart four-factor model

Variables	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)				
Brand advertising/sales	0.13 (0.68)	0.18 (0.60)**	-0.02 (0.53)	0.10 (7.69)		
Market share	0.19 (0.003)**	-0.07 (0.01)			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 (0.00)	9.31 (0.00)	0.26 (0.95)	9.18 (0.00)	2.06 (0.005)	4.34 (0.00)
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<.05 ***p<.001

Note: All estimates are standardized and robust standard errors are presented in parentheses.

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

In summary, the results indicate that the financial marketplace takes a bleak view of the regulatory exposure of omitted risk information, the egregiousness of unsubstantiated effectiveness claims, and the use of DTC advertising. 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 were not found to be significant. The results for the main effects of advertising, market share, and previous citations were 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. I used two other popular models to estimate the abnormal stock returns: the Capitol Asset Pricing Model (CAPM) and the Fama-French three-factor model. The CAPM approach is equivalent to the one-factor market model described above, and the Fama-French three-factor is similar to the Carhart four-factor model without the inclusion of momentum. In both cases the results were not significantly changed (see table 1.4). The omitted variables in the CAPM, however, weakened the power of some of the results.

I used three alternative benchmark portfolios to calculate the market and abnormal returns, namely, (1) a portfolio of firms trading in NASDAQ, (2) a portfolio of firms trading in NYSE, and (3) a portfolio consisting only of pharmaceutical firms. I also calculated equally-weighted and value-weighted versions of abnormal returns. The cross-sectional regression analysis based on these six measures (three portfolios by two types of abnormal return calculation) yields results that did not materially change,

providing confidence in the robustness of the results. Furthermore, I regressed the explanatory variables against the two-day CARs. Table 1.5 shows that the results remain robust to the operationalization of the dependent variable.

In all of these models, I controlled for effects due to time, therapeutic category, and the age of the drug. I conducted this analysis by including year dummies, therapeutic category dummies, and a continuous measure of the time since each drug's approval for marketing in the main effects model. 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, I explored each firm's stock return volatility σ^2_i over two different windows, namely (1) pre-event window (-250,-1) and (2) the post event window (0, 250), where "0" represents the event date. Market volatility σ^2_m was also estimated over the same window. Following standard practice in finance (Schwert 1989, 1115-1117), I calculated the volatility ratio, defined as λ equals the square root of $(\sigma^2_i / \sigma^2_m)$. A comparison of the volatility ratio λ 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 indicating that the event's impact was not on the volatility.

I 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, 83-101; Anderson and Mansi, forthcoming). 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. I used the transformed numerical rating ranging from 1 for AAA and 22 for a D-rating. I examined the average credit rating the month before the event (posting of the FDA citation letter)

Table 1.4. Regression results with alternative models for calculating abnormal returns

Variables	Model 1 using Fama-French 3-factor model	Model 2 using Fama-French 3-factor model	Model 1 using CAPM	Model 2 using CAPM
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 (0.42)***
DTC : TV		-0.06 (0.49)		-0.10 (0.50)*
Brand advertising/sales	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 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<.05 ***p<.001

Note: All estimates are standardized and robust standard errors are presented in parentheses.

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

Table 1.5. Regression results using two-day CARs

Variables	Model 1using CAPM	Model 2 using CAPM	Model 1 using Fama-French 3-factor model	Model 2 using Fama-French 3-factor model	Model 1 using Fama-French 4-factor model	Model 2 using Fama-French 4-factor model
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)
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 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<.05 ***p<.001

Note: All estimates are standardized and robust standard errors are presented in parentheses.

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

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.

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. The study extends the limited extant research on the financial value of negative events, namely deceptive marketing, a phenomenon pervasive in pharmaceuticals as well as in other industries. However, the consequences of this behavior have not been well understood. While it has been thoroughly established that product harm crises and product withdrawals significantly impact firm value, the costs of the regulatory exposure of deceptive marketing have been unclear. Studies in finance and marketing involving negative abnormal returns have only considered events with high direct costs, such as automobile recalls, and have not quantified and decomposed the potentially high indirect costs. In the ethics literature, while ethical attitudes toward marketing actions have been well studied, this analysis is the first to measure the financial value of unethical practices with no direct penalties.

Few past studies on value-destroying events consider the variation in shareholder value between events, and those that do have only included firm characteristics. This analysis shows that characteristics of the event are also significant in explaining the

impact of such events. Drawing on literature in marketing, ethics, medicine, and finance, I develop a set of theoretical hypotheses, which I test by using a unique data set compiled from multiple secondary sources. Using an event study methodology, I find that the exposure of certain forms of deceptive marketing practices can lead to a significant destruction of firm value. Overall, this study shows a noteworthy loss of wealth by investors. The average change in excess returns following an FDA citation was 1%. This translates into a wealth loss of $86 million for the median firm in the sample. Compared to positive events, which have typically been explored in marketing research, the analysis presents a significantly larger impact. Moreover, the analysis finds that some firms are punished for unethical marketing actions in ways that involve no direct costs to the firm.

Some physicians, academics, consumers and other critics have expressed concern that the citations issued by the FDA are not accompanied by a financial penalty (e.g., Applbaum 2006, e189). I find 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, I find that the cited firms do incur a significant financial penalty.

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. The empirical results generally support the framework that I developed based on the concept of stakeholder cost that impacts estimates of legal liability, marketing elasticity, and sales. In the main effects model, egregiousness of the violation and vulnerability of the target audience have significant and negative impacts on market value. Furthermore, as predicted, violations with levels of low egregiousness or

unconfirmed egregiousness (i.e., unsubstantiated superiority claims) do not reduce estimates of future cash flows.

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 the 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 is 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 2006, 14-15). Broadcast media is not significantly related to abnormal returns. Despite the ability of the emotional appeals commonly used in these advertisements to persuade (Griskevicius et al. 2009, 392), the likelihood of deception may be dampened by the perceived untrustworthiness of the medium (Macias, Pashupati, and Lewis 2007, 241-252). The negative results for "other media" are consistent with those of Narayanan, Desiraju and Chintagunta who find synergies among various marketing investments in the pharmaceutical industry that lead to increased ability of a mixed media campaign to persuade (2004, 101-102).

Less intuitive, and perhaps the greatest contribution of this study, are the findings regarding the moderating effect of brand market share. As expected, brand market share does not have a direct impact on abnormal returns. In other words, large brands are not generally punished more than small brands. However, brand market share made a considerable difference in the relationship between the event characteristics and abnormal returns. For high brand market share, egregiousness of violation and target audience explain a large proportion (over 40%) of the variation in abnormal returns following a

citation. Yet, for small brand market share, these factors explained almost none of the variation. Hence, I can conclude that brands with high brand market share are punished more for highly egregious acts or deception aimed at vulnerable populations, but 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 this research will enable corporate managers and financial executives to make more informed decisions about the financial risk of potentially destructive marketing strategies. The findings indicate that managers need to consider both the target audience and the potential harm when communicating with outside stakeholders. Firms will also want to consider how these factors will interact with brand market share and advertising spending.

Although I 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 1.3). 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 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, managers may not be able to guard against misinterpretations that could lead to public harm and, consequently, reduced cash flows for the firm. 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, managers do not need to be concerned that citations will 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, this study offers some important insights. I am 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. The first potential cause may be that firms are not aware of the factors associated with high penalties and are willing to gamble that a citation will have a positive or negligible impact on firm value. Another reason may be that mangers believe that they will not be caught thus leading to moral hazard. Spending on drug promotion in the U.S. is rapidly rising (Domestic Social Policy Division 2005, CRS-4). However, the number of citations issued 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, CRS-24/25). 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, CRS-23). 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.

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

The current study is restricted to a single industry with specific characteristics that make it necessary to use caution when generalizing these findings. Although I do not expect that the overall drop in market value will be as great in many other industries, I do believe that 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 included FDA letters were sent to firms regarding drugs that, on average, had $426 million in sales yearly and represented almost a third of all prescriptions in its treatment category. However, it is important to recognize that this

study focuses on publicly traded firms. Consequently, I can say nothing about the impact of deceptive actions on privately-held firms.

While I did rule out the impact of the FDA citations on the short-term risk of the firm (and attributed all value destruction to the stock returns), the analysis was rather preliminary. Future research should look at alternative risk metrics (e.g., the market, idiosyncratic, and aggregate volatility risks faced by firms) using a more sophisticated method than that used in this study.

The theoretical model considered the estimated impact of future behavior by multiple groups of stakeholders, but the method 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).

This analysis is also limited to the focal firm, but prior research indicates that advertising can have spillover effects on competitors. An analysis of the effects on firm value of competitors, prescription share, and revenue would lead to a better understanding of what can occur in the wake of marketing missteps.

ESSAY 2: THE IMPACT OF INNOVATION POTENTIAL ON MARKETING STRATEGY

INTRODUCTION

Previous research has found that innovation is vital to the viability of firms (Bayus, Erickson, and Jacobson 2003, 202-209; Pauwels et al. 2004, 149-153; Sorescu, Chandy, and Prabhu 2003, 94-98). Firm profits, stock returns, and other financial performance measures fluctuate with a firm's ability to introduce new products (Srinivasan et al. 2009, 34-40; Sorescu and Spanjol 2008, 123-128). Given the criticality of innovation to the firm, it seems logical that managers would use information related to the probability of future product introductions to inform marketing strategies. Yet, the association between innovation and marketing decisions is relatively uncharted.

This study seeks to link the two streams of academic research by addressing how a firm's innovation status relative to a product impacts the level of risk managers are willing to assume in marketing decisions regarding that product. Innovation is "the process of bringing new products and services to market" (Hauser, Tellis, and Griffin 2006, 687). Firms choose to innovate in order to attain temporary competitive advantage and high profits (Roberts 1999, 668). A firm's innovation status refers to the degree and longevity of competitive advantage that the firm can expect from product innovation. Innovation status relative to a particular product is comprised of four dimensions that capture the firm's internal innovation potential (in relation to the focal product) and external threats to profitability of the firm (within the focal product's category).

The four components of innovation status are the firm's strength of innovation pipeline within the product category, the firm's strength of innovation pipeline in all other categories, competitors' strength of innovation pipeline in the product category, and patent protection of the marketed product. For the purpose of this study, the innovation pipeline is defined as the product development portfolio, and the strength of the pipeline refers to the likelihood of the products in the pipeline reaching market. Additionally, the analysis considers the status of innovations already introduced to the market. Most firms choose to protect innovative products with patents. When patents expire, competitors can introduce "me-too" or identical products to the market, which will destroy the firm's competitive advantage and profits (Ceccagnoli 2009, 81).

Drawing mainly from the principles of prospect theory and competitive marketing strategy, I develop a set of hypotheses relating innovation status and managerial risk taking. The high-risk strategy that is examined in this study is deceptive marketing. Deceptive marketing is defined as a marketing practice that contains false or misleading information (Petty 1997, 6). Misleading claims include those lacking balance between benefit and risk information and those simply encouraging potentially injurious actions (Schwartz et al. 2009, 346). The use of deceptive marketing is a prime example of high-risk marketing strategy. The accepted criteria for level of risk are reversibility and the extent of associated downside (Markovitch, Steckel, and Yeung 2005, 1471). Once a deceptive marketing campaign is launched, firms are indefinitely liable for resulting harm (Petty 1997, 4). Furthermore, the results of the previous essay show that the exposure of deceptive can have a substantial negative financial impact.

Using a zero-inflated negative binomial model, I examine the relationship between innovation status and frequency of deceptive marketing as tracked by the U.S. Food and Drug Administration (FDA). The FDA carefully monitors the content of all marketing communications from pharmaceutical firms (Sheehan 2003, 159-162). Based on a sample collected from the FDA, Inteleos, Delphion, and COMPUSTAT, I find that multiple facets of innovation have significant relationships with the use of deceptive marketing. The analysis shows that the strength of a firm's innovation pipeline in a product category and across all other drug categories is negatively related to the use of deceptive marketing for a product. The opposite relationship holds for strength of innovation pipeline of the competitive firms in the category. Patent protection of innovations already introduced to market is also related to the use of deception. Furthermore, I find that some of these relationships are moderated by the extent to which a firm is dependent on the category.

By furthering the understanding of the types of information used by managers in high-risk decisions, this study has critical managerial, policy, and research implications. Managers will be better able to anticipate their competitors' actions given the strength of innovation pipelines in the industry, patent protection of current products, and market dependence. Those shaping public policy will be better equipped to prevent the use of potentially harmful marketing strategies, such as deceptive marketing. Finally, this study will fill important gaps in the current business literature by linking two critical streams of research, innovation and marketing strategy.

CONCEPTUAL BACKGROUND

Innovation

Innovation has been a highly popular subject in business and economics literature over the past few decades. Dozens of antecedents to innovation have been explored, ranging from the influence of competition (Roberts and Amit 2003, 117) to executive migration (Boeker 1997, 228). Moreover, innovation's impact on firm performance has been well established (e.g., Sorescu, Chandy, and Prabhu 2003, 94-98; Sivadas and Dwyer 2000, 40-42; Sood and Tellis, forthcoming). Measures of absolute and relative innovation levels convey critical information about the health of a firm (e.g., Geroski, Machin, and Van Reenen 1993, 198-211; Drucker 1999, 9-35; Sharma and Nelson 2004, 297-308).

Research has concluded that successful innovation is associated with increases in profits and economic rents (Sorescu and Spanjol 2008, 123-125), decreased marketing support costs (Bayus, Erickson, and Jacobson 2003, 207), and stock returns (Srinivasan et al. 2009, 41). On the other hand, the pursuit of innovation can consume significant resources and harm financial performance, especially in the case of failure (Treacy 2004, 29). For instance, pharmaceutical firms spend, on average, $897 million (in year 2000 dollars) to bring a new chemical entity to market (DiMasi, Hansen, and Grabowski 2008, 321). An approved drug that reaches "blockbuster" status can bring a firm upwards of a billion dollars in yearly sales (Topol 2004, 1708). However, less than 20% of patented drug formulations are brought to market (Chandy et al. 2006, 494). Competitive response

to product innovations can also offset potential gains from innovation (Kuester, Homburg, and Robertson 1999, 103-104). In summary, a review of the past findings regarding innovation indicates that new product development introduces much uncertainty regarding the future financial performance of the firm.

Deception

The literature on deceptive strategies and other "unethical" marketing strategies provides more evidence regarding the consequences of these strategies than analysis of the factors explaining or predicting their use. Several studies have found that fraudulent and "unfair" activities, when exposed, have negative financial and reputational repercussions (e.g., Roehm and Tybout 2006, 371-373; Xia, Monroe, and Cox 2004, 1; Karpoff, Lee, and Martin 2008, 589-594; Fich and Shivdasani 2007, 334-335). Behavioral studies have found that deception engenders distrust (Darke and Ritchie 2007, 124-126) and leads to avoidance of the perpetrator (Wang, Galinsky, and Murnighan 2009, 634-642).

However, these negative repercussions have never been compared to the benefits resulting from the fraudulent activities, and the reason that some firms continue to use deception while others do not is still unclear. Marketing researchers have pointed to the importance of examining the factors that encourage the use of deception (Rick and Loewenstein 2008, 645; Mazar, Amir, and Ariely 2008, 651). One study that does examine more specific reasons why "sellers" may not choose to make misleading claims finds that a strong predictor is the likelihood that claims will be verified (Bloomfield and

Kadiyai 2005, 338-339). In practice, firms whose claims have equal likelihood of being verified display different propensities to use deception. This study seeks to examine factors that explain variance in deceptive practices while holding review and regulation constant.

Marketing Strategy Decisions

Several prior research studies have explored various antecedents to "ethical" marketing strategy decisions and processes. One study found that firms do not generally follow normative models of marketing strategy decision-making (Gatignon, Weitz, and Bansal 1990, 390-401). This analysis showed that marketing decisions were not based on brand quality, market growth rate, market size, market concentration, or a firm's familiarity with the market. The only explanatory factor that Gatignon, Weitz, and Bansal found support for was availability of resources (1990, 398). Subsequent research has found that organizational structure and culture are antecedents to marketing strategy making (Menon et al. 1999, 31). Support has also been found for project-level antecedents to marketing strategy comprehensiveness, specifically project rewards, project members' relationships, and task conflict (Atuahene-Gima and Murray 2004, 41-45).

While the above-mentioned studies expose critical antecedents to marketing strategy decisions and effectiveness, the role of innovation is conspicuously absent from this stream of literature. Innovation introduces a great level of uncertainty regarding financial outcomes. This uncertainty has the potential of changing managers' attitude

toward risk when selecting marketing strategies. According to prospect theory, individuals will exhibit risk aversion in the domain of gains and risk-seeking behavior in the face of loses (Kahneman and Tversky 1979, 268). In an application to marketing strategy decisions, Markovitch, Steckel, and Yeung demonstrated that the propensity of a firm to adopt high-risk strategies varies with the stock market performance of the firm (2005, 1475-1476). Audia and Greve also find that, given certain firm characteristics, accounting measures of returns (i.e., return on equity, return on assets, and return on sales) are associated with risk taking in managerial decision making (2006, 89-90). While performance measures incorporate available information about current levels of innovation, they cannot convey information about innovation in specific categories. I argue that in addition to firm-level performance measures, managers may also incorporate innovation information specific to a product when considering high-risk marketing strategies.

HYPOTHESES

Main Effects

There are four dimensions of innovation status that could prompt changes in a firm's marketing strategy for a particular product. I specifically examine whether the likelihood of deceptive marketing for a particular product is related to the focal firm's innovation pipeline strength in the product category, lifespan of patent for the marketed

innovation, competitors' pipeline strength in the product category, and the focal firm's innovation pipeline strength across all product categories.

When managers examine the innovation status of a product and its competitors, I argue that they will be more or less likely to use unlawful marketing practices depending on whether this information is negative or positive. According to the theory put forth by Kahneman and Tversky (1979, 263-290) and supported by subsequent empirical work, individuals are more likely to accept risk when faced with losses (e.g., Hardie, Johnson, and Fader 1993, 390; Thaler 2008, 21-22). On the other hand, individuals that expect financial gains or relative success will avoid activities with great downsides to maintain their current status (Kahneman and Tversky 1979, 268). Consequently, managers that perceive their innovation position as strong will be less likely to use unlawful marketing practices and chance punishment.

One dimension of innovation considered is the focal firm's pipeline strength within a product category, which is the number and innovativeness of promising ideas for new products within the category. The generation of innovations is essential to the creation of competitive advantage and can lead to sustained superior performance (Barney 1991, 112-115; Chandy & Tellis 1998, 474). Thus, the pipeline of products is an appropriate source of information for managers regarding the future prosperity of the firm.

If individuals in a firm perceive the innovation pipeline as strong, the firm is unlikely to put the potential profits from those products at risk. Deceptive marketing can damage the reputation of the firm, as demonstrated in the first essay. Furthermore, if the deception is viewed by shareholders as highly egregious, organized boycotts and lawsuits

could follow. According to the principle of loss aversion, managers will avoid such risks when they foresee gains in the future (Kahneman and Tversky 1979, 268). However, if the innovation pipeline for a product category is weak, managers are more likely risk the potential downsides of deception to reap maximum profit from current products. In some cases, deception is largely ignored (e.g., customers do not boycott and share price does not fluctuate). Yet, the false message of superiority to other products or greater general benefit has still been heard by the public. If the deceptive nature does not receive much attention, managers can hope that the false message will eventually be accepted by consumers and translate into higher immediate profits. Therefore, I hypothesize that a firm's innovation potential for a product category is inversely related to the use of deceptive marketing in that category.

> *Hypothesis 1:* The greater a firm's innovation potential within a product category the lower the likelihood that the firm will employ deceptive marketing strategies for a product in that category.

The second dimension of innovation that could alter a manager's attitude toward risk is the firm's innovation pipeline across all categories. As shown in the literature on attribute spillover, an event related to one product can have spillover effects on other products from the same firm, even products in different categories (Balachander and Ghose 2003, 11-13). Moreover, negative information has been shown to spread to other products within the category, both current and future (Ahluwalia, Unnava, and Burnkrant 2001, 467-468; Roehm and Tybout 2006, 371). Given these findings, if a firm has a

strong pipeline in other categories, I do not expect managers to choose strategies that could jeopardize the firm's status as a thriving entity.

Hypothesis 2: The greater a firm's innovation potential across all categories the lower the likelihood that the firm will employ unlawful marketing strategies for a given product.

The patent protection of the marketed product is the third dimension of innovation that could change the attitude of managers toward risk. When products lose their patent, competitors can be expected to introduce imitation and generic versions of the products at lower cost or superior products using the same technology (Ceccagnoli 2009, 81). In either case, managers can anticipate increased competition and lower profits (Barney 1991, 112-115). Faced with losses, it is argued that managers will be more likely to use risky strategies than when technologies are not protected by patent for an extended future period. Therefore, I hypothesize,

Hypothesis 3: The greater the time to expiry of patents on current innovations in a product category the lower the likelihood that the firm will employ unlawful marketing strategies for a given product category.

The potential of competitors to innovate in a product category can threaten the profitability of products in the same category (Barney 1991, 112-115). Even when a product is protected by a patent, competitors may develop a new technology (e.g., a new chemical compound or molecule in the pharmaceutical industry) that can take away

market share and reduce profits. If managers do not foresee a viable threat from competitors, they will demonstrate loss aversion. If managers anticipate a loss of competitive advantage due to new product launch, they will be more likely to use deception.

Hypothesis 4: The greater the competitors' innovation potential within the product category the greater the likelihood that the focal firm will employ unlawful marketing strategies for a given product category.

Moderating Effects

The analysis also includes a control for market dependence. A firm is said to be dependent on a market if a high proportion of the firm's products are concentrated in that market. It is unclear what the direct impact of market dependence will be on the likelihood of using deceptive marketing. For firms that are market-dependent on a certain category, managers may not be as concerned with negative spill-over to other product categories but also may not want to jeopardize sales critical to firm performance.

However, the moderating effect of market dependence seems less ambiguous. When a firm is dependent on a given market, losses will be greater when innovation potential dwindles, competitors introduce new products, or current patents expire. Managers will feel even more urgency to make drastic changes to strategy. Alternatively, market dependent firms facing high innovation potential, low levels of threats from competition, or a long period of patent protection, will want to protect their current status.

Hypothesis 6: When a firm is highly dependent on a given market, the association will be more negative between the likelihood of a firm employing unlawful marketing strategies for a product category and (a) innovation potential of the focal firm within the category, (b) innovation potential of the focal firm across all other categories, (c) the time before expiry of the patents held in the category, and more positive between the likelihood of a firm employing unlawful marketing strategies for a product category and (d) competitor's innovation potential within the category.

Control Variables

It is important to note that the focus of this study is the role of the innovation profile of firms and their key competitors in the firms' adoption of risky strategies for particular products. I do not study individual risk profiles of managers. However, I control for other critical firm level variables whose non-inclusion could bias the results. In particular, prior research in diversification indicates that the relative performance of firms impacts the adoption of risky strategies (Audia and Greve 2006, 92; Markovich, Steckel, and Yeung 2005, 1468). Thus, a relative measure of firm performance is included in the model.

Furthermore, the analysis includes variables which control for the focal firm's size and financial leverage. Including firm size controls for differences in decision making due to bureaucratization. According to the theory of structural inertia, large firms

have more constraints, such as multiple levels of approval and norms, which indicates that large firms may be less likely to pursue risky strategies (Boulding and Christen 2008, 700; Hannan and Freeman 1984, 149). Financial leverage is included to control for the impact of free cash flow on strategic decision making. Kochhar argues that firms with higher leverage exhibit superior monitoring, which will have a significant impact on managerial actions (1996, 713-718). Lastly, dummy variables are included for the therapeutic category of the focal drug and the year to control for effects of market size and economic conditions, respectively.

RESEACH METHODOLOGY AND DATA

Methodology

The dependent variable of this study, the use of deceptive marketing, is a nonnegative, integer, count variable. Generally, the Poisson distribution is the best fit for such data. However, the sample displays over-dispersion, as the variance is larger than the mean. As a result, the negative binomial model is expected to provide a better fit to the data (Greene 2004, 744). Another issue is that the distribution of the use of deception data contains a large proportion of zeros (93%). This represents a higher proportion of zeroes than is predicted by traditional negative binomial model. To address this issue, I use a zero-inflated model where counts are assumed to be generated from two sources (Greene 2004, 749-750). One source represents a state that reflects only zero occurrences while the other represents a normal counting process that follows the negative binomial

distribution (Lambert 1992, 1). This minimizing specification puts extra weight on the probability of observing a zero.

The zero-inflated negative binomial density for citations for deception for firm *i,* in year *t,* in a category *j* can be presented,

$$P(Deception_i = 0) = \frac{\exp(X_i'\gamma)}{1+\exp(X_i'\gamma)} + \frac{1}{1+\exp(X_i'\gamma)} f(Deception_i = 0, \theta | X_i)$$

$$P(Deception_i = n) = \frac{1}{1+\exp(X_i'\gamma)} f(Deception_i = n, \theta | X_i) \; \forall n > 0$$

where f(·) denotes the negative binomial density with mean $\exp(x_i\beta)$, dispersion parameter α, and $\theta = (\beta' \alpha)$. X is a vector of explanatory variables, and β is the parameter vector associated with X.

The maximum likelihood technique used to estimate the model will produce inflated standard errors if events are correlated across observations. Because the sample includes only 18 firms and over 300 drugs, I expect that observations may be clustered by firm. To alleviate biases that may occur with cluster-correlated data, the Huber/White/sandwich estimator of variance is used to produce more robust measures of variance (Vassolo, Anand, and Folta 2004, 1053-4; Huber 1967, 221-3; White 1980, 817-830).

Data

The sample includes all drugs produced by public pharmaceutical firms in 18 categories from 39 firms, ranging from hypertension to depression to allergic rhinitis. The data was collected for the years 2003 through 2007. I began with 1701 drugs produced by publically-traded pharmaceutical firms and excluded 51 due to missing or contradictory patent information and 22 for missing financial information. The operationalization of variables included in the sample is based on prior studies and data is collected from multiple sources (see table 2.1).

Dependent Variable

The use of deceptive marketing is tracked by the FDA and a record of violations is available to the public. The dependent variable is thus operationalized as the number of citations received by a firm for a product in a given year. In the sample used for analysis, no firm received more than one citation for a product (or single category) in one calendar year. Thus, the coding of the variable is identical to a dummy variable where "1" indicates that deception was used and "0" indicates that deception was not used.

Independent Variables

Innovation potential is measured as the number of drugs in the pipeline adjusted for the phase of development. In the pharmaceutical industry, drugs must pass through three distinct trial phases before approval. At each stage, if the drug fails to meet the requirements of safety and efficacy set by the FDA, the drug may fail. Prior literature has

Table 2.1. Descriptive statistics for select variables

Variables	Operationalization	Mean	Std. Dev.	Min.	Max.	Source
Use of unlawful marketing (*Focal Firm*)	Number of citations issued by FDA in given category	0.07	0.19	0.00	1.00	FDA.gov
Current innovation strength (*Focal Firm*)	(Log of) days until expiry of patent	6.68	2.46	0.00	8.56	FDA.gov, Delphion
Innovation potential in category (*Competitors*)	Number of innovations in pipeline weighted by time-to-market for competitors within category	4.32	2.45	0.00	10.09	Inteleos
Innovation potential in category (*Focal Firm*)	Number of innovations in pipeline weighted by time-to-market for focal firm within category	2.81	1.12	0.00	5.98	Inteleos
Innovation potential in other categories (*Focal Firm*)	Number of innovations in pipeline weighted by time-to-market for focal firm in all other categories	10.86	5.74	1.03	21.45	Inteleos
Dependence on category (*Focal Firm*)	Number of innovations and products in given category/total innovations and products of focal firm	0.05	0.04	0.00	0.21	Inteleos
Debt-to-equity ratio (*Focal Firm*)	(Log of)(Long-Term Debt + Debt in Current Liabilities) /Common Equity	-1.27	1.60	-9.64	2.25	COMPUSTAT
Firm size (*Focal Firm*)	(Log of) number of employees	7.13	2.44	1.63	10.16	COMPUSTAT

shown that the probability that a drug will gain FDA approval dramatically increases as each trial phase is completed and differs dramatically by category (Danzon, Nicholson, and Pereira 2005, 328-330). Therefore, the time-adjusted probability of indication success (TAPIS) is used to measure innovation potential (Girotra, Terwiesch, and Ulrich

2007a, 1456). At the category level, a firm could have n_i drugs entering phase i (i =1,2,3) development stage. The probability of failure at each phase, p_i, is assumed to be constant for each stage of a category (Girotra, Terwiesch and Ulrich 2007a, 1455-1456). Therefore, innovation potential for a firm in a given category is expressed,

$$TAPIS\ (p_1, p_2, p_3, n_1, n_2, n_3) = [(1 - {p_3}^{n_3}) + \alpha_2 {p_3}^{n_3}(1 - {p_2}^{n_2}) + \alpha_1 {p_3}^{n_3} {p_2}^{n_2}(1 - {p_2}^{n_2})]$$

where α is the discount factor for time to market. Drug pipeline information is available from multiple sources. The Inteleos database is used for this analysis and the measure of probability of failure is collected from Girotra, Terwiesch and Ulrich (2007b, ec1-ec8).

Strength of current innovation is measured as days to expiry of patent from the first day of the annual period. This information is publically available on Delphion and verified using the FDA website.

Market dependence is conceptualized as the importance of the category to the firm. To measure this, I use entropy or breadth of the product portfolio. Sorescu, Chandy, and Prabhu operationalized this concept as the fraction of the firm's products in a given category to all products in the firm's portfolio (2003, 90). This data was also collected from Inteleos.

To capture relative performance of the focal firm, a continuous stock return variable is used that is constructed by subtracting the annual industry average stock returns (R_j) from the focal firm's stock return (R_i) for the same year (t) (Markovich, Steckel, and Yeung 2005, 1472). This is expressed,

$$R^{*}_{ijt} = R_{it} - \frac{1}{n}\sum_{j=1}^{n}(R_{jt})$$

Thus, the variable is positive if the firm's stocks have performed better than average for its industry and negative if its performance has been below average.

Therapeutic category, as designated by Inteleos, and year are treated as dummy variables. The logarithmic transformation of number of employees is used to measure firm size, while the debt-to-equity ratio for each firm is used to measure the firm's financial leverage. Debt is calculated as the total of debt in current liabilities and long-term debt, and equity is the total common equity for the firm. The financial data was gathered from COMPUSTAT and CRSP.

RESULTS

The results of the zero-inflated negative binomial regression are reported in table 2.2. For the variables included in the hypotheses, tests of significance are all one-tailed as the predictions are unidirectional. The reported level of significance for the control variables and the main effect of market dependence is based on two-tailed tests as there is no expected direction.

The analysis shows support for all of the main effects hypotheses. A negative relationship between strength of time to expiry of patent and the likelihood of a firm to use deceptive marketing is supported ($p<.05$). I also show that firms are less likely to use

Table 2.2. Estimation results using zero-inflated negative binomial model

Variable	Expected Sign	Estimated Coefficient	Robust S.E.	Significance
Patent protection (Focal)	-	-0.091	0.049	**
Strength of innovation pipeline in category (Competitors)	-	-0.125	0.091	*
Strength of innovation pipeline in category (Focal)	-	-0.029	0.015	**
Strength of innovation pipeline in other categories (Focal)	+	0.051	0.014	***
Dependence on category (Focal)	-/+	0.234	0.268	
Strength of innovation pipeline in category (Focal) * Dependence on category (Focal)	-	0.021	0.023	
Strength of innovation pipeline in other categories (Focal) * Dependence on category (Focal)	-	0.081	0.078	
Patent protection (Focal) * Dependence on category (Focal)	-	-0.056	0.039	*
Strength of innovation pipeline in category (Competitors) * Dependence on category (Focal)	+	0.122	0.071	**
Debt-to-equity ratio (Focal)		-0.370	0.322	
Relative stock returns (Focal)		0.126	0.066	*
Firm size (Focal)		0.092	0.084	
Toxicity		0.549	0.430	
Depression		0.654	0.449	
Acne		-0.289	0.170	*
Hypertension		0.122	0.156	
Attention deficit/hyperactivity disorder		-0.345	0.199	*
Alzheimer disease		0.821	0.687	
Complex partial seizure		-0.559	0.424	
Hyperphosphatemia		0.368	0.453	
Chronic kidney disease		-0.401	0.299	
Congestive heart failure		0.456	0.518	
Erectile dysfunction		0.792	0.550	
Allergic rhinitis		0.279	0.073	***
Cardiovascular disease		0.423	0.419	
Schizophrenia		-0.566	0.610	
Cataract		-0.356	0.249	
Solid tumor		0.793	0.548	
Psoriasis		0.479	0.681	
Year 1		-0.982	0.741	
Year 2		-0.713	0.498	*
Year 3		0.870	0.270	
Year 4		-0.237	0.619	

*p<.10 **p<.05 ***p<.01

Note: Robust standard errors presented in parentheses under coefficient estimates

Note: Tests of significance in the table are one-tailed for variables with a directional hypothesis and two-tailed for those without a directional hypothesis.

deceptive techniques when they have greater innovation potential in both the focal category ($p<.05$) and across all other categories ($p<.10$). Furthermore, the analysis indicates that the innovation potential of competitor's within the category is a strong predictor of likelihood to use deception in advertising ($p<.01$). These results support the conjecture that firms are more likely to undertake unlawful activities when they face high uncertainty regarding innovation.

A direct relationship between market dependence on a product category and likelihood of using illegal techniques is not found in the analysis. However, market dependence does moderate the relationship between some of the innovation measures and citations. A significant negative relationship is supported for the interaction of dependence and time to expiry of patent protection for marketed innovations (H5c, $p<.10$). Thus, when the focal firm is highly dependent on a therapeutic category, the impact of the focal firm's patent protection is more negative. This result suggests that firms are more conservative in their use of risky strategies with newer brands in key markets. I also find strong support for H5d ($p<.05$). The impact of competitors' innovation potential on the likelihood of receiving citations is higher when the focal firm is highly dependent on the category. This relationship implies that the focal firm is willing to accept more risk when a key market is potentially facing a flood of new competition.

I do not find support for H5a or H5b. Thus, I do not find that market dependence changes the relationship between use of deception and a firm's innovation potential in the

category or its innovation potential across other categories. I expected that these relationships would be more negative.

The predictors of excess zeroes (i.e., time to expiry of patent, innovation potential of the focal firm, and innovation potential of competition within the category) are all statistically significant. The alpha is significantly different from zero. The Vuong test indicates that the zero-inflated binomial model is a significant improvement over the standard binomial model, and a likelihood-ratio test indicates that the model provides a better fit than the zero-inflated Poisson model. To further assess the robustness of the results, I also calculate log-likelihood estimates of the standard binomial model and the zero-inflated Poisson model (see table 2.3). I do not find any inconsistencies between the results for the hypothesized relationships and those estimated using the zero-inflated negative binomial model.

DISCUSSION

Summary of Findings

This study was undertaken to bridge a gap between the rich literatures of innovation and marketing strategy. I identify innovation potential as an important element in understanding the use of unlawful marketing strategies, particularly deception. While prior research has identified elements of organizational and individual behavior as determinants of strategy, this analysis shows that innovation potential and patent protection of marketed products are also strong predictors of deceptive activity. While

these findings may be linked only to industries with high dependence on technology, the results have important implications for managers, public policy, and business research within that large sphere of industries.

Table 2.3. Comparison of estimation results from alternative models

Variable	Expected sign	Zero-inflated negative binomal	Zero-inflated poisson	Negative binomial
Patent protection (Focal)	-	-0.029 (0.015)**	-0.022 (0.014)*	-0.043 (0.028)*
Strength of innovation pipeline in category (Competitors)	+	0.051 (0.014)***	0.057 (0.019)***	-0.068 (0.034)**
Strength of innovation pipeline in category (Focal)	-	-0.091 (0.049)**	-0.112 (0.072)*	-0.032 (0.025)**
Strength of innovation pipeline in other categories (Focal)	-	-0.125 (0.091)*	-0.093 (0.054)**	-0.081 (0.046)**
Dependence on category (Focal)	-/+	0.234 (0.268)	0.092 (0.099)	0.079 (0.076)
Strength of innovation pipeline in category (Focal) * Dependence on category (Focal)	-	0.021 (0.023)	-0.011 (0.023)	-0.009 (0.014)
Strength of innovation pipeline in other categories (Focal) * Dependence on category (Focal)	-	0.081 (0.078)	0.037 (0.036)	0.078 (0.068)
Patent protection (Focal) * Dependence on category (Focal)	-	-0.056 (0.039)*	-0.065 (0.035)**	-0.104 (0.078)*
Strength of innovation pipeline in category (Competitors) * Dependence on category (Focal)	+	0.122 (0.071)**	-0.108 (0.054)**	0.087 (0.049)**
Debt-to-equity ratio (Focal)	+	-0.370 (0.322)	-0.234 (0.199)	-0.087 (0.090)
Relative stock returns (Focal)	_	0.126 (0.066)**	0.138 (0.034)***	0.083 (0.041)**
Firm size (Focal)	+	0.092 (0.084)	0.064 (0.059)	0.142 (0.156)

*p<.10 **p<.05 ***p<.01

Note: Robust standard errors presented in parentheses under coefficient estimates

Note: Tests of significance in the table are one-tailed for variables with a directional hypothesis and two-tailed for those without a directional hypothesis.

This analysis is the first to support a link between any measure of innovation potential and marketing strategy actions. I show that when innovation potential is high within a firm across categories or within a focal category, the firm is less likely to use deception within that category. For a standard deviation increase in innovation potential of the firm across categories and within the focal category, the use of deceptive marketing drops by 7.5% and 9.2%, respectively. On the other hand, firms are more likely to use deception when the innovation pipeline of competitors is strong. The use of deceptive marketing for a particular product increases 12.2% for a standard deviation increase in innovation potential of competitors within the category. These effects are consistent with the argument that firms are more likely to adopt risky actions when uncertainty exists, such as potential new competition or a weak innovation pipeline (Kahneman and Tversky 1979, 268).

I also find a significant relationship between unlawful activities and current strength of innovation as measured by time to expiry of the current drug. In these cases, firms seem to be willing to risk being caught in the act of deception to maximize revenue before the product loses much of its profitability.

I do not find a relationship between market dependence and deceptive marketing. One reason for a lack of a significant negative relationship may be that the number of products (or revenue) does not introduce risk unless the number of products (or revenue) is changing. A significant positive relationship does not exist perhaps due to concern regarding negative spill-over to other product categories and jeopardizing sales critical to firm performance.

However, the examination of the contingent role of dependence on the proposed main effects does produce some significant results. When market dependence is high, an increase in competitive innovation potential is more likely to result in the use of deceptive marketing. In contrast, an increase in the focal firm's current innovation status will make the use of deception less likely when market dependence is high. These results are consistent with prior findings that show the relationship between a firm's performance and risk taking is contingent on firm characteristics (Audia and Greve 2006).

The examination of the interaction between dependence and both measures of the innovation potential of a firm does not produce significant results. The lack of significance may be the result of the measure of market dependence. In the future, alternative measures of market dependence, such as revenue from the category as a percentage of firm revenue, should be tested.

Implications and Extensions

Based on these findings, managers will be better able to anticipate their competitors' actions given innovation status in the industry. Close to thirty percent of citations are issued regarding unsubstantiated superiority claims related to competing drugs. Understanding when competitors may launch deceptive acts, especially direct comparative marketing, allows managers to prepare for correcting false information immediately.

The results are also informative for those dictating public policy. When formulating measures to prevent misinformation from reaching consumers, public officials can use this analysis to target those firms most likely to commit unlawful acts. False information, especially about pharmaceutical products, can lead to great public harm as well as high costs to government agencies.

The implications for business research are perhaps the strongest. The current study provides tools for further research on the relationship of innovation and marketing strategy, as well as, furthering ideas in the individual domains. Among many possibilities, future research considering other high-risk marketing strategies, such as the launch of a potentially controversial advertisement or the implementation of a new web-based customer portal, may find strong ties to innovation status.

In terms of strengthening the current study, interaction effects as well as industry effects are obvious extensions. Additional measures of firm risk would further confirm the robustness of the results. Moreover, other measures of innovation strength should also be explored such as the success of a firm in converting pipeline items.

Another interesting extension of this research would be to include other characteristics of the products in the development pipeline. The current study does not distinguish between incremental and breakthrough (or radical) innovations. Several studies have found that pioneering innovations have a far greater positive impact on economic performance (Sorescu and Spanjol 2008, 123-124; Srinivasan et al. 2009, 34-40). Based on this evidence, weighting the strength of the innovation pipeline by the "newness" of the development may explain more variance in use of deception. On the other hand, a recent study has found that incremental innovations in the pharmaceutical

industry are more profitable than radical innovations (Ganuza, Llobet, and Dominguez 2009, 548-9) and other researchers have argued for giving equal weight to innovation projects (Girotra, Terwiesch, and Ulrisch 2007a, 1454). Thus, based on existing literature, it is unclear what, if any, impact including level of innovativeness will have on the results.

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 falsity in the effectiveness 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 falsity in the risk information 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")

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