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Media framing of prescription drug coverage following a recall

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MEDIA FRAMING OF PRESCRIPTION DRUG COVERAGE FOLLOWING A RECALL

A Thesis

Submitted to the Graduate Faculty of the
Louisiana State University and
Agricultural and Mechanical College
in partial fulfillment of the
requirements for the degree of
Master of Mass Communication

in

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by

Rebecca Ann Hotard
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TABLE OF CONTENTS

ACKNOWLEDGEMENTS.....	ii
ABSTRACT.....	iv
CHAPTER 1. INTRODUCTION.....	1
1.1 The Recall.....	1
1.2 Blaming the FDA.....	2
1.3 FDA's Fast Track for Drug Approval.....	3
1.4 Restoring Confidence in the FDA.....	5
1.5 Merck Reconsiders the Recall.....	6
1.6 The Tables Turn.....	8
1.7 Pfizer's Coxibs.....	11
1.8 Image Rebuilding.....	12
1.9 The Role of Direct-to-Consumer Advertising in the Recall.....	12
CHAPTER 2. LITERATURE REVIEW	14
2.1 The DTC Debate.....	14
2.2 The Physician-Patient Relationship.....	15
2.3 The Vioxx Recall.....	16
2.4 Framing Theory.....	17
2.5 Prospect Theory.....	19
2.6 Summary.....	21
2.7 Research Questions.....	23
CHAPTER 3. METHOD.....	24
CHAPTER 4. RESULTS.....	26
CHAPTER 5. DISCUSSION AND CONCLUSIONS.....	43
5.1 Findings.....	43
5.2 Relevance of Findings.....	47
5.3 Limitations and Future Research.....	48
5.4 Conclusions.....	49
REFERENCES.....	51
APPENDIX: CODING INSTRUMENT.....	57
VITA.....	63

ABSTRACT

Direct-to-consumer advertising of prescription drugs receives significant attention from academic researchers. Advertising, however, is not the only way prescription drugs are discussed in the public sphere. Many Americans learn about science through mass media. Additionally, researchers believe readers place more trust in editorial content than in advertisements. This study took a quantitative and qualitative approach to content analysis of prescription drug coverage to examine the effects of the highly publicized and controversial Vioxx recall on the news. Significant changes in framing, drugs mentioned, and prominence of story placement were shown. There were no changes in sources used in prescription drug coverage, and the absence of personal stories in news coverage was an important discovery, which may help explain the drop in prominence of articles in newspapers.

CHAPTER 1 INTRODUCTION

This project originally began as a content analysis of advertising appeals used to sell prescription drugs in direct-to-consumer (DTC) ads. Drug manufacturers are not marketing luxury items. They sell chemicals that are necessary for comfort and health. After much research, it was discovered that advertising appeals of these ads had been analyzed extensively. However, the importance of the political influence of pharmaceutical companies and the delicate public issues associated with their products was made clear. The focus of this study shifted to the pharmaceutical company Merck's recall of its cox-2 inhibitor Vioxx. The Vioxx recall, as demonstrated through news coverage, was a momentous event in the drug industry. This recall may involve dire implications for the future of the Federal Drug Administration (FDA) and drug companies that are facing new public scrutiny over the safety and necessity of some prescription drugs.

Current news reports on prescription drugs convey a rising fear about drug safety. Drug safety is repeatedly called into question and negative messages are given air time as lobbyists clamor for extensive recalls. The political power of drug companies has been criticized by the medical community and by consumer interest groups (Angell, 2004). Members of the FDA have also voiced concerns over the power of pharmaceutical companies (Beardsley, 2005 and Simons, 2005). The purpose of this study was to determine whether media framing of prescription drug news has changed since the recall of Vioxx. A closer look at the events surrounding the recall is instructive.

1.1 The Recall

American pharmaceutical giant Merck recalled its blockbuster arthritis and pain medication Vioxx on September 30, 2004. A news release titled "Merck announces voluntary

worldwide withdrawal of VIOXX” revealed data from a three-year clinical trial that demonstrated an “increased relative risk” of “cardiovascular events” such as heart attack and stroke after 18 months of treatment (Merck, 2004, p.1).

Vioxx increased the risk of cardiovascular events when compared to placebo in the clinical trials. A placebo is a sugar pill given in place of a medication so that patients and researchers believe they are taking and giving drugs (Angell, 2004). Comparison to placebo is a common practice in the clinical trials of pharmaceutical companies. This means that the medication under review only has to be proven more effective than nothing, not that the drug needs to be equally as effective as, or more so than a medication already available (Angell, 2004). If an unapproved drug is more effective than nothing, the FDA review to put a drug on the market can begin. This means that drugs that are worse at treating an illness than drugs already on the market can be approved. There have been few studies designed to illustrate whether one drug is more effective than other drugs at treating a specific medical condition. New drugs in clinical trials typically are not compared to generics and similar brand-name drugs that are available.

1.2 Blaming the FDA

Merck’s withdrawal was called “voluntary,” which indicated that the company made the decision independently, without pressure from the US Food and Drug Administration. The FDA approves and monitors drugs produced and marketed by large pharmaceutical manufacturers (Angell, 2004). The wording of Merck’s initial news release announcing its recall of Vioxx made the FDA seem uninformed about the drugs it is responsible for monitoring. The FDA did not order the recall. Specifically, the news release states that “Merck has informed the US Food and Drug Administration and regulatory authorities in other countries of its decision” (Merck, 2004,

p.1). In a sense, Merck placed itself in the position of monitoring the safety of its drugs while causing the FDA to appear indifferent about a serious safety concern. Almost immediately, the FDA was under fire for its fast approval of understudied drugs and other ethically questionable practices (Beardsley, 2005).

For example, the administration's use of the 1992 Prescription Drug User Fee Act has become extremely contentious. Under the Act, the FDA uses money from pharmaceutical companies to hire drug reviewers (Beardsley, 2005). Medical experts worry that the donations cause the FDA to be less willing to confront industry officials when problems and safety concerns arise. There are also concerns of a conflict of interest and accountability, as voiced by FDA official David Graham, when the same people who approve a drug continue to monitor its safety after it has gone on the market (Beardsley, 2005 & Simons, 2005). It has also been publicized as recently as February 2005 that researchers with ties to the pharmaceutical industry commonly serve on FDA advisory panels, which review safety issues arising from clinical studies (Harris & Berenson, 2005, February 25).

Graham, associate director of science at the FDA's Office of Drug Safety, says the administration is responsible for "100,000 people having heart attacks and as many as 55,000 people dying of those heart attacks" as a result of ignoring the data from Vioxx trials (Simons, 2005, p.32). Graham believes that the FDA is more responsible than Merck for the damages because the FDA has a "public obligation and the responsibility to deal with" unsafe medications (p.32).

1.3 FDA's Fast Track for Drug Approval

In 1992, the FDA responded to pressure from AIDS activists and the pharmaceutical industry to speed up the approval process for "vital medications to treat life-threatening diseases"

by creating a “fast track” (Gorman, Bacon, Thompson & Park, 2005, p.59). Drugs approved on the fast track were not required to be tested for safety over a long-term period prior to approval. Instead, they were to be monitored for unexpected side effects *after* their appearance on the market. It was a move defended by the presumption that problems are more likely to occur when millions of people take a drug than when a few thousand participate in clinical trials (Gorman et al., 2005). Over the years, however, drug companies abused the fast track, seeking a direct route to the market for drugs intended to treat common maladies instead of “life-threatening diseases” (p. 59).

In addition to a the FDA’s fast track for drugs for which it was not intended, drug manufacturers are reluctant to spend money on expensive post-approval safety studies (Gorman et al, 2005). Research indicates that drug companies complete fewer than half of the post-marketing research studies the FDA requires as a condition for fast approval, and the FDA has little authority to order additional trials (Beardsley, 2005).

It is important to ask why millions of people need to take the same drug for a life-threatening disease. Besides AIDS, it is doubtful that millions of people actually suffer from the same life-threatening illnesses. If a fatal illness is common, it is likely that the affected includes mostly poor people unable to pay for expensive brand-name medications. According to medical expert and former editor of the *New England Journal of Medicine* Marcia Angell (2004), even common diseases such as AIDS and malaria are ignored by pharmaceutical companies because poor people do not make a good market. Angell says that drug companies once promoted drugs to treat illnesses, but now “they promote diseases to fit their drugs” (p. 86). Angell goes on to say that uncommon diseases are also of little interest to large pharmaceutical companies, although they are researched by medical and university labs, because “the market is small” (p. 84).

1.4 Restoring Confidence in the FDA

FDA officials are working to reverse the growing perception that it “has been working harder to protect the pharmaceutical industry than the public” (Gorman et al., 2005, p.58). The administration plans to create a board to monitor drugs for safety and side effects after they have been approved for public consumption. It asked Congress for more regulatory power and more money to “stand up to” the pharmaceutical industry (p. 58). FDA officials want the authority to order additional clinical trials whenever safety questions arise (Dunkard, 2005). The FDA also pledges to give the public information about drugs as it is received (Gorman et al., 2005). The administration issued a news release outlining plans to study the drug safety system, publish risk management guidances for pharmaceutical companies and develop a system for acknowledging dissenting opinions of members of drug safety review teams (FDA, 2004).

Also, President George W. Bush appointed Dr. Andrew Von Eschenbach, director of the National Cancer Institute, as the FDA’s new commissioner after the resignation of Lester Crawford on September 23, 2005 (Neergaard, 2005). This appointment signified internal change at the FDA. During Crawford’s tenure recalls of Vioxx, tainted flu vaccines and malfunctioning pace-makers embarrassed the administration. The FDA’s women’s health chief resigned in protest when Crawford ordered a freeze of nonprescription sales of emergency contraception over the objections of scientists who confirmed its safety. Senator Charles Grassley, R-Iowa, spent a year and a half investigating the FDA. Grassley said, “The opportunity to name a new commissioner is a chance to take the agency in a necessary new direction” (Neergaard, 2005, p. 2).

Congress is currently considering new legislation to address drug safety that would make information from clinical trials public, including negative results (Dunkard, 2005).

Acknowledging all results is common scientific practice; hiding and obscuring results is not. Editors of prominent research journals insist that the FDA require drug companies to design trials that take into account effects on all patients instead of only the healthy or young people often used in their studies (Gorman et al., 2005). The use of healthy subjects is a method of minimizing or obscuring side effects caused by the drug under study. These scientists insist on honest, ethical science.

Many studies sponsored by pharmaceutical companies serve as “experimercials” (Brownlee, 2006, p. 157). “An experimercial exists not to advance science, but to increase market share of a drug that has already been approved,” and usually compares a drug to placebo in a select group of patients (p. 157). The combination of bad experimental design and flawed reporting can result in free direct-to-consumer advertising for the drug company. Injudicious media attention serves as an effective marketing tool.

1.5 Merck Reconsiders the Recall

The *New York Times* reported on February 18, 2005, that Merck was considering putting Vioxx back on the market because of the drug’s “unique benefits” (Harris, 2005, Feb. 18, p.18A). Although the other cox-2 inhibitors, or coxibs, Pfizer’s Celebrex and Bextra, show similar clinical risks, the FDA panel advised that all drugs in this class should stay on the market (Schmit, 2005). The panel advised placing warning labels on product packaging warning of the risk of cardiac damage and restricting the use of coxibs. Dr. Garret FitzGerald, an expert on cox-2 inhibitors, believes that Vioxx may have stayed on the market in the first place if its use had been restricted to people with a low risk of cardiovascular disease and a history of gastrointestinal problems (Beardsley, 2005).

Coxibs work by inhibiting the function of cyclooxygenase-2 (cox-2) which is an enzyme that produces prostaglandins, proteins that cause inflammation in painful arthritic joints (Beardsley, 2005). Coxibs became popular because they do not cause the stomach ulcerations and bleeding sometimes caused by older non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin and ibuprofen (Leland, 2005). Although Pfizer and Merck successfully marketed coxibs since 1999, they have not proven the drugs to be more effective at relieving pain than the older non-prescription medications. The FDA advisory panel recommended that the coxibs stay on the market, but that they only be used at the lowest dose (Harris, 2005, Feb. 18). The problem with the drug class is that patients who are at high risk of developing ulcerations on older NSAIDs are often at risk of heart attack and stroke as well (Harris, 2005, Feb. 18).

Some researchers believe that coxibs cause problems because prostaglandins are needed to prevent blood from clotting. Inhibiting prostaglandins means that blood clots may form in the body, leading to heart attack and stroke (Park, 2005). FitzGerald says that cox-2 inhibitors may lead to heart trouble by reducing the heart-protecting properties of the hormone estrogen (Harris, 2004).

Industry analysts called Merck's recall of Vioxx a turning point for the drug industry. Because of Vioxx's benefits for use in segmented markets, FitzGerald believes that pharmaceutical companies may "focus on niche medications designed for particular groups of ailing people" instead of blockbusters aimed at anyone who can be persuaded to take a pill (Beardsley, 2005, p.17). According to medical scientist Marcia Angell, M.D., uncommon diseases do not interest large pharmaceutical companies, despite the extensive research performed by medical and university labs, because "the market is small" (2004, p. 84). In other words, segmented markets are not economically advantageous to large, profit-driven

pharmaceutical manufacturers. Angell writes that drug companies once promoted drugs to treat illnesses, but now “they promote diseases to fit their drugs” (p. 86).

FitzGerald says that useful drugs are being “put at risk by the pursuit of a blockbuster strategy” when promoted through direct-to-consumer (DTC) advertising (Beardsley, 2005, p. 17). Currently, six drug companies not including Merck are researching “personalized medicine,” prescribing doses of medicines based on tests of an individual’s personal genetic capability to break down drugs once they enter the bloodstream (Capell, Arndt, & Carey, 2005). Personalized medicine means developing drugs and diagnostics together, a practice that may simplify the FDA approval process as well as increase response rates in segments of the general population that actually benefit from a drug. Sidney Taurel, CEO of pharmaceutical company Eli Lilly & Co. said, “From a strategic standpoint of meeting the needs of our customers, the current blockbuster model doesn’t work,” (p.76). Personalized medicine may help prevent “Vioxx-style collateral damage” (p.76).

1.6 The Tables Turn

Merck is under fire. The risk of cardiovascular events was not just benignly increased. It was, in fact, doubled by Vioxx (Beardsley, 2005). It did not take long-term use of the drug, 18 months specifically, to cause damage. According to Graham, damage occurred in as little as four months (Science & technology, 2005). Merck officials claim they had no conclusive evidence of the risks caused by Vioxx until September, when the drug was recalled (Feder, 2005). However, results of a study completed in 2000 indicate an increased risk of cardiovascular events (Merck, 2004). Graham holds the FDA responsible, but popular opinion is turning against Merck. Even Graham claimed to be concerned when Senate testimony revealed that Merck tried to design studies to obscure and hide the cardiac risks of Vioxx (Simons, 2005).

Other documents reveal that kickbacks, or payments, to doctors were used by Merck to “neutralize” them, or cause them to prescribe Vioxx to their patients over similar drugs, specifically Pfizer’s Celebrex, which was approved before Vioxx (Meier & Saul, 2005, p.1A). Merck allegedly used payments to garner support from doctors, or at least neutralize their support for competing drugs.

Payments made to influence a doctor’s prescribing habits are illegal. Industry officials skirt this issue by calling kickbacks “grants” meant for scientific or educational purposes (p.1A). Merck issued a statement in response to questions about its marketing program: “Merck believes that the provision of educational grants to support the exchange of information in a medical or scientific form is not only proper but is a valuable contribution” (p.1A). It is important to note, however, that paying doctors to prescribe drugs is not a practice unique to Merck. Lures, bribes and kickbacks are commonly used as marketing components by pharmaceutical companies to garner physician support for copycat drugs, known in the industry as “me-too” drugs (Angell, 2004, p. 16). Important new drugs do not require extensive marketing because they sell themselves. Copies of the same drug, however, require more attention.

Merck introduced Vioxx in the United States in 1999 and marketed the drug in more than 80 countries. Its sales in 2003 topped \$2.5 billion (Merck, 2004). New drugs have six years of exclusivity from generic competition (Angell, 2004). This means that no generic cox-2 inhibitors would be on the market until 2005. Interest groups allege that Merck ignored the risks posed by its drug in 2000 aside from adding a warning to Vioxx labeling in 2002, and put off the recall for years, until exclusivity almost ran out (Beardsley, 2005).

Merck faces 7000 lawsuits to date (Johnson, 2005, Nov. 6). That number increases almost daily. Approximately 20 million people took Vioxx before it was recalled (Berenson,

2005, Aug. 21). Merck officials intend to defend each lawsuit because of their confidence that “Merck acted responsibly” (Merck, 2005, Nov. 3). Two cases have been heard to date. The first, Ernst v. Merck, took place in Texas in August 2005. The jury awarded \$253 million to the widow of a man who died of cardiac arrhythmias, irregular heartbeats, after taking Vioxx for eight months (Johnson, 2005, Aug. 26). Included in that sum is \$229 million in punitive damages. Although Texas caps punitive damages at \$26 million, jurors of the case said they wanted to “punish Merck” and the drug industry (Berenson, 2005, Aug. 21, p.1A). The figure refers to a “2001 Merck estimate of additional profit the company might make if it could delay an FDA warning on Vioxx’s heart risk” (p.1A). The verdict surprised Merck officials, however, because Vioxx caused blood clots that led to heart attacks and strokes after 18 months of use (Merck, 2004). Not only did the plaintiff’s husband take Vioxx for eight months, blood clots did not cause his cardiac arrest. Merck issued a statement that the company plans to appeal the verdict. Jonathan Skidmore, a member of Merck’s defense team, said, “There is no reliable scientific evidence that shows VIOXX causes cardiac arrhythmias, which an autopsy showed was the cause of Mr. Ernst’s death, along with coronary atherosclerosis” (Merck, 2005, Aug. 19).

Merck won its second Vioxx liability suit, Humeston v. Merck. Frederick Humeston of Boise, Idaho, suffered a heart attack on September 18, 2001, after only two months of “intermittent use of VIOXX,” from which he fully recovered (Merck, 2005, Nov. 3). Kenneth Frazier, Merck senior vice president said in an official statement, “Merck acted responsibly—from performing extensive clinical trials comparing VIOXX to NSAIDs or placebo in almost 10,000 patients prior to approval—to monitoring the medicine while it was on the market—to voluntarily withdrawing the medicine when we did” (p.1).

The company is working to repair its image in the backlash it faces over Vioxx. Merck set up a Vioxx (rofecoxib) information center on its Web site. The center includes statements from company officials, news releases, patient refund instructions and up-to-date information for patients, physicians and stockholders. According to Kent, Taylor and White (2003), Web site design indicates an organization's responsiveness to stakeholders. The importance of a Web site lies in its ability to provide stakeholders with a "channel through which organizations can be viewed and better understood" (p. 63). Merck also hired a public relations agency to help rebuild its image through a six-month, \$20 million image campaign (Herskovits, 2005). Merck officials claim the idea for the campaign began in January 2003, well before the Vioxx ordeal began.

1.7 Pfizer's Coxibs

The FDA recalled Pfizer's coxib Bextra on April 6, 2005, due to cardiovascular risks and rare but serious skin reactions (Pfizer, 2005). Pfizer says it disagrees with the recall but will comply with all FDA requests. The FDA also ordered new warning labels for all NSAIDs and the remaining cox-2 inhibitors, citing risks to heart, stomach and skin (Harris, 2005, April 8). The decision to withdraw Bextra was made largely because of a potentially lethal but rare skin reaction and because no unique effects could be attributed to the drug, according to FDA officials. Pfizer also had no long-term studies to prove Bextra's safety (Harris & Berenson, 2005, February 5). The recall comes at an unsteady period for Pfizer. Most of its best-selling drugs will be facing generic competition in the near future (Harris, 2005, April 8).

Celebrex, approved for the treatment of osteoarthritis and rheumatoid arthritis in 1998, is still on the market (Henderson, 2005). Evidence for its safety is mixed. An increase in heart problems has been shown in patients on high doses, but low doses appear to cause fewer effects (Henderson, 2005). Pfizer has been in hot water over Celebrex recently, but not only because of

safety concerns. Celebrex revenue rose after Vioxx was withdrawn from the market, when Pfizer heavily advertised its coxib (Henderson, 2005). Sales in 2004 exceeded \$3.3 billion. Pfizer was ordered to halt false and misleading ads for the drug on January 12, 2005 (Drug Industry Daily, 2005). The FDA said that the ads promoted the unsubstantiated claim that Celebrex could prevent “crippling effects or disability due to arthritis or prevent nursing home institutionalization of elderly patients with arthritis” (p. 1). Pfizer has since agreed to stop DTC ads for Celebrex (Henderson, 2005).

1.8 Image Rebuilding

Richard Clark, Merck’s head of manufacturing, replaced Raymond Gilmartin as Merck’s CEO on May 6 (Berenson, 2005, May 6). The appointment of an insider after outside executives turned down the job may be connected to the effects of the Vioxx recall on “Merck’s proud history and reputation for scientific excellence” (p. 1C). Since Clark’s appointment, Merck announced its implementation of a global restructuring program intended to reduce costs and “enhance competitiveness” (Merck, 2005, Nov. 28). Included in the plan is the elimination of 7,000 jobs and five manufacturing facilities worldwide. Other drug companies plan similar programs, possibly signifying a shift in the pharmaceutical industry toward personalized medicines and away from the blockbuster strategy. Since Clark’s appointment, Merck hired an agency to launch an image-rebuilding campaign (Herskovits, 2005).

1.9 The Role of Direct-to-Consumer Advertising in the Recall

Arnold Eppel, director of the Baltimore County Department of Aging sums up the debate over cox-2 inhibitors by saying that the Vioxx ordeal “reveals less about the drugs themselves than about the ways drugs are marketed” (Leland, 2005). Eppel also notes an increased reliance on pills by people and their physicians. Daniel Solomon, an arthritis specialist in Boston, says

that many people who have taken coxibs did not need to take them (Leland, 2005). Marketing reaches people with various risk factors and medical histories, so even rare side effects can affect large numbers of people, possibly leading to extensive recalls.

CHAPTER 2 LITERATURE REVIEW

This study is based on the presumption that the pursuit of a “blockbuster strategy” of selling drugs by pharmaceutical companies is at the root of extensive recalls (Beardsley, 2005, p. 17). DTC advertising may be a cause of exorbitant prescription drug use by Americans. A comprehensive look at DTC advertising is instructive.

Advertising prescription drugs directly to consumers is legal only in the United States and New Zealand, and the US is the only developed nation without formal government-regulated price-controls on drug costs (Viale, 2003). Ethical problems associated with advertising prescription drugs have been hotly debated since direct-to-consumer advertising was reintroduced in 1985 (Alperstein & Peyrot, 1993). An analysis of pharmaceutical expenditure data and diagnoses has shown that consumer response is proportional to advertising expenditures (Zachry, Shepherd, Hinich, Wilson, Brown, & Lawson, 2002). Studies indicate that direct-to-consumer advertising effectively increases the demand for medications and may impact patient and physician behavior.

2.1 The DTC Debate

The most controversial area of the debate over DTC advertising is whether it can serve the promotional interests of drug companies and also provide adequate and objective information (Cohen, 1988). Supporters of DTC advertising claim that it educates, enhances the physician-patient relationship by encouraging communication, improves patient compliance because patients feel actively involved in their own healthcare, encourages competition and results in lower medication prices (Cline & Young, 2004, Lyles, 2002). Opponents argue that consumers cannot adequately assess the quality of the ads, which neglect or downplay risk information because they are promotional, the physician-patient relationship is harmed, the ads lead to

increased drug prices as well as increased liability for healthcare providers, and they encourage over-medication (Lyles, 2002).

2.2 The Physician-Patient Relationship

Some experts say that increased advertising promotes a “pill for everything” mentality (Hollon, 2004, p.71). Patients may be unresponsive to doctors’ suggestions of lifestyle changes, which are often neglected in DTC advertisements when they believe that all they need is a pill (Bell, Wilkes, & Kravitz, 2000). A survey of 329 adults has shown that patients who are denied requested prescriptions may become angry and 15 percent would consider visiting other doctors until their demands are met (Kravitz, 2000). This survey, although it assesses hypothetical patient reactions, is cited as evidence that DTC ads may damage the patient-physician relationship.

An analysis of pharmaceutical expenditure data and diagnoses has shown that consumer response is proportional to advertising expenditures (Zachry et al., 2002). The most heavily advertised drugs are those that treat the most common conditions: antidepressants, cholesterol-lowering agents, gastric acid reducers, oral antihistamines and antihypertensives (Bell et al., 2000).

Physicians say that DTC ads influence their prescribing habits (Viale & Yamamoto, 2004). A survey showed that one in eight adults received a prescription as a result of requesting a drug seen in an ad (Young, 2002). A survey conducted by the FDA in 2003 indicated that 88 percent of physicians reported that they had been asked for a prescription drug by name by visiting patients (Viale & Yamamoto, 2004). Another survey indicated that some physicians were visited by five patients per week who had specific drug requests (Viale, 2003). The physicians felt that they gave in to pressure to prescribe drugs 30 percent to 60 percent of the

time. These results indicate that DTC advertising does affect the physician-patient relationship, which can be eroded by hostile patient demands.

Physicians have been labeled the “learned intermediary” by DTC advertisers, guarding patients from medicating themselves with unnecessary or potentially harmful prescriptions (Lyles, 2002, p. 86). Taking this stand means that the pharmaceutical companies are not required to provide direct product warnings in their ads; they advise audiences to ask their doctors for more information (Lyles, 2002). Scholars indicate that it is more important than ever that physicians are getting truthful information, because increased advertising combined with increased demand for prescription drugs puts patients at greater risk of being harmed by inappropriate medications (Wilkes, Doblin, & Shapiro, 1992).

This body of research is important to this study because it offers proof of the power of DTC advertising to affect the personal and professional habits of two important publics of pharmaceutical companies—people who consume drugs and physicians who prescribe them. Advertising is not the only, or the most important way information about prescription drugs enters the public sphere, however.

2.3 The Vioxx Recall

The most important question about DTC advertising is whether it can effectively serve the promotional interests of drug companies while providing adequate and objective information (Cohen, 1988). The Vioxx ordeal has shown that this may not be possible. When Merck announced the withdrawal of its cox-2 inhibitor Vioxx, blame initially fell on the FDA. According to some FDA officials, the administration failed the American people by ignoring its public duties in favor of the drug industry. However, in the months following the recall, blame for hurting its customers fell on Merck. Six months after the pharmaceutical giant voluntarily

recalled Vioxx, the efforts of advertising prescription drugs by pharmaceutical companies attracted renewed attention to America's dependence on pills—pills that may not always be necessary to treat the ailments, real or imagined in part because of advertising, that cause people to suffer enough to medicate themselves. In the end, it may have been the marketing machines of drug companies that caused the recall, by inviting many more people than those with legitimate reason to be on the cox-2 inhibitors to take the drugs, magnifying the problems coxibs cause. Merck's pursuit of a "blockbuster strategy," instead of restricted use of a drug that *was* useful to some, may eventually cause its downfall (Beardsley, 2005).

One framing study actually assessed the effectiveness of Merck and Pfizer's attempts to get positive media coverage for their cox-2 inhibitors, Vioxx and Celebrex. Anderson (2001) examined print sources for messages constructed by the public relations engines of Merck and Pfizer. "For the public relations professional, the concept of framing means positioning a story to the media in such a way that journalists will cover it in the desired manner," he writes (p. 450). Although journalists wrote stories following the desired frames of the drug companies, they quoted different sources, including physicians, independent industry analysts and insurance spokespersons (p. 456). The use of sources not affiliated with pharmaceutical companies prevented "totally favorable coverage" (p. 456). Anderson concluded that "the companies may have influenced the press on what to cover but not necessarily what to say" (p. 449). This is an example of the agenda-setting effect of news coverage.

2.4 Framing Theory

Because many Americans learn about science through media coverage, it is important to examine how journalists frame social reality and shape public opinion through the news (Andsager & Smiley, 1998, p. 186). According to framing theory, journalists "select some

aspects of perceived reality and make them more salient in a communicating text, in such a way as to promote a particular problem definition, causal interpretation, moral evaluation and/or treatment recommendation for the item described” (Entman, 1993, p. 55). Frames effectively limit the meaning of messages and shape individual conclusions made about those messages (Hallahan, 1999, p. 207). This is why understanding framing is important. Framing can affect an audience’s perceptions of reality. The effects may be limited, however, if framing affects audiences at all (Scheufele, 1999). Media frames may take the form of the presence or absence of key words, information sources and thematic clusters (Entman, 1991). Understanding the impact media framing may have on public opinion is important because framing of health issues “may affect the nature of regulation, the course of litigation, or the direction of research and development” (Andsager & Smiley, 1998, p. 185). This is important to all studies involving health communication.

Andsager and Smiley (1998) suggest that media may frame science coverage in terms of their own feelings and power imprints. Furthermore, journalists may “suggest attitudes and opinions for the public” (p. 186). Their coverage often, however, involves policy actors from both sides of a controversial technology, such as prescription drugs, offering data and opposing arguments. In their study of news coverage of silicone breast implants, Andsager and Smiley concluded that news media relied most on “frames provided by the most influential policy actors” in a controversy (p. 199). These influential policy actors tend to be large institutions. This may mean that this study will encounter messages and representatives from pharmaceutical companies, balanced by those from the FDA.

Research indicates that negatively framed messages may have greater impact on judgments than positively framed messages (Davis, 1995). Also, messages emphasizing losses

may be more persuasive than those emphasizing gains due to action (Davis, 1995). Negative messages may be perceived as more “important, salient, vivid, fear-inducing, and/or consequential” in comparison to positive frames (p.286).

2.5 Prospect Theory

The prospect theory of decision making can clarify the framing of risky choices (Kahneman and Tversky, 1979). According to this theory, the prospect of a loss impacts decision making more than the prospect of a gain. Health officials have documented that patients make decisions associated with high risks if it involves saving a life or reducing suffering (Hallahan, 1999, p. 214). Conversely, people make less risky decisions if they may result in suffering or death. These conclusions are important to this study because the negative or positive framing of media messages regarding prescription drugs may impact the willingness of media audiences to take medications that may potentially put their health at risk. For example, a person who believes a certain drug meets his needs may be willing to accept the risks associated with taking the drug. If a patient perceives the side effects of the drug as very serious, however, he may not be willing to engage in the risky behavior of taking the drug. In viewing framing from the perspective of the prospect theory, framing refers to the decision-maker’s individual perceptions (Boettcher, 2004, p. 332).

In their assessment of sensitivity to risks, Kahneman and Tversky (1979) concluded that people undervalue high probabilities of risk and overvalue low probabilities. Prospect theory is not only applied to health risks, but political risks as well (Boettcher, 2004). If framing can impact public opinion, it can certainly impact individual risk assessments. Also, negative messages may be perceived as more salient and convincing than positive messages, particularly

on drug safety. Negative messaging may “exert greater judgmental impact,” therefore inducing risk assessment (Davis, 1995, p. 286).

Prospect theory is related to this study in the first research question investigated. All questions investigated hinge on the recall of cox-2 inhibitors, particularly the recall that began the process, that of Vioxx:

RQ 1: How was prescription drug coverage framed and was it framed differently before and after the recall?

It may be that because of the far-reaching effects of such a high profile recall, prescription drug coverage was framed according to safety and drug risks. There may have been a higher incidence of drug safety frames after the recall as opposed to before. There may have been other changes as well.

RQ 2: Was there a significant change in the drugs receiving coverage after the recall?

Presumably, cox-2 inhibitors received more coverage after the recall. Any rises or drops in coverage of other drugs were documented.

RQ 3: How prominent was the placement of prescription drug coverage?

Stories covering the events surrounding the Vioxx recall may have received prominent placement, giving them a greater chance of recognition by audiences.

Framing can impact the level of risk perceived associated with taking prescription drugs and may therefore impact the numbers of people taking drugs. This is a matter of interest to pharmaceutical companies involved in producing, marketing and profiting from prescription drugs; insurance companies paying the bulk of prescription drug costs; lawyers involved in class-action lawsuits against pharmaceutical companies over distorting and hiding negative drug effects; and the medical community, which may benefit from writing and filling prescriptions.

All of these experts have an interest in getting their frames in the news. This relates to the next question under study:

RQ 4: Did the sources used in prescription drug coverage change significantly after the recall?

Framing of news stories is determined, in part, by the sources quoted by journalists. According to Andsager and Smiley, scientists included in health and technology stories are often authoritative sources of “evidence and solutions” (1998, p. 187). This study investigated the sources identified in prescription drug news coverage.

RQ 5: What relationship exists between the scope of an article and the drugs mentioned within it?

This research question enhanced knowledge of the framing of prescription drug coverage by revealing correlations between framing and subjects, news sources and time frames before and after the recall.

Frames investigated in this study include drug safety/regulation, economics, personal health and politics. Drug safety/regulation frames involve drug effects on patients, actions of regulatory bodies such as the FDA, and the risks or benefits of taking the drugs under question. The economics frame includes personal, government, and insurance providers’ spending on drugs. The personal health frame includes personal stories of average consumers about the drugs’ effects on their personal health. Debates over drug laws, costs and other issues between political actors are categorized as politically framed news stories.

2.6 Summary

Pharmaceutical companies have an unfair advantage over other manufacturers in their quest for sales (Hollon, 2004). Health is a necessity, not a commodity. The word “consumer” is being used in reference to people who are patients concerned for their health. Most people are

not qualified to diagnose themselves and may be misled by an ad. Diagnosis requires medical expertise, and improper treatments can have devastating consequences. Patients may be more vulnerable than consumers of non-medical products because of their illnesses. Fear for their health or the symptoms of an illness may impair a patient's decision-making ability (Hollon, 2004). Some ads, specifically those for Viagra, are attributed credit for causing people to begin a dialogue with their doctors that lead to the diagnosis of an illness of which the patient was unaware (Young, 2002). However, DTC ads are not public service announcements; they exist because drug companies realize that patients influence prescribing decisions. Studies show that "consumers do not seem to understand the nature of DTC advertising," making them more susceptible to emotional appeals within ads (Main, Argo, & Huhmann, 2004, p. 123). Ads, by nature, are promotional, manipulating people by their emotions instead of intellect. Faith in the safety and effectiveness of drugs featured in DTC ads imply that viewers perceive them as more trustworthy than ads for other products (p.123). Main, Argo and Huhmann write that the lack of consistency between warning information and visual appeals, particularly fantasy and sex appeals should be a concern because "it is not clear which message consumers are 'taking home'" (p. 138).

Advertising is not the only, or the most important way prescription drugs are discussed in the public sphere, however. The average American relies on news coverage for furthering his or her science education (Andsager & Smiley, 1998). Academics, advertisers and journalists assume that readers place more trust in the editorial content of a medium than the ads contained within it (Baerns, 2003, p. 101). The recall of Vioxx and other cox-2 inhibitors stunned the millions of Americans taking those drugs, and led many others to question the safety of the drugs they were taking. This study investigated through content analysis of prescription drug coverage

the effects of this highly publicized and controversial drug recall. Framing analysis from the perspective of prospect theory, which takes into consideration health risks and benefits, may reveal lasting consequences of the Vioxx ordeal on public opinion in the United States.

2.7 Research Questions

RQ 1: How was prescription drug coverage framed and was it framed differently before and after the recall?

RQ 2: Was there a significant change in the drugs receiving coverage after the Vioxx recall?

RQ 3: How prominent was the placement of prescription drug coverage?

RQ 4: Did the sources used in prescription drug coverage change significantly after the recall?

RQ 5: What relationship exists between the scope of an article and the drugs mentioned within it?

CHAPTER 3

METHOD

A content analysis of prescription drug coverage one year before and one year after the Vioxx recall was completed to answer the questions raised in this research. National print media coverage was analyzed. *The New York Times* and *Washington Post* were analyzed because of the prominence, authority and popularity of these newspapers in US news coverage, and their availability on the database LexisNexis. The news magazines *US News and World Report* and *Newsweek* were analyzed for their national prominence and availability on LexisNexis, and to gain a more comprehensive assessment of print media coverage of prescription drugs. All of these media are nationally elite media, meaning they play a significant role in framing and agenda-setting among other US media, and they reach an elite, opinion-leading audience (Cook, 1989). *The New York Times* was particularly important because of its prestige and wide distribution. *The Washington Post* was important because of its proximity to Capitol Hill lawmakers, who help to frame and work from the agendas set forth in the media. Two independent coders coded all of the articles selected within this two-year timeframe.

According to Wimmer and Dominick (2003), a content analysis allows a researcher to systematically, objectively and quantitatively study recorded communication in order to measure variables. When the content is said to be chosen systematically, it is chosen by “explicit and consistently applied rules” (Wimmer & Dominick, 2003, p. 141). A content analysis is objective, which means that personal opinion and bias on the part of the researcher should not factor into the study; the study should yield the same results if conducted by other researchers. Also, content analyses are quantitative, using standardized questions to accurately represent the content analyzed, accurately report results and allow for statistical interpretation.

This study took both a quantitative and a qualitative approach in analyzing the content of prescription drug stories. Quotations that exemplified a certain frame and those that could be used to analyze shifts in drug coverage were included in the research. A quantitative and qualitative approach to content analysis was the best method to use in order to systematically and objectively compare the content of prescription drug coverage in national elite print media.

A LexisNexis key word search of “prescription drug” and “FDA” yielded 452 articles from the two newspapers. A systematic random sampling technique was performed to obtain fifty articles from each newspaper. Every fourth article was analyzed to ensure that an equal number, 25 articles, was sampled from before and after the Vioxx recall in each newspaper.

A LexisNexis key word search of “prescription drug” resulted in 161 articles from the two news magazines. Through systematic random sampling, every fourth article was coded until twenty articles were chosen from each magazine, ten from before and ten after the Vioxx recall. A total of 140 articles will be analyzed in this study. The frames, drugs discussed, sources quoted and overall scope of the articles were coded.

CHAPTER 4

RESULTS

Merck recalled its blockbuster arthritis and pain drug Vioxx on September 30, 2004 (Merck, 2004). A total of 140 newspaper and news magazine articles were analyzed by two coders in this study, which covered the time period from one year before the Vioxx recall to one year after. A total of 50 articles were coded from each of the newspapers under study, the *New York Times* and *Washington Post*. Twenty articles were coded from each of the news magazines *Newsweek* and *US News & World Report*. Each paragraph of an article constituted an individual coding unit.

After training together, the two coders communicated frequently during and after the coding process. The intercoder reliability coefficient measured the level of agreement between the coders for 26 categories. The intercoder agreement using Cohen's Kappa was 0.99, accounting for the number of chance agreements, the number of ratings given, the number of items rated and the number of times a specific category was used (Emmert & Barker, 1989). This high coefficient may be due to clarity of coding definitions, thorough training, frequent communication between coders, or a combination of these factors.

RQ 1: How was prescription drug coverage framed and was it framed differently before and after the recall?

The dominant frame for each paragraph was coded as drug safety and regulation, economics, personal health, politics or other. A paragraph was occasionally coded as having more than one frame. Some paragraphs were not coded at all. The "other" category applied only if the theme of the article was not listed as a possible frame *and* the theme was perceived to be important or recurring. Paragraphs devoted to dry numbers or ingredient information were often

not coded because of a lack of frame, or having an objective information frame not pertinent to this study.

A drug safety/regulation frame may contain information on side effects, drug risks and benefits, or opinions from professionals:

In another troubling episode, Canadian regulators suspended sales of Adderall XR this winter, citing reports of sudden death. But US officials concluded that the death rate was no greater than expected in light of the kids' underlying medical problems. The FDA suggests only that children with heart defects avoid Adderall XR. (Scholzman, 2005, p. 56)

Also, drug safety/regulation frames may not be about one drug in particular. Sometimes, drug safety/regulation frames focus more on official regulation of drugs:

. . . [N]o drug is completely safe, and there is no foolproof pre-marketing testing. Trials, for sound scientific reasons, are done on people who don't have other diseases or take other medications. But in the real world, that drug will more likely be taken by people who have several health problems, take several medications, or are older or younger than the trial groups. (Fischman & Spake, 2004, p. 36)

Drug safety/regulation frames sometimes appear to utilize fear appeals, which are perceived as more salient than other appeals and may induce risk assessment by audiences (Umphrey, 2003):

"How many babies have to be born with serious defects, how many more women need to have miscarriages, and how many more children have to die before the FDA implements meaningful protections and restriction on the use of Accutane?" he [Representative Bart Stupak, D-Michigan] asked. (Ault, 2004, p.16A)

A paragraph coded as having an economics frame discusses government or personal spending on drugs or insurance policies:

Americans spent more than \$235 billion on prescription drugs in 2004, billions more than they had to, by buying brand-name drugs instead of the generic equivalents, according to a study out last week in the *Annals of Internal Medicine*. . . "You're buying the advertising," says lead author Jennifer Haas, a physician at Brigham and Women's Hospital in Boston. Not all drugs have a generic equivalent. People on prescription drugs should talk to their doctor or pharmacist to see if there is a lower-cost option for them. (Querna, 2005, p. 56)

Another strong example of economics framing appeared in *Newsweek*:

All health systems have pluses and minuses; all ration health care in some way. We ration it, harshly, by income and price. People with money and access command topnotch care. Those without scramble for what they can get. Big businesses negotiate good group-health insurance. Small businesses are pushed against the wall. The healthy find private policies, the sick get kicked out. That's the American Way. (Quinn & Ehrenfeld, 2004, p. 39)

Also, an economically framed paragraph may simply describe the profits to drug companies from drug sales:

The most often cited example for savings is Lipitor, the cholesterol-lowering drug by Pfizer, which last year was the leading American prescription drug for the third consecutive year, with \$6.8 billion in sales. (Tedeschi, 2004, 4C)

Personal health frames, which were less common than expected, contain personal experiences from consumers. Personal health frames can be used to vividly describe personal experiences and to give a human interest color to an article:

When Brandi Jones first started breaking out at 16, the cysts on her chin hurt more than just her vanity. "It was so painful," she says. "My face throbbed like someone had punched me." A dermatologist prescribed antibiotics and topical creams. Neither worked. A few years later she decided to try Accutane, a controversial prescription drug that destroys oil glands. . . Ultimately the drug worked—and now her skin is mostly pimple-free. But Jones isn't sure she'd choose the treatment again. (Setoodeh, Whelan & Williams, 2005, p. 50)

Politics frames involve political actors and debates over drug laws, such as this excerpt from a debate over RU-486, the morning-after pill:

Joseph L. Bruno, the Senate majority leader, broke ranks with his party to support the measure. On the Senate floor, where most bills pass with little debate, Senator Bruno said that he was proud to support the bill, and that others might disagree but they should not cast moral judgment.

Advocates and opponents said they believed the bill had been allowed to come to a vote to help Senator Spano hold onto his seat in Westchester, and, by extension, help the

Republicans retain to their dwindling control of the Senate. They have 35 of the Senate's 62 seats. (Cooper & Santora, 2005, 1B)

There were some significant changes in media framing after the Vioxx recall on September 29, 2004 (Merck, 2004). These results indicate that media framed prescription drug coverage differently before the Vioxx recall than after (see Table 1).

Table 1. Frames in prescription drug coverage before and after the Vioxx recall

Frame	Mean Before Recall	SD	Mean After Recall	SD	F	Sig
Drug Safety	6.76	6.24	6.83	6.37	0.00	0.95
Economics	3.07	3.68	2.17	4.20	1.80	0.18
Personal Health	0.71	2.05	0.08	0.33	5.95	0.02*
Politics	2.51	3.90	1.56	3.16	2.45	0.12
Other	0.12	1.03	0.03	0.25	0.43	0.51

Note: The mean values represent the average number of times a frame occurs per article. Values with * significant when $p < 0.05$

Articles with drug safety/regulation, economics and politics frames occur in relatively equal proportions during the years surrounding the recall. There is, however, a significant decrease in personal health frames in prescription drug coverage after the recall when the data is statistically analyzed using ANOVA.

RQ 2: Was there a significant change in the drugs receiving coverage after the recall?

The articles coded mentioned a wide variety of prescription drugs. Because so many were mentioned, they were placed into the drug classes that were encountered most often during the coding period. These classes are listed below (see Table 2).

Table 2. Drugs covered in national print media before and after the Vioxx recall

Drug	Mean Before Recall	SD	Mean After Recall	SD	F	Sig
Cox-2/ NSAIDs	0.01	0.12	0.25	0.44	20.7	0.00*
Antidepressants	0.14	0.35	0.03	0.18	5.44	0.02*
Stimulants/Amphetamines	0.01	0.12	0.02	0.13	0.02	0.90
Statins	0.13	0.34	0.17	0.38	0.44	0.51
Allergy Medications	0.03	0.16	0.00	0.00	1.71	0.19
Morning After Pill	0.05	0.23	0.09	0.29	0.88	0.35
Antacids	0.03	0.16	0.03	0.18	0.30	0.86
Other Drugs	0.29	0.46	0.33	0.47	0.24	0.62
No Drugs	0.42	0.50	0.22	0.42	6.66	0.01*
Drug Reimportation	0.38	0.49	0.11	0.31	14.7	0.00*

Note: The mean values represent the average number of times each drug class occurs per article. Values with * significant when $p < 0.05$

No significant change is shown in the coverage of stimulants and amphetamines, such as Adderall and Ritalin; statins, or cholesterol-lowering drugs such as Lipitor; allergy medications such as Allegra or Flonase; RU-486, the morning-after pill; antacids such as Prilosec; and drugs in the ‘other’ category, which did not fit into any of the categories that were coded. This is not surprising considering that the most heavily advertised and prescribed drugs are those that treat the most common conditions: antidepressants, cholesterol-lowering drugs, gastric acid reducers, antihistamines and blood pressure drugs (Bell et al., 2000).

There was, however, a significant increase in the coverage of cox-2 inhibitors such as Celebrex, Bextra and Vioxx, and non-steroidal anti-inflammatory drugs, including aspirin and ibuprofen. Such an increase is expected after a recall involving two of the three heavily-

prescribed coxibs on the US market. A significant decrease in the coverage of antidepressants and drug reimportation after the recall is indicated, as is a decrease in the number of articles mentioning no drugs by a specific name or class.

Drug reimportation was a major talking point in politics and elections in 2004. The drug reimportation debate often involved drug safety/regulation, economics and politics frames. Reimporting drugs means shipping drugs produced in the US to other countries, such as Canada and Mexico, then bringing the drugs back into the US. This is done by traveling personally across borders to purchase drugs in those countries, which have government-regulated price controls, or by using Internet pharmacies to order prescriptions that are shipped to American residences from other countries. The US government currently does not enforce price caps on pharmaceutical products (Viale, 2003):

“The question you always ask in politics is ‘Who do you stand with?’” says Senator Dorgan of North Dakota. “The White House and the Senate leadership answer it this way: We are on the pharmaceutical industry’s side. We are not on the side of the American consumer.” (Samuel, 2004, p. 30)

The reimportation debate was framed in many different ways besides politics, including drug safety/regulation and economics themes:

Encouraging patients to bypass local pharmacists and the established safety protocols developed by state pharmacy boards and the FDA threatens patients and the safety of our national drug supply with mislabeled, mishandled, sub-potent or counterfeit drugs. (Boyle, 2004, August 26, p. 22A)

Another example of an economics frame regarding drug reimportation exposes a possible political agenda of drug companies:

A congressional study of price differences recently concluded that a drug in the United States costs 70 percent more on average than the same drug in Canada. Drugmakers argue that they need the higher prices to pay for the research and development that has

made this country the global engine for pharmaceutical innovation, but critics counter that the companies are driven by profits and greed.

According to former FDA commissioner Donald Kennedy, “importing drugs. . . ‘just may be a bad idea whose time has come.’” (Kaufman, 2003, 11A)

An editorial published in *The Washington Post* said that higher prescription drug prices in the US are “politically untenable” and the higher cost “unfairly forces Americans to subsidize the drug consumption of the entire planet” (Editorial, 2004, Aug. 1, 6B). The pharmaceutical industry does have its spokesmen, however, as demonstrated by Pfizer:

From Pfizer’s perspective, the real problem is inappropriately low prices in foreign countries. “The French and Germans and Canadians are not paying their fair share for development of new drugs,” Senior Vice President Charles L. “Chuck” Hardwick said (Connolly, 2004, 1E).

The FDA has representation in media, as well:

The customs lab analysis showed that of 180 drug samples, the majority, 67 percent, either were never approved by the FDA or had been withdrawn from the US market for safety reasons. Five percent contained no active ingredients at all. And 28 percent contained controlled substances prohibited from importation. ...

In exchange for the safety of drugs most Americans take for granted, some may be able to buy more of the medications they need at prices they can afford. It’s too soon to tell if the trade-off will be worth it (Spake, 2004, p. 46).

The reimportation issue is mired in political debate, as shown in editorial writing:

The real issue appears to be to avoid forcing Mr. Bush to choose between signing the bill and angering the drug industry, which donates mightily to G.O.P. campaigns, or vetoing it and infuriating older voters (Editorial, 2004, Sept. 29, 24A).

The results indicate a rise in the amount of coverage of coxibs and NSAIDs, which corresponds with the announcement and fallout of the Vioxx recall. As demonstrated in the introduction of this study, the mounting evidence of a belated recall and prior knowledge of the dangers of Vioxx caused the focus to shift from Merck, the manufacturer of Vioxx, to the FDA and its safety policies (Beardsley, 2005):

[Dr. Bruce Psaty, a professor of medicine and epidemiology at the University of Washington] described the agency's structure as "just what the drug industry desires: a powerful engine to approve new drugs and a weak effort to investigate safety in a postmarketing center" (Harris, 2005, March 4, 15A).

The FDA and US government have been publicly blasted for years about lying in bed with the pharmaceutical industry, so to speak, as exemplified in an excerpt from a *New York Times* article about a medical device manufacturer:

Allowing consumers to sue [drug and medical device] manufacturers would "undermine public health" and interfere with federal regulation of drugs and devices, by encouraging "lay judges and juries to second-guess" experts at the FDA, the government said in siding with the maker of a heart pump sued by the widow of a Pennsylvania man. Moreover, it said, if such lawsuits succeed, some good products may be removed from the market, depriving patients of beneficial treatments.

The threat of lawsuits, it said, "can harm the public health" by encouraging manufacturers to withdraw products from the market or to issue new warnings that overemphasize the risks and lead to "underutilization of beneficial treatments." (Pear, 2004, 1A)

In this example, the government and regulatory agencies seem prepared to curtail the civil rights of American citizens to appease the drug industry's fear of the *threat* of consumer lawsuits, even before they have proven the likelihood of losses by the pharmaceutical industry. The article continues:

Bush administration officials said their goal was not to shield drug companies but to vindicate the federal government's authority to regulate drug products.

Patients and their families said they felt betrayed. (Pear, 2004, 1A)

Public outrage at such an announcement is not surprising. Politicians are not medical experts and the experts at the FDA have lost some consumer faith (Gorman et al., 2005). Furthermore, evidence of faulty clinical trials puts the average consumer at risk. Drug companies tend to use young, healthy people in trials (Gorman et al, 2005). Therefore, drug interactions and negative health effects are not documented until the drug goes to market, when average consumers who

are taking multiple prescriptions for other health problems use new, under-studied drugs or medical devices.

Another instance of lambasting the FDA for protecting the interests of drug companies over the safety of American consumers was found in an article from the *Washington Post*. Senator Charles E. Grassley (R-Iowa) referred to whistleblowers within the administration, saying, “[T]he FDA should value the science of its own employees at least as much as the science presented by drug companies” (Kaufman, 2005, February 20, p. 20A).

On the other hand, concerns were voiced in a *US News and World Report* article that imposing new, more stringent safety precautions could cause more harm than good. Bernadine Healy, M.D., wrote, “As we watch the Vioxx fallout, we should be wary of a scalping party that could leave us so safe we are not safe at all” (2004, p. 37).

The Vioxx recall also renewed concerns of America’s “pill-popping culture” (Rosenwald, 2004, p. 1E). *New York Times* reporter Nicholas Bakalar describes Valium as “an American cultural icon” (2005, 6F). A *Washington Post* writer also addresses Americans’ addiction to pills:

Safety questions about popular pain-killing medications may give people pause over the nation’s pill-popping culture, analysts say, and that would give the beleaguered drug industry something else to worry about.

The tendency to take prescription pills for everyday aches and pains, shyness, allergies, impotence, and other “lifestyle” concerns have helped prop up pharmaceutical revenue. Now analysts say safety concerns may prompt a consumer backlash. ...

“When the average consumer sees the headlines and the news blitz on one drug after another, you would think that the average person is going to become more and more concerned,” said Herman Saftlas, a pharmaceutical analyst for Standard & Poor’s. (Rosenwald, 2004, p. 1E)

Such headlines and news blitz inspired this research. Presumably, people are confused by conflicting medical news, and negative reports may cause people to rethink risks associated with

taking a number of drugs (Umphrey, 2003). Another article attempts to explain the cause of Americans' dependence on drugs:

Steven Findlay, a health care analyst at Consumers Union "thinks consumer caution over lifestyle drugs will subside after a time. 'Americans understand taking pills,' he said. 'It's simple. It's an easy thing to do. And many pills over the years have been very effective. We've come to rely on many of our medicines because we are less willing to change our lifestyles in ways that would lower our risks to some diseases.'" (Rosenwald, 2004, p. 1E)

Therefore, if pills were not as effective in at least providing a placebo effect, making people believe they feel better because they are being medicated, Americans would not take pills so readily (Angell, 2004). Some may argue, however, that direct-to-consumer advertising, legal only in the US and New Zealand, may help to induce some of this behavior (Viale, 2003).

A major point of debate right before the Vioxx recall was the safety of antidepressants, particularly in children. The news coverage established a link between potentially dangerous drugs and direct to consumer advertising:

After the FDA mandated in March that manufacturers state on drug prescription sheets that they may be linked to suicide, prescriptions for the drugs for youngsters continued to climb by nearly 8 percent, the [federal advisory] committee was told.

Some committee members said that such prescribing habits have been driven by advertising. Pfizer, for instance, spends millions of dollars advertising Zoloft, its huge-selling antidepressant. (Harris, 2004, September 15, p. 1A)

After the Vioxx recall, industry analysts said that the pursuit of a blockbuster strategy, or drug companies pinning all hopes for profits on marketing one or two huge-selling, commonly prescribed copycat drugs, would phase out in favor of personalized medicine. This change of direction was actually voiced long before the Vioxx recall:

"You have a real revival in drug development at many companies," said Robert Murphy, a physician at Northwestern University who is helping to test one of the more promising [AIDs] drugs for the Atlanta biotechnology company Pharmasset. "Something's got to happen." (Brown, 2004, February 15, p. 14A)

The quality of drugs and the FDA's processes were called into question at the same time, concerns that were exacerbated after the recall:

The Food and Drug Administration has repeatedly urged antidepressant manufacturers not to disclose to physicians and the public that some clinical trials of the medications in children found the drugs were no better than sugar pills, according to documents and testimony released at a congressional hearing yesterday. (Vedantam, 2004, September 10, p. 2A)

The FDA promised to make reforms in its review policies, including releasing preliminary results:

"The public wants more information about our products and processes," [Stephen Galson, acting director of the FDA Center for Drug Evaluation and Research] said. "They want to know incrementally what's going on, and I think we've been too stingy in the past about putting the information out there." (Kaufman, 2004, November 18, p. 17A)

The FDA appeared to follow through on its promises. This journalist writes that the FDA's policy shift is a direct result of the Vioxx backlash:

A new advisory on Crestor, a cholesterol-lowering drug from AstraZeneca, "reflects a recent policy shift in how and when the FDA releases potentially troublesome information about a product. In the wake of criticism that the agency did not move fast enough in communicating the potential problems with COX-2 painkillers, including Merck's Vioxx, FDA officials said they plan to give out more preliminary information than in the past." (Kaufman, 2005, March 3, 14A)

Not everyone trusts the FDA to keep its word, however, as demonstrated in an editorial appearing in the Washington Post:

For a short time, harmony reigned. But then the pendulum began to swing, the winds of fashion began to blow in a different direction, and the FDA, once a bureaucratic monolith bearing down on the brave new world of pharmaceutical research, somehow managed to become the FDA, a bureaucratic castrato cozying up to the greedy pharmaceutical companies.

Clearly, caution is "in." Patients' rights are "out." Risk-averseness is "in." Hot new research is "out." "There is no doubt that there has been a cultural change," the director of the FDA's Office of New Drugs told a reporter last week. And there is no doubt that Congress, along with everybody else, sincerely believes that the change is, will be, and should be permanent. How little we know of fashion! (Applebaum, 2005, p. 17A)

RQ 3: How prominent was the placement of prescription drug coverage?

There was very little difference in the placement of prescription drug coverage in the newspapers from before and after the Vioxx recall (see Table 3). The majority of the coverage (39.2 percent before and 37.7 percent afterward) was found in the first section of the newspapers. Section A includes national news stories and editorials. More prescription drug coverage was located in the Health and Fitness section after the recall than before. Otherwise, dispersal and amount of coverage remained relatively constant from year to year. There was a considerable difference, however, when comparing coverage located in the first ten pages of the newspapers. Before the recall, 21 percent of prescription drug coverage was found between the first page and 10A. After the recall, that percentage dropped by nearly half to 12.6 percent. This was surprising, given the scope of the recall and the impact additional news about coxibs could have on large audiences.

Generally, section A includes national stories and editorials, section B is the local or metropolitan news section, section C includes business and financial articles as well as some metro stories, section D articles are coded as editorials in this research, section E contains financial news, and section F includes health and fitness stories.

Table 3. Prominence of placement of prescription drug coverage in newspapers by section

Section	Frequency Before (n=76)	% Before	Frequency After (n=64)	% After	Difference (in %)
A	29	39.2	24	37.7	-1.5
B	3	3.90	1	1.60	-2.3
C	12	15.7	11	17.2	+1.5
D	1	1.30	0	0.00	-1.3
E	2	2.60	1	1.60	-1.0
F	5	6.50	7	11.0	+4.5
Total	52	69.2	44	69.1	-0.1

Note: The percentages before and after do not amount to 100%. This table only accounts for stories found in the first six sections of the newspapers. The stories found in the newsmagazines are not included in the data for prominence.

RQ 4: Did the sources used in prescription drug coverage change significantly after the recall?

There was no significant difference in the sources quoted directly and indirectly in prescription drug coverage after the Vioxx recall (see Table 4).

There was a marked decrease in the use of consumers as sources after the recall, which bordered on significance with a p value of 0.07. This was surprising because so many people used Vioxx and other coxibs. A wealth of first-hand accounts to personalize and increase the human interest value of newspaper articles appears not to have been utilized in newspaper writing. Also, the numbers of government and industry officials quoted in prescription drug coverage appears to have remained constant. This may be a reflection on common journalistic practices (Cook, 1989). Journalists prefer expert sources who provide authoritativeness and reliability in their statements.

Table 4. Sources used in prescription drug coverage before and after the Vioxx recall

Source	Mean Before Recall	SD	Mean After Recall	SD	F	Sig
Doctors	0.80	2.03	0.80	1.92	0.00	0.99
Lawyers	0.09	0.33	0.13	0.79	0.11	0.74
Researchers	0.20	0.98	0.34	0.78	0.93	0.34
Pharmaceutical Rep.	0.59	1.09	0.52	1.10	0.17	0.68
Consumers	0.46	1.24	0.16	0.60	3.23	0.07
Academics	0.24	0.54	0.36	0.92	0.98	0.33
Politicians	1.03	1.77	0.77	1.87	0.72	0.40
FDA Representatives	0.80	1.42	0.52	1.20	1.63	0.20
Other	0.20	0.75	0.08	0.32	1.40	0.24

Note: All sources quoted directly and indirectly were coded.

When arranged in a ranked order, the results indicated very little change. Politicians, doctors, FDA spokesmen and pharmaceutical representatives were quoted more often than other sources both before and after the recall. Academics, or industry analysts and consultants, were used as sources by journalists more often than scientific researchers. The use of consumer sources fell after the recall, but consumers were quoted more often than lawyers. A possible explanation for the lack of consumer and lawyer voices in prescription drug news coverage after the Vioxx recall may be traced to the research design of this study. The LexisNexis search criteria did not specify Vioxx as a key word. If the search terms had been made to include Vioxx stories, perhaps more lawyers and human interest stories from consumer sources would have been coded.

RQ 5: What relationship exists between the scope of an article and the drugs mentioned within it?

Crosstabulations were performed to establish correlations between the overall scope, or theme, of the article and the drugs mentioned in the articles (see Table 5). The perceived scope of the article was slightly more subjective than other coding categories. Framing and sources, for instance, were strictly defined and simply required counting. Although the scope was more subjective, the coder's perception of an overall theme was usually determined by the number of frames coded in the article.

Table 5. Crosstabulation between an article's scope and drug class

Scope	Cox-2/ Nsaids	Anti-depress- ants	Stim- ulants/ Amphet- amines	Statins	Allergy Meds	Morning After Pill	Ant- acids	Other	None	Re- imports
Drug Safety/ Regulation	16	10	1	14	2	7	4	35	11	12
Economics	1	2	0	4	0	0	0	5	16	13
Personal Health	0	1	1	0	0	0	0	0	1	0
Politics	0	0	0	3	0	3	0	3	16	11
Other	0	0	0	0	0	0	0	0	2	0
Total	17	13	2	21	2	10	4	43	46	36

Note: Some articles featured drugs from more than one class. The articles that did not mention a drug by name were coded in the "None" category.

The majority of articles featuring coxibs, antidepressants, stimulants, statins, allergy medications, the morning after pill, antacids and drugs that fit into the "other" category were classified as having an overall drug safety/regulation theme. This was the dominant theme throughout this research (see Table 1). Articles that named no drugs tended to have politics and economics themes. This may be a result of articles featuring a politician's career that involved

drug regulation, or it may result from editorial writers who did not reference drugs by name. Another explanation may be that these articles featured drug costs or legislation. Articles that mentioned the reimportation of drugs also ranked high in economics frames. Interestingly, politics, economics and drug safety/regulation frames occurred at similar frequencies in this category. The split in framing this issue further reinforces results presented in answering the second research question: Was there a significant change in the drugs receiving coverage after the Vioxx recall?

The relationship between an article's scope and the medium in which the article was published was also of interest, given each medium's unique background. For example, the *Washington Post*, because of its proximity to national lawmakers and politicians, may have featured more politicized coverage than the *New York Times*. The results indicated this was true (see Table 6).

Table 6. Percentages of article scope distributed in each medium

Source	Drug Safety/Regulation (%)	Economics (%)	Personal Health (%)	Politics (%)	Other (%)	Total (%)
<i>New York Times</i>	68	16	0	12	4	100
<i>Washington Post</i>	74	6	2	18	0	100
<i>Newsweek</i>	40	40	0	20	0	100
<i>US News and World Report</i>	55	10	5	30	0	100
Total	64	15	1.4	18	1.4	99.8

Note: The figures in this table are percentages. A total of 50 articles were coded from each newspaper and 20 were coded from each magazine for a total population of 140 articles.

Prescription drug coverage focused more on politics in the *Washington Post* (18 percent) than the *New York Times* (12 percent), although *US News and World Report* (30 percent) contained most of the articles coded as having a politics scope. *Newsweek* (40 percent) published more articles with economics scopes than any of the other publications. *US News and World Report* utilized personal health scopes more frequently (5 percent) than the other media. Notably, no articles were published in the *New York Times* that were coded as having a personal health scope. Most of the articles that had a drug safety/regulation scope were published in the *Washington Post* (74 percent), while *Newsweek* contained the least (40 percent).

CHAPTER 5

DISCUSSION AND CONCLUSIONS

5.1 Findings

A significant change was found in media framing after the recall of Vioxx on September 30, 2004. Articles with drug safety, economics and politics frames occurred in relatively constant proportions during the years surrounding the Vioxx recall. This was a surprise given the far-reaching effects and fire-storm of attention following the recall. There was, however, a significant decrease in economics frames in prescription drug coverage after the recall. Because the amount of prescription drug coverage was approximately the same before and after the recall, and the proportion of drug safety frames stayed the same, perhaps articles became shorter, with fewer paragraphs to code.

No significant change was found in the coverage of stimulants and amphetamines, such as Adderall and Ritalin; statins, or cholesterol-lowering drugs such as Lipitor; allergy medications such as Allegra or Flonase; RU-486, the morning-after pill; antacids such as Prilosec; and drugs in the ‘other’ category, which did not fit into any of the categories that were coded. This was not surprising considering that the most heavily advertised and prescribed drugs are those that treat the most common conditions: antidepressants, cholesterol-lowering agents, antacids, antihistamines and blood pressure drugs (Bell et al., 2000).

There was, however, a significant increase in the coverage of cox-2 inhibitors and non-steroidal anti-inflammatory drugs. Drugs in this class include the coxibs Vioxx, Celebrex, Bextra, and the NSAIDs aspirin and ibuprofen. This type of increase was expected after a recall involving two of the three heavily-prescribed coxibs on the US market: Vioxx and Bextra. A significant decrease in the coverage of antidepressants and drug reimportation after the recall was indicated, as was a decrease in the number of articles that did not mention drugs by a

specific name or class. Presumably, articles that featured no specific drugs discussed a politician's career or an FDA or Congressional ruling that referenced prescription drugs or legislation.

The results showed a significant drop in drug reimportation frames after the Vioxx recall. Drug reimportation was a major talking point in politics and elections in 2004. The drug reimportation debate often involved drug safety/regulation, economic and political frames. This was further demonstrated in the relationship between the scope of the articles and the drug categories mentioned in the articles. The pharmaceutical industry adopted an economics frame when discussing the issue, explaining high prices in the US by laying blame on other countries for failure to pay prices that cover research and development costs. Incidentally, economics frames were often used by consumers and politicians who supported price regulations on expensive drugs. The FDA preferred a drug safety/regulation frame to inform Americans that cheaper drugs were not always what they appeared to be.

Following prospect theory, this type of framing could induce fear and risk assessment by audiences and may have been intended to deter Americans from buying their prescriptions from outside the country by frightening them. The Bush Administration appeared to prefer telling the public that personally reimporting drugs back into the US was breaking the law. The reimportation issue was often mired in political debate, as shown in editorial writing.

The results of this study indicated little change in the prominence of the newspaper placement of prescription drug coverage by section. When prominence was analyzed by placement in the first ten pages of the first section, however, a distinct difference was noted. Placement in the first ten pages of the newspapers dropped by nearly half after the Vioxx recall. This was surprising considering the impact of such an immense recall and the negative tones that

colored subsequent news coverage of the pharmaceutical industry, prescription drugs and the FDA.

Consumer groups and politicians have publicly criticized the FDA and US government for years for protecting the interests of the pharmaceutical industry over American citizens. The experts at the FDA lost some consumer faith over the Vioxx recall (Gorman et al., 2005). Evidence of faulty clinical trials that put the average consumer at risk recently became public. Drug companies tend to use young, healthy people in drug trials (Gorman et al, 2005). Therefore, drug interactions and negative health effects may not be properly documented until the drug goes to market and is taken by average consumers who are on multiple prescriptions for other health problems. Faulty experimental design or the deliberate manipulation of clinical data can result in “experimericals” intended for use as marketing tools when published in medical journals and publicized in mainstream mass media (Brownlee, 2006, p. 157). The end result is bad science incautiously reported as a scientific breakthrough, which serves as free direct-to-consumer advertising for the drug companies involved.

When the sources used in prescription drug coverage were analyzed, a dearth of input from consumers was noted. There were no significant changes in the sources used in prescription drug coverage after the far-reaching Vioxx recall. Given the media’s historic preference for political and expert sources, this may not be surprising (Cook, 1989). The media’s use of physicians as expert sources was high both before and after the recall. Consumers as sources ranked lower after the recall than before, but consumers were quoted more often than lawyers in this research. More patients had been anticipated as story sources because of their personal experiences with prescription drugs. A possible explanation for the lack of consumer and lawyer voices in prescription drug news coverage after the Vioxx recall may be traced to the research

design of this study. The LexisNexis search criteria did not specify Vioxx as a key word. If the search terms had provided for the specific inclusion of Vioxx stories, perhaps more lawyers and human interest stories from consumer sources would have been encountered.

The lack of first-hand accounts in news coverage that could have personalized news of the recall may be linked to the steep decline in the prominence of prescription drug coverage in the *New York Times* and the *Washington Post*. Before the recall, 21 percent of prescription drug coverage was found between the first page and 10A. After the recall, that percentage dropped by nearly half, meaning that 12.6 percent of the newspaper articles coded in this study were located in the beginning of the first section of the newspapers. Personal stories increase the human interest value of news in mass media. A lack of human interest may have decreased the news value of cox-2 inhibitor stories, relegating them to pages farther away from the front of the papers. When the overall scopes of the articles were analyzed, the results indicated that *US News and World Report* utilized personal health scopes more frequently than the other media. The *New York Times* published no articles that were coded as having a personal health scope.

When the scope, or overall theme of the articles was correlated with the drug categories mentioned in the articles, drug safety/regulation themes were shown to occur most often in this study. Articles that did not name drugs tended to have fewer safety/regulation themes and more politics and economics themes. This may result from articles that featured a politician's career that involved drug costs or legislation, or it may result from editorial writers who did not reference drugs. Articles that mentioned drug reimportation also ranked high in economics themes. This study showed that politics, economics and drug safety/regulation themes occurred at very similar frequencies in articles that discussed reimportation. These results further reinforced the framing results.

The relationship between an article's scope and the medium in which the article was published was also of interest to this study. A medium's background may have provided insight into the reasons behind framing issues related to prescription drug coverage. For example, the *Washington Post*, because of its proximity to national lawmakers and politicians, may contain more politicized coverage than the *New York Times*. The results indicated this was correct. Politicized coverage in the *Washington Post* and *US News and World Report* may have resulted from journalists following their usual beats or providing news in a way editors believed was important to audiences (Scheufele, 1999).

5.2 Relevance of Findings

Noticeably negative and grossly oversimplified medical study results reported in the news media prompted this study. The media has, at times, shown negligence and ignorance in science and health reporting by failing to qualify speculative statements and broadcasting tentative results of a single study in a large body of scientific knowledge as newly confirmed fact in the scientific community. News outlets inform audiences of new breakthroughs without addressing study conditions, results from related studies or current consensus of the experts in the particular field spotlighted. News outlets often neglect to advise audiences whether or how to change behaviors. Science, unlike journalism, is a constant work-in-progress and should be reported accordingly.

As media coverage of prescription drugs focuses on drug safety and regulation, public attitudes about prescription drugs and pharmaceutical companies can be affected. Changes may be traced to framing theory's assertion that the media has the power to impact public opinion through message framing. Risk perceptions may affect personal decisions about taking prescription drugs with questionable or short histories. If public opinion changes, changes in

legislation and drug regulation may follow, impacting the drug industry and its publics, including physicians, consumers, lawyers and insurance corporations.

Changing public and political attitudes may benefit insurance companies in negotiating with pharmaceutical representatives for prescription drug coverage and lawyers involved in lawsuits against drug manufacturers. The impact on physicians and patients, however, may not be entirely beneficial. Pharmaceutical companies frequently sponsor continuing education classes for physicians, which are necessary for doctors to keep their licenses to practice (Angell, 2004). Pharmaceutical companies also finance scientific research conducted in university laboratories, and buy the rights to some patents when results appear promising (Angell, 2004). While the “pill for everything” mentality of Americans may be diminished by negative perceptions of drug companies and their products, based on prospect theory, the impact on the medical field can be enormous (Hollon, 2004, p.71).

5.3 Limitations and Future Research

This study examined a limited number of articles. The investigation could have been more thorough. *Newsweek* and *US News and World Report* offered less relevant information than the two newspapers, *The New York Times* and *The Washington Post*. The news magazines reach an elite audience, as do the newspapers, only without the agenda-setting effects *The New York Times* and *The Washington Post* exert on both print and broadcast media. The prestigious national newspapers may be more likely than the magazines to set agendas of other media because the events reported in daily newspapers, though perhaps not as in-depth as the stories in the magazines, occurred much more recently than those published in magazines.

Future studies should address a longer timeframe to examine changes in media framing over a period of years. This type of study may expose cycles or other triggering factors besides

the Vioxx recall and political campaign platforms. Examining a larger number of newspapers or incorporating different media such as television, radio and/or Internet sources into a study would also help create a more comprehensive analysis and build on this research. Television may be especially important because of its huge, varied audiences. Understanding the resources to which physicians and pharmacists refer their customers may also prove instructive on how and where consumers get information to learn about prescription drugs.

Risk messages contained in direct-to-consumer advertising should be studied in the future. The health belief model may provide an excellent theoretical framework for analysis of the step-by-step process through which audiences are guided to perceive a problem, the risks associated with it, and arrive at the solution of taking the advertised medication (Chew, Palmer, & Kim, 1998).

5.4 Conclusions

This study demonstrated changes in coverage of prescription drugs in national print media after the Vioxx recall. Merck's voluntary recall of its blockbuster cox-2 inhibitor was a momentous event in the drug industry, with varied effects on the industry itself, the FDA and drug consumers and their physicians. The effects of direct-to-consumer advertising on patients and their prescription drug use have been studied extensively. Advertising, however, is not the only way prescription drugs are discussed in the public sphere. The average American relies on news media for furthering his or her science education (Andsager & Smiley, 1998). Furthermore, researchers believe readers place more trust in the editorial content of a medium than the ads contained within it (Baerns, 2003, p. 101). This study took a quantitative and qualitative approach to content analysis of prescription drug coverage to examine the effects of this highly publicized and controversial drug recall on the news.

Framing analysis from the perspective of prospect theory, which takes into consideration health risks and benefits, showed significant changes in framing, drugs and issues discussed, and the prominence of story placement in newspapers. Significant findings of this study include the small number of personal health frames in news coverage, which may be linked to a drop in prominence. The absence of personal stories may have impacted the news value of cox-2 inhibitor coverage, resulting in the plunge in numbers of stories located in the first ten pages of the newspapers. Also, the relationship between the scope of the articles and the drugs mentioned shed light on framing and messaging by the drug industry, the government and the FDA on the issue of drug reimportation, a major talking point in the political campaigns of 2004. After the recall, of course, coverage of this issue dropped significantly as it fell off the media's radar. A much more important issue, a massive drug recall, was at hand.

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APPENDIX
CODING INSTRUMENT

Code Sheet

Case: _____

Coder: _____

Medium (check one):

_____ New York Times

_____ US News and World Report

_____ Washington Post

_____ Newsweek

Placement (fill in answer):

Date of Article: _____

Page Number: _____

Section: _____

Drug Name (check all that apply):

_____ Accutane

_____ Serevent

_____ Bextra

_____ Vioxx

_____ Celebrex

_____ Other (describe): _____

_____ Crestor

_____ Meridia

Framing (count occurrences of the following frames in each paragraph):

Drug Safety / Regulation

Count: _____

Total _____

Economics

Count: _____

Total _____

Personal Health / Testimonials

Count: _____

Total _____

Politics

Count: _____

Total _____

Other (describe): _____

Count: _____

Total _____

Comments (include any quotes that exemplify a particular frame):_____

Quoted Sources (count the number of times each source is quoted):

Doctor(s):_____ Total:_____

Lawyer(s):_____ Total:_____

Researcher(s):_____ Total:_____

Pharmaceutical Spokesman(s):_____ Total:_____

Consumer(s):_____ Total:_____

Academic(s):_____ Total:_____

Politician(s):_____ Total:_____

FDA Representative(s):_____ Total:_____

Other (please indicate):_____ Total:_____

Scope (indicate the dominant frame):

_____ **Drug Safety/Regulation**

_____ **Economics**

_____ **Personal Health**

_____ **Politics**

_____ **Other**

Comments?_____

Code Book

Case: Write the number appearing on the upper right corner of the article.

Coder: Write your initials.

Medium: Indicate whether the article was printed in the *New York Times*, *Washington Post*, *US News and World Report* or *Newsweek* by checking the corresponding blank.

Placement

Date of Article: Write the date on which the article was published.

Page Number: Write the page number on which the article appears.

Section: Write the section in which the article appears. Examples include news, people, health, outdoors, sports, business, etc. If it is not indicated on the article, write N/A. Section A indicates the first section of a newspaper.

Drug Name(s): Check off which drugs were mentioned in the article. If any were mentioned and are not listed, indicate their names in *Other*.

Framing: Count occurrences of each frame in each paragraph of the article. A paragraph may contain frames from one or more categories. Some paragraphs may contain frames that are not listed. Do not code these frames unless there is an important recurring pattern. Indicate recurring frames in *Other*.

Drug Safety/Regulation: An article with a drug safety/regulation frame will discuss effects of the drug on patients, professional opinions on drug safety from regulatory agencies, risks or benefits of a particular drug and/or litigation surrounding drug issues.

Economics: This frame includes personal as well as government spending on drugs.

Insurance coverage may be a theme included in this category.

Personal Health: This frame includes personal stories or testimonials of average consumers about the drugs' effects on their personal health. Drug effects on an individual often accompany litigation news.

Politics: Debates over drug laws, costs, and sources (such as shipping drugs from other countries) between political actors are categorized here.

Other: If a frame does not fit into the above categories, explain the frame here.

Comments: Include quotes from the story that exemplify a particular frame.

Quoted Sources: Count and categorize the number of sources quoted within the story. Include both direct and indirect quotes (attribution and quotations).

Doctors: This category includes medical doctors, often a patient's personal physician, not academics with doctorate degrees.

Lawyers: Any trial or corporate attorney representing patients belongs in this category. Lawyers affiliated with the pharmaceutical company are spokesmen for that company.

Pharmaceutical Spokesman: CEOs, publicists, researchers, company lawyers or other pharmaceutical representatives belong in this category.

Consumers: Patients attesting to their personal experiences should be categorized here.

Academics: This category is for academic experts that may be consulted by reporters for their stories. Economists and industry analysts fit into this category.

Politicians: Some stories may include political actors. Classify them here.

FDA Representative: Sources associated with the drug industry's regulatory agency, the Food and Drug Administration, are classified here.

Other: Any sources that do not fit into these categories should be placed here. Explain the nature and background of the source.

Scope: Identify the dominant frame of the article. Include comments about dominant sources and themes if so desired.

VITA

Rebecca Ann Hotard was born in Opelousas, Louisiana, on July 22, 1982. She earned her Bachelor of Science degree in biology with a minor in mass communication from Nicholls State University in May of 2004. As part of her education at Nicholls, she learned photojournalism, which she practiced in her scholarly travels in England and along the coastline of Louisiana. Her inability to experiment on live insects, crustaceans and fish fry drove her out of the research lab and sparked an interest in science communication. She is still interested in biology, particularly genetics and ecology. She discovered the allure of public relations while studying journalism at Louisiana State University's Manship School of Mass Communication. She plans a future that combines science communication and public relations.