

**SYSTEMATIC ASSESSMENT OF TRUE, MISLEADING AND FALSE CLAIMS IN  
ADVERTISEMENTS FOR PRESCRIPTION AND NONPRESCRIPTION DRUGS ON  
TELEVISION**

by

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*For Sam.*

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John Stewart Mill wrote, in *Principles of Political Economy* "It is hardly possible to overrate the value of placing human beings in contact with persons dissimilar to themselves, and with modes of thought and action unlike those with which they are familiar... Such communication has always been... one of the primary sources of progress." This group of interesting and unique people have helped shape this research. Their contributions have been immeasurable.

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## Abstract

**Background:** False and misleading advertising for drugs can harm consumers and the healthcare system. Because two separate government agencies regulate advertising for drugs, there may be two different definitions of what is false or misleading in prescription versus nonprescription drug ads. Distraction techniques may be used to shape cognition of truthful information, to potentially mislead consumers. No research has previously compared false or misleading claims in prescription and nonprescription drug advertising on television targeted to consumers, nor evaluated use of distraction techniques associated with positive, benefit claims in advertising.

**Research Questions:** Are there differences in the frequency of true, misleading and false claims in prescription and nonprescription drug advertising? Are the claims in drug advertisements associated with distractions before, during and after the claims are presented? Are use of distractions associated with true, misleading, or false claims?

**Methods:** Content analysis was used to identify the most-emphasized claim in 168 unique prescription and nonprescription drug advertisements based on claim iteration, mode of communication, duration and placement. The most-emphasized claim in each ad was classified as being objectively true, potentially misleading, or false. Use of distracting or unrelated visual and audio elements before, during and after the most-emphasized claim were identified and compiled into a overall distraction index. Three coders were trained to evaluate ads and reliability on all variables was good ( $\kappa \geq 0.70$ ).

**Results:** Prescription drug advertisements had more objectively true claims (43%) and fewer false claims (2%), compared to nonprescription drug ads (23% true, 17% false). Misleading claims occurred with similar frequency in prescription (55%) and nonprescription (61%) advertisements. There was more distraction in the period during the presentation of the major claim of the advertise-

ment than before or after. Prescription drug advertisements had more distractions after the major claim due to consistent use of background music. Claims that were more truthful were associated with more distraction before, during, and after the claim.

**Conclusions:** Different government regulations may be resulting in more truthful claims in prescription drug advertising to consumers while potentially misleading or false claims are prevalent throughout prescription and nonprescription drug ads. Truthful claims were weakly associated with more distraction.

## Chapter 1

### Introduction

Television drug advertising is one of the most viewed types of health communication in the marketplace. More than 90% of consumers surveyed say they have ever seen a drug advertisement (Kaiser Family Foundation et al., 2008), and consumers reported seeing television drug advertising more often than magazine advertising (Aikin et al., 2004). Consumers may see up to 30 hours of television drug advertising each year (Brownfield et al., 2004) while only spending 15 to 20 minutes, on average, with their primary care physician (Blumenthal et al., 1999; Lo et al., 2005; Geraghty et al., 2007). In 2010, the pharmaceutical industry spent \$4.3 Bn USD on direct to consumer advertising (Mack, 2011), and television advertising is one of the largest expenditures in the promotion of drugs to consumers, comprising 30% of the media budgets of the top 13 major pharmaceutical companies (Martino & Staton, 2008). Overall marketing budgets for pharmaceutical companies have increased by over 10% every year since 1997 (Frank et al., 2002; Palumbo & Mullins, 2002; Swallen, 2008), and an increasing share of pharmaceutical company budgets are being allocated to marketing expenditures (Donohue et al., 2007). Since 1998, some of the largest increases in promotional expenditure were in the cost of television advertising (Mintzes et al., 2009).

Given the wide consumer exposure to television drug advertising, it is important that the information presented in drug advertising is high quality. However, the current regulatory environment may not be effective in eliminating all false or misleading drug advertising from the marketplace. Regulatory action is rarely able to stop misleading advertising from being aired. Instead, regulatory action may occur months to years after the misleading advertisement has ceased to be promulgated (Office, 2002). As evidenced by the warning letters that FDA issues to drug advertisers for false or

misleading direct-to-consumer advertisements, drug ads may mislead consumers by exaggerating the efficacy of drugs, or by minimizing the risks of drugs (Mack, 2010; Sheehan, 2003; Salas et al., 2008; Benson & Alfors, 2007; Donohue et al., 2007). Further compounding the issue of airing false or misleading advertising, consumers believe that government regulations are highly effective at eliminating false and misleading advertising. Consumers falsely believe that drug ads must be approved before being aired on television (Bell et al., 1999) and consumers strongly favor pre-approval of drug ads before being aired (Huh et al., 2006). False and misleading advertising for drugs is being aired to consumers, and consumers' deception protection skills may be limited by high expectations for regulatory control of the practice.

Not all consumers are misled by false or misleading advertisements, but many are. False claims in drug ads have been demonstrated in experimental studies to lead to false beliefs in a majority of consumers and physicians, and false beliefs increased purchase or prescribing intention (Russo et al., 1981; Oliver et al., 1984; Burke et al., 1988). When magnified by national multi-million dollar advertising campaigns, false beliefs stemming from false claims in drug advertising can lead to significant financial and physical harms to consumers. Rational prescribing and consumer decision-making are reduced when the information marketplace contains false or misleading advertisements (Brody & Light, 2011). For example, widespread advertising to patients and physicians for COX-2 inhibitors Celebrex (celecoxib) and Vioxx (rofecoxib) started soon after the products were approved by FDA, and the number of prescriptions dispensed increased rapidly, thus magnifying the numbers of consumers who may have taken the drug inappropriately before significant cardiovascular harms were found (Spence et al., 2005). Merck was notified by FDA three times between 1999 and 2001 for disseminating false or misleading advertising for Vioxx, and Pfizer, Pharmacia and Searle, the companies that manufactured Celebrex, were notified four times between 1999 and 2005 for disseminating false or misleading advertisements for Celebrex. In another example, illegal marketing of Zyprexa (olanzapine) for unapproved uses (Spielmans, 2009) and suppression of negative publications showing the harms from the drug (Turner et al., 2012) likely led to increased sales of the drug (Kales et al., 2011; Alexander et al., 2011), and eventually a \$1.4 Billion USD settlement with the US Department of Justice for illegal marketing (Kesselheim et al., 2011). In the past 10 years,

more than 7 Billion (USD) in settlement fines have been levied by the US Department of Justice and by the states against pharmaceutical companies that promoted their drugs for unapproved uses, a type of false or misleading advertising (Kesselheim et al., 2011).

Describing the harmful effects of false or misleading advertising is straightforward. Describing what is false or misleading can be difficult. There are different levels or degrees of deception - some things are true, some false, and some in the "grey area" in between truth and falsehood. The Federal Trade Commission (FTC) maintains a definition of false or misleading advertising that has been adopted by most other government agencies, including FDA (see a technical description in Section 2.2, page 9). Given this shared definition, the most functional understanding of what is deceptive in drug advertising is drawn from a history of actions taken by FTC and FDA against deceptive advertising and advertisers. These decisions have created a body of case law defining how FTC interprets deception and a smaller, less detailed collection of letters from FDA to drug manufacturers defining how that agency defines deception. Interpretation of FDA regulations in the past 15 years may have established a higher standard for information content in prescription drug advertising. Most notably, prescription drug advertising must contain full information on the risks of the drug, as well as the benefits. FDA argues that, if an advertisement for a prescription drug does not present information on the benefits and risks of the drug, that advertisement misleads consumers to the overall value of the drug. This interpretation differs from the existing practice of FTC wherein nonprescription drug advertising is not required to convey information about the side effects or contraindications of the drug.

A handful of studies over the past 30 years have systematically examined false advertising of drugs. Most of these studies have explored the content of prescription drug advertisements and advertising targeting physicians. These studies have demonstrated anywhere from 10% to 60% of advertisements for prescription drugs targeted to physicians may be misleading in some regard. Few studies have researched how FDA regulations on prescription drug advertising affect truthful claims in consumer-targeted advertising, and even fewer studies have investigated false or misleading claims in nonprescription drug advertising. With this limited amount of research on false advertising of prescription or nonprescription drugs to consumers, there is a need for more research

in this area. Given the differences in the definition of false advertising of prescription drugs by FDA, and nonprescription drugs by FTC, there is also a need for evidence to compare false advertising for prescription and nonprescription drugs, to elucidate if differences in regulation may be leading to differences in content. The markets for prescription and nonprescription drugs are different in some key ways, especially the need for a physician's prescription to purchase prescription products from a pharmacist, and these differences (summarized in Chapter 2) can lead to different negative outcomes for consumers exposed to false advertising for prescription or nonprescription drugs.

This research was designed to explore false advertising for prescription and nonprescription drugs. In this document, I will describe the research that has been conducted by myself and my coding team to systematically measure the frequency of false and misleading advertising for a sample of current television advertising. Chapter 2 (page 5) will review current definitions of false advertising by FDA and FTC, what is known about false advertising, some theories of false advertising, and introduce the idea that distraction can be used to mislead consumers and distraction may accompany false advertising. Chapter 2 also identifies a typology of true, half-true and false claims used in advertising that will be the basis for evaluating false and misleading advertising. Chapter 3 (page 41) will outline the specific research questions that were explored in this research. Chapter 4 (page 43) outlines the methods for analysis, including the content sampling plan, development of the content analysis instrument, coder training, reliability evaluation, and statistical analysis. Chapter 5 (page 61) will present the results of the study, including descriptions of the sample, the claims selected for analysis, the truthfulness of those claims, and distractions associated with those claims. Chapter 6 (page 89) will review the results and discuss how the results contribute to the knowledge about the phenomenon of false advertising for drugs. Last, Chapter 7 (page 114) will draw conclusions from this research.

## Chapter 2

### Background and Theory on False Advertising for Drugs

In the study of false advertising, a number of specific questions are important to address: What is false and what is true? Who decides what is false? and What motivations are there to create false advertising?

Although these questions bring up deeper philosophical questions about Truth, those answers lie beyond the scope of this research. I assume that Truth is something that can be objectively evaluated and measured, that a researcher has the ability to identify a thing that is "True" by comparing the thing to a set of known facts, and that this comparison will provide important insight into perceptions of Truth. I also assume that something that is not true is also not necessarily false, that there are shades of half-Truth. This pragmatic approach to Truth will guide this research.

Given these underlying assumptions, I will continue to discuss current definitions for false advertising, and how these definitions are being applied by different regulatory agencies within the United States Federal Government. Given these working definitions, I will summarize what is currently known about false advertising for drugs and identify a gap in the knowledge of false advertising for drugs.

In this chapter, I argue that prescription and nonprescription drugs are bought and sold within two distinct, but interrelated markets. Specific characteristics of these markets help buffer consumers against the negative effects of false advertising, however, the market characteristics do not completely protect consumers from harms stemming from false advertising. Hence, there are specific government regulations that define what is false in advertising, define actions that need to be taken to ensure that advertising is not false, and outline the actions that the government may take to limit

false advertising. Building on the current regulatory and market environments for prescription and nonprescription drugs, previous research in false advertising for drugs has followed the government regulations for defining false advertising and surveyed samples of advertising targeting health care providers and consumers, to estimate the prevalence of false advertising in the marketplace and infer how this information may harm consumers. There is a paucity of high-quality research investigating the phenomenon of false drug advertising targeting consumers. Additionally, recent research has recognized that attention modification techniques like distraction can distort consumer perceptions of information, creating false perceptions from otherwise truthful information. A separate body of literature describes how distraction is widely used in drug advertising to affect consumer perceptions. However, there has not been previous research associating use of distraction with false advertising and this study will begin to investigate the associations of deception and distraction.

I propose a synthesis of two separate theories to explain why false advertising may be occurring in spite of government regulation limiting it, and to make predictions about the characteristics of false advertising that will be most relevant to the phenomenon of drug advertising. Ivan Preston's slippery slope theory, outlined in his book *The Tangled Web they Weave*, describes why advertisers may be motivated to sell products to consumers using information that is half-true, and from this, derives a typology of advertising claims, ranked from objectively true to objectively false. Separately, psychological research describes how distraction is used to modify consumer attention when processing information, and how distraction may be intentionally used to distort information and mislead consumers. Merging these two theories together, I argue that distraction is a technique used to enhance deception, and that claims that are half-true or false will be associated with more distraction.

These arguments are outlined in detail below.

## **2.1 Characteristics of the Product Markets for Prescription and Nonprescription Drugs**

Differences in the marketplace for prescription and nonprescription drugs may influence the ability of false advertising to affect consumer product evaluation, product purchase and the efficiency of

the healthcare system. First, prescription drugs can provide greater benefits but also have greater significant side effects than nonprescription drugs and may treat a condition that a physician must diagnose, or may present an unfavorable balance of benefits and risks and require a physician to monitor drug treatment. Conversely, nonprescription products are often taken for self-diagnosed conditions and present a favorable balance of benefit and risk not requiring ongoing monitoring by a physician (Soller, 1998). Second, consumers must interact with a physician and a pharmacist to obtain most prescription drugs, while consumers may purchase nonprescription drugs without consultation with a healthcare professional. Third, the effects of prescription drugs may take physician intervention to assess or manifest over longer periods, while for many nonprescription products, the drug effect is noticeable and immediate (Nguyen et al., 2006). Fourth, due to either the infrequency of use or to the perceived need for the product, consumers engage in high-involvement decision-making when selecting a prescription product (Kim & King, 2009; Kim, 2005). High-involvement decision-making processes often involve information search process, product assessment, purchase decision (whether or not to discuss the drug with the physician) complex purchase process (obtain a prescription, fill prescription at pharmacy) and decision re-evaluation (Engel et al., 1990). Since nonprescription products are purchased more frequently, and often treat conditions that are not severe or life-threatening, the purchase process for nonprescription products doesn't require high involvement and purchase decision-making may not include information search, but instead rely on past experience, brand awareness or loyalty, or word-of-mouth social information (Cosler et al., 1986; Creyer et al., 2001; Hoy, 1994; Stephens & Johnson, 2000). Ultimately, a consumer's evaluation of the benefits and risks of a prescription product will be more influenced by healthcare providers since interaction with healthcare providers is necessary to acquire the product. Consumer evaluation of the risks of nonprescription products may or may not be influenced through interaction with a healthcare provider. Additionally, a consumer with false perceptions about a prescription product interacts with two separate, knowledgeable healthcare providers, first a physician then a pharmacist, providing multiple opportunities to correct false perceptions. False perceptions about a nonprescription product may go unchallenged.

Only a subset of all drugs are advertised to consumers. The characteristics of advertised pre-

scription and nonprescription drugs may also influence consumer's use of information in forming product evaluations, changing the potential effects of false information in drug advertising. First, the prescription drugs that are most advertised are branded, single-source drugs while off-patent, generic or multisource prescription drugs are rarely, if ever, advertised. Thus, high drug prices from patent rents allow for pervasive and high-quality advertising for prescription drugs. Advertised nonprescription products are often multi-source branded products that are off-patent and cannot command the same high prices. Hence there may be greater variation in the advertising budgets and quality of advertisements. Products with strong brand recognition, Allegra (fexofenadine) for one, can command high-quality, pervasive nonprescription ad campaigns, while small manufacturers with lesser-known products, like Cepacol lozenges, have small budgets and may run the same advertisement in niche markets.

Second, nonprescription brands are associated with multiple products and brand extensions while prescription brands are associated with a small handful of drug formulations. For example, the nonprescription Vicks brand is associated with Vicks Vaporub, a topical mentholated rub, and the subbrand Vicks NyQuil, a cough and cold liquid, but also with brand extensions into nebulizers and humidifiers. Cialis, the brand name of one of the most popular advertised prescription drugs, is only used with an as-needed formulation and a daily-use formulation of the same chemical. Nonprescription subbranding and brand extensions provide diversity in advertising that is not seen in prescription brands.

Last, because advertised prescription drugs are still protected by patents, competing prescription products (that are advertised) within the product class are chemically distinct and may have similar, though not identical efficacy and side effect profiles. Until the patent expires, and only after submitting additional information to FDA can competitors with identical formulations enter the market. Few nonprescription products are protected by patents, and under the nonprescription monograph approval procedure, competitors with identical formulations may enter the market easily without prior approval from FDA. While some competing nonprescription products may have unique chemical formulations, some competing nonprescription products may have identical chemical formulations with identical efficacy and side effect profiles. Using advertising to distin-

guish between two identical chemical formulations will be difficult since there are no differences among products. In summary, the advertising for prescription drugs is higher-quality and pervasive, mono-branded, and has comparative leverage based on unique properties of competitors. Nonprescription drug advertising, on the other hand, has variable quality, diverse focus on brand and sub-brand products, and may use advertising to promote differences among identical products.

## **2.2 Regulation of False or Misleading Drug Advertising**

Given that market characteristics are insufficient to eliminate false advertising, or to minimize the harms to consumers, government regulation has been developed to minimize the impacts of false advertising of drugs to consumers.

The Federal Trade Commission (FTC) defines false or misleading advertising as a representation, omission or practice that is likely to mislead a reasonable consumer and is likely to effect the consumer's conduct or decision (Federal Trade Commission, 1984). For the advertisement to be deceptive, it must affect a "reasonable consumer." In practice, at least 20% of people who view the ad must perceive the potentially deceptive implication. In addition, the ad does not have to explicitly cause an individual harm—the ad can have deceptive intent or deceptiveness but not produce actual harm. Lastly, the claim must be "material" or must affect the consumer's conduct or decision.

Per FTC, advertising may also be misleading if the advertiser does not have evidence to back up the advertised claims; a concept called "substantiation." For some objective advertising claims, there is an implication that the advertiser has some "reasonable basis" that the claim is based upon. For example, a claim that "4 of 5 physicians choose BRANDNAME" implies the advertiser asked at least 5 physicians about their brand preference and 4 of those 5 selected the advertised brand. In addition, some claims imply a "level" of evidence and the advertiser must have that level of evidence available. Lastly, if there is a reasonable basis for an objective claim then that claim is material and consumers "would be less likely to rely on claims for products and services if they knew the advertiser did not have a reasonable basis for believing them to be true," (Appended to Thompson Medical Co., 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*,

479 U.S. 1086 (1987), 1984).

Drugs, or products marketed to diagnose, cure, treat or prevent disease (FD&C Act, Sec 201(g)(1)) have important considerations under the definition of false or misleading advertising and advertising substantiation. First, all claims regarding drugs are material because, unlike other products like toilet paper or clothes, drugs make claims about treating disease or otherwise affecting the structure or function of the body, consumers base their purchase decisions upon these claims and would not likely purchase a product that they knew to be dangerous or ineffective. Second, the reasonable basis for making safety or efficacy claims for drugs must be from well-controlled, randomized human clinical studies. FDA possesses the expertise to evaluate clinical evidence, therefore the role of assuring that prescription drug advertising was not false or misleading was transferred from FTC to FDA in 1963 within the Kefauver-Harris amendments to the Food, Drug and Cosmetic Act. A memorandum of understanding between FDA and FTC further clarified that FDA had oversight over prescription drug advertising while FTC had oversight over all other types of advertising.<sup>1</sup> At present, FDA has issued three major guidance documents to supplement the laws and regulations in order to provide a better description of what the agency considers false and misleading (Food et al., 1999, 2004, 2009). Through these guidance documents and through policy statements affiliated with these guidance documents, FDA has made clear that advertising that does not include comprehensive information on the risks of the product is misleading to consumers. Table 2.1 summarizes the regulations pertaining to regulation of drug advertising by the United States federal government.

Recent FTC and FDA decisions can provide insight into how these regulations have been applied to deceptive drug advertising. A review of recent decisions by the FTC (See Appendix A) shows few over-the-counter drugs have been cited in recent years for false or misleading advertising. Instead, most FTC decisions involve nutritional supplements, vitamins and foods making completely or partially unsubstantiated claims. However, some decisions (see Rexall/Sundown Gummy Vitamins case and Kellogg's Mini Wheats case) show more complex cases where FTC argued that evidence didn't fit the advertised claims and judged the advertising misleading.

FDA letters issued to drug manufacturers citing false or misleading advertising support the

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<sup>1</sup>Memorandum of Understanding MOU 255-71-8003, available online at <http://www.fda.gov/AboutFDA/Partnerships/Collaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm>

Table 2.1: Summary of Regulations and Procedures for the Oversight of Consumer-targeted Drug Advertising

<b>Major Laws, Regulations and Guidance Documents</b>	
<b>FTC</b>	The Federal Trade Commission Act, 15 USC 41-58 created a federal agency to regulate "unfair or deceptive acts or practices in commerce." The Lanham Act, 15 USC 22 clearly outlines that false advertising is an unfair or deceptive act or practice. FTC Substantiation Statement added to Thompson Medical vs FTC 479 U.S. 1086 (1987).
<b>FDA</b>	The Food Drug and Cosmetic Act (with amendments) 21 USC 301, esp. the Kefauver Harris Amendments (1963) gave authority to FDA to oversee promotion to physicians. Promotion of pharmaceuticals (21 CFR 202.1, Prescription drug advertisements), the "Fair Balance" requirement (21 CFR 202.1(e)(5)), "brief summary," "major statement," and "adequate provision" requirements (21 CFR 202.1(e)(1)). Definition of "adequate and well controlled studies" (21 CFR 314.126).
<b>Major areas of regulatory oversight/influence</b>	
<b>FTC</b>	Nonprescription drug promotion. Substantiation of Claims. The definition of "false or misleading advertising." <sup>1</sup>
<b>FDA</b>	Prescription drug labeling. Prescription drug promotion. Nonprescription drug labeling
<b>Method of Regulation</b>	
<b>FTC</b>	Administrative law judges decide cases. Cases can be appealed to federal courts. Court procedures and evidence are documented in case records.
<b>FDA</b>	FDA makes laws through notice-and-comment rulemaking. Proposed laws and regulations are published in the Federal Register and anyone can comment on the proposal. Cases may be referred to the Department of Justice.
<b>Ancillary-, informal- or self-regulation</b>	
<b>FTC</b>	The Better Business Bureau's National Advertising Division will review challenges to advertising made by competitors, to help the parties reach a voluntary agreement and if the agreement is violated, they can refer the case to the Federal Trade Commission.
<b>FDA</b>	FDA issues letters to drug companies when their advertising may be in violation of FDA laws and regulations. FDA issued guidance documents in 1997, 2004 and 2009 to clarify definitions of the brief summary/major statement, adequate provision and fair balance.
<b>Specific Requirements for Drug Advertising</b>	
<b>FTC</b>	Advertisements must not be false or misleading. Advertisers must have evidence to substantiate (back up) the claims made in advertisements before those claims are made and the evidence must meet or exceed the implied level of evidence presented in the advertisement.
<b>FDA</b>	Advertisements must not be false or misleading. In order to not be false or misleading, drug advertisements must include information on the risks and contraindications of the drug. These risks are to be presented in a brief summary of risks (in print advertising) or in a major statement of risks with adequate provision to the full brief summary (in broadcast advertising). Advertisers must substantiate all claims with evidence from adequate and well-controlled studies.

<sup>1</sup> False or deceptive advertising is defined as: "There must be a representation, omission, or practice that is likely to mislead the consumer. The act or practice must be considered from the perspective of a consumer who is acting reasonably. The representation, omission or practice must be material." See more at the FTC Policy Statement on Deception appended to Cliffdale Associates 103 FTC 110, 174 (1983). Available at <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>. Accessed May 26, 2011.

argument that FDA considers advertising that does not present comprehensive information on drug risks to be misleading to providers and consumers. From 2001 to 2005, the most frequent violations for professional advertising were minimizing risk information (40%), omitting risk information (63%) and false or misleading safety claims (7%) (Benson & Alfors, 2007). Sheehan (2003) found the most frequent reasons for consumer-targeted advertisements receiving an FDA warning letter were similar to the findings from studies of professional advertising: minimizing risk and exaggerating efficacy information. While FDA has officially accepted the definition of false and misleading advertising posited by the FTC, FDA has additionally determined that advertising for prescription drugs is false or misleading if it excludes information on the risks of drugs. This difference between FTC and FDA has, in practice, created different standards for what is considered false or misleading in advertising for prescription and nonprescription drugs.

### **2.3 Claims in Drug Advertising—A Definition**

Before exploring the previous research on false drug advertising, I need to address some semantic points regarding the study of advertising, specifically, what is the organization of information within an advertisement and how does that effect what can be defined as "true" or "false?"

Advertising can appear as a print ad in a magazine, newspaper or billboard, or a broadcast ad appearing on a website or on television, or less traditional types of advertising, like new "ad-vergames" that combine the brand with a videogame. Regardless of the media, an advertisement will make one or more claims about the product being advertised. An individual claim may be true, and the combination of multiple claims within an advertisement can result in a true advertisement. These claims will serve as the basic unit for analysis in this study, and hence, a specific discussion on what is a "claim" is necessary.

Osgood (1959) narrowly identified claims in print advertising based on grammatical construction. In his rubric, claims were identified as where the brand (product trade name) is associated with an adjective or adjectival phrase that describes the brand or states how the brand will benefit the consumer. The brand and the adjectival phrase are associated by a verb or verb phrase. The simplest version is a three-word sentence containing the brand name, a verb and an adjective, for example,

"Hansen's is best," or "Miller's are top." This method of identification is over-simplistic and fails to identify many of the powerful visual metaphors established in advertisements. Shimp (1979) identified claims, which he called "assertions," as:

" . . . a linguistic construction in which a referent is associated with or dissociated from a complement via a verbal connector...The referent is the advertised brand; a complement is an adjective or adjective phrase that describes the referent or states how the referent's product will benefit the consumer; and the verbal connector is the verb or verb phrase that associates referent and complement. Stated in an alternative fashion, the advertised brand is a sign, and an advertising assertion signifies something about the sign; the thing signified is a significate."

Preston (1994) also discussed the creation of significance and its role in advertising. Per Preston, advertisers are trying to sell the same thing and so give the thing a brand in order to differentiate it from other products: Bayer Aspirin, Thompson's Water Sealant, Kleenex Facial Tissue, etc. Then, in order to sell their brand, they promote the advantages of their brand of the product over other brands of the product. These advertising appeals can be either brand significant, creating in the minds of consumers significant and positive differentiation of the brand from other brands of the product, or product significant, creating in the minds of consumers significant and positive differentiation of the whole slew of products (the advertised brand and all of its competitors) compared to other products. Use of brand significant appeals avoids the problem where advertising stimulates demand for product categories instead of specific brands (Preston, 1994, p 55-57). In his language, "As a result of [product similarities], appeals must be chosen that are positive for the brand, not just for the product. They must differentiate the brand from other brands, in a favorable way, of course. If they don't do that, they are unsuitable for the purpose of selling," (Preston, 1994, p 57). A claim, therefore, is the advertiser's attempt at creating brand significance by using language and symbols to connect the brand with something important that will induce the consumer to purchase the branded product. Preston's language will form the base for a definition of a claim. A claim is a linguistic or symbolic concept that attempts to create brand or product significance in the mind of the consumer.

Although these definitions provide a general idea of what a claim is, they do not provide much support in being able to reliably identify these claims in advertising content. Wilkes et al. (1992) provide one basic categorization of claims that are specific to drug advertising. The researchers asked pharmacist and physician reviewers if they thought a drug advertisement was making different types of claims and then, if the ad uses the claim, rate their agreement with the claim. The list of categories of claims were: the "drug of choice" for at least one condition, more effective than another drug, effective in a broad range of patients (for example, different age groups), useful in a broad range of conditions and diseases, and safe. Although this set of categories is mutually exclusive, the concrete nature of these categories and their focus on measurable drug benefits makes it less likely to include some claims, especially lifestyle and psychological claims. However, almost all claims made in drug advertising will be related somehow to the efficacy of the product—a claim that a drug will improve relationships ultimately relates to the underlying belief that the drug can, for example, reduce sneezing when out-of-doors, alter neurotransmitters to reduce anxiety, or reduce the need to use the bathroom. Therefore, the drug-specific definition of an advertising claim used in this study is:

A linguistic structure or symbolic association that attempts to create brand or product significance in the mind of the consumer; for drugs, often the claim will be that the brand is the drug of choice for at least one condition, more effective than another drug, effective in a broad range of patients (for example, different age groups), useful in a broad range of conditions and diseases, or safe; alternatively the drug claim may imply that the drug may improve general well-being, improve lifestyle, relationships and other social interactions, or provide intangible psychological benefits.

## **2.4 Previous Research into False Claims in Drug Advertising**

Previously published research on false or misleading drug advertising has focused on FDA regulations applied to prescription drug advertising, demonstrating that advertisements are not in compliance with regulations because they contain claims that are only half true, omit important information, or are based on weak evidence. Estimates of the proportions of drug advertisements

in medical journals that omit important information range from 8% to 41% of ads appearing in the journals (Othman et al., 2010) and misleading headlines were found in 32% of a sample of medical journal advertisements (Wilkes et al., 1992). Recently, a comparison of medical journal advertisements to FDA standards for journal advertisements found that half of the advertisements were presenting information that was noncompliant and thus potentially misleading (Korenstein et al., 2011). Studies examining false or misleading advertising for drugs are reviewed in detail below.

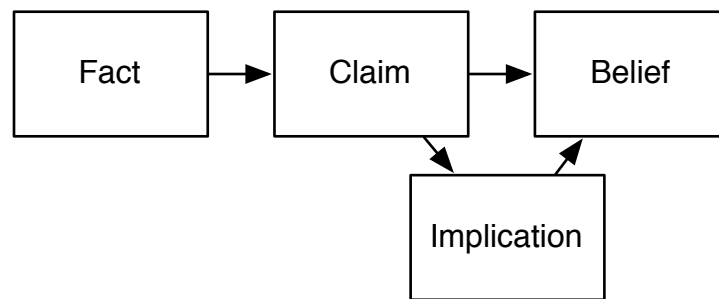


Figure 2.1: Relationship in Advertising Materials Between Facts and Beliefs. Adapted from Russo et al. (1981).

As Preston (1994) and others (Shimp, 1979; Russo et al., 1981) have discussed, advertisements present claims that have implications, predictable interpretations or inferences drawn by consumers, and the claim and its implications lead to beliefs about the product in consumers' minds (see Figure 2.1). In this framework, fact-claim discrepancies may be evaluated using the advertising content alone, but understanding links between claims, implications and beliefs requires research using the advertisement's target audience. Results from studies in target audiences can then be used in subsequent reviews of fact-claim discrepancies. Therefore, after researching claims, implications and beliefs in target audiences, implications can be predicted based on presentation of the claim. Preston (1994) provides the example of the claim, "Nothing works better than a [Faerber] range." The explicit claim is that, of all the ranges available on the market, the Faerber range works just as well as all of the competitors. However, the predictable implication of the claim is a stronger claim that the Faerber range works better than other ranges on the market. Most consumers will see the implication, not the actual claim.

Given this framework, there are four potential ways that claims in drug ads may be evaluated:

- By having reviewers compare claims in advertisements to facts in drug evidence to find objective disagreements, or fact-claim discrepancies
- By doing the above, but additionally having reviewers scrutinize the quality of the evidence supporting the advertised facts.
- By doing all of the above, but also examining the implications of the claims (known from previous research) and if those implications match the evidence.
- By exposing the target audience to advertisements (a set of claims and their presentation) and measuring beliefs.

To some extent, all of these methods have previously been used to evaluate the truthfulness of claims in drug advertising and will be reviewed below.

#### *Fact-claim discrepancies in drug advertising*

Most previous studies on false or misleading drug advertising have focused on fact-claim discrepancies between published facts and advertised claims. These studies evaluate whether or not an advertisement includes a reference to published data and if published data are available. Some studies make a basic comparison between the available published evidence and the advertised claim. Some of these studies make basic evaluations of the types of studies referenced, say, whether the study was published in a journal or available "on file" from the pharmaceutical company.

Accuracy of quotations and references was evaluated by de Lacey et al. (1985). The authors only evaluated the accuracy of the quote or reference, for example, was the volume and page number accurately cited and were the exact words from the reference used in the quotation. In their sample of six British medical journals, misquotations occurred in 10% to 20% of all quotations and reference errors occurred in 8% to 46% of all references (percentages are reported for each journal).

Neumann et al. (2002) evaluated economic claims in medical journal advertisements published between 1990 and 1999 and quantified how many claims were supported by a published study. Economic messages occurred in 11% of the 1,033 unique advertisements in the study sample, and

64% of those claims were backed by some type of referenced publication. The authors did not evaluate if the claims matched the results of the published evidence.

Villanueva et al. (2003) evaluated whether cited claims in medical journal advertisements from Spanish-language medical journals matched with the cited publication. Regardless of the quality of the publication, if the claim agreed with the publication they rated the claim as true. False claims were only when the claim clearly could not have been derived from the study, when the ad claim had no relation to the cited study, when the patients in the study differed greatly from target patients in the advertisement (including extrapolation from animal studies to humans), when the study did not include a subgroup analysis that matched with the ad target population, or when the ad claim clearly exaggerated the results of the study. Of the 102 claims that included citations where the reference was available for review, 44% were not supported by the citation. None of the convenience claims were supported by referenced publications (0 of 3 claims), less than half of the safety claims were supported (6 of 15) and although efficacy claims were the most popular type of claim (84 claims), less than half were supported by the referenced publication (36 of 84).

Keng & Coley (1994) didn't evaluate medical journal advertisements, but focused on a similar piece of mass-communication promotion to physicians: index cards produced by the drug company for physicians to put in their pockets as a quick reference for the drug. These cards have mostly become obsolete since the wide dissemination of pocket computers, but at the time, these cards served as an on-hand reminder of the drug's use and side effects and were expected to be unbiased references for the product. The authors reviewed a convenience sample of these cards and compared the claims on the card to published studies, defining a misleading statement as,

any referenced statement on a file card not being in total agreement with findings from the original reference where there is an intent to distort or if specific information was taken from a review article. A statement that might be "correct" but taken out of context would be misleading. Statements from the abstract, discussion, or conclusion section of a study were not the direct result of the study cited and therefore marked as such.

Their study sample was only 21 cards. On the 21 cards were 334 claims and referenced by 121 different publications. Of these publications, 73% were available for analysis and 85% of claims

were accurately cited, per the definition above.

Often, citations in advertisements are to "data-on-file" or unpublished data held by the pharmaceutical company promoting the drug. Although these types of citations may provide reassurance that the advertised claim is valid, data-on-file are more difficult to obtain and to verify. Unlike previous studies, Cooper & Schriger (2005) went to the effort to request data-on-file from pharmaceutical companies. The authors reviewed advertisements found in major medical journals and quantified how many articles cited referenced publications and how many of those referenced publications were available to the authors for review. For the 438 advertisements in the study sample, 29% included no reference to support ad claims. Of the ads that included citations, there were a total of 590 citations to unique documents. Eighty four percent of the unique documents were available, and more of the journal articles (98%) than data-on-file (20%) were available.

These studies examined the most basic type of fact-claim discrepancies in drug advertising to physicians by investigating references in advertisements, whether the referenced material was available and whether, on a rudimentary level, the citation matched with the claim in the advertisement. These studies demonstrate that claims in physician-targeted drug advertising is often not supported by published evidence. It's important to remember that drugs are unique products in this regard. In order for these claims to be made, the advertiser must have evidence to support the claim. In addition, the process of scientific discovery values free and open dissemination of information about the properties of drugs, creating the opportunity for independent researchers, (and the physician targets of the advertisements) to review the data and make up their own mind about the truthfulness of the claim. Especially as pointed out in Cooper & Schriger (2005), if information is difficult to obtain, it increases the burden of evaluating whether or not the advertised claim is truthful and not misleading.

These studies analyzed the most basic way that a claim may be misleading—direct contradiction with published fact. However, facts may be taken out of context or presented in a distorted manner, leading to a misleading claim. This type of misleadingness is reviewed in the next section.

*Quality of studies supporting claims in drug advertising*

Even though an advertised claim may match with a presented fact in a clinical research study, that does not mean that the claim is objectively true. Facts may be presented in ways that may lead to misleadingness, or the facts themselves may not be as important as presented in the advertisement.

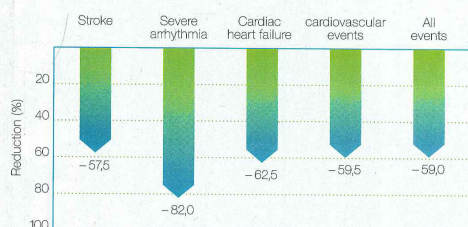
A letter to the editor from the British Medical Journal illustrates an example of how poor quality research studies can be used to present the benefits of a drug in a misleading fashion (Telford et al., 1997). The author criticizes a claim found in a recent advertisement, "referring to the STONE study, the advertisement says 'This prospective placebo-controlled clinical intervention trial has demonstrated for the first time a significant reduction in severe clinical outcomes with the dihydropyridine nifedipine,'" (see Figure 2.2, page 20). The advertisement claim does not convey the serious shortcomings of the design and analysis of the STONE study that limit the generalizability of the findings. The claim, as presented, was factually accurate—that the trial was an intervention and did demonstrate significant reductions. However, in the absence of important limitations to the study design, the implication of the claim—that the clinical intervention was important enough to change clinical practice—was misleading to viewers.

A cluster of studies systematically evaluated the claims in drug advertisements and the evidence supporting those claims, to evaluate if the evidence base was high-quality or poor-quality. Due to the growing trend toward evidence-based medicine in the 2000s, researchers were realizing that evidence to change practice needed to come from high-quality clinical trials. In addition, the evidence to support claims in advertisements should be held to the same high standard since those claims could effect clinical practice.

Bhattacharyya et al. (2003) conducted one of the first studies to not just examine fact-claim discrepancies, but to also examine the underlying evidence to see if the study was high-quality or poor-quality. They examined a random sample of 50 factual claims made in medical journal advertisements published from 2000 through 2001. The way the authors evaluated evidence was simplistic: they asked reviewers if they would publish the results in a peer-reviewed medical journal and if the results of the study would affect their practice. Based on their evaluation of 46 advertising claims where referenced evidence could be found, 24% of claims were supported by high-quality

# Research for the future STONE STUDY\*

**“This prospective placebo-controlled clinical intervention trial has demonstrated for the first time a significant reduction in severe clinical outcomes with the dihydropyridine nifedipine.”\***



Reduction of the endpoints of the study  
\*Gong, L., et al. Shanghai Trial Of Nifedipine in the Elderly (STONE). J. Hypertens. 1996; 14 (10): 1237-1245

**Bayer** 



**Take-Off into the Future**  
Bayer Cardiovascular Research

**Abbreviated Prescribing Information:** See local prescribing information for full details. Adalat® OROS (Oral Retard Osmotic System) nifedipine: Extended release tablets 30 and 60 mg. **Indications:** CHD: Chronic stable angina pectoris, vasospastic angina pectoris. **Hypertension.** **Dosage:** According to patient's needs. Therapy should be initiated with one tablet 30 mg or 60 mg swallowed whole once-a-day (see full prescribing information). **Contraindications:** Hypersensitivity to nifedipine, pregnancy, breast-feeding, cardiovascular shock, combination with rifampicin. **Precautions:** Severe hypotension, overt heart failure, tight aortic stenosis, severe gastrointestinal narrowing, impaired liver function. **Interactions:** Antihypertensive agents, cimetidine may also enhance antihypertensive effect. Combination with beta-blockers in heart failure may be deteriorating. Plasma levels of digoxin or quinidine should be monitored. Diltiazem decreases the clearance of nifedipine. **Side effects:** Initially mild and transient vasodilatation, hypotensive, rarely gastrointestinal, skin and other reactions. See full prescribing information. Very rarely: Transient visual disturbances: Chest pain (if sustained, discontinue therapy). Extremely rare: After chronic use gingival hyperplasia, gynecomastia (both reversible after discontinuation); temporary hyperglycaemia, impaired liver function (including intrahepatic cholestasis), syncopal episodes, systemic allergic reactions, purpura. Ability to drive or operate machinery may be impaired. **Since indications, dosage forms, and strengths may vary from country to country, please consult your local prescribing information. For further information contact Bayer AG, PH PD Adalat®, 42096 Wuppertal, Germany, or the local Bayer subsidiary. Other major brand names of Adalat® OROS: Adalat® CR, Adalat® Crono, Adalat® LA, ChronAdalate® LP. BSS 09/96**

Figure 2.2: An Advertisement for Dihydropyridine Nifedipine from the British Medical Journal, 12 April 1997.

evidence (where the reviewers agreed the evidence could be published in a peer-reviewed scientific journal) and 30% of claims were supported by poor-quality evidence (unpublishable evidence). Fourteen percent of claims were well-supported (reviewers agreed that the data could be used to treat patients), while 44% of claims were poorly supported (the data would not be used to treat patients).

Santiago et al. (2008) investigated the impact of changes in Swiss regulations on the content of drug advertising. In 2002, the Swiss government passed strict regulations on the content of drug advertising to physicians requiring "...that advertisements claims 'have to be accurate, balanced and supported by evidence'. Marketing claims must 'reflect current scientific knowledge' and 'only studies conducted according to good clinical practice' may be cited. Claims in advertisements 'must be quoted accurately, completely and need to be exactly referenced,'" (as cited in Santiago et al., 2008). The authors examined 78 cited claims in unique advertisements from six Swiss medical journals published between 2003 and 2005. Of those 78 claims, half were supported by referenced evidence (47%), while 21% were not supported by the evidence and 32% were based on potentially biased evidence. Reasons why the reference did not support the advertised claim were: false statements, exaggerated statements, unjustified generalizations, absence of a statistically significant relationship in the study, or overgeneralization from non-clinical evidence. Reasons why the evidence may have potentially been biased were: post-hoc reanalysis, poor-quality randomized controlled trial <sup>2</sup>, the claim was from the abstract or conclusion of the study publication, use of results from observational studies, if the study was not peer-reviewed, or if the referenced study was a narrative review.

Recognizing that the sponsor of a research trial often has control over the conduct of the study, van Winkelen et al. (2006) examined references in journal advertisements, but additionally investigated the sponsorship of those references. Their sample of 84 unique advertisements from four major arthritis and rheumatology journals contained 300 references. Of those 300 references, 53 were to randomized controlled trials, systematic reviews or other quality research applicable to the specialty of rheumatology. However, these 53 high-quality references were almost always (98%)

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<sup>2</sup>Poor quality randomized controlled trials were evaluated on the following criteria: the trial was an open study, where neither the patients nor the physicians or outcome assessor were blinded; if studies provided insufficient information about the presence or absence of concealed treatment allocation; if the number of patients lost-to-follow-up was more than 10%; if there were no reasons for drop outs reported; if there was selective reporting of positive outcomes in a study with positive and negative outcomes; and if no intention-to-treat analysis was performed.

sponsored by the advertising pharmaceutical company, and 49% of the referenced high-quality evidence did not support the advertisement claim.

In the most comprehensive analysis of medical journal advertising to date, Korenstein et al. (2011) completed a study evaluating fact-claim discrepancies and the quality of evidence supporting claims in a sample of 83 unique prescription drug advertisements in 12 medical journals published in 2008. The authors evaluated if advertisements met the FDA requirements that describe false or misleading advertising. The evaluation included whether the advertisement met the regulations and guidelines, and whether the advertisement failed to meet the regulation or guideline due to omitted information.<sup>3</sup> Eighteen percent of advertisements were fully adherent to FDA guidelines and were not false or misleading in any way, and half (49.4%) of advertisements were potentially misleading, meaning they did not adhere to one or more of the FDA guidelines. One third of advertisements (32.5%) omitted important information, hence they may or may not be false or misleading.

There are numerous occasions where information cited in prescription drug advertising in medical journals is poor-quality or claims were supported by poor-quality evidence. Because the measurements for quality of references were not consistent across these studies, it's difficult to provide one single number for the frequency of poor-quality evidence to support claims, but generally, more than 10% of references and fewer than half of references did not meet standards for evidence.

### *Implications of claims in drug advertising*

To date, there have been few studies that focused on how prescribers or consumers may be misled by information presented in drug advertisements, or on how specific inferences may be drawn from presented information. A few studies broadly inquired about misleadingness: Korenstein et al.

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<sup>3</sup>For example, section 21 CFR 202.1(3)(e)(6) states "An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it... Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience." The authors measured compliance with this requirement with two questions, "Are there unsupported efficacy claims related to comparisons with other drugs?" and "Were efficacy claims made out of context by comparing to placebo rather than active-control or focusing on surrogate rather than clinical outcomes?"

(2011) asked the general question "Are the headlines or sub-headlines misleading?" and Wilkes et al. (1992) asked broadly "[Are images] used in manner which misleads the reader about efficacy?"

A cluster of studies with similar methodology categorized claims in medical journal advertisements into four categories:

1. Unambiguous clinical outcome: When compared with DRUG X, DRUG Y delivers faster symptom relief.
2. Vague clinical outcome: DRUG X is the new, effective, 20 microgram pill with a low incidence of discontinuation due to skin problems.
3. Emotive or immeasurable outcome: DRUG X—one of a kind or DRUG X—a source of healing power.
4. Non-clinical outcome (eg, drug plasma half-lives or biochemical markers): Using DRUG X resulted in a 30% increase in arterial luminal diameter in post-mortem dissections. Loke et al. (2002)

In a novel addition, the researchers evaluated the presence of emotive claims that ad viewers may interpret as vague, unspecified product superiority claims. These studies are summarized in Table 2.2. These studies demonstrate that there are a substantial number of claims in drug advertising to physicians (15% to 31%) that include claims that may not be factual, not supportable by evidence, and appeal to emotional decision-making.

Unfortunately, there has not been more research in studying the implications of claims in drug advertising. Especially given the interesting findings from the two studies above, there may be significant amounts of emotional appeals being made in advertising for prescription drugs targeted to physicians and other prescribers.

Table 2.2: Types of Outcomes Described in Drug Advertising Claims

Category	Publication					
	Loke et al. (2002)	Lankinen et al. (2004)	Othman et al. (2010)	Othman et al. (2010)	Othman et al. (2010)	Othman et al. (2010)
Journals (Country)	Australian	Finnish	American	Malaysian	Australian	
Journals (N)	6	4	1	1	1	
Sample Year	2000	2002	2005	2005	2005	
Sample Size (Unique Ads)	174	883	85	85	85	
Sample Size (Claims)			318	346	165	
Unambiguous Clinical Outcome	28%	9%	23%	17%	30%	
Vague Clinical Outcome	29%	37%	49%	59%	46%	
Emotive or Immeasurable Outcome	20%	31%	15%	15%	21%	
Non-Clinical Outcome	23%	23%	12%	9%	2%	

*Beliefs from claims in drug advertising*

The studies above used expert reviewers to provide mostly objective assessments of the sample advertisements. Using a different approach, two studies (Wilkes et al., 1992; Sansgiry et al., 1999) asked experts their opinions on content to evaluate if claims were misleading or false. These studies asked experts to review an advertisement and answer questions about different types of claims made in the ad, and whether the expert agreed with the claim.<sup>4</sup>

Wilkes et al. (1992) evaluated the content of 109 prescription drug advertisements from medical journals published in 1990. Reviewers were provided with copies of publications cited in the advertisement, when the publication was available. Most advertisements were reviewed by three separate reviewers. From their evaluation, the most frequently used claim in the sample of advertisements was that the product was the drug of choice for a condition; in 53% of advertisements, two or three reviewers believed that claim was being made and in 28% of advertisements two or three reviewers agreed with the advertised claim while in 30% of ads, two or three reviewers disagreed with the advertised claim. The most controversial type of claim was the claim that the drug was more effective than another drug. In 23% of the ads, two or three reviewers believed the claim was being made, and within those advertisements, reviewers disagreed with the claim in 39% of ads. This study was the first to systematically evaluate claims in drug advertising to physicians and established the methodology of asking trained experts to evaluate advertisements and using consensus of experts as criteria for indicating whether or not an advertisement was false or misleading.

Sansgiry et al. (1999) followed the methods of Wilkes et al. (1992) to review 14 over-the-counter drug advertisements in consumer magazines published in 1994. Similar to Wilkes et al. (1992), their reviewers agreed that the most common claim made in advertisements was the drug was the product of choice, and reviewers also mostly disagreed with the use of the claim. However, the small number of reviewers (5) and reviewed advertisements (14) makes generalization from their results difficult.

Another possible way to evaluate beliefs drawn from advertising was outlined by Russo and

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<sup>4</sup>For example, "Does this advertisement make the claim that the drug is safe?" followed by "Is the claim was keeping with current scientific knowledge about the drug or condition?" with a 4-point likert scale ranging from strongly agree to strongly disagree.

colleagues in the *Journal of Consumer Research* in 1981. They describe an experimental design whereby misleading advertisements are modified to correct for the misleadingness,<sup>5</sup> and four groups of consumers are randomized to view no ad, the original misleading ad, the modified not misleading ad, and a control ad unrelated to the experimental ad. Then beliefs about the product,<sup>6</sup> especially the misleading claim are evaluated in all the groups. Experimental designs of this type have not been used to evaluate physician beliefs drawn from drug advertising, but many of the findings in previous studies would benefit greatly from being confirmed in experimental research of this type.

### *Claims in Drug Advertising Targeted to Consumers*

The research above mostly focused on evaluating fact-claim discrepancies and scrutinizing the evidence supporting claims found in medical journal advertisements targeted to physicians. There has been little research studying the implications of claims and the beliefs claims generate in physicians. In contrast, drug advertising targeted to consumers has focused almost extensively on implications of claims in advertising and the beliefs these claims generate in consumers. There has been minimal research examining fact-claim discrepancies in consumer-targeted advertisements and scrutinizing the evidence used to support claims in consumer-targeted drug ads.

To the best of my knowledge, there have only been two prior studies evaluating fact-claim discrepancies in drug advertisements targeted to consumers. The study by Sansgiry et al. (1999) was discussed above (page 25). A second study from Consumer Reports (1996) examined claims in prescription drug advertising directed to consumers and concluded "two-thirds of the ads were judged to be factually accurate and backed by scientific evidence...But many left out important information or only put it in the fine print." This publication was a consumer-targeted magazine, and so the results were not peer-reviewed nor did the publication include necessary details about the methodology. Since there have only been two previous studies evaluating false or misleading drug advertising to consumers, it is difficult to generalize about the frequency of fact-claim discrepancies in this population of advertisements.

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<sup>5</sup>In their example, an ad for bananas claims that a banana has 80 calories. However, the photograph shows a much larger banana that is likely to have 120 calories. The misleading ad was corrected to say the banana had 120 calories

<sup>6</sup>Given the banana example above, possible belief questions could include "Bananas are healthy for me," "Bananas are low-calorie," and "Bananas have less than 100 calories."

Research investigating implications from claims and consumer beliefs has not focused on misleading information, but instead has focused on misleading presentation. As described below, there has been consumer research on the use of distraction in advertising and how distraction can shape cognition of presented materials (See Section 2.6). Additionally, there have been a number of studies in print and broadcast advertising that evaluated the presentation of benefit and risk information in prescription and nonprescription advertisements (Faerber & Kreling (2012); Royne & Myers (2008); DeLorme et al. (2010) and others reviewed in Lyles (2002)). Benefit and risk information in prescription drug advertisements targeted to consumers is presented using similar modes of communication, but many techniques that would enhance understanding of this information, like use of numbers to quantify benefits and risks, and use of audiovisual presentation, are not being used to improve cognition. Nonprescription drug advertisements, on the other hand, rarely include risk information, and when risk information is included it is not presented in the same manner as the benefit information.

In the study of false and misleading drug advertising targeting consumers, there is little research on fact-claim discrepancies, but a large body of research that describes misleading implications and false beliefs that are generated by ad content. Given that two Federal agencies, the Food and Drug Administration and the Federal Trade Commission, oversee false and misleading drug advertising to consumers, and that these two agencies may have different standards for information being included in drug advertising, there is a need for more research in false and misleading drug advertising to consumers.

## **2.5 Distraction as a Form of Deception**

Shifting gears, the previous research has focused on the FTC definition of false advertising and researchers have based their evaluation of false advertising on the definitions outlined by FTC and FDA. There is a separate area of research that is exploring how psychological techniques can manipulate how consumers view and comprehend information presented in advertisements. Print ads with small-print disclaimers or radio ads with disclaimers read at auction-house speed are common occurrences. These are just two examples of presenting required information but using

psychological techniques to diminish some information, limiting the ability of consumers from fully comprehending what is being presented. Both of these approaches are informative to understanding false or misleading advertising, as it is called by government regulators, or deceptive advertising, as it is called by psychological researchers.

While avoiding actions from FTC or FDA for false advertising, drug manufacturers are required to include negative aspects of their products in advertising. Historically, to reduce the impact of negative information in advertisements, advertisers have been turning to psychological techniques like distractions to shape the way that consumers perceive and comprehend advertised information. Distractions are used in advertising to shape cognition of advertising messages and facilitate deception. "Deceitful marketers use distraction...by engineering distractions in an ad that are timed and located to disrupt processing of the specific disclosures in the ad about drawbacks, risks, and limitations," (Boush et al., 2009, p 45).

FDA and industry have recognized the importance of distractions in reducing comprehension of the information in prescription drug advertising and have taken steps to reduce the use of distractions in prescription drug advertisements (Food et al., 2009). The draft guidance from 2009 on presentation of risk language in broadcast advertisements clearly states that FDA takes into account, "the use of audio or visual components that enhance or distract from the presentation of risk or benefit information...determining the comparability of benefits and risks in a piece," (Food et al., 2009). The pharmaceutical industry trade group, PhRMA, has also issued voluntary industry guidelines stating "risks and safety information should be presented with reasonably comparable prominence to the benefit information, without distraction from the content," (PhRMA, 2008). In effect, FDA and PhRMA have said that distraction is no longer acceptable in drug advertisements as a method to reduce comprehension of risk information.

Distractions are ultimately attempting to control the attention, and thus the cognitive processes of the viewer. A wide array of advertising techniques have been validated as distractors using brain scanning technology and eye-movement tracking. Some examples are "visual size and prominence; visual brightness and vividness; loudness; surprise; novelty; pleasing or puzzling complexity; stimuli people habitually focus on in everyday life because these may be related to basic wants and

needs, such as safety or sex; aesthetic beauty; and habits related to watching a particular medium, for example, center-screen fascination," (Boush et al., 2009, p 45). Distinctive features of visual presentations, especially creation of new objects on the screen or setting in motion objects on the screen can be distracting (Hillstrom & Chai, 2006).

Distractions can work through two methods: limiting perception of information by diverting attention away from innocuously presented information, and by shaping cognitive processes to limit deep thinking about information that is perceived. In the former method, distractions can focus attention on key visual or auditory sections of a message, and lead viewers to selectively perceive specific aspects of the advertisement. In the latter method, distraction can reduce systematic processing of the message, especially counter-arguing against the claims in the advertisement (Petty et al., 1976). Advertisers also build distraction around claims with so-called "bookend distractions" that "...surround a damaging disclosure with a lead-in distracter and an immediate follow-on distracter. The lead-in distraction occupies a consumer's mind right before the damaging disclosure appears, which makes it difficult for the consumer to reorient efficiently toward the damaging disclosure once that becomes available...Marketers place distractions right on the heels of a damaging disclosure to immediately tear people's attention away from thinking about the disclosure if they have noticed it," (Boush et al., 2009, p 48).

This brings up an important issue in the study of distraction in advertising. The same technique (e.g. a large red arrow moves across the screen) can be used as both an attraction technique (an attractor) and a distraction technique (a distractor). If the red arrow moves toward the logo of the advertised brand, it is likely to attract attention toward the important brand name. If the red arrow moves away from a disclosure statement, it is distracting attention away from the disclosure. In fact, the same red arrow can be used in the same scene in an advertisement to simultaneously be an attractor and a distractor. The previous research in distraction in drug advertisement has focused on using techniques solely as distraction away from negative information, specifically risks and contraindications of prescription drugs (see review in Section 2.6, page 30). However, research has demonstrated how attention can be controlled through use of distraction to effectively shape the cognition of messages by viewers. Distractions may disrupt cognitive processing of information

flows, and that reactions to disruption are variable depending on the message presented, the type of distraction and the inherent attitudes and beliefs of the viewer (reviewed in Gardner (1970)). Given the variety of ways that advertisers may use distraction in advertising, previous analyzes of advertising content have focused on identifying distracting elements, but have not explored how those distractions are, in practice, shaping the cognition of viewers.

In addition to shaping message cognition, distractions might give additional signals about the truth or falseness of the claim. Under the deception and distraction theory introduced by Brosch, Friestad, and Wright, a distraction can divert the consumer's attention toward something good that is about to happen (an attractor) or away from something bad that is currently happening (a detractor) (Boush et al., 2009, p 61). Certain types of distractions encourage consumers to think critically, to initiate "hmm. That's weird" thinking, and to pay attention to what is coming up; for example, when a blurry image resolves into a sharp image. Other distractions overload a consumer's cognitive processes, to suppress critical thinking and to induce a passive and unquestioning receptive state, for example rapidly scrolling text, rapid scene changes or pleasant images of beautiful people or babies (Boush et al., 2009, p 45-46). Marketers sandwich their positive claims and negative claims in the middle of distractions, and the type of distraction can give clues as to whether the claim is true or deceptive. A deceptive but positive claim, may be introduced by an attention-getting distractor that also stimulates uncritical and passive thinking and followed by another distractor to stop processing the claim and focus on some other part of the ad. The consumer's attention is on the claim, but not enough attention to critically analyze the claim and then attention is quickly shifted to something else. On the other hand, a truthful positive claim may be introduced by an attention-getting distractor that stimulates critical thinking thus leading to a deeper comprehension of the positive claim and then followed by a distractor that continues to stimulate critical thinking. Most negative claims, also known as disclosures, would be sandwiched between distractors that overload and induce passive thinking, then followed by distractors to divert attention toward something else. Regardless if the negative claim is true or false, a consumer's attention will not be attracted toward it.

## 2.6 Previous Research on Distraction in Drug Advertising

Given the bases for use of distractions in enhancing deception in advertising, a handful of studies have used this theory to study the relationship between provision of risk information and distractions in prescription drug advertising. In these studies, distractions are described as incongruent presentation of audio and visual information (O'Donoghue, 2011; Sumpradit et al., 2004), as specific distracting elements like music changes or rapid animation (Harlow, 2010; Grubbs Hoy & Andrews, 2004), or as consumer-reported distraction (Glinert & Schommer, 2005). The results of content analyses indicate high amounts of distraction (97-99% of print advertisements, Grubbs Hoy & Andrews (2004)), especially during the risk presentation (Harlow, 2010). Experimental evidence points to subjects being more distracted by incongruous audio and visual presentation when risks are more complex, hence when cognitive requirements were higher (Glinert & Schommer, 2005). Additionally, incongruous (versus congruous) presentation of risk and benefit information did not change positive attitudes toward the drug, but reduced comprehension of risk information, and did not change comprehension of benefit information (O'Donoghue, 2011). This evidence points to distraction as an effective means of reducing comprehension of risk information in prescription drug advertising. No studies have specifically studied the effects of distraction on information contained in nonprescription drug advertisements, but from the experimental results (Glinert & Schommer, 2005) it is likely that comprehension of risk information in nonprescription drug ads may be impaired less by distractions since these ads provide fewer risks. However, since previous research on nonprescription drug ads showed that the risk information in nonprescription ads was often presented as text disclaimers on the screen (Faerber & Kreling, 2012), then it is possible that distractions in nonprescription drug ads are not decreasing comprehension of risk information, but instead distracting viewer's attention from disclosures so that the information is not perceived.

Research on distraction often focuses on using distraction to reduce cognition of negative information, but the theory posits that distraction can also be used to enhance cognition of positive information. This type of distraction—distraction surrounding positive information—has not been studied in drug advertising. Especially given the amount of attention that FDA is dedicating to distraction in risk information, distraction in benefit information deserves serious consideration as

well.

## 2.7 Theory

Two related theories will be used in this research study. The slippery slope is a theory and typology that describes one method to categorize truth in advertised claims (Preston, 1994). The deception and distraction framework posed by Boush, Friestad and Wright links use of distraction in advertising and truth of claims (Boush et al., 2009).

### *Preston's Slippery Slope*

In the book *The Tangled Web They Weave* (1994), Preston describes the motivation for use of deception in advertising. Preston outlines a "slippery slope" of advertising claims whereby advertisers stop making wholly truthful advertising claims and slide down the "slippery slope" of half-truth until they reach the "bottom" false claims. In Preston's slippery slope of false advertising claims, use of half-truth stems from the basic desire of advertisers to have consumers perceive the brand as truthfully differentiated from competitors, positively, and to a meaningful degree, create perceptions in consumers' minds that their brand is different from their competitors. "Advertisers want their claims to be true but also brand significant. They want consumers to demand the brand, not just the product. A claim that is only product significant will help sell the product while favoring no brand over any other, by contrast, brand significant claim differentiates a brand from its competing brands, positively, to a meaningful degree," (Preston, 1994, p 58). This creates a problem whereby advertisers are forced to say something about the product in advertising using brand-significant claims, and in the absence of meaningful product differentiation, it is too easy to justify advertising half-truths as being not blatantly false, not illegal, therefore all right and legal. Because advertisers have to say something about their product, they are forced to create a brand significant fact, when there is none. They choose to promote claims that are not objectively true nor significant but easy to find, instead of using objectively true and significant claims. What really matters in the end is not the objective truth, but instead the subjective truth offered up to, taken, and understood by consumers. Consumers view advertising claims and then evaluate the product. Their evaluations determine

their perceptions of the product and their purchase decision is based on the perceptions of the product. Within this continuum of objectively true and subjectively true claims, and significant and insignificant claims (to the brand and to the product) Preston introduces the slippery slope, where claims move from being objectively true and significant to downright false.

### *Objectively True Claims*

Objectively true claims present brand-significant facts and include all of the necessary information for consumers to make purchase decisions. The brand is differentiated from other brands of the same product in a meaningful way and the implications of the claims do not deceive consumers as to their significance or truthfulness. The definition for objectively true claims is more strict than what is typically presented by the Federal Trade Commission as being true. FTC defines falseness and all claims that are not false are allowable and legal. Preston's definition of an objectively true claim goes beyond being "not false" and requires disclosure of the bad and insignificant aspects of the product. Take, for example, the claim that "A Faerber range is the best-built cooktop available." First, the Faerber company doesn't disclose that they're comparing their range to consumer-grade cooktops, not professional-grade cooktops used in restaurants. Second, the build of the cooktop may not be directly related to the actual performance of the product. Under Preston's definition of objective truth, a true claim that the Faerber Company could present would be along the lines of, "A Faerber range is the best-built cooktop, though not the best performing cooktop, available to consumers."

### *Selected Facts Claims*

The first step down the slippery slope are selected facts claims when an advertiser has one or more brand significant facts, and can create brand significance, but fails to also discuss the brand neutral and brand negative facts since that would deter from the consumers evaluation of the product. "...Advertisers will use the brand significant claims and not the [product significant] claims in their ads. They are selective, using what will sell, leaving out what won't, and giving consumers incomplete information...[the advertisers] tell us the good things about their brand and leave out

the neutral and bad...To have selected facts means also to have selected omissions. Nothing that's said is false, yet the total ad does not tell consumers the whole truth." (Preston, 1994, p 61). Preston quotes an advertising executive stating, "you must expect advertising to tell the truth and nothing but the truth, but you must not expect it to tell the whole truth," (Preston, 1994, p 62). Preston argues that this matches with consumer expectations that "advertising doesn't emphasize unfavorable points" and "[consumers] expect to see additional information [on the benefits of competitor's products or disadvantages of the advertised product] in Consumer Reports, and we expect not to see it in ads," (Preston, 1994, p 62).

Selective facts are deceptive when the claim makes false implications. Claims may lead to false implications if an explicitly stated selected fact implies a false understanding about an omitted fact. This effect is buffered in the marketplace by allowing competitors to advertise their brand significant claims in response. Looking at the advertising as a whole, the consumer is given a net impression of the brand positive, neutral, and negative claims. Of course, the problem here is to justify how this type of advertising harms consumers, given the buffeting effect of other ads. Preston argues that selected facts do harm consumers "because selected facts always invite consumers to make their decisions on a basis of less than the entire truth. The explicit content may be fully true and significant but it omits additional information that pertains to objective truth and objective significance," (Preston, 1994, p 63).

Regarding drugs, the most obvious type of selected fact is when an advertisement fails to mention or minimizes the risks of the drug that would be important to the consumer when deciding whether or not to buy the drug or approach their physician about a prescription for the drug. This does not mean that any drug ad claim that fails to disclose every side effect or contraindication of the drug is misleading to consumers. However, when the side effect would be severe enough or occur frequently enough, then it deserves mention. This also means that important attributes of the drug, its route of administration, recommended dosing schedule, limited availability, are also important to include with claims in order to provide objective truth and omission of these attributes may constitute a selected facts claim. For example, if a treatment for a common chronic condition advertises the product is convenient due to once-a-month dosing, but fails to mention

that once-a-month the patient needs to visit the physician to receive the drug as an injection, this claim is not presenting the whole objective truth and would be a selected fact claim.

### *Minimal Facts Claims*

The second step down the slippery slope is minimal fact claims. In using these claims, the advertiser promotes factual claims that are minimally significant or exaggerated.

"Minimal facts are similar to selected ones in being selected and true. But selected facts are objectively significant—alone at least, despite being less so in total context. By contrast, minimal facts are objectively just that—minimal. They are merely promoted as significant. They are "hyped" into meaning more than they otherwise would. To consumers, they are as maximal as the seller can make them," (Preston, 1994, p 68).

Minimal facts are used by advertisers when brand significant facts are not available. Preston points to the manufacture process as the stem of minimal facts. Minor product iterations like adding additional speeds to a blender can be marketed as significant product differences, especially to convince consumers to "upgrade" to the newer product. Apple Computers has become very good at making minor changes to its product lines and selling those minor changes as innovative and significant revolutions to the industry. For some drug products, a pill that is a combination of two already approved drugs may promote itself as new and improved. In this case, the drug is just a combination of two products and may not offer any additional synergistic effects. The claim that the combination drug is new and improved is a minimal fact claim since there is only a minor difference between the combo drug and its constituent parts but the combo drug is being promoted as new and improved.

Minimal facts claims may come from exaggeration of the relevance of information that distinguishes two products. In the realm of drugs, a common example of minimal facts claims is when a drug is statistically different from another drug, but the difference is not clinically significant. Drug A may lower cholesterol, on average, five more points when compared to drug B, but those five additional points are not meaningful in decreasing negative complications like heart attacks. The

two drugs are statistically, though not clinically different. If drug A claims it lowers cholesterol better than drug B, this is a minimal facts claim.

The difficulty with minimal fact claims is in distinguishing when a fact is significant or minimal. Minimalness is in the eye of the beholder. Advertisers push this difference by targeting certain consumer groups that may consider an objectively minimal fact to be maximal, positive and brand significant. These minimal facts may be maximal because of the status they confer. Preston provides the example of the first kid on the block to have a ten-speed bike. The kid thinks that tenth speed is maximal, while the tenth speed is minimal to the last kid on the block to get it, (Preston, 1994, p 70). Extending the life of a terminal cancer patient by three months may be significant, while extending the life of someone with toenail fungus by three months may be unimportant.

Preston defines three subtypes of minimal facts: physical difference, performance differences, and promotional differences. Physical differences, to paraphrase, are subtle differences or changes in manufacturing that produce physical differences in the product that have no objective impact on the product performance. Performance differences are where "no other brand has achieved [the performance measure], which allows the inference that none other could. Such a performance implies an objective brand difference, but there probably isn't one. If a brand could actually perform in a way that it's competitors could not, its maker would certainly say so explicitly," (Preston, 1994, p 71). Performance differences leading to minimal facts claims often happen when one drug in a class obtains FDA approval for a new indication. All of the other products with a similar mechanism of action probably also are effective for the new indication, but they just have not received FDA approval to market the drug for the new indication. Therefore, when Pravachol advertises it is the "only drug in its class" to prevent first and second heart attacks, it is making a minimal facts claim. There is no reason to think one statin is better than any other statin at preventing first and second heart attacks, but Pravachol is the only drug approved. The promotional difference is a claim "based on an existing feature. Although one or more competitors have the same feature, consumers are to infer from the claim that the competitors don't have it when actually the competitors just have never promoted it. Objectively, then, the brand that makes the claim is differentiated only by what it's messages say," (Preston, 1994, p 71).

Minimal facts claims are harming consumers by distorting consumer perceptions of the truth and significance of the brand claims, like selected facts, but in addition, minimal facts distort consumer perceptions of the significance of claims over what is objectively true. Additionally, minimal facts distort perceptions of the permanence of differences between products. Since these are minimal improvements in features, or minimal improvements in performance, it is easy for competitive products to gain those features or improvements.

### *Nonfacts Claims*

Continuing the progression down the slippery slope, nonfact claims are absent of truth and objective significance. Nonfacts are not false. They're hollow statements. Advertisers turn to such claims when there are no selected or minimal facts of use to convey about the brand. Brands may not be differentiated when they are not physically different, when the law prohibits the products from differentiating (gasoline, drugs) or when physical differences are too small to matter. Differences may be minor and perceptible to trained experts—e.g. film grain in Fujifilm versus Kodak, grades of beef marbling, or side effect profiles of Lipitor versus Pravachol. As a consequence, product categories where the products are not differentiated are heavily advertised because there is nothing to differentiate factually, thus more advertising is necessary to create and maintain the seeming of difference. When product distinctions are minimal in the absence of the branded information, this is a strong sign the products are differentiated based on nonfacts.

Nonfact claims come in three varieties: puffery, opinions and nonbrand facts.

*Puffery* is hyperbolic exaggeration of the attributes or benefits of a product, for example, "Our steaks are the best in the entire world." It's unclear what benefit or attribute is being compared—is it the steak's flavor? fat content? the color of the cow it was cut from? It's unclear what other products are being compared—all steaks on the market today? all theoretically possible steaks? all steaks that someone has eaten? Puffery has been specifically protected as legal by the FTC in a series of cases from the 1970s. In brief, consumers aren't expected to believe that the advertiser is stating a fact, but instead is expected to recognize the advertiser is being hyperbolic and using rhetoric to make a point. Puffery is considered a nonfact claim because the claim was supposedly designed to

be meaningless. Fortunately, puffery may be occurring less in the current marketplace than in the 1970s when these legal standards were established (VandenBergh et al., 1983).

*Opinions* give an evaluation of the product and can be from the company, its spokespeople, knowledgeable individuals, or general consumers. Opinions can differ among individuals while facts are the same among all observers. "A brand opinion technically says something only about the speaker. That is why objectively it's a nonfact about the brand. Of course advertisers intend for consumers to regard the opinion as being 'about' the brand," (Preston, 1994, p 82).

*Nonbrand facts* are facts, but they are not about the product itself. Nonbrand facts often associate the product with a type of person or a lifestyle. So when an advertised product, "fits your life," the advertiser is jumping ahead to say "this product is for you" versus saying "this product is good" and allowing the consumer to infer "this good product is for me." "A specific type of consumer is frequently the subject of the ad rather than merely it's object. The consumer's personal profile becomes the appeal that the advertiser makes to that consumer...[Advertisers] are not blocked from appealing to a particular group just because their brand's features or even the product category's features do not naturally attract such folks...[Advertising] tells us virtually nothing about [the advertised product] while devoting it's print space to detailed profiles of persons it thinks we might want to associate with or be like,"(Preston, 1994, p 86). Nonbrand facts may also claim that the product solves a non-existent problem that the consumer may not be aware of having. Halitosis, the medical term for bad breath, was created by the makers of Listerine, and promoted Listerine as the "solution" to the "problem" of bad breath (Twitchell, 2000). Although bad breath existed long before Listerine, the important point is that the company invented a medical term for a common problem and associated their product as a medical solution to that problem. Often these problems may be abstract social or psychological characteristics, like when butter is proposed as a solution to rid mothers of their anxieties about parenting (Fowles, 1994).

### *False Claims*

False claims are objectively false, meaning there is a discrepancy between what is claimed and a known truth. False claims may also be baseless but objective, whereby an advertiser claims to have

a basis for the factual claim when that basis is absent, what FTC calls unsubstantiated claims. This definition is similar to the definition of false advertising from FTC (see Section 2.2).

Preston's typology has more well-defined levels of use of truth, half-truth, and falsehood in claims made in advertising. The slippery slope applies broadly to all advertising, unlike earlier definitions of truth and falsity used in studying claims in prescription drug advertising that narrowly focused on fact-claim discrepancies and FDA regulations. When exploring the different effects of FDA and FTC regulation on use of claims in drug advertising, Preston's slippery slope is necessary to explore the differences in interpretation of what is considered false or misleading in drug advertising. Preston hypothesizes that FTC only views false claims as enforceable and dismisses the other types of claims as illegal. If FDA has set a higher standard for defining truth in advertising, then more grey-area claims on the slippery slope may be considered enforceable as false or misleading by the agency.

### *Theoretical Synthesis*

The basis of Preston's typology is that advertisers use misleading information in order to create a belief in consumers' minds that the advertised brand is different and superior to competing products. As discussed in Section 2.5, distraction is another technique that advertisers can build into advertisements in order to change perceptions of information, and ultimately, to support the larger persuasive intent of the ad—to differentiate the brand from other products. Therefore, in advertising, I expect to find a relationship between deceptive advertising and use of distraction. From the findings of previous research, drug advertisers are using distraction to divert attention away from risk information in prescription drug advertising, but the possibility that drug advertisers are using distraction to divert attention away from positive, benefit information seems contradictory. Why would an advertiser not want consumers to fully comprehend a positive product claim included in an ad? Within Preston's slippery slope, he argues that advertisers are using grey-area claims in order to imply greater significance than is warranted. Distraction that reduces systematic processing of weak grey-area claims may improve the retention of the positive implications of grey-area claims, without revealing the flaws in the advertised claim that may arise from in-depth systematic processing.

Therefore, I expect to see a relationship between false or misleading claims in advertising and use of distraction.

## 2.8 Summary

In summary, I have argued that there are unique characteristics to the markets for prescription and nonprescription drugs, and that there are differences in the regulations of the FDA and FTC that may lead to different definitions of false advertising. The current literature in this area demonstrates that some advertising of drugs is false, but there has not been enough research in false drug advertising to consumers to make predictions about whether there are differences in false advertising for prescription and nonprescription drugs. I outlined Preston's slippery slope theory that informs about why advertisers would make half-true claims in advertisements, and outlined five categories of claims in advertising that vary in the amount of truthfulness to the claim. Last, I associated the practice of distraction in advertising and how distraction may be associated with false advertising.

Prior studies of misleading drug advertising were more focused on professional advertising that can contain detailed and technical discussion of the benefits and risks of drugs. In addition, falsehood was defined in these studies as a fact-claim discrepancy or a claim supported by poor-quality information, without identifying possible misleadingness where true statements were framed to imply other meanings. When consumer advertisements were studied, the methods for analyzing claims were not transparent, making these results difficult to compare to other study results. Only one study has evaluated claims in nonprescription drug advertising specifically, and the small number of advertisements limits generalizability of the findings. Therefore, in the study of misleading claims in advertising for prescription drugs, more research is needed on misleading claims in consumer advertising and in advertising for nonprescription drugs. This is especially important given the different regulations on false and misleading drug advertising targeted to consumers.

## Chapter 3

### Research Questions

Previous research has shown that there are numerous fact-claim discrepancies within prescription drug advertising to consumers and professionals. Additionally, the current regulatory environment has set different standards for false and misleading claims in prescription and nonprescription drug advertising. Preston's theory of advertising deception introduces three types of "grey area" claims that are not factually false, but also not objectively true. FTC recognizes only the factually false claims as legally actionable, but there is evidence that FDA may recognize some of these "grey area" claims as legally actionable. Prescription drug ads to consumers may have fewer "grey area" claims than nonprescription drug ads to consumers due to these regulatory differences. In the first research question, I ask:

*Are there differences in the frequency of true, "grey area" and false claims in prescription and nonprescription drug advertising?*

Next, deception theories posit that advertisers use distractions to shape the cognition of information in advertisements and that distractions can emphasize passive processing of advertising claims over in-depth processing. Previous research has focused almost exclusively on distraction in reducing cognition of negative risk information in prescription drug advertisements. More research is needed in use of distraction and positive benefit information and more research is needed in use of distraction in nonprescription drug advertising. In the second research question, I ask:

*Are the claims in prescription and nonprescription drug advertisements associated with distractions before, during and after the claim is presented?*

Last, according to advertising deception theories, systematic processing of advertising claims results in depth processing of claims and more counter arguing against claims. Passive processing leads to surface processing of claims and less counter arguing. Hence, there is an incentive for an advertiser to present a weak claim based on poor or no evidence in a manner that stimulates heuristic processing and less counter arguing. Similarly, a strong claim based on good evidence may be presented in a way to stimulate systematic processing, increase counter arguing, and resulting in a deep understanding of the advertised claim. In the final research question, I ask:

*Are distractions more likely to be presented before, during, or after "grey area" and false claims? Are there differences in frequency of distractions before during and after true, "grey area" and false claims in prescription and nonprescription advertisements?*

## Chapter 4

### Methods

In this research study, I used content analysis to identify emphasized claims in broadcast prescription and nonprescription drug advertisements, classified those claims into five categories of deceptiveness, and measured distractions before, during and after the claim. In this chapter, the methods for this study are discussed in detail.

#### 4.1 Data Source

Content for this study came from the Vanderbilt TV News Archive (VTNA). The VTNA has archived recordings of the nightly news broadcasts on ABC, CBS, and NBC since 1968 and on CNN since 1992. The recordings included the commercials aired during the broadcasts. Previous surveys of television advertising have shown that the nightly news is a peak placement period for prescription and nonprescription drug advertising (Brownfield et al., 2004). Thus, the VTNA is a retrospective, longitudinal dataset of television recordings that is rich in prescription and nonprescription drug advertising. Staff at the VTNA indexed the broadcasts and commercial segments, thus facilitating sampling of content using systematic sampling techniques. Each commercial segment during the nightly news was abstracted by the staff at the VTNA into a series of keywords separated by semicolons, corresponding to the sequence of advertised brands.<sup>1</sup> For any specific commercial segment, data were available on the date, time, and network when the segment aired. A local copy of the VTNA public index was created to facilitate sampling content. In addition to the content of

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<sup>1</sup>For example: Old Dominion Freightline; Xerox; Advair; "Dads for My Daughters"; Family Leisure; 1-800-PetMeds; CNN "Atlanta Child Murders"

the VTNA public index, we had previously identified VTNA keywords associated with prescription and nonprescription drug advertising (See Faerber and Kreling, 2012, unpublished manuscript) to facilitate sampling prescription and nonprescription drug ads. Briefly, we had matched VTNA keywords with trade name listings in the FDA Orange Book, the list of all FDA-approved products, and flagged other drugs (e.g., biologics, nonprescription products approved before 1938, etc.) that were not included in the Orange Book.

## 4.2 Sampling Plan

As described above, the sampling frame was a list of commercial segments that were aired during the nightly news on ABC, CBS, CNN, and NBC. Since this study was focused on making current observations to the state of deception and distraction in prescription and nonprescription drug advertising, the research sample was comprised of VTNA data from January 2008 through December 2010. Further discussion of the time span for data analysis is in Section 4.9.

In selecting observations, four important considerations were being balanced: the need to obtain a random probability sample of advertising to maximize external validity, the need to eliminate duplicate content from content analysis, the need to obtain a sample of advertising that was balanced across years, and the need to minimize costs of obtaining content. The sample consisted of a random sample of commercial segments that contain one prescription (prescription drug or biologic drug) and one nonprescription (over-the-counter) drug advertisement, stratified by quarter-year. To eliminate duplicate content, the researcher traveled to the VTNA October 2 through 7, 2011 and viewed the contents of each commercial segment before purchasing the content to assure no duplicate drug ads were included in the sample. If duplicate content was found, then the entire commercial segment (one prescription and one nonprescription drug ad) was removed from the sample, and the next randomly selected commercial segment within the strata (containing one prescription and one nonprescription drug ad) was included in the sample. As discussed below in section 4.9 on power analysis, 84 commercial segments were selected for analysis, seven segments from each quarter, thus resulting in a final sample of 84 prescription and 84 nonprescription drug ads.

### 4.3 Extraction and Digital Editing of Advertisements

After reviewing content at the VTNA, high-quality copies of the selected commercial segments were ordered and were delivered on four DVD disks. In order to analyze the content, each advertisement, two per commercial segment, was converted into individual digital files that could be shared with coders for content analysis. The VTNA records standard NTSC television broadcasts using 29.97 frames per second, in 704 by 480 display size, 1.09 pixel aspect ratio, with a constant video bitrate of 6 megabits per second with audio frequency of 4800 hertz and at a constant bitrate of 224 kilobits per second. These recording characteristics were constant throughout the conversion process, so that the final digital files that the coders viewed were the most accurate representation possible of the original broadcasts recorded by the VTNA. The process of converting the sample from DVDs to individual digital files happened over five steps:

1. Each commercial segment was copied from the DVD disk onto a computer hard drive using Handbrake (v0.9.3) software.
2. The digital files for each commercial segment were imported into Adobe Premiere (v CS 5.5) and the researcher identified the start and stop of each advertisement within the commercial segment.
3. The individual prescription and nonprescription drug advertisements within each commercial segment were selected and exported to individual files using the recording settings described above. The final file format used the widely-available AAC (Advanced Audio Codex) for audio encoding, and H.264/MPEG-4 video codex for video encoding, that resulted in files that could be played on most modern desktop computers.
4. Each file was named with the VTNA identification number for the commercial segment, whether the ad was prescription or nonprescription, and the advertised brand of product, (i.e. 966262\_RX\_Lipitor.mp4, 899234\_OTC\_Advil.mp4).

#### 4.4 Identification of the Major Claim

Each advertisement can contain one to many advertising claims and each claim may be true, misleading, or false. But before claims may be categorized, they must all be identified and some or all of the claims selected for further analysis. Three options were possible for this analysis: analyze all of the claims, one randomly selected claim or one important claim in the advertisement. It was not feasible to analyze all of the claims in the advertisement, since this would be too time consuming for a project of this scope. The most important claim was analyzed instead of a randomly selected claim, because the most important claim was likely to be the point that the advertiser was trying to make in the advertisement, and may be more likely to be remembered by a viewer. Thus, the effects on consumers would be greatest since prominent claims are most memorable. A randomly selected claim may not have been memorable.

Each advertisement was unitized into individual claims, based on the methods of Shimp (1979), by identifying claim phrases that associated the brand with a significant.<sup>2</sup> The researcher then rated all claims in the advertisement on four emphasis characteristics: mode of presentation (audio or visual only, audiovisual, or a mix of audio-only, visual-only and audiovisual), count of repetitions or iterations of the claim, duration of the claim measured in seconds, and placement of the claim within the beginning, middle or terminal third of the ad. The measurement instrument is included as Appendix B. From these four emphasis characteristics, an overall emphasis index was calculated for each claim following the rubric in Appendix C. For each advertisement, the claim with the largest emphasis index score was selected as the major claim. If there were multiple claims with the same large emphasis score, then one of the claims with the largest emphasis score was randomly selected as the major claim. Examples of this evaluation are described in Appendix D and storyboards for some advertisements are included as Appendix E.

To evaluate the reliability of this measurement, ten percent of ads (N=17) were coded twice to establish intracoder reliability.

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<sup>2</sup>For example, the claim "Lipitor has been extensively studied for over 16 years," associates the brand Lipitor with the significant "extensively studied," Here significant is meant as an indicator, symbol or sign, not the statistical meaning.

#### 4.5 Categorizing Drug Products into Product Categories

Because there was no authoritative list of drug products within product categories that includes both prescription and nonprescription drugs, the coders categorized the drugs within the sample into categories based on approved indications and drug classes. See Table 4.1 for details on the categorization.

Table 4.1: Product Categories of Sampled Drug Ads.

<b>Class</b>	<b>Products</b>
Allergy	Claritin, Zyrtec, Omnaris, Nasonex
Alopecia	Rogaine
Alzheimer's Dementia	Aricept, Exelon
Analgesics and NSAIDS	Advil, Aleve, Bayer, Celebrex, Excedrin, Tylenol
Antidiabetics	Onglyza
Asthma/COPD	Advair, Singulair, Spiriva, Symbicort
Blood Thinner	Plavix
BPH/Enlarged Prostate	Avodart, Flomax
Cholesterol-Lowering	Caduet, Crestor, Lipitor, Trilipix
Cough and Cold	Alka Seltzer, Coricidin, Mucinex, Rubitussin, Theraflu, Vicks
Erectile Dysfunction	Cialis, Levitra, Viagra
Eye Products	Visine, Restasis
Gastrointestinal	Amitiza, Dulcolax, Miralax, Immodium, Gas-X, Philips
Heartburn	Tums, Pepcid, Nexium, Prilosec, Prevacid, Zantac
Immune Suppressant	Enbrel
Neuropathic Pain	Lyrica
Osteoporosis	Boniva, Evista, Reclast
Overactive Bladder	Toviaz, Detrol, Vesicare
Smoking Cessation	Chantix, Nicoderm
Sleep Aids	Ambien, Lunesta
Topical	Orajel, Lanacane, Cortizone, Preparation H, Cepacol

#### 4.6 Measurement Constructs

In each advertisement, for the major claim, we measured three constructs; the Preston's category for each claim, the characteristics of the claim, and the distractions surrounding the claim. The coding form is included as Appendix F.

### *Preston's Category of Claims*

The major claim within each advertisement was categorized in one of these five categories:

- Objectively True Claim: A claim that presented a brand significant fact and all other facts that would effect consumer decision-making.
- Selected Facts Claim: A claim presented a brand significant fact, but omitted important facts about the drug or the competitor's drug that would affect consumer decision-making.
- Minimal Facts Claim: A claim presented a brand fact, but exaggerated the importance of the fact, promoting the brand fact as significant when it is not.
- Nonfacts Claim: A claim presented a true fact, but a fact that is not about the drug. Often these claims were in the form of puffery, opinions or nonbrand facts.
- False Claim: A claim that was objectively false by directly contradicting evidence, or lacking any evidence to support it.

The categorization scheme was based on the typology of Preston (1994), on review of previous decisions made by FTC and FDA, and on previous research on false and misleading advertising.

The major claim in each advertisement was classified into one of the five categories within Preston's typology based on the Decision flowchart in Figure 4.1. To answer the key questions (in the middle column), content analysts reviewed a series of guiding questions to help answer the main question (See questions on the right of Figure 4.1). These questions came from reviewing previous research, FDA and FTC decisions, and the description of different types of claims in Preston's *The Tangled Web They Weave* (1994). In previous research on false and misleading advertising of drugs, there was a strong emphasis on fact-claim discrepancies and on the quality of studies supporting claims in advertising. These ideas generated questions to guide coders to identify false and minimal facts claims. Often false claims (as defined by FDA and FTC) were unsubstantiated or in direct contradiction to published evidence. This follows with research examining fact-claim discrepancies in medical journal advertising to physicians. Misleading claims, on the other hand, were often due to exaggeration on the part of the advertiser. Previous research on the quality of studies supporting

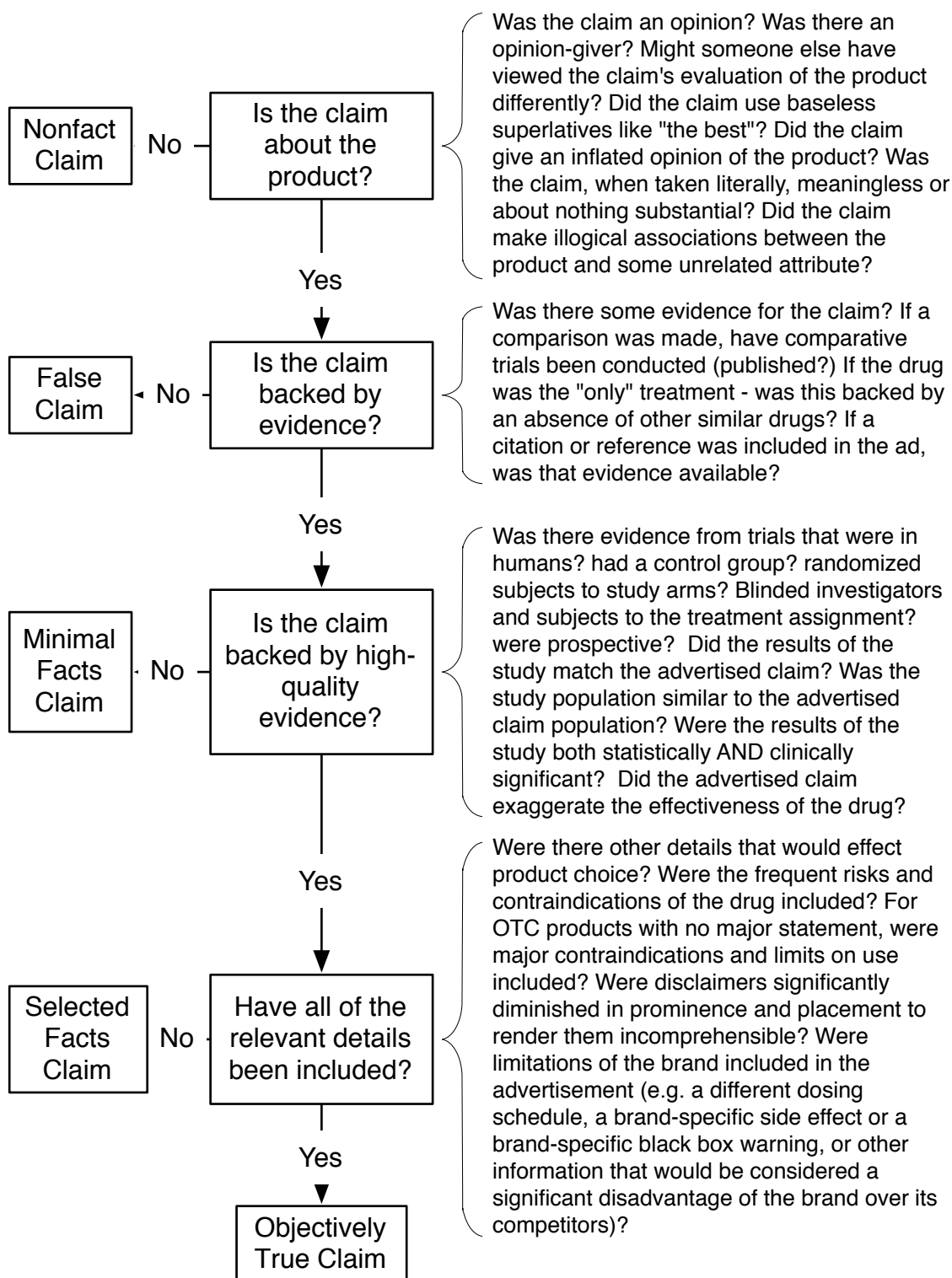


Figure 4.1: Decision Flowchart for Categorizing Claims into Preston's Categories

claims in drug advertising (Section 2.4) illustrated numerous ways that poor-quality evidence had been used in support of advertisement claims. Nonfact claims, especially opinions and nonbrand facts, were extensively described by Preston (1994), and that description, reviewed in section 2.7, guided development of questions to identify nonfacts claims. In addition, nonfacts claims, since these type of claims are not about the drug, don't require comparison against any evidence base. In developing the flowchart, nonfacts claims were identified first before the reviewer examined the evidence supporting the claim.

To help answer these questions the content analysts referred to a pre-determined body of evidence. If a systematic review of comparative effectiveness evidence was available from the Oregon Drug Effectiveness Reviews (DER) Project<sup>3</sup> then that summary served as the primary source of evidence for evaluating claims. If an Oregon DER was not available, the drug's FDA-approved label (for prescription products) or monograph (for nonprescription products) was used to compare claims. If a specific research study was identified or cited, the coders used PubMed database to search for the specific abstract and publication. Some nonprescription products were formulations of multiple drugs with multiple nonprescription monographs and, for these products, the coders searched the brand website, or reviewed the product packaging to get specific details on the formulation and inactive ingredients of the nonprescription drug.

#### *Other Deceptive Characteristics of Claims*

Other measures have been used to measure characteristics of claims in drug advertising, and previous research has associated a set of claim characteristics with false advertising. The specific items are described below.

Shimp (1979) categorized all claims in advertisements as either discussing attributes of the product (the car has a 6-liter engine) or benefits of the product (the car can drive zero to 60 mph in 6.1 seconds). The product must be used in order to experience benefits but attributes are properties of the unconsumed product. For drugs, most effects of the product, including side effects, are classified (by Shimp) as benefits, while characteristics of the competitive or regulatory market (the

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<sup>3</sup>Available online: <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/derp/index.cfm/>

only NSAID approved for tooth pain), and product formulation (long-acting capsule) are typical drug attributes. In addition to benefit or attribute, all claims are either objective or subjective. Objective evaluations of benefits or attributes are evaluated by all observers similarly and may be able to be proven (the car has a 6-liter engine, the car can drive 0 to 60 in 6.1 seconds) while subjective evaluations differ by the observer (the car has a powerful engine, the car can drive fast). Shimp (1979) associates truthful claims with claims that objectively evaluate product attributes while potentially false claims are claims that subjectively evaluate product benefits. Each major claim within the ad was classified as either an attribute or a benefit, and either objective or subjective.

The first research study to systematically evaluate truthfulness in drug advertising was conducted by Wilkes, Doblin and Shapiro (1992). In their study, they investigated five types of drug-specific claims in medical journal advertisements (see discussion of their methods above in section 2.4). These five types of drug advertisement claims were included in the instrument and coders were allowed to indicate if the major claim of the advertisement belonged to zero, one or more of the five categories. Their categories are described in Figure 4.2.

Table 4.2: Five Categories of Claims Specific to Drug Advertisements. From Wilkes et al. (1992).

Type of Claim	Description
The "Drug of choice" for at least one condition.	Recommended products. doctor/expert recommended. #1 prescribed. Top-selling. most trusted. "drug of choice"
More effective than another drug.	better, lasts longer, works stronger,
Effective in a broad range of patients (for example, different age groups)	"people everywhere..." "kids as young as 4" "now approved for [new patient group]"
Useful in a broad range of conditions and diseases	"now approved for [new indication]" list a series of symptoms.
Safe	"safe" "safer" "safety" "safest" "leaves the system quickly" "reversible" treatment

Stryer & Bero (1996) used indicators of "promotional materials" or "educational materials" when evaluating a whole range of advertising from pharmaceutical companies. Items that were relevant

to television advertising (e.g. "use of promotional prose") were included while items that were not relevant to television advertising (e.g. "use of multiple colors") were excluded. Coders indicated if the claim had one or more of these properties.

Table 4.3: Indicators of Promotional or Informational Advertisement Claims. From Stryer & Bero (1996).

<b>Indicator</b>	<b>Description</b>
Compares two or more drugs	A comparative claim will compare or contrast two or more products.
Is an advertising slogan	The claim is an ad slogan, or a short phrase in support of a product that often repeats in the ad.
Makes claims of popularity	The claim asserts the popularity of the product by mentioning the popularity of the product or the extent of use.
Numeric support	The claim is supported by statistical or numeric evidence. This includes "100 percent" to mean "all."
Scientific study or publication	The claim is supported by a reference to a scientific publication or to a research study.

### *Identification of Distractions*

The method for identifying distractions was based on a modification of an instrument that was developed based on Food and Drug Administration guidelines on provision of risk information in drug advertising (Food et al., 2009) and on a theory that distractions stem from changes and discontinuity in presentation of information (Harlow, 2010). In its prior implementation, the instrument was used to measure changes and discontinuity in presentation during the benefits presentation and risk presentation of prescription drug advertisements. For this research, the instrument was modified to measure changes and discontinuity in presentation before and during and after the major claim of the advertisement. The instrument was comprised of 13 questions about audio and visual presentation. See the codebook (Appendix G), and the coding sheet (Appendix F) for details on specific questions.

## 4.7 Reliability

The reliability for three constructs (identification of the major claim, categorization of the major claim, identification of distractions around the major claim) was measured separately. Table 4.4 provides details on measuring reliability for each construct.

Table 4.4: Reliability Measurement for Each Construct

<b>Identification of Major Claim</b>	
Measure	Iteration, mode of communication, duration of claim and placement within the ad for each claim among N claims within each ad.
Reliability Statistic	Cohen's $\kappa$ for discrete variables. Pearson's correlation coefficient (r) for continuous variables.
Content Allocation	Each ad will be coded by one coder.
Reliability Subset	10% overlap
Resolution of Disagreements	All disagreements were resolved using the first measurement.
Intracoder Reliability	10% of content will be coded twice by the same coder.
Minimum Reliability	"Excellent Agreement Beyond Chance" $\kappa > 0.7$ per the standards of Banerjee et al. (1999). Pearson's $r > 0.7$ for continuous variables.
Low Reliability Plan	Revise training manual, retrain and recode.
<b>Classification of Major Claim</b>	
Measure	Categorization of major claim into one of five categories. The five categories are: Objectively True Claim, Selected Facts Claim, Minimal Facts Claim, Nonfacts Claim, Objectively False Claim.
Reliability Statistic	Cohen's $\kappa$
Content Allocation	Each claim will be assessed by two coders.
Reliability Subset	100% overlap.
Resolution of Disagreements	All disagreements were resolved through conference of coders.
Intracoder Reliability	20% of content will coded twice by each coder.
Minimum Reliability	"Excellent Agreement Beyond Chance" $\kappa > 0.7$ per the standards of Banerjee et al. (1999).
Low Reliability Plan	Revise training manual, retrain, and recode.
<b>Characteristics of Major Claim</b>	
Measure	Identification of claim characteristics associated with false or misleading advertising.
Reliability Statistic	Cohen's $\kappa$ Variables with low expected frequencies were adjusted using the methods of (Feinstein & Cicchetti, 1990; Cicchetti & Feinstein, 1990).

Content Allocation	Each claim will be assessed by one coders.
Reliability Subset	25% overlap.
Resolution of Disagreements	Disagreements between coders were resolved through conference of coders.
Intracoder Reliability	Not measured.
Minimum Reliability	"Excellent Agreement Beyond Chance" $\kappa > 0.7$ per the standards of Banerjee et al. (1999).
Low Reliability Plan	Omit variables with low reliability from the analysis.
<b>Distractions Around the Major Claim</b>	
Measure	Identification of changes and discontinuities in content.
Reliability Statistic	Cohen's $\kappa$ for discrete variables. Variables with low expected frequencies were adjusted using the methods of (Feinstein & Cicchetti, 1990; Cicchetti & Feinstein, 1990). Pearson's correlation coefficient (r) for continuous variables.
Content Allocation	Each ad will be assessed by one coder.
Reliability Subset	25% overlap.
Resolution of Disagreements	Disagreements between coders were resolved with a third coding to break ties. Continuous variables were averaged.
Intracoder Reliability	Not measured.
Minimum Reliability	"Excellent Agreement Beyond Chance" $\kappa > 0.7$ per the standards of Banerjee et al. (1999). Pearson's $r > 0.7$ for continuous variables.
Low Reliability Plan	Omit variables with low reliability from the analysis.

For all constructs, coders were trained in the measurement and pretest reliability was evaluated using a convenience sample of ads that were not part of the study sample. The reliability for measuring repetition, mode of communication, claim duration, and placement was an intracoder (test-test) reliability. This decision was made because the major claim needed to be identified before the other measurements could be made. If a second coder had been involved in the evaluation, it would have involved a second extensive training session, measurement and resolution of discrepancies. Additional training for more coders was not feasible within the timeline for the research. Instead the primary investigator (AEF) recoded a 10% random subsample of all advertisements.

Because the identification of distractions and claim characteristics were previously used instruments, these measurement of reliability were the least strict. Each ad was only be coded by one coder, and 25% of content was coded by two coders to establish intercoder reliability. When reliability was low, variables were omitted from the analysis.

Categorization of claims had multiple reliability checks. Since the objectives of this study are dependent up on a reliable categorization of claims, and, due to the complexity of categorizing claims, this measurement process included additional steps to assess both inter- and intra-coder reliability. All claims were categorized by two coders. In addition, all of the ads within a drug class were assigned to the same two coders so that the coders would have less evidence they need to review. All of the randomly sorted ads were divided into batches of 20 ads, and after coding a batch of ads, the coders had the opportunity to ask questions about the ads and the coding. Ten percent of the content was coded by each coder twice, once at the beginning of coding and once at the end. This intracoder reliability measurement established whether or not the measurement was consistent across the period of coding.

#### **4.8 Coder Training and Coding**

The three coders were third-year pharmacy students from the University of Wisconsin-Madison. Third-year pharmacy students were purposefully selected since these students had previously taken two to three semesters of coursework on prescription and nonprescription drugs including method of action, side effect profiles and contraindications. Therefore, the students could rely on their training when evaluating advertisements, but were not yet considered "experts" in pharmacotherapy. Coder training was conducted between November 2011 and January 2012. The first step in the training educated coders about the concepts of advertising substantiation and Preston's slippery slope of claims. The coders reviewed broadcast and print drug advertisements from a convenience sample of current magazines and recent television. Coders also reviewed notable advertisements that were cited by FDA and FTC as being false or misleading. Next, the coders were trained on the specific coding instrument and were guided through coding multiple advertisements. As the coders become more familiar with the instrument, the codebook was extensively revised to clarify definitions, incorporate examples and note exceptions. In the third step, each coder independently coded a sample of prescription and nonprescription drug advertising (not part of the research sample of advertising), and pretest reliability estimates were calculated.

In pretesting, there were a handful of variables with poor reliability, and there was additional

training on these specific variables. In addition, discussion with coders identified that major disagreements among coders as to the Preston category of the major claim were originating with different interpretations of the meaning of the major claim, not from an analysis of the evidence supporting the major claim. Therefore, to improve reliability, the coding process for analyzing the Preston category of the major claim was revised. In the original process, coders watched the ad, then coded the claims based on their personal interpretation of the meaning of the claim. We revised the procedure so that, before coding, all of the coders and the primary investigator (AEF) watched the advertisement and jointly agreed what the claim was stating. The coders specifically did not discuss the relevant Preston's category for the major claim, nor did they know the advertisements they would be assigned to code.

After the first pretest and retraining, a second pretest on a new convenience sample of ads ( $n=10$ ) was conducted to confirm that retraining improved reliability. Reliability in the second pretest was markedly better, or showing strong signs of improvement, so training was concluded and content coding began.

The coding process included multiple checks to assure continued reliability and reduce coder fatigue. To reduce systematic bias that could be introduced by coder fatigue or improved reliability with repetition, coders were presented with the advertisements for coding in the same random order, mixing nonprescription and prescription ads across all time strata. To reduce coder fatigue, coders worked, at most, four hours per day on coding, at most, 50 minutes of every hour and took regular breaks. Coders were instructed to eliminate all environmental distractions including computer pop-ups, cell phone ringers and background noise. Coders worked at a computer to watch content, to enter coding information into electronic coding sheets, and to access reference materials. As described above, the ads were split into 20-ad batches, and at weekly coder meetings, the coders reviewed questions that came up during coding the previous batch of ads, and reviewed the next batch of ads to clarify the interpretation of the major claim. If coders had questions about coding, they discussed the issue with the primary investigator (AEF). If the decision was relevant to other ads, then the discussion was shared with the other coders.

In two advertisements the coders were unable to code the claim based on the information

presented in the ad and the references made available. The first ad presented a complex argument about how Trilipix (fenofibric acid) was able to increase HDL while lowering overall cholesterol. The major claim of the ad was, "Trilipix. There's more to cholesterol." In the second case, an advertisement for Celebrex (celecoxib) contained the major claim, "Understand the risks. Feel the benefits." In both of these cases the claim language was vague and did not discuss specific qualities of the product. To better interpret these claims, we solicited the opinion of two additional reviewers, one Pharmacy faculty member (DK) and one practicing pharmacist and Pharmacy PhD graduate student (KK) for their opinions, as educated consumers, what these claims meant. Eventually, we settled on meanings for the claims and the coders were able to categorize the claim.

After coding and measuring final reliability, disagreements between coders were resolved either through conference to determine the correct coding (Preston's category and claim characteristics) or by having a third coder (AEF) break ties by coding the variables with disagreements (distractions).

The coders used electronic coding forms and use of these forms substantially improved the overall research process. Use of the Qualtrics system helped to decrease data entry errors, eliminate paper-to-computer data entry, and speed up coder performance. The Qualtrics online survey software was modified to allow the coders to use the system for content analysis instead of survey research.

- The coding sheets were programmed as surveys with multiple choice and fill-in-the-blank responses for the questions (See Appendix F).
- Questions were linked to the codebook, so when coders had a question they could quickly refer to the codebook and return to coding.
- Question interdependencies were programmed into the form to assure that dependent questions were answered correctly.<sup>4</sup>
- For each ad, the coder may not have to code all three constructs (claim characteristics, claim categorization, distractions) because of overlap of reliability subsamples. Therefore, the

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<sup>4</sup>For example, if one question asked "What tempo is the music?" the dependency programming would check to see the coder had answered "yes" to the previous question, "Is there music playing during the ad?"

system notified the coder of the constructs they would be coding and skipped the questions for constructs they didn't need to code.

- The forms were set up with placeholders in the questions to help tailor the question to the specific ad the coder was coding.<sup>5</sup>
- Unique hyperlinks were generated for each coder and each ad. The coder would click on the unique link and the web form would open in the web browser. The form would be pre-populated with information on the ad, the constructs to code, and the questions would be tailored to that ad. Qualtrics calls this "passing embedded variables."
- The online survey system kept track of the time that it took to complete each survey, resulting in precise measurements of the coding duration for each ad and each coder.
- If coders made a mistake that needed to be corrected, the Qualtrics system could generate a retake link, that would allow them to go back into the form and make the correction. The Qualtrics system kept track of the changes to their responses in the background.
- The last questions of the survey asked how confident the coder was with their responses and if the coder wanted to discuss their responses with the investigator. If the coder was unsure of their coding or if they indicated they wanted to discuss the coding with the investigator, the Qualtrics system immediately sent an email to the investigator that included details of the ad and the question from the coder. See an example in Appendix H.

#### 4.9 Sample Size and Power Analysis

This sample size was driven by the ability to detect a difference in the proportions of prescription and nonprescription drug ads with claims within each category (5) of Preston's typology. The main objective was analyzed using chi-square test of independence, so a rudimentary power analysis was conducted based on the degrees of freedom of the statistical test and a range of effect sizes (Zar,

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<sup>5</sup>For example, the question may read, "Count the number of words on the screen between seconds X and Y before the major claim," and placeholders would be filled with specific information on the ad to read, "...between seconds 16 and 21..."

1999, p 486-500). This power analysis of the chi-square test was based on the degrees of freedom (5-1=4), possible effect sizes, Type I error level (0.05) and desired power of the test. Three different power calculations were computed for small, medium, and large effect sizes, approximately 10, 25, and 50-percentage point difference in the proportion of ads with a false or misleading claim (See Table 4.5).

Table 4.5: Estimated Sample Sizes to Achieve Expected Power for Different Effect Sizes.

Expected Power	Effect Size		
	Small (10%)	Medium (25%)	Large (50%)
Low (0.7)	969	155	39
Medium (0.8)	1194	191	48
High (0.9)	1541	247	62

Per the power calculation table above, a sample size of 155 would have allowed for the power to detect medium and large differences in the ratio of claims in prescription versus nonprescription advertising with acceptable power. Since the sampling plan called for 12 quarters–worth of data and equal numbers of prescription and nonprescription ads, the sample size was adjusted upward to 168, allowing seven prescription and seven nonprescription ads per quarter for 12 quarters.

#### 4.10 Statistical Analysis

Descriptive statistics were used to summarize the sample characteristics, and emphasis characteristics for each claim within each drug ad. A separate analysis was planned for each research question.

Research question one asked if there are differences in the frequency of true, "grey area" and false claims in prescription and nonprescription drug advertising. To analyze this question the frequencies of objectively true, selected fact, minimal fact, nonfact, and false claims were compared between prescription and nonprescription drug ads using a chi-squared test of independence. Post-hoc comparisons were made using the Bonferroni method to control for inflation of the Type I error rate. Post hoc comparisons included comparing the frequency of each type of claim between prescription

and nonprescription ads, comparing true, "grey area" and false claims, and comparing "grey area" claims versus all other types of claims.

Research question two asked if the major claims in prescription and nonprescription drug advertisements are associated with distractions before, during and after the claim was presented. Descriptive statistics were used to summarize the different types of distractions found before, during, and after the major claim in the advertisements. A composite "distraction index" was calculated from the results of the distraction instrument (see the calculation rubric in Appendix I). Because of differences in the duration of each period before, during, and after the major claim, the variables that were counts of words, characters and cuts were adjusted based on the duration of the period. Therefore, in the distraction index, points were allocated for words per second, characters per second and cuts per second. For statistical analysis, the index was transformed to a normal variable by taking the square root of the value. A twoway ANOVA (type versus distraction) with repeated measures (distraction index measured before, during and after the major claim) was used to analyze differences within each prescription and nonprescription advertisement. Post-hoc Wald tests were used to compare means during each time period, and between prescription and nonprescription ads at each timepoint. When appropriate, Tukey's method of least significant difference was used to adjust for inflation of the Type I error rate.

Research question three asked if distractions are more likely to be presented before, during, or after "grey area" and false claims, and are there differences in frequency of distractions before true, "grey area" and false claims in prescription and nonprescription advertisements. A complex ANOVA with repeated measures, (two types of ads, five categories of claims, measured at three timepoints, predicting the distraction index) was conducted to evaluate the main effect of the type of ad, of the main effect for category of claim for each distraction at each timepoint. Post-hoc Wald tests compared means for each type of claim at each timepoint. When appropriate, Tukey's method of least significant difference was used to adjust for inflation of the Type I error rate.

## Chapter 5

### Results

#### 5.1 Sampling

As described in the methods, the study sample consisted of unique prescription and nonprescription drug advertisements aired during the same commercial break during the nightly news from 2008 through 2010. The sample plan called for selecting seven commercial segments per quarter for 12 quarters, for a total of 84 selected commercial segments, each containing one unique prescription and nonprescription drug advertisement.

In order to ensure there was no duplicate content in the sample, the investigator traveled to the VTNA in Nashville, TN and viewed the ad content before purchase. Overall, 309 advertising segments were reviewed to select 84 for the study sample. As sampling proceeded chronologically in sampling quarters, more additional segments needed to be viewed in order to find unique content. For the first quarter of 2008 (January through March), eight commercial segments were reviewed and seven segments were selected for the study sample. For the fourth quarter of 2010 (October through December), 48 commercial segments were reviewed in order to find seven commercial segments with unique ads.

When viewing the ads, some segments were invalidly included the sampling lists. These commercial segments were invalid because, upon viewing the ad, the advertised product was not a prescription or nonprescription drug.<sup>1</sup> Of the 309 reviewed commercial segments, 32 (10%) were

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<sup>1</sup>For example, the VTNA keyword "icy hot" was associated with a nonprescription mentholated rub, but also with a compression wrap, a type of medical device. Also, "philips" was a keyword frequently associated with a gastrointestinal nonprescription drug, but occasionally the advertisement was for "Philips colon health" a probiotic nutritional supplement.

invalid.

For the remaining 277 valid commercial segments that contained one prescription and one nonprescription drug advertisement, 84 were retrieved for the study sample and 193 were rejected. Most segments were rejected because they included ads that duplicated ads already retrieved for the study sample (n=160). The remaining segments were rejected due to recording errors on the VTNA broadcast (26 segments)<sup>2</sup> or superimposed text or images blocking the content of the ad (7 segments).<sup>3</sup>

The final study sample was comprised of 84 prescription and 84 nonprescription drug advertisements for 65 different brands of products in 21 product categories (Table 5.1). The most frequent brands were Aleve (nonprescription, 12 ads), Cialis (prescription, 10), Advil (nonprescription, 8), AlkaSeltzer (nonprescription, 8), Bayer (nonprescription, 7), and Plavix (prescription, 6). The most frequent product categories were NSAIDS (35 ads), cough and cold remedies (15), erectile dysfunction (14), asthma and COPD (12), heartburn (12), allergy (10), and gastrointestinal remedies (10). Prescription drug ads ranged in duration from 30 to 120 seconds, while OTC ads were shorter, either 15 or 30 seconds.

## 5.2 Identification of the Major Claim

For each advertisement, all positive product claims were identified and, for each claim, four different measures of emphasis were measured: iteration (repetition), mode of communication, claim duration, and starting point of the claim. Ten percent of all ads were recoded twice (n=17) to establish intracoder reliability for these measurements (See Table 5.2). All of the variable reliabilities met the threshold for inclusion so all of the variables were included in the analysis.

In total, there were 996 claims identified, an average of 5.9 claims per ad (range 1 to 14 claims). Table 5.2 summarizes these results. There were slightly more claims in prescription drug ads (6.4 claims per ad) than in nonprescription drug ads (5.4 claims per ad), however, given that the average

<sup>2</sup>For example, if an ad was the last in the commercial segment, there may be two or three seconds of the end of the ad cut off or misidentified as the beginning of the next program segment. Additionally, some broadcasts recordings had audio and video out-of-sync making content analysis impossible.

<sup>3</sup>For example, when there was a tornado watch in the Nashville area, the local broadcast affiliate would superimpose a radar map of the storm and warning text.

Table 5.1: Product Category, Duration, and Network for Advertisements in the Study Sample,

	Frequency			Column Percent		
	OTC	RX	Total	OTC	RX	Total
<b>Product's Drug Category</b>						
Allergy	6	4	10	7%	5%	6%
Alopecia	1	0	1	1%	0%	1%
Alzheimer's Dementia	0	4	4	0%	5%	2%
Antidiabetic	0	1	1	0%	1%	1%
Asthma/COPD	0	12	12	0%	14%	7%
BPH	1	2	3	1%	2%	2%
Blood Thinner	0	6	6	0%	7%	4%
Cholesterol	0	9	9	0%	11%	5%
Cough and Cold	15	0	15	18%	0%	9%
Erectile Dysfunction	0	14	14	0%	17%	8%
Eye Products	1	1	2	1%	1%	1%
Gastrointestinal	9	1	10	11%	1%	6%
Heartburn	11	1	12	13%	1%	7%
Immune Suppressant	0	1	1	0%	1%	1%
NSAIDS	33	2	35	39%	2%	21%
Neuropathic Pain	0	3	3	0%	4%	2%
Osteoporosis	0	8	8	0%	10%	5%
Overactive Bladder	0	7	7	0%	8%	4%
Sleep Aid	0	5	5	0%	6%	3%
Smoking Cessation	1	3	4	1%	4%	2%
Topical Analgesics	6	0	6	7%	0%	4%
<b>Total</b>	<b>84</b>	<b>84</b>	<b>168</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
<b>Duration</b>						
15	62	0	62	74%	0%	37%
30	22	6	28	26%	7%	17%
45	0	1	1	0%	1%	1%
60	0	68	68	0%	81%	40%
75	0	4	4	0%	5%	2%
90	0	2	2	0%	2%	1%
120	0	3	3	0%	4%	2%
<b>Total</b>	<b>84</b>	<b>84</b>	<b>168</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
<b>Network</b>						
ABC	39	39	78	46%	46%	46%
CBS	20	20	40	24%	24%	24%
CNN	2	2	4	2%	2%	2%
NBC	23	23	46	27%	27%	27%
<b>Total</b>	<b>84</b>	<b>84</b>	<b>168</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

Table 5.2: Emphasis Characteristics and Measurement Reliability for Claims in Prescription and Nonprescription Drug Ads.

	Prescription		Nonprescription		Reliability <sup>1</sup>
<b>Ad Population</b>					
Total Ads	84		84		
Total Claims	540		456		
Claims per Ad	6.4		5.4		
Range	2 to 14		1 to 12		
<b>Ad Duration</b>					
mean (s)	61.8		18.9		
range (s)	30 to 120		15 to 30		
SD (s)	15.3		6.6		
<b>Iteration</b>	N	%	N	%	r = 0.80
1	342	63	294	65	
2	99	18	81	18	
3	56	10	50	11	
4	35	6	15	3	
5	10	2	15	3	
6	.	.	1	<1	
<b>Mode of Communication</b>	N	%	N	%	κ = 0.78
Single Mode <sup>2</sup>	219	41	180	39	
Mixed Modes <sup>3</sup>	142	26	97	21	
Bimodal <sup>4</sup>	179	33	179	39	
<b>Claim Duration</b>	N	%	N	%	κ = 0.79
<2 seconds	242	45	289	63	
≥ 2 seconds	298	55	167	37	
Mean (s)	2.4		1.8		r = 0.91
Range (s)	0.25 to 8.4		0.3 to 8.9		
Standard Deviation (s)	1.5		1.1		
<b>Claim Starting Point</b>	N	%	N	%	κ = 0.97
Beginning	236	44	72	16	
Middle	198	37	197	43	
End	106	20	187	41	

<sup>1</sup> Reliability based on 10% of advertisements coded twice to establish intracoder reliability.

<sup>2</sup> Audio-only or visual-only

<sup>3</sup> A mix of audio-only, visual-only or audiovisual

<sup>4</sup> Audiovisual

prescription drug ad was three times longer (61.8 seconds) than the average nonprescription drug ad (18.9 seconds), the difference in claims was likely explained by the longer duration of prescription drug ads.

Each claim was evaluated for four different ways the claim could be emphasized. Most claims were stated only once (one iteration), while about a third of claims were repeated multiple times (two to six iterations). A single mode of communication, whether audio-only or visual-only was most often used to communicate claims and about a third of claims were communicated using both the audio and visual channels. In prescription drug ads, claims were about evenly split between being less than or more than two seconds. Nonprescription drug ads, on the other hand, more often had short claims, less than two seconds long ( $\chi^2=37.42$ ,  $p<0.001$ ).

The main difference in claim emphasis in prescription and nonprescription drug ads was when claims started. Figure 5.1 illustrates the distribution of claim start times in prescription and nonprescription drug ads. These histograms show two different distributions of start times in prescription and nonprescription ads. Prescription ads have a bimodal distribution where few claims start in the period two-thirds to three-quarters of the way through the ad. During this period was when the risks of the prescription drug often were being presented. In addition, there was evidence from this bimodal distribution that negative information in prescription drug ads was sandwiched between positive product claims. Nonprescription drug ads, on the other hand, exhibit a more skewed and normal distribution of claims where most of the claims start around an apex two-thirds of the way through the ad.

For each claim, a claim emphasis score was calculated based on the calculation rubric in Appendix C. Examples of calculations for specific advertisements are found in Appendix D. Table 5.3 summarizes the emphasis score for prescription and nonprescription drug ads. Overall, the claims in nonprescription drug ads were emphasized more than claims in prescription drug ads ( $t=-3.10$ ,  $p=0.002$ ).

From this emphasis score, the most-emphasized claim was selected for further content analysis and when multiple claims had the same high emphasis score, one claim (with a top emphasis score) was randomly selected for further analysis. In 29% of the ads ( $n=48$ ), there were two or more claims

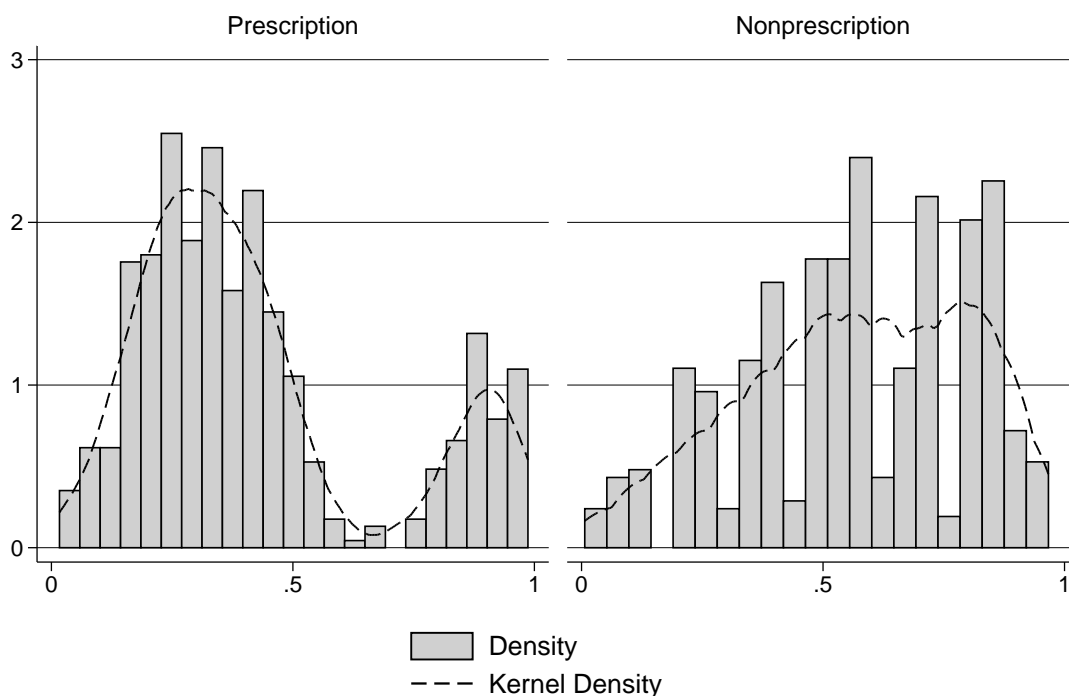


Figure 5.1: Distribution of the Start Times of Claims in Prescription versus Nonprescription Drug Ads. Because prescription ads are much longer than nonprescription drug ads, the x-axis was adjusted to display the time that the claim started as a portion of the ad. For example, if a claim started at second 5 of a 15 second ad, that would be 0.33 of the way through the ad.

Table 5.3: Emphasis Score for Claims in Prescription and Nonprescription Drug Ads

	<b>Prescription</b>	<b>Nonprescription</b>
Mean	6.9	7.2
Range	4 to 13	4 to 13
Standard Deviation	1.9	1.6

with the same top emphasis score.

### 5.3 Reliability

Variable reliabilities are summarized in Table 5.4. Some variables had poor reliability and needed to be dropped from the analysis. The tempo variables had poor reliability and poor agreement, hence were dropped. Additionally, a cluster of variables in the distraction construct<sup>4</sup>, were about transitions between time periods and had poor reliability. These variables were dropped from the analysis as well. However, these variables are necessarily difficult things to measure and they may add more information about the distractions. Therefore, the multivariate analysis was duplicated using these variables with poor reliability (Appendix J) to evaluate if dropping these variables influenced the results. In brief, it didn't have an effect.

A handful of variables had low reliability but high agreement, a phenomenon described in detail previously (Feinstein & Cicchetti, 1990; Cicchetti & Feinstein, 1990). In situations where the expected frequency of the positive case was much greater than the negative case<sup>5</sup> values of Kappa are artificially deflated. Cicchetti and Feinstein offer up an adjustment for Kappa for binomial variables and this adjustment was applied to the cases where agreement was high and reliability was low. Given the adjusted reliability was good, these variables were kept in the analysis.

### 5.4 Claim Characteristics

The first construct in the content analysis measured characteristics of the major claim that may be associated with false or misleading content. The major claim in each advertisement was categorized as objective or subjective, and as an attribute or benefit. Most claims were objective benefits (53%) followed by subjective benefits (27%), objective attributes (14%) and subjective attributes (6%) (see Table 5.5). There were no differences in the frequencies of these types of claims between prescription and nonprescription drug ads ( $\chi^2=2.21$ ,  $p=0.531$ ).

<sup>4</sup>Change in Voiceover during timeperiod, Change in voiceover leading into/just after major claim, Change in music leading into/just after major claim, Sudden sounds leading into/just after major claim

<sup>5</sup>For the variable "Relevance of the major claim to visual presentation" the agreement was 94.1% and  $\kappa=0.29$ . The discrepancy was due to the infrequency of the major claim being irrelevant to the visual presentation — only 3% of major claims were not relevant to the visual presentation.

Table 5.4: Final Reliability Measurements for Study Variables.

Variable	Percent Agreement	Reliability
<b>Claim Characteristics</b>		
Attribute or Benefit	100%	$\kappa = 1.00$
Objective or Subjective	87.9%	$\kappa = 0.88$
Drug of Choice	100%	$\kappa = 1.00$
More effective than another drug	.	n/a <sup>1</sup>
Useful in a broad range of diseases	.	n/a <sup>1</sup>
Useful for a broad range of patients	.	n/a <sup>1</sup>
Safe	.	n/a <sup>1</sup>
Comparative Claim	87.8%	$\kappa = 0.92^2$
Ad Slogan	87.8%	$\kappa = 0.89^2$
Makes claims of popularity	100%	$\kappa = 1.00$
Uses statistical or numerical support	100%	$\kappa = 1.00$
Cites a study or publication	.	n/a <sup>1</sup>
<b>Claim Categorization</b>		
Intracoder reliability	92.3%	$\kappa = 0.90$
Intracoder reliability	100%	$\kappa = 1.00$
<b>Distraction</b>		
Presence of voiceover or speaking actor	85.1%	$\kappa = 0.70$
Change in voiceover during timeperiod <sup>3</sup>	90.9%	$\kappa = 0.59$
Change in voiceover leading into/ just after major claim <sup>3</sup>	75.5 %	$\kappa = 0.44$
Presence of music	94.2%	$\kappa = 0.78$
Recognize the song	92.0%	$\kappa = 0.75$
Tempo of music (Categories of fast, medium and slow) <sup>3</sup>	44.1%	$\kappa = 0.20$
Tempo of music (beats per minute) <sup>3</sup>	.	$r = 0.34$
Change in music leading into/ just after major claim <sup>3</sup>	66.0%	$\kappa = 0.46$
Presence of other sounds	86.2%	$\kappa = 0.71$
Sudden sounds leading into/ just after major claim <sup>3</sup>	56.6%	$\kappa = 0.29$
Relevance of major claim to visual presentation	94.1%	$\kappa = 0.97^2$
Relevance of major claim to audio presentation	97.1%	$\kappa = 0.98^2$
Presence of text on the screen	97.7%	$\kappa = 0.99^2$
Words on the screen	.	$r = 0.96$
Characters on the screen	.	$r = 0.83$
Cuts in the scene	.	$r = 0.67$

Note: See Table 4.4 for description of reliability methods for each construct.

<sup>1</sup> Kappa was undefined because there is no variability in measurement.

<sup>2</sup> Adjusted per the methods of (Feinstein & Cicchetti, 1990; Cicchetti & Feinstein, 1990).

<sup>3</sup> The variable was dropped from the primary analysis.

Table 5.5: Categorization of the Major Claim Truthfulness, based on Shimp (1979).

	Frequency			Percent of N		
	OTC	RX	Total	OTC	RX	Total
Objective Attributes	13	11	24	15%	13%	14%
Objective Benefits	41	48	89	49%	57%	53%
Subjective Attributes	4	6	10	5%	7%	6%
Subjective Benefits	26	19	45	31%	23%	27%
Total	84	84	168	100%	100%	100%

Table 5.6: Characteristics of the Major Claim.

	Frequency			Percent of N		
	OTC	RX	Total	OTC	RX	Total
Drug of Choice	1	1	2	1%	1%	1%
More effective than another drug	3	0	3	4%	0%	2%
Effective in a broad range of patients	1	0	1	1%	0%	1%
Useful in a broad range of diseases	1	0	1	1%	0%	1%
Safe	.	.	0	.	.	0%
Comparative Claim	11	6	17	13%	7%	10%
Ad Slogan	8	13	21	10%	15%	13%
Makes claims of popularity	0	2	2	0%	2%	1%
Uses statistical or numeric support	0	2	2	0%	2%	1%
Cites a study or publication	0	1	1	0%	1%	1%
Total	84	84	168		n/a <sup>1</sup>	

<sup>1</sup> Totals do not add to 100% since the major claim may have more than one characteristic.

Other categories used previously to categorize major claims occurred infrequently (See Table 5.6). Occasionally, the major claim was an ad slogan (13% of major claims) or a comparative claim (10%). Comparative claims were more frequent in major claims in nonprescription drug ads than prescription drug ads while ad slogans were more frequent in major claims in prescription drug ads.

## 5.5 Claim Truthfulness

Based on the typology outlined in *The Tangled Web they Weave* by Preston (1994), each major claim was categorized into one of five truthfulness categories (Table 5.7).

Table 5.7: Truthfulness Category for the Major Claim.

	No.	%
Preston's Category		
Objectively True	55	33%
Selected Facts	19	11%
Minimal Facts	34	20%
Nonfacts	44	26%
False	16	10%
Total	168	100%

Of the five categories of claims, the most common was objectively true claims, but only 33% of claims were in that category: 66% of claims were potentially misleading or false. Of the potentially misleading or "grey area" claims, the most common were nonfacts claims (26%) that did not make a claim about the drug itself, but instead provided an opinion about the product or linked the product with a lifestyle. One in five claims were of the minimal facts type, wherein information about the drug was exaggerated and selected facts claims (11%) were least frequent. Examples of claims within each category are described in Figure 5.2.

## 5.6 Distractions

Different audio and visual components of the ad with the potential to modify the attention or cognition of the viewers were evaluated for the period before, during and after the major claim of each advertisement (Table 5.8). Note that there were 54 advertisements where the major claim occurred at the very end of the ad, meaning there was no time after the major claim to analyze distractions and the variables were not measured for the period after the major claim.

Distractions were measured in the visual and audio channels of the advertisement. The audio channel was divided into three parts: a speaking actor or voiceover, music, and other sounds. During the presentation of the major claim, most advertisements used a voiceover (69%) or speaking actor (25%) to convey information. After the major claim, use of voiceover (55%) or a speaking actor (14%) decreased while having no speaking actor or voiceover increased (10%). Music was audio sounds in the background of the ad that had a repetitive pattern and were uncoordinated with the

Category	Examples
Objectively True	<p>"Lyrica is the only approved treatment for Fibromyalgia." At the time the commercial was aired other products were used off-label to treat Fibromyalgia, but only Lyrica had obtained FDA approval.</p> <p>"Just 2 Aleve have the strength to relieve arthritis pain all day." There was substantial, high-quality evidence to show the 2-pill dose will relieve arthritis pain for 12 hours.</p>
Selected Facts	<p>"Once a Year Reclast" This claim, in context, does not equally convey that the product was an intravenous injection that was taken at the doctor's office.</p> <p>"Prevacid 24Hour is the same medicine but with a new location on the store shelf," omits that Prevacid 30mg was still available prescription-strength, so patients taking the higher dose would not get the same medicine.</p> <p>"Claritin Liquigels are new," The claim was correct that loratadine was recently reformulated into a liquid-filled capsule, hence was new to the market. The claim omits the fact that the product was identical to tablet Claritin that has been on the market for a long time.</p>
Minimal Facts	<p>"Bayer quick release crystals are ready to work faster than caplets or tablets." The formulation may dissolve quicker but it was not taken up by the body any faster nor will it relieve pain faster than other formulations.</p> <p>"Nothing works better than Prevacid" implies that Prevacid is superior to other heartburn remedies when, in fact, it is just as good as other heartburn remedies.</p>
Nonfacts	<p>"Move on up to Aleve," provides the advertisers opinion or recommendation on the choice of product.</p> <p>"AlkaSeltzer is the official cold medicine of the US Ski Team." Product endorsements like this one are the opinion of a famous or identifiable entity and do not say anything about the functioning of the product.</p> <p>"Help bridge the gap between the life you live and the life you want to live [by taking Enbrel]." This claim makes a vague lifestyle association between the product and the life "you want to live."</p> <p>"Levitra works for me. Maybe it can work for you," provides the opinion of the actor in the advertisement about the functioning of Levitra.</p>
False	<p>"Alkaseltzer crystal packs are a taste-free powder." Inspection of the inactive ingredients from the product label include both artificial flavor and sucrose. (See storyboard in Appendix E.)</p> <p>"Orajel worked. It worked 100%." The presentation of this claim implies evidence that the product completely relieves pain in all individuals that use the product. The evidence does not support this claim.</p> <p>"The difference between Advil PM and Tylenol PM is a better night's sleep." The specificity of this claim implied that specific head-to-head comparative evidence was available. No studies had been conducted comparing Advil PM (ibuprofen with diphenhydramine) versus Tylenol PM (acetaminophen with diphenhydramine), only studies comparing ibuprofen with acetaminophen. (See storyboard in Appendix E.)</p>

Figure 5.2: Examples of Claims within each Preston Category

action on the screen. Most ads included music (81%) and there was little change in music before, during or after the major claim. Rarely was the music recognizable (4% of ads). The recognizable music used in drug ads was, "Be My Baby" by the Ronettes (1963), "Viva Las Vegas" by Elvis Presley (1964), "Move on Up" by Curtis Mayfield (1971), and "Fanfare for a Common Man" composed by Aaron Copeland (1942). Other sounds in the ad were often noises corresponding with action on the screen or to emphasize transitions between visual elements.<sup>6</sup> Other sounds were often used before the major claim (46% of ads) but slightly less during (36%) or after (38%) the major claim.

Complexity in the visual channel of presentation was measured with a count of words on the screen, characters (actors) on the screen, and cuts in the scene. Very often (96%) ads included some words on the screen before, during or after the major claim. There were more words on the screen (13.3), characters on the screen (3.2) and cuts in the scene (1.7) in the period before the major claim than after the major claim (12.5 words, 1.3 characters, and 0.9 cuts). However, it was difficult to directly compare the periods before and after the major claim to the period during the major claim, since the period before and after the major claim was fixed at five seconds, but the period during the major claim varied from 0.5 seconds to 6.2 seconds, depending on the duration of the major claim.

From the observed distractions before, during, and after the major claim, an index of distraction was calculated to approximate the total amount of distraction during each period (see the calculation rubric in Appendix I). Like most additive index calculations, this distraction index was expectedly skewed, and was square-root transformed to become a normally-distributed variable. The mean, standard deviation, and range of the distraction index before and after square root transformation is summarized in Table 5.9 and visually summarized as histograms in Figure 5.3. All subsequent results are reported using the normally-distributed transformed distraction index.

On average, the distraction index was largest during the major claim, indicating that there was the most distraction during the major claim (illustrated by the "A" shape curves in Figure 5.4). A oneway ANOVA with repeated measures was conducted to evaluate if there were differences in the amount of distraction before, during, and after the major claim. The assumption of sphericity

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<sup>6</sup>For example, a star swoops around the logo for the drug then alights itself as the dot above the "i" in the brand name. In the background was the sound of a "whoosh" and then a "ding," both considered "other sounds" since they were corresponding to the action on the screen.

Table 5.8: Distractions Before, During, and After the Major Claim.

	Frequency				Column Percent			
	Before	During	After <sup>1</sup>	Total	Before	During	After	Total
<b>Is there a voiceover or speaking actor?</b>								
A voiceover	106	116	63	285	63%	69%	55%	63%
A speaking actor	20	42	16	78	12%	25%	14%	17%
Both	41	8	16	65	24%	5%	14%	14%
None	1	2	19	22	1%	1%	17%	5%
Total	168	168	114	450	100%	100%	100%	100%
<b>Is there music playing in the background?</b>								
Yes	135	137	93	365	80%	82%	82%	81%
No	33	31	21	85	20%	18%	18%	19%
Total	168	168	114	450	100%	100%	100%	100%
<b>Do you recognize the song?<sup>2</sup></b>								
Yes	5	4	4	13	4%	3%	4%	4%
No	130	133	89	350	96%	97%	96%	96%
Total	135	137	93	363	100%	100%	100%	100%
<b>Are there other sounds in the period?</b>								
Yes	77	60	43	180	46%	36%	38%	40%
No	91	108	71	270	54%	64%	62%	60%
Total	168	168	114	450	100%	100%	100%	100%
<b>What relevance does the audio presentation have to the major claim?</b>								
Relevant	.	163	.	163	.	97%	.	97%
Not Relevant	.	5	.	5	.	3%	.	3%
Total	.	168	.	168	.	100%	.	100%
<b>Is there text on the screen?</b>								
Yes	160	161	112	433	95%	96%	98%	96%
No	8	7	2	17	5%	4%	2%	4%
Total	168	168	114	450	100%	100%	100%	100%
Words on the screen (mean)	13.3	10.8	12.5	12.2				
Characters on the screen (mean)	3.2	1.1	1.3	1.9				
Cuts in the scene (mean)	1.7	0.8	0.9	1.2				
<b>What relevance does the visual presentation have to the major claim?</b>								
Relevant	.	156	.	156	.	93%	.	93%
Not Relevant	.	12	.	12	.	7%	.	7%
Total	.	168	.	168	.	100%	.	100%

<sup>1</sup>Total number of claims after the major claim equals 114, due to 54 claims occurring at the end of the ad, leaving no content to analyze after the major claim.

<sup>2</sup> Totals are based on the number of claims where there was music playing in the background.

Table 5.9: Distraction Index Before and After Square Root Transformation for Periods Before, During and After the Major Claim.

	Before	During	After	Total
<b>Distraction Index</b>				
Mean	6.4	9.1	5.7	7.2
SD	2.4	6.1	2.2	4.4
Min	1.2	1.0	0.0	0.0
Max	20.8	51.1	12.2	51.1
<b>Square root transformation</b>				
Mean	2.5	2.9	2.3	2.6
SD	0.5	0.8	0.5	0.7
Min	1.2	1.0	0.0	0.0
Max	4.6	7.2	3.5	7.2

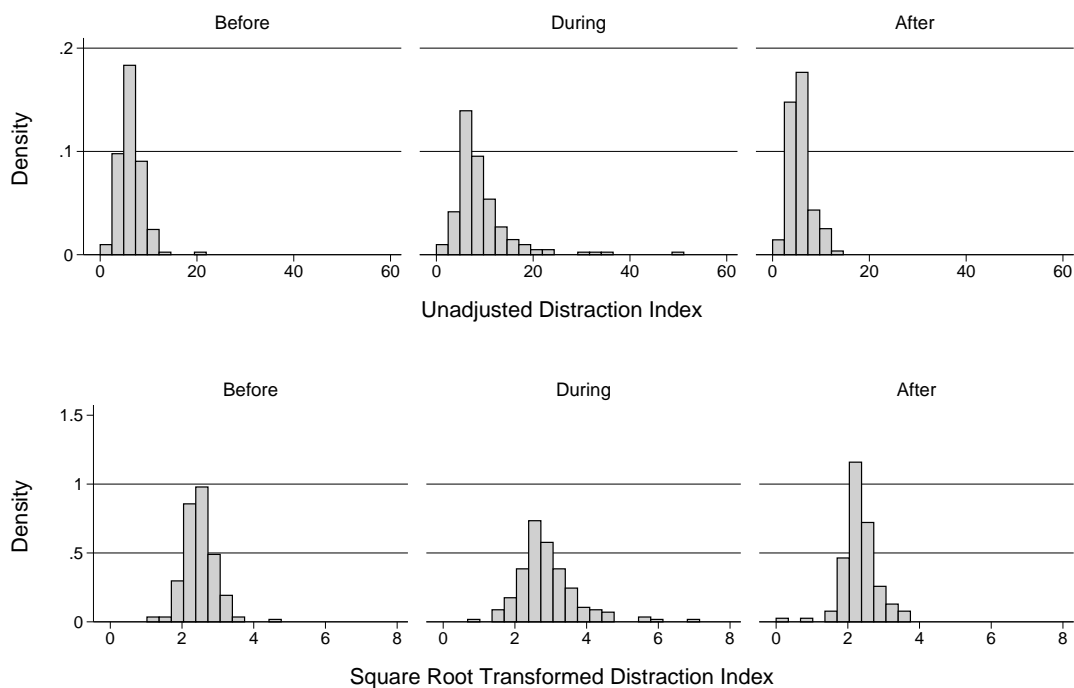


Figure 5.3: Histograms Describing the Distribution of Distraction Index Values Before and After Square Root Transformation for Periods Before, During, and After the Major Claim.

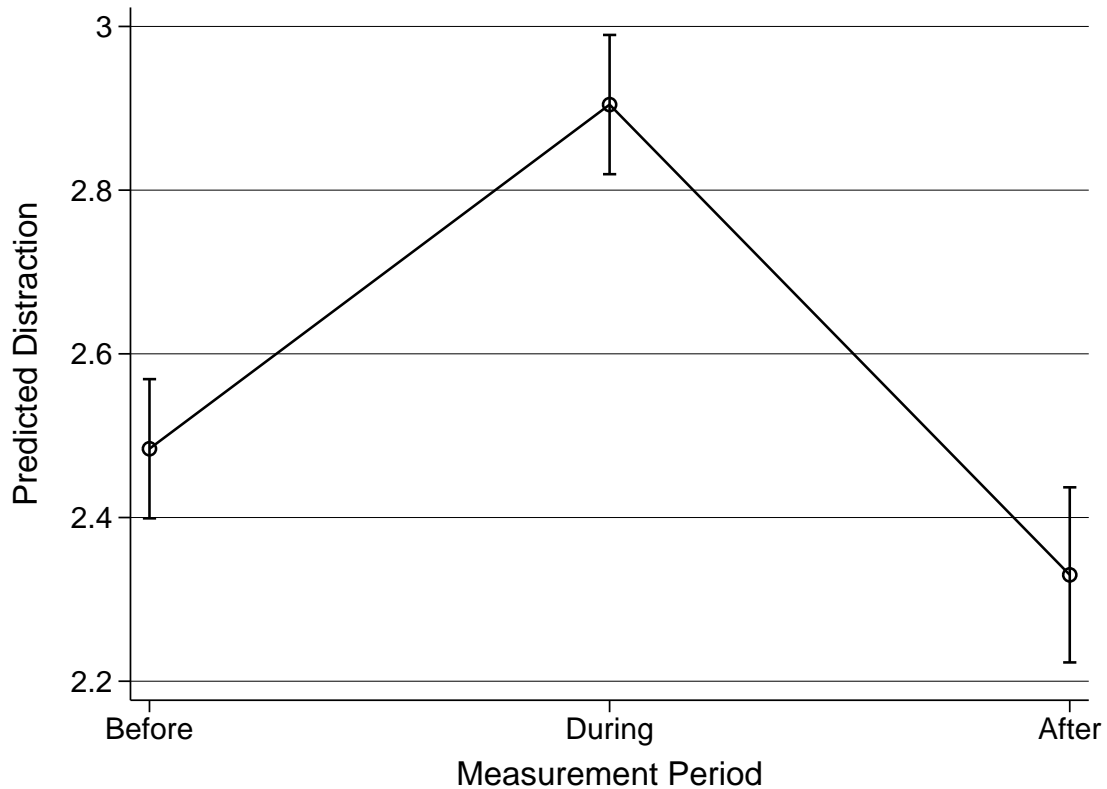


Figure 5.4: Distribution Index Before, During, and After the Major Claim. Bars indicate the 95% confidence interval on the predicted mean.

was met (Hyunh–Feldt Epsilon=0.85), and the variances within each cell were equal, according to Levine’s test ( $F(4,445)=0.41$ ,  $p=0.800$ ). The model was significant ( $F(169,2)=2.25$ ,  $p<0.001$ ), and post-hoc contrasts indicate that the mean distraction before the major claim (2.5 units) was significantly different from the mean distraction during the major claim (2.9 units,  $t=6.90$ ,  $p<0.001$ ), and the mean distraction during the major claim (2.9 units) was significantly different from the distraction after the major claim (2.3 units,  $t=-8.10$ ,  $p<0.001$ ).

## 5.7 Bivariate Relationship Between Claim Truthfulness in Prescription and Nonprescription Drug Ads

Three major variables have been discussed: the type of advertisement (prescription or nonprescription), the truthfulness of the major claim (objectively true, selected facts, minimal facts, nonfacts, or false), and the amount of distraction before, during, and after the major claim. The next set of four analyses will explore the bivariate and multivariate relationships among these variables. This section explores the relationship between the truthfulness of the major claim in the drug advertisement and the type of product advertised (prescription or nonprescription).

Comparing prescription and nonprescription drug ads, (Table 5.10) there were more objectively true claims (43%), and fewer false claims (2%) for prescription drug ads than nonprescription drug ads (23% objectively true, 17% false). There were similar frequencies of selected facts claims (8% of prescription ads, 14% of nonprescription ads), minimal facts claims (18% of prescription, 23% of nonprescription), and nonfacts claims (29% of prescription ads, 24% of nonprescription). Considering these results in another way, there were differences between prescription and nonprescription drug ads in the true versus potentially misleading versus false claims ( $\chi^2=14.51$ ,  $p=0.001$ ), and in true versus false or misleading claims ( $\chi^2=7.81$ ,  $p=0.005$ ). However, comparing just the frequency of misleading claims — all of the selected facts, minimal facts, and nonfacts together, there was no difference in potentially misleading claims in prescription versus nonprescription drug ads ( $\chi^2=0.61$ ,  $p=0.435$ ).

The study was powered to detect differences in the frequency of true, misleading, and false claims in prescription versus nonprescription advertising. The sample size of 168 was chosen to provide adequate power ( $>0.70$ ) to detect medium (0.25) to large (0.5) effect sizes. Post-hoc power analysis was conducted to calculate the observed effect size and observed power given a Type I error rate of 0.05, 5 degrees of freedom and a sample size of 168. The observed effect size was 0.3, a medium effect. The observed power of the  $\chi^2$  test was 0.87.

Table 5.10: Truthful, Misleading, and False Claims in Prescription and Nonprescription Drug Advertising.

	Frequency			Column Percent		
	OTC	RX	Total	OTC	RX	Total
<b>Preston's Category</b>						
Objectively True	19	36	55	23%	43%	33%
Selected Facts	12	7	19	14%	8%	11%
Minimal Facts	19	15	34	23%	18%	20%
Nonfacts	20	24	44	24%	29%	26%
False	14	2	16	17%	2%	10%
Total	84	84	168	100%	100%	100%
$\chi^2=16.40, p=0.003$						
<b>True claims vs misleading or false claims</b>						
True	19	36	55	23%	43%	33%
Potentially Misleading or False	65	48	113	77%	57%	67%
Total	84	84	168	100%	100%	100%
$\chi^2=7.81, p=0.005$						
<b>True vs Potentially misleading vs False claims</b>						
True	19	36	55	23%	43%	33%
Potentially Misleading	51	46	97	61%	55%	58%
False	14	2	16	17%	2%	10%
Total	84	84	168	100%	100%	100%
$\chi^2=14.51, p=0.001$						
<b>Potentially Misleading vs True or False Claims</b>						
True or False	33	38	71	39%	45%	42%
Potentially Misleading	51	46	97	61%	55%	58%
Total	84	84	168	100%	100%	100%
$\chi^2=0.61, p=0.435$						

## 5.8 Bivariate Relationship Between Distractions in Prescription and Nonprescription Drug Ads

Consistent with previous results, there was significantly more distraction in both prescription (2.9 units) and nonprescription ads (2.9 units) during the major claim (Table 5.11). Before the major claim, there were similar amounts of distraction in prescription (2.5 units) and nonprescription (2.5 units) drug ads, but after the major claim, prescription drug ads had more distraction (2.5 units) than nonprescription drug ads (2.2 units). A repeated measures ANOVA (before, during, and after the major claim) by type of advertisement (prescription or nonprescription) was conducted to identify

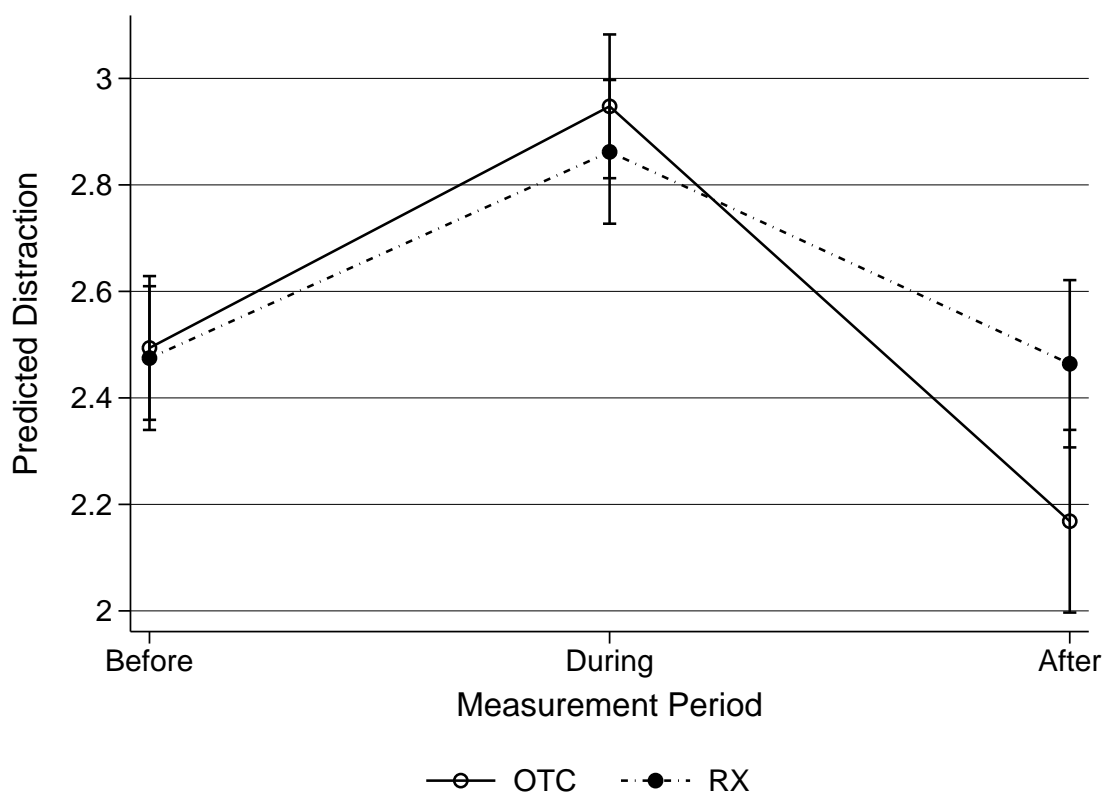


Figure 5.5: Distraction Before, During, and After the Major Claim for Prescription and Nonprescription Drug Ads. Bars indicate the 95% confidence interval on the predicted mean.

significant differences in mean distraction and interactions between prescription and nonprescription ads. The model fit was significant ( $F(5,444)=14.57, p<0.001$ ) indicating there were significant differences in the model. The assumption of sphericity was met (Hyunh–Feldt Epsilon=0.84) and the variances within each cell were equal, according to Levine’s test ( $F(4,445)=0.24, p=0.915$ ). There were significant differences in the amount of distraction in each period ( $F(2,444)=33.85, p<0.001$ ), and a significant interaction between type and period ( $F(2,444)=3.33, p=0.037$ ). Figure 5.5 illustrates the predicted distraction for prescription and nonprescription advertisements. There were differences in the amount of distraction between prescription and nonprescription drug ads only in the period after the major claim ( $F(1,444)=6.21, p=0.013$ ).<sup>7</sup>

<sup>7</sup>A post-hoc Tukey test was not necessary since the main contrast was comparing only two means, the mean distraction for prescription ads after the major claim versus the mean distraction for nonprescription ads after the major claim.

Table 5.11: Mean Distraction Index Before, During, and After the Major Claim for Prescription and Nonprescription Drug Ads

	<b>Before</b>	<b>During</b>	<b>After</b>	<b>Total</b>
OTC	2.5	2.9	2.2	2.6
RX	2.5	2.9	2.5	2.6
Total	2.5	2.9	2.3	2.6

The difference in the total amount of distraction (the distraction index) in prescription and nonprescription drug ads after the major claim doesn't reveal whether there was a difference in the degree of distraction, or a different type of distraction that contributes to the observed differences. Therefore, differences in the frequencies of different specific distraction elements in each advertisement after the major claim in prescription and nonprescription drug advertising were examined.

Comparing the different distraction variables in prescription and nonprescription drug advertising (Table 5.12), the only significant difference was in the use of music in the background of the advertisement. Prescription drug ads used music in 97% of all advertisements while nonprescription drug ads used music in 63% of advertisements. However, the frequency that music was used in prescription and nonprescription ads did not change before, during, and after the major claim of the advertisement (Table 5.13). Therefore, it is unlikely that use of music in the background of the ad was explaining the difference in the difference in the amount of distraction between prescription and nonprescription drug ads after the presentation of the major claim. Unfortunately, this sub-analysis only describes differences in the kind of distraction used, but not necessarily in differences in the degree that distraction was used. Both differences in degree and in kind may be contributing to the significant difference in the amount of distraction following the major claim in prescription and nonprescription drug ads.

Table 5.12: Differences in Specific Distraction Variables in Prescription and Nonprescription Drug Advertising After the Presentation of the Major Claim

	Frequency			Column Percent		
	OTC	RX	Total	OTC	RX	Total
<b>Is there a voiceover or speaking actor?</b>						
A voiceover	28	35	63	54%	56%	55%
A speaking actor	8	8	16	15%	13%	14%
Both	3	13	16	6%	21%	14%
None	13	6	19	25%	10%	17%
Total	52	62	114	100%	100%	100%
$\chi^2=8.80, p=0.032$						
<b>Is there music playing in the background?</b>						
Yes	33	60	93	63%	97%	82%
No	19	2	21	37%	3%	18%
Total	52	62	114	100%	100%	100%
$\chi^2=20.88, p<0.001^*$						
<b>Do you recognize the song?</b>						
Yes	1	3	4	3%	5%	4%
No	32	57	89	97%	95%	96%
Total	33	60	93	100%	100%	100%
$\chi^2=0.20, p=0.654$						
<b>Are there other sounds in the background?</b>						
Yes	22	21	43	42%	34%	38%
No	30	41	71	58%	66%	62%
Total	52	62	114	100%	100%	100%
$\chi^2=0.86, p=0.355$						
<b>Is there text on the screen?</b>						
Yes	50	62	112	96%	100%	98%
No	2	0	2	4%	0%	2%
Total	52	62	114	100%	100%	100%
$\chi^2=2.43, p=0.119$						
Words Per Second	2.14	2.79	2.50			
$t=-1.96, p=0.053$						
Characters per Second	0.21	0.29	0.26			
$t=-1.00, p=0.318$						
Cuts per Second	0.15	0.21	0.18			
$t=-1.36, p=0.176$						

\*Significant difference with an inflation-adjusted alpha of  $\alpha/8 = 0.006$ .

Table 5.13: Percent of Prescription and Nonprescription Drug Advertisements that Included Music in the Background Before, During and After the Major Claim.

<b>Ad Type</b>	<b>Before</b>	<b>During</b>	<b>After</b>
OTC	63%	67%	63%
RX	98%	96%	97%

## 5.9 Bivariate Relationship Between Claim Truthfulness and Distractions

Examining the differences in distraction over each period before, during and after the major claim for each level of truthfulness of the major claim revealed the same "A"-shaped pattern where distraction peaked during the major claim (Table 5.14 and Figure 5.6). Within each category of truthfulness, the same pattern applies: there were significant differences in the amount of distraction between the period before the major claim and during the major claim, and there were significant differences in the amount of distraction during the major claim and after the major claim. In all categories of truthfulness, the mean distraction was larger during the major claim than before or after it. A repeated measures ANOVA was conducted to evaluate if there were differences in distraction before, during or after the major claim for different levels of truthfulness of the major claim. The assumption of sphericity was met (Hyunh-Feldt Epsilon=1.37) and the variances within each cell were equal, according to Levine's test ( $F(4,445)=0.68$ ,  $p=0.604$ ). The overall model was significant ( $F(14,435)=5.69$ ,  $p<0.001$ ) indicating significant differences. As has been seen in the past analyzes of distraction, the main effect for period was significant ( $F(2,435)=29.52$ ,  $p<0.001$ ). There were significant differences in the amount of overall distraction across all three periods between different types of claim truthfulness ( $F(4,435)=2.48$ ,  $p=0.043$ ). The interaction of category over period was not significant ( $F(8,435)=0.60$ ,  $p=0.778$ ). Closer examination of the main effect of category reveals a weak linear decrease in the amount of distraction by truthfulness (Figure 5.7). Objectively true claims had, on average across all three time periods, 2.7 units of distraction, selected facts had 2.7, minimal facts had 2.6, nonfacts had 2.6, and false had 2.4. Pairwise Tukey comparisons of means show that the mean distraction (across all three time periods) for objectively true claims was significantly different than the mean distraction in false claims ( $t=-3.11$ ,  $p=0.017$ ). The standard deviations on these means were variable and the number of observations within each category were also variable, so more detailed analysis was not possible.

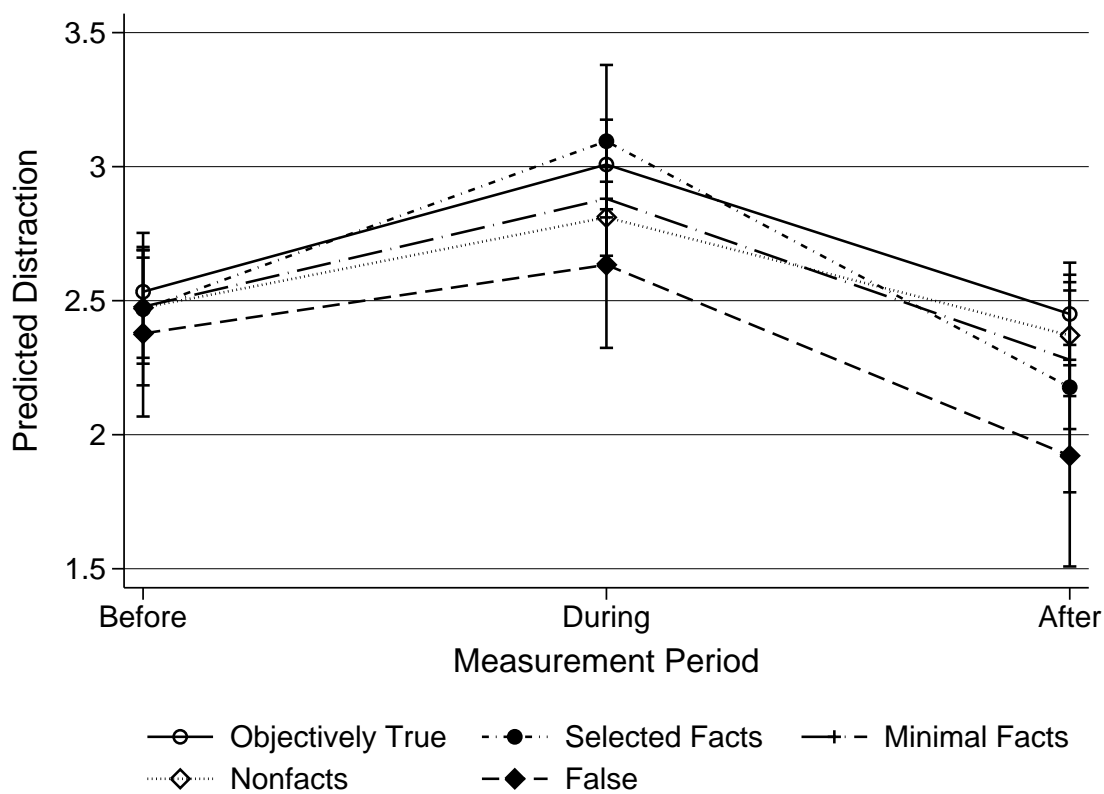


Figure 5.6: Distraction Before, During, and After the Major Claim for Categories of Truthfulness. Bars indicate the 95% confidence interval on the predicted mean.

Table 5.14: Mean Distraction Index Before, During, and After the Major Claim for Different Categories of Truthfulness

	Before	During	After	Total
Objectively True	2.5	3.0	2.5	2.7
Selected Facts	2.5	3.1	2.2	2.7
Minimal Facts	2.5	2.9	2.3	2.6
Nonfacts	2.5	2.8	2.4	2.6
False	2.4	2.6	1.9	2.4
Total	2.5	2.9	2.3	2.6

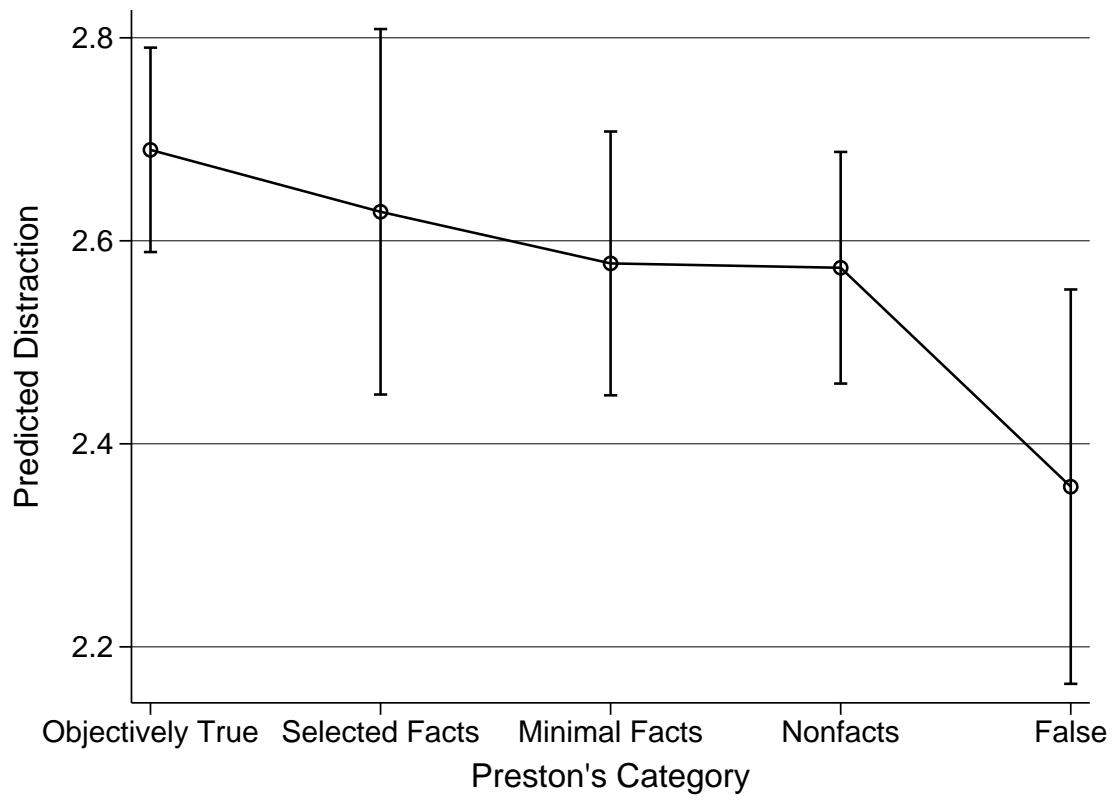


Figure 5.7: Predicted Distraction Within Each Category of Truthfulness.

### 5.10 Multivariate Relationship of Distraction and Truthfulness in Prescription and Nonprescription Drug Ads

Figures 5.8 and 5.9 provide a visual description of the predicted means and interactions. In nonprescription drug ads, the "A" shaped curves with less distraction before and after the major claim are consistent with previous analyses. However, for prescription ads, the false claims and nonfacts claims exhibit a different pattern. There were only two false major claims in prescription drug ads, resulting in large confidence intervals on the predicted mean distraction. However, in prescription drug ads, nonfacts claims exhibit a different pattern of distraction — an almost flat line, indicating constant amounts of distraction before, during, and after the major claim.

A three-way ANOVA with two between factors (category of truthfulness and type of advertisement), and one within factor (period before, during, or after the major claim) was conducted to evaluate differences between the amount of distraction and the truthfulness of the major claim, while separating out differences in prescription and nonprescription drug advertising. The assumption of sphericity was met (Hyunh-Feldt Epsilon=3.07) and the variances within each cell were equal, according to Levine's test ( $F(4,445)=0.84$   $p=0.498$ ). The model fit was significant ( $F(29,420)=3.45$ ,  $p<0.001$ ) indicating there are differences in the three-way model. There were overall differences in the mean distraction before, during, and after the major claim ( $F(2,420)=18.32$ ,  $p<0.001$ ) but not for type of ad ( $F(1,420)=0.03$   $p=0.871$ ) or truthfulness of the major claim ( $F(4,420)=0.82$ ,  $p=0.510$ ). None of the two- or three-way interactions were significant. Given that the main effect for period was significant, like in the previous models, the same "A"-shape pattern emerged, confirmed by Tukey pairwise t-tests comparing the mean distraction before, during, and after the major claim within the ten category-type combinations.

In addition to using Preston's categories to measure the truthfulness of claims in each advertisement, the relationship between Shimp's typology and distraction was reanalyzed in prescription and nonprescription advertisements. These results are found separately in Appendix K. In summary, using a different measure for deceptiveness of the claim, similar results were found where there was a weak, linear relationship between deception and distraction, with more truthful claims associated with more distraction before, during and after the claim.

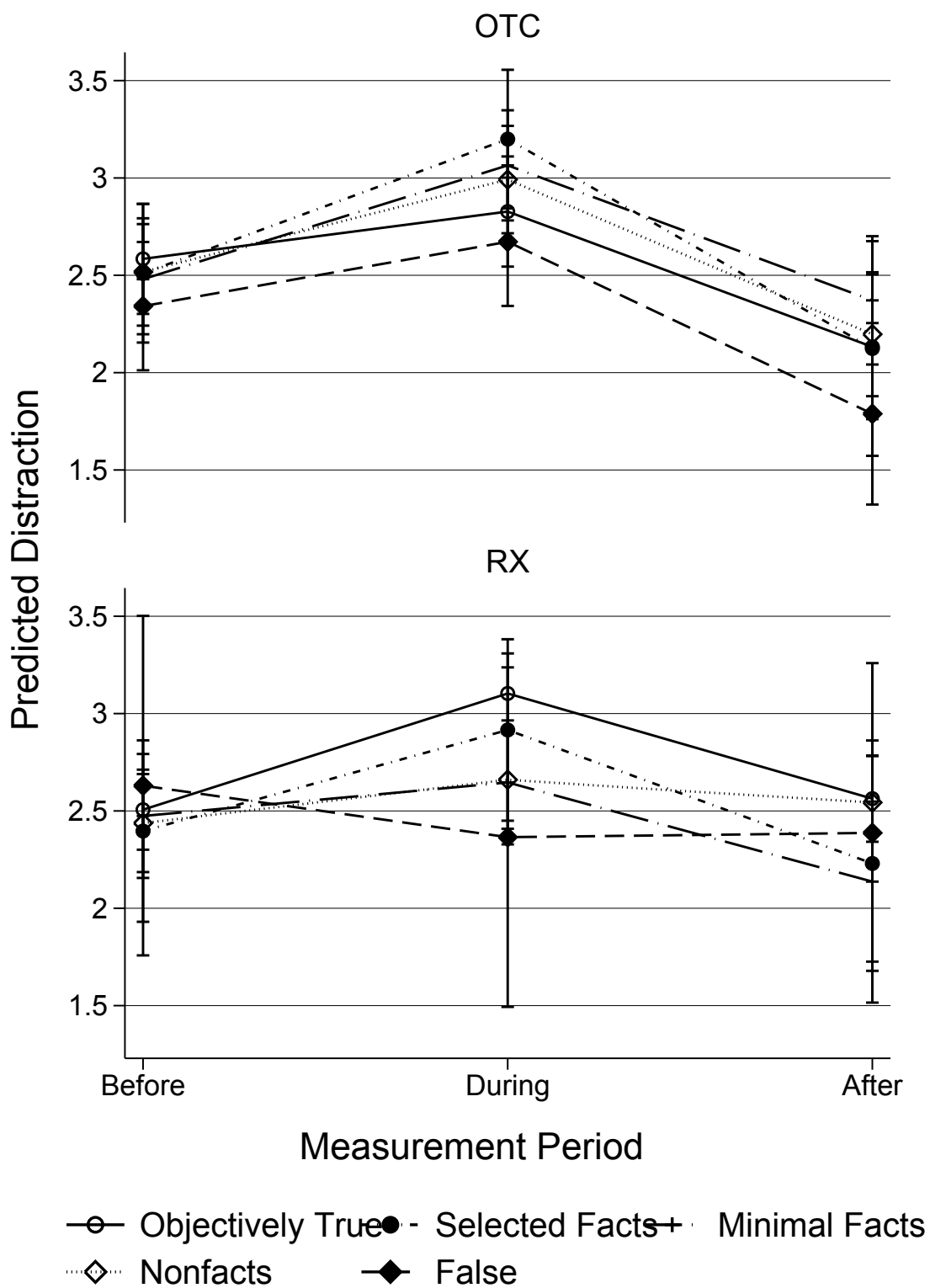


Figure 5.8: Distraction Before, During, and After the Major Claim, by Category of Truthfulness, for Prescription and Nonprescription Drug Advertisements. Bars indicate the 95% confidence interval on the predicted mean.

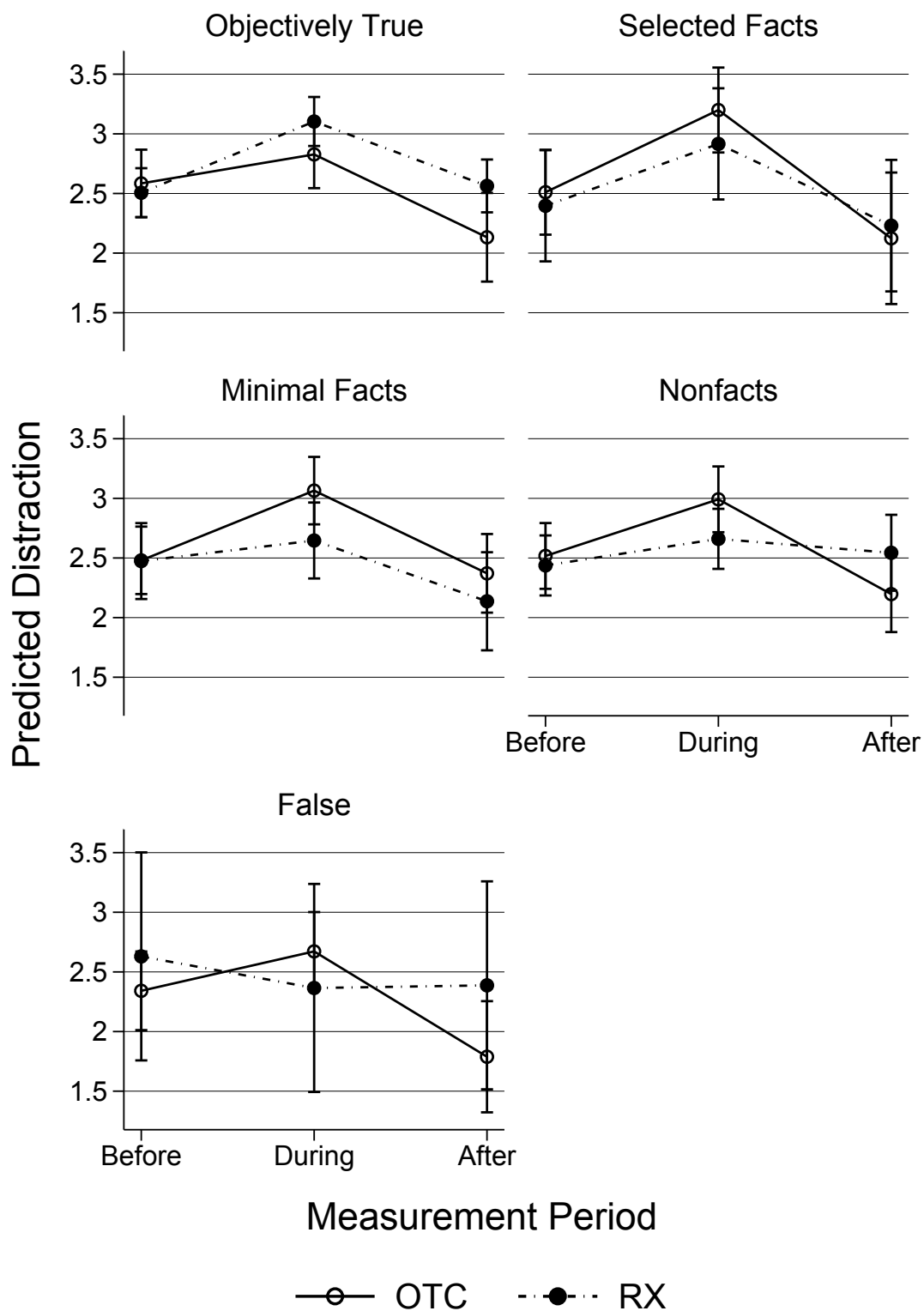


Figure 5.9: Distraction Before, During, and After the Major Claim, by Prescription and Nonprescription Drug Advertisements for Categories of Truthfulness. Bars indicate the 95% confidence interval on the predicted mean.

### 5.11 Summary of Results

The goal of this study was to evaluate the relationship between claim truthfulness and distraction in a sample of prescription and nonprescription television drug advertisements. Prescription drug advertisements had more objectively true claims and fewer false claims, compared to nonprescription drug ads. False claims were more frequent in the sample of nonprescription drug ads. However, misleading claims occurred with similar frequency in prescription and nonprescription advertisements. Overall, two thirds of the major claims in drug advertisements were potentially misleading to consumers by being objectively false, by exaggerating information, by leaving out important information, or by describing something other than the product.

Some elements that could potentially be distracting were frequently included in advertisements, including use of music, frequent shot changes, text on the screen, and off-screen voiceovers. There was more distraction in the period during the major claim of the advertisement than before or after the major claim. Prescription and nonprescription drug advertisements had similar amounts of distraction before and during the major claim, however, after the major claim, there was less distraction in nonprescription drug ads than prescription. There was a weak relationship between the overall amount of distraction before, during, and after the major claim and the truthfulness of the claim. However, in multivariate models describing the relationship between deception and distraction in prescription and nonprescription advertisements these relationships were not found. Overall, there was more distraction during the major claim than before or after it, regardless if the ad was for a prescription or nonprescription drug, or whether the claim was truthful, misleading or false.

## Chapter 6

### Discussion

In the previous chapters, I have outlined the rationale, conduct and results of a study to examine false and misleading advertising in consumer-targeted advertisements for prescription and non-prescription drugs. This study also examined use of distraction techniques in prescription and nonprescription drug advertising and if distraction techniques were associated with false or misleading claims in drug advertising. In this chapter, I will discuss the development of the measures and the results. I posed three research questions, and I will take the opportunity to answer these questions. Following that, I will address some strengths and limitations of this research. Last, I will consider the implications of these findings and ideas for future research.

#### 6.1 Methods

The instrument used in this study was the first time Preston's typology from *The Tangled Web They Weave* was adapted for use in content analysis. Previous studies had used expert review to analyze truthfulness of claims in advertisements. This study took a novel approach and trained coders to evaluate truthfulness of claims. I will discuss the development of the instrument, the advantages and disadvantages of content analysis methodology versus expert review methodology, and the use of experts in this study.

Preston's typology from *The Tangled Web They Weave* was modified for use as a content analysis instrument. To my knowledge, no previous study had used this typology to classify advertisement claims as objectively true claims, selected fact claims, minimal fact claims, nonfact claims or false claims. Some previous studies had evaluated puffery and opinions (types of nonfact claims)

(Simonson & Holbrook, 1993; VandenBergh et al., 1983; Robinson et al., 2004; Morris et al., 1989; Shimp, 1979; Richards, 1990) and factually false claims (Korenstein et al., 2011; Santiago et al., 2008; Othman et al., 2010; Cooper & Schriger, 2005, and others, reviewed in Section 2.4) but no previous research has evaluated false or misleading advertising claims using the same methods used here.

Preston's typology was only one of a few attempts to categorize claims in advertising based on truthfulness or deceptiveness. Preston based his typology on the motivations of advertisers and the actions of the Federal Trade Commission, but other scholars have based their typologies on research in consumer perceptions, deceptiveness, or information processing (Hastak & Mazis, 2011). Because this study was designed to evaluate differences in content stemming from differences in regulation and enforcement, Preston's typology allows me to draw inferences about the creators of content and the effects of regulations. Other theories would have facilitated inferences about the effects of misleading claims on consumers. Alternative typologies will be important when evaluating the potential effects of misleading advertising on consumers.

Operationalizing Preston's typology into a measurement instrument was a new aspect of this research. The instrument was developed from the theory presented in *The Tangled Web They Weave*, previous research in false or misleading advertising to physicians, and from review of recent decisions by FDA and FTC involving misleading advertising. The decision flowchart (Figure 4.1) and codebook description of categories (Appendix G) proved to be essential tools for evaluating claims.

The largest hurdle for reliable measurement was due to differences in the interpretation of claims, not in the categorization of the claim once the meaning was determined. Reviewing the meaning of claims was integral to our ability to reliably categorize the claims. Claims were difficult to analyze because the major claim often used words that were vague or encoded. Vague language was used to simplify medical terms or to evade using medical terms inappropriate for television.<sup>1</sup> Encoded language defined a term and used it throughout the ad.<sup>2</sup> The coders watched the ad and interpreted vague or encoded terms, so a vague and encoded claim like, "When the moment is right,

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<sup>1</sup>For example, ads for erectile dysfunction treatments used "be ready" as a euphemism for achieving an erection and ads for constipation treatments used "your body's natural rhythm" as a euphemism for regular bowel movements.

<sup>2</sup>"Better breathing" in steroid inhaler advertisements was used to mean the product worked fast and improved lung function.

you can be ready" was decoded to mean, "When presented with an intimate situation (the moment) using BRANDNAME can help the patient achieve an erection (be ready.)" The reason that this step was unexpected was because previous research in false or misleading advertising targeted to physicians did not discuss any coded language that made claims complex or difficult to understand. It was possible that physician-targeted ads contain vague or encoded language and that previous researchers may have considered these types of claims to be advertising slogans and did not try to analyze what slogans were saying about the product. Alternatively, vague and encoded language could also be unique to consumer-targeted drug advertisements.

Second, because of the technical nature of the evaluation in previous studies of false and misleading advertising for drugs, the original proposal included a panel of experts for the coders to consult for disagreements of scientific or medical fact. Ultimately, the panel was only used to interpret two of 168 claims. In these two claims, the expert panelists provided their opinions on the meaning of claims, rather than providing their expertise on scientific or medical fact. This was unexpected because previous research in false or misleading advertising in medical journal articles had included technical content. Instead, experts were asked to provide their opinions as knowledgeable consumers, to help decode complex claims. There are two possible explanations for why the expert panel was not more frequently relied upon to interpret scientific or medical fact. One, there may be more technical content in claims in physician-targeted versus consumer-targeted drug advertisements, so expertise was necessary to answer some questions of scientific or medical fact. Consumer-targeted ads may have less technical content and so expertise was not required to evaluate claims. Two, the prior training of the third-year pharmacy students who coded content may have been sufficient to answer all of the questions of scientific or medical fact. The technical content in claims in consumer-targeted drug ads warrants further study.

Last, previous studies that measured false or misleading advertising targeting physicians had used the consensus of experts to determine whether an advertisement was false or misleading (Wilkes et al., 1992; Sansgiry et al., 1999; Villanueva et al., 2003; Korenstein et al., 2011, and others). This study, on the other hand, used content analysis and trained coders to perform standardized measurements to reliably evaluate truthfulness of claims in advertisements. These two different

methods have advantages and disadvantages.

One advantage of using experts to review claims is, due to their expertise, experts don't need to be trained to make evaluations. The content analysts in this study were not experts, so they needed many hours of specialized training specific to the measurement instrument to compensate for their lack of expertise. On the other hand, previous studies using expert consensus to review claims needed many experts reviewing a few ads. Wilkes, Doblin and Shapiro (1992) used 109 experts, each reviewing one to three ads, while this content analysis study used only three coders, each reviewing around 80 ads. It's unclear if either study method is more cost-effective or results in greater validity, using a little time from a lot of experts, or using a lot of time from a few coders.

Expert evaluation studies relied on consensus of experts to determine if a claim was true or not in a process similar to peer review used in medical journals. A handful of experts reviewed the claim and independently evaluated the truthfulness of the claim. Then, if a majority of experts agreed the claim was true (or false), that was considered the consensus evaluation of the claim. A claim was true when a majority of experts said it was true. In using content analysis methodology, coders were trained on the measurement and their agreement was calculated. This type of agreement is different from expert consensus because, as part of the process of evaluating measure reliability, minimum thresholds for agreement were determined beforehand and the coders kept practicing evaluating claims until they met the threshold for agreement. In essence, coder training and measuring pilot reliability ensured the coders would always have consensus. The advantage with content analysis is that, after training, one coder could have evaluated each ad, reducing the amount of duplicate reviews. To evaluate distractions, each ad was coded by only one coder, with some overlap to confirm the agreement (reliability) was maintained throughout the coding process.

In expert evaluation, the criteria that experts use to review "truthfulness" of claims is based on their expertise. A physician, after gaining medical knowledge, medical training and experience practicing medicine, uses that knowledge, training and experience to evaluate an advertisement claim. Wilkes et al. (1992) used physicians who also served as peer reviewers for medical journals, assuring their experts had additional specialty knowledge in critiquing medical journal publications. In this study, the coders were third-year pharmacy students that received additional hours of

specialty training on how to evaluate claims in advertisements using the instruments developed for this research. The pharmacy students had basic knowledge of pharmacology and could use some of their knowledge to evaluate claims in advertisements. The additional training standardized the process they used to evaluate advertisements. In the expert review studies, the process that experts used to evaluate claims was not as transparent and the experts had no specialty training on the measurement instrument. The content analysis methodology ensured that the specific questions on the measurement instrument were understood in the same way by the coders. With expert evaluation, it is possible that, even though the experts agree, they may have different reasons for why they agree. With content analysis methodology, it may be more apparent what the coders are measuring.

Last, the process of developing a codebook, training coders and measuring their reliability helped to standardize the process of evaluating claims in advertisements. Another researcher could use the same codebook, provide similar training and determine acceptable reliability, and, in theory, come up with the same results as in this study. Content analysis provides better replicability than expert evaluation. Evaluation of experts, to some degree, is based on the sample of experts that participate as expert reviewers, so it's not clear that if a different group of experts were to evaluate the same advertisements they would come to the same consensus about the claims.

I have highlighted three interesting aspects of the development and implementation of the methods for this study. The methods of this study were unique because this study was the first time that Preston's typology had been used as a theoretical basis for a content analysis instrument, and because this study used trained coders instead of experts. Next, I will discuss the results of the study and answer the research questions posed in Chapter 3.

## **6.2 Research Question One: Are there differences in the frequency of true, misleading and false claims in prescription and nonprescription drug advertising?**

There were measurable differences in the frequency of true and false claims in prescription and nonprescription drug advertising on television. Prescription drug advertisements contained more objectively true claims (43%) and fewer false claims (2%), compared to nonprescription ads (23%

objectively true claims and 17% false claims). However, there were no observed differences in the extent that misleading claims appeared in prescription and nonprescription drug ads. Selected facts claims, minimal facts claims, and nonfacts claims occurred with similar frequency in prescription and nonprescription drug ads.

There have only been a small number of previous studies that have investigated false or misleading advertising for drugs targeting consumers. As discussed previously Sansgiry et al. (1999) studied 14 nonprescription print advertisements and demonstrated that, depending on the type of claim being made, 33% (Safety) to 71% (More effective than another drug) of claims were rated by reviewers as misleading. Although the methodologies were different, both this study and the previous study have demonstrated that there was some portion of advertisements for nonprescription drugs that were potentially misleading to consumers.

For prescription drug advertisements, claims most often were categorized as objectively true (43%), meaning these claims presented accurate information about the product without omission or exaggeration. However, less than a third of claims in nonprescription drug ads were objectively true (29%). Consumers should be able to make product choices based on an objectively true claim in nonprescription drug advertising without intervention from a physician or pharmacist. These results point to a potential problem where consumers viewing nonprescription drug advertisements may get complete information to make optimal drug choices in one in three advertisements. In the other two of three advertisements, omissions, exaggerations, meaningless associations and false statements can directly influence consumers' product choices and incorrect beliefs stemming from these claims may go uncorrected. Even though consumers often have the perception that nonprescription drugs are "safer" than prescription drugs (Droege et al., 2007), this does not mean advertisers for nonprescription drugs have less responsibility to provide truthful and not misleading information in their advertising.

About a quarter of claims in prescription (29%) and nonprescription drug ads (24%) were categorized as nonfact claims. These types of claims do not provide any information about the benefits or risks of the product. Instead, the claim associated the drug with a lifestyle or provided an opinion about the product. When consumers evaluate a drug, they evaluate both the benefits and

risks of the product, but also if the product is suitable for them. The inclusion of contraindications of the drug often define suitability of the product, (e.g. "Do not take DRUGNAME if you are taking MAOI inhibitors,"). This research has demonstrated that drug advertisements frequently are making lifestyle associations between the product and the intended consumer. Consider the claim from an Enbrel (etanercept) advertisement, "Help bridge the gap between the life you live and the life you want to live." This claim asserts that the product is suitable for individuals aspiring to live a different style of life, the "life you want to live." These types of lifestyle associations are used in advertising to target a specific audience with the message in the advertisement and have nothing to do with the medically-appropriate subpopulation of patients who should take the drug. The Enbrel claim is accompanied with visuals of a young woman walking out of her bedroom in her pajamas and into her kitchen fully dressed, to help feed breakfast to her young children. The implication is that the drug will provide some abstract health-related benefit, but also that the life "you want to live" includes caring for children and participating in family life.

Nonfacts claims may also be opinions from celebrities, unnamed actors, reputable professionals like physicians, or the advertiser. Although we did not measure the specific proportion of nonfacts claims that provided opinions, these claims were present in prescription and nonprescription drug advertisements. Consider the examples of an unnamed actor in a Levitra (vardenafil) commercial claiming, "Levitra worked for me. Maybe it can work for you," or when Sally Field, a famous actress claimed in a Boniva (ibandronate) advertisement, "Studies show that 9 of 10 women stopped their bone loss. I know I did [stop my bone loss]." These types of opinions are another form of meaningless claim that say nothing about the product itself, but instead provide the subjective evaluation of the product from the opinion-giver. The consumer is expected to identify with the spokesperson and consider their opinion a valuable assessment of the product. But the consumer may not consider the strong bias behind these opinions.

In the brief review of recent decisions by FDA and FTC (Appendix A), nonfact claims have not often been cited as false or misleading. FTC has established that puffery, a form of unsubstantiated superiority claim, and hyperbole, an extreme form of exaggeration are not misleading because consumers recognize these claims as rhetorical devices or figments of speech and not as claims

making substantive comparisons among products. In addition, FTC has made some decisions, outside of the area of drug advertising, to specify how paid spokespersons may be used in advertisements (like Sally Field, above) without deceiving consumers. These regulations generally state that spokespersons who are paid by a company to speak about the product must disclose they are receiving payment for their promotion and that actors cannot claim to provide professional opinions about products.<sup>3</sup> However, to my knowledge, there have been no decisions by either agency about whether the opinions provided by spokespersons or unnamed actors may, by themselves, be misleading to consumers.

False claims were rare in prescription (2%) ads but more common in nonprescription (17%) ads. These claims were blatant factual discrepancies or unsubstantiated claims. For example, AlkaSeltzer claimed the "fast powder packs," a reformulation of the product packaged like a packet of sugar and made to be stirred into hot drinks, was "taste free." However, both sucrose and artificial flavorings are listed as inactive ingredients of the product label. Dulcolax claims the product will "make yourself comfortable" while abdominal cramping and diarrhea were side effects in the majority of individuals using the product. Lanacane claims to be the "Every itch fighter" and specifically lists "poison ivy" as an itch treated by the product. However benzocaine, the active ingredient in Lanacane is explicitly contraindicated for use in poison ivy.

There were also a number of false claims that made strong associations between the product and an outcome that had not been tested in clinical investigations. For example a Gas-X advertisement portrayed a man fumbling through a job interview due to being distracted by the pain and discomfort of gas. During the interview, he takes Gas-X and, later, is shown smiling and shaking hands with the interviewer, demonstrating he has succeeded in impressing the interviewer. The claim "Gas X. Pressure's Off." was interpreted to mean both the literal interpretation that Gas-X will relieve gas discomfort, but also that relieving that discomfort will lead to better performance during the job interview. We could find no evidence to support the latter implication of the claim, hence it was judged as false. These claims made the general argument that if you take drug X it leads to outcome A. Outcome A is associated with even better outcome B, through indirect evidence. The consumer

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<sup>3</sup>This is why some advertisements will say "Physician depiction" when an actor is in character as a physician in an advertisement.

is led to believe if they take drug X, it will lead to outcome B, although there is no evidence of the connection between drug X and outcome B.

The last type of false claims were wholly unsubstantiated claims. For example, Advil PM ads make the claim, "The difference [between Advil PM and Tylenol PM] is a better night's sleep." The visuals depict a mock "sleep study" where two individuals take different pills, lay down in separate beds, and the person who took Advil PM is shown sleeping soundly while the person who took Tylenol PM is restless. This direct product-to-product comparison implies that there is evidence to support superiority of Advil PM over Tylenol PM. Detailed examination of the evidence for this claim found some studies comparing ibuprofen to acetaminophen, but no studies directly comparing the PM formulations (that include diphenhydramine). Some of the previous studies of false and misleading advertising targeted to physicians have taken the additional steps to contact drug companies for evidence that would support their claims. We opted not to contact the drug manufacturer and instead relied on published evidence. It makes sense for physician-targeted advertisements to contain promotional claims based on recently completed trials, internal company "data on file," or other unpublished evidence, since physicians need the most up-to-date information on drugs to make prescribing decisions. Consumer-targeted advertisements, on the other hand, ibuprofen and acetaminophen (for this example) are generically-available products and have been on the market for decades and nonprescription status for almost 30 years, in the case of ibuprofen.

False claims met the FTC definition for being false, as discussed above in Section 2.2. These claims either factually disagree with evidence or are unsubstantiated. Fortunately, false claims are not common, but regulations and enforcement actions by FDA and FTC are designed to eliminate these claims from the marketplace.

To answer research question one: Yes. There are differences in false and misleading claims in prescription and nonprescription advertisements. Prescription drug advertisements contain more objectively true claims while nonprescription drug ads contain more false claims. Both types of advertisements have equal numbers of potentially misleading claims: selected facts claims that leave out important details, minimal facts claims that exaggerate, and nonfacts claims that don't provide any information about the drug. Possible reasons for these differences are explained below

in Section 6.6.

### **6.3 Research Question Two: Are the claims in prescription and nonprescription drug advertisements associated with distractions before, during and after the claim is presented?**

In drug advertising, distraction techniques were frequently used in the periods before, during and after the most-emphasized major claim of the advertisement. In the periods around the major claim, ads frequently included music, text on the screen and used voiceovers instead of speaking actors. Often there was more than one character on the screen, and more than 10 words. The major claim itself was often presented with relevant visual and audio presentations. This means that the visual presentation and the audio presentation supported, rather than detracted from, the presentation of the major claim.<sup>4</sup> Unlike the use of background music or voiceovers, relevant visual and audio presentation are evidence of attraction - drawing attention toward - rather than distraction - drawing attention away.

Previous research has demonstrated a link between distraction and presentation of risk information in prescription drug ads (previously reviewed in Section 2.6). Commonly used techniques include rapid scene changes, animation and incongruous presentation of audio and visual information. This study demonstrated that these same techniques are also used during presentation of positive product claims within the advertisement.

After measuring specific distraction (or attraction) techniques, these variables were combined into a composite distraction index that indicates how much distraction (or attraction) is occurring during the period of measurement. Variables that were considered to increase the amount of distraction included use of voiceovers, music in the background, recognizable songs, other songs in the background, use of more words on the screen, more characters (actors, not letters) and more frequent cuts. Additionally, visual or audio presentation that was not relevant to the major claim was considered distracting. Analysis of this distraction index showed there was a peak in

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<sup>4</sup>For example, if an actor speaks the major claim while looking into the camera, both the audio (the speaking) and visual presentation (the actor's lips moving) are supporting and are relevant to the major claim. On the other hand, if a major claim is simply text on the screen, only the visual presentation is supporting the major claim.

distraction during the presentation of the major claim, and that before and after the major claim were lesser amounts of distraction. As will be discussed later, this pattern holds regardless of the type of advertisement (prescription or nonprescription) and whether the major claim was truthful, misleading or false. Some specific types of distraction were more frequently used during the major claim including use of voiceovers and more words superimposed on the screen.

As described above (Section 2.5, page 27), it is not clear if the distraction index is measuring intent to divert attention away from the major claim, or attract attention toward the major claim. This research demonstrated an association between positive benefit information in advertisements and use of attention modification techniques, casting doubt on the overall premise that identification of a handful of "attention modification" techniques in content analysis is sufficient to separate out use of attractors from distractors in advertisements. Unfortunately the content analysis measurement was not specific enough to distinguish between the two - nor was the instrument designed for that purpose. For convenience sake, I will continue to refer this measure the "distraction index" and describe it as a variable that measures the amount of "distraction."

Given the multiple contributions to a one point increase in the distraction index, there was a consistent pattern of higher distraction index values during the major claim of the ad. Certainly something is changing in the advertisement during the presentation of the major claim. Since only one claim in each ad was studied, it is unclear from these results how this increase in distraction relates to the amount of distraction throughout the ad (Figure 6.1). The peak could reflect an advertisement-wide peak in distraction simultaneously occurring with the presentation of the most-emphasized claim within the advertisement. This would provide a strong validation of the method for identifying the most-emphasized major claim. Additionally, it is possible that the amount of distraction before and after the major claim may be troughs, low points in the amount of distraction, and that the peak during the presentation of the major claim may reflect a return to "normal" amounts of distraction. In this case, the periods before and after the major claim represent times of little to no distraction. Without additional measurement, it is unclear if either interpretation is correct. An alternative plan to analyzing the most-emphasized claim in the advertisement would be to analyze a randomly selected claim in the advertisement. Analyzing a randomly selected claim,

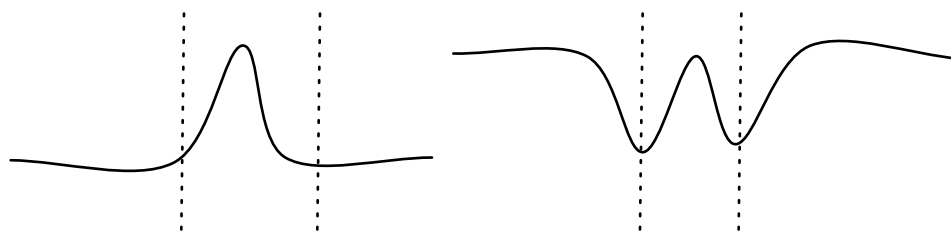


Figure 6.1: Two Interpretations of the Increased Distraction Before, During and After the Major Claim. On the left is the possibility that the peak is a true peak in the total amount of distraction throughout the advertisement. The right line illustrates how the major claim could be surrounded by two periods of little to no distraction.

in addition to the most-emphasized claim would provide a comparator to better understand if the most-emphasized claim is also the peak of distraction within the ad.

To answer research question two: There was frequent use of distraction techniques including voiceovers, music, and text on the screen before, during and after the major claim of each drug advertisement. An aggregated distraction index was found to be greater during the presentation of the major claim than before or after the major claim. The interpretation of this "distraction index" is difficult because the same measured techniques can be used to distract attention away from something or to attract attention toward it.

#### **6.4 Research Question Three: Are distractions more likely to be presented before, during, or after misleading and false claims? Are there differences in frequency of distractions before during and after true, "grey area" and false claims in prescription and nonprescription advertisements?**

Theory predicts that distraction techniques may be associated with deceptive claims in advertisements. Distraction may be used to reduce perception and cognition of deceptive claims so that consumers process claims quickly, making judgments based on heuristics and biases. Distraction may also suppress cognition leading to consumers avoiding systematic processing mechanisms that may reveal the deception. Heuristic processing of advertising results in general positive impressions, brand awareness and possibly emotional association. As discussed above, the same attention modifiers may be used to enhance cognition and to attract attention, leading to systematic

processing of truthful claims, greater information retention and more effective advertising.

This study examined the differences in distraction before, during and after the major claim and the deceptiveness of the major claim in prescription and nonprescription drug advertising. As was described in the section above, in all different analyses, there was more distraction during the major claim than before or after it - the "A" shaped curve. The "A" shaped curve was consistent when examining distraction around claims in prescription versus nonprescription ads, and in claims that were truthful, misleading and false.

When examining differences in distraction before, during and after the major claim in prescription and nonprescription drug advertisements, there was a significant difference in the amount of distraction after the presentation of the major claim. Prescription drug ads had more distraction after the major claim than nonprescription drug ads. These differences were due to prescription ads consistently including music before, during and after the major claim while nonprescription ads more often discontinued music after the major claim. The difference may be explained by the presence of the major statement of risks and contraindications in prescription drug ads. As Figure 5.1 illustrates, the positive claims in prescription ads are placed before and after the major statement of risks and contraindications. The observed differences in distraction in prescription drug advertisements may represent techniques used to separate the major statement of risks and benefits from the positive product claims.

In both prescription and nonprescription drug ads there is a weak association between the amount of distraction before, during, and after the major claim in an advertisement and the truthfulness of the claim. Bivariate analyses of the relationship between distraction and deception showed that more truthful claims were associated with greater amounts of distraction. However, in multivariate models this relationship was not significant. In addition to measuring deception using Preston's typology, deception for each claim was also measured using Shimp's typology wherein claims are either objective or subjective, and either describing a product attribute or benefit. This analysis also demonstrated the same weak linear relationship between more truthful claims and greater distraction.

As originally proposed, my hypothesis was that more distraction was associated with less

truthful claims, however the results showed more distraction was associated with more truthful claims. As discussed above, attention modification techniques may serve to both distract attention away from misleading claims, but may also attract attention to truthful claims. The positive association between truthfulness and distraction supports the latter hypothesis: drug advertisements contained attention modifiers to draw attention toward positive product claims that were more truthful and less misleading. For example, in many prescription ads, the major statement of risks and benefits was presented using a voiceover and occasionally superimposed text unrelated to the product claims (often the statements of internet URLs, telephone numbers and references to printed materials as part of the adequate provision statements). However, when the major claim followed immediately after the major statement, there was a shift to using a speaking actor and superimposed text to reinforce the major claim message (relevant visuals).

The weak relationship between deception and distraction may be because there is a weak relationship between the two variables, or may be because there were too few ads to make powerful comparisons. Further studies with more advertisements, more analyzed claims within each advertisement, and more observed distraction variables will all contribute to improving the ability to detect statistical differences in the relationship between deception and distraction.

To answer research question three: There are some differences in use of distraction in prescription and nonprescription drug advertisements, but the instrument used may not have captured enough types of distraction to give a complete picture of the differences. There is a weak association between deception and distraction: more truthful claims were presented with more distraction. These results point to a flaw in the measurement that measured attention modification techniques, but could not distinguish between attention modifiers that attracted attention toward something or distracted attention away from something. More refinement of the instrument is necessary to better measure the relationship between deception and distraction.

## **6.5 Strengths and Limitations**

In the body of literature on false and misleading advertising for prescription and nonprescription drugs, this study represents the first comparative study to quantify false and misleading advertising

for both prescription and nonprescription drugs. There have been few studies in this area and no comparative studies have previously been reported. Additionally, the study sample represents one of the largest samples of contemporary drug advertising aired on television. Further, this study successfully took a new approach to the analysis of false and misleading advertising. Previous studies had relied on consensus from experts to determine if the ads were false or misleading. This study, instead, trained coders with some knowledge of prescription and nonprescription drugs, and measured intercoder reliability rather than consensus to establish measure validity. Further research using these instruments will confirm whether or not this method is more replicable than expert review. Last, this was one of the first studies to theoretically tie together separate research in deception and distraction in drug advertising, and to evaluate deception and distraction in the same sample of advertisements.

The design and conduct of this study posed some limitations to the internal and external validity of this study. Before drawing conclusions about the research findings, I will discuss these limitations in detail.

The study sample was designed to maximize external validity while minimizing costs to obtain the sample. Theoretically, the study sample that would have provided the most external validity would be a random sample of all television advertising on all television networks during all parts of the broadcast day. While data of this nature are available from commercial vendors, the cost of obtaining a dataset is prohibitively expensive. Instead, data were obtained from the Vanderbilt Television News Archive. The VTNA only covers one thirty-minute period (the nightly news) on a handful of major networks. However, results from censuses of television broadcasts have demonstrated that the nightly news is a peak placement period for drug advertising (Brownfield et al., 2004). In addition, the nightly news is watched by an audience that is older than other television audiences, making the advertising slots during the nightly news a target for drug advertisers who want to reach older consumers who take more drugs. While these characteristics lead to more drug advertising during the nightly news, whether or not this may systematically bias the internal validity of the study is questionable. Potentially, since drug advertisers are competing for prime slots during the nightly news, high-quality advertisements would fill the available slots, limiting the

likelihood of low-quality, possibly misleading advertisements to be shown. Additionally, networks have a disincentive to air false or misleading advertising, since it may affect public perception on the quality of their broadcasting. If this is the case, assuming networks can evaluate the quality of advertisements and only select high-quality, truthful advertising, then there would be little to no false or misleading advertising during the nightly news, or any other period of the broadcast day. In both mechanisms, there are overall limits to the occurrence of false and misleading advertising, but neither of these effects would affect prescription or nonprescription advertising more. Sampling advertising during the VTNA may result in lower estimates of the overall incidence of false or misleading advertising, but would not affect the relative incidence of false or misleading advertising for prescription versus nonprescription drugs.

In order to halve the cost of the study sample, commercial segments were chosen for the sample that contained one prescription and one nonprescription advertisement. This sampling plan ensured that the prescription and nonprescription drugs were matched on broadcast characteristics like date, time and network. However, this procedure reduced the sampling frame down to only commercial segments that included one prescription and one nonprescription drug ad. These two-drug-ad commercial segments differed from the population of commercial segments in two ways: they more often appeared on ABC, rather than CBS, NBC or CNN, and were marginally longer (0.05 seconds) in duration. It is unclear if these sampling biases would affect the evaluation of the ads included in the segments.

In selecting the major claim of the ad, the most-emphasized major claim was analyzed instead of analyzing all claims or analyzing a randomly selected claim. This selection reduced coder fatigue that might have occurred with analyzing all 996 claims identified in the sample of 168 drug ads. The unintended effect of this method selecting a claim meant that the results are not directly comparable to prior studies that analyzed all of the claims in an advertisement.

Some distraction variables had poor reliability and were omitted from the analysis. The measurement of tempo of the music was poor and subsequent studies may reconsider novel methods to identify the tempo of the music in advertising. In Harlow (2010) and this study, neither were able to reliably measure the tempo of the music in the background of advertisements. Additionally,

reliability of identifying distractions leading into and just after the major claim may have been due to lack of precision of the start and end time of the major claim. Subsequent content analyses will benefit from use of video viewing software that can identify timepoints to the tenth of a second, rather than to a whole second.

In addition to poor reliability of some variables, the distraction instrument only measured the presence of a handful of common distraction techniques. There are other distraction techniques that were not measured and these nonmeasured distraction techniques may be more influential on consumers viewing an ad. In addition, there may be some attention modification techniques that are designed to attract the viewer's attention away from the environment and to the advertisement being presented on the television. These types of attention modifiers will strongly influence whether or not a consumer even sees the advertisement, let alone whether the consumer perceives and processes details within the ad.

In categorizing each claim as an objectively true claim, a selected facts claim, a minimal facts claim, a nonfacts claim or a false claim, the coding team first discussed the claim to determine the meaning of the claim. The coders were able to reliably classify the claim only after agreeing on the meaning of the claim. This added a degree of subjectivity in evaluation of the claims, and future studies using this method will need to determine how to standardize this process of clarifying the meaning of claims.

It is possible that measurement similarities in identification of the most-emphasized claim in the advertisement may be related to the identification of distractions before, during and after the most-emphasized claim. In selecting the major claim, each claim was ranked with one of four characteristics: repetition of the claim, mode of presentation, duration of the claim, and where the claim was presented in the advertisement. These characteristics may be related to the specific measurement of distraction before, during and after the claim. In identifying the major claim, claims were classified as being presented using audiovisual (dual-mode) communication, audio- or visual-only communication (single-mode) or a combination of these techniques (mixed-mode). In measuring distraction, there was not a specific variable to measure the mode of communication, however, in measuring whether the audio and visual presentation were relevant to the major claim

involved a different way of analyzing the modes of communication. An ad that had relevant audio and visual presentation to the major claim likely had audiovisual presentation of the major claim, an important measure of emphasis. Additionally, claims that appeared at the end of the advertisement were more emphasized than claims at the beginning of the ad. This increased the likelihood that claims would appear at the very end of the advertisement and there would not be distraction measured after the major claim.

Last, the design of the study resulted in the twoway and threeway ANOVA analyses having unbalanced designs, meaning there were different numbers of observations for each combination of type of ad, truthfulness of claims, and observations with each period before, during and after the major claim. Unbalanced ANOVA analyses are less powerful than balanced ANOVAs, so balanced designs are usually preferred. However, this analysis was not the primary analysis for the study, and so the study was not designed for more powerful balanced ANOVAs. Future studies that have distraction as the primary analysis can be designed to balance the number of claims within each category.

## **6.6 Implications of These Findings**

Some implications of this research on consumer deception were discussed above. Here, I will focus on how these results may guide policy changes.

One way to interpret the results of this study is that there is more truthful and less false advertising for prescription drugs. Conversely, the results could be interpreted as there is less truthful and more false advertising for nonprescription drugs. Therefore, FDA regulations could be effective in increasing the amount of truthful consumer-targeted advertising for prescription drugs, or FTC regulations could be failing to prevent false advertising for nonprescription drugs. It's unclear if either interpretation is completely correct. Additionally, there was some false or misleading advertising for both prescription and nonprescription drugs, so neither regulatory system is completely effective in eliminating false or misleading advertising from the marketplace.

Pharmaceutical marketers create prescription and nonprescription drug advertisements within two different regulatory environments. First, FDA and FTC have different ways that each agency

creates standards for conduct of advertisers: for FDA, in the form of regulation and guidance, and for FTC, in the form of regulation and case law precedent. Second, these agencies also have different mechanisms for enforcing regulations. FDA issues warning letters to companies that may be broadcasting false or misleading advertising, collaborates with the Department of Justice in criminal cases, and rarely can require advertisers to issue corrective advertising to fix public perceptions. FTC has administrative law judges that hear evidence in cases and make decisions based on precedent, and these cases may be appealed to other courts. FTC also relies heavily on the actions of the National Advertising Board within the Better Business Bureau to arbitrate disputes involving false or misleading advertising between competitors. Third, FDA may act proactively to review advertising before it is disseminated. In the case of new drugs to the market, FDA reviews all of the advertising materials as part of the new drug review process. In 2012, FDA also clarified a new program to pre-review all television advertising for prescription drugs before being aired (Food et al., 2012). FTC, on the other hand, primarily works in response to consumer and industry complaints and does not, to our knowledge, have a system of pre-review of advertisements.

These results have shown that, in two different regulatory environments, there are significant differences in the frequency of true, misleading and false claims in advertisements. There are four different mechanisms that could be explaining how the differences in regulation are affecting content creation, and thus the frequency of false or misleading advertising in the marketplace.

First, differences in regulations can affect decision-making during the advertising creation process, shaping the content being produced. Regulations can serve as a list of requirements (thou shalt) and restrictions (thou shalt not), setting boundaries on the acceptable content that can be included in advertisements. FDA regulations (21 CFR 201.1) outline a series of ways that an advertisement is definitely misleading or possibly misleading, but these regulations necessarily lack detail and cannot address all possible situations of false and misleading advertising, thus leaving some uncertainty about what may be false or misleading. FTC does not have regulations with similar detail and specificity for nonprescription drug advertising, which may lead to greater uncertainty about what may be false or misleading in decisions during the creation of nonprescription advertisements. With prescription ads, possibly misleading claims are identified during the creation process and

changed to be more truthful. With nonprescription ads, there is more uncertainty, and thus more misleading or false claims are created.

Second, FTC and FDA both have along history of enforcement actions that provide specific cases of what the agency considers misleading. Enforcement actions, like decisions in FTC cases or FDA warning letters are enforcement are public notices directed to a specific company that has disseminated false or misleading advertising. Additionally, these enforcement actions also serve as a deterrent to other companies who may make similar advertising. Enforcement actions could lead to content not being created as enforcement serves as a deterrent to creation. The reason why there are more false claims in nonprescription drug advertisements may be due to a lack of specific examples of false or misleading nonprescription drug advertising.

Third, the lack of proactive monitoring of advertising content by FTC may be allowing more false or misleading advertising for nonprescription drugs go unnoticed in the marketplace. FTC operates mainly in response to consumer and competitor complaints and brings a lawsuit against a company only after substantial numbers of consumer or competitor complains have been brought. Therefore, the case in question involves multiple advertisements in many channels that may have been disseminated over months or years. FDA, on the other hand, has multiple ways of monitoring ad content (described above) and often warns a company about one specific advertisement that is false or misleading. The system of enforcement by FTC may catch broad campaigns of misleading or false advertising, but may not catch individual advertisements that make claims that are false or misleading, leading to the belief that if the ad was not cited as misleading, then it's truthful.

Fourth, of course, there are many other differences - beyond government regulation - in the markets for prescription and nonprescription drugs that may explain differences in false and misleading advertising. Prescription and nonprescription products involve different purchase processes, different competitive environments, and different sets of business norms. Any of these characteristics could directly or indirectly affect the creation of false or misleading advertising in a variety of ways.

It is unclear which of these mechanisms, or a combination of mechanisms, is explaining the how regulations are affecting content. Further research may be designed to study the content creation

process in detail and to determine what mechanisms may be explaining the connection between regulation and content.

Preston's typology sets a high standard for truthfulness in advertising and, in using Preston's theory to guide this research, this study also used a high standard for categorizing an advertisement claim as "objectively true." FTC recognizes only false claims as actionable and does not recognize the potential for nonfacts, minimal facts and selected facts claims to potentially mislead consumers. Since there were no measurable differences in the frequency of selected fact, minimal fact, and nonfact claims in prescription versus nonprescription advertising, FDA may also not consider these types of claims as actionable. As a class of products, drugs are unique due to the significant physical harms to the individual and to the financial harms to the healthcare system that can occur from misconceptions stemming from false advertising. Additionally, while a consumer may be able to independently evaluate qualities of many consumer goods, the consumer may not be able to evaluate the qualities of drugs, due to lack of personal experience with the product or specialized medical knowledge. Preston's typology establishes a higher standard for truth in advertising that is applicable to advertising of drugs to consumers due to these differences between drugs and other products.

If there is a higher standard of truthfulness for advertising for prescription drugs, critics point out that nonprescription drugs are "safe" and false advertising for nonprescription drugs may be less harmful than false advertising for prescription drugs. First, although consumers perceive nonprescription drugs to be safer than prescription drugs, (Droege et al., 2007), all nonprescription drugs do have some side effects and contraindications. No drug is completely safe. Second, like prescription drugs, nonprescription drugs must be safe and effective in order to be marketed in the United States,<sup>5</sup> and products that switch from prescription to nonprescription must provide additional evidence to support that consumers may take the drug appropriately based on information on the product label. Both prescription and nonprescription drug advertisers have a substantial body of evidence to use to support their advertised claims. Third, false or misleading advertising for

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<sup>5</sup>There is a small set of nonprescription drugs that were on the market before 1938 that were "grandfathered" and allowed to continue to be marketed without having to demonstrate the product was safe or effective. Some common examples are topical mentholated rubs, aspirin, and bismuth-containing antacids. Although some of these products continue to be marketed (Vicks VapoRub, Bayer aspirin, PeptoBismol) FDA is taking some action to gather evidence on the safety and efficacy of these products.

nonprescription drugs may, in fact, cause more harm to consumers due to the lack of intervention from a healthcare provider that could correct false beliefs about the advertised drug or provide alternative treatments (see a detailed argument in Section 2.1).

It is important to consider these findings in light of the broader legal structure governing false and misleading advertising. Under United States law, advertising is a type of "commercial speech," and advertisers have been granted protection from government regulation that limits speech under the First Amendment of the United States Constitution. Advertisers have First Amendment rights to advertise, however, court decisions have generally established that advertising that is false or misleading is granted no protection, and government may regulate this type of speech without infringing on advertisers' rights.<sup>6</sup> For truthful and not misleading advertising, the government may pass regulations and limit this type of speech only under certain conditions.<sup>7</sup> The amount of constitutional protection afforded to commercial speech is based on whether or not the advertisement is false or misleading.

This study has provided some of the first comparative evidence to support that there are more objectively true claims and fewer false claims in prescription drug advertisements than in nonprescription drug advertisements. These differences may be due to different definitions of what is false or misleading in drug advertising, or due to different enforcement of existing regulations. These findings may help to understand the in-effect constitutional protection afforded to prescription and nonprescription drug advertisers. Two similar industries may be afforded different amounts of constitutional protection against government regulation of commercial speech, depending on the class of product being advertised. A "false" claim in a prescription drug ad may not be considered "false" if included in a nonprescription drug ad. FDA's definition of false or misleading may be more broad than the FTC definition. A broader definition of false and misleading advertising for prescription drugs widens the possible types of regulation that FDA may pass and not infringe on the First Amendment speech protection of advertisers. Within the same market, and occasionally for the same manufacturer, depending on the product being advertised, there may be more or less

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<sup>6</sup>Truthful and not misleading advertising that promotes illegal activities, and political advertising, which is political speech, not advertising, are two exceptions, but this is a separate issue.

<sup>7</sup>Established in the *Central Hudson* case (447 U.S. 557. 1980.), the government regulation must be narrowly tailored to directly further a substantial government interest.

constitutional protection of the advertisers' speech, and more or less ability for the government to regulate.

Often the conclusion from this argument is that the ability of FDA to regulate speech should be limited to match the scope of the FTC, and to afford more speech rights to advertisers. However, this conclusion ignores the important reasons that false or misleading advertising is not afforded constitutional protection.

Why are advertisers not given First Amendment protection for their advertising that contains false or misleading claims? The courts have recognized in a large body of case law that advertising is conveying information about a product or service that is intended to persuade the recipient to make an economic transaction and ads are speech prepared by advertisers who have sufficient opportunity to ensure their messages are truthful and not misleading. False or misleading advertising is intentionally misleading. Advertisements are not spontaneous utterances and do not occur in the context of interpersonal communication, situations where the court has recognized the importance of protecting false speech. In addition, under some theories, speech is protected because of the important role that free speech, press and assembly play in the functioning of a democratic government,<sup>8</sup> and all speech, true or false, contributes to the functioning of a democracy. The courts have not recognized an important role of commercial speech in democracy and, given the rationale above, there is no need to protect false commercial speech. Given these two characteristics, that commercial speech that is false or misleading was crafted to deceive, and that false or misleading advertising plays no role in democracy, the justification for affording constitutional protection to advertisers to craft messages that are false or misleading is under-weighted by the need to reduce the known harms from false or misleading advertising.

To repeat words from the introduction of this dissertation: False and misleading advertising harms consumers. Especially for drug advertising, where the products are expected to directly affect the body, a higher standard for truthfulness may be justified by the increased harms that can arise from inappropriate use of drugs stemming from false beliefs engendered by false advertising. This study was the first to show that there are more false claims in advertising for nonprescription drugs aired in the marketplace. In addition, almost half of all claims were not factually false, but otherwise

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<sup>8</sup>Democratic meaning self-governing, not the political party.

potentially misleading to consumers. When viewing potentially false or misleading advertisements, consumers are making inferences about the benefits, risks and suitability of drugs based on false claims, claims that promote the suitability of drugs by making misleading associations to lifestyle choices rather than medical conditions, claims that exaggerate the possible benefits of the drug, and claims that leave out important details that consumers need to make choices among products. These harms should be considered when evaluating the potential effects of regulations that are aimed at reducing false or misleading advertising.

## 6.7 Future Research

This study leaves two immediate questions unanswered. First, considering all claims in the advertisements, are there differences in the amount of false or misleading claims in prescription and nonprescription drug ads? The reliable method for analyzing claims in prescription and nonprescription drug advertisements introduced in this study could be used to answer this question. Analysis of the truthfulness of the remaining 828 identified claims will provide the answer to this important question, and potentially provide additional cases to increase power to detect a relationship between the truthfulness of the claim and the amount of distraction before, during and after it. Additionally, studying of all of the claims in the advertisements would allow comparisons among the results from analysis of the characteristics of claims to results from previous studies. This analysis could update knowledge of these characteristics in a current sample of prescription drug advertising and expand our knowledge of the content of nonprescription drug advertising.

Second, are attention modifying techniques used during the major claim in each advertisement attracting attention toward the major claim or away from the major claim? Unfortunately, the instrument used in this study was not able to distinguish between attractors and distractors. In order to make this distinction a new instrument will need to be developed. The next step toward developing an instrument with this sensitivity is to complete a qualitative content analysis whereby a small number of advertisements are analyzed in great detail to assess the attention modifiers surrounding the major claim. This research can provide rich detail about use of attention modifiers that can be used to develop a content analysis instrument with the sensitivity to distinguish attractors

from distractors.

Additionally, like all content analyses, results from previous studies were used to identify the types of advertising claims that would lead consumers to form false inferences about the advertised product. These studies were helpful in developing the content analysis instruments, but additional studies will be necessary to confirm that consumers are being misled by these claims. The methods described in Section 2.4 from Russo et al. (1981) wherein misleading advertisements are modified to correct for the misleading claim, will provide a valuable framework to validate if these claims are misleading consumers.

Broadly, more research is needed to quantify the occurrence of false and misleading drug advertising to consumers in other channels like the internet and magazines. In addition, this study has demonstrated the utility of Preston's slippery slope typology of claims to distinguish truthful, misleading and false claims in advertising. Since Preston's typology is not specific to drugs, it may be adapted and applied to advertising for other types of health-related products.

## Chapter 7

### Conclusions

False and misleading advertising for drugs may harm consumers by leading to inappropriate use of medications. This study was developed to systematically examine false or misleading claims in prescription and nonprescription drug advertising, and to associate false or misleading claims with use of distraction techniques before, during and after the claim. Content analysts evaluated the most-emphasized claim in each drug advertisement, reliably categorized the claim into one of five categories of truthfulness, and identified common distraction techniques surrounding the most-emphasized claim.

FDA and FTC have different regulations defining what is considered false or misleading in drug advertising and different enforcement of those regulations. This study has demonstrated that the differences in regulation and enforcement may be leading to more false advertising for nonprescription drugs in the marketplace. Alternatively, the results could be interpreted that FDA regulations are leading to more truthful prescription drug advertising. Regardless of the effects of regulation on false or misleading advertising, this study demonstrated, using a narrower definition of truthfulness, that two-thirds of prescription and nonprescription ads were potentially misleading to consumers.

In addition to evaluating truthfulness of claims in drug ads, this study explored use of distraction techniques surrounding the most-emphasized claim. Distraction was greatest during the presentation of the claim, and more truthful claims were associated with use of more distraction techniques. This points to two potential uses of the same techniques: to distract attention away from negative information and to attract attention toward positive information. Future research will

involve developing a more sensitive instrument that can distinguish between distraction techniques used to attract versus detract attention.

## **Appendix A**

### **Recent Decisions Made by FDA and FTC Regarding Prescription or Nonprescription Drug Advertising**

Year	Product	Noncompliant Materials	Drug Indication	Information Sources Cited in Warning Letter	Description of Claims	FDA's Description of False or Misleadingness	Slippery Slope Category	Justification	FTC Case (If Applicable)
FDA	2010 Vivitrol	DTC DVD and Brochure	for treating alcohol dependence in people who are already detoxed	PI,	A DVD with patient testimonials about how well the drug worked for them. Risk information of the drug was restricted to the last few minutes of the presentation and was shown as rapid scrolling on-screen text with no audio presentation. The brochure is 20 pages long and only shares the risk information on the last few pages. Each page has a disclaimer to see the full risk information in the back of the brochure.	Minimization of Risk Information	Selected Facts Claim	Although the risk information is present in the ad, the ability for a consumer to comprehend this information seems to be explicitly diminished, therefore, is selected facts since only part of the presentation is made and the risk information is reduced.	
					The promotional materials claim that the drug can improve relationships, emotions, work performance and overall quality of life. The company framed the presentation as the drug resulted in sobriety with improved quality of life. FDA saw the direct implication that the drug would improve quality of life, not that sobriety would improve QOL.	Overstatement of Efficacy	False Claim	There is no evidence whatsoever that the drug can produce the effects implied by its claims.	
					Testimonials had claims that the product had been used successfully for a longer duration than had been shown in clinical interventions.	Overstatement of Efficacy	Minimal Facts Claim	There is evidence for use in some durations, but not in the extended duration proposed in the advertisement. The evidence presented is of good quality (since it is in the PI) but	
FDA	2004 Kaletra	Print Ad	HIV treatment	PI	Ad uses a series of pictures of the same man at 1 year intervals over 5 years and states, "Where do you see yourself in 5 years? Talk to your doctor about Kaletra. Still undetectable. Still in control." FDA assessed this material implied that use of the drug would allow the individual to live for 5 years. No brief summary is included with the print ad. The drug had not been tested for outcomes like improving survival, reducing HIV antibodies to undetectable levels or maintaining control of HIV levels for 5 years.	Omission of Risk Information	False Claim	There is no evidence whatsoever that the drug can produce the effects implied by its claims.	
FDA	2009 Embeda	News Release	narcotic pain reliever	PI	Embeda was created to prevent addicts from crushing the extended release opioid pain reliever and ingesting all of the narcotic immediately. It has a center core of anti-opioid medication that could, in theory, if taken with opioid, reduce the euphoric effects of the drug. The video news release (like a press release but with video) claim that "EMBEDA is the first opioid approved by the FDA with pharmacological properties developed in response to the need for opioid analgesics that could reduce drug liking and euphoria when tampered with by crushing or chewing." The drug was tested for reducing pain, not for these abuse-related outcomes.	Omission and Minimization of Risk	Selected Facts Claim	Some information is provided about risk, but some of the major fatal risks and the information on correct use of the product is omitted.	
						Broadening of Indication	Selected Facts Claim	The indication is for pain management, but due to counterindications, the product cannot be used in certain populations. The indication is broadened by not including information that the drug shouldn't be used by certain populations.	
						Misleading Claims	False Claim	There is no evidence whatsoever that the drug can produce the effects implied by its claims.	
FDA	2009 Mirena	Consumer Program Script	birth control	PI	Mirena is a hormone-releasing IUD. The materials were a script for a presentation made to consumers over a company-sponsored dinner. The materials made claims that Mirena will result in more spontaneous intimacy and happier relationships. In trials, 5% of women reported decreased libido.	Overstatement of Efficacy	False Claim	There is evidence that Mirena affects sexual desire, and the information in the PI directly contradicts the information provided in the presentation.	
						Unsubstantiated Claims	False Claim	There is no evidence that Mirena will result in happier relationships.	



FTC	2011 Gummy Vitamins made by Nature Smart and Rexall Sundown	Multi-campaign	Vitamin	Product packaging and advertising claim the product contains DHA and links DHA doses of 100mg/g with improvements in brain and eye development in children. Product actually contains 100 mcg, 1/1000th of the purported effective dose.	Minimal Facts Claim	The product may contain the beneficial product, but not in significant amounts to produce the exaggerated benefits.	FTC File No. 1023080
FTC	2008 Daniel Chapter One maker of Bio*Shark 7 Herb Formula, GBU, and BioMixx	Multi-campaign	Nutritional Supplement/Vitamin	Manufacturer claimed their product could inhibit tumor formation or growth, eliminate tumors, treat/cure cancer, and heal effects of radiation therapy and chemotherapy.	Unsubstantiated Claims	The claim is not backed by any evidence whatsoever.	Case No. 10-1064 FTC File No. 0823085
FTC	2010 Dannon, Activia and DanActive	Multi-campaign	Food	Citations to published research in peer-reviewed journals Dannon claimed that Activia Yogurt and DanActive Dairy Drink relieved irregularity and helped prevent colds and flu. Dannon's evidence to support the claims showed the product was effective over time, but failed to mention that the product was no more effective over time than the control group of the trial. Dannon made claims that probiotic yogurt helped strengthen the immune system thus leading to fewer colds and flu. These claims were not backed by "significant scientific agreement" (from the NLEA) in order to have FDA-approved qualified health claims.	Minimal Facts Claim	The claim is backed by evidence, but that evidence is of poor quality and is misinterpreted in supporting the claim.	FTC File No. 0823158
FTC	2010 Nestle Boost Kid Essentials	Multi-campaign	Food	Citations to published research in peer-reviewed journals Another one of these exaggerated claims based on weak scientific evidence linking probiotics with improved immunity. Nestle Boost Kid Essentials claims to reduce the risk of colds and upper respiratory infections, reduce children's sick-day absences, and reduce the duration of acute diarrhea. Some claims, like strengthening immunity were subject to the substantial scientific agreement standard. Claims about reducing the duration of diarrhea, reducing sick-day absences are subject to a higher standard of substantiation evidence - competent and reliable scientific evidence - in this case, well-controlled randomized human clinical studies. Boost Kid Essentials is claiming that their product can effect disease, and thus, is not a food, but a drug. They had evidence that some types of nutrition supplements (not their product) and a supplement containing the bacteria in their straw produced these effects, but the trials were not using their product or an equivalent product.	Minimal Facts Claim	Here, there is unspecified poor quality scientific evidence (not from specific trials of this product) thus, the body of scientific evidence on the link between probiotics and immune system is too weak to make this claim.	FTC File No. 0923087
FTC	2010 Wellness Support Makers of WGN Diabetes Pack and Insulin Resistance Pack	Multi-campaign	Vitamin/Dietary Supplement	Citations to published research in peer-reviewed journals WGN claimed their vitamin supplements could lower blood sugar with no side effects, that they have scientific studies showing 31.9% reduction in blood sugar, improve weight loss, sleep quality, reduce need for medications. Needless to say, they have no competent and reliable scientific evidence to support these claims.	False/Misleading Statements	There is no evidence whatsoever that the drug can produce the effects implied by its claims.	Case No. 10-0723179 FTC File No. 0723179

FTC	2010 POM Wonderful campaign	Multi-campaign	Food	POM Wonderful claimed to have clinical evidence to support that Pom Wonderful could help with prostate, cardiovascular health. They conducted self-funded research in prostate health and their small studies were positive. However, this contradicts with published evidence from a larger trial that found no effects. POM Wonderful conducted a number of self-sponsored research trials with their product, but have been systematically spinning negative results into positive and deceptive health claims.	False and Misleading Representations, Unsubstantiated Representations	Minimal Facts Claim	The claims are backed by some evidence which is spotty.	FTC File No. 082-3122
FTC	2010 IOVATE Health maker of Acceils, ColdMD, and GermMD	Multi-campaign	Vitamin/Dietary Supplement	Iovate made claims that its vitamin supplements could improve weight loss and prevent disease, claims that must be backed by competent and reliable scientific evidence. They are lacking such evidence.		False Claim		FTC File No. 072 3187 Case No. 10-CV-587
FTC	2010 Bronson Diet Centers makers of Chinese Diet Tea	Multi-campaign	Food	Bronson claimed the Chinese Diet Tea would assist weight loss by reducing absorption of sugar and fat. This was one case of many within the FTC's "Big Fat Lie" campaign to reduce unsubstantiated and exaggerated weight loss claims.	Unsubstantiated Claims	False Claim		FTC File No.: 042 3115 Civil Action No. 304-CV-1866
FTC	2010 Direct Marketing Concepts makers of Coral Calcium, and Supreme Greens	Multi-campaign	Nutritional Supplement/ Vitamin	Direct marketing concepts claimed that their Coral Calcium Daily and Supreme Greens vitamin/nutritional supplement mixtures would improve a wide range of physical ailments. They had no evidence to substantiate any of these claims, whether from competent and reliable scientific evidence.				
FTC	2009 Carter-Reed Dynacor Basic Research	Multi-campaign	Nutritional Supplement/ Vitamin	Also part of the FTC "Big Fat Lie" campaign.				FTC Case No 002-3300
FTC	2009 Airborne	Multi-campaign	Nutritional Supplement/ Vitamin	Airborne has claimed in its advertising to strengthen the immune system, to help prevent colds and fight germs, to reduce cold severity and to protect against disease in crowded areas. Since their claims go beyond nutrition affecting the structure or function of the body (e.g. reduce cold severity) the company needed reliable and competent scientific evidence to support their claims, which they did not have.	Unsubstantiated Claims	False Claim		FTC Case No 08-CV-05300, FTC File 072 3183
FTC	2009 Kellogg's Mini Wheats Cereal	Multi-campaign	Food	Kellogg's made the claim that Mini Wheat's cereal can help kids stay alert through the morning. They conducted clinical research to demonstrate their claim, but their comparator was NOT another breakfast cereal, but instead was compared to NO breakfast. Hence, their claim implies a brand superiority for Mini Wheats, but in reality, is supporting a product-specific claim for eating breakfast.	Selected Facts Claim		The advertisers claim that eating Mini Wheats for breakfast produces superior attentiveness but fails to mention that eating ANY breakfast - theirs or their competitors' - will produce the same effect.	FTC File No. 082 3145

## **Appendix B**

**The form to code the emphasis for each claim in the drug ad.**

**Basic Ad Information**

What is the VTNA ID code for the commercial segment?

What is the brand of product advertised?

Is the product a prescription or nonprescription product?

- Prescription
- Nonprescription

What is the duration of the ad? (in seconds)

**claims**

List the text and implications of all identified claims in the Advertisement.

Claim 1	<input type="text"/>
Claim 2	<input type="text"/>
Claim 3	<input type="text"/>
Claim 4	<input type="text"/>
Claim 5	<input type="text"/>
Claim 6	<input type="text"/>
Claim 7	<input type="text"/>
Claim 8	<input type="text"/>
Claim 9	<input type="text"/>
Claim 10	<input type="text"/>
Claim 11	<input type="text"/>
Claim 12	<input type="text"/>
Claim 13	<input type="text"/>
Claim 14	<input type="text"/>
Claim 15	<input type="text"/>

**Claim Characteristics**

The following questions are about the identified claim, "\${Im://Field/1}"

How many times is the claim repeated?  
 \${q://QID1/ChoiceGroup/AllChoicesTextEntry}

What modes of communication are used for the claim?

---

- Audio only or Video Only
- A mix of audio-only, video-only or audiovisual
- Audiovisual

What is the duration of the claim? (in tenths of seconds)

---

What is the duration of the claim?

---

- Less than 2 seconds
- 2 or more seconds

At what point in the ad does the claim start? (in tenths of seconds)

---

The ad is \${q://QID7/ChoiceTextEntryValue} seconds long. In which third of the ad does the claim start?

---

- The beginning third of the ad
- The middle third of the ad
- The end third of the ad

## Appendix C

### Calculation Rubric for the Emphasis Index Score

- (Iteration) Count how many times the claim, or a variant are repeated in the ad. Variants are recognizable as the same claim, but do not need to use the exact same words. 1 point for each iteration.
- (Mode of Presentation)
  - 1 point for audio-only or visual-only presentation.
  - 2 points for a mixed presentation of audio- or visual-only presentation mixed with some audiovisual presentation.
  - 3 points for an audiovisual presentation.
- (Duration) Use a stopwatch to time the duration of the claim to the nearest second.
  - 1 point for a claim with duration of less than 2 seconds.
  - 2 points for a claim of greater than 2 seconds.
- (Placement) Divide the ad into three equal time segments. Indicate within which third the claim begins.
  - 1 point for the beginning third.
  - 2 points for the middle.
  - 3 points for the end.

## **Appendix D**

### **Example Calculations for the Emphasis Index Score**

Table D.1: Example Calculations for Identifying the Major Claim for the Three Advertisements with the Highest Average Emphasis Score. The major claim of the advertisement is highlighted in boldface type.

Claim	Iteration	Mode of Comm	Duration	Start	Emph.
<b>Claritin</b>					
I get Claritin Clear with Claritin Liquigels.	2	Audiovisual (+3)	≥2 sec (+2)	Beginning (+1)	8
Claritin Liquigels are new	2	Mixed (+2)	<2 sec (+1)	Middle (+2)	7
Claritin Liquigels are the first allergy medicine	1	Single-mode (+1)	<2 sec (+1)	Middle (+2)	5
Claritin Liquigels are the only allergy medicine	1	Single-mode (+1)	<2 sec (+1)	Middle (+2)	5
Claritin Liquigels are nondrowsy	1	Single-mode (+1)	<2 sec (+1)	Middle (+2)	5
Claritin Liquigels have pure liquid power	2	Single-mode (+1)	<2 sec (+1)	Middle (+2)	6
Claritin Liquigels are a powerful... way to live Claritin Clear	3	Audiovisual (+3)	≥2 sec (+2)	End (+3)	11
<b>Claritin Liquigels are... a new way to live Claritin Clear.</b>	3	Audiovisual (+3)	≥2 sec (+2)	End (+3)	11
<b>Boniva</b>					
I never thought I could do more than stop my bone loss, but then my doctor told me I could with...Boniva.	5	Audiovisual (+3)	≥2 sec (+2)	Beginning (+1)	11
Once monthly Boniva	1	Audiovisual (+3)	<2 sec (+1)	Beginning (+1)	6
Boniva works with your body to help stop bone loss	5	Audiovisual (+3)	≥2 sec (+2)	Beginning (+1)	11
Boniva works... to help reverse bone loss.	3	Audiovisual (+3)	<2 sec (+1)	Beginning (+1)	8
Studies show after 1 year on Boniva 9 out of 10 women stopped and reverse their bone loss.	5	Audiovisual (+3)	≥2 sec (+2)	Beginning (+1)	11
I know I did stop and reverse my bone loss after taking Boniva.	1	Audiovisual (+3)	<2 sec (+1)	Middle (+2)	7
<b>I wanted to stop my bone loss, but I did more. I reversed my bone loss with Boniva.</b>	5	Audiovisual (+3)	≥2 sec (+2)	End (+3)	13
Boniva can help you stop losing and start reversing	5	Audiovisual (+3)	≥2 sec (+2)	End (+3)	13
<b>Aleve</b>					
Just 2 Aleve can keep back pain away	3	Mixed (+2)	≥2 sec (+2)	Middle (+2)	9
Aleve works all day	2	Single-mode (+1)	<2 sec (+1)	End (+3)	7
With Aleve you take fewer pills than Tylenol	1	Single-mode (+1)	<2 sec (+1)	End (+3)	6
Rachel chose Aleve and 2 pills	3	Single-mode (+1)	<2 sec (+1)	End (+3)	8
Rachel received a day free of pain	3	Single-mode (+1)	<2 sec (+1)	End (+3)	8
2 pills	3	Single-mode (+1)	≥2 sec (+2)	End (+3)	9
<b>All day relief.</b>	3	Single-mode (+1)	≥2 sec (+2)	End (+3)	9

Table D.2: Example Calculations for Identifying the Major Claim for the Three Advertisements with the Lowest Average Emphasis Score. The major claim of the advertisement is highlighted in boldface type.

Claim	Iteration	Mode of Comm	Duration	Start	Emphasis
<b>Chantix</b>					
Robin quit smoking with Chantix and a support plan	1	Single-mode (+1)	$\geq 2$ sec (+2)	Beginning (+1)	5
<b>Chantix I can take it and still smoke while it built up in my system</b>	1	Audiovisual (+3)	$\geq 2$ sec (+2)	Beginning (+1)	7
Chantix is a non-nicotine pill	1	Single-mode (+1)	<2 sec (+1)	Beginning (+1)	4
Chantix is proven to help people quit smoking	1	Single-mode (+1)	<2 sec (+1)	Beginning (+1)	4
In studies, 44% of Chantix users were quit during weeks 9-12 of treatment (compared to 18% on sugar pill).	1	Single-mode (+1)	$\geq 2$ sec (+2)	Beginning (+1)	5
Chantix reduces the urge to smoke	1	Single-mode (+1)	<2 sec (+1)	Beginning (+1)	4
<b>Tylenol PM</b>					
Tylenol PM works with your body	1	Mixed (+2)	<2 sec (+1)	Middle (+2)	6
Tylenol PM ease the aches and pains that keep you awake	1	Single-mode (+1)	$\geq 2$ sec (+2)	Middle (+2)	6
Tylenol PM helps you fall asleep	1	Single-mode (+1)	<2 sec (+1)	Middle (+2)	5
Tylenol PM works in a non-habit-forming way	1	Single-mode (+1)	<2 sec (+1)	End (+3)	6
<b>Feel better with Tylenol PM</b>	1	Single-mode (+1)	$\geq 2$ sec (+2)	End (+3)	7
<b>Aricept</b>					
Prescription Aricept can help with mom's dementia	2	Single-mode (+1)	<2 sec (+1)	Beginning (+1)	5
It's thought that Aricept may help reduce the breakdown of a vital chemical in the brain	1	Mixed (+2)	$\geq 2$ sec (+2)	Beginning (+1)	6
Studies showed Aricept slows the progression of Alzheimers symptoms	1	Single-mode (+1)	$\geq 2$ sec (+2)	Middle (+2)	6
Aricept improves cognition	1	Single-mode (+1)	<2 sec (+1)	Middle (+2)	5
Aricept slows the decline of overall function	1	Single-mode (+1)	<2 sec (+1)	Middle (+2)	5
Aricept is well-tolerated	1	Single-mode (+1)	<2 sec (+1)	Middle (+2)	5
<b>If Aricept helps mom be more like herself longer that's everything to us</b>	2	Single-mode (+1)	$\geq 2$ sec (+2)	End (+3)	8

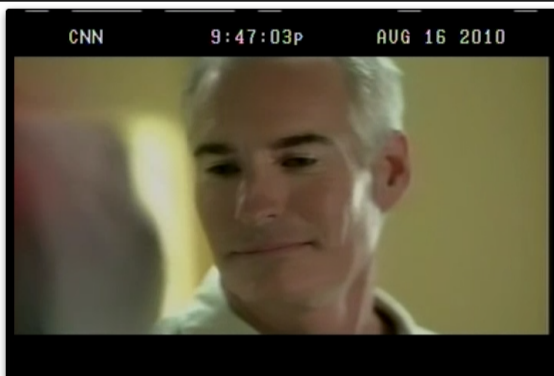
## Appendix E

### Storyboards for Selected Advertisements

The three top-emphasized claims are in bold font with the emphasis score for the claim.

#### E.1 Storyboard for Cialis Advertisement

60 seconds



(Man 1 and woman 1 are painting a room.)  
**One look can turn the every day into romantic.**



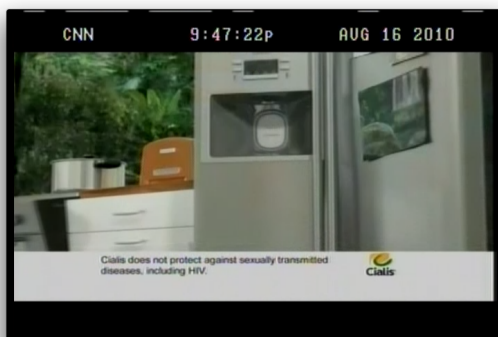
(Man 2 and woman 2 are in a basement doing laundry.) **An accidental touch can turn ordinary into something more. Moments can change anytime...**



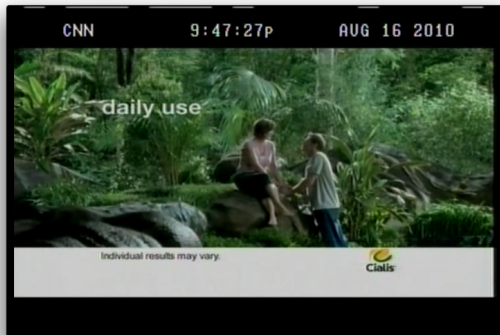
(Man 2 and woman 2 embrace and smile.)  
 ...just like that. And when they do, **men with  
 erectile dysfunction can be more confident  
 in...**



(Man 3 and woman 3 chopping vegetables in  
 the kitchen.) **...their ability to be ready with  
 Cialis for Daily Use. (6)**[Cialis. By prescrip-  
 tion only for men with erectile dysfunction.]



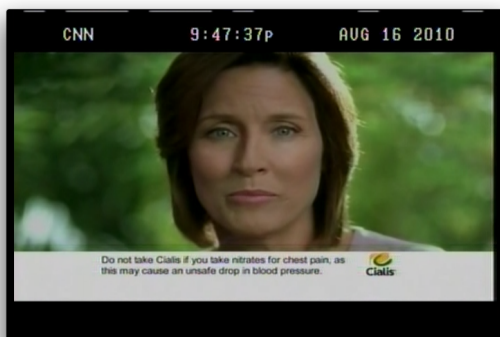
(Kitchen transforms into nature scene.) **Cialis  
 for Daily Use is clinically proven low-dose  
 tablet you take every day (6).** [Cialis does not  
 protect against sexually transmitted diseases,  
 including HIV.]



(Spokesman 1 and spokeswoman 2 walk through nature scene.) **So you can be ready anytime the moment is right. (7)** [Cialis][Individual results may vary.]



Tell your doctor about your medical condition and all medications, [Especially mention alpha blockers, antifungals, HIV or high blood pressure medications.] and ask if you're healthy enough for sexual activity.



Don't take Cialis if you take nitrates for chest pain as this may lead to an unsafe drop in blood pressure.



(Reflection of spokesman 1 and spokeswoman 2 in running water.) Don't drink alcohol in excess with Cialis. [See our ad in Golf Digest.] Side effects may include headache, upset stomach, delayed back ache or muscle ache.



(Spokesman 1 and spokeswoman 2 sit by river and kiss.) To avoid long term injury, seek immediate medical help for an erection lasting more than 4 hours. [Cialis.com] [1-877-4-Cialis]



If you notice any sudden decrease or loss of hearing or vision, stop taking Cialis and call your doctor right away.



(Man 2 and woman 2 relaxing in bathtubs.)  
Ask your doctor if Cialis for Daily Use is right  
for you. [Cialis][Lilly][Daily Use]



(Man 3 and woman 3 relaxing in bathtubs.)  
For a 30-tablet free trial offer go to Cialis.com.  
[Go to cialis.com for a 30-tablet FREE TRIAL  
OFFER of Cialis for daily use.]

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## E.2 Storyboard for AlkaSeltzer Advertisement

15 seconds

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(Woman sneezes while approaching a vending machine.) Ah-choo! Transform drinks you want [Juices, Soda, Tea, Coffee, Water]



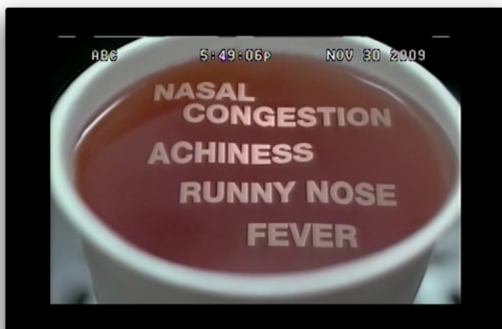
(pushes button to receive tea from machine) into cold medicine you need. [Use only as directed]



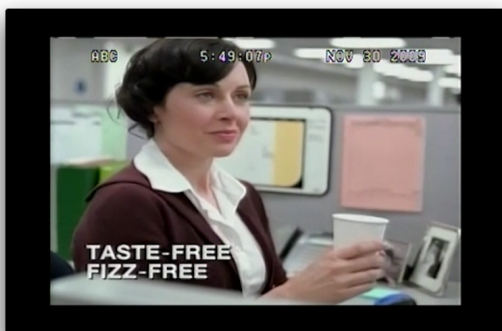
(Hand within machine pours powder into tea.)  
Introducing fast crystal packs



(Zoom in on product.) **A new way from Alka-Seltzer Plus**



(Steaming tea is shown.) **to get cold and flu relief (7)** [Nasal Congestion Achiness Runny Nose Fever]



(Woman drinks tea and smiles.) In a **taste-free (8) fizz-free powder (8)**



(Product shot.) AlkaSeltzer Plus [Alka-Seltzer Plus Fast Crystal Packs]

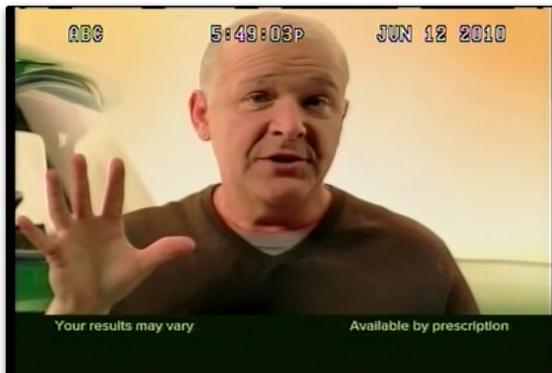
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### E.3 Storyboard for Symbicort Advertisement

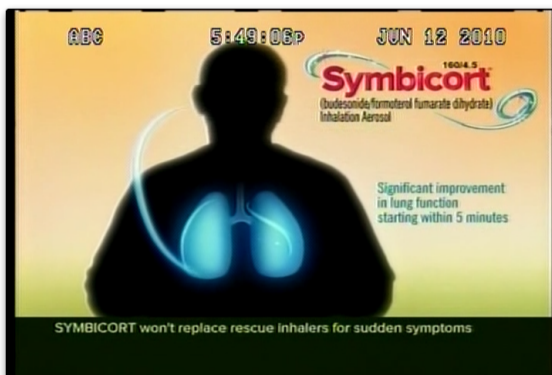
60 seconds



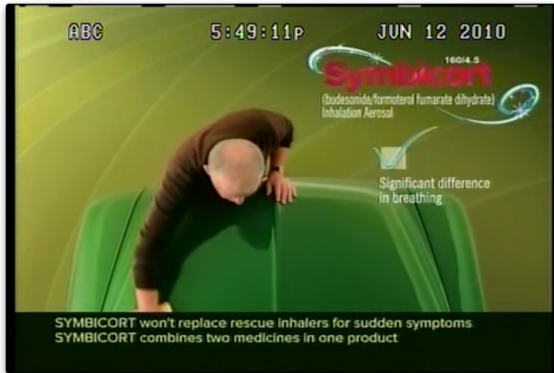
(Man polishes antique green truck while talking to camera.) With COPD I was short of breath so I couldn't always do what I wanted to do [Chronic Obstructive Pulmonary Disease includes chronic bronchitis and emphysema]



But 5 minutes ago I took Symbicort And Symbicort is already [your results may vary. Available by prescription]



(Animation of man's lungs turning blue.) helping significantly improve my lung function [Significant improvement in lung function starting within 5 minutes] [SYMBICORT won't replace rescue inhalers for sudden symptoms]



So today I've noticed a significant difference in my breathing [Significant difference in breathing] [SYMBICORT won't replace rescue inhalers for sudden symptoms. SYMBICORT combines two medicines in one product]



and I'm doing more of what I want to do. [significant difference in breathing] [SYMBICORT won't replace rescue inhalers for sudden symptoms]



So we're clear, it doesn't replace a rescue inhaler for sudden symptoms [SYMBICORT won't replace rescue inhalers for sudden symptoms]



My doctor said Symbicort is for COPD including chronic bronchitis and emphysema. It should not be taken more than twice a day. [Use SYMBICORT only twice a day, every day]



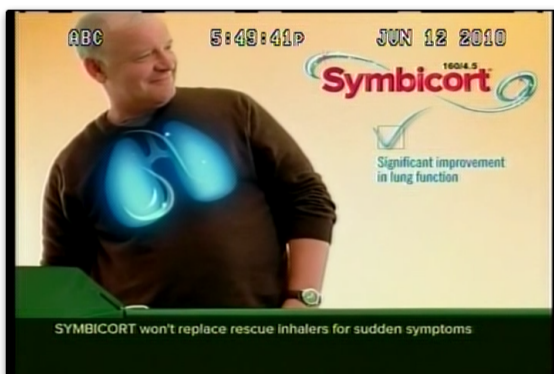
Symbicort may increase your risk of lung infections osteoporosis and some eye problems [Use SYMBICORT only twice a day, every day]



Tell your doctor if you have a heart condition or high blood pressure before taking it [Use SYMBICORT only twice a day, every day]



My COPD often meant I had to wait to do what I wanted to do [Your results may vary]



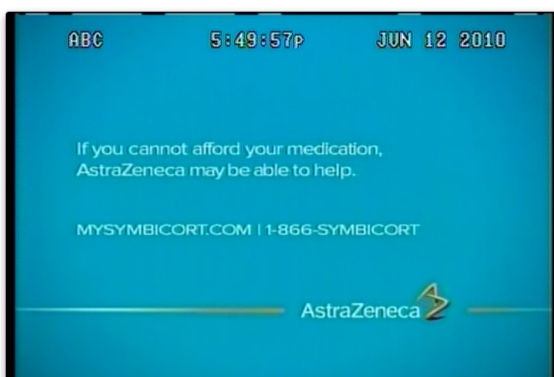
Now I take Symbicort and it significantly improves my lung function (11) starting within 5 minutes. [significant improvement in lung function] [SYMBICORT won't replace rescue inhalers for sudden symptoms]



Symbicort has made a significant difference in my breathing.(12) Now more of my wants are can-dos (10) [Significant improvement in lung function] [Significant difference in breathing] [See our ad in Ladies Home Journal] [1-866-SYMBICORT MySymbicort.com]



Ask your doctor about Symbicort today. I got my first prescription free. Call or go online to learn more [Free prescription offer] [1-866-SYMBICORT MySymbicort.com] [Subject to eligibility rules] [restrictions apply]

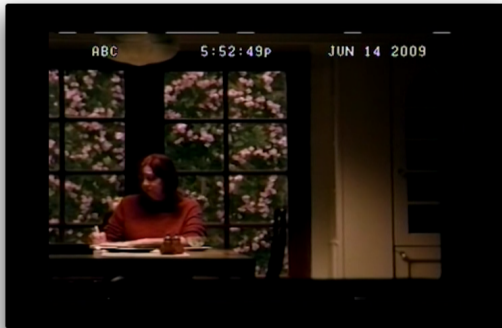


If you cannot afford your medication, AstraZeneca may be able to help. [1-866-SYMBICORT MySymbicort.com]

## E.4 Storyboard for Exelon Advertisement

60 seconds

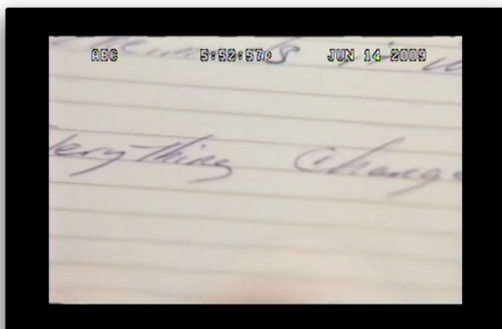
---



(Adult daughter writes in journal with voiceover.) Mom was diagnosed with moderate Alzheimer's. [Mild to moderate alzheimer's disease]



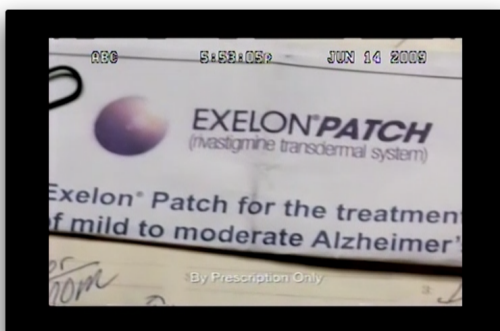
(Blurry shot of adult daughter assisting elderly mother.) It was tough news to hear.



(Daughter writes in journal.) Everything changed.



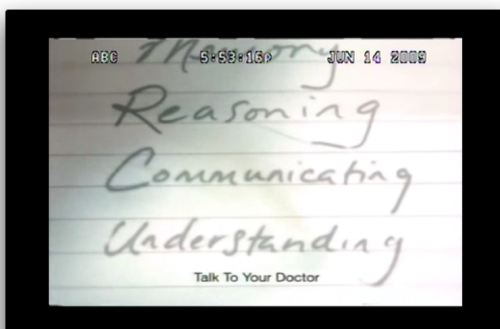
(Rapid scene cuts with antique photos lead to blurry shot of mother's face resolves to clarity.)  
I didn't know what to do.



(Daughter clips patient information pamphlet for Exelon into journal.) Right about then, our doctor mentioned the Exelon Patch [by prescription only]



(Daughter kisses mother on forehead.) He said it releases medicine continuously for 24 hours



(Daughter writes words in journal.) He said **it could help with her cognition (6)** [individual results may vary] which includes things like **memory reasoning communicating and understanding (7)** [talk to your doctor]



(Daughter closes journal on desk.) The most common side effects of Exelon patch are nausea vomiting and diarrhea the likelihood and severity of these side effects may increase as the dose increases



(Daughter helps mother to sit on bed.) Patients may experience the loss of appetite or weight



(Mother smiles. Daughter clasps hands with mother.) Patients who weigh less than 110 pounds may experience more side effects



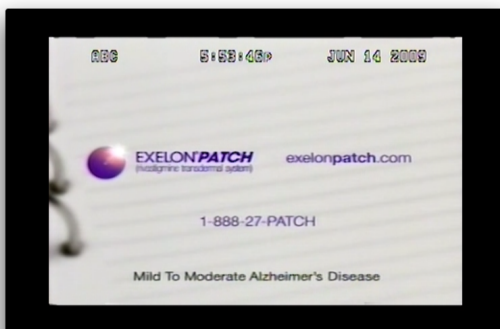
(Zoom in on clasped hands.) People at risk for stomach ulcers or who take certain other medicine should talk to their doctor because serious stomach problems such as bleeding may worsen. [See our ad in Woman's Day Magazine]



(Blurry shots of daughter moving through house. Daughter sits in chair.) Mom's diagnosis was hard to hear. [Ask your doctor]



(Daughter speaks directly into the camera.)  
**But there's something I can do. (8)**



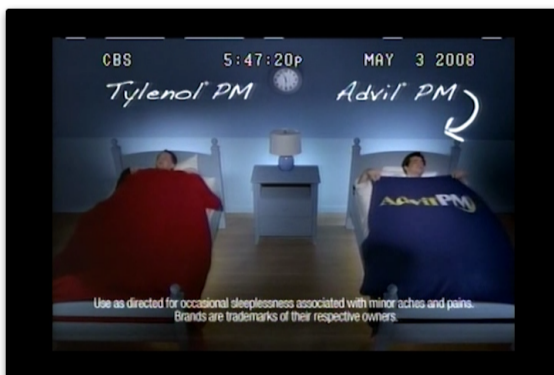
(Cut to white screen, resolve to product logo.)  
Ask your doctor about the Exelon Patch. Visit Exelonpatch.com to learn more. [exelonpatch.com 1-888-27-PATCH Mild to Moderate Alzheimer's Disease]

## E.5 Storyboard for Advil Advertisement

15 seconds



I'm doing my own sleep study.



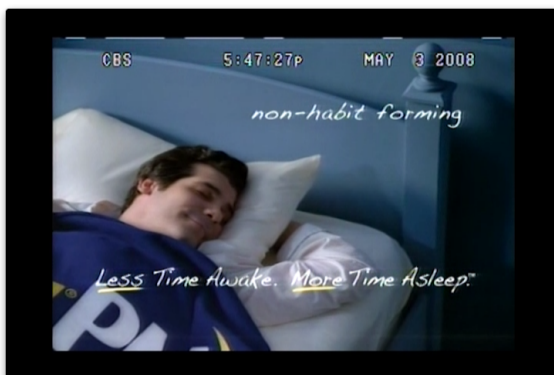
Advil PM or Tylenol PM [Use as directed for occasional sleeplessness associated with minor aches and pains. Brands are trademarks of their respective owners.]



The Advil PM guy is spending less time awake... [Less time awake. More time asleep.]



...with annoying aches and pains... (7)



and more time asleep (8) [non-habit forming]



Advil PM. The difference is a better night's sleep. (9) [Wyeth Advilpm.com]

---

## E.6 Storyboard for Coricidin Advertisement

15 seconds



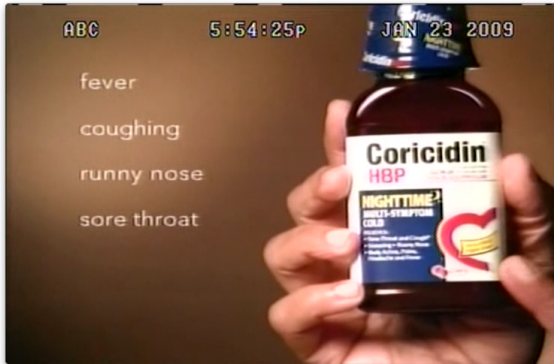
(Spokeswoman talks to the camera while sitting on a bed in her pajamas.) I have high blood pressure. **So when I get a cold...** [S. Epatha Merkerson]



(Closeup on product.) I take [Coricidin] (6) powerful cold medicine with a heart. [Use as directed]



Well now there's **new Coricidin HBP nighttime (7).**



(Closeup on product.) For nighttime cold relief with a heart. [fever coughing runny nose sore throat



From the only cold brand that won't raise your blood pressure. (9) Coricidin HBP.

---

## **Appendix F**

**The form for coding the characteristics, category and distractions for the Major Claim.**

### Claim Characteristics

The ad you will be coding is:  
 \${e://Field/vtnaid} - \${e://Field/brand}.

The ad is \${e://Field/adduration} seconds long.

The major claim is: \${e://Field/majorclaim}  
 The major claim starts at second \${e://Field/start\_s} of the ad and is \${e://Field/duration\_s} seconds long.

Please watch the advertisement now and make note of the major claim.

---

Which coder are you?

---

- Matt  
 Mike  
 Scott  
 Addi

You will be coding the claim characteristics of the major claim. Click Next to continue.

---

You don't need to code claim characteristics for this ad. Please click the Next button to continue.

---

Please answer the following questions about the major claim of the ad: \${e://Field/majorclaim}

---

The claim is...

---

- objective.  
 subjective.

The claim is...

---

- an attribute.  
 a benefit.

The claim asserts that the advertised product is...

---

- The "drug of choice" for at least one condition  
 More effective than another drug  
 Effective in a broad range of patients (e.g. different age groups)  
 Useful in a broad range of conditions and diseases  
 Safe

The claim has one or more of the following properties:

---

- Compares two or more drugs  
 Is an advertising slogan  
 Makes claims of popularity  
 Uses statistical or numeric support to back claims  
 Uses a scientific study or publication to back claims

You indicated above that the claim makes a comparison among two or more drugs. Answer the following three questions about the major claim: \${e://Field/majorclaim}

---

Select the type of comparative claim... (Faerber)

---

- The claim makes a **specific** comparison.
- The claim makes a **nonspecific** comparison.

Select the type of comparative claim... (Faerber)

---

- The claim makes a comparison to **specific** other products.
- The claim makes a comparison to **vaguely specified** other products.
- The claim makes a comparison to **nonspecific** other products.

Select the type of comparative claim... (O'Donoghue)

---

- Indication
- Mechanism of action
- Dosing
- Risk
- Other
- 

(sorry about the blank page... You would have answered questions about comparative claims here. Please skip onto the next page.)

---

### **Distractions Before**

You will be coding the distractions before the major claim in this ad. Click next to continue.

---

You don't need to code the distractions before the major claim in this ad. Click next to continue.

---

Answer the following questions about seconds  $\{e://Field/prestart\}$  to  $\{e://Field/preend\}$  BEFORE the major claim.

---

Does the major claim begin when the ad begins? Also, is there no ad before the major claim to code distractions before the major claim?

---

- Yes
- No

Is there a voiceover or speaking actor?

---

- Yes, a voiceover
- Yes, a speaking actor
- Yes, both a speaking actor and a voiceover
- No. None of the above.

Is there music playing in the background?

---

- Yes
- No

Do you recognize the song?

---

- Yes

- No
- Not applicable

Consider the entire advertisement, not just the specified time period. What is the tempo of the music in beats per minute?  
(leave blank if there is no music in the background)

How would you best describe the tempo of the music?

- Slow (Up to 80 BPM)
- Moderate (81-120 BPM)
- Fast (121 BPM or higher)
- Not applicable

Are there other sounds (besides music, a voice over, or a speaking actor) in the background?

- Yes
- No

Answer the following questions about seconds  $\{e://Field/prestart\}$  to  $\{e://Field/preend\}$  BEFORE the major claim.

Leading into the major claim Is there a change in the music?

- Yes
- No
- There is no music in the background.

Leading into the major claim, are there sudden sounds like a crescendo, a crashing noise, or other sudden sounds?

- Yes
- No
- There are no sounds in the background.

Is there a change in voice-over or speaking actor between seconds  $\{e://Field/prestart\}$  to  $\{e://Field/preend\}$  before the major claim?

- Yes
- No
- There is no voice-over or narrator

Is there a change in voice-over or narrator before the major claim versus during the major claim?

- Yes
- No
- There is no voice-over or narrator

Answer the following questions about seconds  $\{e://Field/prestart\}$  to  $\{e://Field/preend\}$  BEFORE the major claim.

From seconds  $\{e://Field/prestart\}$  to  $\{e://Field/preend\}$  before the major claim, is there text on the screen?

- Yes

No

Count the total number of words on the screen from seconds \${e://Field/prestart} to \${e://Field/preend} before the major claim.

---



Count the total number of unique characters from seconds \${e://Field/prestart} to \${e://Field/preend} before the major claim.

---



Count the total number of shot changes from seconds \${e://Field/prestart} to \${e://Field/preend} before the major claim.

---



### **Distractions During the Major Claim**

You will be coding the distractions during the major claim in this ad. Click next to continue.

---

You don't need to code the distractions during the major claim in this ad. Click next to continue.

---

Answer the following questions about seconds \${e://Field/duringstart} to \${e://Field/duringend} DURING the major claim.

---

Is there a voiceover or speaking actor?

---

- Yes, a voiceover
- Yes, a speaking actor
- Yes, both a speaking actor and a voiceover
- No. None of the above.

Is there music playing in the background?

---

- Yes
- No

Do you recognize the song?

---

- Yes
- No
- Not applicable

Are there other sounds (besides music, a voice over, or a speaking actor) in the background?

---

- Yes
- No

Answer the following questions about seconds \${e://Field/duringstart} to \${e://Field/duringend} DURING the major claim.

---

Is there a change in voice-over or narrator during the major claim?

- Yes
- No
- There is no voice-over or narrator

During the major claim, what relevance does the visual presentation have to the major claim?

- Relevant
- Not Relevant

During the major claim, what relevance does the audio presentation have to the major claim?

- Relevant
- Not Relevant

Answer the following questions about seconds  $\{e://Field/duringstart\}$  to  $\{e://Field/duringend\}$  DURING the major claim.

From seconds  $\{e://Field/duringstart\}$  to  $\{e://Field/duringend\}$  during the major claim, is there text on the screen?

- Yes
- No

Count the total number of words on the screen from seconds  $\{e://Field/duringstart\}$  to  $\{e://Field/duringend\}$  during the major claim.

Count the total number of unique characters on the screen from seconds  $\{e://Field/duringstart\}$  to  $\{e://Field/duringend\}$  during the major claim.

Count the total number of shot changes from seconds  $\{e://Field/duringstart\}$  to  $\{e://Field/duringend\}$  during the major claim.

### **Distractions after the Major Claim**

You will be coding the distractions after the major claim in this ad. Click next to continue.

You don't need to code the distractions before the major claim in this ad. Click next to continue.

Answer the following questions about seconds  $\{e://Field/poststart\}$  to  $\{e://Field/postend\}$  AFTER the major claim.

Does the major claim end when the ad ends? Also, is there no ad remaining after the major claim to code distractions after the major claim?

- Yes
- No

Is there a voiceover or speaking actor?

---

- Yes, a voiceover
- Yes, a speaking actor
- Yes, both a speaking actor and a voiceover
- No. None of the above.

Is there music playing in the background?

---

- Yes
- No

Do you recognize the song?

---

- Yes
- No
- Not applicable

Are there other sounds (besides music, a voice over, or a speaking actor) in the background?

---

- Yes
- No

Answer the following questions about seconds  $\{e://Field/poststart\}$  to  $\{e://Field/postend\}$  AFTER the major claim.

---

Just after the major claim Is there a change in the music?

---

- Yes
- No
- There is no music in the background.

Just after the major claim, are there sudden sounds like a crescendo, a crashing noise, or other sudden sounds?

---

- Yes
- No
- There are no sounds in the background.

Is there a change in voice-over or speaking actor between seconds  $\{e://Field/poststart\}$  to  $\{e://Field/postend\}$  after the major claim?

---

- Yes
- No
- There is no voice-over or narrator

Is there a change in voice-over or narrator during the major claim versus after the major claim?

---

- Yes
- No
- There is no voice-over or narrator

Answer the following questions about seconds  $\{e://Field/poststart\}$  to  $\{e://Field/postend\}$  AFTER the major claim.

---

During seconds  $\$(e://Field/poststart)$  to  $\$(e://Field/postend)$  after the major claim, is there text on the screen?

- Yes
- No

Count the total number of words on the screen during seconds  $\$(e://Field/poststart)$  to  $\$(e://Field/postend)$  before the major claim.

Count the total number of unique characters during seconds  $\$(e://Field/poststart)$  to  $\$(e://Field/postend)$  before the major claim.

Count the total number of shot changes during seconds  $\$(e://Field/poststart)$  to  $\$(e://Field/postend)$  before the major claim.

**Claims Evaluation**

Answer the following questions about the major claim.

$\$(e://Field/majorclaim)$

The major claim starts at second  $\$(e://Field/start_s)$  of the ad and is  $\$(e://Field/duration_s)$  seconds long.

Is the claim about the product?

	Yes	No	Not Applicable
Is the claim an opinion?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Is there an opinion-giver?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Might someone else view the claim's evaluation of the product differently?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does the claim use superlatives?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does the claim give an inflated or "puffed" evaluation of the product?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Is the claim, when taken literally, meaningless or about nothing substantial?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does the claim make illogical associations between the product and some unrelated attribute?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Is the claim about the product?</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Is the claim backed by evidence?

	Yes	No	Not Applicable
<b>Is there some evidence for the claim?</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If a comparison among drugs was made, have comparative trials been conducted (published?)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If the drug is the "only" treatment - is this backed by an absence of other similar drugs?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If a citation or reference is included in the ad, is that evidence available?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Do the results of that evidence match with the stated claim?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Is the claim backed by high-quality evidence?

\*If the evidence is from the FDA label, answer these questions "yes."

	Yes	No	Not Applicable
Is there evidence from trials that were in humans?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did the trial have a control group?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did the trial randomize subjects to study arms?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did the trial blind investigators and subjects to the treatment assignment?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Was the trial prospective?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Was the study population similar to the advertised claim population?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Are the results of the study both statistically AND clinically significant?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does the advertised claim exaggerate the effectiveness of the drug?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Is the claim backed by high-quality evidence?</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Have all of the relevant details been included?

	Yes	No	Not Applicable
<b>Are all of the relevant details that would effect product choice included in the presentation?</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Are the frequent risks and contraindications of the drug included? (for OTC products with no major statement, are major contraindications and limits on use included?)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Are disclaimers prominent enough and placed appropriately to ensure consumers are able to see the disclaimers?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Are limitations of the brand which would be considered a significant disadvantage of the brand over its competitors included in the advertisement? (i.e. a different dosing schedule, a brand-specific side effect or a brand-specific black box warning, )	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### Claim Determination

The current score for evaluating the claim is:  $\{gr://Claim\%20Emphasis/Score\}$

---

Based on the score, please pick the category that the claim belongs in:

---

- Objectively True Claim (0 Points)
- Selected Facts Claim (1-9 points)
- Minimal Facts Claim (10-99 points)
- Nonfacts Claim (100-999 points)
- False Claim (>1000 points)

How strongly do you agree with this categorization?

---

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

Summarize your rationale for categorizing the claim.

---

**Closing**

How confident are you in the coding of these variables?

---

- Very confident
- Confident
- Neither confident nor unsure
- Unsure
- Very unsure

Did you consult with other coders, the investigators or the expert panel in order to code one or more items?

---

- Yes
- No

Would you like to review the coding of one or more items with the investigators or other coders?

---

- Yes
- No

Do you have any comments or questions on the coding for the investigator?

---

Click the next button to lock in your responses. If you have questions or want to make changes, email Addi for a Retake Survey link.

---

## Appendix G

### Detailed codebook including variables and their interpretation

#### G.1 Claim Characteristics

##### *Attribute of Benefit*

Code each claim as either an attribute or benefit. Shimp (1979) defined attributes and benefits as:

Advertising significates refer either to what the advertised brand is or has (i.e., attributes of the brand) or to what it will do for consumers (i.e., provide benefits). Stated more formally, an attribute significate represents a logical property of the sign even when the sign is in a static or un-consumed state. For example, in the assertion "Brand X has only 96 calories," the significate (only 96 calories) is a logical property of the sign. Consumption is a non-essential precursor to the realization of this property.

If, however, in the assertion "Brand X tastes good," the Significate (tastes good) is clearly a benefit rather than an attribute since consumption is a prerequisite to its realization.

When specifically evaluating drug-specific claims:

- drug side effects and indications are benefits
- drug dosing, pill shape, manufacturer are attributes
- market competition characteristics/exclusivity "only" drug is an attribute of the state of the market

Some examples:

- Pepto Bismol "When you need big relief you, you need PeptoMax" (benefit)
- Cepacol: "Our competitors can't do both soothing and coating" (attribute because it's a competitive characteristic)

### *Objective or Subjective*

Attribute and benefit significates can, in turn, be distinguished as either objective or subjective. In an objective signification, the thing signified is tangible and has physical reality. Consider the following significations: "Brand Y has a diesel engine" and "Brand Y will get 50 miles per gallon." Both the attribute significate (a diesel engine) and the benefit significate (50 miles per gallon) are obviously physical properties, thus satisfying the criterion for objective significates. The claim may be both false AND objective. It needs to be provable or testable or "truthy."

A subjective significate, by comparison, is one which is entirely perceptual and devoid of a counterpart physical property. In the assertion that "Brand Y is attractive." the significate (is attractive) has no objective meaning outside that given to it by the individual information processor. Subjective claims may vary by individuals.

Some examples:

- Toyota Prius is a hybrid car. (Objective)
- Toyota Prius is a fast car. (subjective)
- Trek bike has 21 speeds. (Objective)
- Blue is the coolest color of my trek bike. (subjective)
- Dell computer has premium sound. (Subjective)
- Toyota RocketKar is a fast car. (subjective)
- Flonase nasal spray- "now kids as young as 4 can use Flonase" (Objective and true)
- Cepacol: "Our competitors can't do both soothing and coating" (Objective)
- Pepto Bismol "When you need big relief you, you need PeptoMax" (subjective)

Table G.1: Types of Drug-Specific Advertising Claims

Wilkes, Doblin, Shapiro Category	Examples
The "Drug of choice" for at least one condition.	Recommended products. doctor/expert recommended. #1 prescribed. Top-selling. most trusted. "drug of choice"
More effective than another drug.	better, lasts longer, works stronger,
Effective in a broad range of patients (for example, different age groups)	"people everywhere..." "kids as young as 4"
Useful in a broad range of conditions and diseases	"now approved for [new patient group]" "now approved for [new indication]" list a series of symptoms.. i.e. flonase ad lists "congestion runny nose stuffy nose headache" i.e. pepto bismol ad lists nausea heartburn indigestion, upset stomach and diarrhea as treated by the drug.
Safe	"safe" "safer" "safety" "safest" "leaves the system quickly" "reversible" treatment

#### *Types of Drug-Specific Ad Claims*

Wilkes et al. (1992) refer to 5 types of claims made in medical journal advertisements targeted to physicians. These types of claims were also used in the work on OTC ads by Sansgiry et al. (1999).

#### *Promotional and Informational Indicators*

The next group of items comes from Stryer and Bero (1996) which they use as indicators of "promotional materials" or "educational materials" when evaluating a whole range of pieces from pharmaceutical companies. They originally proposed 14 promotional characteristics and 12 educational characteristics, but only these items are relevant to television advertising directed to consumers. (i.e. "multiple colors - item is printed in more than one color" only applies to print advertising, not television)

**Compares two or more drugs** - A comparative claim will compare or contrast two or more products. The products do not have to be specified. Comparative claims may just assert some type of superiority over other products, without specifying the other products or the way in which the advertised product is better. To note, the ad must compare drugs, not drug treatment to other treatments (i.e. saying a statin is better than diet and exercise at lowering cholesterol is not

considered a comparative claim since it does not compare products.) Note that all claims that are "drug of choice" or "more effective than another drug" ARE comparative claims.

**Is an advertising slogan** - The claim is an ad slogan, or a short phrase in support of a product that often repeats in the ad. Examples include:

- "all day strong. All day long." [Aleve]
- "Works like a dream." [Ambien]
- "Like no other pain reliever in the world." [Bayer]
- "The choice is clear." [benefiber]
- "There's only one." [Boniva]
- "More complete from A to Zinc." [Centrum Vitamins]
- "Ends your sore throat emergency." [Cepacol]
- "When you've always gotta go." [Detrol]
- "I trust my heart to Lipitor." [Lipitor]
- "Mucinex In. Mucus out." [Mucinex]
- "I'm ready" [Neulasta]
- "The power to calm. The power to comfort. The power to quit successfully." [Nicoderm]
- "You can be heartburn free with Pepcid AC."
- "Just one and heartburn's done." [Pepcid AC]
- "Help prevent the acid with Prevacid."
- "Requip can put your RLS to rest."
- "Visine gets the red out."
- "A different way to help fight cholesterol." [Zetia]
- "Love the air" [Zyrtec]
- "Get Claritin Clear" / "Live Claritin Clear"
- "When the moment is right, you can be ready." [Cialis]
- "What ache?" [Excedrin]
- "For a good night's sleep from start to finish" [Ambien]

- "Restore your body's natural rhythm." [Miralax]
- "Taking care with Vesicare."
- "Year long protection for on-the-go women." [Reclast]
- "Discover a restful Lunesta Night."
- "Feel better." [Tylenol]

**Makes claims of popularity** - The claim asserts the popularity of the product by mentioning the popularity of the product or the extent of use. The numeric popularity could be specific (over a million people have tried...) or could be nonspecific (lots of people have tried... more people are trying...)

**Numeric support** - The claim is supported by statistical or numeric evidence. This includes "100 percent" to mean "all."

**Scientific study or publication** - The claim is supported by a reference to a scientific publication or to a research study.

## G.2 Claim Categorization

Each claim will be categorized as being:

- Objectively True,
- Selected Facts,
- Minimal Facts,
- Nonfacts, or
- False

based on the category definitions outlined below. In order to classify each claim, study these definitions and the examples in detail. Additional examples are also available in the summary of FDA and FTC decisions tables (included in the dissertation as Appendix A).

In determining the relevant category for each claim, using the decision flowchart to guide your analysis. Start at the top and answer the right-hand questions about the presented claim. Work your way down the flow chart until you have a potential category.

Once you've answered the questions, the coding form (Qualtrics) will suggest a categorization based on your answers. You will be asked how strongly you agree or disagree with the categorization. In addition, you'll be asked to explain the rationale for your categorization. Please be descriptive.

### *Preston's Category of Claims*

#### *Objectively True Claims*

Objectively true claims present brand-significant facts and include all of the necessary information for consumers to make purchase decisions. The brand is differentiated from other brands of the same product in a meaningful way and the implications of the claims do not deceive consumers as to their significance or truthfulness. Take, for example, the claim that "A Faerber range is the best-built cooktop available." First, the Faerber company doesn't disclose that they're comparing their range to consumer-grade cooktops, not professional-grade cooktops used in restaurants. Second, the build of the cooktop may not be directly related to the actual performance of the product. Under Preston's definition of objective truth, a true claim that the Faerber Company could present would be along the lines of, "A Faerber range is the best-built cooktop, though not the best performing cooktop, available to consumers."

#### *Selected Facts Claims*

The first step down the slippery slope are selected facts claims when an advertiser has one or more brand significant facts and can create brand significance, but fails to also discuss the brand neutral and brand negative facts since that would deter from the consumers evaluation of the product. "...Advertisers will use the brand significant claims and not the [product significant] claims in their ads. They are selective, using what will sell, leaving out what won't, and giving consumers incomplete information...[the advertisers] tell us the good things about their brand and leave out the neutral and bad...To have selected facts means also to have selected omissions. Nothing that's

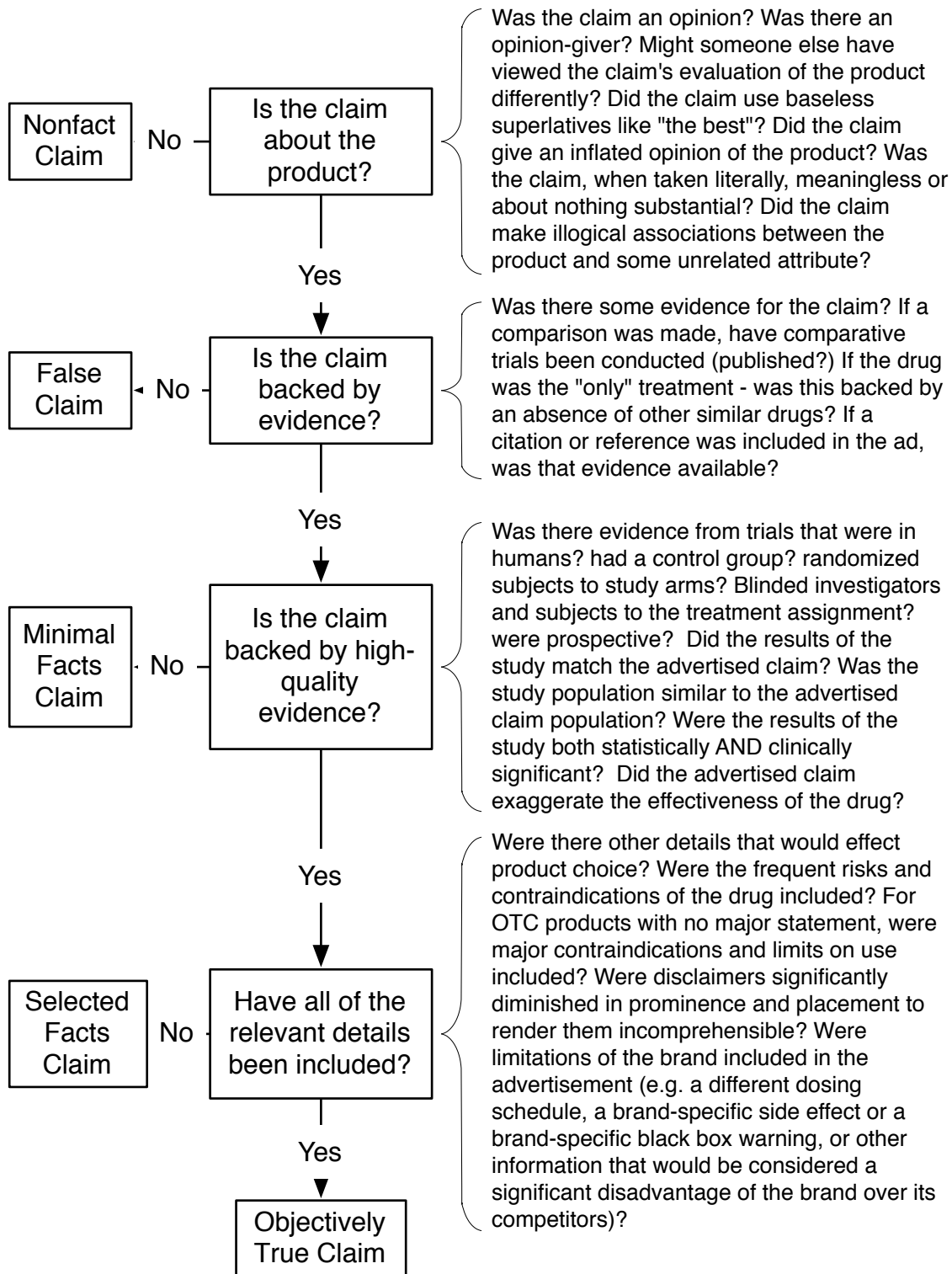


Figure G.1: Decision Flowchart for Categorizing Claims into Preston's Categories

said is false, yet the total ad does not tell consumers the whole truth." (Preston, 1994, p 61).

Regarding drugs, the most obvious type of selected fact is when an advertisement fails to mention or minimizes the risks of the drug which would be important to the consumer when deciding whether or not to buy the drug or approach their physician about a prescription for the drug. This does not mean that any drug ad claim that fails to disclose every side effect or contraindication of the drug is misleading to consumers. However, when the side effect would be severe enough or occur frequently enough, then it deserves mention. This also means that important attributes of the drug, its route of administration, recommended dosing schedule, limited availability, are also important to include with claims in order to provide objective truth and omission of these attributes may constitute a selected facts claim. For example, if a treatment for a common chronic condition advertises the product is convenient due to once-a-month dosing, but fails to mention that once-a-month the patient needs to visit the physician to receive the drug as an injection, this claim is not presenting the whole objective truth and would be a selected fact claim.

#### *Minimal Facts Claims*

In minimal facts claims, the advertiser promotes factual claims that are minimally significant or exaggerated.

"Minimal facts are similar to selected ones in being selected and true. But selected facts are objectively significant—alone at least, despite being less so in total context. By contrast, minimal facts are objectively just that—minimal. They are merely promoted as significant. They are "hyped" into meaning more than they otherwise would. To consumers, they are as maximal as the seller can make them," (Preston, 1994, p 68).

For some drug products, a pill that is a combination of two already approved drugs may promote itself as new and improved. In this case, the drug is just a combination of two products and may not offer any additional synergistic effects. The claim that the combination drug is new and improved is a minimal fact claim since there is only a minor difference between the combo drug and its constituent parts but the combo drug is being promoted as new and improved.

Minimal facts claims may come from exaggeration of the relevance of information that distinguishes two products. In the realm of drugs, a common example of minimal facts claims is when a drug is statistically different from another drug, but the difference is not clinically significant. Drug A may lower cholesterol, on average, 5 more points when compared to drug B, but those 5 additional points are not meaningful in decreasing negative complications like heart attacks. The two drugs are statistically, though not clinically different. If drug A claims it lowers cholesterol better than drug B, this is a minimal facts claim.

Preston defines three subtypes of minimal facts: physical difference, performance differences, and promotional differences. Physical differences, to paraphrase, are subtle differences or changes in manufacturing which produce physical differences in the product that have no objective impact on the product performance. Performance differences are where "no other brand has achieved [the performance measure], which allows the inference that no other could. Such a performance implies an objective brand difference, but there probably is not one. If a brand could actually perform in a way that it's competitors could not, its maker would certainly say so explicitly," (Preston, 1994, p 71). Performance differences leading to minimal facts claims often happen when one drug in a class obtains FDA approval for a new indication. All of the other products with a similar mechanism of action probably also are effective for the new indication, but they just have not received FDA approval to market the drug for the new indication. Therefore, when Pravachol advertises it is the "only drug in its class" to prevent first and second heart attacks, it is making a minimal facts claim. There is no reason to think one statin is better than any other statin at preventing first and second heart attacks, but Pravachol is the only drug approved. The promotional difference is "a claim based on an existing feature. Although one or more competitors may have the same feature, consumers are to infer from the claim that the competitors do not have it when actually the competitors just have never promoted it. Objectively, then, the brand that makes the claim is differentiated only by what it's messages say," (Preston, 1994, p 71).

### *Nonfacts Claims*

Nonfact claims are absent of truth and objective significance. Nonfacts are not false. They're hollow statements. Advertisers turn to such claims when there are no selected or minimal facts of use to convey about the brand. Brands may not be differentiated when they are not physically different, when the law prohibits the products from differentiating (gasoline, drugs) or when physical differences are too small to matter. Differences may be minor and perceptible to trained experts—e.g. film grain in Fujifilm versus Kodak, grades of beef marbling, or side effect profiles of Lipitor versus Pravachol. As a consequence, product categories where the products are not differentiated are heavily advertised because there is nothing to differentiate factually, thus more advertising is necessary to create and maintain the seeming of difference. When product distinctions are minimal in the absence of the branded information, this is a strong sign the products are differentiated based on nonfacts.

Nonfact claims come in three varieties: puffery, opinions and nonbrand facts.

*Puffery* is hyperbolic exaggeration of the attributes or benefits of a product, for example, "Our steaks are the best in the entire world." It's unclear what benefit or attribute is being compared—is it the steak's flavor? fat content? the color of the cow it was cut from? It's unclear which other products are being compared—all steaks on the market today? all theoretically possible steaks? all steaks that someone has eaten?

*Opinions* give an evaluation of the product and can be from the company, its spokespeople, knowledgeable individuals, or general consumers. Opinions can differ among individuals while facts are the same among all observers. "A brand opinion technically says something only about the speaker. That is why objectively, it's a nonfact about the brand. Of course advertisers intend for consumers to regard the opinion as being 'about' the brand," (Preston, 1994, p 82).

*Nonbrand facts* are facts, but they are not about the product itself. Nonbrand facts often associate the product with a type of person or a lifestyle. So when an advertised product, "fits your life," the advertiser is jumping ahead to say "this product is for you" versus saying "this product is good" and allowing the consumer to infer "this good product is for me." "A specific type of consumer is frequently the subject of the ad rather than merely it's object. The consumer's personal profile

becomes the appeal that the advertiser makes to that consumer...[Advertisers] are not blocked from appealing to a particular group just because their brand's features or even the product category's features do not naturally attract such folks...[Advertising] tells us virtually nothing about [the advertised product] while devoting its print space to detailed profiles of persons it thinks we might want to associate or be like,"(Preston, 1994, p 86). Nonbrand facts may also claim that the product solves a non-existent problem that the consumer may not be aware of having. Halitosis, the medical term for bad breath, was created by the makers of Listerine, and promoted Listerine as the "solution" to the "problem" of bad breath (Twitchell, 2000). Although bad breath existed long before Listerine, the important point is that the company invented a medical term for a common problem and associated their product as a solution to that problem. Often these problems may be abstract social or psychological characteristics, like when butter is proposed as a solution to rid mothers of their anxieties about parenting (Fowles, 1994).

### *False Claims*

False claims are objectively false, meaning there is a discrepancy between what is claimed and a known truth. False claims may also be baseless but objective, whereby an advertiser claims to have a basis for the factual claim when that basis is absent, what FTC calls unsubstantiated claims.

Preston's typology has more well-defined levels of use of truth, half-truth, and falsehood in claims made in advertising. The slippery slope applies broadly to all advertising, unlike earlier definitions of truth and falsity used in studying claims in prescription drug advertising that narrowly focused on fact-claim discrepancies and FDA regulations. When exploring the different effects of FDA and FTC regulation on use of claims in drug advertising, Preston's Slippery Slope is necessary to explore the differences in interpretation of what is considered false or misleading in drug advertising. Preston hypothesizes that FTC only views false claims as enforceable and dismisses the other types of claims as illegal. If FDA has set a higher standard for defining truth in advertising, then more grey-area claims on the slippery slope may be considered enforceable as false or misleading by the agency.

### G.3 Distractions

This construct measures distractions 5 seconds before, during and for 5 seconds after the major claim of the advertisement. Some questions ask about the specific time period, and other questions ask about the transition into and out of the major claim. For each major claim, you will answer similar questions about all three time periods.

About audio presentation: The audio portion of the ad is composed of three sub-channels: a voice, music and other sounds. The voice is spoken language from a person. The music has a rhythm and is loosely correlated with the action on the screen. Other sounds are correlated with the action on the screen.

Answer the following questions about seconds X to Y [BEFORE | DURING | AFTER] the major claim. note: These second markers are estimates of the start and stop of the major claim. Use the presented start and stop of the major claim as the "hard" line between before the major claim and during the major claim (and for after...)

In some cases, the major claim occurs at the very beginning or (more often) the very end of the drug ad. In this case, you cannot code the distractions before (or after) the major claim because there is no ad remaining to code. in these cases, there is a question that asks, "Does the major claim [begin | end] when the ad [begins | ends]? Also, is there no ad [before | after] the major claim to code distractions [before | after] the major claim?" answer "Yes" to indicate that you can't code the distractions before (or after) the major claim.

Is there a voiceover or speaking actor?

- Yes, a voiceover A voiceover is a spoken voice without an identifiable actor.
- Yes, a speaking actor A voice and a face are visible. The face does not have to be directly talking into the camera.
- Yes, both a speaking actor and a voiceover
- No. None of the above.

Is there music playing in the background?

- Yes
- No

Do you recognize the song? Any trace of recognition will do. If there are lyrics to the song, you're probably meant to recognize it.

- Yes
- No
- Not Applicable

What is the tempo of the music in beats per minute? Goto the website [tempotap.com](http://tempotap.com) and follow the instructions to measure the tempo of the music. If you are unsure of whether you're tapping on the downbeat or on every beat, use your sense of the tempo of the music to tell you if the beat is fast or moderate and tap accordingly (remember the Mucinex swing music example? It's a fast song.)

How would you best describe the tempo of the music?

- Slow ( Up to 80 BPM)
- Moderate (81-120 BPM)
- Fast (More than 121 BPM)
- Not applicable

Examples of slow songs are:

- Pomp and Circumstance the graduation march song.
- Silent Night, the Christmas carol.

Examples of moderate songs are:

- Most everything by Taylor Swift

Examples of fast songs are:

- The music from the Yaz ad "Goodbye to you" with the balloons
- "Lust for life" by Iggy Pop
- "Brakish" by Kitty or any other speed-metal song.
- Most dance techno songs

Are there other sounds (besides music, a voice over, or a speaking actor) in the background?

- Yes
- No

These sounds are often correlated with other things happening in the ad.

(THIS QUESTION WAS DELETED ON 1/15/12) (Before and After Only) [Leading into | Just after] the major claim is there a change in the tempo of the music?

- Yes, the music got faster.
- Yes, the music got slower.
- No, the tempo stayed the same.
- There is no music in the background.

(THIS QUESTION WAS DELETED ON 1/15/12) (Before and After Only) [Leading into | Just after] the major claim, is there a change in the volume of the music in the background?

- Yes, the music got louder.
- Yes, the music got quieter.
- No, the volume stayed the same.
- There is no music in the background.

(THIS QUESTION WAS ADDED ON 1/15/12) (Before and after only) [Leading Into | Just after] the major claim, is there a change in the music in the background?

- Yes
- No
- There is no music in the background

If there are any changes in the music check yes. These changes could be increases or decreases in volume, tempo, key (pitch). The music could start or stop.

(Before and After Only) [Leading into | Just after] the major claim, are there sudden sounds like a crescendo, a crashing noise, or other sudden sounds?

- Yes
- No
- There are no sounds in the background.

Is there a change in voice-over or narrator between seconds X to Y [before | during | after] the major claim?

- Yes
- No
- There is no voice-over or narrator

(Before/ After Only) Is there a change in voice-over or speaking actor [before versus during | during versus after] the major claim?

- Yes
- No
- There is no voice-over or narrator

(During Only) During the major claim, what relevance does the visual presentation have to the major claim?

- Relevant The visual presentation reinforces the major claim through text on the screen or audiovisual presentation (an actor talking to the camera) or through an animation or acting-out of the major claim, or display of the product packaging.
- Not Relevant There is a weak association between the major claim and the visual presentation. The visual presentation may reflect a general positive emotionality, but still be considered not relevant.

(During Only) During the major claim, what relevance does the audio presentation have to the major claim?

- Relevant The audio reinforces the major claim, which is often presented in the audio channel.
- Not Relevant The major claim is presented visually and the accompanying audio doesn't reinforce the visual message.

For seconds X to Y [before | during | after] the major claim, is there text on the screen? Include any text appearing on product packaging, as "supers"

- Yes
- No

Count the total number of words on the screen from seconds X to Y [before | during | after] the major claim. Note that when counting words, only count the words you can read. If text is too small to read on the screen, do not count those words. If a product package is shown covered with words, only count the largest words on the package. URLs and telephone numbers count only as one word each. Words that stay during a shot change should not be recounted. If the words disappear and reappear after a shot change then count them again.

Count the total number of unique characters from seconds X to Y [before | during | after] the major claim. (From Harlow) Please count the total number of unique characters (actors, animals, animated figures) on screen during the [time period]. Please count any unique character that you can see any part of during the segment. If you are certain a character is repeated multiple times,

only count them once. Conversely, if you aren't certain that a character is unique, count them again. This way we will error on the side of over-counting characters rather than under-counting.

Count the total number of shot changes from seconds X to Y [before | during | after] the major claim. (From Harlow) Count the total number of times the shot changes during the risk statement. A shot change is indicated by a "cut" in the reel. Always count a shot change into the major claim during the major claim. Count a shot change at the very end of the major claim as AFTER the major claim.

## **Appendix H**

**Example of an automated survey notice generated when a coder had a question for the investigator.**

**From:** qualtrics@qualtrics.com  
**Subject:** Questions on Visine Ad from Matt  
**Date:** January 31, 2012 8:12:34 PM CST  
**To:** afaerber@wisc.edu  
**Reply-To:** qualtrics@qualtrics.com

---

Matt has completed coding a **Visine ad (ID: )**.

The claim: " Visine tired eye relief " was coded as **Objectively True Claim (0 Points)**

Rationale: I put objectively true because i believe revival of eyes means relubrication which this does with moisturizers.

Agreement with the coding: Strongly Agree

Confidence in the coding: Neither confident nor unsure

Comments and questions:

Not really sure how to do the preston categorization because I am not sure if I have the correct meaning of revive.

## Appendix I

### Calculation Rubric for the Distraction Index Score

Points were allocated for the following values of these variables.

Is there a voiceover or speaking actor?

- Yes, a voiceover +1
- Yes, a speaking actor
- Yes, both a speaking actor and a voiceover
- No. None of the above.

Is there music playing in the background?

- Yes +1
- No

Do you recognize the song?

- Yes +1
- No
- Not applicable

Are there other sounds (besides music, a voice over, or a speaking actor) in the background?

- Yes +1

- No

From seconds X to Y before the major claim, is there text on the screen?

- Yes +1
- No

Count the total number of words on the screen from seconds X to Y before the major claim.

- Divide the total number of words by the duration of the period being measured. Assign points (rounded to a tenth of a point) for the number of words per second.

Count the total number of unique characters from seconds X to Y before the major claim.

- Divide the total number of characters by the duration of the period being measured. Assign points (rounded to a tenth of a point) for the number of characters per second.

Count the total number of shot changes from seconds X to Y before the major claim.

- Divide the total number of shot changes by the duration of the period being measured. Assign points (rounded to a tenth of a point) for the number of shot changes per second.

During the major claim, what relevance does the visual presentation have to the major claim?

- Relevant
- Not Relevant +1

During the major claim, what relevance does the audio presentation have to the major claim?

- Relevant
- Not Relevant +1

## Appendix J

### Reanalysis of Complex ANOVA Using All Measured Distraction Variables, Including Variables with Poor Reliability

In the primary analysis, there were distraction variables with poor reliability that were dropped from the analysis. In this Appendix, I present a summary of those omitted variables, construct a distraction index that uses these omitted variables, and replicate the threeway ANOVA analysis of the relationship between distraction and deception in prescription and nonprescription drug advertisements.

Table J.1 summarizes the frequency of the omitted variables before, during and after the presentation of the major claim.

Table J.1: Distractions Before, During and After the Major Claim

	Frequency				Column Percent			
	Before	During	After	Total	Before	During	After	Total
Is there a change in voice-over or speaking actor during the period?								
Yes	33	2	17	52	20%	1%	18%	12%
No	133	160	78	371	80%	97%	82%	87%
N/A	0	3	0	3	0%	2%	0%	1%
Total	166	165	95	426	100%	100%	100%	100%
Is there a change in voice-over or narrator during the transition into/out of the Major Claim?								
Yes	44	.	34	78	27%	.	30%	28%
No	121	.	60	181	73%	.	54%	65%
N/A	1	.	18	19	1%	.	16%	7%
Total	166	.	112	278	100%	.	100%	100%

How would you best describe the tempo of the music?								
Slow	9	.	.	9	7%	.	.	7%
Moderate	70	.	.	70	55%	.	.	55%
Fast	48	.	.	48	38%	.	.	38%
Total	127	.	.	127	100%	.	.	100%
Just before/after the major claim Is there a change in the music?								
Yes	54	.	43	97	42%	.	47%	44%
No	76	.	49	125	58%	.	53%	56%
Total	130	.	92	222	100%	.	100%	100%
Just before/after the major claim, are there sudden sounds like a crescendo, a crashing sound or other sudden sounds?								
Yes	43	.	26	69	57%	.	63%	59%
No	33	.	15	48	43%	.	37%	41%
Total	76	.	41	117	100%	.	100%	100%

These five additional variables were included in the calculation of the distraction index. Like the original analysis, the index was root-transformed to become a normal variable. The resulting distraction index had a greater mean (2.8) than the original (2.6), but similar distribution (SD including variables with poor reliability  $SD=0.69$ , excluding variables with poor reliability  $=0.68$ ) and followed a similar pattern where there was more distraction during the major claim than before or after.

A complex ANOVA was conducted to describe the relationship between deception and distraction in prescription and nonprescription advertisements. Like in the original model, the model fit was significant ( $F(29,420)=3.63$ ,  $p<0.001$ ) and there was a significant main effect for period ( $F(2,420)=15.42$ ,  $p<0.001$ ). However, when analyzed using the distraction index with more variables, the interaction between the type of ad (prescription or nonprescription) and the truthfulness of the major claim was significant ( $F(4, 420)=3.74$ ,  $p=0.005$ ). Examining the predicted mean distraction within prescription and nonprescription ads for each category, major claims in prescription drug ads (averaged before, during and after the major claim), have more distraction (2.96 units) than nonprescription ads (2.6 units). There were no other differences in the amount of distraction between prescription and nonprescription advertisements.

The main analysis was rerun using a modification of the dependent variable that includes distraction variables that were measured with poor reliability. The reanalysis was essentially the

same as the main analysis. Therefore, I conclude that the exclusion of the variables with poor reliability did not effect the results.

## Appendix K

### Reanalysis of the Complex ANOVA Using Shimp's Typology

The primary analysis measured the relationship between truthfulness of claims and distraction in prescription and nonprescription drug ads, using Preston's typology as a measurement of truthfulness of the major claim. In addition to this method of measuring deception, each claim was categorized as being an objective attribute, a subjective attribute, an objective benefit or a subjective benefit (Shimp, 1979).

Since this is an alternative method of evaluation of truthfulness in drug ad claims, it was important to evaluate the relationship between these two measures of deception and to reanalyze the threeway ANOVA using this alternative measure of deception and compare the results. Table K.1 is a tabulation of Shimp's and Preston's categorization of the 168 ad claims.

There is a positive association between Shimp's categories and Preston's categories, as measured by Kramer's V statistic ( $V=0.38$ ). Interpretation of a V statistic is similar to interpretation of a Pearson's r correlation coefficient. There is a moderate, positive association between measuring deception using Preston's categories and using Shimp's.

Additionally, examining the mean distraction for each combination of Preston's category and Shimp's category (Table K.2), shows there is a linear relationship in the amount of distraction in both Shimp's categories and in Preston's.

The model described in Section 5.10 was reanalyzed using Shimp's category as a variable to measure truthfulness instead of Preston's category. The model fit was significant ( $F(23, 426)=4.26$ ,  $p<0.001$ ). The test met the assumption of sphericity ( $H-F$  Epsilon= $4.56$ ) and had homogeneous variances according to Levine's test ( $F(4,445)=0.59$   $p=0.670$ ). Like in the earlier model, the effect

Table K.1: Crosstabulation of Preston's Typology and Shimp's Typology

Preston's Categories	Shimp's Categories				Total
	Objective Attribute	Objective Benefit	Subjective Attribute	Subjective Benefit	
Objectively True	8	44	0	4	55
Selected Facts	5	9	0	5	19
Minimal Facts	3	20	2	9	34
Nonfacts	7	8	6	23	44
False	1	9	2	4	16
Total	24	89	10	45	168
Objectively True	15%	78%	0%	7%	100%
Selected Facts	26%	47%	0%	26%	100%
Minimal Facts	9%	59%	6%	26%	100%
Nonfacts	16%	18%	14%	52%	100%
False	6%	56%	13%	25%	100%
Total	14%	53%	6%	27%	100%
Objectively True	33%	48%	0%	9%	33%
Selected Facts	21%	10%	0%	11%	11%
Minimal Facts	13%	22%	20%	20%	20%
Nonfacts	29%	9%	60%	51%	26%
False	4%	10%	20%	9%	10%
Total	100%	100%	100%	100%	100%

Table K.2: Mean Distraction for Shimp's and Preston's Categories Averaged Before, During, and After the Major Claim.

Preston's Categories	Shimp's Categories				Total
	Objective Attribute	Objective Benefit	Subjective Attribute	Subjective Benefit	
Objectively True	2.56	2.70	.	2.70	2.68
Selected Facts	2.80	2.69	.	2.37	2.65
Minimal Facts	2.90	2.56	2.50	2.54	2.58
Nonfacts	2.72	2.76	2.59	2.44	2.57
False	2.87	2.48	2.46	1.93	2.37
Total	2.71	2.65	2.54	2.44	2.60

of period was significant ( $F(2,426)=15.12, p<0.001$ ) and the similar "A" shaped curves appeared where there was more distraction during the major claim than after. In this model there was a significant main effect for Shimp's category as well ( $F(3,426)=3.15, p=0.025$ ) indicating there were differences in the amount of distraction, averaged before, during and after the major claim, for both prescription and nonprescription drug ads. There were also no significant differences in the distraction in prescription versus nonprescription ads. Comparing the estimated predicted distraction, claims that were objective attributes were presented with more distraction (2.7 units) than objective benefits (2.7 units), subjective attributes (2.6 units) or subjective benefits (2.4 units). Using pairwise comparisons among means, and adjusting for alpha inflation using Tukey's method, the difference in mean distraction between objective benefits and subjective benefits was significant ( $t=-2.88, p=0.025$ ). None of the two-way or three-way interactions in the model were significant.

In conclusion, deception in claims in drug ads was successfully measured two ways, using Preston's categories of truthfulness (1994) and Shimp's typology (1979). These measures were moderately correlated, indicating both were measures of truthfulness of the major claim in drug advertisements. Re-examination of the relationship between deception and distraction in prescription and nonprescription drug ads using Shimp's typology led to similar findings as with Preston's. However, likely due to the smaller number of categories in Shimp's typology (4) versus Preston's (5), the main effect of deception was significant. There is a weak linear association between deception, as measured by Shimp's categories, and distraction in drug advertisements.

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