Distraction and the Provision of Risk and Benefit Information in Prescription Drug Television Advertising

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ABSTRACT

Jennifer Harlow: Distraction and the Provision of Risk and Benefit Information in Prescription Drug Television Advertising
(under the direction of Heidi Hennink-Kaminski, Ph.D.)

Direct-to-consumer (DTC) advertising of prescription drugs is one of the fastest growing and most controversial forms of consumer marketing. One criticism of DTC advertising is that it misleads consumers by providing them with benefit information while distracting them from information about drug risks. Despite this, there has been very little scholarly research about the prevalence of distracting elements during the presentation of risk and benefit information in DTC television advertising. This thesis was designed to fill this gap in literature and its purpose is two-fold. First, the thesis proposes a definition of distraction in television advertising, drawing from the capacity model of attention and the related conceptual frameworks of information load and information relevance. Second, it reports the results of a content analysis of 58 DTC television advertisements. Findings suggest that some forms of distraction are more prevalent during risk information than during claims about drug benefits. Given the pervasiveness of DTC advertising on television, this study has clear implications for consumers, public policy makers, health care providers, and pharmaceutical marketers.

DEDICATION

To my parents, Doug and Anne Harlow

For giving me the gift of opportunity

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CHAPTER ONE

Introduction

Direct-to-consumer (DTC) advertising of prescription drugs is one of the fastest growing forms of consumer marketing. Since its controversial beginning in the 1980s, prescription medicine has become the second largest advertising category in the U.S. market, only led by automotive (Nielsen, 2009). In 2008 alone, American pharmaceutical companies accounted for $5.1 billion in advertising expenditures. According to IMS Health (2004), a for-profit source for pharmaceutical marketing intelligence, promotional spending has yielded increased sales for at least 49 brand-name drugs. A Kaiser Family Foundation (2003) study of return on investment in DTC advertising found that at least 90% of the brands demonstrated positive returns with an average yield of an additional $4.20 in sales for every dollar spent. The growth in prescription drug advertising has inspired great interest in this category among marketing practitioners, scholars and the medical community.

While annual expenditures keep going up, the debate over the merits and effectiveness of DTC advertising also escalates. Proponents of DTC advertising contend that the explosion in prescription drug advertising is fueling a trend toward better-informed consumers and emphasize its potential to educate consumers and encourage beneficial dialogue between physicians and patients (Kravitz & Bell, 2007). Prior research demonstrates that consumers utilize information in DTC ads in decisions about their health care (Desphande, Menon, Perri & Zinkhan, 2004; Huh, DeLorme, & Reid, 2004) and that it

can increase consumers' awareness of medical conditions and treatments (Perri & Dickson, 1988; Perri & Nelson, 1987). These findings were echoed by a Food and Drug Administration (FDA) report (2003) that concluded that DTC ads can serve positive public health functions such as increasing public awareness of treatable conditions and prompting consumers to seek appropriate treatment from their doctors.

Critics of DTC advertising argue that prescription drugs should not be promoted in the same manner as other consumer products. Currently, the United States and New Zealand are the only two countries that permit DTC advertising (Roth, 2003). Opponents have raised concerns that the ads contribute to over-diagnosis (Mintzes, 2003), patient anxiety, disruption of the patient-physician relationship, rising health care costs (Kravitz & Bell, 2007), and the medicalization of conditions that were previously regarded as ordinary, non-medical aspects of the human condition (Conrad, 2005).

In the United States, the FDA regulates the content of DTC advertisements, specifying that such ads cannot be false or misleading and requires that DTC advertisers give a "fair balance" of information about benefits and risks. These risks may include side effects, allergic reactions, or contraindications. A growing body of literature is largely critical of DTC advertisers, arguing that DTC ads mislead consumers by providing them with benefit information while failing to comply with the FDA's fair balance requirement, which requires that "[T]he presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness or safety" (FDA, 1997, p.2).

The bulk of DTC advertising dollars have been spent on television, accounting for 62% of total DTC media spending in 2008 (Neilsen, 2009). Television ads create special fair

balance compliance challenges for marketers of prescription drugs and policy makers because of the interplay of two different sensory modalities (audio and visual) used to present risk and benefit information. Broadcast prescription drug ads are required to present major product risks in the audio portion of the ads. In a new Draft Guidance proposed in May 2009, FDA regulators recommend that risks should be "presented in clear, understandable language without distraction" (p.20). The draft guidelines do not offer a definition of distraction per se, but suggest that message elements such as background visuals and on-screen text can interfere with consumer comprehension by distracting attention away from the information being presented.

Despite the fact that the FDA has specifically recognized distraction in DTC advertising as a potential concern with implications for marketers and consumer safety, there has been very little scholarly research about the prevalence of distracting elements during the presentation of risk and benefit information in DTC broadcast ads. The purpose of this study is two-fold: 1) to propose an operational definition of distraction in television advertisements to help guide policy makers and pharmaceutical marketers and 2) to assess the prevalence of distracting elements in DTC prescription drug television advertisements.

The following section describes the FDA's existing authority to regulate DTC advertising and current policy issues related to distraction. Prior research on DTC television advertising is then discussed, focusing specifically on studies that have examined features of DTC ads with implications for fair balance of risk and benefit information. The paper then provides a definition of distraction in DTC advertising, drawing from the capacity model of attention (Kahneman, 1973) and related conceptual frameworks of information load and information relevance.

CHAPTER TWO

Background

Regulation of DTC Advertising

A 2005 Congressional Report defined direct-to-consumer (DTC) prescription drug advertising as "any promotion designed by pharmaceutical companies to communicate to the public about prescription drugs through the lay media" (Vogt, 2005, p.1). DTC ads usually fall into one of three categories:

1. *Product-claim ads* contain the brand name of a drug and claims about the product's therapeutic use for a particular health condition;

2. *Help-seeking ads* contain information about the particular health condition that the drug treats and encourage consumers to talk to their doctor about the condition, but they do not contain the drug's brand name nor do they mention any claims about a drug's uses;

3. *Reminder ads* call attention to a drug's brand name but do not mention any particular condition or make claims about the product's uses.

The Federal Food, Drug and Cosmetic Act (FFDCA) provides the statutory requirements for marketing a prescription drug in the United States.[1] When the FFDCA was enacted in 1938, most prescription drug promotion was in the form of written material directed at physicians. In 1962, Congress added section 502(n) to the Act, giving the FDA jurisdiction over drug labeling and advertising. The section included several important requirements for the marketing of new drugs. New drugs must be proven safe and effective

[1] Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 – 399 (1938).

before they can be sold in the United States, and any claims about the product's uses or effectiveness must be substantiated by adequate clinical testing. This requirement that all claims must be substantiated is the legal framework for the FDA's jurisdiction over product-claim advertising.

In 1969, the FDA issued regulations for product-claim advertising.[2] Product-claim ads must have four characteristics:

1. They cannot be false or misleading;
2. They must present a "fair balance" of claims about the drug's therapeutic uses and effectiveness *and* the drug's risks
3. They must contain "facts" that are "material" to the drug's use;
4. They must include all risks from the drug's approved labeling in a "brief summary."

Prior to 1999, the FDA did not distinguish between print and broadcast ads. However, the requirement that product-claim ads had to provide a "brief summary" that included all risks from a drug's approved labeling made it nearly impossible for advertisers to use broadcast ads. The product label contains information about all risks including side effects, contraindications, and precautions. Because broadcast advertisements are often only 30- or 60- seconds long, it was difficult for advertisers to include this type of detailed information.

In August 1999, the FDA issued its *Guidance for Industry: Consumer-Directed Broadcast Advertisements* that made it much easier for pharmaceutical companies to advertise prescription drugs on television. The 1999 guidance represented **"**the Agency's current thinking [at the time] on procedures to fulfill the requirements for disclosure of

[2] 21 C.F.R. § 202.1

product information," (FDA, 1999, p.1). Guidances are not binding law, but are designed to help industry members comply with current regulation. The FDA's 1999 guidance paved the way for drug companies to use broadcast media for product-claim ads without a brief summary, provided that they included the advertised drug's most important risks, called a "major statement" (FDA, 1999, p.2). The major statement is required to be in the audio portion of the advertisement, but can be in the video portion as well. The regulations also require that broadcast advertisements must "present a fair balance between information about effectiveness and information about risk" (FDA, 1999, p.2).

In assessing fair balance, the FDA not only looks at the number and quality of specific benefit and risk statements, but also at the "net impression" of all the elements communicated in the message as a whole (FDA, 2009, p. 4). In a 2009 draft guidance, the FDA responded to requests for specific guidance about how it evaluates adequate risk information in promotional messages (FDA, 2009). The draft guidance suggests that in order to ensure comparable benefit and risk presentations, manufacturers should consider not only the *time* devoted to benefits and risks and the *number* of statements about each, but also the comprehensibility of the language used and the type of information provided. The 2009 draft guidance specifically warns against "the use of audio or visual components that enhance or distract from the presentation of risk or benefit information" (FDA, 2009, p. 11).

If an ad is deemed to be violative, the FDA's Division of Drug, Marketing, Advertising and Communications (DDMAC) team can issue a "warning letter" to the pharmaceutical company asking that the ad be stopped. The 2009 draft guidance followed warning letters sent from the FDA to Novartis and Bayer HealthCare Pharmaceuticals that cite distracting background visuals during the presentation of risk information. The FDA

(2003a) warned Novartis regarding its Lamisil commercial that "the distracting animated visuals and sound effects hamper the communication of the risk information. In addition, SUPERs [text superimposed on-screen] appear on the bottom of the screen during this busy activity [of the commercial animation], thus further distracting from this important information" (p.3). Similarly, a warning letter sent to Bayer HealthCare Pharmaceuticals regarding an ad for the Premenstrual Dysphoric Disorder (PMDD) drug YAZ said that the audio communication of serious risk disclosures during the "major statement" is minimized by distracting visuals, numerous scene changes, and other competing modalities such as background music, which combined to interfere with the presentation of the risk information (FDA, 2009a). Schering-Plough Corp was ordered to discontinue an ad for allergy drug Nasonex after a congressional hearing determined that background visuals in the ad had the potential to distract consumers from side effect information (FDA, 2008). The ad featured a bee that flew around during a description of side effects but simply hovered while benefits were being explained.

The heightened concern about distraction in DTC advertising has triggered self-regulation. Drug companies and medical device manufacturers have responded by adopting voluntary advertising principles for presenting risk information in a manner free from distraction. The most recent revision of the Pharmaceutical Research and Manufacturers of America (PhRMA)'s voluntary *Guiding Principles* (2008) says that DTC advertising should be designed to achieve a balanced presentation of both the benefits and risks of the advertised medicine "in a clear, conspicuous and neutral manner, and without distraction from the content" (p.7).

Further demonstrating its interest in the issue of distraction in DTC advertising, the FDA has initiated a study on the impact of distracting visuals on viewer comprehension of the risks and benefits of advertised drugs (2008). In its proposed study, *Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in DTC Prescription Drug Ads*, the FDA's DDMAC project team suggests that if visuals in a broadcast ad distract the audience from carefully considering the audio presentation of a drug's risks, the ad will not convey an accurate net impression of the benefits and risks of the advertised product.

The FDA's proposed study will examine the role of textual elements and background visuals in the processing of risk information. Advertisers often place superimposed text ("SUPERS") onto the screen to clarify spoken information or to provide extra information that is not included in the audio. For example, during the required description of product's most serious and frequent risks in the ad's audio, information such as adequate provision statements ("See our ad in…") and limits to indication statements may appear on screen. The FDA suggests that this text potentially has the power to distract viewers from the more important audio information if it is inconsistent with the audio portion. The FDA study will also investigate the distracting effect of visuals with a positive tone during the audio presentation of risk information.

While the purpose of the FDA study is to investigate the effect of distracting creative elements on consumer comprehension of risk information, there is little scholarly research to address the extent to which distraction is actually prevalent in today's DTC advertising landscape. Consequently, this thesis is designed to fill this gap in literature by investigating

the prevalence of distracting message elements in product-claim advertising in order to inform future DTC advertising policy and pharmaceutical marketing practices.

CHAPTER THREE

Literature Review

A Definition of Distraction

In order for DTC advertising to educate consumers, messages must provide information they need to make informed decisions. For DTC advertising to be persuasive, it must result in positive attitudes and safe use. There is growing concern about the extent to which DTC advertising is both persuasive and educational about drug risks and benefits.

A key feature of product-specific DTC drug advertising is the balance of benefit and risk information presented to consumers. A number of studies have concluded that consumers comprehend benefit information better than risk information in DTC ads (Abernathy & Adams-Price, 2006; Day, 2005; Glinnert & Schommer, 2005). Television ads create special fair balance compliance challenges for three reasons: the interplay of two different sensory modalities (audio and visual), the amount of information communicated in a relatively short period of time, and the incongruent nature of the two types of information presented (possible positive and negative outcomes of using the product). These characteristics of DTC television ads create opportunities for distraction of consumers from information in the message.

Distraction in DTC television advertising is not specifically defined in FDA regulations or in industry self-regulation. Previous research in psychology and mass communication, however, suggests several circumstances in which distraction from

information in advertisements is likely to occur. In cognitive psychology, distraction is defined simply as divided attention (Hunt & Ellis, 2004). Capacity models of attention (Kahneman, 1973) assume that our psychological resources are finite; that is, every person, regardless of expertise, only has a certain amount of cognitive capacity to devote to various mental tasks. Different tasks require different amounts of this capacity, and the number of activities that can be done simultaneously is determined by the capacity that each requires. Attention is the process of allocating cognitive resources to various mental tasks. Attention is important in determining which mental tasks are accomplished and how well they are performed. Thus, distracting, or dividing viewers' attention from information in a message can affect how well viewers comprehend that information. Previous research suggests that both information load and the relevance of information presented in one channel to the other have the potential to distract consumers.

Distraction as information load. Information load refers to "the variety of stimuli (in type and number) to which the receiver must attend" (Jacoby, 1977, p. 569). Research on consumer information processing (Bettman, 1975; Jacoby, Speller, and Kohn, 1974) suggests that information overload, or too much information, may reduce subjects' attention and comprehension. Experimental studies in consumer psychology research have demonstrated a number of television advertising elements that can contribute to information load and divided attention: music (Hahn and Huang, 1999), presentation rate (Wingfield, Lindfield & Goodglass, 2000), and animation (Hong, Thong, & Tam, 2004).

Mass communication researchers have conceptualized the two types of distraction inherent in television advertising as visual distraction and audio distraction (See Tiege, 1975; Festinger & Macoby, 1964). In terms of audio distraction, experimental studies have

demonstrated that both music and the rate of speech can affect information load. The presence of music in advertising messages can affect message processing, and both the tempo and familiarity of the music can moderate these effects. Background music in TV advertising is information offered to viewers in addition to the main message. Fast tempo music requires more processing resources than slower tempo music (Hahn & Hwang, 1999). While the presence of any music increases information load, familiar music can actually facilitate message processing because it attracts viewers' attention to the message. Conversely, unfamiliar music makes message processing more difficult because it distracts attention away from the message.

The rate at which spoken information in an advertisement is presented can also affect information load. Successful comprehension of spoken information routinely occurs for speech presented at an average rate of 140 to 180 words per minute (Wingfield, Lindfiled, and Goodglass, 2000). A presentation rate of greater than 180 wpm is considered insufficient for successful comprehension of speech communication.

The FDA recognizes the impact of audio information load elements on the distraction potential of DTC television advertisements. The 2009 guidance notes several audio factors that the FDA will consider when evaluating distraction in television ads including verbal pace, volume, and the presence of background music during the presentation of both benefit and risks (FDA, 2009).

In terms of visual distraction, both the presence and speed of animation on-screen can distract consumers away from other audio and visual elements of the message (Hong, Thong, & Tam, 2004). On-screen animation attracts viewers' attention and distracts it away from the audio portion, and faster animation is more distracting than slower animation. The FDA also

recognizes the impact of visual information load elements on the distraction potential of DTC commercials. The 2009 guidance (FDA, 2009) says that graphics such as on-screen text, busy scenes, frequent scene changes and moving camera angles can "misleadingly minimize the risks of the product being promoted by detracting from the audience's comprehension of the risk presentation" (p. 20).

Based on this literature review, Table 1 summarizes the operational definition of distracting audio and visual elements that can contribute to information load.

Table 1
Information Load Elements

Channel	Message Elements
Audio	Presence of music Music familiarity Music tempo Other sounds (besides music) Speech presentation rate
Visual	Presence of animation Number of superimposed words Busy scenes (number of models) Number of scene changes Number of camera-angle changes

Distraction as irrelevant stimulation. Television is a two-channel communication medium involving two sensory modalities, audio and visual. In mass communication literature, visual information is considered irrelevant to audio information when it is not a "matching representation of information across communication channels" (Baron, Baron, & Miller, 1973, p. 310). In studies of the effects of distraction on persuasion, distraction is often conceptualized as the presentation of stimulation in one channel that is irrelevant to

information in the other channel (See Tiege, 1975; Festinger & Macoby, 1964). To the extent that visual elements such as superimposed text or background visuals are irrelevant to the information being concurrently presented in the audio channel, viewers are distracted *from* the audio channel and *to* the video channel. Persuasion studies have demonstrated that compelling emotional appeals such as humor (Strick, van Baaren, Holland, & van Knippenberg, 2009) and sex (Reichert, Heckler, & Jackson, 2001), when irrelevant to the context of the information being provided in the ad, can distract viewers from carefully considering the information.

In scholarly literature, the term "irrelevant" is used synonymously with the terms "discrepant" (Tiedge, 1975) and "incongruous" (Romer, 1979) to describe concurrently presented information in advertising. While scholarly literature uses the term "irrelevant" stimulation to describe distracting content, the FDA uses the terms "competing" and "inconsistent" (2008, p.3). In the 2009 guidance, the FDA refers to irrelevant visual elements during the audio presentation of risk information as "competing, compelling visual information" (p.3).

To operationalize competing, compelling visuals in its current experimental evaluation of the impact of distraction in DTC television advertisements, the FDA incorporates two types of visual elements, superimposed text and background visuals. That study has three independent variables: visual consistency with audio risks (VCAR), tonal consistency with audio risks (TCAR) and the presence and consistency of superimposed text (SUPERS). The FDA defines VCAR as visual information that either reinforces the product's risks being presented in the audio channel (consistent conditions) or reinforces the product's benefits (inconsistent condition) (2008). The experimental conditions will examine

the effects of different types of visual information such as text, background visuals and visual demonstrations. Reinforcing text is defined as a verbatim repetition of the audio risk; "competing" text will include contextual information for understanding usage and will not contain risk or benefit information. In inconsistent conditions, participants will see a visual demonstration of the product's benefits.[3] The degree or magnitude of consistency or inconsistency (very consistent, somewhat consistent, neutral, somewhat inconsistent, and very inconsistent) will be manipulated by the number of statements interspersed with images of the drug logo. The brand logo is considered a "neutral" image and in neutral conditions, the brand logo will be the only thing on screen during the entire risk presentation.

The FDA defines tonal consistency with audio risks as scenes that show patients "living their lives" (FDA, 2008, p. 29), such as socializing with family and friends and enjoying recreational activities. While the FDA notes that it would be unrealistic for DTC advertisers to show visual images of patients experiencing side effects, the agency hypothesizes that visuals that are positive in tone will impede comprehension of audio risk information more than neutral images. Moreover, the FDA suggests that images evoking a mildly positive tone will hinder comprehension less than those that are strongly positive.

Drawing from the literature review, Table 2 summarizes the ways in which the two types of visual elements may be irrelevant to the audio presentation of risk and benefit information.

[3] The DTC ad being manipulated for the experimental treatment is for a blood pressure medicine. In the inconsistent conditions, participants will see blood pressure numbers decreasing from a high, dangerous number to an ideal number within a normal range.

Table 2:
Irrelevant Visual Elements by Commercial Segment

Commercial Segment	Type of Irrelevant Visual Element	Description
Risk	Superimposed text	Audio statement of drug risks while superimposed text presents information irrelevant to drug risks
	Background visuals	Audio statement of drug risks while background visuals depict information irrelevant to drug risks
Benefit	Superimposed text	Audio statement of drug benefits while superimposed text presents information irrelevant to drug benefits
	Background visuals	Audio statement of drug benefits while background visuals depict information irrelevant to drug benefits

When examined as information load and irrelevant visual elements, distraction in DTC advertising can influence processing of risk- and benefit- information and consumers' net impression of the risks and benefits of the advertised drug by drawing cognitive resources away from some information and to other information.

Distraction as defined in prior content analyses of DTC advertising. Only three content analyses to date have examined DTC television advertising (Frosch, Kruger, Hornik, Crohnolm, & Barg, 2007; Kaphingst, Dejong, Rudd, & Daltroy, 2004; Macias, Pashupati, and Lewis, 2007). Of those, two were specifically designed to examine features of DTC

television ads that might interfere with consumer comprehension of the risk information required in product-claim ads. While they did not specifically address the concept of distraction, both studies examined elements of advertisements that can increase information load and irrelevant visual stimulation during the audio presentation of risk information. Macias, Pashupati, and Lewis (2007) examined in what format risk information was presented and what proportion of total commercial time is devoted to risk information. The television advertisements they analyzed were broadcast during a seven-day period in July 2003 on four major television network stations (ABC, CBS, FOX, NBC) and three cable networks (CNN, MSNBC, and Lifetime) in the Southeastern United States. They found that almost all ads provided the risk information only in the voice-over audio channel while the video channel presented information irrelevant to the risk information (97.8%). Only 2.2% included the risk information in both the audio channel in the voice-over and the visual channel and in the form of superimposed text. For both 30- and 60-second ads that included risk information, an average of 13% of commercial time was devoted to risk information.

Kaphingst and colleagues (2004) analyzed product-claim DTC television advertisements by examining features that may interfere with customer comprehension of risk information. They focused on product-claim advertisements broadcast during February and March 2001 on the three major television network stations in Boston, Massachusetts. They measured fact density, or the number of facts given about a drug's benefits and risks, and the type of visual information shown during the audio presentation of risk information. They found that while ads provided an average of six facts about drug benefits and an average of 10 facts about risks, the average number of facts-per-second was much lower for benefits (.54 facts/sec) than for risks (.78 facts/sec.), indicating that viewers had more time to

absorb benefits facts than risk facts. Additionally, they found that 91% of ads they studied showed positive or neutral visual images during the presentation of risk information. Ninety-six percent gave text references to at least one source of product information (for example, a print ad) during the audio presentation of risk information. None showed text messages containing risk information while the risk information was being presented in audio form. The type of information conveyed through on-screen text included print ad reference, website address, toll-free number, and variations in effectiveness. While these studies are useful in providing insight into the provision of risk information in television prescription drug ads, they do not specifically address the concept of distraction that is inherent in the television medium and has become a growing concern for regulators.

Only one content analysis to date has specifically examined distraction in DTC advertising. A content analysis by Hoy and Andrews (2004) assessed prime-time television advertising adherence to the Federal Trade Commission (FTC)'s "clear and conspicuous" disclosure requirements. While this study was not specific to DTC drug ads, the study examined commercials for any type of product that required disclosure, including drug ads.

In their definition of distraction, Hoy and Andrews incorporated the concepts of information load and irrelevant stimulation. They defined distraction as "extraneous nonverbal elements such as music, sound effects, and unrelated pictorial information" (2004, p.173). They found that 99.5% of ads that included risk information in the form of superimposed text had some form of distraction while the SUPER was on-screen. Almost all (99.2%) had competing sounds, including music; 33.3% had scene changes, and 86.6% had moving visuals. Of ads with audio risk information, 97.3% included distraction during the disclosure. Thirty-seven percent had a scene change, 89.6% had moving visuals, and 95.9%

had other sounds, including music occurring concurrently. Only 2.7% had no distracting elements during the audio presentation of risk information. In addition to specifically addressing distraction during the presentation of risk disclosure, Hoy and Andrews (2004) also measured the presentation rate of audio risk information. They found that 52.6% of ads that contained audio risk information provided the disclosure at a rate of over 132 words per minute and 36.6% were faster than 180 words per minute.

The Hoy and Andrews study was designed to examine adherence to the FTC's "clear and conspicuous" standard for risk disclosure. Similarly, Macias, Pashupati, and Lewis (2007) and Kaphingst and colleagues (2004) examined the provision of risk information in DTC television advertisements. The main limitation of interpreting findings of these studies within the context of the FDA's fair balance requirement is that they examined distracting elements only during the presentation of risk information. Television is a very "deep" medium in that it employs audio, imagery and textual components. Commercials often employ moving visuals, music, scene changes and imagery with positive tone throughout the message, not just during the risk segment. In order to assess distraction within the context of fair balance, it is necessary to determine if distracting elements are not only present during risk segment, but also more frequent than during the benefit segment of the commercial.

Research Questions

In order to examine the prevalence of distraction during the risk and benefit segments of DTC television advertisements, this study operationalizes distraction in terms of both audio and visual elements that contribute to information load and the relevance of visual elements to audio information. Previous research has employed various qualities of both message content and format in defining information load and information relevance in

television advertisements. In this study, information load will be operationalized using the visual and audio elements summarized in Table 1.

RQ1: What are the differences, if any, in the use of visual information load elements between the risk and benefit segments of the advertisements in terms of:
RQ1a: presence of animation,
RQ1b: number of super-imposed words,
RQ1c: busy scenes (number of models),
RQ1d: number of scene changes, and
RQ1e: number of camera-angle changes?

RQ2: What are the differences, if any, in the use of audio information load elements between the risk and benefit segments of the advertisements in terms of:
RQ2a: presence of music,
RQ2b: music familiarity,
RQ2c: music tempo,
RQ2d: presence of other sounds (besides music), and
RQ2e: presentation rate (words per second)?

Because a presentation rate of fewer than 180 words per minute is considered sufficient audio information load, and thus is necessary for successful comprehension of speech communication, the study also asks:

RQ3: What are the differences, if any, in the sufficiency of audio presentation rate between the risk and benefit segments of the advertisements?

The relevance of visual elements to audio information is defined as the extent to which the visual elements are a "matching representation" (Baron, Baron, & Miller, 1973, p. 310) of audio information.

RQ4: What are the differences, if any, in the relevance of background visuals to the audio statements between the risk and benefit segments of the advertisements?

RQ5: What are the differences, if any, in the relevance of superimposed text to the audio statements between the risk and benefit segments of the advertisements?

CHAPTER FOUR

Method

The study is a content analysis of the properties of DTC prescription drug television ads broadcast during a constructed week in January 2010. Content analysis is a standard method for advertising research (Kolbe & Burnett, 1991) and has been used in other research to examine trends in prescription drug advertising. The strength of the method for evaluating message content and characteristics is that the ads will be obtained and analyzed in their naturally occurring forms. Although content analyses do not directly measure media effects, they can provide an empirical starting point for generating new research about effects (Kassarjian, 1977). Moreover, concern about the effects of message content on audience is meaningless without knowledge about the content (Riffe, Lacy, & Fico, 2005).

Content analysis involves drawing representative samples of content, training coders to use the category rules developed to measure or reflect differences in content, and measuring the reliability (agreement or stability over time) of coders in applying to rules (Riffe, Lacy, & Fico, 2005). Data are then analyzed to describe the patterns and characteristics appropriate for addressing the specific research questions and hypotheses.

Sampling Procedure

This study employed a convenience sample of commercials recorded during a 14-day period from January 4 – January 17, 2010. To obtain a representative probability sampling of DTC ads across all seven days of the week and across various day parts, blocks of

programming were recorded using a constructed week. The constructed week comprised six day parts: morning (6-10 a.m.), morning daytime (10 a.m.-1 p.m.), afternoon daytime (1-4 p.m.), early fringe (4-8 p.m.), prime time (8-11 p.m.), and late fringe (11 p.m. – 2 a.m.). Programs were recorded from the four major broadcast networks (ABC, CBS, NBC, and FOX) (See Appendix A for constructed week). Broadcast networks were selected due to the national nature of DTC advertising and the exploratory nature of this study. These stations target a broad audience, whereas cable channels usually target a narrower demographic group. This approach yielded a total of 160 hours of programming from the following local network affiliates in the Raleigh, NC market: WTDV (ABC), WRAL (CBS), WNCN (NBC), and WRAX (FOX). The sampling procedure yielded a total of 195 direct-to-consumer product-claim advertisements for the 14-day period. Of these, 58 were unduplicated ads. As described later, the study focused on unduplicated product claim ads.

Unit of Analysis

Given the focus of this project on product-claim television advertisements targeted directly to consumers, advertisements were included in the sample if they (1) advertised a prescription drug, (2) stated the brand name of the drug; and (3) gave at least one medical indication for the drug. Each commercial was given a unique identifier and was saved as an MPEG file on a DVD. The researcher then compared each ad manually and counted the first instance of an ad in the "unduplicated" sample. An ad was considered unique if any format or content varied from another ad. The unique MPEG video files were compiled onto a DVD.

As noted by Reid, King and Kreshel (1994), the decision whether to include duplicate ads in content analyses of advertising is based upon the research objectives. Because the

purpose of this study is to examine the prevalence of distracting content in prescription drug advertising as an industry practice and not to infer the frequency with which consumers encounter messages with distracting content, duplicates will not be included in the analysis. The sampling procedure yielded a total of 195 direct-to-consumer product-claim advertisements for the 14-day period. Of these, 58 were unduplicated ads.

Coding Categories

The coding dimensions were derived from the literature discussed earlier about information load and information relevance and included, but were not limited to, variables specifically addressed in the FDA's 1999 *Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion*. The coding sheet (Appendix B) was derived from the template used in Macias, Pashupati, and Lewis's analysis of DTC ad content (2007) and Hoy and Andrews's prior analysis of disclosures in television advertising (2004).

The research questions ask about the audio and visual elements of the advertisements during the presentation of risk and benefit information. Thus, the code sheet was organized in three sections: 1) the advertisement characteristics, 2) risk disclosure profile, and 3) product claim profile. The first part of the code sheet captured characteristics of the commercials including broadcast date, network, day part, ad length, brand name, pharmaceutical company, and medical condition being treated.

The second part of the code sheet, the risk disclosure profile, measured the characteristics of the audio statement of drug risks, and the other audio and visual elements presented concurrently during the audio statement of drug risks. Coders were instructed that the risk disclosure profile was specific to the portion of the ad in which information about

drug risks were presented verbally. Risk information was defined as information about side effects, allergic reactions, or contraindications. This definition was based on the FDA's requirement that the brief summary include:

1. Who should not take the drug
2. When the drug should not be taken
3. Possible serious side effects of the drug and, if known, what can be done to lower the chance of having them
4. Frequently occurring, but not necessarily serious, side effects (FDA, 2009).

The third section of the code sheet was the product claim profile. The product claim profile was specific to the rest of the commercial in which the audio channel was dedicated to benefit information. The FDA defines benefit information as "all claims about the advertised drug or what it does" (2009). Based upon this definition, limitations on effectiveness were included as part of the benefit information.

The same information load and information relevance variables included in the disclosure profile were coded in the product claim profile.

Information load. Research question 1 asked if there are any differences in the use of visual information load elements between the risk and benefit segments of the advertisements. Visual information load was measured by the presence of animation, number of super-imposed words, number of models, number of scene changes, and number of camera-angle changes. Coders were asked to indicate if animation or text was present (yes/no). If text was present, they coded the number of words on screen. Coders also indicated the number of models on screen during the audio risk information and the number of times the camera angles and scenes changes.

Research question 2 asked if there are any differences in the use of audio information load elements between the risk and benefit segments of the advertisements. Audio information load was measured by the presence, tempo, and familiarity of music, the speech presentation rate, and the presence of other sounds Coders were asked to indicate if music was present (yes/no), if it was familiar to them (yes/no), and whether they considered the beat to be fast, medium, or slow. They indicated the presence of other background sounds and how many words were spoken during the risk and benefit information. To control for the effect of duration of risk and benefit information on the number of audio and visual elements, coders were asked to indicate the length of each commercial segment to the nearest tenth-second. Then, the number of audio and visual information load elements per second was calculated for each commercial segment.

To answer research question 3 about the sufficiency of speech presentation rate during the risk and benefit segments, coders were asked to indicate the amount of time devoted to risk and benefit information, to the nearest tenth of a second. The presentation rate was then calculated as number of words per minute.

Relevance of visual elements to audio information. Research questions 4 and 5 pertain to the relevance of visual elements to the audio presentation of risk and benefit information. If superimposed text was present, coders also indicated whether that text was neutral, relevant or irrelevant to the audio information presented during the risk and benefit segments. Text was considered to be neutral if it solely provided identifying information, such as a Web site address, brand name or logo. For the risk segment, text was considered relevant if it reinforced or repeated audio statements of drug risks. Irrelevant text was defined as providing information other than drug risks, such as usage directions, product

benefit claims, or directing viewers to another information source (e.g., "Please see our ad in…"). For the benefit segment, text was considered to be relevant only if it reinforced or repeated audio statements about drug benefits. Irrelevant text was defined as providing information other than drug benefits, such as usage directions, drug risks, or directing viewers to another information source (e.g., "Please see our ad in…"). If there were both relevant and irrelevant text on-screen during the audio statement of risks, coders were asked to indicate their overall impression of relevance.

Similarly, coders recorded the relevance of background visuals to the audio statements in the risk and benefit segments of the advertisements. For the risk segment, it was acknowledged that advertisers are not likely to show visuals of someone experiencing side effects. However, background visuals were considered to be relevant to the audio information if what was happening on screen "matched" the audio statements about drug risks (for example, if the person on screen was telling the audience about drug risks). Irrelevant visuals reinforce the benefits of taking the drug. An example would be positive imagery of people happily "living their lives" while a voiceover talks about drug risks.

Development of coding sheet. A convenience sample of six unique DTC commercials that aired on the *NBC Evening News* during November 2009 and were not part of the sample were reviewed in the development of the coding sheet to ensure that coding dimensions were mutually exclusive, exhaustive, and adequately captured the content. Face validity (Riffe, Lacy, & Fico, 2009) of the coding categories was assessed by providing the coding sheet and two sample ads to two master's students at the Duke University who were not official coders for the study. These students assessed their ability to complete the coding sheet for both ads using the information provided in the training manual.

Coding Procedure & Pilot Study

Three graduate students in journalism and mass communication at the University of North Carolina at Chapel Hill for whom English is their native language were employed as paid coders. Coders were provided with a training manual that described the coding procedure and defined the content categories. The purpose of the training manual was to ensure valid findings and to make future replications of the research possible. The researcher facilitated an initial three-hour training session for coders. The purpose of the coder training was to familiarize them with the content being analyzed and to establish consistent coding procedures.

A three-step process was used to train the coders. First, the researcher reviewed the coder training manual, warned coders against coder fatigue, and specified that they should begin each coding session by reading the coding protocol. Second, coders practiced using the coding protocol by coding two DTC commercials as a group. Third, coders were asked to independently code one additional ad after the group discussion to help identify troublesome variables and determine points of clarification to discuss before the pilot study. To avoid sensitizing the coders to the data set, the commercials for this part of training were ads that aired previously on the *NBC Evening News* and thus were not part of the sample.

An official pilot study was conducted to check inter-coder reliability and the clarity of the coding sheet and definitions. Coders coded a convenience sample of twelve unique DTC commercials that previously aired on the *NBC Evening News* and were not part of the sample. A pretest is critical in content analysis to establish reliability. Inter-coder reliability was assessed in the pretest using the percentage of agreement method, which measures the degree of relevance between coders applying the same set of categories to the same content

(Kassarjian, 1977). Each coder was given a DVD of the commercials and a stopwatch. They were asked to enter data directly into an Excel spreadsheet on one computer while viewing the DVD either on a television or on a second computer. Upon completion, coders sent the Excel file to the researcher. Inter-coder reliability was calculated using the percentage agreement method (Kassarjian, 1977).

Table 3 reports the percentage agreement for all variables in the pilot study. All but eight variables (in boldface) achieved the acceptable 80% level as proposed by Riffe, Lacy and Fico (1998).

Table 3
Pilot Study Results

Variable Name	Percent Agreement
Network	100.0%
Day	91.6%
Daypart	91.6%
Drug name	100.0%
Company name	91.6%
Commercial length	91.6%
Medical condition	100.0%
Risk continuity	100.0%
Risk time	83.3%
Risk words	83.3%
Risk music	100.0%
Risk music familiarity	100.0%
Risk music tempo	83.3%
Risk other sounds	91.6%
Change in tempo	91.6%
Change in volume	91.6%
Change in voiceover	91.6%
Risk text	100.0%
Risk text word count	83.3%
Risk text relevance	83.3%
Risk background visuals relevance	83.3%
Risk animation	**75.0%**
Risk animation speed	83.3%
Risk character count	**50.0%**
Risk scene changes count	**41.6%**
Risk camera angle changes count	**41.6%**
Benefit time	83.3%
Benefit word count	75.0%
Benefit music	91.6%
Benefit music familiarity	100.0%
Benefit music tempo	66.6%
Benefit other sounds	83.3%
Benefit text	100.0%
Benefit text word count	83.0%
Benefit text relevance	83.0%
Benefit background visuals relevance	83.0%
Benefit animation	**66.6%**
Benefit character count	**50.0%**

Benefit scene changes count	**50.0%**
Benefit camera angle changes count	**41.6%**

Thus, additional training was provided for those eight variables.

Number of scene and camera angle changes. Percentage of agreement for number of scene changes during the risk segment was only 41.6% and 50% during the product-claims. Number of camera angle change yielded only 41.6% agreement for both risk and benefit segments. A discussion with the coders revealed that it was often difficult to distinguish between a moving camera angle and a scene change. Subsequently, these four variables were condensed into two variables: number of shot changes during risk statement and number of shot changes during product claims. A shot change was redefined in the coding manual as a "cut" in the reel.

Number of characters on screen. The two variables number of characters on screen during the verbal risk statement and number of characters on screen during the product-claim segments yielded 50% and 50% agreement, respectively. This is understandable given that many of the commercials include scenes in public places such as restaurants and parks where there are large numbers of characters in the scene. Coders were asked to judge the number of characters more carefully and the operational definition was reiterated. Coders were asked to count any unique characters that they could see any part of during the segments.

Presence of animation. The two presence of animation variables yielded 78% agreement for the risk segment and 66.6% agreement for the product-claim segment. Follow- up discussions with coders revealed that there was disagreement about whether moving or flashing text was considered animation. Coders were given further definition of animation as any illustration, drawing or graphic that moves.

Following the pilot study, the three coders then independently coded every unique ad in the sample. To ensure independence, coders were asked not to discuss the ads with one another, but to refer to the directions on the coding instructions for completing the data file. Coders entered data directly into an Excel file according to directions on the code sheet.

Inter-coder reliability

Reliability scores for the 39 variables were calculated using Perreault and Leigh's (1989) reliability index. The reliability index (I_r) has been noted by a number of researchers (e.g., Kolbe & Burnett, 1991; Hoy & Andrews, 2004) as the best measure for inter-judge reliability for nominal data based on subjective judgment. The strength of the method is its ability to account for the number of category options for a given variable when considering chance agreement.

The overall percent agreement among the three coders was calculated for each variable in the 58 unique ads. The overall percent agreement was then used to calculate the reliability index (I_r). The estimated reliability indexes are included in Table 4. The reliability indexes for all but three variables (in boldface) exceeded the critical value of .85 as suggested by Perreault and Leigh (1989).

Table 4
Perreault & Leigh Reliability Index

Variable Name	Percent Agreement	Categories	Ir
Network	100.0%	4	1.00
Day	100.0%	7	1.00
Daypart	100.0%	6	1.00
Drug name	100.0%	27	1.00
Company name	97.0%	9	0.98
Commercial length	97.0%	6	0.98
Medical condition	98.0%	21	0.99
Risk continuity	93.0%	2	0.93
Risk time	86.0%	59	0.93
Risk words	88.0%	169	0.94
Risk music	100.0%	2	1.00
Risk music familiarity	100.0%	2	1.00
Risk music tempo	**45.0%**	**3**	**0.42**
Risk other sounds	93.0%	2	0.93
Change in tempo	86.0%	4	0.90
Change in volume	86.0%	3	0.89
Change in voiceover	95.0%	2	0.95
Risk text	100.0%	2	1.00
Risk text word count	88.0%	84	0.94
Risk text relevance	97.0%	3	0.98
Risk background visuals relevance	86.0%	3	0.89
Risk animation	88.0%	2	0.87
Risk animation speed	95.0%	3	0.96
Risk character count	95.0%	85	0.97
Risk screen changes count	95.0%	22	0.97
Benefit time	86.0%	50	0.93
Benefit word count	78.0%	133	0.88
Benefit music	98.0%	2	0.98
Benefit music familiarity	100.0%	2	1.00
Benefit music tempo	**62.0%**	**4**	**0.70**
Benefit other sounds	**83.0%**	**2**	**0.81**
Benefit text	100.0%	2	1.00
Benefit text word count	79.0%	179	0.89
Benefit text relevance	98.0%	3	0.98
Benefit background visuals relevance	83.0%	3	0.86
Benefit animation	95.0%	2	0.95
Benefit character count	78.0%	179	0.88
Benefit shot changes count	88.0%	16	0.93

The two variables risk music tempo (I_r=.42) and benefit music tempo (I_r=.70) did not achieve the .85 level, largely because the categories, “fast,” “medium,” or “slow” tempo are so subjective. Similarly, the other sounds during the product claims variable only yielded I_r = .81. These three variables were dropped from the analysis.

CHAPTER FIVE

Results

Sample Description

The sampling procedure yielded a total of 195 direct-to-consumer product-claim advertisements for the 14-day period. Of these, 58 were unduplicated ads. For the total sample, including duplicate ads, the largest proportion (37%) were on ABC, followed by NBC (29%), CBS (28%), and FOX (6%). Seventeen percent of the ads were broadcast Monday, 19% Tuesday, 21% Wednesday, 9% Thursday, 14% Friday, 8% Saturday, and 12% Sunday. Twenty-four percent were during the early fringe day part (4-8 p.m.), followed by 21% afternoon daytime (1-4 p.m.), 20% prime time (8-11 p.m.), 17% morning (6-10 a.m.), 7% morning daytime (10 a.m.-1 p.m.), and 2% late fringe (11 p.m.-2 a.m.).

For the unduplicated sample, psychiatric and neurological disorders (such as depression and Alzheimer's) were the most frequently targeted conditions, accounting for 14 (24%) of the ads. Cardiovascular disease (such as high cholesterol and Peripheral Artery Disease) was the next most frequent, with 11 (19%) of the sample. The following conditions: respiratory conditions (6), erectile dysfunction (6), osteoporosis (3), nicotine addiction (3), overactive bladder (3), allergies (1), contraceptive device (1), enlarged prostate (1), and hypotrichosis (inadequate eyelashes) (1) made up the remaining 57% of the sample. The majority (44; 75.9%) of the unique ads were 60-second ads, 3.4% (2) were 30-second ads, 13.8% (8) were 90, and 5.2% (3) were another length.

Information Load

Research questions 1 and 2 operationalized distracting content as the use of visual and audio elements that increase information load.

Visual information load elements. Research question 1 asked whether there were differences in the presence of animation, presence of and number of superimposed words, number of models, and number of shot changes between the risk and benefit segments of the advertisements. As shown in Table 5, superimposed text was present in the risk (100%) and benefit (100%) segments of all ads. Animation was present more often during benefit information (70.7%) than during risk information (8.6%) (χ^2= 46.69, df = 1, $p \leq .001$).

On average, there were more superimposed words during the benefit segments (M = 58.4, SD = 29.5) than the risk segments (M = 28.0, SD = 19.4) (t = -6.56, df = 98.51, $p \leq$ .001). Similarly, there were more shot changes during the benefit segments (M = 10.8, SD = 4.2) than the risk segments (M = 6.8, SD = 6.0) (t = -4.18, df = 102.3, $p \leq .001$). However, there was no difference in the average number of characters on screen between the risk (M = 11.2, SD = 12.9) and benefit segments (M = 11.8, SD = 10.8) (t = -0.27, df = 110.0, p = .79).

Table 5
Visual Information Load Elements by Commercial Segment

Element	Benefit N	Benefit Percent	Risk N	Risk Percent	χ^2	*df*	*p*
Presence of superimposed text	58	100.0	58	100.0	undefined	1	≤ .001
Presence of Animation	41	70.7	5	8.6	46.69	1	≤ .001
	Benefit *M*	Benefit *SD*	Risk *M*	Risk *SD*	*t*	*df*	*p*
Number of superimposed words	58.4	29.5	28.0	19.4	-6.56	98.5	≤ .001
Number of characters	11.8	10.8	11.2	12.9	-0.27	110.0	NS
Number of shot changes	10.8	4.2	6.8	6.0	-4.18	102.3	≤ .001

Audio information load elements. Research question 2 asked whether there were differences in the presence of music, music familiarity, presence of other sounds besides music, and presentation rate between the risk and benefit segments of the advertisements. As shown in Table 6 music was present in the risk (98.3%) and benefit (98.3%) segments of all but one ad. Music was familiar in only one ad in both the risk (1.7%) and benefit segments (1.7%). Sounds other than music were present more often during benefit information (25.9%) than risk information (3.4%) (χ^2= 9.93, *df* = 1, *p* = .002).

Table 6
Audio Information Load Elements by Commercial Segment

Element	Benefit		Risk		χ^2	*df*	*p*
	N	Percent	N	Percent			
Presence of music	57	98.3	57	98.3	undefined	1	NS
Familiar Music	1	1.7	1	1.7	undefined	1	NS
Presence of other sounds	15	25.9	2	3.4	9.925	1	≤ .01

Average information load per second. As shown in Table 7, more total commercial time (in seconds) was devoted to benefit information (M = 39.1, SD = 14.1) than to risk information (M = 26.5, SD = 12.6) (t= -5.06, df = 112.6, $p \leq .001$). There were more words spoken per second during risk information (M = 3.4, SD = 0.3) than during benefit information (M = 2.6, SD = 0.4) (t= 13.19, df = 102.8, $p \leq .001$). There were more superimposed words on-screen per second during benefit segments (M = 1.5, SD = 0.7) than the risk segments (M = 1.1, SD = 0.6) (t= -3.75, df = 111.3, $p \leq .01$). Shot changes were also more frequent during the benefits (M = 0.3, SD = 0.1) than risks (M = 0.22, SD = 0.1) (t= -2.41, df = 113.17, p = .017). There was no significant difference in the number of characters on screen per second between the benefit and risk segments.

Table 7
Information Load Elements by Commercial Segment

Element	Benefit *M*	Benefit *SD*	Risk *M*	Risk *SD*	*t*	*df*	*p*
Total commercial time (sec)	39.1	14.1	26.5	12.6	-5.06	112.6	≤ .001
Spoken words/sec	2.6	0.4	3.4	0.3	13.19	102.8	≤ .001
Superimposed words/sec	1.5	0.7	1.1	0.6	-3.75	111.3	≤.001
Shot changes/sec	0.3	0.1	0.2	0.1	-2.41	113.2	≤ .05
Characters/sec	0.3	0.3	0.5	0.8	1.66	69.9	NS

Sufficiency of Audio Presentation Rate. Research question 3 asked if there was a difference in the sufficiency of audio presentation rate between the risk and benefit segments of the advertisements. As demonstrated in table 8, the audio risk information (98.3%) was presented at a rate over 180 wpm in all but one of the ads. In contrast, the benefit information was presented at a sufficient rate of 180 or fewer wpm in nearly all (93.1%) of the ads (χ^2 = 93.49, df = 1, p ≤ .001).

Table 8
Sufficiency of Audio Presentation Rate by Commercial Segment

	Benefit N	Benefit Percent	Risk N	Risk Percent
≤ 180 wpm	54	93.1	1	1.7
> 180 wpm	4	6.9	57	98.3
χ^2 = 93.49, df = 1, p ≤ .001				

Relevance of visual elements to audio information

Research questions 4 and 5 pertain to the relevance of visual elements to the audio presentation of risk and benefit information. Research question 4 asked whether there were

differences in the relevance of background visuals to the audio information provided during the risk and benefit segments of the ads. As shown in Table 9, background visuals were irrelevant more often during audio risk information (82.8%) than during audio benefit information (0.0%) ($\chi^2 = 78.51$, $df = 5$, $p \leq .001$).

Research question 5 asked whether there were differences in the relevance of superimposed text to the audio information provided during the risk and benefit segments of the ads. Similar to the background visuals, superimposed text was irrelevant more often during audio risk information (74.1%) than during audio benefit information (60.3%) ($\chi^2 = 124$, $df = 5$, $p \leq .001$).

Table 9
Relevance of Visual Elements to Audio Information by Commercial Segment

Visual Element	Benefit		Risk	
	N	Percent	N	Percent
Background Visuals				
Relevant	58	100.0	10	17.2
Irrelevant	0	0	48	82.8
$\chi^2 = 78.51$, $df = 1$, $p \leq .001$				
Superimposed Text				
Relevant	20	34.5	12	20.7
Irrelevant	35	60.3	43	74.1
Neutral	3	5.2	2	3.4
$\chi^2 = 124$, $df = 5$, $p \leq .01$				

CHAPTER SIX:

Discussion

The purpose of this study was to advance knowledge about distracting content in DTC prescription drug advertising, first by providing an operational definition of distraction in television advertisements, and then by assessing the prevalence of distracting elements in prescription drug advertisements on televisions. To provide a definition of distraction in television advertising, the study drew from the capacity model of attention and the related conceptual frameworks of information load and information relevance. Guided by this definition, the study then analyzed message elements that may increase information load and the relevance of visual elements to audio information during the risk and benefit segments of 58 product-claim DTC television advertisements. Overall, the content analysis revealed mixed findings about the use of distraction during benefit and risk segments of DTC advertisements, potentially adding another layer of complexity to the DTC advertising debate. This chapter discusses the findings, the theoretical and practical implications of the findings, and opportunities for future research.

Distracting Elements during the Risk and Benefit Information

The research questions asked whether there were differences in distracting content between the risk and benefit segments of DTC television advertisements.

Visual information load. When examined through the lens of visual information load, distracting elements such as superimposed text, animation, and shot changes were more

prevalent during benefit information than risk information. This suggests that consumers have a much greater visual information load while benefit information is presented over the audio channel than when risk information is presented. This greater information load during the benefit segment may reduce audience attention to and thus hamper comprehension of benefit information. However, while message elements increase visual information load during benefit segments, audio information load is much greater during risk segments.

Audio information load. The audio presentation rate of spoken information was significantly faster during the presentation of risk information than benefit information. Furthermore, the risk information in all but one advertisement was presented at a rate much faster than considered comprehensible by the average consumer. At the same time, claims about drug benefits were presented much slower, and almost all of the ads presented benefits within the presentation rate necessary for successful comprehension. This suggests that consumers have much less time to comprehend audio risk information than benefit information are may be more likely to understand information provided about drug benefits than about drug risks. In discussing the findings about the presentation rate of spoken information, it is important to note that the FDA requires that the "major statement" (FDA, 1999, p.2) of the drug's most important risks be presented over the audio channel. This may mean that the FDA places greater importance on the audio channel as an information source than the video channel. Future research could examine the differences, if any, in comprehension of audio and visual risk and benefit information as well as the relative impact of visual information load and audio information load on comprehension.

Relevance of visual elements to audio information. Although visual information load was much greater while benefit information was being presented over the audio channel

than when risk information was presented, the visual information was overwhelmingly more relevant to audio benefit information than to audio risk information. Distraction in terms of irrelevant visual stimulation was more prevalent during risk information than benefit information. Both superimposed text and background visuals are more likely to be irrelevant to audio risk information. This suggests that consumers may be distracted away from the content of audio risk information and toward the irrelevant visual content that reinforces information other than drug risks, such as usage instructions, product benefits, or other advertisements. Therefore, while the visual information load may contribute to greater consumer understanding of benefit information than risk information, irrelevant visual stimulation may lead to lesser comprehension of risk information than benefit information. Future research could extend these findings to examine the relative impact of information load and information relevance on comprehension.

Theoretical Implications

This research is situated within the capacity model of attention (Kahneman, 1973). Based on the capacity model of attention, the foundation of this study is that distracting, or dividing viewers' attention from information in an advertisement can affect how well viewers comprehend that information. The focus of this research was not to examine how the content of prescription drug advertising, specifically distracting content, affects consumer comprehension of risk and benefit information. Rather, the objective was to provide insight into the prevalence of distracting content.

The centrality model of communication content illustrates why content analysis can be an important tool in building theory about mass communication processes and effects (Riffe, Lacy, & Fico, 2005). Communication content is viewed as central to the

communication process because it can be seen both as a result of contextual factors such as individual differences or socio-political, cultural, regulatory forces as well as the cause of a number of individual, social, or cultural effects. Accordingly, findings from this study about the prevalence of distraction in DTC television advertisements might inform future studies about the forces that shape the content of DTC ads and the effects of distracting content on comprehension. Guided by the capacity model of attention, future experimental research may examine the relationships between audio presentation rate, irrelevant visual content, and comprehension of drug risks and benefits.

Practical Implications

Findings suggest that there are differences in the use of distraction content in risk and benefit information in DTC television advertisements. This raises several implications for consumers, health care providers, and health public policy makers.

Consumers. One criticism of DTC advertising is that it is more focused on persuading than educating. The average consumer often does not have enough knowledge about pharmaceutical products to evaluate claims made about the therapeutic effectiveness of a drug or to assess their personal risk from information gleaned from advertising. While consumers rely on physicians and pharmacists to prescribe and explain the appropriate treatment, today's active health care consumers need to know the important risks and benefits to consider when making decisions about which drugs to talk with their doctors. Distracting content may interfere with consumer comprehension of risk and benefit information. If they are able to comprehend one type of information better than another, they may not obtain all of the necessary information about the risks and benefits of the drug with which to make an informed decision.

Health care providers. The study also has implications for health care providers. Health care providers are in daily contact with patients who may ask about prescription drugs that they have seen advertised on television. It is important for health care providers to understand that due to distracting content, patients may not fully understand the claims about the effectiveness of a drug or information about drug risks as portrayed in advertisements. As a result, practitioners may need supply this information during office visits. Additionally, to the extent that health care providers rely on information in DTC advertisements, their comprehension of risks and benefits may also be impeded due to distraction.

Regulators. This study has two important implications for the FDA. First, given the vague definition of distraction in current industry guidance, this study provides an objective, quantifiable way with which to define and evaluate distraction in DTC television advertisements. One recommendation is that the FDA adopt the definition of distraction as audio and visual information load and irrelevant visual stimulation in industry guidance, which will help pharmaceutical advertisers comply with the fair balance requirements. Second, a number of findings speak to the issue of fair balance in the presentation of risks and benefits. One finding is that, on average, advertisements devoted more time to risks than to benefits. However, consumers were given more time to absorb spoken information about drug risks than drug benefits. If consumers are better able to understand audio risk information than audio benefit information, fair balance might not be achieved. This suggests that the FDA should consider the presentation rate of spoken information in addition to visual elements when assessing distraction in advertisements. Moreover, if irrelevant visuals in advertisements distract the audience from carefully considering the audio

presentation of a drug's risks, the ad will not convey an accurate net impression of the benefits and risks of the advertised drug.

Limitations

As with any research study, limitations to the study must be considered in interpreting the results. First, this study was an exploratory, descriptive content analysis and therefore can make no assumptions about the effects of distracting content on the audience. Nor can this study determine what risk or benefit information consumers take away from a television advertisement. Although this study operationalized risk and benefit information as information directly stated over the audio channel, a reasonable consumer may infer drug benefits from indirect visual information.

Additionally, as with any content analysis, the findings from this study are limited to the sample selected. In this case, the sample was drawn from broadcasts on network television during a two-week period. Therefore, the results may not represent all prescription drug television advertisements currently being broadcast. Furthermore, it is possible that characteristics of ads may change over time, especially in response to cultural shifts and regulatory changes. Future research using longitudinal studies may examine these trends.

Lastly, assumptions about the prevalence of distracting content in DTC advertising based on the findings in this study are limited to the variables measured. Future research may examine other variables that were not accounted for in this study but may be distracting, including changes in volume, voiceover, or narrator within risk and benefit segments.

CHAPTER 7:

Conclusion and Future Directions

This study begins to fill a gap in the DTC advertising literature – the prevalence of distracting content in DTC prescription drug television commercials. Consumers are becoming more active participants in their own health care, making it increasingly important to ensure that consumers can learn both risk and benefit information from these advertisements. The importance of this study is underscored by the growing concern among scholars, regulators, and the medical community about the extent to which DTC advertising is both persuasive and educational about drug risks and benefits. Although this study examines just one aspect of DTC ad content, distraction, it is an important step in better understanding how well DTC television ads are meeting FDA requirements for the fair balance of benefits and risk information. Additionally, this study defined distraction in an objective, quantifiable way that both regulators and pharmaceutical advertisers can use in creating and evaluating DTC ad content.

Overall, this research furthers our understanding of distracting content of direct-to-consumer prescription drug advertising on television. Specifically, the study proposed a definition of distraction in television advertising and revealed that some forms of distraction are more prevalent during risk information than during claims about drug benefits. These findings raise issues about the use of distracting content in DTC advertising and its implications for consumer understanding of risk and benefit information.

Immediate next steps include extending the study to include a larger population of DTC television advertisements, rather than attempting to infer characteristics of ads from this sample. Additionally, future experimental work may extend the findings to examine the effects of distracting content on consumer comprehension of risk and benefit information, attitudes toward DTC advertising and drug brands, and intention to talk to their doctors about and advertised drug.

Also, survey research could examine consumer perceptions of DTC advertising as an information source. Leveraging findings in this study, a future study may examine how distracting consumers perceive prescription drug commercials to be and if there is a relationship between that perception and attitudes toward DTC advertising.

This research also provides a foundation on which to explore the impact of regulatory forces on advertisers' decision-making about content of DTC ads. For example, what influence do self-regulatory efforts have on the presentation of benefit and risk information in DTC ads? As evidenced by the rise in the adoption of voluntary advertising principles, a partnership exists among drug companies, medical device manufacturers, and the Pharmaceutical Research and Manufacturers of America to present risk information in a manner free from distraction. However, even with industry self-regulation practices, this study demonstrates that some types of distraction are prevalent during the presentation of risk information.

Direct-to-consumer advertising is a profitable endeavor for pharmaceutical companies. Responsible communication of risk and benefit information is important to ensure that a campaign will not be stopped due to a fair balance violation. Moreover,

presenting both risks and benefits clearly and without distraction will help ensure consumer trust, discourage stricter regulation, and foster good industry relations.

Appendix A: Constructed Week

NWK	Daypart	Mon	Tues	Wed	Thur	Fri	Sat	Sun	Daypart	Mon	Tues	Wed	Thur	Fri	Sat	Sun
ABC (11)	MO(6-10 a)	x							MO(6-10 a)	x						
	MD (10 a – 1 p)		x						MD (10 a – 1 p)		x					
	AD(1-4 p)			x					AD(1-4 p)			X				
	EF (4-8p)				x				EF (4-8p)				X			
	PT (8-11p)					x			PT (8-11p)					X		
	LF (11 p– 2a)						x		LF (11 p– 2a)						X	
CBS (5)	MO(6-10 a)							X	MO(6-10 a)							X
	MD (10 a – 1 p)	x							MD (10 a – 1 p)	x						
	AD(1-4 p)		x						AD(1-4 p)		x					
	EF (4-8p)			x					EF (4-8p)			X				
	PT (8-11p)				x				PT (8-11p)				X			
	LF (11 p– 2a)					x			LF (11 p– 2a)					X		
NBC (17)	MO(6-10 a)						x		MO(6-10 a)						X	
	MD (10 a – 1 p)							x	MD (10 a – 1 p)							X
	AD(1-4 p)	X							AD(1-4 p)	X						
	EF (4-8p)		X						EF (4-8p)		X					
	PT (8-11p)			X					PT (8-11p)			X				
	LF (11 p– 2a)				x				LF (11 p– 2a)				X			
FOX (50)	MO(6-10 a)					x			MO(6-10 a)					X		
	MD (10 a – 1 p)						x		MD (10 a – 1 p)						X	
	AD(1-4 p)							x	AD(1-4 p)							X
	EF (4-8p)	x							EF (4-8p)	x						
	PT (8-11p)		x						PT (8-11p)		x					
	LF (11 p– 2a)			x					LF (11 p– 2a)			x				

Appendix B: Code Sheet and Variable Definitions

CODING INSTRUCTIONS: DISTRACTION IN TELEVSION ADVERTISING OF PRESCRIPTION DRUGS (February 8, 2010)

Project Overview

The purpose of this study is to examine the content of television commercials advertising prescription drugs. Specifically, I am interested in identifying the presence (or absence) of distracting content in the commercials, and to what extent distraction is present during the risk disclosure versus the rest of the commercial.

The FDA requires that prescription drug ads that make claims about a product's medical benefits also include a "fair balance" of information about product risks. In television commercials, this information is called the "major statement." The major statement of drug risks is required to be in the audio portion of the ad but can be in the video portion as well. Recently, regulators have become increasingly concerned that creative elements of the commercials distract audience attention away from this important risk information so that they can't comprehend it.

Previous research in consumer psychology and mass communication suggests that both the *amount* of information as well as the *relevance* of visual information to audio information can affect audience attention and comprehension.

Coding Assignment

You will each code the same commercials. These commercials aired on the four major networks (ABC, CBS, FOX, NBC) during two weeks in January. They were recorded on my DVR, downloaded and saved to a DVD in MPEG format. You will need access to media playing software in order to view the video files and complete the coding sheet.

Process

Here is an overview of the content analysis process that we will follow:

1. Coder Training
2. Pilot Study
3. Inter-coder Reliability Check for Pilot
4. Additional Training as Needed
5. Coding
6. Final Inter-Coder Reliability Check

Coding Procedure

You will each be given an Excel spreadsheet (Drug Ad Data.xls) to record your data.

1. Every commercial has been given a unique ID for its file name.

2. Watch each commercial one time all the way through, prior to coding, in order to identify the risk disclosure segment(s) of the commercial. Note whether risks are presented in one continuous segment or interspersed throughout.
3. When coding, please use one row per commercial, entering data from left to right according to the Codebook.
4. If you have questions about a variable, please flag the commercial and ask me.
5. Continue until all variables for each commercial have been coded and the Excel spreadsheet is complete.
6. Email the spreadsheet to me (jdharlow@email.unc.edu) once all coding has been complete. The last day to submit data to me is Monday, February 22, 2010.

Coding Definitions

The Code Book can be organized into three sections:

1. **Commercial Characteristics (A-H):**
   These variables are straightforward and easy to code.

   Items A-D can be coded from the file name, which is the unique commercial ID.

2. **Risk Disclosure Variables (I-Z):**
   These variables are specific to the portion of the ad in which information about drug risks are presented verbally. Risks may include side effects, allergic reactions, or contraindications ("do not take if…"). Risks do not include limitations on effectiveness.

   Variables I – K measure the characteristics of the audio statement of drug risks.

   Continuity of Risk Disclosure (I): The major statement of drug risks may be presented in one continuous segment or interspersed throughout the ad. For this variable, you will need to choose between "continuous" or "interspersed." **If risks are interspersed throughout the ad, please consider each segment of risk information when coding the remainder of the risk disclosure variables.**

   Amount of Time Devoted to Risks (J): Add up the total amount of commercial time devoted to risk information to the nearest tenth of a second. If interspersed throughout the ad, add together the length of all segments. For disclosures that are presented concurrently, (for example, if during the audio statement of risks, there is text on-screen about risks) only count that time once.

Number of Words in the Audio Disclosure (K): Please count the total number of words in the audio risk statements.

Variables L – O measure the presence (or absence) of other audio elements during the required audio statement of drug risks. If present, these variables should be relatively straightforward and easy to code.

Variables P-R ask about the transition from the main promotional message of the ad to the risk statement. Here I am interested in noticeable changes in the audio portion of the ad when the ad begins to talk about drug risks. In other words, is the risk statement set off by a change in tempo, volume, or voiceover/narrator/announcer?

Variables S – U measure the presence (or absence) and characteristics of text on screen during the required audio statement of drug risks.

Presence of text on screen (S): is simply asking if there is on-screen text during the presentation of risk information.

Number of Words on-screen during the Audio Disclosure (T):
Please count the number of words on screen during in the audio risk statements. If words are presented more than once, please count every time the words are presented in a new orientation or position.

Relevance of on-screen text (U): This asks about the relevance of on-screen text during the risk disclosure to the audio risk information being presented. In other words, does the on-screen text reinforce the risk information, contradict the risk information, or is it neutral?

> Please indicate that text is relevant only if it repeats something said about drug risks.
>
> Irrelevant text may give the viewer more information, but not about drug risks. This information may include directions about usage, claims about product benefits, or it may direct viewers to another information source ("Please see our ad in…").
>
> Please indicate that text is neutral only if it is identifying information but does not give any information about risks or benefits of the drug. For example, a Web site address, brand name or logo.
>
> If there is both relevant and irrelevant text on-screen during the audio statement of risks, please indicate your overall impression of relevance.

Variables V – Z measure the characteristics of background visuals during the required audio statement of drug risks. Here, background visuals refers to everything happening on screen (besides text).

Relevance of background visuals (V): Here I am interested in the relevance of background visuals to the audio risk information. This is similar to the previous question about the relevance of on-screen text. While I realize that an advertiser is not likely to show background visuals of someone experiencing side effects, the visuals may reinforce the risk information being presented, reinforce the benefits of taking the drug, or it may remain neutral.

> Relevant visuals reinforce the risk information being presented verbally. Please indicate that visuals are relevant if what is happening on screen "matches" the audio channel. (For example, if the person on screen is telling the audience about drug risks instead of a voiceover saying something different than what appears on screen.)
>
> Irrelevant visuals reinforce the benefits of taking the drug. An example would be positive imagery of people happily "living their lives" while a voiceover talks about drug risks.
>
> Please indicate that visuals are neutral only if it is identifying information but does not give any information about risks or benefits of the drug. For example, a Web site address, brand name or logo.
>
> If there is both relevant and irrelevant imagery on-screen during the audio statement of risks, please indicate your overall impression of relevance.

Presence and Speed of Animation (W-X): Here I am asking about any type of animation on screen during the verbal risk statement. Animation is defined as an illustration, drawing or graphic that moves (for example, an animated character or an animated demonstration). If present, these animation variables should be relatively straightforward and easy to code.

Number of Characters (Y): Please count the total number of unique characters (actors, animals, animated figures) on screen during the verbal risk segment. Please count any unique character that you can see any part of during the segment.

Number of Shot Changes (Z): Count the total number of times the shot changes during the risk statement. A shot change is indicated by a "cut" in the reel.

3. Product Claim Variables (AA-AM):

These variables are specific to the rest of the commercial; all parts of the commercial in which the audio channel is not dedicated to risk information.

Variables AA-AC measure the characteristics of the audio channel during the product claim portion of the commercial.

Amount of Time Devoted to Product Claims (AA): Add up the total amount of commercial time NOT devoted to risk information to the nearest tenth of a second.

Number of Words in Product Claims (AB): Please count the number of words spoken in the product claim segments.

Variables AC – AF measure the presence (or absence) of other audio elements during product claims. If present, these variables should be relatively straightforward and easy to code

Variables AG – AI measure the presence (or absence) and characteristics of text on screen during the product claims.

Presence of text on screen (AG) is simply asking if there is on-screen text during the product claims.

Number of Words on Screen during Product Claims (AH): Please count the number of words on screen during the product claim segments. If words are presented more than once, please count every time the words are presented in a new orientation or position.

Relevance of on-screen text (AI): This asks about the relevance of on-screen text during the product claim to the benefit information being presented. In other words, does the on-screen text reinforce the benefit information, contradict the benefit information, or is it neutral?

> Please indicate that text is relevant only if it repeats a benefit/product claim.
>
> Irrelevant text may give the viewer more information, but not about benefits of using the product. This information may include directions about usage, information about product risks, or it may direct viewers to another information source ("Please see our ad in…")
>
> Please indicate that text is neutral only if it is identifying information but does not give any information about risks or benefits of the drug. For example, a Web site address, brand name or logo.

If there is both relevant and irrelevant imagery on-screen during the product claims, please indicate your overall impression of relevance.

Variables AJ – AM measure the characteristics of background visuals during the product claims. Here, background visuals refer to everything happening on screen (besides text).

Relevance of background visuals (AJ): Here I am interested in the relevance of the background visuals to the audio benefit information. This is similar to the previous questions about relevance.

Relevant visuals reinforce the benefits of using the drug while product claims are being presented verbally. Please indicate that visuals are consistent if what is happening on screen "matches" the audio channel.

Irrelevant visuals reinforce the risks associated with the drug.

Please indicate that visuals are neutral only if it is identifying information but does not give any information about risks or benefits of the drug. For example, a Web site address, brand name or logo.
If there is both relevant and irrelevant imagery on-screen during the audio statement of risks, please indicate your overall impression of relevance.

Presence of Animation (AK): Here I am asking about any type of animation on screen during the product claims. Animation is defined as an illustration, drawing or graphic that moves (for example, an animated character or an animated demonstration). If present, these animation variables should be relatively straightforward and easy to code.

Number of Characters (AL): Please count the total number of unique characters (actors, animals, animated figures) on screen during the product-claim segments. Please count any unique character that you can see any part of during the segments.

Number of Shot Changes (AM): Count the total number of times the shot changes during the product-claim segments. A "shot change" is indicated by a "cut" in the reel.

Codebook:
Distraction in Television Advertising of Prescription Drugs

A. ID Unique name for each commercial (file name).
Ex: AMOLF-14

B. NWK Network on which ad aired. First ONE letter of file name.
Ex: AMOLF

1	ABC
2	CBS
3	FOX
4	NBC

C. DAY Day on which ad aired. Second TWO letters of file name.
Ex: AMOLF

1	Monday
2	Tuesday
3	Wednesday
4	Thursday
5	Friday
6	Saturday
7	Sunday

D. DPRT Daypart in which ad aired. Last TWO letters of file name.
Ex: AMOLF

1	Morning
2	Morning Daytime
3	Afternoon Daytime
4	Early Fringe
5	Prime Time
6	Late Fringe

E. DRGNAME Brand name

F. CONAME Name of the pharmaceutical company (if provided). Please enter 0 if not provided.

G. LENGTH Commercial length the nearest second.

1	15
2	30
3	60
4	75
5	90

6	Other

H. MEDCOND Medical condition being treated

I. RSKCONT Are risks presented in one continuous segment or interspersed throughout the ad?

0	Continuous
1	Interspersed

J. RSKTIME Total amount of commercial time devoted to risk information (to the nearest tenth of a second).

K. RSKWRD Number of words in audio disclosure

L. RSKMUS Is there music playing during the verbal statement of risks?

0	No (Skip to V.O)
1	Yes

M. RMUSFAM Do you recognize the song?

0	No
1	Yes

N. RMUSTMP How would you best describe the TEMPO of the music?

1	Fast
2	Medium
3	Slow

O. ROTHSND Are there other sounds (besides music) in the background during the verbal statement of risks?

0	No
1	Yes

P. CNGTMP Is there a change in tempo of the background music?

0	No Music
1	Yes, it got faster.
2	Yes, it got slower.
3	No, it stayed the same.

Q. CNGVOL Is there a change in volume?

0	No
1	Yes, it got louder.
2	Yes, it got quieter.

R. **CNGVO** Is there a change in voice-over or narrator?

0	No
1	Yes

S. **RSKTXT** Is there text on screen during the risk disclosure?

0	No (Skip to V)
1	Yes

T. **RTXTWC** Total number of words on screen during audio disclosure

U. **RTXTCNS** Relevance of on-screen text during risk disclosure

1	Relevant
2	Irrelevant
3	Neutral

V. **RVISCNS** Relevance of background visuals during risk disclosure

1	Relevant
2	Irrelevant
3	Neutral

W. **RVISAN** Is there animation on screen during the risk disclosure?

0	No (Skip to Y)
1	Yes

X. **RVISANS** Animation Speed

1. Faster during the risk statement than during the rest of the ad
2. The same speed as the rest of the ad
3. Slower during the risk statement than during the rest of the ad

Y. **RVISCH** Total number of <u>unique</u> characters on screen during risk statement.

Z. **RVISSC** Total number of shot changes during risk statement.

AA. **BENTIME** Total amount of commercial time devoted to product claims (to the nearest tenth of a second).

AB. BENWRD Number of words in product claim.

AC. BENMUS Is there music playing during the product claim?

0	No (Skip to AG)
1	Yes

AD. BMUSFAM Do you recognize the song?

0	No
1	Yes

AE. BMUSTMP How would you best describe the TEMPO of the music?

1	Fast
2	Medium
3	Slow

AF. BOTHSND Are there other sounds (besides music) in the background during the product claims?

0	No
1	Yes

AG. BENTXT Is there text on screen during the product claims?

0	No (Skip to AK)
1	Yes

AH. BTXTWC Number of words on screen during product claims.

AI. BTXTCNS Relevance of on-screen text during product claims.

1	Relevant
2	Irrelevant
3	Neutral

AJ. BVISCNS Relevance of background visuals during product claims.

1	Relevant
2	Irrelevant
3	Neutral

AK. BVISAN Is there animation on screen during product claims?

0	No
1	Yes

AL. BVISCH Total number of <u>unique</u> characters on screen during product claims.

AM. BVISSC Total number of shot changes during product claims.

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