ANALYSIS OF THE RISK AND BENEFIT INFORMATION PRESENTED IN BROADCAST DIRECT-TO-CONSUMER ADVERTISING

by

ARTHUR SIGIRD THORSEN III

(Under the Direction of Randall L. Tackett)

ABSTRACT

The Food and Drug Administration (FDA) mandates that prescription drug advertisements cannot be false or misleading in any particular, must reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in the promotional piece and should present information about effectiveness and information about risk in a balanced manner.[4,11] This study evaluates the a sampling of the current broadcast Direct-to-Consumer Advertising with the newly released FDA guidance document titled Presenting Risk Information in Prescription Drug and Medical Device Promotion. DRAFT GUIDANCE May 2009. The fair balance presentation of risk and benefit information within a cross section of drug advertisements was examined during two national nightly network television news broadcasts from May 25, 2009 to June 25, 2009.

Index words: Direct-to-Consumer Advertising, Prescription drugs, Pharmaceutical, Risk, Benefit, Contraindications, Side effects.

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B.S., Millsaps College, 1996

A Thesis Submitted to the Graduate Faculty of The University of Georgia in Partial Fulfillment of the Requirements for the Degree

MASTER OF SCIENCE

ATHENS, GEORGIA

2009

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August 2009

DEDICATION

This thesis is dedicated to my mom and dad. Thank you for all of the sacrifices you have made allowing me to get to where I am today.

ACKNOWLEDGEMENTS

I would like to thank Dr. Tackett, my advisor, for his patience and advice while I prepared this thesis. I would also like to thank Dr. Brooks and Dr. Mullis for taking the time to participate as part of my advisory committee. I greatly appreciate their valuable insights which directed me to complete this project.

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CHAPTER 1

INTRODUCTION

A vast number of people in the United States if they have seen the advertisement of the baby-boomer generation couple who have rekindled their flame with the "little blue pill" or a rooster walking down a street searching for a new home after a woman took a sleeping pill. These ads may project that the miracle drugs have finally arrived but do they also make people aware of the risks or side effects of the drug? This type of advertising is called direct-to-consumer advertising (DTCA) and it is causing quite a controversy in the pharmaceutical community.

Background

"In 1962, the Food and Drug Administration (FDA) was given the authority to regulate prescription drug advertising by the Kefauver-Harris Amendment to the Federal Food, Drug and Cosmetic Act (FDCA) of 1938."[7] This amendment required that advertisements about drugs had to inform the public truthfully of the side effects of the drug. This amendment was added to the FDCA after the thalidomide tragedy that occurred in 1957 to 1961. Thalidomide was thought to be originally developed by the Nazi's as an antidote for sarin nerve gas.[8] Another indication of the drug was for the treatment of morning sickness in pregnant women.[37] Structurally, thalidomide is an optical isomer with left-handed phthalimide ring enantiomer a known tetratogen.[38] Tetratogens cross the placental barrier affecting the formation and function of the placenta.[39] The effects of thalidomide were soon seen in thousands of babies.[8,37]

Therefore, in October 1962 proof of safety and efficacy became law in the marketing of pharmaceuticals.[7,40]

Until the 1980's, drug manufacturers only marketed and advertised to health care providers due to the fact that consumers could not purchase prescription medication on their own. Therefore, the only way to get information about a certain drug was from a learned intermediary such as a doctor or pharmacist. But in the early 1980's, some drug manufacturers began advertisements that simply stated the price of a specific drug or some other general information which companies called public service campaigns. "The 1982 campaign for Oraflex® (benoxaprofen) changed the direction of DTCA from price or general information to product-specific promotion by distributing press kits and videotapes for the broadcast media."[9] However, this advertising was to be short lived. Benoxaprofen had some serious adverse events which resulted in deaths.[9] Of its own accord, the manufacturer removed the drug from the market.[9,41] This incident of adverse events became a concern for the FDA which thought it necessary to evaluate the effect of DTCA on the public since there were no regulations or experience in this area.[41] In an effort to fully evaluate the actual effect of DTCA, the FDA requested a voluntary moratorium in 1983 and asked that effective communication between consumers, industry and medical professionals commence so that more information on the effects of DTCA could be discussed.[41] In 1985, the FDA ended the voluntary moratorium and issued the Federal Register Notice 50 FR 36677 with the conclusion that the current regulations, which were established in the 1960's and geared toward medical professionals, were enough to protect the public.[10, 42]

Beginning in the 1990's, DTC broadcast ads were used in a limited manner. This was due to the lengthy disclosure needed to fulfill the brief summary requirement, containing the disclosure of adverse events.[10] Unfortunately, there was no guidance available on the most effective way to satisfy the risk disclosure requirement.

Purpose of the Research

This study evaluated the compliance of the recently released FDA guidance document, Presenting Risk Information in Prescription Drug and Medical Device Promotion, DRAFT GUIDANCE May 2009, with the presentation of risk and benefit information of the current broadcast DTCA during two major network nightly television news broadcasts every Monday through Friday from May 25, 2009 to June 25, 2009.

The goal of this thesis was to examine how the risk and benefit information in broadcast DTCA's was presented to the target audience with respect to several research questions. These questions were developed from the DRAFT guidance and previous research completed by Kaphingst[1] and Zheng and Cheng[2].

RQ 1: How is the risk information presented?

RQ 2: How is the benefit information presented?

RQ 3: How is the side effect and contraindication information presented?

RQ 4: What label information is presented?

RQ 5: Is there any indication of efficacy (i.e. clinical trial information, effectiveness information, FDA mentioned)?

RQ 6: Is there an indication that the drug is prescription only?

RQ 7: Is the adequate provision fulfilled?

RQ 8: Is there a noticeable disposition change or emotional appeal over the course of the ad?

Potential Outcome of this Research

A primary outcome of this research will be the evaluation of the effectiveness of the new DRAFT guidance document for current DTCA and the risk and benefit presentation to the target audience. This should give an indication of where the industry is and where the industry needs to be in relation to the DRAFT guidance. Another goal of this research is to identify any pitfalls concerning the fair balance and adequate provision requirements of the current DTCA. This research should initiate future research in the development of a standard for all broadcast DTCA so that consumers are fully aware of the risks as well as the benefits of a drug.

CHAPTER 2

LITERATURE REVIEW

There is an extensive amount of research published on the various types of DTCA and the presentation of the risk and benefit information presented to the target audience. For example Huh and Cude explored in 2004 "the content of prescription drug websites, specifically focusing on the quantity and quality of risk information."[21] Their results indicated that the risk and benefit information is present, but the way that each is presented differs. The risks and benefits were not presented in a manner that presents a fair share or equal balance to both. "Fair balance is one of the most important aspects of the FDA's prescription drug advertisement regulations, because consumers are able to make sound decisions with a complete understanding of the advertised drug's benefits and risks." [20,21] The fair balance regulation is thought to give the consumer the necessary information that will allow them to make an educated healthcare choice. In an analysis of product-specific print drug advertisements, Wilkes, et al.[25] address the fact that proponents of DTCA argue that "DTC promotions educate the public about medical conditions and their treatments hinges on the quality of drug information available to consumers through advertising."[25] However, according to Wilkes et al.[25] , Bell et al.[26] , and Macias et al.[27], education is "highly variable."[25,26,27] Not everyone has access to the same quality or level of education or has the same capacity for retention of information. Thus, every step should be taken to provide information available to the public that is clear and understandable on every educational level. In 2009, Maxian also points this out when she references a study performed by the Henry J. Kaiser Family Foundation which "found that although ads may inform the public about health problems and their treatments, the amount the ads educate the public is dependent

upon the public's knowledge of the health problem in the ad."[7,31] The same Kaiser study also showed "the ads were able to communicate successfully basic information such as the name of the medicine and what it treats, they had more mixed results in terms of leaving respondents with information about the medicines."[31] If the consumer has trouble understanding the information presented about the drug, what would be the result if the risk or side effect information is incomplete? "Minimal risk disclosures may deny consumers vital information, and may fail to provide an adequate framework for evaluating the risks of the medication."[29] Duration of information also plays a part in the consumer's ability to comprehend the risk and benefit disclosures. "Lengthy risk disclosures, however, may not be understood and may adversely affect the advertiser's selling message (i.e., the benefits of using the medication)."[29] Davis has evaluated the completeness of the side effect information and the target audiences' awareness of safety of the drug in his 2000 publication. The first evaluation had two different risk statements. One statement was, "Like any prescription drug, Fosamax may cause side effects. The most common side effects are: stomach and muscle, bone or joint pain."[20] The second risk statement was similar to the first in wording however, any side effect that was reported at a level of 3% or more was reported. The results from this study showed "that adoption of a 3% base level for side effect reporting has a significant effect on a drug's appeal, as measured by consumers' rating of their likelihood to recommend or purchase the drug."[20]

The second evaluation also examined two risk statements. The complete statement allowed the advertiser to determine the completeness of the statement by allowing them to set their own minimum level of side effects, but all of the side effects had to be greater than or equal to the occurrence rate of the lowest side effect chosen. The incomplete statement was directly from the manufacturers labeling however, all side effects had to have the numeric rate of

occurrence listed. "Mean scores for drugs described with the incomplete description always fell on the positive (i.e., "more safe") end of the rating scale, whereas the mean scores for the drugs presented with the complete description fell on the neutral to negative (i.e., "less safe") end of the scale."[20]

In a print DTCA, the consumer can re-read the ad as many times as necessary to understand the material and they even can take the ad to their physician. With broadcast DTCA, it is much more difficult to process the ad due to the limited amount of time and the amount of information presented. There have been several studies on the effect of comprehension of risk and benefit information. Kaphingst et al. analyzed fifty adults with limited literacy and the comprehension of information presented in DTCA.[28] The participants were asked to watch three DTCA's and answer prepared questions regarding the advertisements. They found that the "descriptive data and multivariate results indicated that these three advertisements were less successful in communicating risk information than other information."[28] This was found to be "consistent with the results of a Kaiser Family Foundation study, which showed low recall of side effects information from three DTC television advertisements."[28,31]

Another aspect of content analysis is visual cues and an association of effectiveness with the healthy, active attractive people that appear in broadcast DTCA. Welch Cline and Young found that "many prescription ads are for products associated with serious debilitating medical conditions, the image associated with products is one of "health". In fact, more than 90% of ads depicting people show exclusively healthy looking people, and more than half show people engaged in physical or social activity." [30] These visual cues that project a healthy, active life after taking the medication may be suitable for a less severe condition but not when the affliction is arthritis or cancer.[30]

With such importance on risk and benefit content along with the way it is presented to the target audience and the new DRAFT guidance that was recently released, an analysis of the current broadcast DTCA risk and benefit content and presentation would be prudent.

Division of Drug, Marketing, Advertising, and Communication

The Division of Drug, Marketing, Advertising, and Communication (DDMAC) within the Center for Drug Evaluation and Research (CDER) that is responsible for implementing and regulating DTCA in all forms of promotional pieces. This authority comes from two sources. One, the Federal Food, Drug and Cosmetic Act (FFDCA) that states in Section 502(n) that ads must display the established name, the formula showing quantitatively each ingredient of such drug to the extent required for labels, other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations.[11] The second source is from the Code of Federal Regulations, Title 21, part 202 which states that "advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation shall contain a brief summary of all necessary information related to side effects and contraindications."[13]

According to the DDMAC website under the DDMAC Organization Listing option, there are three content review groups titled Direct to Consumer Review Group I through III. [32] Within these groups are four to five reviewers who have a listed specialty for review such as oncology drugs, pulmonary & allergy, psychiatry, and anesthetics, analgesics & rheumatology. The

responsibility of these content review groups is to review all submitted promotional labeling for content, clarity and adherence to the regulations.

If the DDMAC finds an ad to be in violation of the law, there are two response options available; a Notice of Violation (NOV) or a warning letter can be issued. A NOV is a notification to the manufacturer about a minor violation. This letter tells the company that the drug is misbranded due to misleading information. The company then has 30 days to respond to the letter detailing a plan for retraction of all the promotional materials to the drug in question.

The warning letters "put the recipient on notice of the FDA's intent to initiate further regulatory action against the recipient if it refuses to rectify the offending practice promptly." [24] Royne and Myers state that between 2004 and 2005 nineteen letters were issued to drug manufacturers concerning advertisements "on an average, eight months after the materials were originally communicated to consumers."[22] Although the manufacturer is within the regulations, the public has been exposed to the ad for some time and the misleading effect has already occurred. A report in July 2008 from the U.S. General Accounting Office (GAO) to the U.S. Senate Committee on Finance regarding the FDA's Oversight of the Promotion of Drugs for Off-Label Uses stated that in 2007, DDMAC received 68,000 promotional pieces for review. [36] "FDA reports it is unable to review all submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health. However, FDA does not prioritize its reviews in a systematic manner but rather relies on its staff to sort through large volumes of material and select submissions for review. FDA is also hampered by the lack of a system that consistently tracks the receipt and review of submitted materials."[36] According to the DDMAC website regarding enforcement actions currently for 2009 (January to June), twenty-five warning letters have already been issued.[32]

Regulatory

There are three types of advertisements that the FDA allows: a) Product-claim advertisements, b) Reminder advertisements and c) Help-seeking advertisements. In her address to the U.S. Senate Special Committee on Aging, Dr. Rachel Behrman details the three types of ads:

> "Product-claim" ads are those ads which generally include both the name and product and it's use, or make a claim or representation about a prescription drug. Claims of drug benefits, such as safety and effectiveness, must be balanced with relevant disclosures of risks and limitations of efficacy. This balanced presentation of drug therapy is commonly referred to as "fair balance." In addition, when used in print ads, sponsors must provide a brief summary of risk information included in the product's FDA-approved labeling or, for broadcast "product-claim" ads, provide convenient access to the approved labeling. In our regulations, the phrase "adequate provision" is used to identify the convenient access label option.[10]
>
> "Reminder" ads may disclose the name of the product and certain specific descriptive information such as dosage form (i.e., tablet, capsule, or syrup) or price information, but they are not allowed to give the product's indication (use) or to make any claims or representations about the product. Reminder ads specifically are not allowed for products with serious warnings (called "black box" warnings) in the approved labeling. The regulations specifically exempt "reminder" ads from the risk disclosure requirements because historically they were designed generally to remind health care professionals of a product's availability. These ads can be confusing and frustrating to consumers-and potentially misleading-but, increasingly, we find them to be testing the limits of what might be considered a product claim.[10]
>
> "Help-seeking" ads discuss disease or condition and advise the audience to "see your doctor" for possible treatments. They need not include any risk information. Because no drug product is mentioned or implied, this type of ad is not considered to be a drug ad and is not regulated by the FDA, but we enthusiastically support their use and have issued draft guidance on the subject.[10]

These types of ads were fine for printed publications but were difficult for broadcasting due to the length of information they have to contain and the limited amount of time available for a television commercial. The finalization of the Guidance for Industry in 1999 stated that broadcast DTCA's did not have to contain a brief summary but had to contain a major

statement.[5] The major statement did not have to detail all of the side effects and risk information but only the major risks in a manner that is easily understood by the target audience.[5]

"Drug companies are required to submit final prescription drug advertising materials to the FDA when they are first shown to the public."[12] However, the companies are not required to submit advertisements to the FDA before being circulated for public view.[12, 35] As long as the ad is sent to the FDA before it is released to the public, it is considered to be within the regulations. If the ad contains inaccurate or misleading information, the public has possibly been exposed to the ad for quite some time before the FDA has time to review the content of the advertisement.[12] Some companies do voluntarily submit their advertising materials to the FDA for review before being distributed.[12] However, this is not required by law.

Guidance for Industry

The FDA released a Federal Register Notice in 1995 calling for discussion of DTCA. The result of this meeting was a draft of Guidance for Industry: Consumer-Directed Broadcast Advertisements that was released in 1997 and finalized in 1999. "The Guidance described an approach for ensuring that audiences exposed to prescription drug advertisements on television and radio have convenient access to the approved labeling of the advertised product. The proposed approach consisted of reference in the broadcast ad to four sources the consumer could use to obtain more detailed labeling information: a toll-free number, a website address, a concurrently running print advertisement, and their health care professional."[10] This reference was called the *adequate provision*. The adequate provision could be met if the ads directed the audience to the four informational sources. The guidance also required the inclusion of a *major statement*. As indicated previously, this statement reveals the "products major risks in either the audio or audio and visual parts of the presentation."[5] However, the guidance does not focus on

the ways in which to satisfy the major statement requirement. Upon finalization of this guidance, pharmaceutical companies began to increase their product specific broadcast advertisements.

In May 2009, a new draft guidance was released titled "Presenting Risk Information in Prescription Drug and Medical Device Promotion". To keep within the boundaries of the stipulations set by the FFDCA and the FDA, this draft states that ads "cannot be false or misleading, must reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in the promotional piece, and should present information about effectiveness and information about risk in a balanced manner."[4] The FDA has stated that the review of the risk information does not only focus on what the risk statement says, but the net impression the risk statement makes on the entire ad. "The purpose of the evaluation is to determine whether the piece ***as a whole*** conveys an accurate and non-misleading impression of the benefits and the risks of the promoted product."[4]

The DRAFT guidance has three topics under the section heading of **FACTORS CONSIDERED IN THE REVIEW OF RISK COMMNUNINCATION[4].** Within these three topics are points that note several key issues instructing the advertisers how to effectively present the risk and benefit information according the the FDA's current thinking.

The first topic is **GENERAL CONSIDERATIONS[4]** that contains four sub-topics. The first sub-topic details how the use of consistent, accurate, comprehensible language that describe the benefit as well as the risk information in a way that is not misleading for the target audience. This means that if the target audience is the consumer, the ads cannot be presented with medical terminology that is unfamiliar to the average consumer. If the ad is specifically for health professionals, the language can be presented with medical terminology.

The second sub-topic presents instructions on the use of signals. Signals are visual cues that draw your attention to a specific topic. The FDA states that the use of signals has to be presented such that if a signal for a benefit is displayed, the same presentation must be made for the risk information.[4]

Framing risk information is the third sub-topic. The manner in which the risk information is presented may have a negative effect or mask the severity of the risk. "Risk information should be presented in the same terms or with the same degree of specificity as benefit information."[4] If the risk information is framed in a way that decreases the seriousness of the risk, the consumer would in effect be mislead.

The last of the four sub-topics is the hierarchy of risk information. Murdock analyzed the recall capacity using word lists of 10-40 words. A person can recall up to five pieces of information presented at the beginning of a list and approximately eight pieces of information at the end of a list.[33] Therefore, the DRAFT suggests that the most pertinent risk information should be presented at either the beginning, end or at both parts of the ad. The "FDA also considers the order in which the risk information is presented to determine whether this ordering suggests that certain risks apply only to certain populations or only certain conditions when this is not the case."[4]

The second topic is **CONSIDERATIONS OF CONTENT**[4]. There are two sub-topics contained here. The first sub-topic examines the quantity of information that is presented during the advertisement. Naturally, the information presented in a thirty second ad does not contain the amount of information that a sixty second ad presents.[4] In this instance, inserting a lot of information in a thirty second ad "can affect *cognitive load*, the mental effort required to understand the various components of information in the piece."[4] Again, the FDA notes that the

risk and benefit information must be equally presented and must be appropriate for the target audience. The most important benefits and risks must be provided in the time frame so that the product is not misleading or inaccurate. However, as shown by Botvinik and Plaut as the number of recallable units increase, a person's recall ability decreases.[34] The FDA does recognize that there might be more benefits than risks and is not necessarily expecting a one to one ratio, but more of an equal promotion of both in format. The following factors are listed in the guidance and denote the criteria the FDA uses to compare the risk and benefit presentation:

-The number of statements about benefits and risks
-The completeness and depth of detail given about benefits and risks
-The amount of time (in both the audio and visual portions) devoted to benefits and risks in a video, audio, or broadcast communication.
-The amount of space devoted to benefits and risks in a print communication
-The use of audio or visual components that enhance or distract from the presentation of risk or benefit[4]

In the evaluation, the FDA uses the above criteria to analyze the ad's projection of the risk content to the target audience.

The second sub-topic in Considerations of Content is Materiality and Comprehensiveness. "Generally speaking, *materiality* is determined by the degree to which information is objectively important, relevant, or substantial to the target audience."[4] In other words, an ad will be branded as misleading if information about its risks are left out. Materiality information is defined as anything that may influence the target audience when considering to use or prescribe the product. Such as the "relevant properties of a product, whether or not the product is appropriate for them or their patients, and whether or not they are willing to accept the risks or burdens associated with using or prescribing a product."[4] Generally, the most serious or frequent risks are considered germane and should be presented to the audience.

The DRAFT guidance lists the following five questions that the DTCA should answer for content consideration;

1. What the drug is used for
2. Who should or should not take a drug
3. What can be expected from the drug
4. What patients should ask their healthcare professionals about a drug
5. What patients should tell their healthcare professionals about before or while taking a drug.[4]

The third topic is **CONSIDERATION OF FORMAT**[4] in which the FDA examines how the ad is presented with respect to "location, proximity, type size, type style, and contrast when evaluating these materials."[4] This topic has two sub-topics. Sub-topic one refers to print promotion. Sub-topic two refers to non-print promotion. In non-print promotion, the FDA addresses the issue of images that are superimposed (SUPERs) in formatting. If an ad has SUPERs presented during an audio explanation of risk, the images must be similar to the risks being described. If not, the images must be explained so as not to mislead the audience. SUPERs must also be legible and not blend in with the background. Audio formatting is also essential. When risk information is presented in an audible format, it should be at a volume and pace equal to the benefit information.[4] If not, the ad can be considered misleading by not presenting an "accurate impression of the product."[4]

Pharmaceutical Research Manufactures of America

The Pharmaceutical Research Manufactures of America (PhRMA) is a group whose members are the leading biotechnological and pharmaceutical research firms in the United States. As stated on the website, PhRMA's mission "is to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical/biotechnology research companies."[14] In the preamble to the PhRMA's Guiding

Principles Direct to Consumer Advertisements About Prescription Medicines, the Association states that providing information to the public about prescription medicines benefit their health by:

> Increasing awareness about diseases;
>
> Educating patients about treatment options;
>
> Motivating patients to contact their physicians and engage in a dialogue about health concerns;
>
> Increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated; and
>
> Encouraging compliance with prescription drug treatment regimens.[18]

PhRMA has also stated that they have a duty to adhere to the regulations set forth by the FDA.

The principles found in the PhRMA Guiding Principles Direct to Consumer Advertisements About Prescription Medicines are summarized as follows:

1. DTCA can benefit the public by increasing disease awareness, education, and promoting physician-patient relationships and drug compliance.
2. Following the regulations, the ads should be accurate, should not mislead the target audience, have evidence to back up the claims, and have a balance in the risk and benefit information.
3. Broadcast DTCA should educate the target audience about the drug and the condition for use. The consumer must be aware that the broadcast DTCA are promoting prescription drugs.
4. DTCA should distinguish between over-the-counter and prescription advertisements.
5. The broadcast DTCA should cultivate a healthy physician-patient relationship.
6. The companies should educate the heath care professionals before disseminating ads to the public as well as keeping the physicians apprised of new findings regarding the drug.
7. If new risk information concerning the drug arises, the companies should stop or amend the DTCA to keep the public informed.
8. Before a company releases its broadcast ad, they should submit it for FDA review.
9. Broadcast ads should direct the consumer to additional sources of information and other choices for applicable conditions.
10. A product that is mentioned by name should state the indication and the associated risks.

11. Risk, benefit and safety information presented in broadcast DTCA should be presented so that the target audience can understand the information given without distraction and directed to their physician for more information.
12. All DTC advertising should respect the gravity of the conditions to which the medicines are advertised.
13. Broadcast DTCA's should be age appropriate.
14. Broadcast DTCA's should promote a healthy lifestyle.
15. Drug companies should provide help for those with limited insurance and those without.[18]

PhRMA established an Office of Accountability that is charged with the task of monitoring the commentary regarding the industries adherence of the guiding principles. This Office publishes a public report that reflects these comments. However, this Office has no regulatory or legal enforcement power.

Critics, such as Frosch et al., state that the guidelines are "perhaps purposefully, vague"[19] and also point out that companies are not required to follow the guidelines and that compliance is voluntary. PhRMA claims that DTCA's educate consumers and give them the ability to take control of their health care. To facilitate this idea, the PhRMA website has a specific list of topics that the consumer should address with their health care provider and a list of questions if given a new medication.[14]

Pros vs. Cons

As with any controversial topic, there is an ever present difference of opinions of the pros and cons relating to the topic. That holds true for DTCA's. Physicians, law makers, industry professionals, consumer advocates, and regulatory officials all have their own opinions. Proponents of DTCA's claim that the ads allow the consumer to be more aware of their symptoms and this promotes a healthier doctor-patient relationship.[12,18]

The pharmaceutical industry is of the opinion that they have an obligation to educate the public regarding the drugs made available to the public. With this knowledge, the patient will be

empowered about available treatments and more active in their healthcare.[12] This information however, is fundamentally designed to increase sales for the manufacturer by promoting the drug.[44] The industry states that the amount of literature available to the public allows them to make an informed decision about their health care is the main benefit and "outweighs any potential negative consequences."[22]

Critics of DTCA's say that the doctor-patient relationship suffers. Time that could be spent evaluating the patient is spent explaining misconceptions and why a certain drug that the patient saw on TV is not appropriate for the course of their health care.[12,22] It is possible that this will encourage "doctor shopping" where the consumer will find a physician who will give them the medication they request. DTCA's persuade the audience to be aware of certain symptoms and conditions that may be a sign of a problem. "Because these vague symptoms are commonly found in normally functioning individuals, consumers tend to screen or more accurately, "pre-diagnose" themselves as depressed, and proceed to "experts" for professional diagnosis."[6] Antagonists also feel that DTCA's are thought to be a reason of increasing pharmaceutical costs by promoting the more expensive name brand drugs over the less expensive generics.[12] Opponents are of the opinion that DTCA's promote the image of taking a pill is the cure instead of making changes in diet, maintaining an exercise regime and healthy lifestyle change.[12] Shaw states that "these advertisements can convey misleading information about the drugs, exaggerating the benefits and understating the risks."[12]

If one observes a DTCA from the beginning to end, the actor appears to be suffering from some type of pain or affliction as indicated by the grimace or distraught look on the actor's face. Then, after explaining their past situation before discovering the drug, their disposition changes to a joyful, pain-free or active mood. This is intended to give the impression that the drug will

cure the condition or illness and allow the patient to return to normal. To a viewer, this can be perceived as the drug is safe and works after one dose. This emotional claim can also be spun to reflect a negative aspect of regret when not taking the medication. Frosch et al. discovered "almost all ads used positive emotional appeals, and more than two thirds used negative emotional appeals."[19] These emotional appeals may influence consumers to request a specific drug just because of the advertisement and not because of the potential benefit or ignoring the risks. "The lack of relevant, important information, coupled with the focus on emotional appeals displayed in current DTC ads, may greatly limit the often touted educational value of the practice."[22]

In the past years, a significant amount of literature has addressed fair balance of risk and benefit, ad content, and the pros and cons of the various types of DTCA. The FDA regulations require that the ads have a fair balance of risk-benefit information and that they can not be false or misleading. In light of the new DRAFT guidance released in May 2009, this researcher is unaware of any literature that compares the fair balance of the risk-benefit presentation in the current DTCA to the recently released DRAFT guidance for Presenting Risk Information in Prescription Drug and Medical Device Promotion. A comparison of the current DTCA risk-benefit presentations to the DRAFT guidance would seem beneficial so that the industry can assess their current compliance with the DRAFT and begin to make the necessary modifications if needed.

CHAPTER 3

METHODOLOGY

The overall goal of this research is to examine the current broadcast DTCA presentation of the risk and benefit information with regards to the FDA guidance document, Presenting Risk Information in Prescription Drug and Medical Device Promotion DRAFT GUIDANCE May 2009. This research will provide an indication of where the industry is, and where it will need to be in relation to the current DRAFT guidance. The research questions (RQ) to be answered are:

RQ 1: How is the risk information presented?

RQ 2: How is the benefit information presented?

RQ 3: How is the side effect and contraindication information presented?

RQ 4: What label information is presented?

RQ 5: Is there any indication of efficacy (i.e. clinical trial information, effectiveness information, FDA mentioned)?

RQ 6: Is there an indication that the drug is prescription only?

RQ 7: Is the adequate provision fulfilled?

RQ 8: Is there a noticeable disposition change or emotional appeal over the course of the ad?

There is a significant amount of work that has been performed in the analysis of the risk and benefit information in DTCA by researchers such as Frosch et al.[19], Davis et al.[20], and Bell et al.[26] This research is modeled after the work performed by Kaphingst et al[1]. and Zheng and Cheng[2]. The unique aspect of this research is that it is an evaluation of a cross section of DTCA

with respect to the new DRAFT guidelines where the previous work only had access to the Guidance for Industry, Consumer-Directed Broadcast Advertisements, August 1999.

In 2004, Kaphingst et al.[1] analyzed the content of 23 product-specific broadcast DTCA and their potential educational benefit shown in 2001 on three major television networks (ABC, CBS, and NBC) in Boston, Massachusetts between the hours of 10 AM and 4 PM.[1] Cable news was not evaluated due to the fact that cable was not available to everyone. The DTCA was defined as a commercial that "advertised a prescription drug, stated the name of the drug, and gave at least one indication for the drug."[1] Kaphingst et al.[1] used coding that referred to the FDA's requirements for broadcast DTCA. This coding divided the commercials into three groups according to the risk and benefit information presented, the fulfillment of the adequate provision requirement and any educational content that was presented. The Presentation of Risk and Benefit information had two sub headings: 1) Fact Density – here the number of facts regarding the risks and benefits were calculated (replicated in this research), 2) Presentation of Risk Information – this examined the overall presentation of risk information as it being one continuous segment, if a voice over or different announcer was used and the speed, tone or volume the information was delivered. The analysis of voice over or if a different announcer presented the risk information was replicated in this research.

Kaphingst et al.[1] evaluated the Adequate Provision requirement as a single topic and examined if the ads gave direction to additional sources of information (replicated in this research). The Educational Content has six sub-headings: 1) Use of Medical Terminology – examining the use of medical language versus non-medical language, 2) Effectiveness and Indication Information - which would indicate if the drug worked or if an undiagnosed individual may need to seek help, 3) Information-Seeking Behaviors Encouraged by Ads – if the

ads told consumers to look else where for information, 4) Difficult-to-Read Print – difficult to read font size or placement of text, 5) Information Source – whether the announcer was a physician, celebrity or anonymous, and 6) Use of Story Narrative – if the ad used background visuals to assist the presentation. It is important to note that this research will not evaluate the use of difficult-to-read print. Kaphingst et al.[1] found that more time seemed to be dedicated to the presentation of benefits of the drug then given to the risks. The risk information was presented in one continuous segment rather than in sections throughout the ad. Some medical and laymen terminology was used to explain medical ideas. The time frame given to the audience to absorb the benefit information was longer than the time frame for the risk information which was thought to effect the fair balance requirement. "Complete references to additional product information were given only in text, casting doubt on whether these ads are making the "adequate provision" for dissemination of detailed product information."[1] These results allowed Kaphingst et al.[1] to conclude that the educational benefit of the ads might not be effective.

Like Kaphingst et al.[1], Zheng and Cheng[2] sampled the DTCA that were broadcast on two major networks (CBS and NBC) from July 1, 2006 to October 19, 2006 to analyze the presentation of the risk and benefit information presented in ten - sixty second intervals. Again, no cable channels were examined due to it not being available to everyone. "DTC advertisements were broadcast most frequently during the evening news programs on both networks."[2] Zheng and Cheng[2] used TiVo as the recording device. They defined the samples as "every content-specific DTC advertisement of 60 seconds."[2] The thirty second ads were not included in the evaluation. Regarding the risk and benefit presentation, Zheng and Cheng[2] found that "even after repeatedly listening to the particular portion of the DTC ads containing risk

information, researchers still had a hard time writing down every single piece of risk information."[2] It was also discovered that "DTC ads tend to present risk information at a much faster pace then the rest of the information content."[2] The average number of risks and benefits presented were fairly equal but the benefits were given in audio and visual formats whereas the risk information was presented only by audio.[2] Like Kaphingst et al.[1], Zheng and Cheng found that mostly "positive or neutral visuals"[2] were shown during the presentation of the risk information. This was thought to distract the viewer's attention from the information begin presented.[2]

This research was modeled after the previous studies performed by Kaphingst et. al[1] and Zheng and Cheng[2] using similar coding definitions and techniques; however, multiple researchers were not used. This research only used one researcher that examined the DTCA therefore, conclusion on issues such as disposition change and speed of presentation represent the opinion of a single researcher.

Utilizing a Motorola DVR as the recording device, this research examined the presentation of the risk and benefit information that was available to the American public on two major television networks. Analogous to Zheng and Cheng[2], this research evaluated the national nightly news broadcasts beginning on May 25, 2009 to June 25, 2009. The thirty minute news recordings were scheduled Monday through Friday at 6:30 pm and 7:00 pm EST (NBC Channel 11 WXIA and ABC Channel 2 WSBT) in Atlanta, Georgia. Within this thirty minute time frame, the sixty second prescription DTCA commercials presented during the break in the news broadcasts were examined. Employing the capabilities of the DVR, the coder was able to pause, rewind and fast forward allowing ample time to review the ads and document the findings.

The definition of an advertisement was any prescription pharmaceutical ad that was shown between the opening greeting to the sign off of the news anchor. Over-the-Counter (OTC), reminder ads, or medical devices were not analyzed. If an ad for the same indication by the same manufacturer was shown but presented with different actors, it was counted as a separate ad.

Coding

In an effort to follow the work performed by Kaphingst et al.[1] and Zheng and Cheng[1], a coding scheme to denote risk, side effect, contraindication and benefit information was used. Kaphingst et al.[1] counted facts that were contained in the risk and benefit information. Zheng and Cheng[2] counted the risk and benefit information and gave the average number of each that were found. However, neither study denoted what words were used to signify what started the risk or benefit information. One difference in this research was the use of key or descriptor words to indentify the start of the risk and benefit statements. The reasoning for using the descriptor words was to establish the key point identifying when the risk, side effect, contraindication, and benefit information began. These key words are noted later in each detailed descriptive section of the methodology.

Different from Kaphingst et al.[1], this research did not evaluate the educational content of the DTCA, the severity of the side effects, the frequency of possible occurrence of the side effects in humans, the formatting of the printing within the ads, any volume changes in the ad, if the ad's spokesperson was someone famous, or the use of a narrative story. This was due to the fact that the main topic of this research evaluates the risk and benefit information only.

Similar to Kaphingst et al.[1], this research lasted approximately one month, evaluated the adequate provision, the audio or visual presentation of the risk-benefit information, the "Fact

Density"[1], and the number of risks and benefits presented. To go a step further, this research also determined the number of side effects and contraindications that were given; The pace of the risk and benefit presentation, the use of medical terminology, whether a voice over or different announcer was used and the amount of time allotted for the benefit and risk information presentations.

Parallel to Zheng and Cheng[2], this research recorded the indication of each advertised drug, the pace of the risk and benefit presentation, the use of a voice over or different announcer when the risk and benefit information is given; use of verbal effectiveness appeal with key words indicating efficacy, ease of use of the drug with key words signifying convenience or time to onset of the medication after ingestion; and safety aspects with key words such as "safe", "naturally", or other.

In contrast to Zheng and Cheng[2], this research was not evaluated for three months, did not divide the ads in ten second intervals, did not evaluate any statistical information given, if any music was used during the presentation, the venue used during the commercial, race of the actors, the number of people in the ad, the number of cuts or edits, or any social-psychological enhancements. This was due to the fact that the main focus was on the fair balance of the risk and benefit information.

It was unclear to this researcher in both Kaphingst et al.[1] and Zheng and Cheng[2] if the risk, side effect and contraindication information was captured individually or collectively as the overall risk information. This research examined the number of risks, side effects and contraindications separately. Kaphingst et al.[1] did capture information about side effect severity and the possible frequency of occurrence of side effects. This information was not captured in this research.

In addition to the above evaluation criteria, this research also included any mention of the FDA or clinical trial information to give the impression of any additional safety factors. If the ads were for gender specific drugs targeting one gender over the other and if any label information was presented indicating dose frequency. Also evaluated was the drug name and concentration, if the manufacturer was displayed, a disposition change of the actor simulating the before and after effects of the medication to evaluate the perception of effectiveness. The last evaluation was if the ads presented that the drug was available by prescription only to notify consumers that they have to see their health care professional before obtaining the medication.

During risk evaluation, the key words:

- Risk
- People At Risk
- Other

(Note: if Other was chosen the significant word was recorded. This is applicable for the key word "Other" throughout this research.)

were used to identify the subject of the sentence that would denote risk. The vehicle for the risk communication was documented as an AUDIO or VISUAL indicator. Another analysis was whether or not the risk information was presented in a pace that changed from the beginning of the commercial. If the pace was determined to be at a speed that was faster than the beginning of the commercial, the pace was considered "fast". If the pace did not change, it was considered normal. The examination of risk also determined if a voice over or different announcer was used. The number of risks that were presented were counted and documented. The time in seconds needed to determine the length of the Risk Statement presented during each ad was documented. An important note is that the Risk Statement presentation was defined as the risk,

side effect and contraindication information. This was due to the fact that some ads presented key words in a pattern that described risk - side effect – contraindication - side effect or a similar variation. Capturing each individually proved to be difficult. However, each risk, side effect, and contraindication was captured individually.

The benefit information was documented in the same fashion. The key words used to identify benefit information were:

- Prevents
- Help
- Controls
- Relieves
- Comforts
- Manages
- Saves Lives
- Reduces
- Other.

Again, the vehicle for the benefit communication was documented as an AUDIO or VISUAL indicator. An analysis of whether or not the benefit information was presented in a pace that changed from the beginning of the commercial was evaluated. Analogous to the risk determination, if the pace was determined to be at a speed that was faster than the beginning of the commercial, the pace was considered "fast". If the pace did not change, it was considered normal. The examination of a voice over or if different announcer was used was recorded as well. The number of benefits presented and the time in seconds to give the benefits was also documented.

The side effect information also utilized key words such as:

- Tell your Doctor If
- May Experience
- Serious
- Frequent
- Unexpected
- Side Effects
- Stop

Again, the vehicle for the side effect communication was documented as an AUDIO or VISUAL indicator. The number of side effects given was also documented. The pace of the side effect, voice over or different announcer information was recorded to compare with the benefit information. The time in seconds to present the side effect information was captured in the Risk Statement.

The contraindications were determined by the key words:

- If You Have
- Consult Your Doctor
- Don't
- Harmful
- Should Not
- People With
- If You Are Taking
- Other

As previously indicated above, the vehicle for the contraindication communication was documented as an AUDIO or VISUAL indicator. The number of contraindications given was also documented. The contraindication information was also analyzed for pace, voice over, or a announcer change. The time in seconds to present the contraindication information was captured in the Risk Statement time.

Labeling information was also recorded. Label information consisted of the drug name, dose (defined as how often the medication is indicated for use), active ingredient concentration, or any other label information.

To examine any perceived indication of effectiveness of the medication, the actor's disposition and any clinical trial information stated was also recorded as well as efficacy key words such as "breakthrough", "only", "number one" etc. An indication of the disposition change was defined as the actor showing signs of pain, sadness or any discomfort before the benefit information then after the benefit information was presented a smile, signs of laughter, pain free movement, etc. was seen. The clinical trial information cue was if the statements such as "studies show" or "clinical trials show".

Words such as "safe", "natural", "non addictive", "convenient", "quick", "fast acting" or "economical" were recorded as an indication of convenience of the drug. To indicate the availability of the drug, any information notifying the audience that access was by "prescription only" was captured. The format of the prescription indication was also recorded either being audio or visual. Any notification of the name of the manufacturer was recorded. Any mention of the Food and Drug Administration was captured as an indication of safety to the consumer. The presentation of clinical trial was captured as support for efficacy however, no results or statistical information was recorded.

According to the current guidance, the target audience has to be directed to four other sources of information to fulfill the adequate provision requirement.[5] Therefore information such as a company website, magazine/periodical, telephone number to call, referring the viewer to their physician, or any other source of information was recorded. Any gender specific ads were also noted.

Finally any additional information, such as payment assistance or free trial offers, was recorded as an indication of persuasion to use the drug.

CHAPTER 4

RESULTS AND CONCLUSIONS

Beginning on May, 25, 2009 and ending after the 7:00 PM national news broadcast on June 25, 2009, one hundred and thirty two ads were analyzed. A total of twenty-four different brand name prescription drug advertisements were recorded. The sixty second ads presented a total of thirteen different indications that were evaluated for their compliance with the new DRAFT guidance "Presenting Risk Information in Prescription Drug and Medical Device Promotion." It should be noted that due to the unavailability of any additional resources, one recorder made all the observations in this research.

The indication shown most frequent was high cholesterol, presented in five different advertisements (20.83%). Two of the ads were from the same company but had different presentations. The most frequent advertisement from the same manufacturer was allergy relief, with thirteen ads (9.85%). The overall frequency of the ads ranged from one (0.76%) to thirteen (9.85%).

Only fifteen (62.5 %) of the ads disclosed the name of the manufacturer. Out of the fifteen, Pfizer was mentioned most frequently with four ads (27%) presented for different indications. Five of these manufacturers are in the United States (Note: Two of these five ads were a combination of a U.S. and a foreign manufacturer). Seven of the fourteen manufacturers were listed as one of the top twenty pharmaceutical manufacturers in an internet article by Contract Pharma Magazine.[45] Nine of the twenty-four ads (37.5%) neglected to disclose the manufacturer. An internet search of the drug name revealed that six (66%) of these ads were related to a U.S. manufacturer (Note: Two of the six were a combination of a U.S. and a foreign

manufacturer). Seven of the nine ads were listed as a 2009 top twenty pharmaceutical manufacturer.[45]

RQ 1: How is the risk information presented?

The number of key words that indicated the beginning of risk information was limited to two, "Risk" and "People at Risk". Out of the twenty-four ads analyzed, thirteen (54%) specifically pointed out the risks associated with the drug. These risks were presented in an audio format thirteen times (54%) and were presented in five ads (20%) using a visual format. These risks were presented with a voice over or had different announcer seven times (29%). Two separate ads mentioned that a risk of "death" or "suicide" is associated with the advertised drug. The range of time for the risk presentation was eleven to forty-five seconds (Note: this time included the risk, side effect and contraindication information as it was presented in one continuous segment). The number of risks given during the risk information presentation ranged from one to eleven risks. The most frequent number of risks given was two (20.83%). The pace at which the risk information was presented was slow or normal eight times (62%) and considered fast five times (38%), (Table 4.1).

Table 4.1:Risk Information

Key Words	**# Given**	**%**	**Format**	**# of Ads Containing Format**	**%**
Risk	13	54.17	Audio	13	54.17
People at Risk	1	4.17	Visual	5	20.83
			V/O	7	29.17
# of Risks Given	**Frequency**	**%**	**Pace**	**# Observed**	**%**
1	4	16.67	Fast	5	38.46
2	5	20.83	Slow/normal	8	61.54
4	1	4.17			
5	1	4.17			
11	1	4.17			

All descriptors for the risk information were considered to be presented in laymen's terms and no medical jargon was noticed. The risks that were presented in a visual format were difficult to notice when trying to listen to the audio information, but were seen upon rewinding and reviewing the ad. Some text gave additional risks that were not fully described by the accompanying audio. According to the DRAFT, this does not comply with the proper use of SUPERs. The text should run concurrently with the audio and be similar enough so as not to give a misleading impression. The hierarchy of risks was not evaluated due to the researcher not having a medical background thus not being able to determine the severity. However, in two separate ads, the words "death" and "suicide" were mentioned.

The pace, voice over and change in announcer in this research was greater than the findings in nearly the same amount of ads examined in Kaphingst et al..[1] A possible explanation of this difference in results could be due to the fact that this data is subjective to the individual reviewers. Zheng and Cheng[2] determined that the pace of the risk presentation was faster than the pace of the rest of the commercial, this agrees with the findings in this research.

Kaphingst et al. found that the number of mean number of risks presented was ten in a time frame of three to twenty-three seconds. This research found that the mean number of risks presented was two and the time was in a range of eleven to forty-five seconds. Kaphingst et al. did not calculate the fact density of the individual risk, side effect and contraindications as in this research. The difference in the time of presentation could be explained by the fact that this research combined risk, side effect and contraindication information.

The average number of risks found in current DTCA was less than the findings in Zheng and Cheng[2] (2 vs. 4.9). A possible explanation is that this research used key words to determine

the beginning of risk information and as previously stated, classified the risks separate from the side effect and contraindication information.

RQ 2: How is the benefit information presented?

Twenty-four ads contained a benefit statement. The most frequent benefit key word was "help" and was mentioned seventeen (70%) times. Each ad presented the benefit key word in an audio format, and twelve times (50%) the benefit information was given in a visual format. Five times (20%) the benefits were presented with a voice over or by a different announcer. The range of time for the benefit presentation was one to twenty-eight seconds. This is less than the amount of time dedicated to the risk information. The average number of benefits presented was three, the number of benefits given during the benefit information presentation ranged from one to five benefits. The most frequent number of benefits given was three (29%), (Table 4.1). The number of benefits presented in current DTCA's is in close agreement with the 4.66 benefits presented in the research of Zheng and Cheng.[2] The pace of presentation of the benefit information was considered normal for all advertisement assessed. This is also in agreement with Zheng and Cheng who found the benefit presentation to be slower than the remaining part of the DTC ad.[2] The format of the benefit presentation agreed with Zheng and Cheng[2] in that every ad used an audio format. The percentage of the benefit information being presented in both audio and visual formats was higher in this research. An explanation of this is that Zheng and Cheng analyzed more advertisements that might account for the difference in the percentages.

Kaphingst et al.[1] found that the mean number of benefits presented was ten. This is greater than the average number of benefits in this research. Even though the number of ads

analyzed was similar, the reason for the difference is unclear to this researcher. Kaphingst et al.[1] did not capture the pace of the benefit information.

Table 4.2: Benefit Information

Key Words	# Given	%
Reduces	3	12.5
Relieves	5	20.83
Help	17	70.83
Stop	2	8.33
Slows	1	4.17
Significantly Lowers	1	4.17
Improves	3	12.5

# of Benefits Given	Frequency	%
1	6	20.83
2	4	16.67
3	7	29.17
4	4	16.67
5	3	12.5

Format	# of Ads Containing Format	%
Audio	24	100
Visual	12	50
V/O	5	20.83
Pace	**# Given**	**%**
Fast	0	0
Slow/normal	24	100

RQ 3: How is the side effect and contraindication information presented?

The most frequent side effect recorded was "Side Effect" that was presented nineteen times (79%) and the most frequent contraindication recorded was "Consult your Doctor" at nine times (38%). The average number of side effects given was four, the range of the number of side effects presented was two to fourteen, with three (33%) being the most frequent number of side effects. The range of the number of contraindications presented was one to twelve and the most frequent number of contraindications given was four (20%) with an average of five contraindications given. The side effects and contraindications were all presented at least in an audible format with a visual side effect presentation seen once (4%) and a visual contraindication presentation seen twice (8%). Some of the visuals displayed additional information that the

audio did not completely describe. This is in contrary to what the DRAFT guidance requires. The audio and visual information should be close in the claim that is being stated. The text was usually presented at the bottom of the screen in white letters making it difficult for this researcher to notice on the first viewing of the commercial. This is also in contrast to the DRAFT guidance stating that the SUPERs should be "reasonably visible under typical viewing conditions."[4] The side effects and contraindications used a voice over fifteen times (63%). The pace of the side effect and contraindication was considered "fast" four times (17%) in this research (Tables: 4.3 & 4.4).

Table 4.3: Side Effect Information

Key Words	**# Given**	**%**	**# of Side Effects Given**	**Frequency**	**%**
Side Effects	19	79.17	2	5	20.83
Serious	8	33.33	3	8	33.33
Tell Dr If	13	54.17	4	1	4.17
May experience	3	12.5	5	3	16.67
Life Threatening	1	4.17	6	4	16.67
Suicidal Thoughts	1	4.17	7	1	4.17
Sign of	1	4.17	8	1	4.17
Increase	1	4.17	14	1	4.17
Fatal	1	4.17			
Format	**# of Ads Containing Format**	**%**	**Pace**	**# Given**	**%**
Audio	24	100	Fast	4	16.67
Visual	1	4.17	Slow/normal	20	83.33
V/O	15	62.5			

Table 4.4: Contraindication Information

Key Words	# Given	%	# of Contraindications Given	Frequency	%
Avoid	1	4.17	1	1	4.17
Consult Dr	9	37.5	2	4	16.67
Not for everyone	6	25	3	4	16.67
Don't	7	29.17	4	5	20.83
If you have…	5	20.83	5	3	12.50
Should not	5	20.83	6	2	8.33
People with	2	8.33	8	2	8.33
If you are taking	1	4.17	10	2	8.33
			12	1	4.17
Format	**# of Ads Containing Format**	**%**	**Pace**	**# Given**	**%**
Audio	24	100	Fast	4	16.67
Visual	2	8.33	Slow/normal	20	83.33
V/O	11	45.83			

RQ 4: What label information is presented?

The name of the drug was presented in all twenty-four ads, and the dose (i.e. the number of times the consumer can take the medication) was presented twelve times (50%). The active ingredient concentration (i.e. milligrams, micrograms, etc.) was presented ten times (42%) (Table 4.5).

Table 4.5: Label Information

	# Given	%
Name	24	100.00
Dose	12	50.00
Active Conc.	10	41.67

The labeling data was captured to assess the length to which the manufacturer would go to give the consumer other avenues for research than just fulfilling the adequate provision. This also provides some indication of the package insert with the dosing and active concentration.

This is helpful to both patients and healthcare processionals. There is no requirement in the DRAFT guidance for labeling information being presented.

RQ 5: Is there any indication of efficacy (i.e. clinical trial information, effectiveness information, FDA mentioned)?

The most frequent indication of efficacy (Table 4.6) was the word "Only" which was presented five times (20%) in all the twenty-four ads. The most frequent efficacy term used in Zheng and Cheng[2] was "effective" (51.2%).[2] The terms "Quick" and "Fast Acting" were each presented once (4%) as an indication of convenience (Table 4.7). Zheng and Cheng[2] found that the term "convenience" (31.7%) was used most often. The difference is possibly due to the number of ads that were analyzed between the two studies.

A notification of a clinical study associated with the drug was given six times (25%) (Table 4.8). The approval of the FDA was mentioned five times (20%) (Table 4.9). The term "Well Tolerated" was used once (4%) to give a level of safety (Table 4.10). The terms "safe", "natural", and "non-addictive" were used for relaying safety in Zheng and Cheng.[2]

Table 4.6: Efficacy Information

Cues	# Given	%
Only	5	20.83
Unlike Others	1	4.17
Proven	4	16.67
Works Differently	2	8.33
#1 prescribed Treatment	1	4.17
Compared To	3	12.50
No Other	1	4.17

Table 4.7: Convenience Information

	# Given	%
Quick	1	4.17
Fast Acting	1	4.17

Table 4.8: Clinical Indication Information

	# Given	%
Yes	6	25.00
No	18	75.00

Table 4.9: FDA Information

	# Given	%
Yes	5	20.83
No	19	79.17

Table 4.10: Safety Information

	# Given	%
Well Tolerated	1	4.17

RQ 6: Is there an indication that the drug is prescription only?

The prescription only availability of the drug was seen in all ads (Table 4.11). It was presented in an audio format seven times (29%) and a visual format seventeen times (71%). The previous research did not evaluate the indication of the drug being prescription only nor does the DRAFT guidance. The PhRMA guiding principles do state that ads should state if a drug is prescription or not. This complies with the principles.

Table 4.11: Prescription Information

	# Given	%
Audio	7	29.17
Visual	17	70.83

RQ 7: Is the adequate provision fulfilled?

The adequate provision requirement that directs the consumer to at least four different additional sources of information was presented in all the commercials. The additional sources were websites, magazines/periodicals, toll-free telephone number and a doctor. This fulfills the requirement in the Guidance for Industry – Consumer-Directed Broadcast Advertisements. August 1999and is considered adequate for the advertisement assessment. This is different than the results found in Zheng and Cheng[2] that showed the ads that were analyzed only directed the viewer to a toll-free number (95.1%), magazine (92.7%) or a website (82.9%) and did not direct the consumer to a doctor. The reason for this difference is not known by this researcher. The current Guidance for Industry, Consumer-Directed Broadcast Advertisements (1999) requires that the adequate provision be fulfilled.

RQ 8: Is there a noticeable disposition change or emotional appeal over the course of the ad?

An emotional disposition change (Table 4.12) from before taking the medication to after taking the medication was seen eight times (33%). Note that this is subjective due to the fact that there was one data recorder. However, future research should further assess the impact of the disposition change as an indication of effectiveness and the persuasive impact on the consumer to build on what has already been accomplished by other researchers in the community.

Table 4.12: Disposition Change Information

	# Given	%
Yes	8	33.33
No	16	66.67

Additional information (Table 4.13) that might be perceived as persuasive such as reduction of prescription costs or a free trial offer was recorded. The manufacturer offered possible prescription payment assistance four times (17%). There is current research being performed in this area.

Table 4.13: Additional Information

	# Given	%
$ off Prescriptions	1	4.17
Free Trial offer	2	8.33
If cant afford medication, the manufacturer may be able to help	4	16.67

Gender information was recorded (See. Table 4.14). Seventy percent of the ads were not gender specific. The male to female ads were almost equal in presentation frequency.

Table 4.14: Gender Information

	# Given	%
Men	3	12.50
Women	4	16.67
Neutral	17	70.83

Conclusions

Based on the research observations, this study shows the current DTCA does not comply with the net impression requirement in presenting the risk and benefit information as a whole in the DRAFT guidance. The benefit information was always presented in an audio format with the accompaniment of visual presentation half of the time and a voice over occurrence of 20%. The complete risk information (which includes the risk, side effect and contraindication information) was presented in an audio format 85% and visual format 11% with a 45% voice over during the presentation. This result indicates that the consumer does not have an equal exposure of the risks and benefits of the drug during the advertisement (See Table 4.15). When separated, the side effect and contraindication information was presented in an audio format in every ad but was still not equal to the visual presentation of the benefit information. This does not comply with the DRAFT guidance, "Considerations of Content."[14]

Table 4.15: Average Overall Benefit and Risk Format Information

Average Overall Benefit Format			**Average Overall Risk Format**		
Audio	24	100.00	Audio	20	84.72
Visual	12	50.00	Visual	3	11.11
V/O	5	20.83	V/O	11	45.83
Average Pace			**Average Pace**		
Fast	0	0.00	Fast	4	15.28
Slow/normal	24	100.00	Slow/normal	15	63.89

The pace of presentation of the benefit information was recorded at a normal pace 100% of the time where-as the risk information was presented in a faster-than-normal-pace 15% of the time. This shows that the consumer may not have enough time to fully understand the complete risk information. This is in agreement with Zheng and Cheng[2].

When the findings in this research are compared to the criteria the DRAFT guidance uses for consideration of content when presenting the risk and benefit information in broadcast DTCA the results show that:

- The number of statements about benefits and risk are not equal
- This research did not compare the risk and benefit information to additional sources to determine the completeness or severity of the information presented. The ads always pointed the target audience to other resources to find information.
- The amount of time (in both audio and visual portions) devoted to benefits and risks in a video, audio or broadcast communication are not equal. More time was given to the presentation of risk. This does not comply with the DRAFT guidance.
- The amount of space devoted to benefits and risks in a print communication was not equal. The benefits were presented in print (visual) were very noticeable. In contrast, the risk information was located usually at the bottom of the screen and difficult to notice. (For this research, the print communication was interpreted as the printed visuals for the risk and benefit information.)
- The use of audio or visual components that enhance or distract from the presentation of risk or benefit information was apparent in the fact that the visual risk information was not as noticeable as the visual benefit information. Also the

visual risk information was not always concurrent with what the audio was presenting. This does not comply with the DRAFT guidance.

It is important to note that the completeness and depth of detail given about the risk and benefit information was not analyzed due to the fact that this research did not compare against other informational sources.)

The criteria comparison for the DTCA content regarding the risk and benefit information indicates that the current DTCA would not be in compliance with the DRAFT guidance.

Comparing the most frequent number of benefits presented (3, see Table 2) with the cumulative risks (risks = 2, side effects = 3, contraindications = 4, total = 9), this shows that there is more risks for the consumer to remember than benefits. According to Murdock, the average number of risks, side effects and contraindications does exceed the maximum number of words (five at the beginning and eight at the end) that a person can recall.[33] The time dedicated to each is also different. The time given to the benefit information (1-28 seconds) was not equal to the time given to the risk information (11-45 seconds). This result is an imbalance and could have an effect on the DRAFT guidance statement that the "quantity of information can affect the net impression of the piece."[14] The net impression of the benefit and risk statements in the current DTCA is not similar.

The materiality of the ads in the consideration of the target audience was addressed by addressing the following statements (Note: the severity of the risk was not analyzed):

1. Relevant properties of a product.[4]

   This was shown by the presentation of the risk and benefit information of each ad. There is a difference in the way that each was presented but this statement was fulfilled as in this research considered compliant with the DRAFT guidance.

2. Whether or not the product is appropriate for them or their patients.[4]

   Each ad stated the contraindication and possible side effects that are related to the drug. The ads did direct the viewer to their health care professional for more information. This is considered compliant with the DRAFT guidance.

3. Whether or not they are willing to accept the risks or burdens associated with using or prescribing a product.[4] The manufacturer guides the consumer to their physician to determine if the benefits of the medication outweigh the risks and if it is appropriate for their health care plan. The ads direct the patient to several additional different sources of information so they can make an informed decision. This is considered to be compliant with the DRAFT guidance.

The comprehensiveness consideration of the target audience was determined by answering the following five questions:

1. What is the drug used for? [14]

   This question was answered by the thirteen indications that were recorded. The audience was made aware of the indication at the start of the advertisement before the benefit information was presented.

2. Who should or should not take a drug? [14]

   This question was answered by the benefit and contraindication information that was presented. The ratio of information was not equal (See Tables 2 and 4) and the time given to each was not balanced.

3. What can be expected from the drug? [14]

   This was answered by the benefit and side effect information. The number of each presented (See Tables 2 and 3) and the time dedicated to each was not equal.

4. What patients should ask their healthcare professionals about a drug? [14]

   This question was answered by presenting the contraindication information key words

   The ads did state who should not take the drug.

5. What patients should tell their healthcare professionals about before or while taking a drug?[14]

   This was answered by the side effect information. The ads were clear about what to tell the health care professional when requesting the medication but the pace and amount of information contained in the presentation may have an effect on the ability of the consumer to recall the facts.

The addressing the criteria for materiality and comprehensiveness shows that current DTCA is in compliance with the" Consideration of Target Audience"[14] part of the DRAFT guidance.

Discussion

In overall comparison, this research finds that the risk and benefit presentation does not comply with the expected requirements of the DRAFT guidance. The formatting of the risk and benefit information was not balanced as indicated by the results found in examination of the audio, visual and voice over aspects of the ad. The pace of each presentation was also not equal and balanced.

The three materiality criteria were found to be compliant with the DRAFT guidance. It should be noted that from this research it was determined that the true spirit of the criteria should be better explained. The relevancy of the product, the appropriateness and the acceptance of the possible burdens of the drug were found to be loosely described. The relevancy of those criteria to the overall formatting and presentation should be linked. The materiality and

comprehensiveness have a direct link to the format and content of the risk and benefit information.

Comparison of the current DTCA to the comprehensiveness consideration of the target audience found in the DRAFT guidance revealed that three out of the five content criteria were not met. Again, the DRAFT guidance should be more specific in determining how to fully answer these questions. Analogous to the materiality criteria, the comprehensiveness is related to the overall format presentation of the risk and benefit information. This research has determined that the content of the risk information is greater than the content of the benefit information. This shows that there is an imbalance in the risk and benefit presentation and may effect the consumers ability to recall all of the risk information. The advantage in formatting the benefit information has over the risk information is an imbalance that may mislead or misinform the audience. This research indicates that pharmaceutical manufacturers will have to modify their current advertising campaigns to be in compliance if and when the new DRAFT guidance is finalized.

Over the course of the research, it was determined that without the ability to rewind the DVR allowing the opportunity to count the risk and benefit information, this study would be near impossible for one researcher. The coders in Zheng and Cheng[2] found this to be true was well. A possible solution to this would be to present the risk and benefit in both audio and visual formats with the same attention, emphasis and pace of presentation. This will point out the benefits as well as the risks equally, so that the target audience will visualize and be able to recall of the information.

Limitations during this research were that there was only one researcher, the recording device and the key words used to notify of the coming risk and benefit information were not

validated. Validation would provide a solid frame work for future research so that consistent data capture will be made. Future researchers should take this into consideration. By validating the recording instrument and key words to indicate the start of the risk and benefit presentation that all DTCA might use, a possible standard for DTCA review might be developed. This will provide assurance that the fair balance requirement is met without question. Future research should consider analysis over a longer duration and use multiple researchers so that a greater number of ads will be evaluated and the subjectivity variable will be removed. Future research might also evaluate the additional sources in the adequate provision to determine the completeness of the information presented in the broadcast DTCA.

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