DIRECT-TO-CONSUMER ADVERTISING OF PHARMACEUTICALS:

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A CONTENT ANALYSIS

THESIS

Presented to the Graduate Council of Texas State University-San Marcos in Partial Fulfillment of the Requirements

for the Degree

Master of ARTS

by

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CHAPTER 1

INTRODUCTION TO THE STUDY

The direct-to-consumer (DTC) approach has historically been a broad based, effective mechanism for advertising across several markets. The televised DTC approach, however, is a relatively new marketing strategy within the prescription pharmaceutical industry, employed exclusively in the United States. As regulated by the Food and Drug Administration (FDA), prescription pharmaceutical manufacturers have been permitted to advertise directly to the consumer since the 1980's. In the early stages of pharmaceutical DTC advertisement, the FDA called for a two-year voluntary moratorium to examine the effects of such advertising as well as the advertisements' adherence to FDA regulations of the time (Pines, 1997). After the moratorium, the FDA determined that DTC advertising of prescription pharmaceuticals would fall within legal bounds and pharmaceutical companies were permitted to broadcast their DTC advertisements to the public (Pines, 1997). FDA regulations for DTC broadcast advertisements are more elaborate than regulations for DTC print advertisements. Print advertisements for prescription medication must include a "brief summary" (Hill, 2005). This summary must include information on the product's side effects, contraindications, and effectiveness (21 >C.F.R. [section] 202.1 e, 2004, as cited in Hill 2005). Often the brief summary is plainly the warning language on labels of the FDA-approved medication (Pham, 2004).

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In addition to a brief summary, broadcast advertisements must include a "major statement", which must include the medication's major side effects and contraindications within the audio or audio-visual segments of the commercial (Hill, 2005). The amount of time it would take within a broadcast advertisement to remain in compliance with both the major statement and brief summary requirements made DTC advertising costs exorbitant. In response, the FDA issued a directive in August, 1997 that effectively lessened the costs of DTC advertising (Hill, 2005). The directive allows for use of an "adequate provision" in place of a brief summary. The adequate provision must include the display of (1) a toll-free number, (2) a current publication that includes a summary of FDA-approved labeling for the medication, (3) a statement that tells consumers to consult with their physician, and (4) a web site address that displays product information (Hill, 2005). In essence, this directive has reduced the amount of time pharmaceutical companies are required to spend on the air providing consumers with product information by directing them to other sources for information about the medication. However, Aiken (2003) reports that only 43% of consumers who viewed a DTC advertisement said that the ad caused them to seek more information about their health or the drug advertised. This implies that even when consumers are given alternate resources to locate information about advertised medications, these resources may only be utilized by less than half of the viewers.

Loosening the laws concerning DTC advertising of prescription pharmaceuticals has resulted in the widespread public promotion of prescription medication with less information about the risks and precautions. The implications are great; the consumer is being informed with relatively little educational material about potentially addictive pharmacotherapeutics, and asking to receive prescription drugs from their physicians without the necessary medical knowledge it requires to provide accurate diagnosis and proper treatment regimen.

As regulations were relaxed, spending for DTC advertising of prescriptions skyrocketed over a short 5-6 year period¹. Clearly, DCT advertising promotional dollars have risen substantially in recent years. Previously, the majority of pharmaceutical advertising dollars were focused on medical schools because those new physicians were shown to be susceptible to the influence of the sales of drugs (Harelik, Johnston, Rivers & Ryan, 1975; Johnston, Harelik, & Ryan, 1976). At present, major pharmaceutical companies are tapping into a segment of the advertising market that has formerly been untouched: the consumer.

Today's pharmaceutical manufacturers are utilizing four major types of promotion: (1) *detailing*, which is drug representatives' sales activities directed towards physicians, (2) *sampling*, which is the distribution of free drug samples from drug sales representatives to office-based physicians, (3) *DTC advertising*, and (4) *medical journal advertising* (Impact of, 2003 and Donohue, & Berndt, 2004). Promotional spending is not proportionate among different promotional activities. An estimated fifty-five percent of pharmaceutical promotional dollars have been allocated to sampling, twenty-nine percent to detailing, fourteen percent to DTC advertising and two percent in medical journal advertising ("Impact of", 2003). Although DTC advertising remains a relatively small portion of promotional spending within the industry, DTC advertising has maintained a steady rise in spending with an average increase of twenty-eight percent annually from 1996 to 2001 ("Impact of", 2003).

¹ Spending for DTC advertising of prescription drugs skyrocketed from \$596 million in 1995 to \$1.2 billion in 1997 (Nordenberg, 1998). A second approximation of DTC expenditures ranged from almost \$1 billion in 1996 to \$2.5 billion in 2000 (Narayanan, Desiraju, & Chintagunta, 2004). Other studies have estimated much higher promotional spending by pharmaceutical manufacturers with \$9.2 billion in 1996 to \$19.1 billion in 2001.

The increase in promotional spending parallels an increase in consumer spending. Recent studies have noted that United States consumers spending for prescription medication alone tripled between 1990 and 2001, with a sixteen percent increase from 2000 to 2001 ("Impact of", 2003). Interestingly, current research suggests that return on investment (ROI) for DTC advertisements are relatively low (Narayanan et al., 2004). Research results are mixed on the cost effectiveness of direct marketing to consumers. Neslin (2001) reports the ROI for every \$1 spent on detailing is \$1.72, but the ROI for every \$1 spent on DTC is \$.19. Wittink (2002) also reports substantial differences in returns for detailing versus DTC advertising. Among brands launched between 1998 and 2000 that exceed \$500 million in annual revenue, ROI per dollar for detailing was \$11.60, and the corresponding ROI for DTC was \$1.30 (Wittink, 2002). Narayanan et al., (2004) found that the average returns for detailing of Allegra, Claritin, and Zyrtec were \$1.28, \$1.49, and \$1.10 respectively while returns for DTC advertisements of the same brands were \$0.85, \$0.66, \$0.76. In a synthesis of multiple variables, a positive interaction between detailing and DTC occurred such that detailing of a product has a greater impact when combined with DTC advertising of the same brand (Narayanan et al., 2004). This finding is notable because it illustrates a synergistic effect between pharmaceutical promotional categories. However, this research does reflect how the rising cost of prescription medications may confound the data. It is possible that consumers may have increased prescription drug spending because the cost of medication has risen substantially.

An increase in consumer spending on prescription pharmaceuticals may be an indicator of increased public awareness of DTC advertising of prescription medication (Bell, Kravitz & Wilkes 1999). In a random-digit dialing telephone survey, Bell and colleagues (1999) found that 329 respondents recognized 3.7 of 10 drugs on the survey. Awareness of specific drugs varied from 72% for Claritin to 8% for Buspar. Researchers concluded that DTC advertisements guided one third of respondents to ask their doctors about specific drugs, and one fifth of respondents to ask for a prescription (Bell et al., 1999). Interestingly, 43% of respondents believed that only "completely safe" drugs could be advertised (Bell et al., 1999).

In Prevention Magazine's "Annual Survey on Consumer Reactions to Direct-to-Consumer Advertising of Prescription Drugs," the public's report of having heard or seen an ad for prescription drugs grew from 63% in 1997 to 85% in 2002 (1997; 2002). This growth marks added consumer exposure and potentially interest in prescription medication. Similar to Bell and colleagues' (1999) findings, the survey determined one in three adults claim they have spoken with their doctor regarding a commercialized drug, and almost half of those leave the office with a prescription for that drug ("Annual Survey", 1997; "Annual Survey", 2002). The 2003 Kaiser Foundation Report determined this data indicates 13% of Americans have obtained a specific prescription in response to having seen a drug ad ("Impact of", 2003).

DTC advertising remains a significant source for driving prescription pharmaceutical sales. Patients who request medication have a high likelihood of receiving them (Kravitz, et al., 2005). Kravitz and colleagues (2005) found among standardized patients seeking help for major depression, 53% of those requesting brand-specific antidepressants received prescriptions, 76% of those requesting general antidepressant medication received prescriptions, and 31% of those who made no request received an antidepressant prescription.

Research on DTC advertising of pharmaceuticals has taken several approaches. One approach has been to determine whether or not the advertisements are 'fair and balanced' in providing benefit and risk information about the drug. Another approach has been to provide sufficiently high quality educational material presented in DTC advertisements. A third area of research has been to examine the implications of gender roles in pharmaceutical advertisements. Finally, another angle of research has been aimed at determining the effects of DTC advertising on the patient/physician relationship. The current research study presents a systematic approach to analyze some of the prominent issues of televised DTC advertising on recent commercials of prescription drugs with the intention of adding substance and breadth to the current body of DTC research on prescription pharmaceuticals.

A content analysis of eighteen televised DTC commercials of prescription pharmaceuticals will provide an empirical basis for examining trends and patterns of risk, benefit and educational messages. Eighteen commercials of prescription medications will be analyzed for content. Specifically the indications will comprise: asthma, high blood pressure, restless leg syndrome, herpes, arthritis, memory/Alzheimers, migraine headaches, osteoporosis, cancer, heart attack, bladder control, high cholesterol, sleep-aid, and allergies.

More specifically, the following content analysis aims to address three research questions:

- 1. On average, will benefit messages occur more frequently than risk messages?
- 2. On average, will more time be spent on benefit messages than risk messages?
- 3. Is there adequate educational content present in televised DTC commercials such that each commercial presents at least 4 of the 7 educational content variables (described below)?

For purposes of this research, 'benefit messages' include claims of effectiveness such as improved clinical indicators, enhanced positive affect, enhanced physical appearance, enhanced ability, and enhanced freedom. Examples of benefit messages include and are not limited to: "lowers blood pressure," "enjoy life," "relieve fear," "sleep better," "clears up skin," "improves strength/stamina," and "gain personal control." 'Risk messages' include threats, disclaimers, and warnings of side effects. Examples of risk messages include and are not limited to: "x happens if condition is left untreated," "can't promise," "decreases symptoms but does not eliminate risk," "side effects include nausea, dizziness and vomiting, etc." It is expected that, among the televised DTC prescription pharmaceutical commercials analyzed, benefit messages will occur more frequently. Additionally, it is expected that more time will be spent on benefit messages than risk messages.

For purposes of this research, 'educational content' includes seven variables: (1) mention of information about symptoms of the condition, (2) mention of information about the condition's precursors or prevalence, (3) attempts to clarify misconceptions about the condition, and (4) mention of the drug's mechanism of action, (5) success rate and (6) treatment duration, as well as (7) mention of alternative treatments. It is expected that among televised DTC prescription pharmaceutical commercials analyzed, there will not be provision of adequate educational content, with presentation of less than four educational content variables on average.

CHAPTER TWO

CORE RESEARCH ANGLES OF DTC ADVERTISING OF PHARMACEUTICALS

Fair and balanced advertising

The messaging in DTC advertising of prescription pharmaceuticals is an integration of promotional and informational material. Among the most pertinent messages conveyed, perhaps, are the risks and benefits of medication. The ways in which these messages are portrayed will likely have an effect on subsequent consumer health literacy and behavior. The interest in DTC pharmaceutical research that achieves 'fair balance' is predicated on the Food and Drug Administration's (FDA) regulation of DTC advertising requiring a fair balance in the disclosure of risk and benefit information of the drug being advertised along with a summary of side effects, contraindications, and effectiveness (Federal Food, 1962). The objective of this content analysis is not to determine whether or not these commercials are in compliance with FDA. However, FDA regulations will serve as a framework for analyzing certain variables. The Federal Food, Drug, and Cosmetic Act (the Act) requires that advertisements of prescription drugs contain certain information pertaining to the product's uses and risks (Federal Food, 1962). The Act requires advertisements to disclose a "brief summary" which includes information concerning side effects, contraindications, and effectiveness

of the drug advertised. The Act previously required a "major statement" for all televised advertisements of prescription medication. The major statement requirement involves the disclosure of the product's major risks in the audio and visual or audio segments of the advertisement. However, the introduction of the "adequate provision" requirement eliminates the need for a major statement among broadcast advertisements.

The importance of providing consumers with 'fair and balanced' medical information is critical to consumers' health knowledge and health behavior. Objective medical advertisements allow consumers the information they need in order to make informed decisions about their health and health care. Biased medical advertisements that offer more benefit information than risk information may mislead consumers (Huh & Cude, 2004). In a content analysis of DTC television advertisements, researchers found that the audience, on average, had more time to absorb 'benefit' facts than 'risk' facts (Kaphingst, Dejong, Rudd, & Daltroy, 2004). Additionally, physicians have reported that of their patients who ask about a specific prescription drug, most patients understand the benefits of the medication better than its risks (Aiken, 2003). These results may suggest that some DTC television advertisements are not having the desired effect of conveying a fair balance between a medication's risks and benefits.

The Department of Health and Human Services issues warning letters to pharmaceutical corporations who are not in compliance with FDA regulations of DTC commercial advertisements. Levitra and Celebrex provide two examples of prescription drug advertisements that were not in compliance with FDA regulations of DTC commercial advertisements.

Levitra is a (Bayer Pharmaceuticals Corporation) pharmaceutical that is prescribed to aid with sexual activities in males diagnosed with Erectile Dysfunction (ED). In one televised advertisement of Levitra, the commercial failed to include FDA required indication and risk information. Namely, it did not include the specific indication for the drug. Additionally, the commercial implied superiority without submitting supportive evidence to the FDA of this claim. A warning letter sent in April 2005 from the Advertising and Communications Department of the FDA requested the immediate termination of promotional materials for Levitra that have claims similar to the ones reviewed in that letter (Hankin, 2005b).

Celebrex is a (Pfizer Inc.) non-steroidal inflammatory drug (NSAID) that can be prescribed to relieve arthritis pain. In one DTC televised advertisement of Celebrex, the commercial failed to include required risk information including major side effects and contraindications as well as the required 'brief summary'. A warning letter sent in January 2005 from the Advertising and Communications department of the FDA requested the immediate termination of promotional materials for Celebrex that have claims similar to the ones reviewed in that letter (Hankin, 2005a).

In addition to fair balance of risk and benefit information within televised DTC commercials for prescription medication, an educational component aids in the dissemination of valid medical material concerning the advertised drug. Consumers are more receptive to messages of benefit than risk (Aiken, 2003; Kaphingst et al., 2004) and may be self-diagnosing rather than allowing their doctor to recommend their prescriptions. With the FDA's allowance of an 'adequate provision', the consumer is urged to ask their doctor *about* prescriptions, not ask directly for prescriptions. Suggesting that consumers' consulting with their doctors about medication is for good reason: Physicians are specifically educated about prescription drugs. If DTC advertisements are to remain within the constraints of the FDA regulations they must give educational content to relate valuable information to the consumer.

Educational Content

Proponents of DTC advertising maintain that DTC advertisements have an educational component that is beneficial to conscientious consumers. The "educational component" however, is a loose term that differs in meaning across studies. Some research broadly identifies the educational component simply as educational material such as information about medical conditions or information concerning the treatment of medical conditions (Bell, Wilkes, & Kravitz, 2000). More specifically and to satisfy purposes of this research, educational components to televised DTC advertisements should include one or more of the following: information about the symptoms of the condition, the condition's precursors or prevalence, the drug's success rate, treatment duration, identification of the drug's mechanism of action, clarification of misconceptions about the condition, and mention available alternative treatments.

In one prominent study, Bell and colleagues found that print advertisements provided minimal educational content (Bell et al., 2000). In a sample of 320 advertisements taken from popular magazines during 1989-1998, a content analysis determined that although the name of the drug and condition and list of symptoms were given in many of the advertisements, few advertisements gave information concerning the condition's precursors or prevalence, the drug's mechanism of action, its success rate, treatment duration, and/or alternative treatments (Bell et al., 2000). This examination of educational criteria lends itself to the body of empirical data that call for more educational content to be present in DTC advertisements.

The main benefit of having an educational component in DTC advertisements may be the provision to consumers of knowledge about a medical condition and the introduction of a potential drug therapy. Some research has suggested this added knowledge which DTC advertisements brings to consumers helps people identify health problems and encourages them to get help (Kapihingst et al., 2004). Additionally it is possible that the more educated the consumer is, the better prepared they are to interact with health care professionals, which may produce greater satisfaction with treatment options as well as compliance to drug therapies. A down shot of the educational component is that patients might misinterpret complex medical information and anticipate incorrect diagnosis and treatment plans (Welch Cline, 2003). They might also lack trust in physicians to give them the best therapies for their unique situations (Welch Cline, 2003). People who do not trust their physicians to be their cooperative health officials may search for unconventional means to address their health concerns.

In recent years, health-information seeking consumers have searched beyond the traditional doctor's office and into alternative approaches to health and healing. The growth of complementary and alternative medicine (CAM) may be an indication of an educated society that is interested in finding solutions to their health concerns, of a less educated society willing to believe claims with little empirical evidence, or of a desperate society looking for quick answers to problems that do not have simple solutions. Despite this increase of interest and participation in CAM, the communication patterns between CAM practitioners and patients offer little evidence-based research (Welch Cline, 2003). The area of communication patterns between CAM practitioners and patients between

Opponents of DTC advertising claim that drug promotion and health education are incompatible goals. Chao (2005) evaluated the fulfillment materials of 26 drugs to determine the educational content present in each. The general purpose of fulfillment materials is to supply the consumer with more information via such mechanisms as a web-site or toll free phone number. Thus, it was expected to find more educational content in fulfillment materials rather than in the print advertisement alone. Educational content was assessed by determining consistency with

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FDA approved labeling, instructiveness, and consumer orientation (Chao, 2005). DTC fulfillment materials had more educational content than the DTC print advertisements. However, neither advertisement nor fulfillment materials were sufficient in meeting the suggested sixth to eighth-grade reading level (Chao, 2005).

Whether DTC advertising is educational or promotional may be beside the point. Research aimed at evaluating educational versus promotional content lacks the ability to explain the effects such advertisements have on the consumer. However, such research has contributed in explaining how DTC advertising has raised consumer awareness of available prescription drugs in the market (Lyles, 2002). By raising consumer awareness, DTC advertising may influence the degree to which patients communicate with their physicians, as well as an overall awareness of health and health behavior.

Gender

More than 20 years of research has consistently found that the majority of both print and televised DTC advertisements are targeted at women (King, 1980; Hawkins & Aber, 1988; Bell, Kravitz, & Wilkes, 2000; Brownfield, Bernhardt, Williams, & Parker, 2004). In a recent study, researchers found that based on a sample of printed DTC drug advertisements from 18 diverse magazines, most advertisements were gender-neutral, but that women were more likely to be targeted than men (Bell et al., 2000). Although many medical conditions cross gender, age, and cultural boundaries (Norman, 2004), current research suggests that the timing and frequency of televised DTC advertisements specifically target both women and elderly viewers (Brownfield, et al., 2004).

Another area on research bias finds that, traditionally, females are also represented in drug ads in medical journals more often than males (King, 1980). Moreover, the images of women in such ads are often negative and outdated (Hawkins & Aber, 1988). And, as such, these portrayals of women have affected physician gender bias in prescription activity (Safran, Tarlov, McHorney, & Ware 1997). For example, Safran and colleagues (1997) found that after controlling for illness behavior differences within male and female patients, male physicians issued prescriptions to females four times more than to male equivalents.

The traditional physician/patient relationship has been a version of the 'doctor knows best' or 'paternalistic' model. That is, the more traditional paternalistic models of patient/physician communication were exclusively one-way--from the physician to the patient (Deshpande, Menon, & Perri, 2004). Welch Cline (2003) found that there is broad concurrence in the research that the physician-patient relationship model is changing from paternalistic to consumerism. Similarly, Deshpande and colleagues (2004) found evidence of a shift from a paternalistic model to shared decision-making. In a shared decision-making model, the patient has more involvement in choosing from therapeutic preferences (Deshpande et al., 2004). The shared decision making model allows decision making and information exchange to be two-way between patient and physician (Deshpande et al., 2004). Such a model may increase patient/physician compatibility and social acceptance, but it also may lead to unnecessary pressure on and questioning of the health care provider.

Patient/Physician Communication

In most situations the patient and physician have the mutual goal of promoting the health of the patient. In this light, the communication between a patient and physician is essential for

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accurate assessment and diagnosis. Thus, promoting patient and physician communication can be seen as one of the benefits of DTC advertising (Donohue & Berndt, 2004).

Young and Welch Cline (2005) assessed certain textual cues in advertisements to determine what motivates consumers to communicate with health care providers. Based on the analysis of a large sample of advertisements from consumer magazines, researchers observed both instrumental and identity cues as motivational factors in consumer/physician communication. Four instrumental motivational cues were identified as (1) incentives, (2) informational rewards, (3) medical rewards, and (4) instrumental punishments (Young & Cline, 2005). Among these four, the most common instrumental motivational cue was medical rewards. Such rewards relate positive medical outcomes with the advertised drug. Gaining freedom and achieving normality in one's life were the most frequent motivational cues associated with identity. Because this study did not incorporate the consumer's responses to the textual messages of the advertisements, the findings are limited in their ability to purport what messages actually prompt communication between consumer and physician (Young & Welch Cline, 2005).

Regardless of an improved, more communicative relationship between patient and physician, the effects of DTC advertising are mediated by the physician (Donohue & Berndt, 2004). The adequate provision requirement asserts that DTC broadcast advertisements must contain language that recommends physician consultation (Hill, 2005). Physicians however, are influenced by multiple promotional materials beyond DTC advertising (Kaiser Foundation Study, 2003) and must reconcile these to the highest benefit of their patient. Often the physician is privy to a wider array of background facts about the drug via detailing. Both proponents and opponents of DTCA of prescription drugs agree that physicianpatient communication as well as health literacy have increased as an effect of DTC advertising (Welch Cline & Young, 2004). Increased health literacy may empower the consumer in their perceived ability to take control of their health (Deshpande et al., 2004), but whether DTC advertising of prescription pharmaceuticals is educational and empowering to the consumer or persuasive and promotional remains a controversial topic.

CHAPTER THREE

METHOD

Design and Procedure

The initial step in creating the sample for this study was to collect as many DTC commercials for prescription pharmaceutical as possible. The sample was collected during the months of January and February 2006 from four major television networks: ABC, CBS, FOX, and NBC. These networks were chosen due to their broad target audience as well as their availability to every viewer who has a television within the broadcast range as well as to those on cable and satellite services. During the first two weeks of obtaining the sample, commercials were recorded during the times when day time soap operas were aired (12-2pm) and prime time news hours (5-7pm). Although these times appeared to be optimal for recording DTC prescription drug commercials, the sample was notably limited. In order to acquire a broader sample, commercials were recorded onto a DVD. Fifteen unique indications were compiled with minimal overlap in three of the indications.

Specifically the indications recorded were: asthma, high blood pressure, restless leg syndrome, herpes, arthritis, memory/alzheimers, migraine headaches, osteoporosis, cancer, heart attack, bladder control, high cholesterol, sleep-aid, and allergies. Overlap occurred with two commercials for sleep aids, two commercials for cholesterol, and two commercials for allergy nasal sprays. All eighteen commercials were used in the final analysis, which included advertisements for the following pharmaceuticals: Singulair, Toprol XL, Requip, Valtrex, Humira, Aricept, Imitrex, Nexium, Boniva, Neulasta, Plavix, Vesicare, Crestor, Zetia, Ambien CR, Lunesta, Nasonex, and Flonase. The final sample was then burned onto a single DVD for easy viewing. The primary researcher (female) and one additional rater (male) then viewed the compilation of DTC pharmaceutical advertisements and completed the protocol for each ad independently in order to establish inter-rater reliability for fifty-two measures. The second rater was selected from an associate of the primary researcher with the goal of reducing potential gender bias in ratings. A copy of the rating sheet can be found in Appendix A. To assess inter-rater reliability the percent agreement in ratings was examined and found to be 97.5%. Because of the high level of agreement between raters, the ratings of the first rater were used for subsequent analyses in SPSS.

Results

Eighteen DTC prescription pharmaceutical commercials were analyzed to address the four hypotheses previously mentioned. First, it was hypothesized that benefit messages would occur more frequently than risk messages. Descriptive statistics for the number of each type of message can be found in Table 1. A dependent measures t-test found no statistically significant difference at the .05 level between number of benefit messages and number of risk messages per commercial [t(17)=-1.374, p>.05]. Although slightly more risks are presented, the average number of risk messages and average number of benefit messages are balanced for the commercials used in this sample (See Table 1).

Table 1: Descriptive Statistics for number of benefit and risk messages

| | Mean | Ν | Std. | Std. Error |
|----------------------|--------|----|-----------|------------|
| | | | Deviation | Mean |
| No. BENEFIT messages | 3.3333 | 18 | 1.74895 | .41223 |
| No. RISK messages | 3.5000 | 18 | 1.94785 | .45911 |

Second, it was hypothesized that more time will be spent on risk messages versus benefit messages. A dependent measures t-test found no statistically significant difference at the .05 level in the absolute amount of time spent on risk versus benefit messages [t(17)=-2.025, p>.05). Slightly more time on average was spent on risk messages than benefit messages in this sample (See Table 2). Additionally, raw data indicates that only five of the 18 commercials spent more time on benefit messages than on risk messages. Upon further investigation, a dependent measures t-test found a significant difference between the average seconds per message for benefit versus average seconds per message for risk [t(17)=-2.444, p<.05). Risk messages had more seconds per message on average than did benefit messages (See Table 3).

Table 2: Descriptive Statistics for time spent in seconds on benefit and risk messages

Mean N Std. Std. Error Deviation

| | | Deviation | Mean |
|---------|--------------------|--------------------------|---|
| 12.7856 | 18 | 7.19443 | 1.69574 |
| 17.4128 | 18 | 6.09927 | 1.43761 |
| | 12.7856 17.4128 | 12.7856 18 17.4128 18 | Deviation 12.7856 18 7.19443 17.4128 18 6.09927 |

Table 3: Descriptive Statistics for average seconds per message for benefit and risk message

| | Mean | Ν | Std. | Std. Error Mean |
|---------------------|--------|----|-----------|-----------------|
| | | | Deviation | |
| Density of BENEFITS | 4.1205 | 18 | 1.83218 | .43185 |
| Density of RISKS | 7.1058 | 18 | 5.20345 | 1.22647 |

Third, it was hypothesized that among the televised DTC prescription pharmaceutical commercials analyzed, there would not be provision of adequate educational content, with presentation of less than four of the possible seven educational content variables on average. A single-sample t-test determined the average number of educational messages per commercial was 2.89, which is below the expected four messages per commercial that was hypothesized but differentiates from zero educational messages [t(17)=-3.688, p<.05] (See Table 4).

| Table 4: One-Sample Statistics for Adequate Educational Content | | | | |
|---|----|--------|----------------|-----------------|
| | Ν | Mean | Std. Deviation | Std. Error Mean |
| No. Educational Measures | 18 | 2.8889 | 1.27827 | .30129 |

CHAPTER FOUR

DISCUSSION

Interpretation and evaluation of findings

The results regarding the first two research questions in this study indicate that the number of risk messages per commercial is not significantly different than the number of benefit messages per commercial. Additionally, absolute time spent on risk messages versus benefit messages was also not significantly different. The review of literature indicated that in general, patients tend to absorb more benefit messages than risk messages (Kaphingst et al., 2004) and understand benefit messages better than risk messages (Aiken, 2003). Contrary to what was expected, slightly more risk messages were shown than benefit messages, and slightly more time was spent on risk messages than benefit messages. This finding illustrates the importance of knowing the absolute times and frequencies of risk and benefit information when researching the effects of DTC messages. Furthermore, risk messages had more seconds per message on average than did benefit messages. Depending on the frequency of both risk and benefit messages, this finding has implications for the speed in dissemination of risk and benefit messages.

The results regarding the third research question indicates the average number of educational messages per commercial was 2.89. For purposes of this research, 'adequate'

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educational material was defined as having at least four of the seven defined educational variables. The number four was chosen to represent 'adequate' educational content ' because utilizing four educational messages is slightly more than half of the defined educational variables. According to the main researcher in this study, representation equal to or less than half of the defined educational variables would not provide 'adequate' educational content.

Limitations of this research

The sample of commercials is limited to television broadcast material from January – February 2006 and as such may be biased in terms of sample size and variety of advertisements. Future research may wish to include a broader sampling of commercials obtained over a longer time-span. Additionally, with a larger sample, there exists potential for finding statistically significant results.

A second limitation of this research is that content analysis cannot address health behavior of the consumer. By nature, content analysis provides an avenue to explore the form and content of multiple variables which may affect health behavior and does not measure health behavior itself. Content analysis cannot measure consumer perception of material and responses to the advertisements.

A third limitation falls within the design of the variables researched. The current study fails to fully examine the gender bias that may be present in DTC commercials. For example, this study defines the variable for rating the 'spokesperson' as "the person speaking or narrating the commercial – this does not include actors/actresses silent performances, but *only* the person/people speaking." This does not allow the coder's to specify information based on the actors, which may be of different gender, ethnicity, and age.

Recommendations for future research

Due to the breadth of this analysis, several areas for future research may be extracted from this research. First, future research might wish to address the differences in drug advertisements directed to consumers versus drug advertisements directed to sales representatives or to physicians. A second area for future research to consider involves the communication and/or marketing patterns between patients and CAM professionals. Trends in ethnicity within DTC medical advertisements may provide an avenue for future research to explore. Finally, the assessment of medical health education curricula with specific consideration toward measuring how much attention is placed towards DTC marketing of pharmaceuticals would be a possibility for future research.

APPENDIX

Content Analysis for DTC Televised Commercials Tiffany's Thesis Project

Name of Rater:_____ Date Rated:______

<u>DIRECTIONS</u>: Please answer all questions. All questions are numbered in parenthesis. Answers do not have to be made in numerical order. Useful definitions are listed below some questions for clarification.

1. Issues of Fair Balance (among risk and benefit information)

- Fact Density:
 - (1) -# facts given about drugs benefits, including repetitions of a fact:

Operational definition of benefit facts: Includes claims of effectiveness including -improved clinical indicators: 'lowers blood pressure' -enhanced positive affect: 'enjoy life' 'relieve fear' 'sleep better' -enhanced physical appearance: 'clears up skin' -enhanced ability: 'improves strength/stamina' -enhanced freedom: 'choice, personal control'

(2) -# facts given about drugs risks, including repetitions of a fact:

Operational definition of risk facts: -threats: 'x happens if condition is left untreated' -disclaimers: 'can't promise', 'decreases symptoms but does not eliminate risk' -side effects: direct examples of side effects

- Information-seeking Density:
 - (3) -# ways presented to obtain more information (800#, website, 'see our ad in x magazine' etc.)

• Presentation Logistics:

(4) -relative font size of risk information in relation to benefit information: (larger / smaller / equal / not relevant): 1 2 3 4 (5) -relative volume of risk information in relation to benefit information: (louder / softer / equal / not relevant) 1 2 3 (6) -relative speed of risk information in relation to benefit information: (faster / slower / equal / not relevant) 1 2 3 4 (7) -relative length of time allocated to risk info. in relation to benefit info.: (longer / shorter / equal / not relevant) 1 2 3 4 2. Educational Value: (8) -mention of information about symptoms of the condition: Y/N

(9) -mention of information about the condition's precursors or prevalence: Y/N

(10) -attempts to clarify misconceptions about the condition: Y/N

(11) -identification/mention of drug's mechanism of action: Y/N

(12) -mention of drug's success rate (includes "individual results may vary"): Y/N

(13) -mention of drug's treatment duration: Y/N

(14) -mention of alternative treatments: Y/N

3. Gender messages

Characters: spokesperson must be the person speaking or narrating the commercial – this does not include actors/actresses silent performances, but *only* the person/people speaking:

- single spokesperson or narrator
 - (15) gender: M/F

(16) spokesperson or narrator: seen/unseen

(17) facial expression: positive/negative/neutral

- (18) estimated age: (1) infancy –childhood; (2) adolescence/teenagers;
 (3) college-aged through age 25; (4) adults age 25 and older (5) senior adults age 50 and over.
- multiple spokespeople
 - (19) how many total:
 - gender:

(20) total # males seen:

(21) total # females seen:

(22) total # males unseen:

- (23)total # females unseen:
- facial expression:
 - (24) male 1: positive/negative/neutral
 - (25) male 2: positive/negative/neutral
 - (26) male 3: positive/negative/neutral
 - (27) male 4: positive/negative/neutral
 - (28) male 5: positive/negative/neutral
 - (29) female 1: positive/negative/neutral
 - (30) female 2: positive/negative/neutral
 - (31) female 3: positive/negative/neutral
 - (32) female 4: positive/negative/neutral
 - (33) female 5: positive/negative/neutral
- estimated age:
 - (34)male 1: (1) infancy –childhood; (2)
 - adolescence/teenagers; (3) college-aged roughly age 18 through age 25; (4) adults age 25 and older (5) senior adults age 50 and over.
 - (35) Male 2: (1) (2) (3) (4) (5)
 - (36) Male 3: (1) (2) (3) (4) (5)
 - (37) Male 4: (1) (2) (3) (4) (5)
 - (38) Male 5: (1) (2) (3) (4) (5)
 - (39) Female 1: (1) (2) (3) (4) (5)
 - (40) Female 2: (1) (2) (3) (4) (5)
 - (41) Female 3: (1) (2) (3) (4) (5) (42) Female 4: (1) (2) (3) (4) (5)
 - (43) Female 5: (1) (2) (3) (4) (5)
- 4. Patient/physician relationship
 - (44) Mentions to 'ask your doctor' within the risk information: Y/N
 - (45) Mentions to 'ask your doctor' within the benefit information: Y/N
 - (46) Mentions to 'ask your pharmacist' within the risk information: Y/N
 - (47) Mentions to 'ask your pharmacist' within the benefit information: Y/N
- 5. Other general aspects of the advertisement:
 - (48a) Use of background music: (1)Y/N
 - (48b) If yes: positive/negative/neutral
 - (49) Use of music in advertisement jingle: Y/N
 - (50) Use of catch-phrase or slogan: Y/N
 - (51) Length of commercial:
 - (1) 0-15 seconds (2) 30 seconds (3) 45 seconds; (4) 1 min. (5) over 1 min.

REFERENCES

Aiken, K.J., (2003). The impact of direct-to-consumer prescription drug advertising on the physician-patient relationship. Presentation at Direct-to-Consumer Promotion Public Meeting, September 22, 2003. (accessed March 10, 2006, at http://www.fda.gov/cder/ddmac/aikin/sld001.htm).

Annual Survey on Consumer Reactions to Direct-to-Consumer Advertising of Prescription

Drugs. (1997). Prevention Magazine.

Annual Survey on Consumer Reactions to Direct-to-Consumer Advertising of Prescription

Drugs. (2002). Prevention Magazine.

Antonuccio, David, and others, "Psychotherapy vs. Medication for Depression: Challenging the Conventional Wisdom," Paper presented at the Annual Meeting of the American Psychological Association (101st, Toronto, Ontario, Canada, August 20-24, 1993).

Baukus, R., (2004). DTC Advertising. Journal of Health Communications, 9: 563-564.

- Bell, R.A., Kravitz, R.L., & Wilkes, M.S., (1999). Direct-to-Consumer Prescription Drug Advertising and the Public. *Journal of General Internal Medicine*, 14(11), p. 651.
- Bell, R.A., Kravitz, R.L., & Wilkes, M.S., (2000). Direct-to-Consumer Prescription Drug
 Advertising, 1989-1998: A Content Analysis of Conditions, Targets,
 Inducements, and Appeals. *The Journal of Family Practice*, 49(4), 329-335.

- Bell, R.A., Wilkes, M.S., & Kravitz, R.L., (2000). The Educational Value of Consumer-Targeted Prescription Drug Print Advertising. *The Journal of Family Practice*, 49(12), 1092-1098.
- Berndt, E.R., (2005). To Inform or Persuade? Direct-to-Consumer Advertising of Prescription Drugs. *The New England Journal of Medicine*, 352(3): 325-328.
- Brownfield, E., Bernhardt, J., Phan, J, Williams, M., & Parker, R. (2004). Direct-to-Consumer Drug Advertisements on Network Television: An Exploration of Quantity, Frequency, and Placement. *Journal of Health Communication*, Nov-Dec., 9:6.
- Chao, B.A., (2005). Evaluating the educational content of direct-to-consumer fulfillment materials. *American Journal of Health-Systems Pharmacists*, 62, 620-625.
- Deshpande, A., Menon, A., Perri III, M., (2004). Direct-to-Consumer Advertising and its Utility in Health care Decision Making: A Consumer Perspective. Journal of Health Communication, 9: 499-513.
- Donohue, J.M., & Berndt, E.R., (2004). Effects of Direct-to-Consumer Advertising on Medication Choice: The Case of Antidepressants. *Journal of Public Policy & Marketing*, 23(2), 115-127.

DTC National: the source for DTC leaders. http://www.dtcnational.com/

Federal Food, Drug, and Cosmetic Act, 1962, Amended, 21 U.S.C.A. - 352 et seq.

Hankin, Joan, (2005a). Facsimile Letter. United States Food and Drug Administration. (Celebrex) Retrieved Feb. 27, 2006 from

http://www.fda.gov/cder/warn/2005/12560-letter.pdf -

Hankin, Joan, (2005b). Facsimile Letter. United States Food and Drug Administration.

(Levitra) Retrieved Feb. 27, 2006 from

http://www.fda.gov/cder/warn/2005/Levitra.pdf.

- Harelik, J.H., Johnston, P.M., Rivers, N.P., Ryan, M., (1975). Pharmacists and Physician Evaluation of Drug Information Sources. *American Journal of Hospital Pharmacy*, 32:594-597.
- Hawkins, J.W., & Aber C.S., (1988). The content of advertisements in medical journals: distorting the image of women. *Women Health*, 14(2): 43-59.
- Hill, J.C., (2005). The learned intermediary doctrine and beyond: exploring direct-toconsumer drug advertising liability in the new millennium. *Defense Counsel Journal*, 72(4): 362-380.
- Holbert, R.L., & Stephenson, M., (2003). The Importance of Indirect Effects in Media
 Effects Research: Testing for Mediation in Structural Equation Modeling.
 Journal of Broadcasting & Electronic Media, 47(4), 556-572.
- Huh, J., Cude, B.J., (2004). Is the Information "Fair and Balanced" in Direct-to-Consumer Prescription Drug Websites? *Journal of Health Communication*, 9: 529-540.
- Impact of Direct-to-Consumer Advertising on Prescription Drug Specific Spending. The Kaiser Family Foundation. June 2003. <u>www.kff.org</u> The Henry J. Kaiser Family Foundation.
- Johnston, P.M., Harelik, J. and Ryan, M.R., (1976). The Adequacy of Physicians' and Pharmacists' Sources for Drug Information. *Drug Information Journal* 10: 16-19.
 Kaphingst, K.A., Dejong, W., Rudd, R.E., & Daltroy, L.H., (2004). A Content Analysis

of Direct-to-Consumer Television Prescription Drug Advertisements. *Journal of Health Communication*, 9: 515-528.

King, E., (1980), Sex bias in psychoactive drug advertisements. *Psychiatry*, 43(2), 129-137.

Kravitz, R.L., Epstein, R.M., Feldman, M.D., Franz, C.E., Azari, R., Wilkes, M.S.,
Hinton, L., Franks, P., (2005), Influence of Patients' Requests for Direct-toConsumer Advertised Antidepressants: A Randomized Controlled Trial., *Journal*of the American Medical Association, 293(16), 1995-2002.

Late News; New Zealand to ban DTC advertising by '06. Advertising Age, 76(36), p1. Retrieved 11/15/2005 from <u>http://www.web1.infotrac.galegroup.com/itw/infomark/315/307/70973065w1/purl</u> <u>=rc1_EAIM_...</u>

Lewis, C., (2003). The Impact of Direct-to-Consumer Advertising. FDA Consumer Magazine, March-April 2003. Retrived 11/15/2005 from http://www.fda.gov/fdac/features/2003/203 dtc.html.

- Lyles, A., (2002). Direct Marketing o Pharmaceuticals to Consumers. *Annual Review of Public Health*, 27: 73-91.
- Narayanan, S., Desiraju, R., & Chintagunta, P.K., (2004). Return on Investment Implications for Pharmaceutical Promotional Expenditures: The Role of Marketing-Mix Interactions. *Journal of Marketing*, 68: 90-105.
- Neslin, S.A. (2001). "ROI Analysis of Pharmaceutical Promotion (RAPP): An Independent Study," Association of Medical Publications.

Nordenberg, T., (1998). TV Drug Ads that Make Sense. Consumers Research

Magazine, (81)3, 28-31.

- Norman, J. (2004). Gender Bias in the Diagnosis and Treatment of Depression. International Journal of Mental Health, 33:2, 32-43.
- Rabin, K., (2004). DTC Advertising for Prescription Medicines: Research and
 Reflections as the Second Decade Ends. *Journal of Health Communications*, 9: 561-562.
- Pham, C.Q., (2004). The Learned Intermediary Doctrine and DTC Advertising, 26 Los Angeles Lawyer, at 16.
- Pines, W.L., (1997). New Challenges for Medical Product Promotion and Its Regulation, 52 Food & Drug, L.J., 61, 62.
- Safran, D.G., Rogers, W.H., Tarlov, A.R., McHorney, C.A., and Ware, J.E. Jr., (1997). Gender Differences in Medical Treatment: the case of physician-prescribed activity restrictions. *Social Science & Medicine*, 45(5), 711-723.
- Sherry, J.L. (2004). Media Effects Theory and the Nature/Nurture Debate: A Historical Overview and Directions for Future Research. *Media Psychology*, 6: 83-109.
- Sotirovic, M., (2003). How Individuals Explain Social Problems: The Influences of Media Use. *Media and Explanations of Social Problems, 122-137.*

United States Department of Health and Human Services. Guidance for Industry:

<u>Consumer-Directed Broadcast Advertisements.</u> Rockville, MD: Center for Drug Evaluation and Research, Food and Drug Administration, 1999. Retrieved February 5, 2006 from http://www.fda.gov/cder/guidance/1804fnl.pdf.

Welch Cline, R.J., (2003). At the intersection of micro and macro: opportunities and

challenges for physician-patient communication research. *Patient Education and Counseling*, 50: 13-16.

- Welch Cline, R.J., & Young, H.N., (2004). Marketing Drugs, Marketing Health Care Relationships: A Content Analysis of Visual Cues in Direct-to-Consumer Prescription Drug Advertising. *Health Communication*, 16(2), 131-157.
- Wittink, Dick R. (2002), "Analysis of ROI for Pharmaceutical Promotions (ARPP)," paper presented to the Association of Medical Publications, (September 18, 2002), (available at <u>http://www.vioworks.com/clients/amp/</u>, retrieved March 3, 2006).
- Wosinska, M., (2005). Direct-to-Consumer Advertising and Drug Therapy Compliance. Journal of Marketing Research, vol. XLII, 323-33.
- Young, H.N., & Welch Cline, R.J., (2005). Textual Cues in Direct-to-Consumer Prescription Drug Advertising: Motivators to Communicate With Physicians. *Journal of Applied Communication Research*, 33(4), 348-369.

VITA

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