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Direct-to-Consumer advertising of prescription medicines: framing with imprecise frequency descriptors

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DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION MEDICINES:
FRAMING WITH IMPRECISE FREQUENCY DESCRIPTORS

A Thesis

Submitted to the Graduate Faculty of the
Louisiana State University and
Agricultural and Mechanical College
In Partial Fulfillment of the
Requirements for the Degree
Master of Mass Communication

in

The Manship School of Mass Communication

by
Mikah Zangla
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DEDICATION

I wish to dedicate this thesis to Bobby and Rita Zangla, the two most unselfish and generous people I know. Their endless mental, emotional, and financial support has afforded me the opportunity to accomplish all of my educational goals. Through their example, I've learned, hard work is sometimes its own reward, that anything worth starting, is worth finishing, and that a parent's love for his or her child is the most unending and unconditional kind of love.

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ABSTRACT

The purpose of the study was to determine how often and to what degree “imprecise frequency descriptors” are used in prescription drug print ads. These descriptors along with the side effects they describe were compared to their corresponding prescription medicine websites and analyzed to determine whether or not the general public is being misinformed and/or misled in terms of side effect warnings by current drug advertising. Content analysis of Direct-to-Consumer (DTC) prescription drug advertisements found in five of the top seven magazines most likely to be consumed by readers over age 65 was the method of investigation for this study. The time frame of the magazines studied, was, August 2002 to July 2003.

Using SPSS and descriptive statistics, results indicated that within DTC advertising, there is a great potential to mislead. For example, all of the side effects listed in the advertisements were also listed on their corresponding drug websites. Though, in some cases, the side effects with the highest incidence percentages on the websites were not listed at all in the advertised side effect warning. Some side effects with incidence levels of over 30% on the websites were listed in the advertisements but were provided with “imprecise frequency descriptors” such as “may include” or “most common.” The difference in website and magazine side effect descriptions present a question of credibility. It appears from the discrepancy between the website side effect descriptions and magazine side effect warnings that the magazines are at best incomplete and probably misleading.

Possible suggestions for correcting the situation could include mandatory guidelines for side effect warnings including the number of side effects, inclusion of percentages, font size, and placement of the side effect warning.

JUSTIFICATION

This study determines how often and to what degree “imprecise frequency descriptors” are used in direct-to-consumer prescription drug advertisements that appear in consumer magazines targeted at readers over age 65. Much attention has been paid in recent years to the graying of America. Jewler and Drewniany (2001) note, “the 50-plus American population is 65 million strong and is growing larger everyday. Every eight seconds, a baby boomer turns 50” (p. 37). People over age 65 were chosen for this study because the magazines examined for content analysis are those most likely to be read by people in this age category according to Mediamark Research (2000). Magazines were selected as the advertising medium to be measured because no media source is utilized more often for those in the 45 + age category than a book or magazine. This includes such categories as watching television, going online, renting a movie, and listening to the radio according to a Jupiter Media Metrix survey of over 3,000 individuals in May 2001. In order to help the knowledge base of research on direct-to-consumer prescription drug advertisements, this study illustrates the prevalence, scale, and completeness of drug ads while attempting to better define risk statement completeness as applied to side effect warnings. Cultivation Theory and Media Framing Theory will also be examined in relation to direct-to-consumer ads.

Since direct-to-consumer advertising is such a recent trend, there is limited research on prescription drug ads and their impact. This being the case, an exploratory study of what prescription drug ads are saying is called for. The objective of this research is to determine whether or not the FDA’s mandate of “fair balance” in regard to side effect warnings is being achieved in print drug advertisements.

Departing from the previous practice of promoting medications to doctors and pharmacists, pharmaceutical companies are now selling their products directly to patients through direct-to-consumer (DTC) prescription drug advertisements on television and in magazines (Lewis, 2003). DTC prescription drug advertising is defined as any promotional effort by a pharmaceutical company to offer prescription drug information to the general public through consumer-oriented media (Pierpaoli, 1986). Examples of this, which are given by the Food and Drug Administration, include, “advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television and telephone communication systems” (Palumbo & Mullins, 2002, p. 428).

The money spent on prescription drugs is the fastest growing expense in the health care industry, and many in the medical arena attribute this economic rise to the pharmaceutical industry’s emphasis on DTC advertising (Melby, 2003). Grant (1998) notes: “It is hard to turn on the TV or open a magazine without seeing advertisements promoting the latest advances in baldness treatments or drugs for heart disease” (p. 15). Consumer advocates claim the recent onslaught of prescription drug advertisements has resulted in patients demanding brand name prescriptions in place of less expensive, older, but still reliable medications (Melby, 2003).

This concern was underscored in November 2003, when Congress passed a bill giving senior citizens the option to purchase a drug discount card that supporters say will save them up to 25%. This voluntary drug benefit program starts in 2006 but includes premiums, deductibles, and shared costs. According to supporters, senior citizens with

the highest drug bills will save the most money and those with minimal costs could possibly end up paying more than before (Stone, 2003).

The content of DTC prescription drug advertisements is controlled by Food and Drug Administration (FDA) regulations which analyze prescription drug advertisements from a content perspective to be sure they are not, “deceptive, misleading, or do not in other ways violate any applicable rules and regulations” (Davis, 2000, p. 351). Furthermore, the FDA examines DTC prescription drug advertisements in terms of the principle of “fair balance.”

The principle of fair balance requires that a DTC prescription drug print advertisement present a balance of risk and benefit information within the context of the advertisement. However, the advertisers are not required to print all side-effects or risks, nor are they required to print the degree or severity of the possible side effects (Davis, 2000). Director of the Division of Drug Marketing, Advertising, & Communication, Thomas Abrams notes: “the duty of the FDA is only to regulate the content of the promotion to ensure it is truthful and balanced” (Edwards, 2003, p. 63).

It was concluded in Davis’ (2000) research that: (1) “Two equivalent drugs (with equivalent benefits and risks) may be perceived differentially by consumers because of differences in the number of side effects presented in their risk statements,” and (2) “Drugs appear to be safer than they actually are because of the number and types of side effects included in their risk statement” (p. 366). Therefore, the FDA concept of fair balance, which allows for incomplete information, may result in drugs appearing safer than they are. Furthermore, consumers are more likely to make poor medical decisions

when they have incomplete or imperfect knowledge of the possible risks and benefits associated with alternate prescription drugs (Viscusi, Magat, & Huber, 1986).

DTC prescription drug advertisements usually take one of three approaches to communicate drug related side effects. The most precise approach in disclosing risk information provides percentages of drug related side effects and compares those levels to those observed in individuals in a placebo group, a slightly less precise approach to providing risk information, uses percentages of side effects without a placebo group. The third approach is the use of imprecise frequency descriptors (Davis, 1999). Imprecise frequency descriptors consist of phrases such as, “some people may experience,” “may cause,” “low incidence/occurrence” and are not clearly defined anywhere else in the advertisements.

The 40 million people over age sixty-five in the United States consume 40% of the prescription drugs sold (Price, 2003). In a survey by Age Wave IMPACT, an integrated marketing firm that specializes in targeting older adults, it was concluded that, of more than 90% of people over 50 years old who said they saw or heard ads for prescription drugs, 35% went on to speak to their primary care physician about it (Hollon, 1999). Grant (1998) notes: “Elderly patients who are most in danger of becoming over-medicated were first to be targeted by prescription drug ads” (p. 17).

Davis (2000) states, “further research is needed to help better define ‘risk statement completeness’” (p. 367). Davis (2000) also posed the following questions to be addressed in future research:

- 1) Should ‘completeness’ be defined in terms of the number of side effects reported? In terms of a minimum incidence level? In terms of the most common

side effects? And how is most common defined? 2) Does 'completeness' require numeric indicators in the risk statement? For example, is the statement, 'the major side effects are headache and nausea' equivalent in terms of completeness with the statement, 'the major side effects are headache (66%) and nausea (45%)?' (pp. 367-368).

These questions remain unanswered. The purpose of this study is to answer these questions and address prior researcher's suggestions for further research.

LITERATURE REVIEW

Direct-to-Consumer prescription drug advertising was virtually unheard of until the early 1980's. However, recently it has radically changed the way prescription drugs are marketed (Holtz, 1998). As mentioned, DTC prescription drug ads are any promotional effort by a pharmaceutical company to offer prescription drug information to the general public through consumer-oriented media (Pierpaoli, 1986).

Currently, pharmaceutical companies face no federal laws that restrict how they promote their products directly to consumers, and there is no limit on the amount of money used to finance those advertisements (see Appendix C). In 2002, drug companies spent over \$2.5 billion on DTC ads (Edwards, 2002). It was recently reported that in 2000, Merck spent the same amount (\$161 million) on DTC advertising for *Vioxx*, as Dell Computers spent on its entire advertising campaign (Sullivan, 2002).

Since DTC prescription drug advertising has only been prevalent for the past two decades, research on its effects on the public is limited. Media spending in support of DTC drug advertising has increased considerably over the past several years, making DTC prescription drug advertising one of the fastest growing categories of consumer advertising (Davis, 1999).

According to a 1998 Prevention magazine survey of consumer reactions to DTC advertising, one-third of the 163 million Americans who have seen or heard a DTC television, print or radio drug ad have spoken to their doctors about the medicine. Of those, 15 million asked their doctor for the drug, and 80% left the office with a prescription in hand (Weissman, 1998).

Regulation of DTC Advertising

Until the early 20th Century, individual states were responsible for regulating domestically produced foods and drugs (Swann, 2003). During this time, newspapers, billboards, and store shelves were overflowing with “patent medicines,” all claiming to have amazing healing powers. These “medicines” refer to unregulated products that were marketed to make money for their patent holders (Moyers, 2002).

Many of the diseases these “medicines” claimed to cure, such as diabetes and cancer, are still incurable today. Americans purchased these drugs because access to medical doctors was very limited and they had little money to spend on expensive prescription medicines. Several “patent medicines” contained high percentages of alcohol and narcotics, such as morphine, cocaine, and opium. Others had ingredients now known to be very dangerous to the human body, like mercury, formaldehyde, and salicylic acid (Moyers, 2002). Although these products made consumers feel better for a limited time, they didn’t measure up to their claims of curing diseases ranging from the common cold to tuberculosis.

By the end of the 19th Century, muckraking journalists began writing about these fraudulent drugs and their distributors. Journalists like Samuel Hopkins Adams and Upton Sinclair exposed in gruesome detail the hazards of the marketplace, which later pushed Dr. Harvey Washington Wiley, a chemist in the Department of Agriculture, to encourage congressional action. On June 30, 1906, after nearly 100 regulatory bills had been introduced to Congress, president Roosevelt signed the Food and Drugs Act also known as the Wiley Act. The main premise of the law rested on the regulation of product labeling. The food and drug labels could no longer be false or misleading, and

the presence and amount of dangerous ingredients such as alcohol, heroin, and cocaine had to be listed on the product (Swann, 2003).

In 1927, the Bureau of Chemistry became the Food, Drug, and Insecticide Administration. Three years later, the name was shortened to its present version, the Food and Drug Administration (FDA). In 1962, authority over prescription drug advertising was transferred from the Federal Trade Commission (FTC) to the FDA. By 1971, The FDA was granted explicit and primary authority over prescription drug advertising (Calfee, 2002).

The FDA first dealt with direct-to-consumer promotion in the mid 1970's, issuing a regulation that authorized advertising prescription drugs to consumers as long as the pharmaceutical company made no representations about the safety or effectiveness of the product. In 1983, the FDA requested a voluntary moratorium on DTC ads, due to the lack of formal policy concerning DTC advertisements, so that it could consider the issue in detail (Noah, 1997).

In the two years following the moratorium on DTC ads, the FDA published two studies concerning the effects of prescription drug promotion aimed at the general public. One study, commissioned by the agency, showed that consumers retained more information about the advantages of products than about the risks. This study also differentiated between print and broadcast, finding that print advertising was a better format for conveying lasting risk information (Morris & Millstein, 1984). The other study was conducted by the FDA itself in 1985, and it concluded that consumers wanted more information about prescription drugs specifically, and healthcare generally and would

view DTC advertising in a favorable light (Morris, Brinberg, Klimberg, Rivers, & Millstein, 1986).

In 1985, the FDA lifted the freeze on DTC ads, concluding that, for the time being current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers. The FDA then persuaded the pharmaceutical industry to submit on a voluntary basis all proposed consumer promotions for informal pre-clearance (Noah, 1997).

The provisions the FDA first placed on advertising were one paragraph long, and required only that the advertisement include the drug's generic name and formula, and a brief summary describing the effectiveness of the drug and its risks (Palumbo & Mullins, 2002). The FDA then developed regulations that impart two major requirements on prescription drug advertisements. First, print ads were required to give a "brief summary" of the drugs side effects, warnings, and precautions, as well as the indication for use. In recent times, the "brief summary" has come to mean attaching much of the package insert with the advertisement (Noah, 1997). Second, for DTC ads, the FDA has interpreted the "fair balance" doctrine to mean that balancing information should be in the primary text of the ad, in language understood by consumers, so they can evaluate drug benefit claims and form accurate opinions about the drugs (Kalb, Dunlop, McEnroe, & Stein, 2003).

The FDA focuses on the specific information contained in the body of the advertisement and accepts multiple forms of risk presentation, ranging from specific quantitative data to the use of imprecise frequency descriptors. As long as the

information presented provides equal emphasis on benefits and risk, and there is no significant risk of information, “fair balance” is assumed to exist (Davis, 1999).

The FDA permits three types of DTC prescription drug advertisements: 1) product claim advertisements, which include both the product name and specific therapeutic claims, 2) reminder ads, which provide the name of a product without stating its use, and 3) help seeking ads, which inform consumers of new but unspecified treatment options for diseases or conditions (Gardner, Mintzes, & Ostry 2003).

In 1985, Masson and Rubin of the Federal Trade Commission (FTC) summarized what they considered the benefits of direct ads in the *New England Journal of Medicine* (Grant, 1998). They pointed out three main types of information communicated through DTC prescription drug advertising that help patients choose appropriate medications. 1) Direct ads educate consumers on the reality of diseases. 2) When a patient is informed of symptoms of such diseases, they are more likely to consult a doctor. 3) Ads can inform patients of side effects that may have been overlooked by a doctor (Grant, 1998).

After ten years of regulating DTC advertising under the same system used for promotions directed at healthcare professionals, the FDA officially announced an interest in revisiting the issue. In 1995, the agency published a notice announcing a public meeting and invited comments. It was then that the FDA formally communicated its intent to reconsider direct-to-consumer advertising of prescription drugs (Noah, 1997).

In 1997, the FDA issued a preliminary “Guidance for Industry” that reinterpreted FDA regulations without actually changing any regulations. In restating traditional requirements, the Guidance stated that in addition to being non-deceptive, prescription drug ads must also: 1) include a “major statement” conveying all of the product’s most

important risk information in a consumer-friendly language, and 2) communicate all information relevant to the product's indication, including limitations to use in consumer-friendly language (Palumbo & Mullins, 2002).

The Guidance does provide recommendations for fulfilling the “adequate provision requirement”: 1) Disclosure in the advertisement of an operating toll-free number, through which the consumer should be given the option of having the labeling mailed to them in a timely manner or having it read to them over the phone. 2) Reference in the ad to an alternative mechanism, such as reference to a print advertisement, to provide package labeling to consumers with restricted access to the Internet or those who are uncomfortable actively requesting additional information. 3) Disclosure in the advertisement of an Internet web page address that provides access to the package labeling. 4) Disclosure in the ad that pharmacists, or healthcare provider, may provide additional information (FDA, 1999).

In 1999, the FDA created a consumer survey on DTC advertisements. After reviewing the preliminary survey results, a final Guidance on DTC advertising was released. The requirements remained virtually unchanged from 1997. The FDA also stated that it had not found any compelling evidence that DTC advertising had tended to cause any of the harms of which it had been accused (Calfee, 2002).

The FDA does not have unlimited power to regulate prescription drug advertising. For example, the agency can neither entirely prohibit nor routinely demand pre-clearance of proposed ad campaigns without some exceptional circumstances. Also, in order to disseminate drug-advertising regulations, the FDA must use formal rulemaking procedures that provide interested parties with a right to demand a hearing. In the past,

the agency has experienced various problems in using these types of procedures (Noah, 1997).

DTC Advertising Around the World

The United States and New Zealand are the only two countries in the world that allow prescription drug advertising. In Europe, the European Union (EU) has required member states to prohibit direct-to-consumer advertising of prescription drugs. The EU legislation bans all forms of prescription drug advertising aimed at the general public and also prohibits the distribution of free samples of prescription drugs to anyone other than people authorized to write prescriptions. Prescription drug promotion may be aimed at doctors and pharmacists but is still subject to monitoring (Palumbo & Mullins, 2002).

The EU has however, recently began a limited experiment in which manufacturers would be allowed to provide consumers with information on treatments for three therapeutic categories through pamphlets and other materials, but only in response to consumer requests and in websites. Those categories for which drug ads are being allowed are diabetes, AIDS, and asthma (Calfee, 2002).

Like Europe, Canada prohibits DTC promotion of prescription drugs. The practice has been banned in Canada since 1949. Recently, the Canadian Food and Drug Regulations have allowed ads that are aimed only at professionals and contain only the name, price, and quantity of the drug. A self-regulation group known as the Therapeutic Products Programme (TPP) was given the power to monitor all prescription drug ads in Canada, but the Pharmaceutical Advisory Board (PAB) maintains a code of acceptable

electronic broadcast advertising standards, which apply only to ads to healthcare professionals (Palumbo & Mullins, 2002).

Although the EU prohibits DTC prescription ads, the widespread use of the Internet and digital television, and patient demand for product information leads many to believe that DTC advertising is inevitable in Europe. Supporters of DTC advertising in Canada have also argued that Canada's strong regulations do little when America's close border permits Canadians to view American advertisements through television, magazine, and even radio broadcasts (Palumbo & Mullins, 2002).

There is also a growing concern by those against DTC ads in Canada and Europe that treating prescription drugs as a commodity would eventually drive up the price of government-funded healthcare systems. Both the Canadian government and the EU want to make sure that objective information is given to patients rather than information that is based strictly on profit as a motive (Sullivan, 2002).

Like Europe and Canada, public healthcare is provided by the government in New Zealand, the only country other than the United States that allows DTC advertising of prescription drugs. The Research Medicines Industry (RMI) Association of New Zealand, a non-profit professional trade association, has analyzed both sides of the debate and has come to the conclusion that DTC ads can serve a public benefit. The RMI does believe however, that DTC ads may put pressure on the government's pharmaceutical budget and on doctors to prescribe drugs if requested by a patient. The RMI has also concluded that these ads are driven by commercial considerations and are insufficient for consumers to make well-informed decisions. Like the United States, New Zealand has

regulations regarding DTC ads. For instance, the Fair Trading Act of 1986 makes “unfair and misleading” advertising an offense. But also, much like the United States, it has been very unclear in the past as to which ads are “unfair” and “misleading.” (Collins, 2001)

Research Concerning the Miscomprehension of DTC Advertising

Because DTC prescription drug promotions are becoming increasingly more prevalent, the potential for misinformation and consumer misunderstanding is a major concern of the medical community (Krieger, 1983). A 1992 study of physicians found that 88% of patients asked for a drug by brand name, up from 45% in 1989 (Liebman, 1993). Research by the FDA pointed out that about 25% of those who were exposed to DTC prescription drug ads asked their physicians about the medical conditions they saw in the ad (FDA, 1999).

This concern may be well founded according to two studies. In 2002, Balazs, Yermolovich, and Zinkham researched attitudes and information-seeking behavior related to DTC prescription drug advertising among the elderly. The study concluded that DTC ads encouraged older consumers to seek more prescription drug information from friends and doctors. More than 50% of the respondents asked doctors or pharmacists about a drug seen in DTC ads and 30% requested a specific medication by name. About 20% asked about the medical condition they saw in DTC ads. While this is good news for drug companies, the impact on consumers is less clear.

A second study by Morris, Brinberg, Klimberg, Rivera, and Millstein (1986) examined the degree to which television and magazine ads for two fictitious drugs were miscomprehended. The study found that over two-thirds of the respondents believed that a fabricated arthritis drug was better than aspirin when the scientific data for the class of

drugs allowed no such assumption. They concluded that, “the use of the term ‘miscomprehension’ rather than the traditional term ‘misleading’ implies that the receiver rather than the source or the message is the cause for the failure to correctly recall or identify certain information” (p. 111).

Incomplete Risk Statements

One problem that has been identified is with what researchers call incomplete risk statements. The “incomplete risk statement,” has the operational definition: “a subset of all potential side effects are always presented, and in all cases, not all side effects at or above the 3% criterion are presented.” (Davis, 2000, p. 351) For example, “like any prescription drug, Fosamax may cause side effects. The most common side effects are: stomach and muscle, bone or joint pain” (p. 351).

Davis’ (2000) study examined the relationship between risk statement completeness and the perceptions of DTC advertised prescription drugs, concluding, “consumers rate the safety and appeal of drugs described with an incomplete risk statement significantly more positive than comparable drugs described with a more complete risk statement” (p. 349). In seven of the eight cases studied, consumers were considerably more likely to “recommend or purchase” a drug when the description was accompanied by an incomplete risk statement instead of a complete risk statement.

The 1998 Prevention magazine survey also concluded that only 21% of consumers who see DTC ads think they are very clear. Many people who saw an ad for a brand-name drug later said they did not know what the drug was for, even if they themselves had the symptoms described in the ad (Weissman, 1998).

Davis' 1999 study concluded that, "Consumers cannot accurately estimate side effect incidence when that effect is described by an imprecise frequency descriptor; in all but one case, consumers' average estimate of a side effect's incidence greatly exceeds the actual level of that effect and in the remaining case greatly underestimates actual level of incidence" (p. 142).

Cultivation Theory

Cultivation Theory argues that media "cultivates" or creates a worldview that, although possibly inaccurate, becomes the reality because people believe it to be so (Baran & Davis, 2003). This being the case, a careful study of exactly what ads say will be helpful in determining why the elderly feel encouraged to request these medicines.

While no previous study has linked Cultivation Theory to DTC prescription drug advertising, it is still a viable theory today, recent studies have examined Cultivation and its connection between levels of acculturation, viewing of daytime television talk shows, and beliefs about social reality (Woo & Dominick, 2003). Another set of research by Gross and Aday (2003), tested Cultivation Theory by comparing the effects of watching local news broadcasts with direct experience measures of crime and the fear of victimization. statistics indicate it is occurring. Research by the Kaiser Family Foundation (2001) found that DTC ads prompt many people, especially the elderly and those in poor health, to talk to their doctors about a medicine they have seen advertised.

Media Framing Theory

The theory of media framing can be addressed when studying the effects of incomplete frequency descriptors, such as "in rare cases," "low incidence," and "most common." In the 1920's, Walter Lippman proposed that the media would control public

opinion by focusing attention on selected issues while ignoring others (Baran & Davis, 2003). Although Lippman was concentrating on newspaper readership, this theory could be applied to advertisements as well.

For instance, in a study by Bell, Kravitz, and Wilkes (1999), it was concluded that many people mistakenly believe that DTC advertisements go through preliminary review by government regulators and that only “completely safe” and “extremely effective” drugs can be advertised. The subjects who held these incorrect beliefs tended to be more aware of DTC ads and were more willing to act on them. With flowery language and happy people frolicking in fields of wild flowers, DTC prescription drug ads are framing drugs and possibly making the risks associated with them seem less threatening.

The warnings presented in DTC drug ads are only partially absorbed by consumers, leaving them an overall perception that the advertised ailment is safely treatable, and not with the feeling that there is the possibility that the treatment may be unsafe or inappropriate in many cases (Melby, 2003). The American Medical Association argues that the current advertising offers only “snippets of information,” instead of more substantial data that a patient might need to make a truly informed decision (Marks, 2001).

Surveys of patients by the FDA emphasize that the quality of information provided in DTC advertising is questionable. These surveys point out the inadequacies of the information presented by drug marketers, and patients’ misconceptions about rules governing the quality and content of DTC advertising (Hollen, 2004). In one FDA consumer survey, 58% of the respondents said that the advertisements “make the drugs seem better than they are.” (Henney, 2000, p. 2242)

Although there is very little research regarding media framing, it is still used in various realms of mass communication studies today. For example, a recent study by Zavestoski, Agnello, Mignano, & Darroch (2004), explores media framing of toxic crises and apathy of these events by local citizens. Another study by Fuyuan (2004), examined the effects of media framing on voter understanding of political campaign advertisements in an attempt to understand the relationship between media frames and audience responses.

This study will forward the understanding of cultivation and media framing theories by applying them to magazine advertisements. Little research on the effects of direct-to-consumer prescription drug promotions and a great and growing concern for the effects of this type of advertising make this an important issue.

This leads to the following research questions.

RQ1: How complete is print drug advertising in regard to side effects?

RQ2: Do actual percentages of side effects listed on websites correspond to side effect frequency descriptors used in print ads?

RQ3: Are certain side effects more common?

RQ4: Does ad size or ad length correlate to the number of side effects listed?

METHODOLOGY

Content analysis was chosen as the method of investigation for this study. In content analysis, certain aspects of the occurrence under study are coded and analyzed to disclose information.

The goal of this content analysis was to determine how complete direct-to-consumer prescription drug advertising actually is. Because of this consumer focus, the sampling frame was consumer magazines rather than medical journals. In order to locate magazines likely to feature prescription drugs, the sampling frame was drawn from those likely to be read by the elderly, who make up a large portion of the prescription drug market.

Unit of Analysis

In this study, the units of analysis were prescription drug advertisements found five of the top seven consumer magazines most likely to be read by the elderly. In order for an advertisement to be coded, it had to appear in one of the five magazines chosen between the months of August 2002 and July 2003. The top seven consumer magazines were chosen for two reasons: 1) to ensure manageability of the sample size; and 2) the elderly are the largest target audience of prescription drug advertisers. According to Mediamark Research Inc. (2000), the consumer magazines with the highest readership of people over age 65 are: *Modern Maturity*¹ (also known as *AARP the Magazine*), *Catholic Digest*, *Yankee*, *Saturday Evening Post*, and *Prevention*. *VFW Magazine* and *American Legion Magazine* were listed in the Mediamark (2000) study before *Catholic Digest*,

¹ *Modern Maturity* changed its name to *AARP the Magazine* in April 2003, and will hereafter be referred to as *AARP the Magazine*.

Yankee, *Saturday Evening Post*, and *Prevention* but were not evaluated because they are read by a primarily male audience and are not consumer magazines.

Coding Sheet A

Prescription drug advertisements were analyzed using a coding sheet (see Appendix A). The coding sheet includes, magazine name, date, and page number on which ad appears. If an ad was more than one page long, the number of pages was recorded and the size of the pages coded. Font size of the ad was also coded. The number of side effects listed was noted as well. Some ads do not contain side effect warnings; the frequency of the occurrence of these types of ads was also recorded. The ad size and number of side effects listed was correlated using Pearson's product-moment correlation coefficient.

Imprecise frequency descriptors were also coded. Examples of these imprecise frequency descriptors are: "in rare cases," "may include," "less commonly," "most frequently," "may cause," "low incidence/occurrence," "may occur," "some people may experience," and "usually mild."

The product, or prescription name, and product category were recorded on the coding sheet. The product categories consist of: 1) pain relief, 2) depression/mood, 3) health aid, 4) asthma/allergy, and 5) other. For example, *Lipitor* is a prescription drug for high cholesterol and would fit in the "health aid" category. *Glucovance*, a prescription drug used to aid in controlling Type II Diabetes would also fit in the "health aid" category. There is a blank space next to "other" for the drugs that do not fit the first four categories.

The occurrence of a “call to action” was also noted. The categories of a “call to action” by the ad include, whether or not the ad urges the consumer to: 1) contact his/her physician, 2) contact a pharmacist, 3) visit website listed on ad, or 4) call toll free number listed on ad.

The size of the warning and the size of the ad were coded using width by height in picas and converted into inches to determine the area of the warning. The type size of the warning and the total area of the warning were coded using a pica ruler, which uses a base 10 unit of measure called picas. Pica measurement is common in visual layout. The height type of the individual letters and words of the warning were measured in points and compared to that of the title of the advertisement.

The occurrence of foldout ads were recorded as well as the use of inside front cover, inside back cover, or back page covers. These are noteworthy as publishers typically charge advertisers more for these choice locations. They also usually require that cover space be full- page and in four colors (Jugenheimer, Barban, & Turk, 1992). Layout of the ad was also analyzed by whether it is single or multi-page, whether the warning is written in color or in black and white, and if the ad itself contains color or is completely black and white.

The presence of a detailed description of the drug within the ad was recorded as well as the type size of the description. The occurrence of a celebrity spokesperson or famous endorser of the drug was also recorded as well as the name of that celebrity.

Coding Sheet B

A second coding sheet (see Appendix B) was used to evaluate prescription drug websites. The coding sheet contains the name of the product, as well as its website. The

number of side effects listed on the site in addition to the occurrence of percentages of those effects was coded. If the drug website warning does contain percentages, each side effect and its' percentage were listed and compared to the drug's corresponding print ad.

Two coders were used and trained with descriptors beforehand. A 10% overlap was evaluated for intercoder reliability or intercoder agreement.

RESULTS

One hundred sixty-five advertisements were analyzed in 50 magazines. These 50 came from five different publications (*AARP the Magazine*, *Catholic Digest*, *Yankee*, *Saturday Evening Post*, and *Prevention*), which are among the top seven read by those age 65 and older (MediaMark, 2000). The time frame studied was August 2002 to July 2003. *AARP the Magazine* yielded 24 drug advertisements, *Catholic Digest* contained eight, *Yankee* contained three, *Saturday Evening Post* contained 41, and *Prevention* contained 89.

A second coder coded 10% of the ads. Individual observed agreement ranged from 82% to 100 % with an average of 98%.

Every ad analyzed took up at least one full magazine page. One ad (.6%) was five pages long, 11% (22) of the ads were four pages long, and 29.1% (48) were three pages long. Fifty-one point five percent (85) were two pages long and only 5.5% (9) of the ads were one page long. The type size of the advertisements' titles ranged from one (.6%) advertisement with a 10-point title to 1.8% (3) of the ads having 46-point titles. Sixteen-point font (20%) was the most common size used. Over 51.5% of the ads analyzed had titles that were written in less than 20-point font size.

Of the 165 ads coded, 93.9 % contained a side effect warning. While just over 6% of the ads contained no side effect warnings, 8.5% had one side effect listed, 8.5% had two side effects listed, 29.1% had three side effects listed and 29.7% had four side effects listed (see Table 1). Warnings with fewer than four listed side effects made up over 52% of the total ads.

Table 1

Side Effect Occurrence in Advertisements

Number of side effects listed	Frequency	Percent	Cumulative percent
0	10	6.1	6.1
1	14	8.5	14.5
2	14	8.5	23.0
3	48	29.1	52.1
4	49	29.7	81.8
5	9	5.5	87.3
6	2	1.2	88.5
7	10	6.1	94.5
8	8	4.8	99.4
11	1	.6	100

One hundred thirty two (81%) ads contained imprecise frequency descriptors. In those 132 ads, 13 different imprecise frequency descriptors were used. “Most common” was used 38.6% (51) of the time to describe the severity of the side effects listed. “Usually mild” was listed as an imprecise frequency descriptor in 27.3% (36) of the advertisements. The IFD used that were not listed on the coding sheet were “commonly reported” and “more often” which were listed 1% (2) and 3.5% (7) of the time respectively. The only two IFD’s that were listed on the coding sheet but were not used in the ads were, “could cause” and “may increase.”

Sixty side effects were identified in the ads (not including side effects listed on the websites). The number of side effects listed in the ads ranged from 11 (.6%) to zero (6.1%). Eight-point five percent (14) of the ads contained one side effect, 8.5% (14) also listed two effects, 29.1% (48) listed three effects, and 5.5% (9) listed five side effects. One point two percent (2) of the ads contained six side effects, 6.1% (10) listed seven effects, and 4.8% (8) of the ads listed eight side effects in their warnings. The most common number of side effects listed was four, which was listed 29.7% (49) of the time. Drug advertisements that listed three or less side effects made up 52.1 % of the total ads.

Of the 60 different side effects used in the drug advertisements, diarrhea was listed 34.8% (54) of the time in the 165 ads analyzed. Headache was a side effect for 25.8% (40) of the ads, nausea/upset stomach was listed 21.3% (33) of the time, stomach/abdominal pain was listed 18.1% (28) of the time, and muscle pain/cramps /weakness was listed in 17.4% (27) of the 165 ads coded.

In regard to the websites, all 33 prescription drugs advertised had websites, however, 7% (14) of the 165 ads did not provide the drugs' web addresses. Eighty-five side effects were listed on the websites. Of the 85 side effects listed, "headache" was mentioned as a side effect for 21 of the 33 medicines. The most common side effects in occurrence in the website drug descriptions were, "headache," listed for 69.6% (23) of the drugs, "nausea/upset stomach" for 66.7% (22), "fatigue/asthenia/lack of strength" for 54.5% (18), and "stomach/abdominal pain," "diarrhea," and "dizziness" were each listed as side effects for 51.5% (17) of the 33 drugs.

Of the 33 prescription medicines that made up the 165 ads analyzed, fourteen of the 33 drugs were advertised at least five or more times each. *Zocor*, a prescription

medicine for high cholesterol, was advertised in 8.5% or 14 different times in the 165 total ads. *Vioxx*, a drug used to treat pain associated with Osteoarthritis, was advertised 7.9% of the time (13 ads), *Nexium*, a prescription for heartburn was advertised 7.3% of the time (12 ads), *Plavix* a prescription medicine that helps prevent heart attacks and strokes was advertised 6.7% of the time (11 ads), and *Allegra*, a prescription allergy medicine, *Procrit*, a drug for chemotherapy related anemia, and *Singulair*, an asthma drug were each advertised 6.1% of the time (10 ads). There were eight drugs advertised only one time, making up 0.6 % each of the total drugs promoted.

The medications were identified in five categories as described in the methods section. Of the 33 advertised medications, 30% (49) of the ads were for “health aid,” which contains such drugs as those listed for high cholesterol, hypertension, and type II diabetes. Approximately 28% (46) medicines were in the “others” category. The “others” category included ads for drugs that did not fit in the “health aid,” “allergy,” “depression,” or “pain relief.” Examples of the drugs placed in the “other” category are, *Arimidex*, an early breast cancer treatment and *Aricept*, a medicine for the treatment of early symptoms related to Alzheimer’s disease. *Procrit* a drug for chemotherapy related anemia, and *Plavix*, a medicine for the prevention of blood clots were also placed in the “other” category. Twenty-three percent (38) were for “pain relief,” 19% (31) were for Asthma/Allergy, and 0.6% (1) drug was for “depression.”

Every single one of the 165 ads contained a call to action, including those ads for *Vioxx* and *Procrit* that did not contain side effect warnings. Content categories for the call to action were, (1) contact physician, (2) contact pharmacist, (3) link to website, and (4) toll free number. All 165 (100%) ads analyzed advised readers to contact their physician

regarding the advertised drug, however, none of the ads advised readers to call a pharmacist. A toll free number was available in 93.3% (154) of the ads, and a link to the prescription website was provided in 91.5% (151) of the ads.

The average area of the side effect warning was three inches. However, the sizes of the magazines need to be taken into account. *Saturday Evening Post* (8 X 10 $\frac{3}{4}$) was the largest magazine, while *Prevention* and *Catholic Digest* (5 $\frac{1}{4}$ X 7 $\frac{1}{2}$) were the smallest. *AARP the Magazine* (8 X 10 $\frac{1}{2}$) and *Yankee* (6 X 9) fell between the others in terms of size.

The type size of the warning ranged from 6 to 12 points. Approximately 53.9% (89) of the warnings were in 8-point. Twenty-two point four percent (37) were in 6-point, 17% (28) were in 10-point. There was 0.6% (1) ad with a 12-point side effect warning. The other 6.1 % were the 10 advertisements that did not contain a side effect warning at all.

None of the ads were fold-out, on inside back covers or outside back covers, but 95% (157) of the 165 ads were multi-page. Only nine of the ads were on single pages and they were all for *Vioxx*.

There were 6.1% (10) inside front cover ads. All these were in *Prevention Magazine*. Although this position only made up 6.1% of the total advertisements, the inside front cover had more prescription medication ads than any other location. All of the ads were in color, although 49.7% (77) of the side effect warnings were in black and white.

Vioxx was the only medicine advertised that did not contain a detailed description with every one of its ads. The other 94% (156) of the ads contained detailed descriptions

of their respective drugs. Although nine *Vioxx* ads did not contain a detailed description of the drug, four ads for the product did.

Celebrity endorsers were shown in 13.5% (22) of the ads. The six celebrity endorsers were professional figure skater Dorothy Hamill for *Vioxx*, professional golfers Jack Nicklaus for *Altace* and Nancy Lopez for *Synvisc*, and NFL football coach Dan Reeves in an ad for *Zocor*.

In regard to the highest recorded incidents of the side effects on the websites, “application or injection site reaction” led (47% listed incidence) followed by ‘cold and flu symptoms’ (39.7%), “upper respiratory infection” (38.1%), “hot flashes” (35%), and “nausea” (31%).

On the websites, percentages of side effect occurrence were listed for 90.9% (30) of the medicines. The three websites (9.1%) that did not contain percentages were for *Viagra*, *Synvisc*, and *Noritate*.

DISCUSSION

Magazines for senior citizens are replete with ads for prescription drugs although some were much more heavily inclined in this area than others. For instance, *Prevention* had twenty-nine times more ads than *Yankee* for the same time period. Although both of these magazines are published on a monthly basis, two of the magazines analyzed were not. *AARP the Magazine* and *Saturday Evening Post* are published bi-monthly. Although this doesn't explain why some magazines contained more ads than others, it does indicate that had these magazines been published every month, there would most likely have been over two hundred ads in the five magazines analyzed in the one year time period studied.

Most of the ads did contain side effect warnings, although it is surprising that not all did. Six point one percent (10) of the ads contained no side effect warnings whatsoever. While this may not seem significant in the grand scheme, all but one of the 10 ads were for *Vioxx*, the other was a single ad for *Procrit*. It is also surprising that although *Vioxx* was analyzed nine times without a side effect warning, it did contain a side effect warning and detailed description for four of its advertisements.

Although almost 20% (31) of the ads coded did not contain imprecise frequency descriptors, it must be considered that 10 of those 31 ads must be disregarded because they contained no side effect warning at all. So, in actuality there were only 21 ads out of the 165, which listed side effects but used no imprecise frequency descriptors.

RQ1 asked, "How complete is print drug advertising in regard to side effects?" Using the websites as a benchmark, it appears the ads fall very short of being complete. Of more concern is the possibility that the ads are actually misleading. For instance,

while *Protopic* lists a 47% incidence of “application or injection site reaction” among users on their website, its magazine advertising does not include “application site reaction” at all, much less as one of *Protopic*’s “most common” side effects. Likewise, *Xenical* lists a 39.7% incidence of “cold and flu like symptoms” and 38.1% incidence of “upper respiratory infection” among its prescription users on its website, while the drug’s advertisements don’t list “cold and flu like symptoms” or “upper respiratory infection” at all as one of *Xenical*’s side effects. It seems unlikely that consumers faced with imprecise frequency descriptors such as “some people may experience” and “most common” would realize the incidence level was over 37%, or one in three people who try the medicine are likely to experience the side effects (See Table 2).

Table 2

Side Effects Listed on Websites with Highest Percentages of Incidence

Drug	Side effect	Incidence Percentage	IFD from from ad	Does ad warning list web side effect
<i>Protopic</i>	application site reaction	47%	most common	no
<i>Xenical</i>	cold/flu symptoms	39.7%	some people may experience	no
<i>Xenical</i>	upper respiratory infection	38.1%	some people may experience	no
<i>Arimidex</i>	hot flash	35%	most common	yes
<i>Effexor XR</i>	nausea	31%	may include	yes

This ambiguity of the language used to describe high side effect incidence levels is only part of the problem. The warnings on the magazine ads themselves do not appear to be presented in a way that is conducive to senior citizen comprehension. While this

was described in the earlier justification and literature review, this study further supports this viewpoint.

For instance, side effect warning point sizes ranged from only 12 points to 6 points. Considering that most seniors are afflicted with presbyopia, a condition that causes near vision to fade starting in the early to mid 40's. Presbyopia is the most common eye condition in the United States, and is estimated to affect over 90 million Americans between now and 2014 (Lee & Bailey, 2004). Because of this age related eye condition, the type size used may be unreadable to many consumers of the magazines studied.

Framing theory suggests that media messages are packaged so as to allow certain desirable interpretations and rule out others. If this is true with prescriptive medications, consumers who read only magazines and do not call toll-free numbers or utilize websites are unlikely to see the full picture. By pointing out the discrepancies between the advertised side effect warnings and the actual prescribing information listed on drug websites, this study indicates that DTC prescription drug advertisements are leaving out valuable information thereby “framing” exactly what they want consumers to know about their respective medicines.

Because this study did not contain human subjects or consumer evaluations, it is more difficult to prove Cultivation Theory in relation to direct-to-consumer advertising. It would however be quite useful in future research involving surveys or experiments regarding magazine promotions of prescription drugs. For example, subjects could be asked to read a year's subscription to the five magazines chosen, and then asked to fill out a questionnaire regarding the ailments, drugs advertised, and side effects listed for

each advertisement. This type of study would better explore the realm of Cultivation Theory in regard to advertisements.

The difference in website and magazine side effect descriptions presents a question of credibility. The magazine ads side effect warnings are presented in an authoritative manner, which may lead many consumers to assume they are definitive. It appears from the discrepancy between website side effect descriptions and magazine side effect warnings that the magazines are at best, incomplete and probably misleading. A future study examining prescription drug package inserts and comparing them with drug websites and magazine print ads would help better explain the differences this study illustrated between ads and websites.

RQ2 was “Do actual percentages of side effects listed on websites correspond to side effect frequency descriptors used in print ads?” All of the side effects listed in the advertisement warnings were also listed on their corresponding drug websites. Though, in some cases, the most common side effect listed on the website was not listed in the advertised side effect warning. As mentioned previously, the drug *Protopic* lists “application site reaction” as having a 47% incidence rate on its website, however, in the drug’s advertisement, it doesn’t list “application site reaction” at all. It does list “stinging,” “burning,” and “itching,” as its’ “most common” side effects which could be ascertained as “application site reactions,” but it still doesn’t justify why “application site reaction” was not listed at all.

Unlike *Protopic*, the prescription drug *Arimidex* lists “hot flash” as a side effect that is “most common” in its advertisement, and also lists “hot flash” on its website as occurring 35% of the time. Likewise, *Effexor* lists “nausea” with the imprecise frequency

descriptor “may include” in its ad, but lists “nausea” with a 31% chance of occurrence on its website. It is highly unlikely that consumers read a phrase such as “may include” and even possibly “most common,” and estimate that an average of two out of five people who are prescribed these medicines also experience these side effects.

RQ3 was “Are certain side effects more common?” Certain side effects definitely were more common, however, there was a serendipitous finding. In the ads, “diarrhea” was the most common side effect, while on the website, “headache” was listed most often. Although the advertisements and websites did not have the same side effect listed most often, they did have four of the same side effects in each of their top five side effects in occurrence. Four of the top five side effects they shared were, “headache,” “diarrhea,” “nausea/upset stomach,” and “stomach/abdominal pain” (See Table 3).

It must also be taken into consideration that the drug ads listed 60 side effects, while the drug websites listed 85 different side effects. This is the reason for the large difference in the percentages of occurrence listed for each side effect in the ads and on websites. If a reader relied on the print ads alone, he or she would get no information about 25 other side effects.

RQ4 was “Does ad size or ad length correlate to the number of side effects listed?” A simple look at descriptive statistics suggests ad size does not positively correlate with number of side effects. The longest ad was five pages and the shortest was one page. The most side effects listed were 11 and the least were zero. If longer ads correlated to a greater number of side effects, we would expect to find the ads with five pages tending to have more side effects than those with one page. This was not the case. It was discovered

however, that two pages was the most common length of a prescription advertisement, and that a magazine is twice as likely to have a four-page ad than a single page ad.

Table 3

Advertised Side Effects Compared with Drug Website Side Effects

Ad Side Effect	% of Occurrence (X / 165)	Website Side Effect	% of Occurrence (X / 33)
diarrhea	34.8 %	headache	69.7 %
headache	25.8 %	nausea	66.7 %
nausea/upset stomach	21.3 %	fatigue/asthenia/ lack of strenght	54.5 %
stomach/abdominal pain	18.1 %	stomach/abdominal pain	51.5 %
muscle/pain/cramps/ weakness	17.4 %	diarrhea	51.5 %
		dizziness	51.5 %

A Pearson's Product Moment Correlation test was run using the number of pages and the number of side effects listed in the ads as variables. The significance level was .93, not significant at the .05 alpha level, indicating ad size did not correlate to the number of side effects listed.

Anecdotal evidence illustrates this. An ad for *Xenical* that was five pages listed only four side effects, while an ad for *Effexor XR* that was three pages, listed 11 side effects. The finding that there was no correlation between ad size and number of side effects is interesting in that it appears the space available to an advertiser is not one of the criteria used to assess how many side effects will be listed.

As mentioned in the literature review, there is no legal requirement regarding disclosure of side effects. It appears that ads in magazines may fall short of suggestions made by the FDA pertaining to DTC.

As discussed previously in the literature review, the FDA issued the “Guidance for Industry” in 1997. The Guidance reiterated the FDA requirement that prescription drug ads must be non-deceptive. It also added two more requirements, 1) that a “major statement” must be used to give all of the products most important information in an easy to understand language, and 2) the ad must give all information relevant to the product’s indication, including limitations to use in an easy to understand language (Palumbo & Mullins, 2002).

It appears the drug ads are following the Guidance’s requirement of using a “major statement” but this study suggests that drug ads are not adhering to the requirement of conveying “all of the product’s most important risk information.” This is illustrated by the fact that some ads do not contain side effects with incidence levels of over 30%. It is also evident in the fact that three of the drug websites did not contain side effect percentages in their warnings.

Even though most of the websites did contain percentages, it must be kept in mind, as a limitation to this study, that website information is provided by the drug company and in many cases is not precise. The website is still a public relations vehicle for the prescription drug distributors. Another limitation to this study concerns the fact that the advertising agencies hired to promote these prescription drugs for pharmaceutical companies were not consulted regarding their advertising practices. An attempt to find out which ad agencies are being utilized by pharmaceutical companies was unsuccessful.

A future study concerning DTC could contact pharmaceutical company public relations departments or find out which advertising agencies are being used. Trade literature could also be analyzed to better understand the practices used in DTC promotion.

It is however, interesting to note that less than 10 pharmaceutical manufacturers are doing most of the advertising. Eight companies produced more than 66.7% (22) of the 33 drugs advertised. *Pfizer*, produced five of the drugs studied, *Merck* produced four, *Sanofi-Synthelabo* or *Bristol-Meyers Squibb* produced three, and *AstraZeneca*, *Dermik*, *Aventis*, *GlaxoSmithKline*, and *Wyeth* each produced two of the 33 drugs studied. A future study could look at corporate culture and decision-making in regard to DTC advertising. Another study could also examine the effect of DTC on doctors and whether or not DTC prescription drug advertising is putting undo pressure on physicians to prescribe certain medications.

Also mentioned in the literature review, the United States and New Zealand are the only two countries in which DTC advertising is allowed. It is also pointed out that the EU, Canada, and New Zealand all have government provided public health. With the recent legislative action, regarding Medicare and prescription discount cards, and the graying of the baby boomer generation in America, it is surprising that the FDA has not decided to reevaluate its regulations regarding DTC advertising.

This study also supports a previous study, mentioned in the literature review, in which it was concluded that many people mistakenly believe DTC advertisements go through preliminary review by government regulators and that only “completely safe” and “extremely effective” drugs can be advertised (Bell, Kravitz, & Wilkes, 1999). This

study further supports the idea that people are being misled by these ads and are unable to make well-informed decisions based on the information they receive from DTC ads.

It is also of interest that some websites (*Viagra*, *Synvisc*, *Noritate*) had no side effect percentages listed whatsoever. Coupled with the fact that the magazine advertisements for these products did not list the side effect percentages, the consumer is left with no readily accessible information about the drugs' clinical information.

One unexpected finding was in regard to celebrity endorses who turned out to be all athletes. In one case, celebrity endorser Dorothy Hamill was pictured in ads for *Vioxx* that had no side effect warnings. While this does not reflect directly on the research questions of this study, it suggests an area for future research. For example, a study regarding consumers' perceptions of athletes as "the picture of health" and whether or not seeing an athlete promote a certain drug would make an average person more inclined to inquire about that particular drug.

Also of some concern is the lack of formal communication research regarding misleading advertising and more importantly, DTC promotions of prescription medicines. Most of the studies regarding prescription drugs and their promotions have been published in medical journals. It is often overlooked that DTC advertising isn't just a medical phenomenon; it is also the largest and fastest growing advertising niche in the United States.

Overall, the findings indicate advertising appears to paint a false picture of medications. This false picture is in some cases the result of ambiguity, such as in the case of imprecise frequency descriptors that may be misleading. In other cases, important information such as side effect warnings or side effect percentages was left out.

Also of some concern is the type size used to describe side effects. Because there are no formal rules or enforced regulations governing this conduct, it cannot be considered illegal. There is current precedence in regard to required warnings in the area of cigarette promotion on both packaging and print advertising. Advertisers may want to consider whether they wish to police themselves or risk future government regulation.

Within DTC advertising, there is a great potential to mislead. Possible suggestions for correcting the situation could include mandatory guidelines for side effect warnings including number of side effects, inclusion of percentages, font size and placement.

This research is exploratory. Further research is necessary to determine if consumers are misled by DTC prescription drug ads. This could take the form of experiments and surveys in which populations of various age groups are asked to evaluate ads. Experimental research could also compare remedial ads with larger sized warnings to current ads for evaluation of possible industry guidelines. Evaluation of television and print ads in a comparative study would also help provide a foundation of research.

Other future research could possibly address precision ratings across certain pharmaceutical companies or drugs. The studies could find out whether or not certain pharmaceutical distributors and advertisers are doing a better or more complete job of portraying risk information. Other suggestions include research on similar drugs for the same ailments. If there are various medications for the same ailments, does this greater competition mean that ads are becoming more imprecise in their warnings in order to sell their product or make it appear more desirable.

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APPENDIX A
CODING SHEET A

CODING SHEET A

1. ID # _____
2. Coder: _____
3. Magazine Name: (1) AARP the Magazine (2) Catholic Digest (3) Yankee
(4) Saturday Evening Post (5) Prevention
4. Magazine Date: _____
5. Page # _____
6. Ad Size: width _____ height _____ other _____
(measured in picas; if more than 1 page, write page size in other blank)
7. Type Size of Title: _____
(measured in points)
8. Does Ad contain side effect warning? (1) yes (2) no
(if no skip to #14)
9. How Many Side Effects are Listed? _____
10. Does Ad Contain Imprecise Frequency Descriptors? (1) yes (2) no
(if no skip to #13)
11. Imprecise Frequency Descriptors (IFD's): (mark all that apply)

(1) in rare cases (2) may include (3) may cause (4) may occur

(5) may increase (6) most common (7) could cause (8) low incidence

(9) low occurrence (10) some people may experience (11) usually mild

(12) less commonly (13) most frequently (14) other (fill in) _____
12. Write all Side Effects Listed and Their Corresponding IFD (Number) from # 12
if applicable:

_____	_____
_____	_____
_____	_____
_____	_____

- 13. Product:** _____
(name of prescription drug)
- 14. Product Category:** (1) pain relief (2) depression/mood (3) health aid
(4) asthma/allergy (5) other (fill in) _____
- 15. Does Ad Contain Call to Action?** (1) yes (2) no
(if no, skip to # 17)
- 16. Call to Action:** (1) contact physician (3) link to website
(2) contact pharmacist (4) toll free number
- 17. Size of Warning:** width _____ height _____
(measured in picas)
- 18. Type Size of Warning:** _____
(measured in points)
- 19. Ad is Foldout:** (1) yes (2) no
- 20. Ad has a Multi-Page Layout:** (1) yes (2) no
- 21. Inside Back Cover:** (1) yes (2) no
- 22. Inside Front Cover:** (1) yes (2) no
- 23. Back Page Cover:** (1) yes (2) no
- 24. Ad Contains Color:** (1) yes (2) no
- 25. Warning is in Color:** (1) yes (2) no
- 26. Ad contains detailed description of drug:** (1) yes (2) no
(if no, skip to #28)
- 27. Type size of detailed description:** _____
(measured in points)
- 28. Ad contains celebrity endorser:** (1) yes (2) no
(if no, skip #29)
- 29. Name of Celebrity:** _____

APPENDIX B
CODING SHEET B

CODING SHEET B

1. Product: _____
(name of prescription)

2. Http:// Address: _____

3. How Many Side Effects are Listed? _____

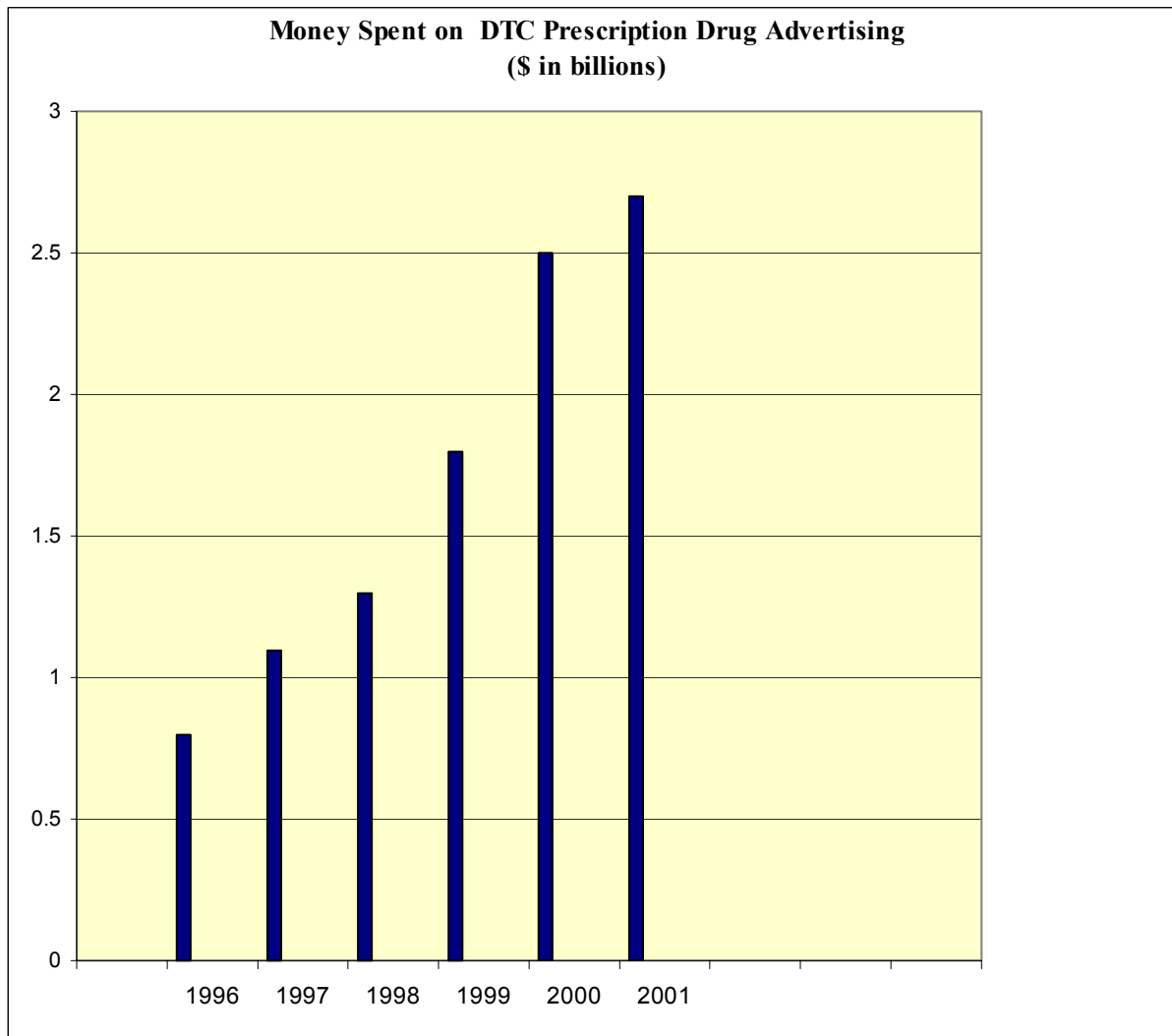
4. Are Percentages of Occurrences Listed with Side Effects? (1) yes (2) no
(if no, skip #5)

5. Write all Side Effects Listed and Their Percentages of Occurrence:

_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

APPENDIX C

MONEY SPENT ON DTC PRESCRIPTION DRUG ADVERTISING



Source: Kaiser Family Foundation and Sonderegger Research Center. (November, 2001).
Prescription drug trends, a chart book update. Retrieved March 28, 2004 from
<http://www.kff.org>

VITA

Mikah Zangla, an Alexandria, Louisiana, native, received her bachelor's degree in communication disorders with minors in linguistics and Italian, from Louisiana State University in 2001, and completed her master's degree in mass communication from Louisiana State University in 2004. She currently resides in Baton Rouge.