RACIAL DISPARITIES IN DIRECT-TO-CONSUMMER PHARMACEUTICAL ADVERTISING

by

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ABSTRACT

STEPHANY DE SCISCIOLO CAVALLO. Racial disparities in direct-to-consumer pharmaceutical advertising. (Under the direction of DR. TERESA L. SCHEID)

Reducing health disparities by increasing access to health information is a national priority. Research demonstrates that direct-to-consumer advertising (DTCA) is effective in educating consumers about health issues. However, research also identified racial disparities in such advertising. In 2009, the Food and Drug Administration (FDA) issued a report that included a number of recommendations for enhancing the ability of DTCA to reach disadvantaged populations, including racial and ethnic minorities. This study compared the pharmaceutical advertisements placed in five popular women's magazines published prior to and following the 2009 FDA report to assess the impact of these recommendations on the content and appearance of advertisements placed in magazines of differing racial orientation.

DEDICATION

In memory of my father,

Thomas A. De Scisciolo,

whose spirit continues to give me the strength to

embrace all of life's challenges with enthusiasm and a sense of humor.

ACKNOWLEDGMENTS

I would like to acknowledge the unwavering support of my committee chair, Dr. Teresa Scheid. Throughout what at times seemed like an impossible task, Teresa offered food, drink, and constant words of encouragement. Her belief in my work and her pride in my efforts were incentive enough to push forward. She was truly the "wind beneath my wings."

I would also like to thank the many friends who contributed in so many ways, both large and small. In particular, my study buddy, Maureen Walsh Koricke, provided a constant source of strength as we tackled writing our dissertations together. We share a special bond—one that I will never forget and will always be grateful for.

Lastly, I would like to thank my family, particularly my husband Guy. Not once did he ever ask me whether I would finish. Not once did he suggest that I discontinue my work, even when I was battling breast cancer. Not once did he complain when I couldn't do something because I had to work on my dissertation. His patience and support were endless. Without him, this dream of mine would never have become a reality.

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CHAPTER 1: INTRODUCTION

The variability in health status among different population groups in the United States remains a much studied issue in health policy. Despite a significant national investment in health care and widespread technological advancement (e.g., new drugs, better facilities, state-of-the art equipment), the fact remains that some groups of people are healthier than others. For example, a 2011 report from the Centers for Disease Control and Prevention (CDC) indicates that African Americans fare more poorly than Caucasians on virtually every morbidity and mortality health outcome measure, with the exception of motor-vehicle-related deaths (CDC, 2011). African Americans, as well as other minorities, have less access to health care and preventive services, are more likely to live in unhealthy housing and breathe unhealthy air, and are at greater risk for developing a chronic disease than Caucasians (CDC, 2011). As a result, the life expectancy of the African American population is 3.8 years less than that for the Caucasian population based on 2010 data (Murphy, Xu, & Kochanek, 2013). In contrast, the life expectancy of the Hispanic population is 2.3 years greater than for the Caucasian population and 6.1 years greater than for the African American population (Murphy et al., 2013), suggesting that something other than minority status is negatively impacting the health of African Americans in this country.

While the difference in life expectancy between African Americans and Caucasians has been declining, the relative risk differences between the African American and Caucasian populations for individual diseases remain significant. For example, an African American with hypertension has a far greater risk of dying from the disease than does a Caucasian (Murphy et al., 2013). In fact, for 8 of the 15 leading causes of death in the United States in 2010, the rate of death among African Americans in the United States was greater than among Caucasians, with Black to White, age-adjusted ratios ranging from a low of 1.1 for influenza and pneumonia to a high of 2.4 for essential hypertension and hypertensive renal disease (Murphy et al., 2013). Many reasons have been cited for such disparities. It is not the goal of this dissertation to evaluate either the issue of whether health disparities do in fact exist in the United States or the reasons why they exist. Rather, the purpose of the study was to examine a potential source of disparity—direct-to-consumer pharmaceutical advertising (DTCA).

Advertising pharmaceuticals directly to consumers is big business. Drug companies spent over $4.3 billion in 2010 advertising their products. Nearly one-third of these funds were dedicated to print advertising. During the mid-2000s, researchers in several disciplines studied pharmaceutical advertising using the theoretical constructs common to their individual fields of study. Each study made an important contribution to the literature regarding the effectiveness and appropriateness of DTCA, resulting in a lively debate about its relative merits. Communications experts are concerned about the ability of consumers to understand the information presented in the advertisements (Kaphingst, Rudd, DeJong, & Daltroy, 2003; Stokes, 2005; Rubinelli, Nakamoto, Schulz, & de Saussure, 2006; Mackert & Love, 2011), while health economists worry that such

advertising will steer patients towards higher priced drugs (Hausman, 2008; Block, 2007). Sociologists warn about the medicalization of America as more and more drugs are introduced to treat so-called lifestyle conditions (e.g., erectile dysfunction, menopause) (Conrad & Leiter, 2008; Payton & Thoits, 2011). To make sense of the vast amount of literature written about DTCA within the context of health policy, this study synthesized, integrated, and expanded upon the findings of this earlier research using the framework of two popular models of individual health behavior: social cognitive theory and the health belief model.

Whatever one's opinion of DTCA, it is clearly one of the most widely recognized types of advertising.[1] Numerous studies have reported a high degree of awareness of pharmaceutical advertising among those surveyed (Bell, Kravitz, & Wilkes, 1999; Calfee, 2002; Weissman, et al., 2003; Aiken, Swasy, & Braman, 2004; Thomaselli, 2006; Lee & Begley, 2010), as well as a tendency to discuss advertised drugs with their doctors (Allison-Ottey, Ruffin, and Allison, 2002; Weissman, et al., 2003; Thomaselli, 2006). Researchers have also pointed out the potential of DTCA to impact health disparities (Fry et al., 2007; Avery, Kenkel, Lillard, Mathios, & Wang, 2008; Ball, Liang, & Lee, 2009; Crawley, Hisaw, & Illes, 2009; Young and Eckrich, 2013). To the extent that DTCA serves to motivate individuals to seek additional information from their physicians, racial disparities in the frequency and content of such advertising may contribute to the poorer health outcomes experienced by the African American population, in particular. On the

[1] See Chapter 2 for a detailed discussion of the advantages and disadvantages of DTCA. While this dissertation is premised on the health promotion potential of pharmaceutical advertising, critics of this form of advertising contend that DTCA can have a negative impact on people's health by manipulating them to seek unnecessary, and potentially harmful, medications.

other hand, advertising that appeals to a black audience, either through its appearance or content, and which prompts individuals to discuss health concerns with their physicians can be invaluable to our efforts to improve health outcomes within this community.

Recognizing the health promotion potential of DTCA, the Food and Drug Administration (FDA) issued a series of recommendations in 2009 aimed at enhancing the ability of DTCA to reach disadvantaged populations. Among these recommendations, four served as the basis for this study (FDA, 2009, p. 26):

(1) "Use communicators in the advertisements and channels to disseminate messages that the target populations rate as credible."

(2) "Produce help-seeking or other ad campaigns concerning diseases and health issues that have particular relevance to the target community."

(3) "Provide information and relevant nondrug interventions (e.g., diet and exercise) that patients should consider."

(4) "Provide information on any available discounts or patient assistance programs that can help low income individuals obtain medications."

To determine the impact of the FDA recommendations on the appearance and content of DTCA, research questions (RQs) were designed to specifically evaluate differences in advertising that may have resulted from the FDA recommendations. As such, RQs were tied directly to the FDA recommendations as follows:

RQ1: Does the frequency of pharmaceutical advertising vary based on the racial orientation of the magazine? (Recommendation 1)

RQ2: Did the frequency of pharmaceutical advertising appearing in black-oriented women's magazines increase following the 2009 FDA report? (Recommendation 1)

RQ3: Do the types of drugs advertised vary by the racial orientation of the magazine? (Recommendation 2)

RQ4: Have the types of drugs advertised become more concordant with the health risks of the race of the magazine's readers following the 2009 FDA report? (Recommendation 2)

RQ5: Does the race of the models used in DTCA vary based on the racial orientation of the magazine (Recommendation 1)

RQ6: Did the percentage of advertisements featuring black models increase following the 2009 FDA report? (Recommendation 1)

RQ7: Does the provision of information about nondrug interventions vary based on the racial orientation of the magazine? (Recommendation 3)

RQ8: Did the percentage of advertisements that include information about nondrug interventions increase following the 2009 FDA study? (Recommendation 3)

RQ9: Does the provision of information about available discounts or patient assistance programs vary based on the racial orientation of the magazine? (Recommendation 4)

RQ10: Did the percentage of advertisements that include information about available discounts or patient assistance programs increase following the 2009 FDA study? (Recommendation 4)

The study focused on pharmaceutical advertising found in print media. While pharmaceutical companies spend a large portion of their budgets on television advertising, magazine advertising remains strong. Bulik (2011) notes that, in 2010, drug companies spent the largest portion of their advertising budget on magazines (32.5 percent) followed closely by network television at 31.5 percent. (The industry also

spent 12.7 percent of its advertising budget on cable television, 8.1 percent on syndicated television, and 2.4 percent on television spots. All told, the industry dedicated a total of 55 percent of its advertising dollars on television (Bulik, 2011)). With respect to pharmaceuticals, magazine readers are more likely to have discussed an ad seen in a magazine with their doctors than one seen on television (MPA, 2013). In fact, some pharmaceutical companies are considering reducing the amount of television advertising they do as a result of regulatory and consumer backlash (Hensley, 2005; Japsen, 2012). In addition, people are more likely to buy products seen in magazine ads than products advertised on television or the Internet (MPA, 2013).

Because the FDA recommendations were targeted to improving the ability of DTCA to reach minority populations, magazine titles examined in this dissertation represented two genres: magazines that are read primarily by white women (*Family Circle* and *Good Housekeeping*) and magazines that are read primarily by black women (*Ebony* and *Essence*). A fifth magazine, *O, The Oprah Magazine*, which is read by both black and white women, was selected as an additional point of comparison. The selection of women's magazines[2] reflects the fact that women tend to make the medical decisions for their families (Keitel, 2000; Kaiser Family Foundation, 2003; Abel, Lee, & Weeks, 2007; Mastin, Andsager, Choi, & Lee, 2007). Furthermore, previous research has found that women's magazines contain more DTCA than other magazine genres, and women, rather than men, are more likely to pay attention to these ads (Mastin et al., 2007).

[2] For the purposes of the study, women's magazines are defined as those which discuss a broad range of issues relevant to women and which possess a predominately female readership.

Magazine readership remains strong among African Americans. According to the MPA Factbook 2013/2014, published by The Association of Magazine Media (MPA), 91 percent of adults surveyed read at least one magazine during the previous six months (MPA, 2013). On average, African Americans read more magazine issues (14.6) monthly than the average number of issues (10.0) read by all U.S. adults (MPA, 2013).

To determine the impact of the FDA recommendations on pharmaceutical advertising, DTCA found in magazine issues published between January 2008 and December 2009 (i.e., the "before FDA report" period) was compared to DTCA found in magazines published between January 2011 and December 2012 (i.e., the "after FDA report" period). Because the FDA report was published in September 2009, magazine issues published in 2010 were excluded from the study sample. It was assumed that pharmaceutical companies would need some period of time to implement the FDA report recommendations in their ongoing advertising campaigns.

Data analysis was conducted in three phases. The purpose of the first analysis phase was to determine whether the frequency and type of pharmaceutical advertising varied on the basis of the racial orientation of the magazine in which it appeared and its publication date (RQ1 through RQ4). In this phase, 237 magazine issues were reviewed and a total of 1,163 pharmaceutical advertisements were identified. Of these, 1,090 were product claim ads and 73 were help-seeking advertisements. (The FDA defines a product claim ad as one that mentions the name of a drug and the condition that it treats, while help-seeking ads describe a particular medical condition but do not mention a specific drug (FDA, 2012a).) Data were compiled by year for each magazine title, and

descriptive statistics were used to ascertain the means for each magazine title and year for the following variables:

- total number of magazine pages
- total number of advertising pages
- total number of advertising pages dedicated to DTCA
- percent of advertising pages as a function of total magazine pages
- percent of DTCA as a function of total magazine pages
- percent of DTCA as a function of total advertising pages

Data were filtered by racial orientation to allow the frequency of pharmaceutical advertising to be compared based on the racial orientation of magazine. Data were then sorted by the relationship of the magazine's publication date to the FDA report date (i.e. "before" or "after"). This allowed data from magazines published before the FDA report to be compared to data from magazines published after the FDA report. Independent sample t-tests were used to evaluate the significance of differences in means.

To evaluate differences in the types of drugs advertised, the name of each drug and the medical condition for which it is used to treat were recorded. Medical conditions were grouped into 16 disease categories based on the work of Bell, Wilkes, and Kravitz (2000). Frequency distributions were obtained for the name of the drugs advertised and the disease category in which they fell. Trends in the data were analyzed to determine whether differences in the types of drugs advertised pre- and post-FDA report publication could be discerned. These data were also compared to the leading causes of death for Caucasians and African Americans to determine how relevant the advertised product was to the health issues and diseases of most concern to each group.

The second phase of analysis examined in more depth a subset of 439 advertisements that promoted drugs used to treat life-threatening conditions, including Alzheimer's disease, cancer, cardiovascular disease, depression, diabetes, and respiratory illness. This analysis phase focused on identifying changes in the appearance and content of DTCA published after the FDA report (RQ5 through RQ10). Each ad was coded in terms of whether it used a human model or likeness, a cartoon character, or an inanimate object, such as a chart or diagram. If the ad featured a human model or likeness, the race, age, and gender of each model was recorded. The race of the primary model was also noted.

Next, the type of appeal used in each ad was determined. Through the use of both visual and textual cues, advertisers may appeal to either an individual's emotions or intellect or both (Macias, Pashupati, & Lewis, 2007). Rational appeals tend to motivate individuals through the use of logical and informational arguments (Main, Argo, & Huhmann, 2004). Emotional appeals can be either positive or negative. Positive emotional appeals try to evoke a favorable consumer response by conveying a sense of warmth, happiness, or relief (Main et al., 2004). Negative emotional appeals can inspire feelings of anger, fear, or sadness (Main et al., 2004). Ads can include both rational and emotional appeals. Chapter 4 provides the coding scheme for the type of advertising appeal used.

Ads were also coded for the answers to the following yes/no questions:

- Is the reader offered help in finding patient support services?
- Is the reader referred to a Web site for additional information?
- Is the reader given a telephone contact for additional information?

- Is the reader encouraged to talk with a doctor or another individual?
- Is the reader offered monetary incentives or other financial support?
- Are alternative therapies, such as diet and exercise, suggested to the reader?
- Is the reader encouraged to report negative side effects of prescription drugs to the FDA?

This latter information item is a requirement of the Food and Drug Administration Amendments Act of 2007. It was purposely included in the analysis to measure the pharmaceutical industry's responsiveness to a regulatory requirement. Appendix A presents the data collection code sheets used in the two analysis phases described above.

A third phase of analysis was conducted to qualitatively compare the appearance and content of ads for the same drug placed in different magazine genres during the same month and year. For example, an ad for Januvia, a diabetes medication, which was published in the June 2008 issue of Ebony magazine was compared to an ad for Januvia that appeared in the June 2008 issue of Good Housekeeping. A total of 10 drugs, within the six disease categories of interest, were advertised in both black-oriented magazines and white-oriented magazines during the same month and year. (Drug ads that appeared in the crossover magazine were omitted from this phase of the analysis since its target audience is less defined.) Twenty-seven ad versions were evaluated. While limited in scope, the study was the first to examine this aspect of DTCA, which warrants further research.

The next chapter of the dissertation reviews the current literature, particularly the results of previous content analyses of pharmaceutical advertising in magazines. A brief history of the evolution of DTCA is presented, and current DTCA regulations are

discussed. The debate about the value of DTCA is summarized within the context of its potential to reduce health disparities by providing health information to disadvantaged populations.

Chapters 3 and 4 present the results of the study. Chapter 3 focuses on the first phase of the analysis and looks at the frequency and type of pharmaceutical advertising that appeared in the five women's magazines providing data for this research. Chapter 4 discusses the results of the second and third phases of the analysis which examined the appearance and content of a subset of the DTCA identified in Phase 1. Chapter 5 discusses the implications of the study results on health policy and offers some policy recommendations. Study limitations are identified, and future research opportunities are highlighted.

CHAPTER 2: LITERATURE REVIEW

The United States is just one of two industrialized countries (New Zealand is the other) that currently permits pharmaceutical companies to advertise directly to the consumer (Almasi, Stafford, Kravitz, & Mansfield, 2006; Calfee, 2002). DTCA encompasses pharmaceutical companies' efforts to reach consumers directly via all forms of media, including print (magazines, newspapers, billboards), broadcast (radio, television), and the Internet (Ventola, 2011; Sokol, Wackowski, & Lewis, 2010). The Food and Drug Administration (FDA), which regulates DTCA in the United States recognizes three categories of drug advertisements: product claim ads, reminder ads, and help-seeking ads (FDA, 2010; Silver & Stevens, 2009; Ventola, 2011). Product claim ads are defined as those advertisements that "name a drug and the condition it treats"; reminder ads are those advertisements that "give the drug's name, but not the drug's uses"; and help-seeking ads are those advertisements that "describe a disease or condition, but don't recommend or suggest specific drugs" (FDA, 2010). Only product claim ads must provide information regarding both the benefits and the risks associated with taking the advertised drug (Silver & Stevens, 2009; Ventola, 2011).

This chapter reviews the history of pharmaceutical advertising in the United States, including industry spending patterns and government regulation. A theoretical framework is presented, and the advantages and disadvantages of DTCA are discussed.

The chapter closes with a summary of previous content analyses of print pharmaceutical advertising and identifies how the research presented in this dissertation addresses several key gaps in the literature.

2.1 The Evolution of Direct-to-Consumer Advertising

A review of the history of DTCA in the United States is fascinating. Since its very beginnings at the turn of the 20th century, pharmaceutical advertising has come full circle. Newspapers in the late 1800s and early 1900s were filled with advertisements for various patent medicines claiming to cure a wide variety of ailments (Silver & Stevens, 2009). The consumer's right to self-medicate was considered sacrosanct (Donohue, 2006). However, in 1905, the American Medical Association (AMA) created the Council of Pharmacy and Chemistry. The Council's objectives were to encourage patients to use physician-prepared medications and to discourage the use of patent medications (Donohue, 2006). The AMA considered self-medication "a threat to the medical profession" (Donohue, 2006, p. 665).

Early attempts to discourage self-medication by the AMA led to an increase in information provided to consumers, based on the assumption that, given the right information, consumers could identify effective medications (Donohue, 2006). By World War II, physicians had asserted their authority over patient decisions, and DTCA was virtually nonexistent (Donohue, 2006). By the 1960s, 90 percent of the advertising money spent by pharmaceutical companies was directed at physicians rather than the public (Donohue, 2006).

The focus of pharmaceutical advertising started to turn in the 1970s with the birth of the patients' rights movement (Donohue, 2006). Consumer groups began to demand

more information about prescription drugs, voicing their concerns that physicians did not adequately explain the possible side effects of the drugs that they prescribed to their patients (Donohue, 2006). In response to these concerns, as well as its own research, the FDA ultimately adopted a plan to encourage drug companies to voluntarily provide information to consumers (Donohue, 2006). Soon afterward, pharmaceutical companies began targeting their advertising efforts at consumers (Donohue, 2006; Wilkes, Bell, & Kravitz, 2000). Initially limited to print media (Donohue, 2006), pharmaceutical advertising is now ubiquitous as consumers are exposed to advertisements in newspapers, magazines, television, and on the Internet.

One interesting aspect of the history of DTCA in the United States is the changing positions taken by the key stakeholders over time, particularly the pharmaceutical companies. Early opponents to DTCA included not only physicians, but the drug companies as well (Donohue, 2006). In the early 1980s, executives of pharmaceutical groups advocated "strict limits, if not an outright ban on prescription drug advertising to the public" (Donohue, 2006, p. 678). Consumer groups, who had demanded that patients to be given more information about their prescription drugs, also opposed DTCA, preferring instead for such information to be provided in patient package inserts (Donohue, 2006). And consumers themselves disagreed with the notion that DTCA would better inform their medical decision making. Donohue (2006) reported that surveys of consumers conducted during this time period indicated the following:

> More than three-quarters of consumers disagreed with the statement that they could decide about using a drug, and 63 percent disagreed with the statement that patients could tell whether a prescription drug ad was misleading (p. 677).

Today, consumers and physicians appear to have softened their stance against DTCA. As people strive to become better educated consumers of medical services, DTCA is one readily accessible source of health information (Huh & Becker, 2002). An FDA survey conducted in 2002 found that 43 percent of those who responded said they had sought more information about either a drug or their health based on a pharmaceutical advertisement (FDA, 2004). Thirty-two percent said that DTCA helped them "make better health decisions" (FDA, 2004). In addition, many physicians now recognize that DTCA can provide their patients with important information and may serve as a means to encourage dialog about conditions that they might otherwise feel too embarrassed to discuss (Donohue, 2006; Finlayson & Mullner, 2005). In 2000, the AMA acknowledged that DTCA could "increase patient awareness about treatment options and enhance patient-physician communication" (Calfee, 2002). The AMA further conceded that "[a]dvertising directly to the public educates patients, enabling them to better understand and participate in medical care" (Calfee, 2002).

Pharmaceutical companies have similarly embraced direct-to-consumer advertising. Since the FDA relaxed its pharmaceutical advertising guidelines in 1997 (see the following section), the amount of money expended by drug companies on DTCA has risen exponentially from about $700 million in 1996 to a peak of $5.4 billion in 2006 (Bulik, 2011). In 2010, the industry spent about $4.3 billion, with nearly 60 percent of the resources dedicated to advertising drugs associated with the following conditions: stomach; sleep disorder; contraception; impotence; allergy and asthma; arthritis; heart, blood pressure, and cholesterol; and mental health (Bulik, 2011). Well over half of this amount was spent to advertise a mere 25 drugs (Bulik, 2011). Magazine advertising

accounted for roughly 30 percent of expenditures, while advertising on all forms of television outlets (including network TV, syndicated TV, cable TV, and spot TV) accounted for approximately 55 percent (Bulik, 2011). Advertising on the Internet accounted for about 5 percent of expenditures (Bulik, 2011). Figures 2-1 through 2-3 offer a graphical presentation of this information.

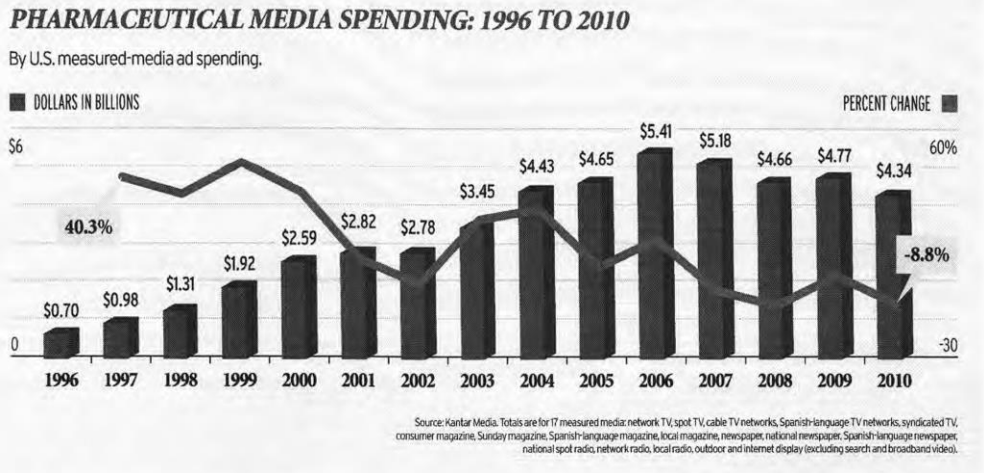

Figure 2-1: DTCA spending over time
(Bulik, 2011, p. 5)

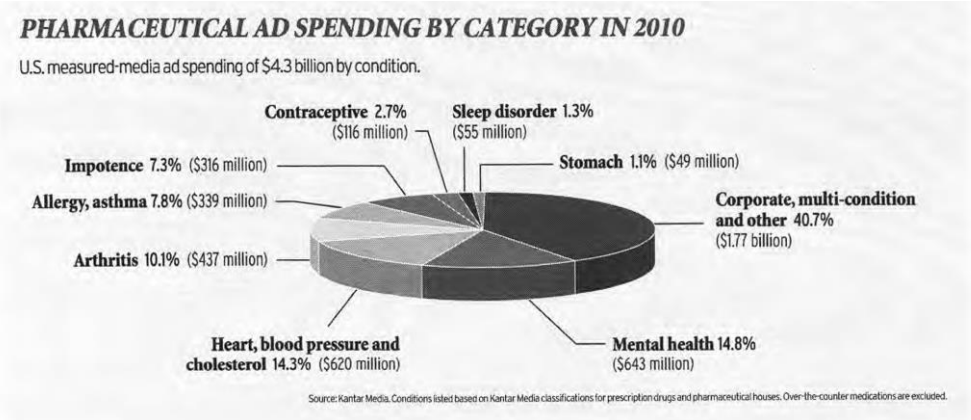

Figure 2-2: DTCA spending in 2010 by drug category
(Bulik, 2011, p. 7)

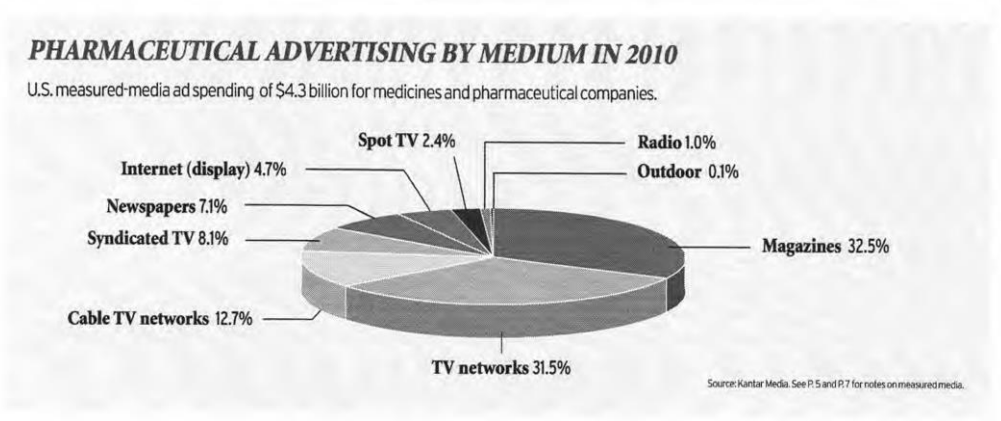

Figure 2-3: Percentage of DTCA spending in 2010 by medium
(Bulik, 2011, p. 9)

2.2 Regulating Pharmaceutical Advertising

Despite their popularity, the safety and efficacy of patent medications was questionable. Many of these concoctions contained less-than-healthful ingredients, such as alcohol, formaldehyde, mercury, and morphine (Silver & Stevens, 2009). In 1906, Congress passed the first of what would become a long string of laws aimed at regulating the promotion and distribution of pharmaceuticals. Figure 2-4 provides a timeline of Federal action, beginning with the 1906 Pure Food and Drugs Act and ending with the Food and Drug Administration Amendments Act (FDAAA) of 2007. Table 2-1 highlights the significant aspects of each piece of legislation, as well as actions taken by the FDA to specifically regulate DTCA.

As mentioned before, the issuance of the FDA's guidelines for broadcast advertisements led to a proliferation in the amount of DTCA to which consumers are exposed, as well as the amount of money spent on advertising aimed at the consumer by the pharmaceutical companies. Particularly relevant to the proposed study is the FDAAA of 2007. Section 901 of the Act requires the FDA to submit to Congress a report on the

ability of DTCA to communicate to subsets of the general population, including "racial and ethnic minority communities" (FDA, 2009, p. i). The Act went on to direct the Secretary of Health and Human Services as follows:

> The Secretary shall utilize the Advisory Committee on Risk Communication established under this Act to advise the Secretary with respect to such report. The Advisory Committee shall study direct-to-consumer advertising as it relates to increased access to health information and decreased health disparities for these populations. (FDA, 2009, p. i).

In this charge to the Secretary of Health and Human Services, Congress recognized the potential of DTCA to increase access to health information and decrease health disparities within specific population subsets. Inherent within this direction is the concern that DTCA may not be reaching these population subsets in a sufficient manner. In its report to Congress, the Secretary noted that "[r]esearch on DTC advertising of prescription medications has shown that this advertising can educate consumers about health issues" (FDA, 2009, p. iv). However, the Secretary further acknowledged that "research also shows that DTC advertising can have negative consequences and that improvements can be made to increase its effectiveness as a communication tool for population subgroups" (FDA, 2009, p. iv). The report provided a number of recommendations for enhancing the ability of DTCA to reach disadvantaged populations and called for further research into the potential impact of DTCA on "improving access to health information and reducing health disparities" (FDA, 2009, p. iv.).

Figure 2-4: A history of DTCA regulations

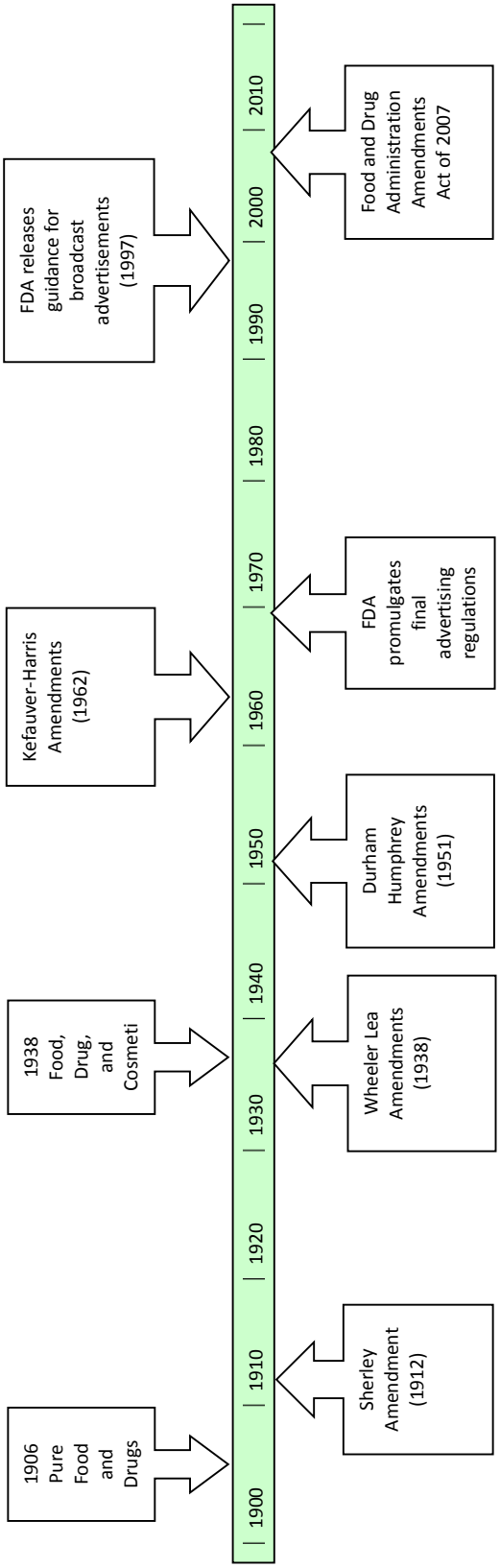

Table 2-1: Significant events in the history of DTCA regulation

Event	Purpose
1906 Pure Food and Drugs Act[1]	• Prohibited the sale across state lines of illegal food and drugs. • Implemented product labeling standards.
Sherley Amendment (1912)	• Prohibited drug labels from making inaccurate therapeutic claims.
1938 Food, Drug, and Cosmetic Act (FDCA)	• Established the Food and Drug Administration. • Required drugs to be safe and to be approved by the FDA before marketed. • Expanded drug labeling requirements.
Wheeler Lea Act (1938)	• Awarded the Federal Trade Commission (FTC) jurisdiction over drug advertising. • Exempted advertisements in medical journals from regulatory authority.
Durham Humphrey Amendments (1951)	• Created a "statutory definition" of prescription drugs.
Kefauver-Harris Amendments to the FDCA (1962)[2]	• Required that drugs be proven safe and effective before marketed. • Required that drugs meet a "high standard of scientific evidence." • Transferred regulatory authority over prescription drug advertising from FTC to FDA.
FDA Final Advertising Regulations (1969)	• Required advertisements to present "information in brief summary relating to side effects, contraindications, and effectiveness."[3] • Required advertisements to present a "fair balance" of information about the drug's benefits and side effects.[4] • Required print advertisements to include a "brief summary" conveying the risk information found in drug's package labeling.[5] • Required broadcast advertisements to convey a drug's major risks and provide a brief summary or make "adequate provision…for dissemination of the approved or permitted package labeling in connection with the broadcast presentation."[6]

Table 2-1: (continued)

Event	Purpose
FDA Draft Guidelines (1997) and Final Guidelines (1999) for Consumer-Directed Broadcast Advertisements	• Clarified the phrase "adequate provision." • Provided guidance on how advertisers could fulfill the adequate provision requirement. • Exempted certain advertisement types (reminder, help seeking) from regulatory requirements.
Food and Drug Administration Amendments Act (FDAAA) of 2007	• Requires FDA to report to Congress on DTCA and "its ability to communicate to subsets of the general population, including elderly populations, children, and racial and ethnic minority communities."[7]

[1] Unless otherwise noted, the majority of information presented in this table was taken from Donohue (2006) and Gellad and Lyles (2007).
[2] Donohue (2006), p. 670.
[3] FDA (1999), p. 1.
[4] Donohue (2006), p. 671.
[5] FDA (1999), p. 1.
[6] FDA (1999), p. 1.
[7] FDA (2009), p. i.

Among the recommendations contained in this report (FDA, 2009, p. 26), the following four are particularly applicable to the proposed study:

(1) Use communicators in the advertisements and channels to disseminate messages that the target populations rate as credible.

(2) Produce help-seeking or other ad campaigns concerning diseases and health issues that have particular relevance to the target community.

(3) Provide information about relevant nondrug interventions (e.g., diet and exercise) that patients should consider.

(4) Provide information on any available discounts or patient assistance programs that can help low income individuals obtain medications.

2.3 Theoretical Framework

Researchers from several disciplines have examined DTCA using the organizing frameworks common to their fields. In a review of the health policy literature, two models stand out as being particularly relevant to the proposed study. Both the health belief model and social cognitive theory have been used to evaluate the relationship of DTCA to health promotion (Duerksen et al., 2005; Mackert & Love, 2011; Young, Lipowski, & Cline, 2005). These models are used to explain health behaviors. Motivating individual health behavior is a complex union of a person's health beliefs, societal cues, and organizational influences that takes place within the context of an ever changing environment (Schommer & Hansen, 2005). Although this dissertation seeks to determine the effects of the FDA report recommendations on DTCA, the importance of these effects is determined by the role that DTCA plays in motivating health behavior. Thus, it is important to understand these models and the ways in which they have been used in previous studies of DTCA.

The health belief model, illustrated in Figure 2-5, was developed in the 1950s by the U.S. Public Health Service to explain why people did not participate in disease prevention and protection programs (Glantz, Rimer, & Lewis, 2002). The model is based

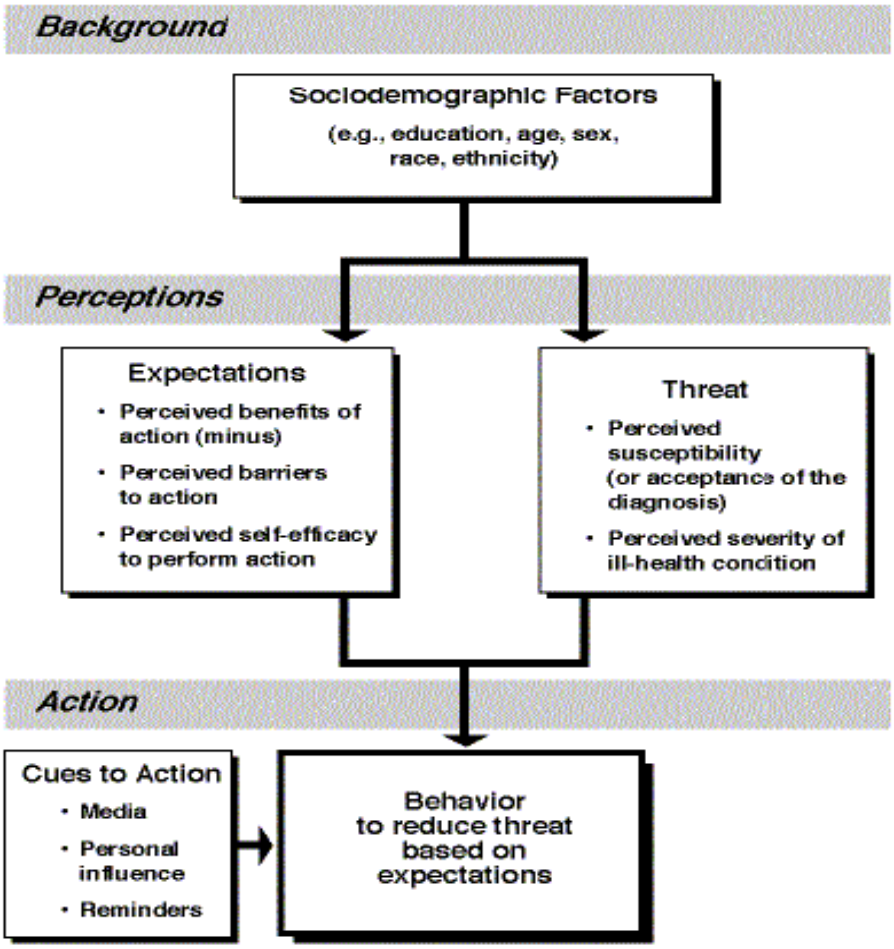

Figure 2-5: The health belief model

on the individual's perceived susceptibility to a disease, the perceived threat of the disease, and the perceived benefits to behavior change (Glantz et al., 2002). As Glantz et al. (2002) explain:

> people will take action to prevent, to screen for, or to control ill-health conditions if they regard themselves as susceptible to the condition, if they believe it would have potentially serious consequences, if they believe that a course of action available to them would be beneficial in reducing either their susceptibility to or the severity of the condition, and if they believe that the anticipated barriers (or costs of) taking the action are outweighed by this benefits. (pp. 47–48)

Mackert and Love (2011) compared the content of DTCA directly to the individual elements of the health belief model. They identified four key constructs of the

theory: "perceived susceptibility, perceived severity, perceived benefits, and perceived barriers" (Mackert & Love, 2011, p. 207). An analysis of 82 pharmaceutical advertisements within this framework revealed that the vast majority of advertisements provided information about perceived benefits and perceived barriers (98.8 percent included statements about both the clinical benefits of the advertised drug and its possible side effects). However, few (less than 20 percent) made statements associated with perceived susceptibility (e.g., population risk of a disease) or perceived severity (e.g., the consequences of the disease). These researchers acknowledged that DTCA does provide some useful information, but felt that it omitted some valuable educational material, such as information about disease prevalence (Mackert & Love, 2011).

The health belief model also recognizes that certain external cues, such as education, personal relationships, and the media, can motivate health behavior. Repeated exposure to pharmaceutical advertising can be a cue to action, sparking individuals to seek additional information either from their doctor or another media source, such as a Web site or hotline (Duerksen et al., 2005). Duerksen et al. (2005) noted that differences in knowledge about health risks, disease symptoms, and treatment options have been tied to racial disparities in health status. Their study of health-related advertising in women's magazines is based on the underlying premise of the health belief model that knowledge impacts "individual perceptions of health risk and the benefits of preventive action" (Duerksen et al., 2005, p. 2).

Duerksen et al. (2005) found fewer advertisements promoting healthy behaviors in magazines read by African American and Hispanic women than in magazines oriented towards Caucasian women. Advertisements promoting products with potentially

negative health consequences were more likely to feature African American models than Caucasian models. These results led the researchers to conclude the following:

> To the extent that individual levels of health education and awareness can be influenced by advertising, variations in the quantity, quality, and content of health-related information among magazines read by different ethnic groups may contribute to disparities in health behaviors and health status (p. 7).

Social cognitive theory, as illustrated in Figure 2-6, contends that behavior is a dynamic concept, dependent on an individual's environment and personal characteristics (Glantz et al., 2002). The continual interaction among personal factors, environmental influences, and behavior is known as "reciprocal determinism." Glantz et al. (2002) elaborate further:

> Behavior is not simply the result of the environment and the person, just as the environment is not simply the result of the person and behavior. Instead, these three components are constantly influencing each other. A change in one component has implications for the other. (p. 168).

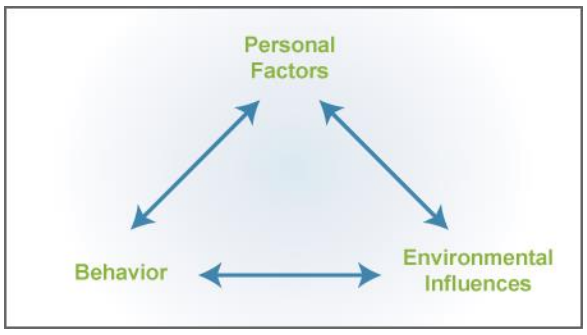

Figure 2-6: Social cognitive theory

Observational learning and role modeling are important components of the theory because individuals learn not only from their direct experiences, but also through watching the behavior of others (Young & Cline, 2005). Behavior change results when observed behaviors result in rewards that motivate actions (Cline & Young, 2004). However, behavior change is also based on an individual's belief about whether he or she is able to perform the behavior (Young et al., 2005). DTCA can be considered a channel through which "role modeling and reinforcement of behaviors are communicated to individuals" (Schommer & Hansen, 2005, p. 355).

In two separate studies, Young and Cline examined both the textual and visual cues contained within DTCA. Using social cognitive theory as their framework, they explain,

> From the perspective of social cognitive theory, DTCA must facilitate a complex social influence process in order to be effective (Cline & Young, 2004). Ads must both sell the product to consumers and motivate them to engage in appropriate, credible, and persuasive interaction with health care professionals (Young & Cline, 2005, p. 363).

These researchers looked at 225 unique pharmaceutical advertisements in 18 popular magazines. In their study of visual cues, Young and Cline (2004) found that ads tended to reinforce gender-based stereotypes. Half of the ads that featured women promoted drugs used to treat obstetric or gynecological problems or psychiatric disorders. In contrast, two-thirds of ads for cardiovascular drugs featured men only, although cardiovascular disease is the leading cause of death for both men and women. They also found that the race and ethnicity of the models used in the ads did not necessarily reflect the severity of the disease in minority populations. For example, although cardiovascular disease and cancer are the leading causes of death for Caucasians, African Americans,

and Hispanics, all of the ads for drugs used to treat these conditions featured white models only. However, African American models dominated ads for HIV/AIDs drugs, although less than 40 percent of AIDs patients in the United States are Black. These findings led Cline and Young (2004) to conclude the following:

> …beyond promoting social stereotypes lies the potential for DTCA's visual cues to reinforce already existing disparities in access to health information and, to the extent that ads promote visits to physicians, disparities in access to health care (p. 154).

Using the same database, Young and Cline (2005) also examined the textual cues contained in DTCA. They found that ads tended to focus on the positive attributes of the products they promoted by repeatedly referring to medical rewards, such as effectiveness, symptom improvement, and product superiority. They also found that the textual messages reinforced the relationship between the product advertised and positive identity characteristics, such as good health, normalcy, attractiveness, and self-empowerment. Textual cues often complement visual cues and together "paint an appealing picture of medications' users and the medical consequences of product use (Young and Cline, 2005, p. 364).

Kean and Prividera (2007) also used social cognitive theory as a framework in their examination of product ads placed in magazines with differing racial orientation. Although these researchers did not look specifically at pharmaceutical advertising, their work is relevant to the current study because they evaluated differences in the types of products advertised and the race of models used to advertise these products as a function of the racial orientation of the magazine in which the ads appeared. They based their research on the following construct grounded in social cognitive theory:

> African American women are likely to learn and execute behaviors from models with whom they identify and see as rewarded for particular behaviors. Based on this premise, the types of products, claims made regarding these products, and the visual images involved in selling these products may all act as models for behavior (p. 295).

Kean and Prividera (2007) found differences in the 141 advertisements they examined based on race. The black-oriented magazine (*Essence*) contained a far greater percentage of fast food advertisements (13 percent) than did the white-oriented magazine (*Cosmopolitan*). (From a public health perspective, this is concerning since obesity is a greater problem among more African American women than among non-Hispanic white women (CDC, 2013)—but that is a topic for another dissertation!) They also found fewer ads for weight loss products in the black-oriented magazine than in the white-oriented magazine. While these findings are not directly relevant to the current study, the methods and theoretical constructs employed helped to frame the research questions investigated and the research design used. In particular, the following observation underscores the importance that ad appearance and content can have to the educational and motivation value of DTCA:

> …an individual is more likely to imitate behaviors that are engaged in by models to whom the observer feels similar, who have qualities that the observer finds attractive, and/or who are rewarded for their behaviors. Therefore, print advertisements that included images of women the reader can relate or feel similar to, as well as print advertisements that make claims of reward or success due to product consumption, are more likely to be imitated through product liking and/or consumption (Kean & Prividera, 2007, p. 296).

2.4 DTCA: Education or Manipulation?

Evaluating consumer response to DTCA within the context of the health belief model and social cognitive theory presumes that pharmaceutical advertising has a

positive impact on improving health outcomes. Through this lens, DTCA is linked to changing expectations (the health belief model) and perceptions or personal factors (social cognitive theory) to motivate consumers to take actions that will enhance their health. Consequently, this dissertation focuses on the positive aspects of DTCA. However, many critics of DTCA argue that pharmaceutical advertising actually manipulates people's health beliefs causing consumers to seek unnecessary medical treatment (Finlayson & Mullner, 2005) and creating new disease categories (Conrad & Leiter, 2004). The debate over the relative merits of DTCA continues even as pharmaceutical advertising becomes more and more a part of our daily life. Three sources in particular offer a comprehensive, well-documented review of the literature. A recent text, *Advertising and Society: An Introduction*, edited by Carol J. Pardun, dedicates a chapter to direct-to-consumer pharmaceutical advertising (Barnes, Capella, Taylor, Treise, & Jung, 2014). Three essays within that chapter offer an argument against DTCA and two counterarguments in favor of its continued presence. Similarly, Auton (2004) and Ventola (2011) provide a critical review of existing research as each of these authors discuss the popular arguments for and against DTCA.

Many of the concerns about DTCA stem from its intended purpose which, like all advertising, is to encourage consumers to buy products (Pardun, 2014). Without a doubt, DTCA sells drugs. That is its intent, first and foremost, and that is what it does. Although proponents tout its educational value, critics argue that the information presented is incomplete, incomprehensible, and misleading (Rubinella, Nakamoto, & Schulz, 2007; Ventola, 2011). FDA regulations require a fair balance in an ad's discussion of benefits and side effects, the goal of which is to "prevent advertisers from

minimizing or hiding drug-associated risks and from overemphasizing drug benefits" (Davis & Meader, 2009, p. 57). The Pharmaceutical Research and Manufacturers of America (PhRMA) has adopted a set of voluntary guidelines consistent with the FDA regulations that call for DTCA to present accurate, balanced, and well-supported information about a drug's intended risks and benefits (Arnold & Oakley, 2013). However, some studies have demonstrated that this is often not the case (Ventola, 2011; Macias, Pashupati, & Lewis, 2007), and FDA enforcement of its own regulations is inadequate (Government Accountability Office, 2006). However, Arnold and Oakley (2013), in their study of television advertising for erectile dysfunction medications, found that most of the ads evaluated met the requirement that major risks be discussed.[3]

The level of health literacy necessary to fully understand the information presented in DTCA is another major concern. Several studies have evaluated literacy levels required by pharmaceutical advertising (Kaphingst, Rudd, DeJong, & Daltroy, 2004; Kaphingst, DeJong, Rudd, & Daltroy, 2004; Mackert & Love, 2011; Arnold & Oakley, 2013). The general consensus of these studies has been that information contained within DTCA is often written at a reading level above what is usually recommended for materials intended for the general public (Ventola, 2011). In particular, information contained in the brief summary was found to require a reading ability at the college or graduate-school level (Kaphingst, Rudd, DeJong, & Daltroy, 2004).

[3] However, Arnold and Oakley (2013) found many areas of noncompliance with the industry's guidelines resulting in children being "exposed to a total of over 100 billion erectile dysfunction impressions via television commercials during the period of study" (p. 532).

Concerns have also been expressed that DTCA implies that drugs alone are the key to improving one's health, thereby discounting the value of health–promoting lifestyle changes (Auton, 2004; Ventola, 2011).[4] Few ads suggest alternatives to medication and may lead consumers to reject recommendations about diet and exercise as unnecessary (Ventola, 2011). Overprescribing is another oft-cited issue. Doctors may feel pressured by their patients to prescribe a particular drug or risk losing them to another practitioner (Auton, 2004; Hollon, 2005; Ventola, 2011). Or, they may be more likely to put a patient on a requested drug rather than encouraging alternative, nonmedical therapies that may be equally effective (Angell, 2005). Rather than encouraging a meaningful dialog between a physician and patient, DTCA may strain that relationship by placing the two at odds over a prescription request (Ventola, 2011).

The economic consequences of overprescribing as a result of DTCA have been explored by Hausman (2008), Block (2007), and Mintzes et al. (2003) among others. Advertising tends to be heaviest for newer, more expensive drugs for which pharmaceutical companies retain their patents regardless of whether they are more effective than older therapies (Avorn, 2003). Singh and Smith (2005) cite a 2003 study by the Kaiser Family Foundation which demonstrated a 1 percent increase in pharmaceutical sales for every 10 percent increase in DTCA. In an increasingly medicalized society, DTCA fuels the demand for "a pill for every ill" (Moynihan & Cassels, p. 103) and has led to accusations of disease mongering—creating an illness solely for the purpose of selling more drugs (Moynihan & Henry, 2006). Some studies have concluded that DTCA leads to an increase in prescriptions for the advertised

[4] See Stokes (2005) for an interesting discussion of the "pharmaceutically empowered consumer."

medications, which in turn leads to increased societal costs (Mintzes et al., 2003; Wosinska, 2002). Block (2007) cautions, however, that such costs must be evaluated against the benefits associated with addressing previously untreated or undertreated disease.

The strongest arguments in favor of DTCA rest on the notion that DTCA does lead people to discuss advertised drugs with their physicians. Research demonstrates that DTCA has empowered the patient to engage in conversations with their physicians about their health (Bell et al., 1999; Allison-Ottey, Ruffin, & Allison, 2002; Deshpande, Menon, Perri, & Zinkhan, 2004; White, Draves, Soong, & Moore, 2004; Porter, 2011). Weissman, Blumenthal, Silk, Zapert, Newman, and Leitman (2003) found that 35 percent of the 3,000 individuals they interviewed had been motivated by DTCA to discuss a drug or medical condition with their physician. Advertisements for potentially embarrassing, but serious health problems, can encourage patients to overcome the stigma associated with such conditions and talk with their physician about their symptoms. Auton (2004) provides two examples:

> The Merck campaign for Proscar—a treatment for benign prostatic hyperplasia—is widely regarded as having been successful in raising awareness about a medical condition that men were reluctant to discuss with their doctor. In 1997 a drug campaign was run for treatment for genital herpes thought to be affecting up to 45 million people in the USA. In a survey of those responding to a toll-free number, 45% claimed to have visited their physician within three months of seeing the campaign (p. 32).

And we all know the story of the little blue pill. An aggressive marketing by Pfizer, the manufacturer of Viagra, led to 2.9 million prescriptions being written within its first three months on the market (Conrad & Leiter, 2004).

One advantage to patients being more active in their health care decisions is the greater likelihood that they will comply with their medication regimens (Deshpande et al. 2004; White et al., 2004). Ventola (2011) report the results of a 2004 FDA survey in which one-third of physicians stated that DTCA increased medication compliance among their patients. A similar study by Harvard University, Massachusetts General Hospital, and Harris Interactive also reported that 46 percent of physicians credited DTCA with increasing patient compliance (Ventola, 2011). A third study reported by Ventola (2011) found that patients who requested and received a prescription from their doctor after seeing DTCA were "the most compliant of any group tested" (Ventola, 2011, p. 673).

DTCA may also reduce the underdiagnosis and undertreatment of medical conditions (Ventola, 2011). For example, several studies have been done to determine the effect of DTCA on the diagnosis and treatment of depression. Donohue, Berndt, Rosenthal, Epstein, and Frank (2004) examined the treatment patterns of over 30,000 depressed individuals using insurance claims filed between 1997 and 2000. They found that antidepressant DTCA may encourage a depressed individual to seek medication therapy but has no effect on medication adherence (Donohue et al., 2004). Bell, Taylor, and Kravitz (2010) surveyed 148 members of a depression forum and found that, while DTCA increased awareness of antidepressants, most survey respondents expressed ambivalence toward the ads themselves. However, almost 40 percent of respondents indicated that they had initiated "some form of conversation with their doctor due to an advertisement" (Bell et al., 2010, p. 248).

A 2002 national survey of individuals exposed to DTCA found that, among those who sought out their physicians based on seeing a pharmaceutical ad, 25 percent were

diagnosed with a condition of which they were previously unaware (Weissman et al., 2003). New diagnoses included such serious conditions as hypertension, diabetes, and depression (Weissman et al., 2003). Meade-D'Alisera, Merriweather, and Wentland (2001) noted the value of DTCA in raising awareness of urinary incontinence and encouraging individuals to seek treatment. A study of women exposed to DTCA for drugs used to treat postmenopausal osteoporosis were significantly more likely to seek out and receive bone density tests (Hollon, Larson, Keopsell, & Downer, 2003). Mastin et al. (2007) conclude that the "repetitive nature of DTCA may serve as a valuable tool to create awareness regarding underdiagnosed diseases" (p. 57), leading those who see such advertising to consult with their health care providers more often than those who do not.

While patients are more empowered by DTCA, there is nothing to suggest that the professional prerogative of physicians has been compromised. Using a nationally representative survey of 21,000 adults, White et al. (2004) concluded that DTCA has "little to no disruptive effect on the doctor-patient relationship" (p. 57). While the relationship remains unchanged, the discussion may differ as better informed patients engage their physicians in conversations about their health (White et al., 2004). Ultimately, however, the physician remains the "final arbiter of patient care" (White et al., 2004, p. 58). In addition, DTCA offers physicians some advantages. Increased patient participation may result in more focused interactions and lessen the time constraints that many physicians feel (Deshpande et al., 2004). Doctors may choose to prescribe advertised drugs because patients might be more adherent or more aware of the benefits of a particular drug (Hausman, 2008). Similarly, a physician might prescribe an

advertised drug knowing that future exposure to DTCA could serve as a reminder to take the medication or refill a prescription (Hausman, 2008).

Despite legitimate concerns, DTCA is likely to remain a key way that individuals learn about medical conditions and potential therapies. As Avery, Kenkel, Lillard, Mathios, and Wang (2008) point out, "[t]he public health implications of DTC advertising depend upon its ultimate impact on medical treatment, health behaviors, and health outcomes" (p. 15). Its ability to reduce health disparities by increasing access to information among ethnic or racial minority populations has been recognized by the National Medical Association (NMA). In a survey of its members, 90 percent of physicians responding reported that their patients were prompted to ask their medical opinion based on seeing a pharmaceutical advertisement (Allison-Ottey, Ruffin, & Allison, 2002). Seventy-two percent were asked for a particular treatment based solely on an ad (Allison-Ottey, Ruffin, & Allison, 2002). Most importantly, a majority of physicians felt that DTCA was a benefit to their patients, "particularly as it relates to education regarding disease states" (Allison-Ottey, Ruffin, & Allison, 2002, p. 201).

As mentioned earlier, the focus of this dissertation is on the positive aspects of DTCA. However, it would be irresponsible not to acknowledge the potential negative consequences to an individual and to society as a whole if DTCA manipulates people into taking a drug that they do not need for a condition that they do not have. Although physicians, as well as insurance companies, serve as moderators between the pharmaceutical company and consumers (presumably only prescribing and paying for medically necessary medications), research demonstrates that DTCA leads to increased prescription rates (Finlayson & Mullner, 2005). In some cases, DTCA has led to an

expansion in prescribing patterns to encompass individuals whose need for the drug would once have been considered marginal (Avorn, 2003). Consequently, concerns that DTCA inspires unnecessary and potentially dangerous uses of prescription medications should not be minimized (Singh & Smith, 2005).

2.5 Previous Content Analyses of DTCA

A number of previous content analyses have evaluated various aspects of DTCA to determine whether differences exist in the advertisements placed in magazines aimed at disparate audiences. Because the current study is limited to print magazines, the most relevant research also focused on analyzing the content of print ads. The results of content analyses of pharmaceutical advertising appearing in other forms of media, such as television and Internet, were considered less pertinent, but such studies were reviewed as a means of honing research questions and refining research methods.

A comprehensive review of the literature revealed 12 content analyses of DTCA found in magazines tailored to a broad range of audiences. One additional content analyses of advertisements for consumables (e.g., food, drink, vitamins, and supplements) was included because it focused on differences in advertising placed in magazines targeted to two racially diverse audiences (Blacks and Whites). Thus, it was deemed relevant to the current study.

Appendix B discusses in detail each of these studies. This section provides an overview of previous research and highlights ways in which the current study builds upon and extends this earlier work. Researchers varied the magazines evaluated, the time periods examined, and the methods used. All of these studies found some difference in the advertising that appears in magazines targeted to a general audience and those

targeted to a specific population subset, such as African Americans, women, or the elderly.

Taken together, these studies reveal the following:

- All magazines evaluated contained DTCA (with the exception noted above). Nearly 1,600 magazine issues were reviewed, with the earliest issues being published in 1989 and the latest in 2007.
- The amount of pharmaceutical advertising found in magazines grew dramatically during this time, with the greatest amount of growth reported in magazines targeted to African Americans (Mastin et al., 2007).
- Women were more likely to be targeted than men (Abel, Lee, & Weeks, 2007; Woloshin, Schwartz, Tremmel, & Welch, 2001; Bell, Kravitz, & Wilkes, 2000)
- Several studies found that magazines targeted to a black audience had significantly less health-promoting advertising (including DTCA) than magazines read by a predominately white audience (Omonuwa, 2001; Duerksen et al., 2005; Kean & Prividera, 2007). One study (Crawley, Hisaw, & Iles, 2009) did not report a difference in ad volume based on magazine audiences.
- White models were used more frequently than black (or other minority) models (Main, Argo, and Huhmann, 2004; Duerksen et al. 2005). Mastin et al. (2007) found that ads in magazines targeted to African Americans were more likely to feature African American models than ads in magazines targeted to a Caucasian audience.
- The type of drugs advertised varied as a function of the magazine's target audience. African American magazines were less likely to include advertisements

for drugs used to treat the most prevalent diseases within the African American community (Crawley, Hisaw, and Iles, 2009; Mastin et al., 2007; Duerksen et al., 2005; Cline & Young, 2004; Omonuwa, 2001).

- Common appeals included medication effectiveness, convenience, symptom control, and innovativeness (Bell, Kravitz, & Wilkes, 2000; Abel, Lee, & Weeks, 2007). Main, Argo, and Huhmann (2004) found that emotional appeals, which were more common, could be either positive or negative. Pinto (2000) reported that the type of appeal did not vary with the type of drug advertised.

The studies described above all point to differences in the appearance and content of pharmaceutical advertising based on a magazine's intended audience. Given the potential that DTCA has to narrow health disparities by improving information access, any differences should be biased towards increasing knowledge among racial and ethnic minority populations. However, these results do not appear to suggest this. Since the last DTCA reviewed in the literature was published in 2007, we cannot be sure what strides, if any, have been made to reach these underrepresented populations.

2.6 Conclusion

The study reported in this dissertation closes several key gaps in the existing literature. First, the study updates the literature by examining DTCA published as recently as 2012 (the last DTCA looked at by previous researchers was published in 2007). The current study evaluates the impact on DTCA of the 2009 FDA report, which was issued in response to Section 901 of the FDAAA of 2007, with its focus on increasing access to health information and decreasing health disparities among racial and ethnic minority populations. Using both qualitative and quantitative methods, the

study uncovers trends in the frequency of DTCA, as well as its appearance and content, as a function of a magazine's racial orientation. DTCA published before the 2009 FDA report is compared to DTCA published after the report to determine whether the pharmaceutical industry has made efforts to better tailor their advertising campaigns to enhance the educational and motivational value of DTCA, particularly among readers of black-oriented women's magazines.

CHAPTER 3: THE FREQUENCY AND TYPE OF PHARMACEUTICAL ADVERTISING IN WOMEN'S MAGAZINES

The differences in health status between Blacks and Whites in the United States is well documented. The Centers for Disease Control and Prevention (CDC) reported in 2011 that African Americans fare more poorly than Caucasians on virtually all health outcome measures, with the exception of motor-vehicle-related deaths (CDC, 2011). African Americans, as well as other minorities, have less access to health care and preventive services, are more likely to live in unhealthy housing and breathe unhealthy air, and are at greater risk for developing a chronic disease than Caucasians (CDC, 2011). Consequently, the life expectancy for African Americans is 3.8 years less than for Caucasians based on 2010 data (Murphy, Xu, & Kochanek, 2013).

While direct-to-consumer pharmaceutical advertising remains a hotly debated topic, its potential to impact health disparities has been recognized by a number of researchers (Fry et al., 2007; Avery et al., 2008; Ball, Liang, & Lee, 2009; Crawley, Hisaw, & Illes, 2009; Young & Eckrick, 2013). Numerous studies have reported a high degree of awareness of pharmaceutical advertising among those surveyed (Bell, Kravitz, & Wilkes, 1999; Calfee, 2002; Weissman, et al., 2003; Aiken, Swasy, & Braman, 2004; Thomaselli, 2006; Lee & Begley, 2010), as well as a tendency to discuss advertised drugs with their doctors (Allison-Ottey, Ruffin, & Allison, 2003; Weissman et al., 2003; Thomaselli, 2006).

Recognizing the potential of DTCA to increase access to health information and decrease health disparities within specific population subsets, including "racial and ethnic minority communities" (FDA, 2009, p. i), Congress directed the FDA to determine whether DTCA was reaching such populations in a sufficient manner. In its report back to Congress, the FDA noted that "[r]esearch on DTC advertising of prescription medication has shown that this advertising can educate consumers about health issues" (FDA, 2009, p. iv). However, the report did acknowledge that "research also shows that DTC advertising can have negative consequences and that improvements can be made to increase its effectiveness as a communication tool for population subgroups" (FDA, 2009, p. iv). The report provided a number of recommendations for enhancing the ability of DTCA to reach disadvantaged populations and called for further research into the potential impact of DTCA on "improving access to health information and reducing health disparities" (FDA, 2009, p. iv).

Pharmaceutical advertising is big business. In 2010, the industry spent about $4.3 billion on advertising a variety of drugs to treat a myriad of diseases. While television advertising claimed the largest percent of these expenditures (approximately 55 percent), magazine advertising remained strong, with slightly more than 30 percent of the industry's advertising budget devoted to this media outlet. A recent study published by the Association of Magazine Media (MPA) found that 91 percent of adults surveyed had read at least one magazine during the previous six months (MPA, 2013). African Americans read more magazine issues per month (14.6) than the average number of issues (10.0) read by all U.S. adults (MPA, 2013). Critical to this study is the finding that

magazine readers are more likely to have discussed an ad seen in a magazine with their doctors than one seen on television (MPA, 2013).

This chapter examines differences in the amount of pharmaceutical advertising found in five popular women's magazines as a function of the magazine's racial orientation. The types of drugs advertised are compared as well. Particular emphasis is given to changes in the frequency of advertising and the type of drugs advertised in magazines published before and after the 2009 Food and Drug Administration's (FDA's) report to Congress. By comparing differences in pharmaceutical advertising placed in magazines published before and after the FDA report, this chapter will provide the first insight into whether or not drug manufacturers have responded to the FDA's recommendations. The chapter begins with an overview of previous research in this area (Section 3.1). Section 3.2 discusses the methods used to select the magazines surveyed and to identify the pharmaceutical advertising found within each issue. Section 3.3 describes the types of statistical analyses used, and Section 3.4 presents the results of these analyses. Section 3.5 provides a detailed discussion of the observed differences in both the frequency of advertisement placement and the types of drugs advertised. Section 3.6 offers some final observations and draws conclusions as to the impact of the FDA report on the amount and type of pharmaceutical advertising placed in the five women's magazines reviewed.

3.1 Background

A number of content analyses have been conducted on pharmaceutical advertising appearing in print magazines. Of the 13 discussed in Chapter 2 and summarized in Appendix B to this dissertation, one-third directly examined differences in DTCA based

on the racial orientation of the magazine (Crawley et al., 2009; Duerksen et al., 2005; Mastin et al., 2007; Omonuwa, 2001). Of these, most found that white-oriented magazines contained a substantially larger proportion of DTCA than black-oriented magazines. For example, Duerksen et al. (2005) found that 76 percent of the prescription drug ads identified in their sample were placed in the mainstream white-oriented magazines analyzed. Similarly, Omonuwa (2001) found that white-oriented magazines had an average of 10.1 pharmaceutical ads for the three months included in his study, while the black-oriented magazines averaged only 1.6 during the same period. Only Crawley et al. (2009) did not find a significant variation in the number of ads placed based on the racial orientation of the magazine.

However, Crawley et al. (2009) did find differences in the type of drugs advertised as a function of the magazine's target audience. Advertisements for drugs to treat life-threatening conditions and mental health conditions were more likely to appear in white-oriented magazines. Advertisements for drugs to treat infectious disease and nonlife-threatening chronic diseases were more likely to appear in black-oriented magazines. Omonuwa (2001) also found a difference in the types of drugs advertised as a function of the magazine's target audience. Unlike readers of white-oriented magazines during the study period, readers of black-oriented magazines were not exposed to ads for drugs used to treat Alzheimer's disease, constipation, depression, dyspepsia, high cholesterol, joint pain or inflammation, menopause, osteoporosis, tobacco abuse, or weight reduction. Readers of white-oriented magazines were not exposed to advertisements for drugs to treat human immunodeficiency virus (HIV) or contraceptive drugs.

Recognizing the potential for DTCA to improve information access and reduce health disparities, the FDA report includes the following two recommendations relevant to the types of drugs advertised and the frequency with which these ads appear in magazines:

(1) "Use communicators in the advertisements and channels to disseminate messages that the target populations rate as credible" (FDA, 2009, p. 26).

(2) "Produce help-seeking or other ad campaigns concerning diseases and health issues that have particular relevance to the target community" (FDA, 2009, p. 26).

Based on these recommendations, pharmaceutical companies should shape their advertising campaigns to better inform those that see them by placing print ads in magazines that are commonly read by the targeted population, by running television ads during shows that are commonly watched by the targeted population, and by using the Internet and social media to reach the targeted population as appropriate. Ads should feature models or celebrity spokespeople to which the target audience can relate, and the drugs advertised should treat diseases common to the target audience. In this way, pharmaceutical companies can fulfill their commitment to "promote health and disease awareness as part of their DTC advertising" and "responsibly educate the consumer about that medicine and, where appropriate, the condition for which it may be prescribed." (These excerpts were taken from Pharmaceutical Research and Manufacturers of America, "PhRMA Guiding Principles: Direct to Consumer Advertisements about Prescription Medicines," as quoted in Arnold and Oakley, 2013).

To evaluate the impact of these recommendations on DTCA appearing in women's magazines published before and after the report, this chapter will address the following research questions identified in the first chapter of this dissertation:

RQ1: Does the frequency of pharmaceutical advertising vary based on the racial orientation of the magazine?

RQ2: Did the frequency of pharmaceutical advertising appearing in black-oriented women's magazines increase following the 2009 FDA report?

RQ3: Do the types of drugs advertised vary by the racial orientation of the magazine?

RQ4: Have the types of drugs advertised become more concordant with the health risks of the race of the magazine's readers following the 2009 FDA report?

If pharmaceutical companies were to have adopted these recommendations, one would expect to see an increase in the amount of DTCA placed in magazines read by black women and a shift in the types of drugs advertised to better align them with the diseases of greatest concern to the black community.

3.2 Data Collection

Five women's magazines were selected for the study based on previous research and current circulation figures. The study focuses on women's magazines because women tend to make the medical decisions for their families (Abel et al., 2007; Mastin et al., 2007). In 2003, the Kaiser Family Foundation reported that mothers "play a key role in coordinating and ensuring access to health care for their children" (Kaiser Family Foundation, 2003, p. 4). They also "assume an important role as caregivers of relatives who are sick, disable, or elderly" (Kaiser Family Foundation, p. 4) A 2010 article that appeared in *Time* magazine noted that, in two-thirds of U.S. households, women are the

primary health care decision makers (Kluger, 2010). Furthermore, earlier researchers found that women's magazines contain more DTCA than other magazine genres and women, rather than men, are more likely to pay attention to these ads (Mastin et al., 2007).

Duerksen et al. (2005) identified *Family Circle* and *Good Housekeeping* as the top two women's magazines read by a predominantly white audience and *Ebony*[5]and *Essence* as the top two magazines read by a predominantly black audience based on 2002 circulation rates. Current circulation figures (second half of 2013) indicate that *Good Housekeeping* and *Family Circle* are the second and third most widely circulated women's magazines read by a predominantly white audience,[6] and *Ebony* and *Essence* remain the top two magazines read by black women (Alliance for Audited Media, 2013). A fifth magazine, *O, The Oprah Magazine*, which is read by both black and white women was selected as an additional point of comparison. Table 3-1 summarizes the relevant demographic information of the magazines selected for the study.

[5] Although *Ebony* may not be considered a "women's magazine," many of its articles and the majority of its advertising is aimed at female readers. For example, in the magazine issues reviewed for this study, non-DTCA advertising included numerous promotions for hair products, cosmetics, and women's clothing. Recipes and parenting tips were often included in each issue. Articles frequently focused on style trends, relationships, and other content characteristic of women's magazines.

[6] The most widely circulated women's magazine is *Better Homes and Gardens* with a circulation rate of 7,615,581. However, this magazine has a home-focused orientation and was therefore not considered appropriate for the purposes of this study.

Table 3-1: Readership demographics

Magazines	Paid Circulation[1]	%Female[2]	%White[2]	%Black[2]	Median[2] Age	Median Household Income[2]
Ebony	1,280,350	65	10	90	42.5	54,240
Essence	1,060,774	75[3]	6[3]	92[3]	43.3	40,800
Family Circle	4,092,525	100	89[3]	9[3]	53.0	60,074
Good Housekeeping	4,348,641	90	74	11	55.4	63,300
O, The Oprah Magazine	2,386,601	87	64	30	49.9	66,900

[1] Circulation averages for the six months ended December 31, 2013. Source: Alliance for Audited Media, December 31, 2013.
[2] Except where noted otherwise, data were taken from the 2014 media kits for each magazine.
[3] Source: Duerksen et al., 2005. Data reported are for fall 2000. Although these data could be considered outdated, there is no reason to suspect that these percentages would be significantly different today.

To determine whether the 2009 FDA report had an effect on the types of drugs advertised and the placement of DTCA in the selected magazine titles, issues dated January 2008 to December 2009 (i.e., the "before FDA report" period) were compared to issues dated January 2011 to December 2012 (i.e., the "after FDA report" period). Because the FDA report was published in September 2009, magazine issues published in 2010 were excluded from the study sample. It was assumed that pharmaceutical companies would need some period of time to implement the FDA report recommendations in their ongoing advertising campaigns.

Back issues of magazines were purchased either from individuals advertising on EBay or from oldmags.com, a commercial vendor located through the Internet. The integrity of each magazine issue was verified, and magazines with missing pages were replaced. For the most part, each magazine title was published 12 times a year.

However, in 2008 and 2009, *Family Circle* was published a total of 15 times with two issues published in April, October, and November. For these years, the first issue published within a given month was included in the study population. In the case of *Ebony*, only 11 issues were published in 2009, 2011, and 2012. The study population consisted of a total of 237 individual magazine issues representing the primary monthly issue of each magazine title.[7]

Data collection comprised a three-step process. The first step consisted of manually counting each magazine page.[8] The inside front cover, as well as the inside and outside back cover, was included in the count since these pages featured some form of advertising. Next, the total number of advertising pages was counted. Finally, the total number of DTCA pages was counted. Full-page advertisements were counted as one page; if a portion of a page included an advertisement, no matter what the size, then the page was counted as a one-half page advertisement. Advertisement inserts that were significantly smaller than the standard magazine page, such as coupon booklets, were excluded from all counts.

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[7] Recognizing that my study population is incomplete, I intend to collect data from the six magazine issues omitted from the current research.

[8] I discovered early on that the way in which a magazine is paginated does not reflect the actual number of pages in the issue. For example, some magazines do not assign page numbers to multi-page advertising spreads. For the purposes of this research, it was imperative that the magazine page counts were accurate. I achieved this by manually counting each page. To ensure accuracy in page counts, all 48 issues of *Family Circle* were double counted. When differences in page counts occurred, the issue was triple counted and the two matching pages counts were used. Initially, nearly half the magazines had to be recounted because of slight differences (i.e., a single page or less) in either total page counts or total advertising page counts. No differences were observed in the DTCA page counts. After adopting the use of a rubber fingertip and creating a code sheet on which I tallied the number of magazine pages, the number of advertising pages, and the number of DTCA pages, the number of issues needing to be triple counted went to zero. Consequently, issues of *Ebony*, *Essence*, *Good Housekeeping*, and *O, The Oprah Magazine* were counted only once. However, given the sizeable number of magazine pages counted (nearly 49,000), any remaining error in page count would be randomly distributed and unlikely to affect the study results. (The number of magazines pages counted was computed by multiplying the average number of pages per issue (205) by the number of issues examined (237)).

The DTCA page count included both product claim ads and help-seeking ads. In nearly all cases, product claim ads included the FDA-required product information (i.e., the "brief summary") and were thus easily identifiable. Mastin et al. (2007) also used the presence of this information to identify ads used in their study. Help-seeking advertisements mentioned a particular medical condition, such as macular degeneration, but did not identify a particular drug. Only those help-seeking ads sponsored by a pharmaceutical company were included in the DTCA count. No reminder ads appeared in the study sample.

Each magazine issue was assigned a unique identification number, and the following information was recorded on individual code sheets:

- ID #
- magazine name
- publication date
- number of pages
- number of advertising pages
- number of DTCA pages
- percent of advertising pages
- percent of DTCA as a function of total magazine pages
- percent of DTCA as a function of total advertising pages

In addition, each pharmaceutical advertisement that appeared within a particular magazine issue was assigned a unique identification number, and the name and manufacturer of the drug, the page number on which the ad appeared, and the medical condition for which the drug is to be used was recorded. These data were then entered

into a database for further analysis. In addition, variables were included to identify the racial orientation of the magazine and whether the publication date fell before or after the FDA report date.

3.3 Data Analysis

The unit of analysis for the data presented in this chapter is the individual magazine issue. Version 22 of the Statistical Package for the Social Sciences (SPSS) was used for all statistical analyses. Data were compiled by year for each magazine title, and descriptive statistics were used to ascertain the means for each magazine title and year for the following variables:

- total number of magazine pages
- total number of advertising pages
- total number of advertising pages dedicated to DTCA
- percent of advertising pages as a function of total magazine pages
- percent of DTCA as a function of total magazine pages
- percent of DTCA as a function of total advertising pages

To account for the fewer number of issues of *Ebony* magazine published in 2009, 2011, and 2012, as well as the variability in the number of pages per magazine issue, a further calculation was performed. In a method similar to that employed by Crawley et al. (2009), the density of DTCA was standardized by dividing the total number of pharmaceutical ads appearing in a given year by the total number of magazine pages for that year and multiplying by 100. This calculation was repeated for every magazine title for each publication year.

Since the study focuses on the difference between black- and white-oriented magazines, rather than the difference between individual magazine titles, the data collected from *Ebony* and *Essence* magazines were collapsed into a single category, "Black-Oriented Magazines," and the data for *Family Circle* and *Good Housekeeping* were collapsed into a single category, "White-Oriented Magazines." Data from *O, The Oprah Magazine* were categorized as "Crossover Magazine." Similarly, since the study's goal is to discern whether a significant difference exists in the frequency of DTCA before and after the FDA report was issued, the data collected from issues published before the FDA report (i.e., 2008 and 2009) were collapsed into a single category, "Before FDA Report," and the data collected from issues published after the FDA report (i.e., 2011 and 2012) were collapsed into a single category, "After FDA Report."

To respond to RQ1, data were filtered by racial orientation to allow the frequency of pharmaceutical advertising to be compared based on the racial orientation of the magazine. Means were calculated for each publication year. To respond to RQ2, data were sorted by the relationship of the magazine's publication date to the FDA report date (i.e., "before" or "after"). This allowed data from magazines published before the FDA report to be compared to data from magazines published after the FDA report to determine whether the report recommendations had resulted in an increase in the amount of DTCA appearing in black-oriented women's magazines. Independent sample t-tests were used to evaluate the significance of differences in means.

Descriptive statistics were also used to characterize all DTCA found in the 237 magazine issues reviewed. For the product claim ads, the name of each drug was identified, as well as the medical condition for which it was intended to treat. Since

help-seeking ads do not mention a particular drug, these ads were characterized by medical condition only. Medical conditions were then grouped into the following 16 categories based on the work done by Bell et al. (2000):

- Allergies
- Cancer
- Cardiovascular
- Cosmetic
- Dermatological
- Diabetes
- Gastrointestinal/Nutritional
- Infections (Non-HIV)
- Musculoskeletal
- Obstetric/Gynecological
- Ophthalmological
- Psychiatric/Neurologic
- Respiratory
- Tobacco Addiction
- Urological
- Other

Minor adjustments were made to the categories identified by these researchers. Specifically, the category entitled "Dermatologic" was split into two: "Dermatologic" and "Cosmetic" to distinguish between those drugs used to treat serious dermatological conditions, such as psoriasis, and those used for cosmetic purposes, such as reducing fine

lines and wrinkles. The category "HIV/AIDS" was omitted because no advertisements appeared for drugs used to treat this medical condition. A new category, "Ophthalmological," was created to capture drugs used to treat chronic dry eyes. A final category "Other" comprises any medical condition not otherwise categorized.

To address RQ3 and RQ4, which relate to the types of drugs being advertised, frequency distributions were obtained for the name of the drugs advertised and the medical conditions treated. As described previously, data were collapsed to create three categories for racial orientation: black-oriented magazines, white-oriented magazines, and crossover magazine. Publication data were also collapsed to allow a comparison of drug types advertised before and after the issuance of the FDA report. Because of the relatively small number of ads in many of the above categories, the mean of each category was not computed. Instead, the trends in these data were identified, and these trends were then considered within the context of the FDA report recommendations.

3.4 Results

Every issue of the white-oriented magazines (n=96) contained at least one pharmaceutical advertisement. Four issues of *Ebony* (n=45) and six issues of *Essence* (n=48) lacked DTCA. Only one issue of the crossover magazine (n=48) did not include a single pharmaceutical ad. A total of 1,163 pharmaceutical advertisements were identified; of these, 1,090 were product claim ads and 73 were help-seeking ads. Tables 3-2 and 3-3 present the number of ads of each type appearing in each magazine title by publication year. Examining Table 3-2, we can see that the greatest number of product claim ads were placed in 2008, while the fewest were placed in 2012. Note also that the number of ads varied only slightly between issues in the same magazine genre

(i.e., 88 ads in *Ebony* versus 83 in *Essence*; 378 in *Family Circle* versus 370 in *Good Housekeeping*).

Table 3-2: Product claim advertisements

Year	Ebony	Essence	Family Circle	Good Housekeeping	O, The Oprah Magazine	Total
2008	32	24	85	111	56	308
2009	21	19	105	96	27	268
2011	23	23	97	95	54	292
2012	12	17	91	68	34	222
Total	88	83	378	370	171	1,090

By contrast, the number of help-seeking ads increased from 16 in 2008 and to 27 in 2012, as seen in Table 3-3.

Table 3-3: Help-seeking advertisements

Year	Ebony	Essence	Family Circle	Good Housekeeping	O, The Oprah Magazine	Total
2008	2	2	4	7	1	16
2009	1	2	8	3	0	14
2011	3	0	3	6	4	16
2012	2	0	10	9	6	27
Total	8	4	25	25	11	73

The number of magazine pages varied not only by magazine title, but also by year. For example, the number of pages in the 2008 *Family Circle* issues ranged from as few as 131 to as many of 229. For this same year, the number of pages in *Ebony* ranged from 151 to 217. A similar variation can be seen across years. In 2008, the number of pages of *O, The Oprah Magazine* ranged from 227 to 359, but in 2012 the number of pages ranged from 147 to 255. To adjust for these differences, an ad density value was calculated as described previously. Table 3-4 presents the results of these calculations.

Table 3-4: Advertisement density

Year	Ebony	Essence	Family Circle	Good Housekeeping	O, The Oprah Magazine
2008	1.5	1.1	3.9	4.2	1.7
2009	1.6	1.0	4.6	3.7	1.0
2011	1.7	1.0	4.6	3.9	2.2
2012	0.8	0.9	4.9	3.3	1.7

As we can see from Table 3-4, the density rates in *Family Circle* and *Good Housekeeping* were substantially greater than the rates found in *Ebony*, *Essence,* and *O, The Oprah Magazine*. To enable the statistical significance of the identified differences in the frequency of DTCA to be determined, the mean values of the following key variables were calculated: number of magazine pages, number of advertising pages, number of pharmaceutical advertising pages, percent of advertising pages, percent of DTCA as a function of all magazine pages, and percent of DTCA as a percent of all advertising pages. Table 3-5 presents the means for each of these variables for each year by magazine title.

Table 3-5: Descriptive statistics for key variables by year by magazine (2008, 2009, 2011, and 2012)

Year	# of Magazine Pages Mean (SD) (Min–Max)	# of Advertising Pages Mean (SD) (Min–Max)	# of DTCA Pages Mean (SD) (Min–Max)	% of Advertising Pages Mean (SD) (Min–Max)	% of DTCA as a Function of All Magazine Pages Mean (SD) (Min–Max)	% of DTCA as a Function of All Ad Pages Mean (SD) (Min–Max)
FAMILY CIRCLE						
2008 n=12	191.00 (SD=34.67) (131–229)	106.08 (SD=21.58) (69–130)	15.83 (SD=5.52) (6–24)	0.553 (SD=0.021) (0.518–0.578)	0.086 (SD=0.038) (0.033–0.178)	0.156 (SD=0.072) (0.060-0.338)
2009 n=12	205.33 (SD=50.93) (131–309)	115.71 (SD=30.20) (70–173)	20.67 (SD=8.28) (10–36)	0.562 (SD=0.024) (0.530–0.601)	0.099 (SD=0.028) (0.057–0.161)	0.176 (SD=0.045) (0.107–0.269)
2011 n=12	181.67 (SD=33.57) (127–237)	102.67 (SD=23.07) (69–138)	21.25 (SD=5.75) (12.5-31.5)	0.561 (SD=0.029) (0.514-0.603)	0.118 (SD=0.030) (0.084-0.187)	0.211 (SD=0.060) (0.147-0.364)
2012 n=12	173.50 (SD=27.65) (107–219)	99.38 (SD=17.60) (58.5–126.5)	20.00 (SD=5.69) (8–27.5)	0.571 (SD=0.022) (0.540–0.600)	0.114 (SD=0.028) (0.075–0.165)	0.200 (SD=0.044) (0.137-0.275)
GOOD HOUSEKEEPING						
2008 n=12	240.33 (SD=22.75) (205–269)	126.50 (SD=15.64) (98.5–147)	20.92 (SD=7.00) (7–32)	0.525 (SD=0.022) (0.480–0.551)	0.088 (SD=0.031) (0.027–0.138)	0.169 (SD=0.063) (0.051–0.274)
2009 n=12	223.83 (SD=25.29) (189–269)	113.92 (SD=19.62) (85–146)	18.75 (SD=5.96) (12–29)	0.506 (SD=0.035) (0.450–0.568)	0.084 (SD=0.027) (0.045–0.134)	0.166 (SD=0.050) (0.089-0.278)
2011 n=12	213.33 (SD=20.05) (187–245)	108.79 (SD=17.71) (86.5–134.5)	21.83 (SD=7.26) (9–34.5)	0.507 (SD=0.035) (0.463–0.556)	0.102 (SD=0.032) (0.044–0.173)	0.201 (SD=0.066) (0.090–0.367)
2012 n=12	198.17 (SD=13.63) (179–233)	95.17 (SD=17.16) (61–127)	14.38 (SD=5.41) (4–25.5)	0.478 (SD=0.061) (0.323–0.547)	0.073 (SD=0.028) (0.020–0.134)	0.154 (SD=0.056) (0.039–0.267)

Table 3-5: (continued)

Year	# of Magazine Pages Mean (SD) (Min–Max)	# of Advertising Pages Mean (SD) (Min–Max)	# of DTCA Pages Mean (SD) (Min–Max)	% of Advertising Pages Mean (SD) (Min–Max)	% of DTCA as a Function of All Magazine Pages Mean (SD) (Min–Max)	% of DTCA as a Function of All Ad Pages Mean (SD) (Min–Max)
EBONY						
2008 n=12	188.17 (SD=17.59) (151–217)	83.08 (SD=13.27) (61.5–105.0)	5.71 (SD=2.78) (2.0–11.5)	0.439 (SD=0.041) (0.373–0.490)	0.030 (SD=0.014) (0.010–0.056)	0.070 (SD=0.033) (0.023–0.115)
2009 n=11	126.82 (SD=11.68) (115–147)	54.32 (SD=7.89) (41–66)	4.05 (SD=2.34) (0.0–7.5)	0.428 (SD=0.044) (0.357–0.508)	0.032 (SD=0.019) (0.000–0.059)	0.073 (SD=0.041) (0.000–0.126)
2011 n=11	139.73 (SD=10.09) (131–163)	48.64 (SD=8.76) (34.5–60.5)	4.96 (SD=2.39) (0.0–8.0)	0.346 (SD=0.044) (0.236–0.408)	0.035 (SD=0.016) (0.000–0.052)	0.099 (SD=0.039) (0.000–0.138)
2012 n=11	153.36 (SD=12.09) (139–183)	59.50 (SD=9.15) (48.5–82.5)	2.91 (SD=2.30) (0.0–6.0)	0.387 (SD=0.034) (0.349–0.451)	0.020 (SD=0.016) (0.000–0.043)	0.052 (SD=0.045) (0.000–0.124)
ESSENCE						
2008 n=12	199.33 (SD=34.03) (123–233)	104.63 (SD=20.32) (63.0–125.6)	4.42 (SD=2.46) (0.0–7.5)	0.523 (SD=0.027) (0.479-0.567)	0.022 (SD=0.012) (0.000–0.048)	0.043 (SD=0.024) (0.000–0.092)
2009 n=12	174.67 (SD=18.95) (153–211)	95.29 (SD=15.18) (76–126)	3.88 (SD=2.56) (0.0–8.5)	0.544 (SD=0.042) (0.491–0.609)	0.022 (SD=0.016) (0.000–0.048)	0.041 (SD=0.028) (0.000–0.085)
2011 n=12	184.00 (SD=28.33) (127–243)	101.21 (SD=18.15) (60.0–128.5)	3.92 (SD=2.22) (0.0–8.0)	0.548 (SD=0.034) (0.472–0.595)	0.020 (SD=0.010) 0.000–0.033)	0.037 (SD=0.019) (0.000–0.062)
2012 n=12	160.83 (SD=18.36) (123–187)	85.33 (SD=16.86) (41.5–101.5)	2.96 (SD=2.13) (0.0–6.5)	0.526 (SD=0.065) (0.337–0.582)	0.018 (SD=0.012) (0.000–0.035)	0.033 (SD=0.023) (0.000–0.064)

Table 3-5: (continued)

Year	# of Magazine Pages Mean (SD) (Min–Max)	# of Advertising Pages Mean (SD) (Min–Max)	# of DTCA Pages Mean (SD) (Min–Max)	% of Advertising Pages Mean (SD) (Min–Max)	% of DTCA as a Function of All Magazine Pages Mean (SD) (Min–Max)	% of DTCA as a Function of All Ad Pages Mean (SD) (Min–Max)
O, THE OPRAH MAGAZINE						
2008 n=12	285.67 (SD=47.01) (227–359)	154.42 (SD=33.97) (110.5–201.0)	9.33 (SD=3.81) (4–15)	0.536 (SD=0.036) (0.477–.588)	0.034 (SD=0.017) (0.012–0.066)	0.064 (SD=0.034) (0.021–0.136)
2009 n=12	221.50 (SD=35.23) (173–291)	108.96 (SD=28.04) (71.5–162.5)	4.92 (SD=2.46) (0.0–8.5)	0.485 (SD=0.049) (0.413–0.558)	0.022 (SD=0.011) (0.000–0.038)	0.046 (SD=0.025) (0.000–0.091)
2011 n=12	220.75 (SD=36.97) (165–276)	112.58 (SD=27.44) (70–159)	11.33 (SD=4.84) (6–23)	0.503 (SD=0.044) (0.419–0.576)	0.053 (SD=0.022) (0.024–0.087)	0.106 (SD=0.047) (0.042–0.186)
2012 n=12	197.17 (SD=30.11) (147–255)	95.96 (SD=22.21) (55.5–139.0)	7.25 (SD=5.22) (1.5–16.5)	0.481 (SD=0.048) (0.378–0.545)	0.036 (SD=0.232) (0.007–0.077)	0.076 (SD=0.047) (0.016–0.161)

We can see from Table 3-5 that advertising in general represented a large proportion of each magazine. *Family Circle* had the largest percentage of advertising pages, ranging between 55 and 57 percent. *Ebony* had the lowest percentage of advertising pages, ranging from a low of 35 percent to a high of 44 percent. Focusing in on DTCA, we find that pharmaceutical advertising represented a small percentage of the total magazine pages in all five magazine titles (i.e., typically less than 10 percent). However, if we look at the percentage of DTCA as a function of just the number of advertising pages, we see that pharmaceutical advertising represented a relatively large proportion of the advertising appearing in *Family Circle* (16 to 21 percent), *Good Housekeeping* (15 to 20 percent), and *Ebony* (7 to 10 percent). On the other hand, less than 5 percent of the ads found in *Essence* promoted pharmaceuticals. The percent of DTCA as a function of all advertising pages found in *O, The Oprah Magazine* ranged from less than 5 percent in 2009 to just over 10 percent in 2011.

3.4.1 Differences in Means

To respond to RQ1 and RQ2, the frequency of DTCA appearing in black-oriented magazines was compared to the frequency of DTCA appearing in the white-oriented magazines. Values were calculated for the following variables:

- percent of DTCA as a function of all magazine pages
- percent of DTCA as a function of all advertising pages

These two variables serve to eliminate differences in the frequency of DTCA associated with differences in the size of the magazine (in terms of number of pages) and the amount of total advertising (in terms of number of advertising pages). Using descriptive

statistics, the means for these variables were computed using the new categories for racial orientation and publication date. Table 3-6 summarizes the results.

Table 3-6: Differences in DTCA before and after publication of FDA report

TOTAL MAGAZINE PAGES		
	Before	After
Black-Oriented Magazines	0.027 (SD=0.015) (n=47)	0.023 (SD=0.015) (n=46)
White-Oriented Magazines	0.089 (SD=0.031) (n=48)	0.102 (SD=0034) (n=48)
Crossover Magazine	0.028 (SD=0.015) (n=24)	0.044 (SD=0.024) (n=24)
TOTAL ADVERTISING PAGES		
	Before	After
Black-Oriented Magazines	0.056 (SD=0.034) (n=47)	0.054 (SD=0.041) (n=46)
White-Oriented Magazines	0.167 (SD=0.057) (n=48)	0.191 (SD=0.059) (n=48)
Crossover Magazine	0.055 (SD=0.031) (n=24)	0.091 (SD=0.049) (n=24)

From Table 3-6 we can see that the frequency of DTCA varies not only on the basis of a magazine's racial orientation, but also on its issue date relative to publication of the FDA report. For example, if we look at the mean of DTCA as a function of total advertising pages, we see that the mean for the black-oriented magazines and the crossover magazine was virtually identical (0.056 and 0.055, respectively) in the issues published in 2008 and 2009. However, if we look at the means for the more recent issues (i.e., 2011 and 2012), we see a difference. The mean for black-oriented magazines is relatively unchanged (0.054), while the mean for the crossover magazine increased from

0.055 to 0.091. The mean amount of DTCA appearing in white-oriented magazines was greater than either the black-oriented or crossover magazines regardless of publication date.

An independent samples t-test was used to determine the statistical significance of these observed differences. In each case, the null hypothesis assumed that there would be no difference in the mean frequency of advertising based on the racial orientation of the magazine. The alternative hypothesis suggested that more pharmaceutical advertising would be found in the white-oriented magazines and the crossover magazine than in the black-oriented magazines based on the results of previous research. Means were analyzed both before and after publication of the FDA report. Table 3-7 presents these results.

Table 3-7: Mean differences in DTCA frequency based on racial orientation of magazine

	BEFORE		AFTER	
	% of All Magazine Pages	% of All Advertising Pages	% of All Magazine Pages	% of All Advertising Pages
White x Black	0.063 (p=.000)	0.111 (p=.000)	0.079 (p=.000)	0.137 (p=.000)
Black x Crossover	-0.002 (p=.704)	0.112 (p=.000)	-0.021 (p=.006)	-0.036 (p=.002)
White x Crossover	0.061 (p=.000)	0.112 (p=.000)	0.058 (p=.000)	0.100 (p=.000)

The results in Table 3-7 can be used to answer RQ1 which asks whether the frequency of pharmaceutical advertising varies based on the racial orientation of the magazine. We can see that in virtually all cases, the difference in means is statistically significant. As we hypothesized, the frequency of DTCA appearing in white-oriented magazines in statistically greater than in either the black-oriented magazines or the

crossover magazine ($p < .001$). However, the difference in DTCA frequency between the black-oriented and crossover magazines is not significant when considered as a function of all magazines pages ($p > 0.05$), but becomes significant when examined as a function of just the advertising pages ($p < .001$). The negative value found when comparing the mean of the black-oriented magazines to the crossover magazine reflects the fact that the black-oriented magazines has less DTCA than the crossover magazine as a function of total magazine pages in the period before the FDA report was published and as a function of both total magazine pages and total advertising pages in the period after publication of the FDA report.

RQ2 explores the impact of the FDA report recommendations on the frequency of advertising appearing black-oriented magazines. Independent samples t-tests were again used to evaluate the differences between the frequency of DTCA before and after the publication of the FDA report for each magazine genre. In each of these cases, the null hypothesis assumed that there would be no difference in the mean frequencies of advertising based on the racial orientation of the magazine. The alternative hypothesis assumed that the amount of DTCA placed in both the black-oriented magazines and the crossover magazine would increase as a result of the FDA recommendations. Table 3-8 presents these results.

Table 3-8: Mean differences in DTCA frequency before and after FDA report

Magazine Genre	% of All Magazine Pages	% of All Advertising Pages
Black-Oriented	-0.004 (p=.263)	-0.002 (p=.819)
White-Oriented	0.012 (p=.065)	0.025 (p=.041)
Crossover	0.016 (p=.007)	0.036 (p=.004)

Table 3-8 suggests that the publication of the FDA recommendations had no impact on the amount of DTCA appearing in either the black-oriented or white-oriented magazines. The difference between the means of these groups was not found to be significant ($p>0.05$). However, in looking at the values for the crossover magazine, we do find that the difference in the mean amount of DTCA, as a percentage of advertising pages, represents a significant increase ($p<.01$). Negative values in Table 3-8 reflect a relative decrease in DTCA pre- and post-FDA report.

3.4.2 Differences in Drug Type

As discussed above, both product claim ads and help-seeking ads were identified in the study sample. Product claim ads mention a specific drug and the medical condition for which it is used, while help-seeking ads only mention a particular medical condition. For the purposes of this study, these two types of ads were analyzed separately. However, product claim ads are most relevant to the research questions posed and will be the focus of much of the analysis.

Ninety-five drugs were represented in the 1,090 product claim advertisements identified. Table 3-9 provides an inventory of the drugs advertised for all years and all magazine titles included in the study sample. Drugs were classified by the medical condition noted in the individual advertisement. Some drugs were advertised for more than one purpose (e.g., Cymbalta is used to treat depression and fibromyalgia), but only three drugs (Enbrel, Humira, and Singulair) are used to treat conditions in different categories of medical conditions. Consequently, Enbrel and Humira appear in both the "Dermatologic" (psoriasis) and "Musculoskeletal" (rheumatoid arthritis) categories, and Singulair appears in both the "Allergies" and "Respiratory" (asthma) categories.

The greatest number of drugs advertised (21) fall into the "Psychiatric/ Neurologic" category. This is not surprising since the drugs in this category are used to treat the widest range of conditions, including Alzheimer's disease, attention deficit and hyperactivity disorder (ADHD), chronic pain, depression, epilepsy, fibromyalgia, insomnia, migraines, and restless leg syndrome. Ads in this category represented nearly 31 percent of the total number of product claim ads identified. Drugs to treat postmenopausal osteoporosis were the next most frequently advertised drugs over the study period, representing 17.2 percent of the product claim ads identified, followed by drugs to treat respiratory conditions, such as asthma and chronic obstructive pulmonary disorder (COPD), representing 11.3 percent of these ads. The fewest number of ads promoted drugs to treat cancer, with a single ad for each of two cancer drugs (Arimidex and Femara) appearing only once in the four-year study period.

Table 3-9: Advertised drugs

Medical Condition	Brands	No. of Ads	Percent
Allergies	EpiPen, Singulair	4	0.4
Cancer	Arimidex, Femara	2	0.2
Cardiovascular	Caduet, Crestor, Lipitor, Livalo, Lovaza, Niaspan, Plavix, Pradaxa, TriCor, Vytorin, Xarelto, Zetia	109	10.0
Cosmetic	ArteFill, Botox Cosmetic, Dysport, Latisse, Restylane, SculptraAesthetic, Vivite	38	3.5
Dermatologic	Enbrel, Humira, Oracea	23	2.1
Diabetes	FlexPen, Januvia, Lantus, Victoza	53	4.9
Gastrointestinal/Nutritional	AcipHex, Amitiza, Transdermal Scop	19	1.7
Infectious (Non-HIV)	FluMist, Fluzone, Gardasil, Incivek, Prevnar 13, Tamiflu, Valtrex, Zostavax	68	6.2

Table 3-9: (continued)

Medical Condition	Brands	No. of Ads	Percent
Musculoskeletal	Actonel, Boniva, Celebrex, Cimzia, Enbrel, Evista Humira, Orencia, Prolia, Reclast, Remicade, Simponi, Synvisc-One, Vimovo	188	17.2
Obstetric/Gynecological	Estring, Mirena, NuvaRing, Plan B, Premarin Vaginal Cream, VagiFem, Yaz	51	4.7
Ophthalmological	Restasis	14	1.3
Psychiatric/Neurologic	Abilify, AmbienCR, Aricept, Botox, Concerta, Cymbalta, Exelon Patch, Horizant, Keppra, Lunesta, Lyrica, Mirapex, Nuedexta, Pristiq, Provigil, Rozerem, Seroquel XR, Topamax, Treximet, Ultram ER, Vyvanse	332	30.5
Respiratory	Advair Diskus, Dulera, Flovent Diskus, Pulmicort Respules, Singulair, Spiriva HandiHaler, Symbicort	123	11.3
Tobacco Addiction	Chantix	7	0.6
Urological	Detrol LA, Enablex, Toviaz, VESIcare	59	5.4

As anticipated, the types of drugs advertised varied by magazine title and by year. Table 3-10 compares the types of drugs advertised in each magazine title by year of publication. Examining the data in Table 3-10 reveals some interesting trends.

Table 3-10: Types of drugs advertised by year by magazine title

Disease Category	2008		2009		2011		2012	
	# of Ads	%	# of Ads	%	# of Ads	%	# of Ads	%
EBONY								
Allergies	---	---	---	---	---	---	---	---
Cancer	1	3.1	---	---	---	---	---	---
Cardiovascular	8	25.0	5	23.8	---	---	---	---
Cosmetic	---	---	---	---	---	---	---	---
Dermatologic	---	---	---	---	---	---	---	---
Diabetes	6	18.8	5	23.8	7	30.4	3	25.0
Gastrointestinal/ Nutritional	---	---	---	---	---	---	---	---
Infectious (Non-HIV)	1	3.1	---	---	3	13.0	7	58.3
Musculoskeletal	3	9.4	3	14.3	5	21.7	---	---
Obstetric/ Gynecological	---	---	---	---	---	---	---	---
Ophthalmological	---	---	---	---	---	---	---	---
Psychiatric/ Neurologic	6	18.8	4	19.0	6	26.1	---	---
Respiratory	7	21.9	4	19.0	2	8.7	2	16.7
Tobacco Addiction	---	---	---	---	---	---	---	---
Urological	---	---	---	---	---	---	---	---
Total	32	100.0	21	100.0	23	100.0	12	100.0

Table 3-10: (continued)

Disease Category	2008		2009		2011		2012	
	# of Ads	%	# of Ads	%	# of Ads	%	# of Ads	%
ESSENCE								
Allergies	---	---	---	---	---	---	---	---
Cancer	---	---	---	---	---	---	---	---
Cardiovascular	---	---	---	---	---	---	---	---
Cosmetic	---	---	---	---	---	---	---	---
Dermatologic	---	---	---	---	---	---	---	---
Diabetes	6	25.0	3	15.8	4	17.4	3	17.6
Gastrointestinal/ Nutritional	---	---	---	---	---	---	---	---
Infectious (Non-HIV)	4	16.7	---	---	7	30.4	3	17.6
Musculoskeletal	2	8.3	---	---	---	---	---	---
Obstetric/ Gynecological	5	20.8	6	31.6	2	8.7	3	17.6
Ophthalmological	---	---	---	---	---	---	---	---
Psychiatric/ Neurologic	5	20.8	7	36.8	6	26.1	6	35.3
Respiratory	2	8.3	3	15.8	4	17.4	2	11.8
Tobacco Addiction	---	---	---	---	---	---	---	---
Urological	---	---	---	---	---	---	---	---
Total	24	100.0	19	100.0	23	100.0	17	100.0

Table 3-10: (continued)

Disease Category	2008		2009		2011		2012	
	# of Ads	%	# of Ads	%	# of Ads	%	# of Ads	%
FAMILY CIRCLE								
Allergies	---	---	---	---	---	---	1	1.1
Cancer	1	1.2	---	---	---	---	---	---
Cardiovascular	9	10.6	16	15.2	8	8.2	3	3.3
Cosmetic	---	---	---	---	2	2.1	---	---
Dermatologic	---	---	2	1.9	---	---	---	---
Diabetes	1	1.2	1	1.0	6	6.2	3	3.3
Gastrointestinal/ Nutritional	10	11.8	5	4.8	---	---	---	---
Infectious (Non-HIV)	4	4.7	7	6.7	7	30.4	11	12.1
Musculoskeletal	15	17.6	15	14.3	28	28.9	17	18.7
Obstetric/ Gynecological	---	---	2	1.9	3	3.1	7	7.7
Ophthalmological	---	---	---	---	2	2.1	---	---
Psychiatric/ Neurologic	26	30.6	30	28.6	27	27.8	28	30.8
Respiratory	9	10.6	14	13.3	6	6.2	21	23.1
Tobacco Addiction	---	---	2	1.9	---	---	---	---
Urological	10	11.8	11	10.5	8	8.2	---	---
Total	85	100.0	105	100.0	97	100.0	91	100.0

Table 3-10: (continued)

Disease Category	2008		2009		2011		2012	
	# of Ads	%	# of Ads	%	# of Ads	%	# of Ads	%
GOOD HOUSEKEEPING								
Allergies	1	0.9	---	---	1	1.1	1	1.5
Cancer	1	1.2	---	---	---	---	---	---
Cardiovascular	15	13.5	16	16.7	9	9.5	10	14.7
Cosmetic	---	---	---	---	4	4.2	2	2.9
Dermatologic	1	0.9	3	3.3	---	---	---	---
Diabetes	1	0.9	---	---	---	---	3	4.4
Gastrointestinal/ Nutritional	2	1.8	---	---	---	---	---	---
Infectious (Non-HIV)	---	---	6	6.3	---	---	2	2.9
Musculoskeletal	30	27.0	16	16.7	25	26.3	9	13.2
Obstetric/ Gynecological	---	---	5	5.2	3	3.2	5	7.4
Ophthalmological	---	---	---	---	4	4.2	2	2.9
Psychiatric/ Neurologic	34	30.6	35	36.5	32	33.7	22	32.4
Respiratory	12	10.8	6	6.3	9	9.5	21	23.1
Tobacco Addiction	2	1.8	3	3.1	---	---	---	---
Urological	13	11.7	6	6.3	5	5.3	---	---
Total	111	100.0	105	100.0	95	100.0	68	100.0

Table 3-10: (continued)

Disease Category	2008		2009		2011		2012	
	# of Ads	%	# of Ads	%	# of Ads	%	# of Ads	%
O, THE OPRAH MAGAZINE								
Allergies	---	---	---	---	---	---	---	---
Cancer	---	---	---	---	---	---	---	---
Cardiovascular	8	14.3	---	---	2	3.7	---	---
Cosmetic	12	21.4	5	18.5	9	16.7	4	11.8
Dermatologic	---	---	3	11.1	8	14.8	3	8.8
Diabetes	1	1.08	---	---	---	---	---	---
Gastrointestinal/ Nutritional	2	3.6	---	---	---	---	---	---
Infectious (Non-HIV)	5	8.9	1	3.7	---	---	---	---
Musculoskeletal	13	23.2	---	---	4	7.4	3	8.8
Obstetric/ Gynecological	---	---	2	7.4	4	7.4	4	11.8
Ophthalmological	---	---	---	---	4	7.4	2	5.9
Psychiatric/ Neurologic	12	21.4	13	48.1	18	33.3	15	44.1
Respiratory	3	5.4	1	3.7	1	1.9	3	8.8
Tobacco Addiction	---	---	---	---	---	---	---	---
Urological	---	---	2	7.4	4	7.4	---	---
Total	56	100.0	27	100.0	54	100.0	34	100.0

While the number of ads placed in both *Ebony* and *Essence* decreased over the course of the study period, the reduction was far more dramatic in *Ebony*. In 2008, *Ebony* included 32 pharmaceutical ads, while in 2012 only 12 appeared—a decline of nearly 60 percent. In addition, the number of disease categories treated by the advertised drugs dropped from seven in 2008 to only three in 2012. On the other hand, while the number of pharmaceutical ads found in *Essence* declined 30 percent, the number of disease categories only decreased by one.

We see a similar decline in pharmaceutical advertising appearing in *Good Housekeeping*. The number of ads fell from 111 in 2008 to 68 in 2012—a decline of nearly 40 percent. However, the number of disease categories only declined by one. Pharmaceutical advertising in *Family Circle* remained relatively constant over the study period, although the number of disease categories also fell by one. *O, The Oprah Magazine* experienced a decline of about 40 percent in the number of pharmaceutical ads and a similar loss of a single disease category.

Although the number of disease categories did not change much (except in the case of *Ebony*), the actual categories represented varied by year and by magazine title. For example, drugs to treat postmenopausal osteoporosis were advertised in *Essence* in 2008 but not in any subsequent year. Drugs to treat tobacco addiction were advertised only in *Family Circle* and *Good Housekeeping* and only in 2008 and 2009. No drug to treat overactive bladder symptoms was advertised in any issue of *Ebony* and *Essence*. Cardiovascular drugs were not advertised at all in *Essence*, although they were advertised in *Ebony* but not in 2011 or 2012.

To answer RQ3, which questions whether the types of drugs advertised vary by the racial orientation of the magazine, it was necessary to compare the types of drugs advertised in white-oriented magazines with those advertised in the black-oriented magazines and the crossover magazine. Table 3-11 summarizes the percentage of drugs advertised in each disease category by the racial orientation of the magazine. Data were further consolidated by publication year—either before publication of the FDA report (2008 and 2009) or after (2011 and 2012).

Table 3-11: Types of drugs advertised by racial orientation of magazine (percent of ad total)

Disease Category	BEFORE			AFTER		
	Black	White	Crossover	Black	White	Crossover
Allergies	---	0.3	---	---	0.9	---
Cancer	1.0	0.3	---	---	---	---
Cardiovascular	13.5	14.1	9.6	---	8.5	2.3
Cosmetic	---	---	20.5	---	2.3	14.8
Dermatologic	---	1.5	3.6	---	0.9	12.5
Diabetes	20.8	0.8	1.2	22.7	3.4	---
Gastrointestinal/ Nutritional	---	4.3	2.4	---	---	---
Infectious (Non-HIV)	5.2	4.3	7.2	26.7	5.7	---
Musculoskeletal	8.3	19.1	15.7	6.7	22.5	8.0
Obstetric/ Gynecological	11.5	1.8	2.4	6.7	5.1	9.1
Ophthalmological	---	---	---	---	2.3	6.8
Psychiatric/ Neurologic	22.9	31.5	30.1	24.0	31.1	37.5
Respiratory	16.7	10.3	4.8	13.3	13.7	4.5
Tobacco Addiction	---	1.8	---	---	---	---
Urological	---	10.1	2.4	---	3.7	4.5

Table 3-11 further documents many of the previous observations. The white-oriented magazines had a broader range of drugs advertised, with at least one

pharmaceutical ad appearing in each disease category sometime during the study period. The black-oriented magazines lacked advertising for drugs to treat allergies, gastrointestinal/nutritional conditions, ophthalmological concerns, tobacco addiction, and urological issues. Readers of *O, The Oprah Magazine* were not exposed to any ads for drugs to treat allergies, cancer, and tobacco addiction in issues published during the study period.

To shed further light on these differences, Appendix C tabulates data for each individual drug advertised. Tables 3-12 and 3-13 summarize these data. Table 3-12 provides information on the three most prevalent drugs advertised in each magazine genre for the time period before and after publication of the FDA report recommendations. Table 3-13 compares the most prevalent disease categories advertised in each magazine genre for the same time periods.

Table 3-12: Three most prevalent drugs advertised

	BEFORE	AFTER
Black-Oriented	(1) Januvia (2) Lyrica (3) Advair Diskus	(1) Januvia (2) Gardasil (3) Lyrica, Pristiq
White-Oriented	(1) Vyvanse (2) Actonel (3) Cymbalta	(1) Cymbalta (2) Advair Diskus (3) Premarin Vaginal Cream
Crossover	(1) Cymbalta (2) Abilify, Gardasil, Lyrica (3) Crestor, Evista, Plavix, Singulair	(1) Abilify (2) Lyrica (3) Premarin Vaginal Cream

Table 3-13: Three most prevalent disease categories advertised

	BEFORE	AFTER
Black-Oriented	(1) Psychiatric/Neurologic (2) Diabetes (3) Cardiovascular	(1) Infectious (Non-HIV) (2) Psychiatric/Neurologic (3) Diabetes
White-Oriented	(1) Psychiatric/Neurologic (2) Musculoskeletal (3) Cardiovascular	(1) Psychiatric/Neurologic (2) Musculoskeletal (3) Respiratory
Crossover	(1) Psychiatric/Neurologic (2) Cosmetic (3) Musculoskeletal	(1) Psychiatric/Neurologic (2) Cosmetic (3) Dermatologic

It is interesting to note the differences in the most popular drugs versus the most prevalent disease categories advertised. While the most popular drug advertised in the black-oriented magazines was Januvia, the medical condition for which it is prescribed, diabetes, was not the most prevalent disease category. Similarly, Premarin Vaginal Cream was the third most advertised drug in both the white-oriented and crossover magazines after the publication of the FDA report, but the "Obstetric/Gynecological" disease category was not among the top three advertised in any magazine genre during either the time period before or after the FDA report. These tables highlight the importance of looking at not only the drug advertised, which can reflect a manufacturer's desire to gain widespread exposure for a new product, but also the disease category, which tempers the influence of a single drug marketing campaign on overall DTCA trends.

RQ4 probes the relationship of the drugs advertised to the health risks faced by the magazines' targeted audiences. Table 3-14 lists the leading causes of death for Blacks and Whites in the United States in 2010 (Heron, 2013). Although the study reviewed only women's magazines, it is appropriate to consider the leading causes of

death for both men and women in the United States since research shows that women are more likely to participate in the health care decisions for all family members, including children, grandchildren, spouses, and elderly parents (Abel et al., 2007; Kaiser Family Foundation, 2003; Kluger, 2010; Mastin et al., 2007). Therefore, although a drug advertised might not be relevant to the health of the woman reading the magazine, it could be relevant to the health of one of her family members.

For both Blacks and Whites, heart disease and cancer are the leading causes of death. Table 3-14 documents the variation in the cause of death between Blacks and Whites in the United States. Black Americans have a greater risk of dying from stroke or diabetes than do white Americans, but white Americans are more likely to die from chronic low respiratory disease and Alzheimer's disease. Homicide is the 8th leading cause of death for black Americans, although it is not in the top 10 for white Americans. On the other hand, suicide is the 10th leading cause of the death for white Americans but is not among the top 10 causes of death for black Americans.

Table 3-14: Leading causes of death in U.S. in 2010

BLACK	WHITE
Heart Disease	Heart Disease
Cancer	Cancer
Stroke	Chronic Low Respiratory Disease
Diabetes	Stroke
Unintentional Injury	Unintentional Injury
Kidney Disease	Alzheimer's Disease
Chronic Lower Respiratory Disease	Diabetes
Homicide	Influenza and Pneumonia
Septicemia	Kidney Disease
Alzheimer's Disease	Suicide

The FDA report recommendations dealt particularly with the relevance of DTCA to the health issues faced by the targeted community. In other words, are the drugs advertised used to treat the serious medical conditions faced by those exposed to the ads? Tables 3-15 and 3-16 match the drugs advertised in the black-oriented magazines, both before and after the FDA report, to the leading causes of death in the black community. Tables 3-17 and 3-18 provide the same comparison for DTCA appearing in white-oriented magazines. Those causes of death for which there is no pharmaceutical remedy, such as unintentional injury, were omitted from the tables.

From Table 3-15, we see that at least one drug was advertised in either *Ebony* or *Essence* or both during 2008 and 2009 that addressed 5 of the top 10 leading causes of death among black Americans in 2010. However, in 2011 and 2012, these magazines no longer included ads for drugs used to treat heart disease, cancer, or stroke (see Table 3-16). In addition, the number of drugs advertised to treat diabetes and chronic low respiratory disease declined during this period. One possible explanation for this decline is that it is tied to the overall decrease in the amount of DTCA appearing in black-oriented magazines published in 2011 and 2012. However, the difference in the means pre- and post-FDA report was not found to be statistically significant (see Table 3-9). Therefore, we may assume that pharmaceutical manufacturers chose not to advertise drugs used to treat life-threatening diseases in favor of drugs prescribed for other conditions. From Table 3-11, we can see that this is true. Note the sizeable uptick in the percentage of ads that fall in the "Infectious (Non-HIV)" category—from 5.2 percent in 2008 and 2009 to 26.7 percent in 2011 and 2012. (This increase was

driven primarily by an aggressive ad campaign promoting Gardasil, a vaccination against human papillomavirus (HPV)).

Table 3-15: Drugs advertised in black-oriented magazines and associated cause of death (before FDA report publication)

Cause of Death	Drugs Advertised
Heart Disease	Caduet
Cancer	Femera
Stroke	Plavix
Diabetes	FlexPen, Januvia, Lantus
Kidney Disease	N/A
Chronic Lower Respiratory Disease	Advair Diskus, Pulmicort Respules, Spiriva HandiHaler
Septicemia	N/A
Alzheimer's Disease	N/A

Table 3-16: Drugs advertised in black-oriented magazines and associated cause of death (after FDA report publication)

Cause of Death	Drugs Advertised
Heart Disease	N/A
Cancer	N/A
Stroke	N/A
Diabetes	Januvia, Victoza
Kidney Disease	N/A
Chronic Lower Respiratory Disease	Advair Diskus, Flovent Diskus, Symbicort
Septicemia	N/A
Alzheimer's Disease	N/A

In contrast, we continue to see advertising for a wide variety of drugs used to treat medical conditions of concern to white Americans. With the exception of cancer and stroke, issues of *Family Circle* and *Good Housekeeping* published in 2008 and 2009 advertised numerous drugs to treat heart disease, chronic low respiratory disease, stroke, diabetes, and suicide (see Table 3-17).

Table 3-17: Drugs advertised in white-oriented magazines and associated cause of death (before FDA report publication)

Cause of Death	Drugs Advertised
Heart Disease	Caduet, Crestor, Lipitor, Lovaza, Niaspan, TriCor, Vytorin, Zetia
Cancer	Arimidex
Chronic Low Respiratory Disease	Advair Diskus, Pulmicort Respules, Singulair, Spiriva HandiHaler, Symbicort
Stroke	Plavix
Alzheimer's Disease	N/A
Diabetes	Januvia, Lantus
Influenza and Pneumonia	N/A
Kidney Disease	N/A
Suicide	Abilify, Cymbalta, Pristiq

Table 3-18: Drugs advertised in white-oriented magazines and associated cause of death (after FDA report publication)

Cause of Death	Drugs Advertised
Heart Disease	Lipitor, Livalo, Lovaza, Niaspan, Xarelto, Zetia
Cancer	N/A
Chronic Low Respiratory Disease	Advair Diskus, Dulera, Flovent Diskus, Symbicort
Stroke	Pradaxa
Alzheimer's Disease	Aricept, Exelon Patch
Diabetes	Lantus, Victoza
Influenza and Pneumonia	FluMist, FluZone, Tamiflu
Kidney Disease	N/A
Suicide	Abilify, Cymbalta, Pristiq, Seroquel XR

As can be seen in Table 3-18, this trend continued after publication of the FDA report. In fact, these later magazine issues included ads for drugs used to treat Alzheimer's disease and influenza and pneumonia. Taken together, these four tables suggest that pharmaceutical manufacturers are making less of an effort to place

advertisements for drugs to treat life-threatening diseases in black-oriented magazines than they are in placing such ads in white-oriented magazines.

To some extent, pharmaceutical advertising in the crossover magazine mirrored that of the white-oriented magazines for the pre-FDA report time period (see Appendix C). Drugs to treat heart disease, chronic low respiratory disease, stroke, diabetes, and suicide were found in issues published in 2008 and 2009. However, in issues published in the time period following the FDA report, ads no longer appeared for drugs used to treat stroke and diabetes—two diseases of significant concern for both black and white readers.

Although the focus of this study is on product claim ads, help-seeking advertisements can also be a valuable source of health information. Because these types of ads do not mention a specific drug, but instead alert the reader to a medical condition, they may in fact be perceived more favorably. The FDA report recognizes the value of such advertisements and recommends an increase in help-seeking campaigns targeted to medical conditions particularly relevant to minority communities. (See report recommendation 4 highlighted in Chapter 1 of this dissertation.) Table 3-19 characterizes the 73 help-seeking advertisements found in terms of the racial orientation of the magazine and the disease category addressed. An increase in the number of help-seeking ads over time was observed in both the white-oriented and crossover magazines. The most significant increase in help-seeking ads appeared in *O, The Oprah Magazine* and was driven by a campaign by Allergan, Inc. related to chronic migraines. Only black-oriented magazines saw a decrease in the number of help-seeking ads pre- and post-publication of the FDA report, although the number of ads related to diabetes

increased. However, ads related to cancer and cardiovascular conditions were eliminated. Since the number of these ads is small compared to the number of product claim ads found, it would be inappropriate to assign too much weight to the variations observed. However, this is the first study to collect data on help-seeking ads and the results do suggest a need for further study.

Table 3-19: Help-seeking ads by racial orientation of magazine

Disease Category	BEFORE						AFTER					
	Black		White		Crossover		Black		White		Crossover	
	#	%	#	%	#	%	#	%	#	%	#	%
Allergies	---	---	---	---	---	---	---	---	5	17.9	---	---
Cancer	1	14.3	---	---	1	100.0	---	---	2	7.1	1	10.0
Cardiovascular	5	71.4	---	---	---	---	---	---	---	---	---	---
Diabetes	1	14.3	3	13.6	---	---	3	60.0	---	---	---	---
Infectious (Non-HIV)	---	---	5	22.7	---	---	---	---	6	21.4	2	20.0
Musculoskeletal	---	---	7	31.8	---	---	---	---	3	10.7	---	---
Ophthalmological	---	---	5	22.7	---	---	---	---	5	17.9	---	---
Psychiatric/ Neurologic	---	---	---	---	---	---	---	---	4	14.3	5	50.0
Urological	---	---	2	22.7	---	---	---	---	3	10.7	1	10.0
Other[1]	---	---	---	---	---	---	2	40.0				
TOTAL	7	100.0	22	100.0	1	100.0	5	100.0	28	100.0	10	100.0

[1] Sickle Cell Anemia

3.5 Discussion

The above results update previous research and highlight continued differences in the frequency of DTCA and the types of drugs advertised based on a magazine's racial orientation. The impact of the FDA report recommendations on these aspects of pharmaceutical advertising was explored in depth and the results are discussed below. Section 3.5.1 addresses RQ1 and RQ2 as they relate to the frequency of pharmaceutical advertising. Section 3.5.2 discusses RQ3 as it relates to the type of drugs advertised, and Section 3.5.3 addresses RQ4 as it relates to the relationship of the drugs advertised to the health risks faced by the readers of the three magazine genres studied. Section 3.5.4 notes the limitations of the current study.

3.5.1 Frequency of Pharmaceutical Advertising

On all measures, the amount of pharmaceutical advertising appearing in white-oriented magazines was far greater than that appearing in either black-oriented magazines or the magazine read by both black and white women. In terms of absolute numbers, the ratio of DTCA appearing in white-oriented women's magazines versus that appearing in black-oriented women's magazines was, on average, more than four to one based on the data provided in Tables 3-2 and 3-3. The ratio between the crossover magazine and each of the two black-oriented magazines was nearly two to one, with *O, The Oprah Magazine* having twice the pharmaceutical advertising as either *Ebony* or *Essence*. On the other hand, both *Family Circle* and *Good Housekeeping* had twice the DTCA as *O, The Oprah Magazine.*

In terms of advertisement density, Table 3-4 indicates that the white-oriented magazines had substantially more pharmaceutical advertising than either the

black-oriented magazines or the crossover magazine, although the relative amounts of advertising for each magazine were similar. (From Table 3-5, we can see that *Ebony* had, on average, the least amount of advertising with 40.0 percent of its pages dedicated to ads, and *Family Circle* had the most amount of advertising with 56.2 percent of its pages dedicated to ads.) *Family Circle* and *Good Housekeeping* averaged 4.5 and 3.8 pharmaceutical ads per 100 magazine pages, respectively. *Ebony* and *Essence* averaged 1.4 and 1.0 ads per 100 magazine pages, respectively. *O, The Oprah Magazine* averaged 1.7 ads per 100 magazine pages. These figures include both product claim ads and help-seeking ads.

Independent sample t-tests confirm these observations. The difference in the amount of DTCA found in white-oriented magazines, both in terms of percent of all magazine pages and percent of all advertising pages, versus that found in black-oriented magazines, was found to be statistically significant, as shown in Tables 3-7 and 3-8. Similarly, the amount of DTCA found in white-oriented magazines versus the crossover magazine was also statistically significant. However, the difference in DTCA between the black-oriented magazines and the crossover magazine was not statistically significant for magazines issued before the FDA report (i.e., 2008 and 2009).

A two-step process was next used to determine the impact of the FDA report recommendations on the frequency of DTCA. First, the means of each magazine group (i.e., black-oriented, white-oriented, and crossover) were compared to one another for each of two time periods (i.e., before the report publication and after the report publication). The results reported in Table 3-8 indicate that there was no statistical difference between the means for the black-oriented magazines and the white-oriented

magazines. In other words, pharmaceutical manufacturers did not significantly increase the amount of advertising they placed in either of these magazine genres in the 2011/2012 timeframe. However, the difference in the means for the crossover magazine was statistically significant. The advertisement density figures for *O, The Oprah Magazine* are consistent with this conclusion—the average number of ads per 100 magazine pages for issues published in 2008 and 2009 was 1.4; the average number of ads per 100 magazine pages for issues published in 2011 and 2012 was 3.9, an increase of 150 percent (see Table 3-4).

The next step was to compare the means of the issues published before the FDA report to the means of the issues published after the FDA report for each of the three groups using the data reported in Table 3-6. In all but one case, the differences in the means before and after the FDA report was published were statistically significant. In other words, the difference in the amount DTCA found in white-oriented magazines versus black-oriented magazines was statistically significant both before and after the FDA report recommendations were published. The same is true for the differences between the amount of DTCA found in black-oriented magazines versus the crossover magazine and the white-oriented magazines versus the crossover magazine for the time period following the FDA report. However, the difference in the mean amount of DTCA as a percentage of all magazine pages between the black-oriented magazine and the crossover magazine was not significant for the time period before publication of the FDA report.

These results reinforce the findings of previous researchers, such as Mastin et al. (2007) and Omonuwa (2001). Magazines read predominantly by black women continue

to have significantly less pharmaceutical advertising than those read predominantly by white women. The one magazine included in the study that is read by both white and black women also had less DTCA than magazines read predominantly by white women, although it did have more DTCA than the magazines read predominantly by black women. More critical to the analysis however is that pharmaceutical advertising did not increase significantly in the black-oriented magazines after the publication of the FDA report recommendations. Instead, the differences in mean DTCA pre- and post-FDA report were statistically insignificant. As a percentage of total magazine pages, the mean DTCA in black-oriented magazines decreased from 0.027 to 0.023 (p=.263) pre- and post-FDA report. As a percentage of total advertising pages, the mean DTCA decreased from 0.056 to 0.054 (p=.819). On the other hand, *O, The Oprah Magazine* did show a statistically significant increase in the amount of DTCA found in issues published after the FDA report (0.055 to 0.091 (p=.004)), as did the white-oriented magazines (0.167 to 0.191 (p=.004)) when DTCA is considered as a percentage of all advertising pages.

The fact that black-oriented magazines continue to have significantly less DTCA than white-oriented magazines suggests that differences in ad placement are intentional either on the part of pharmaceutical manufacturers or on the part of magazine publishers. If we revisit the advertisement density figures in Table 3-4, we see that, while the ad density fell in *Ebony* between 2008 (1.5 drug ads per 100 magazine pages) and 2012 (0.8 drug ads per 100 magazine pages), it remained relatively constant in *Essence* over the same time period (1.1 drugs ads per 100 magazine pages in 2008 versus 0.9 drugs ads per 100 magazine pages in 2012). These results suggest that drug manufacturers still value print advertisements in this magazine genre. Again, looking at Table 3-4, we see

that the advertisement density in *Ebony* magazine remained virtually constant in 2008, 2009, and 2011, dropping precipitously in 2012. It is possible that *Ebony*'s publishers adopted a policy of limiting the amount of pharmaceutical advertising or the cost of advertising in *Ebony* became prohibitively expensive for certain pharmaceutical companies, but more research would be necessary to confirm such a conclusion.

3.5.2 Type of Drugs Advertised

The type of drugs advertised varied not only by the racial orientation of the magazine, but also by the date of publication. As reported in Table 3-12, the top three drugs advertised in black-oriented magazines in 2008 and 2009 were Januvia (used to treat diabetes), Lyrica (used to relieve nerve pain), and Advair Diskus (used to treat asthma and COPD). In contrast, the top three drugs advertised in white-oriented magazines during the same period were Vyvanse (used to treat ADHD), Actonel (used to treat postmenopausal osteoporosis), and Cymbalta (used to treat either depression or nerve pain). The top drug advertised in *O, The Oprah Magazine* in 2008 and 2009 was Cymbalta. Tied for the second most popular drug advertised were Abilify (used to treat depression), Gardasil (a vaccine against HPV), and Lyrica. Crestor (used to treat high cholesterol), Evista (used to treat postmenopausal osteoporosis), Plavix (used to reduce the risk of clots), and Singulair (used to treat asthma) were the third most prevalent drugs advertised.

Januvia remained the most popular drug advertised in the black-oriented magazines published in 2011 and 2012, followed by Gardasil. Lyrica and Pristiq (another drug used to treat depression) were tied for the third most popular drugs advertised during this time period. In the white-oriented magazines, Cymbalta was the

most popular drug advertised, followed by Advair Diskus and Premarin Vaginal Cream (used to treat vaginal dryness). The most popular drugs advertised in *O, The Oprah Magazine* during 2011 and 2012 were Abilify, Lyrica, and Premarin Vaginal Cream.

These results are quite different than those reported by previous researchers. Omonuwa (2001) found that black-oriented magazines lacked advertisements for drugs to treat osteoporosis, Alzheimer's disease, high cholesterol, and depression, although they did include ads for antiviral agents, oral contraceptives, vaginal antifungal agents, analgesics, impotence agents, and antihistamines. Readers of white-oriented magazines would not be exposed to ads for drugs that treat HIV or provide contraception. Mastin et al. (2007) found that black-oriented magazines were more likely to contain DTCA for drugs used to treat women's health issues and sexually transmitted diseases. Crawley et al. (2009) found that black-oriented magazines were more likely to include ads for products to treat colds and allergies and chronic, non-life-threatening diseases.

In contrast, the results of this study found that the drugs advertised most prevalently in the black-oriented magazines are used to treat significant health risks, including diabetes, depression, and asthma. The most popular drugs advertised in the white-oriented magazines were used to treat ADHD, asthma, depression, postmenopausal osteoporosis, and vaginal dryness. The most prevalent pharmaceuticals advertised in the crossover magazine included drugs to treat asthma, depression, postmenopausal osteoporosis, and vaginal dryness, as well as cardiovascular conditions. These data suggest that magazine readers are more likely to be exposed to advertisements for drugs that treat serious medical conditions, regardless of the targeted audience, than was previously found.

If we look at the most prevalent disease categories advertised (see Table 3-13), we find a similar pattern. Although they did not specifically evaluate the relationship between a magazine's racial orientation and the disease categories advertised, Bell et al. (2000) found that the most common disease categories advertised were dermatologic conditions, HIV/AIDS, and obstetrical/gynecological conditions. Crawley et al. (2009) did contrast magazines targeted to black audiences (*Essence, Jet, Black Enterprise*) to those targeted to general audiences (*Cosmopolitan, People, Forbes*) and found that the general audience magazines were more likely to include DTCA for life-threatening conditions and mental health conditions.

The results of this study indicate that the DTCA found in the magazines surveyed were also more likely to address serious medical conditions, regardless of the magazine's genre, than previously found. From Table 3-13, we see that the disease category comprising the most drug advertisements in 2008 and 2009 for all magazine genres was "Psychiatric/Neurologic." For black-oriented magazines, the second most popular category was "Diabetes," and third most popular was "Cardiovascular." For white-oriented magazines, the second most popular category was "Musculoskeletal," followed by "Cardiovascular." The second and third most popular disease categories in *O, The Oprah Magazine* were "Cosmetic" and "Musculoskeletal," respectively.

The prevalence of disease categories changed slightly in the 2011 and 2012 time period. In the black-oriented magazines, the three most popular disease categories were "Infectious (Non-HIV)," "Psychiatric/Neurologic," and "Diabetes," respectively. The "Psychiatric/Neurologic" disease category remained the most prevalent in both the white-oriented magazines and the crossover magazine during this time period. The

second and third most popular disease categories in the white-oriented magazines were "Musculoskeletal" and "Respiratory," respectively. "Cosmetic" and "Dermatologic" were the second and third most popular categories in *O, The Oprah Magazine* during this time period.

These results suggest that pharmaceutical companies are advertising drugs used to treat serious medical conditions more frequently in both black-oriented and white-oriented women's magazine than previously found. However, the category entitled "Psychiatric/Neurologic" is extremely broad and includes drugs used to treat not only depression and chronic pain, but also ADHD and insomnia. Using the data reported in Appendix C to drill down into this category, we find that nearly two-thirds of the ads appearing in black-oriented magazines published before the FDA report were for drugs used to treat either depression or chronic pain. After publication of the FDA report, all of the drugs advertised in this magazine genre were used to treat either depression or chronic pain. In contrast, over 40 percent of the ads in this category that appeared in white-oriented magazines published before the FDA report were used to treat either ADHD or insomnia. However, after the FDA report was published only three ads appeared for a sleep aid and no ads appeared for a drug to treat ADHD. All other drugs advertised in the white-oriented magazines were used to treat serious psychiatric or neurologic conditions. These detailed results also suggest a more concerted effort on the part of pharmaceutical manufacturers to advertise drugs used to treat serious medical conditions in black- and white-oriented women's magazines published in 2011 and 2012 than in earlier issues.

Only the crossover magazine included drugs used to treat cosmetic conditions, such as wrinkles and frown lines, among the top three disease categories advertised. This is likely to be less a function of its racial orientation since it is read by both white and black women and more a function of its median age (49.9) and median household income ($66,900) (see Table 3-1). Interestingly, no drugs used to treat cosmetic conditions were advertised in the black-oriented magazines either before or after the FDA report, and these types of drugs were only advertised in the white-oriented magazines after the report publication date.

Appendix C documents some other interesting patterns in the types of drugs advertised based magazine genre and publication date. Advertising for allergy remedies only appeared in white-oriented magazines. Drugs to treat cancer were not advertised in the crossover magazine, and only appeared in the black- and white-oriented magazines prior to the publication of the FDA report. Advertisements for cardiovascular drugs did not appear in black-oriented magazines published after the FDA report recommendations. Similarly, advertising for drugs to treat diabetes did not appear in issues of the crossover magazine published in either 2011 or 2012. Gastrointestinal/nutritional drugs were not advertised in any magazine genre in 2011 or 2012. Advertising for drugs that fell into the "Infectious (Non-HIV)" categories did not appear in issues of the crossover magazine published in either 2011 or 2012. Only one drug, Restasis, was advertised in the "Ophthalmological" category, and ads for this drug appeared only in the white-oriented and crossover magazines. Drugs for tobacco addiction were not advertised in the post-FDA report time period, and no drug for urological conditions was advertised in any issue of the black-oriented magazines.

3.5.3 Concordance with Health Risks

As noted earlier, the types of drugs advertised in all magazine genres analyzed are more likely to treat serious medical conditions than previously reported. Another important dimension of this discussion as it relates to narrowing health disparities is whether those drugs advertised in the black-oriented magazines treat conditions that pose the greatest health risks to the black community in the United States. Since women tend to participate in the health care decisions for their families (Abel et al. 2007; Kaiser Family Foundation, 2003; Kluger, 2010; Mastin et al., 2007), it was important to consider the leading causes of death for both men and women. Table 3-15 suggests a positive alignment between drug and disease in the black-oriented magazine issues published prior to the FDA report (i.e., 2008 and 2009). The fact that drugs used to treat diabetes were the most prevalently advertised in black-oriented magazines is particularly promising since diabetes disproportionately affects blacks, especially black women who are nearly twice as likely to be diagnosed with diabetes as white, non-Hispanic women (CDC, 2014a).

However, only one drug (Caduet) used to treat heart disease was advertised in *Ebony and Essence* during this time period, while eight cardiovascular drugs were advertised in *Family Circle* and *Good Housekeeping*. Only Crestor was advertised in *O, The Oprah Magazine*. While heart disease is the number one cause of death for both blacks and whites, the CDC reports that, in 2009, black adults were 30 percent more likely to die from heart disease than non-Hispanic white men (CDC, 2014b). Blacks are also more likely to suffer from key risk factors, such as high blood pressure and obesity. For example, the CDC reports that black adults are 40 percent more likely to suffer from

high blood pressure than non-Hispanic white adults, and black women are 1.6 times more likely than non-Hispanic white women to have high blood pressure (CDC, 2014b). Similarly, Blacks are 1.5 times more likely to be obese as non-Hispanic Whites, and black women were 80 percent more likely to be obese than non-Hispanic white women based on 2011 data (CDC, 2014c).

Table 3-16, which looks at the types of drugs advertised after the publication of the FDA report (i.e., 2011 and 2012), paints a discouraging picture. While drugs to treat diabetes remained the most heavily advertised in black-oriented magazines, the number of such drugs decreased from three to two. More concerning, however, is that drugs used to treat heart disease, cancer, and stroke were not advertised at all in either *Ebony* or *Essence* during this time period. Pharmaceutical companies continued to advertise cardiovascular drugs in the white-oriented and crossover magazines during the same time period. These results suggest that, not only did the pharmaceutical industry ignore the FDA recommendations, but they also advertised far fewer drugs used to treat life-threatening conditions in black-oriented magazines after the report was published.

Help-seeking advertisements can also provide health information. Table 3-19 does identify an increase in the number of help-seeking ads after publication of the FDA report, particular in the crossover magazine. However, a closer examination shows a 30 percent decrease in the number of help-seeking ads (from 7 to 5) that appeared in the issues of *Ebony* and *Essence* (i.e., the black-oriented magazines) published in 2011 and 2012. More significantly however is the decrease in the number of help-seeking ads related to cardiovascular disease that appeared before the report was published (5) versus after (0). Ads related to diabetes did increase from one to three during this same time

period, however. The largest increase in the help-seeking ads that appeared in the crossover magazine were associated with an ad campaign focused on chronic migraine headaches.

3.5.4 Limitations

This phase of analysis has several limitations. Only five magazine titles and four years were selected for review. A lag period of 15 months between the publication of the FDA report in September 2009 and the first magazine issue considered post-FDA report was considered adequate. It is possible that pharmaceutical companies were adjusting their ongoing ad campaigns well into 2011 and that reviewing magazine issues published in 2013 would have yielded different results.

The study focused on a single minority (Blacks) and evaluated only magazines read by women. Therefore, the findings cannot be generalized to other minorities, such as Hispanics and Asians, or to other magazine genres, such as entertainment or news. It is possible that pharmaceutical companies place much of their advertising directed to black readers in magazines other than *Ebony* and *Essence*, although circulation figures and previous research would not suggest this. Furthermore, because this study only evaluated print ads, pharmaceutical companies may have increased their advertising to minority populations after publication of the FDA report using other media outlets, such as television or the Internet.

Another limitation unique to this phase of the analysis was the possibility of human error in the manual counting of magazine pages and pharmaceutical ads. The study sample consisted of 237 magazines with an average page count of 205 for a total of

nearly 49,000 pages. It is possible some magazine issues were miscounted, although such error would be randomly distributed.

While the analysis discusses results in the context of pre- and post-FDA report publication, causality between the report and any decrease in advertising frequency is not presumed. Companies make advertising decisions for a variety of reasons. To some extent the data collected represent the natural ebb and flow of advertising—advertising focus shifts away from older drugs as new drugs enter the market. For example, Januvia was introduced in October 2006 (FDA, 2014) and was advertised in all three magazine genres in 2008 and 2009. Victoza, another medication to treat diabetes, was introduced in January 2010 (FDA, 2014). Ads for this drug appear in 2011 and 2012. The data also reflect the changing popularity of certain drugs, such as Yaz, a birth control pill that was also advertised to treat acne and premenstrual syndrome. Introduced in 2006, Yaz quickly became a best seller claiming an 18-percent market share in 2008 (Singer, 2009). However, evidence of a higher risk of potentially fatal blood clots among users of Yaz and other birth control pills containing drospirenone led to numerous lawsuits and regulatory action (Wilson, 2011). Consequently, although Yaz was heavily advertised in the black-oriented magazines in 2008, no advertisements for Yaz appeared in 2009, 2011, or 2012. Therefore, while an increase in the frequency of advertising appearing in black-oriented magazines could indicate that pharmaceutical companies had chosen to implement the FDA report recommendations, any decrease in advertising should not be construed as an intentional rejection of the report's recommendations.

A final threat to the internal validity of this phase of the analysis is the possible impact that both the recession of 2008 and the reported 20-percent decrease in

pharmaceutical advertising dollars between 2006 and 2010 (see Figure 2-1) had on the observed frequency of DTCA. Although the number of advertisements decreased from 308 in 2008 to 222 in 2012 (a 28-percent decline), the relative percentage of DTCA as both a function of total magazine pages and total advertising pages increased significantly in both the white-oriented and crossover magazines. The decline in advertising placed in black-oriented magazines was not found to be statistically significant. However, future research in this area should control for this limitation.

3.6 Conclusions

Both the health belief model and social cognitive theory rely on knowledge to provide the necessary impetus for behavior change. DTCA is one source of information that may contribute to changing people's perceptions regarding susceptibility to disease and their ability to take action to treat it. Mastin et al. (2007) and Duerksen et al. (2005) suggest that the repetitiveness of DTCA can inform individuals and prompt them to preventive action. However, if pharmaceutical advertising is to positively impact the health of those it seeks to influence, then it is important that drugs used to treat significant health risks comprise the majority of such advertising. Furthermore, if pharmaceutical advertising is to be an effective tool in combating the disparities in health between Blacks and Whites in the United States, then it must promote drugs that treat the diseases that are of greatest concern to the black community. Congress noted its concern that pharmaceutical advertising was not reaching certain populations, including "racial and ethnic minority communities" (FDA, 2009, p. i), when it directed the FDA to study DTCA as it "relates to increase access to health information and decreased health

disparities for these populations" (FDA, 2009, p. i). FDA reported the results of its review to the Congress in September 2009.

This phase of the dissertation analysis looked specifically at the frequency of pharmaceutical advertising both before and after publication of the FDA report. Results indicate that differences in advertising frequency between black- and white-oriented magazines continue. The study also looked at the type of drugs advertised both before and after the FDA report was published. Again, the types of drugs advertised and the medical conditions they treat varied based on the racial orientation of the magazine. However, in all cases, the drugs advertised were more likely to treat serious medical conditions than previously reported.

The most disappointing results from a policy perspective were found when comparing the drugs advertised to the causes of death. Only a small percentage of drugs advertised are used to treat life-threatening conditions. While the most prevalent drug advertised in the black-oriented magazines is used to treat diabetes (a disease that disproportionately affects black Americans), far fewer ads for cardiovascular drugs (another disease of particular concern for the black community) appeared in black-oriented magazines than in white-oriented magazines.

The question was raised at the beginning of this chapter whether the FDA report had any impact on the frequency of pharmaceutical advertising or the types of drugs advertised. Based on the results presented, we would have to conclude that it did not. The disparities between white-oriented and black-oriented magazines in the frequency of advertising noted by previous researchers remains unchanged. Nor did the report have any impact on the frequency of advertising placed in black-oriented magazines—that

amount remained relatively constant over the study period. The types of drugs advertised did address serious medical conditions in the black community, particularly diabetes. However, the most prevalent disease category advertised after publication of the FDA report was "Infectious (Non-HIV)," driven by advertisements for Gardasil, the vaccine administered to young adults to prevent HPV. This category was followed by "Psychiatric/Neurologic," which encompasses conditions not listed in the leading causes of death for Blacks in the United States. "Diabetes" fell from the second most prevalent disease category advertised in black-oriented magazines prior to the FDA report to the third most prevalent after publication of the FDA report. Most significantly, the disease category, "Cardiovascular," which had been the third most advertised category pre-FDA report publication, was not included in the top three disease categories advertised post-FDA report.

Pharmaceutical companies also did not use their help-seeking advertisement campaigns as a vehicle for conveying important health information to black readers. Although there was a significant increase in the number of help-seeking ads after publication of the FDA report, these ad campaigns were not attached to life-threatening diseases. Instead, campaigns that appeared prior to the FDA report that did highlight heart disease and stroke were dropped from all three magazine genres in the issues published after 2009.

Based on these results, we must conclude that the FDA report had no impact on the advertising decisions made by pharmaceutical companies in terms of either the frequency with which they place ads in magazines read by black women or the types of drugs advertised. The next chapter of this dissertation examines the appearance and

content of DTCA. Differences in the advertisements found among the five magazines included in the study sample are identified and discussed.

CHAPTER 4: THE APPEARANCE AND CONTENT OF PHARMACEUTICAL ADVERTISING IN WOMEN'S MAGAZINES

The previous chapter examined the frequency and type of pharmaceutical advertising placed in five women's magazines published January 2008 through December 2009 and January 2011 through December 2012. This chapter takes that analysis one step further and looks at the individual characteristics of a subset of the advertisements identified. Specifically, each ad was evaluated in terms of its appearance (visual elements) and content (text elements). The differences in ads were then compared as a function of the racial orientation of the magazine in which they appeared and the time period in which the magazine was published (i.e., before or after the 2009 FDA report). By comparing the appearance and content of pharmaceutical advertising published before and after the FDA report, this chapter will provide further insight into whether or not the pharmaceutical industry has responded to the FDA's recommendations.

The chapter begins with an overview of the theoretical constructs underpinning the possible value of DTCA as a health promotion tool (Section 4.1). Section 4.2 discusses the methods used to select the advertisements evaluated and the way in which individual advertising elements were coded. Section 4.3 describes the quantitative and qualitative analyses conducted, and Section 4.4 presents the results of these analyses. Section 4.5 discusses the differences observed in both the appearance and content of advertising placed in different magazine genres during the study period, including a

comparison of ads for two drugs that were placed in different magazine genres during the same month and year. Section 4.6 offers some final observations and draws conclusions as to the impact of the FDA report recommendations on the appearance and content of pharmaceutical advertising placed in the five women's magazines reviewed.

4.1 Background

Researchers from several disciplines have examined DTCA using the organizing frameworks common to their fields. In a review of the health policy literature, two models stand out as being particularly applicable to the proposed study. Both the health belief model and social cognitive theory have been used to evaluate the relationship of DTCA to health promotion (Duerksen et al., 2005; Schommer & Hansen, 2005; Young, Lipowski, & Cline, 2005). The health belief model (see Figure 2-5) was developed in the 1950s by the U.S. Public Health Service to explain why people did not participate in disease prevention and protection programs (Glantz, Rimer, & Lewis, 2002). The model is based on the individual's perceived susceptibility to a disease, the perceived threat of the disease, and the perceived benefits to behavior change (Glantz et al, 2002.). As Glantz et al (2002) explain:

> …people will take action to prevent, to screen for, or to control ill-health conditions if they regard themselves as susceptible to the condition, if they believe it would have potentially serious consequences, if they believe that a course of action available to them would be beneficial in reducing either their susceptibility to or the severity of the condition, and if they believe that the anticipated barriers (or costs of) taking the action are outweighed by the benefits (pp. 47–48).

In his discussion of the relevance of the health belief model to pharmaceutical advertising, Roth (2003) identifies a two-step process in which consumers become engaged in positive health behaviors. In the first step, an individual becomes convinced

that he or she is susceptible to a disease or serious illness. In the second step, an individual identifies an appropriate solution that he or she can implement. Hence, drug advertisements often provide information about a disease and its symptoms, as well as the benefits of using the advertised product to provide relief (Roth, 2003). The health belief model also recognizes that certain external cues, such as education, personal relationships, and the media, can motivate health behaviors. Repeated exposure to pharmaceutical advertising can be a cue to action, sparking individuals to seek additional information either from their doctor or another media source, such as a Website or hotline (Duerksen et al., 2005).

Social cognitive theory (see Figure 2-6) contends that behavior is a dynamic concept, dependent on an individual's environment and personal characteristics (Glantz et al., 2002). The continual interaction among personal factors, environmental influences, and behavior is known as reciprocal determinism. Glantz et al. (2002) elaborate further:

> Behavior is not simply the result of the environment and the person, just as the environment is not simply the result of the person and behavior. Instead, these three components are constantly influencing each other. A change in one component has implications for the other (p. 168).

Consequently, behaviors are learned through "observation, role models, and responses from others" (Kean & Prividera, 2007, p. 289). An individual is more likely to "model the behaviors of people with whom they identify or feel similar to" (Kean & Prividera, 2007, pp. 289–290). Hence, visual cues in advertising, such as race, gender, and age, can help gain the attention of the targeted audience (Mastin et al., 2007).

As discussed previously, a number of content analyses have been conducted on pharmaceutical advertising appearing in print magazines (see Appendix B). Several of

these studies found a positive correlation between the race of the models that were used in an advertisement and the race of the readers of the magazine in which it appeared. Mastin et al. (2007) and Kean and Prividera (2007) found that pharmaceutical advertisements that appeared in black-oriented magazines were more likely to feature black models. Similarly, advertisements that appeared in white-oriented magazines were more likely to feature white models. Researchers also found that the race of the models used in an advertisement varied by product type. Main et al. (2004) found that prescription drug advertisements featured more white models than nonpharmaceutical advertising. Mackert and Love (2011) also found that a relatively smaller proportion of the pharmaceutical ads they evaluated featured black models as compared to white models (nearly 50 percent of ads featured white models while less than 20 percent featured black models). Duerksen et al. (2005) observed that white models were more likely to be used than black models to advertise health-promoting products, while black models were more likely to be used than white models to advertise health-diminishing products, such as fast food and alcohol. Cline and Young (2004) found a difference in the type of drugs advertised as a function of model race. Black models were not used in ads for cardiovascular- or cancer-related medications, but dominated ads for HIV/AIDS drugs. These researchers noted the potential for DTCA to perpetuate health disparities:

> Consider the potential disparity-promoting function of DTCA with regard to ethnicity for cardiovascular disease and cancer…. The principle of *homophily* suggests that consumers are more likely to attend to and be persuaded by sources perceived as similar to themselves. However, in our samples, ads for cancer- and cardiovascular-related products feature White people only….Ethnic minorities are ignored and thus likely fail to gain any educational value that DTCA offers regarding the leading causes of death (Cline & Young, 2004, p. 153).

Researchers also evaluated the type of appeals used in pharmaceutical advertising. Through the use of both visual and textual cues, advertisers may appeal to either an individual's emotions or intellect or both (Macias, Pashupati, & Lewis, 2007). Shaughnessy, Slawson, and Bennett (1994) noted that pharmaceutical advertising "provides information intricately combined with logical and emotional appeals, slogans, wishful thinking, behavior modification techniques, and gimmicks" (p. 563). The results of previous content analyses confirm this observation. In their evaluation of over 300 pharmaceutical ads, Bell et al. (2000) found the most common appeals to be innovativeness, effectiveness, symptom control, and convenience. In contrast, Main et al. (2004) found that emotional rather than rational appeals dominated the promotional part of the advertisements that they assessed. Woloshin et al. (2001) found a mix of both emotional and rational appeals in the 67 advertisements they analyzed. Most of the ads (87 percent) included some sort of benefit statements, while virtually all (98 percent) explicitly identified side effects. Over half (67 percent) of the ads used an emotional appeal, particularly the desire to "get back to normal" (p. 1144). However, no previous study has explored the relationship between the type of appeal used in a particular advertisement and the racial orientation of the magazine in which it was placed.

The 2009 FDA report included several recommendations relevant to the appearance and content of pharmaceutical advertising. Specifically, the following recommendations are applicable to this phase of the analysis (FDA, 2009, p. 26):

(1) "Use communicators in the advertisements and channels to disseminate messages that the target populations rate as credible."

(2) "Produce help-seeking or other ad campaigns concerning diseases and health issues that have particular relevance to the target community."

(3) "Provide information and relevant nondrug interventions (e.g., diet and exercise) that patients should consider."

(4) "Provide information on any available discounts or patient assistance programs that can help low income individuals obtain medications."

Based on these recommendations, pharmaceutical companies should create advertising campaigns tailored to the readers of magazines in which they intend to place ads. Models used in these ads should reflect the predominant race of the magazine's readers; messages should be clear and easy to understand. Ads should include information on alternative, nonpharmaceutical therapies, as well as information about financial assistance. Ads that embrace these recommendations should enhance their educational value and further empower consumers in their health care decision making.

To evaluate the impact of these recommendations on DTCA appearing in women's magazines published before and after the report, this chapter will address the following objectives and research questions identified in the first chapter of this dissertation:

RQ5: Does the race of the models used in DTCA vary based on the racial orientation of the magazine?

RQ6: Did the percentage of advertisements featuring black models increase following the 2009 FDA report?

RQ7: Does the provision of information about nondrug interventions vary based on the racial orientation of the magazine?

RQ8: Did the percentage of advertisements that include information about nondrug interventions increase following the 2009 FDA report?

RQ9: Does the provision of information about available discounts or patient assistance programs vary based on the racial orientation of the magazine?

RQ10: Did the percentage of advertisements that include information about available discounts or patient assistance programs increase following the 2009 FDA report?

If pharmaceutical companies were to have adopted these recommendations, one would expect to see an increase in the number of advertisements that feature black models, particularly in ads placed in black-oriented magazines, and an increase in the number of ads that suggest nondrug interventions and that provide information on financial assistance.

4.2 Data Collection

The first phase of the analysis identified 1,090 product claim advertisements. This type of ad mentions a specific drug and the medical condition for which it is used. These 1,090 ads promoted 95 different drugs falling into 15 categories of medical conditions (see Table 3-9). Because the focus of this dissertation is on the potential impact of DTCA on health disparities, only those drugs used to treat life-threatening conditions were considered in the second phase of analysis. Consequently, out of the initial 1,090 ads, 439 were identified for further analysis. Within this group, 158 represented unique versions of an ad. An ad version was considered to be unique if it differed in any of its graphic or written elements or if it included a postcard or other tear out that the reader could use to obtain additional information. The 158 ads identified

promoted 31 individual drugs used to treat the following conditions: Alzheimer's[9] disease, cancer, cardiovascular disease, depression,[9] diabetes, and respiratory illness. Table 4-1 provides the total number of ads and the total number of unique ads within each disease category.

Table 4-1: Frequency of pharmaceutical advertisements by disease category

Disease Category	# of Drugs Advertised	# of Advertisements	# of Unique Advertisements
Alzheimer's Disease	2	17	3
Cancer	2	2	2
Cardiovascular	12	108	46
Depression	4	137	43
Diabetes	4	53	17
Respiratory	7	122	47
TOTAL	31	439	158

4.2.1 Code Sheet Development

A code sheet was developed (see Appendix A) to evaluate and document several elements of each advertisement. For each of the 158 unique ad versions identified above, the name of the coder and the advertisement identification number were recorded. Next, the type of drug, the medical condition it is used to treat, and the manufacturer were documented. Finally, the size of both the promotional part of the ad and the brief summary (in terms of magazine pages) was noted.

The visual and written content of the promotional part of each ad was then coded. The ad was coded for the use of human models or likenesses, cartoon characters, or inanimate objects, such as diagrams or illustrations. If an ad featured human models,

[9] Drugs used to treat Alzheimer's disease and depression were originally coded as "Psychiatric/ Neurologic" (see Chapter 3). For the purposes of the Phase 2 analysis, these ads were recoded as either "Alzheimer's" or "Depression."

their race, gender, and age were recorded. If the ad included more than one human model, the race of the primary model was also noted. Race was coded as either Black, White, Other, or Unknown. Gender was coded as either male, female, or unknown, and age was coded as either child, adult, or senior. An ad was considered to use a human

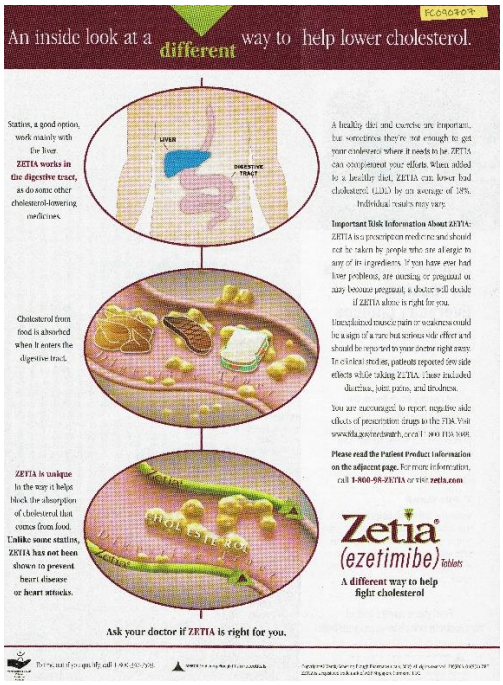


Figure 4-1: Advertisement for Zetia (*Family Circle*, September 2011)

likeness if the race of the person depicted could be discerned. For example, Figure 4-1 is an ad for Zetia. Note the cutaway of a person's digestive tract. Because the race of the torso illustrated is discernable, this ad was coded as using a human model whose race is White. The ad also included additional graphic images to convey how Zetia works. Therefore, the ad was coded as using inanimate objects.

Given that the advertisements evaluated in this phase of the analysis promote drugs used to treat potentially life-threatening diseases, few ads featured a cartoon character. However, a series of ads for the antidepressant drug, Abilify, did use a cartoon

character to depict depression (see Figure 4-2). This ad was coded as using a white female adult model and a cartoon character.

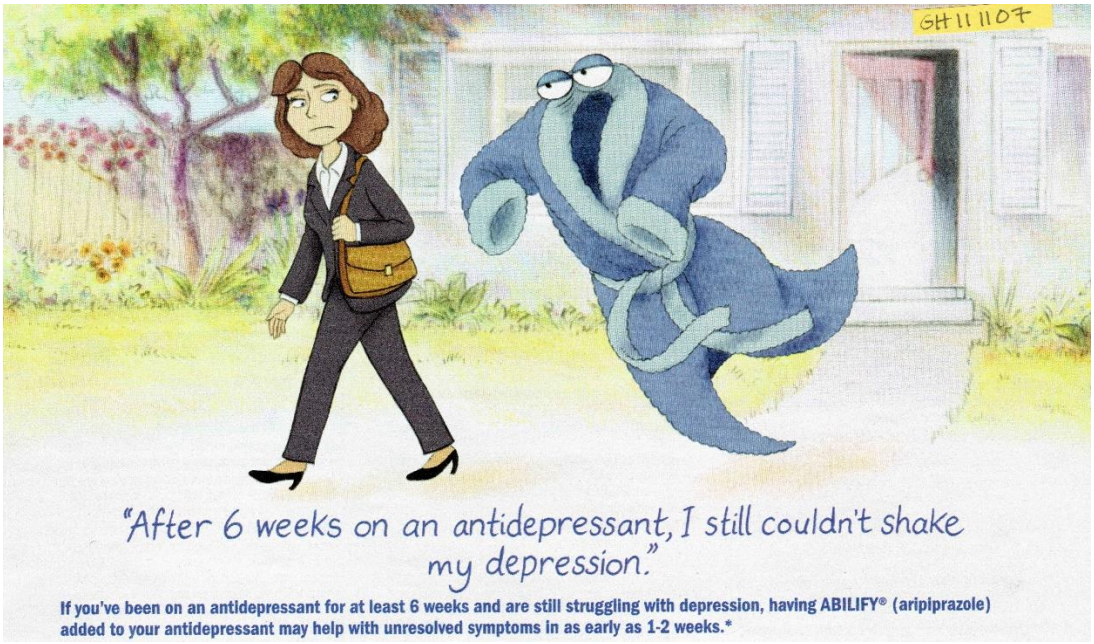


Figure 4-2: Advertisement for Abilify (*Good Housekeeping*, November 2011)

Next, the type of appeal used in the ad was considered. Appeals can be either rational or emotional. Many of the ads examined included both rational and emotional appeals. Rational appeals tend to motivate individuals through the use of logical and informational arguments (Main et al., 2004). Pharmaceutical ads may provide information related to the drug's effectiveness, social or psychological benefits, ease of use, and safety. Emotional appeals can be either positive or negative. Positive emotional appeals try to evoke a favorable consumer response by conveying a sense of warmth, happiness, or relief (Main et al., 2004). Such appeals may also be humorous, nostalgic, fanciful, or sexual (Main et al., 2004). Negative emotional appeals can inspire feelings of anger, fear, or sadness (Main et al., 2004). Tables 4-2 and 4-3 provide the coding scheme

used for recording appeal type. This scheme is based on the work of Main et al. (2004) and Bell et al. (2000).

The work of Bell et al. (2000) focused on the product claims made in the advertisement. These researchers identified four key attributes—effectiveness, social-psychological enhancements, ease of use, and safety—as well as a number of descriptors for each. Building on Bell et al. (2000), Main et al. (2004) coded their ads for both rational and emotional appeals. Unlike Bell et al. (2000), they did not identify individual attributes associated with rational appeals, coding instead for the mere presence of such an appeal. In terms of emotional appeals, Main et al. (2004) coded for both positive and negative appeals, noting whether the positive appeals used humor, nostalgia, fantasy, or sex appeal.

Table 4-2 is taken from Bell et al. (2000) and modified to capture the attributes and descriptive phases found in the advertisements included in the current study.

Table 4-2: Coding of rational appeals

Claimed Attribute	Description of Drug
Effectiveness	
Effective	"lowers," "helps," "proven," "more effective," "works to," "showed improvement," "improve," "reduce"
Innovative	"the first," "only," "different," "works differently"
Powerful	"highest approved dose," "concentrated," "combines two proven medicines," "one pill that does two things," "treats both"
Prevention	"reduce the risk," "help stay protected," "prevent symptoms"
Reduced Mortality	"help save lives"
Symptom Control	"treat the symptoms," "treats many symptoms," "symptom improvement," "helps control the symptoms"

Table 4-2: (continued)

Social-Psychological Enhancements	
Lifestyle	"may help me lose some weight," "fits into my busy life," "breathe better"
Psychological	"help reduce your risk," "can reduce your risk"
Ease of Use	
Convenience	"once-daily," "once a day," "easy to use," "daily," "no regular blood tests"
Quick Acting	"as soon as two weeks," "in as early as 1–2 weeks"
Safety	
Safe	"over 8 years of safety and efficacy data," "approved," "FDA approved," "extensively studied," "steroid-free," "#1 prescribed"
Natural	"a prescription made from nature," "made from a natural ingredient"

Coding emotional appeals was more nuanced in some cases. Emotions can be conveyed both visually and textually. In addition, some ads relied on both positive and negative emotional appeals. Table 4-3 presents a selection of visual and textual cues associated with the types of emotional appeals coded by Main et al. (2004). Again, the images and text were found in the advertisements included in the study sample. Because of the purpose of the drugs advertised, no fantasy or sex appeals were found.

Table 4-3: Coding of emotional appeals

Emotion	Images	Text
Positive Emotional Appeals		
Warmth, Happiness. Empowerment	Grandmother and granddaughter blowing bubbles, child blowing pinwheel, photo of woman with boxing gloves	"My asthma…under control with the help of SYMBICORT"; "take center stage in your own life"; "I am a strong woman"; "Doctors removed my lump, not my spirit"; "Today, I took steps to balance my Type 2 Diabetes"
Humor	A cutway of $1 bill with George Washington seen blowing bubbles; elephant sitting on woman in a recliner; illustration of animated bathrobe following woman	
Nostalgia	Pictures of previous events in the featured model's life; daughter hugging her elderly mother	"Throughout my life, mom has been there for me. Now it's my turn"; "I want to give to the man who gave me a sense of harmony"
Negative Emotional Appeals		
Fear	Word "Emergency" printed across page; photo of person on gurney being rushed through hospital corridor	"Is your asthma really under control, or do you just think it is?"; "I never thought it could happen to me. A heart attack at 53"; "Are you kidding yourself?"

Table 4-3: (continued)

Emotion	Images	Text
Sadness	Photo of emotionally distraught young woman; illustration of woman looking in a mirror seeing what she could be doing if she were not depressed; dog holding ball looking longingly at its master who looks back vacantly	"Depression hurts"; "hello hurts"; "With depression, simple pleasures can simply hurt"; "Depression can make you feel like you have to wind yourself up to get through the day"
Guilt	Mother holding daughter who is obviously having trouble breathing	"If she needs a rescue medicine more than twice a week, this could be your wake up call"; "Is your child's asthma really under control, or do you just think it is?"; "a kid who's got what your kid's got is out doing what your kid's not"

When coding for the type of appeal, both the text and the images used in the ad were considered. Figure 4-1 is an example of an ad that uses only a rational appeal. The illustrations used are informative rather than provocative, explaining to the reader how Zetia works and why it differs from other cholesterol lowering drugs. In contrast, the Abilify ad (Figure 4-2) relies primarily on an emotional appeal, combining the elements of humor, in the form of a bathrobe (the embodiment of depression) chasing after a woman, and fear as the expression on the woman's face conveys to the reader her distress that she has been unable to shake her depression. The text provides the rational appeal, explaining that Abilify "may help with unresolved symptoms in as early as 1–2 weeks." This ad was coded as having both a rational (effective; quick-acting) and emotional appeal (humor; fear).

An ad for Cymbalta (Figure 4-3), another antidepressant, has an extremely strong emotional appeal, both in its visual and textual cues. The young woman featured in the ad appears to be emotionally distraught, which is confirmed by the first half of the tag line, "Depression hurts." The second half of the tag line, "Cymbalta can help," suggests that Cymbalta may offer relief. The text lets the reader know that Cymbalta "treats many symptoms of depression." Like the Abilify ad, this ad was coded as having both a rational (effective) and emotional (sadness) appeal. However, the emotional appeals used to promote Abilify and Cymbalta are quite different. The Abilify ad uses both humor (a positive emotion) and fear (a negative emotion) to convey its message. The Cymbalta ad relies on a negative emotion (sadness) alone. The coding sheet included subcategories to capture the more subtle differences between positive and negative emotional appeals.

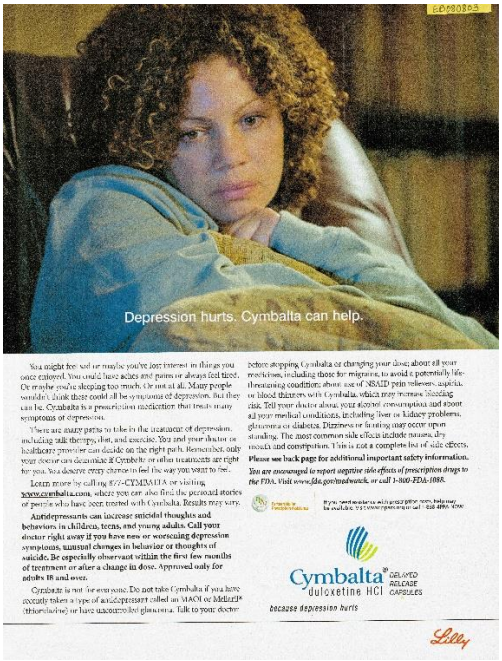


Figure 4-3: Advertisement for Cymbalta (*Ebony*, June 2008)

Pharmaceutical ads may also include other information, such as an offer to help in finding patient support services or a Web site address and telephone number from which the reader can gain additional information. The 2009 FDA report recommended that ads provide information about nonpharmaceutical interventions (e.g., diet and exercise), as well as information about discounts or other programs to assist patients in obtaining medications (FDA, 2009). Ads should also encourage readers to talk with their doctor or healthcare provider about the product. Finally, the FDAAA of 2007 requires that print ads include the statement, "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch, or call 1-800-FDA-1088" (FDA, 2012b).

The code sheet included the following series of yes/no questions to document whether or not each ad included such information:

- Is the reader offered help in finding patient support services?
- Is the reader referred to a Web site for additional information?
- Is the reader given a telephone contact for additional information?
- Is the reader encouraged to talk with a doctor or another individual?
- Is the reader offered monetary incentives or other financial support?
- Is the reader informed of nondrug interventions, such as diet and exercise, which might be helpful?
- Is the reader encouraged to report negative side effects of prescription drugs to the FDA?

Any offer of patient support services was coded affirmatively. Such offers might include a postcard to send off for an informational brochure or CD-ROM, a Web site

offering supportive tips for making positive lifestyle changes, or a Web site detailing patient and caregiver resources. Similarly, any offer of financial assistance, whether it be a free 30-day trial or a referral to the Partnership for Prescription Assistance or a similar manufacturer-sponsored program, was coded affirmatively. However, such information had to have appeared within the promotional part of the ad, where it is most likely to be seen, rather than within the brief summary.

The inclusion of Web site addresses and telephone numbers was fairly obvious, although some were associated with monetary incentives rather than additional disease and treatment information. However, after visiting a few of these Web sites, it was determined that regardless of the stated purpose in the ad, all provided additional substantive information about the drug and its purpose. Therefore, if the ad referred the reader to either a Web site or telephone number or both it was coded affirmatively.

While no ad suggested that an alternative therapy, such as dietary changes, would be as effective as a pharmaceutical intervention, several did suggest that improved diet and increased exercise could be used in conjunction with the drug. Others suggested the use of a drug when exercise and diet were not enough (this sentiment was found in many of the ads for cholesterol lowering medications). If the ad mentioned any lifestyle change, no matter the context, this question was coded in the affirmative.

Each ad was also coded for the appearance of the statement required by the FDAAA encouraging consumers to report negative side effects. This is a regulatory requirement resulting from the same statute in which Congress directed the FDA to study DTCA as it "relates to increased access to health information and decreased health disparities for these populations" (FDA, 2009, p. i). This variable was included as a basis

for comparing the response of pharmaceutical companies to a regulatory requirement found in the FDAAA versus the voluntary recommendations contained in the 2009 FDA report.

4.2.2 Procedure and Reliability

Once the code sheet was initially developed, both the author and an independent colleague pretested it on five pharmaceutical ads that appeared in magazines outside the sample universe. After comparing the pretest results, minor revisions were made to the code sheet to aid in interpretation of graphic images. The author reviewed the coding procedures with a second coder, and five ads outside of the sample universe were jointly coded to enhance reliability. The author coded all of the 158 ads in the sample; the second coder coded a random subsample of 10 percent of the ads (n=16).

Average percent agreement for the 20 variables used in this phase of the analysis was 90.3 percent, and average kappa for 17 of the 20 variables was 0.81 (range 0.05–1.0). Interrater reliabilities reported as Cohen's kappas were: use of human models (1.0), use of cartoon characters (1.0), use of inanimate objects (0.59), race of primary model (.82), social/psychological enhancement (.48), ease of use (.50), safety (0.05), positive appeal (.74), humor appeal (.64), negative appeal (.87), patient support services (1.0), Web address (1.0), telephone number (1.0), referral to health care provider (1.0), offer of financial assistance (1.0), mention of nondrug interventions (1.0), and statement regarding the reporting of negative side effects to the FDA. Kappas could not be calculated for 3 of the 20 variables because the value assigned by one of the two raters remained constant, thereby creating an error in SPSS. However, the percent agreement

for these three variables was greater than 50 percent—rational appeal (93.8 percent), effectiveness (62.5 percent), and nostalgic appeal (93.8 percent).

Agreement between the two raters was weakest among the variables associated with the types of claims made in the ads (effectiveness, social/psychological enhancement, ease of use, and safety). However, in all cases, the percent of agreement was at least 50 percent. In addition, these variables are not central to the study's research questions. Therefore, the results of the primary researcher were used in the final analysis. An independent third party will resolve the observed differences prior to future analysis.

4.3 Data Analysis

This level of analysis focused on the individual advertisement. SPSS Version 22 was used for all statistical analyses. A total of 158 unique ads were coded; however, the ID numbers for identical ads were noted on the coding sheet. Data were then entered for the entire subset of 439 advertisements.

Using the same methods described in Chapter 3, the data collected from *Ebony* and *Essence* magazines were collapsed into a single category, "Black-Oriented Magazines," and the data for *Family Circle* and *Good Housekeeping* were collapsed into a single category, "White-Oriented Magazines." Data from *O, The Oprah Magazine* were categorized as "Crossover Magazine." Similarly, data collected from magazine issues published before the FDA report (i.e., 2008 and 2009) were collapsed into a single category, "Before FDA Report," and data collected from issues published after the FDA report (i.e., 2011 and 2012) were collapsed into a single category, "After FDA Report." In this way, advertisements placed in different magazine genres could be compared, and differences in ad appearance and content across time could be identified.

Qualitative techniques were used to evaluate each advertisement. Qualitative observations were then translated into quantitative, categorical variables to facilitate statistical analyses. Descriptive statistics (i.e., frequency distributions and cross-tabulations) were used to ascertain quantitative differences in the appearance and content of the ads as a function of the racial orientation of the magazine in which they appeared and their publication date relative to the 2009 FDA report. A Chi-square test for independence was used to explore the associations among the categorical variables. In some cases, a difference in proportions test was also used to determine the statistical significance of percentage differences pre- and post-FDA report publication (such as a change in the percentage of black models used in advertisements found in black-oriented magazines).

4.4 Results

Of the 439 pharmaceutical ads included in this phase of the analysis, a total of 206 ads appeared in magazines published before the FDA report, and 233 appeared in magazines published after the report. The following results pertain only to this subset of 439 advertisements. All observations made refer only to this subset of ads and not to the universe of DTCA discussed in Chapter 3.

Within the 206 ads published before the FDA report, 22 drugs were advertised. The 233 ads published after the report promoted 21 different medications. Drugs used to treat cancer, cardiovascular disease, diabetes, depression, and respiratory illness were advertised in magazines published before the 2009 FDA report. Drugs used to treat Alzheimer's disease, cardiovascular disease, diabetes, depression, and respiratory illness were advertised in magazines published after the 2009 FDA report. Table 4-4 presents

the distribution of ads by disease category before and after publication of the FDA report, and Figure 4-4 illustrates these data.

Table 4-4: Types of drugs advertised by disease category before and after publication of FDA report

Disease Category	Before	After	Total
Alzheimer's			
N	0	17	17
%	0.0	100.0	100.0
Cancer			
N	2	0	2
%	100.0	0.0	100.0
Cardiovascular			
N	76	32	108
%	70.4	29.6	100.0
Depression			
N	44	93	137
%	32.1	67.9	100.0
Diabetes			
N	24	29	53
%	45.3	54.7	100.0
Respiratory			
N	60	62	122
%	49.2	50.8	100.00
Total	206	233	439
%	46.9	53.1	100.0

χ^2 (5, n=439) = 53.50, $p < .001$

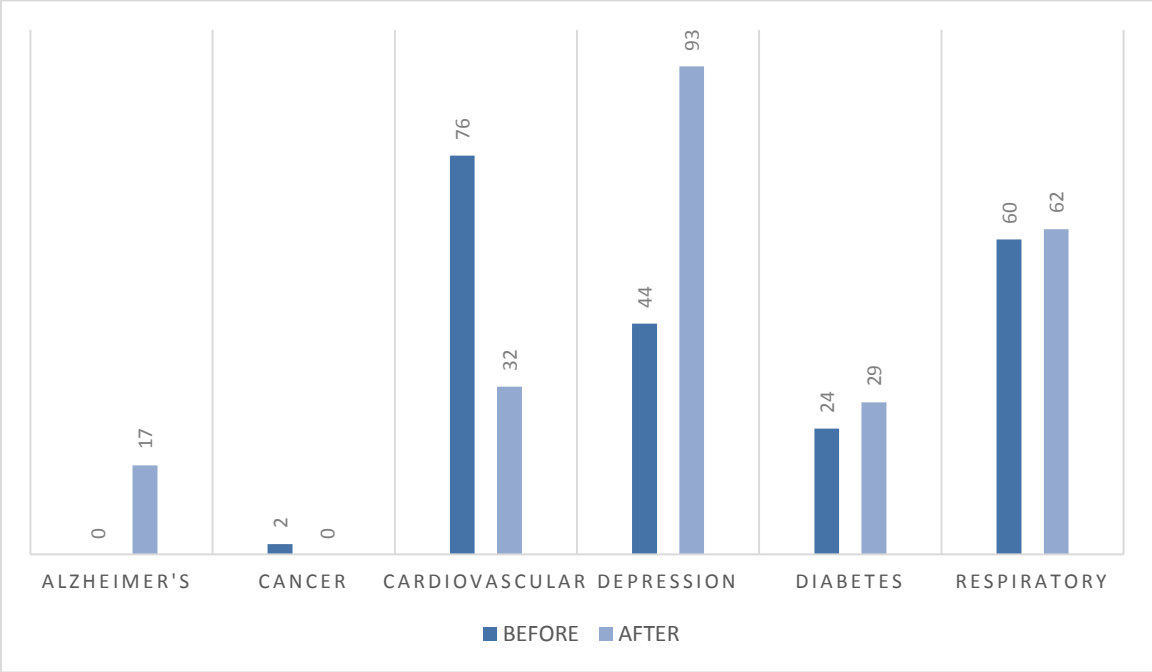


Figure 4-4: Distribution of DTCA by disease category
before and after publication of FDA report

From Table 4-4 and Figure 4-4, we can see variation in the frequency of the various types of drugs advertised pre- and post-FDA report. The most notable differences occurred in the number of ads for cardiovascular drugs, which declined from 76 (36.9 percent) to 32 (13.7 percent). In contrast, antidepressants increased from 44 (21.4 percent) to 93 (39.9 percent). Both of these differences are statistically significant at the 95 percent confidence level. A Chi-square test for independence indicated a positive association ($p < .001$) between the type of drug advertised (by disease category) and the year in which the ad was published (either pre- or post-FDA report).

The three drugs most advertised before the FDA report was published were Advair Diskus, used to treat asthma or COPD (12.6 percent of all ads); Plavix, used to reduce the risk of blood clots (11.7 percent); and Abilify, used to treat depression and

bipolar disorder (11.2 percent). In contrast, all three of the drugs (Cymbalta (12.4 percent), Abilify (10.7 percent), and Pristiq (10.7 percent)) most advertised in 2011 and 2012 (the period after publication of the FDA report) are used to treat depression.

The number of pages devoted to the promotional part of the advertisement was greater in ads published after the FDA report than before. The promotional part of the vast majority of ads (84.0 percent) published in 2008 and 2009 was a single page; less than 5 percent of the ads included a two-page promotional spread and less than 1 percent included a three-page promotional spread. By contrast, one-third of the ads published in 2011 and 2012 featured a two-page promotional spread, although none featured a three-page promotional spread. Many of these longer ads were associated with the drug Cymbalta. Nearly all of the ads examined, regardless of publication date, dedicated a single page to the brief summary material.

The majority of DTCA evaluated in this phase of the analysis featured at least one human model or likeness. In 2008 and 2009, 156 ads (75.7 percent) included a human model. In 2011 and 2012, this number increased to 216 (92.7 percent). Again, this difference was driven by the overall increase in ads for medications used to treat Alzheimer's disease or depression, all of which featured human models. It was possible to identify the race of the models used in all but six of the ads.

Nearly 60 percent of ads published in 2008 and 2009 included an inanimate object of some sort, whether it be a chart, diagram, or an image of the actual medical device, such as an inhaler or injection pen. That proportion declined to 43 percent for ads published in 2011 and 2012. Few ads in any year studied included cartoon characters.

To respond to the research objectives posed at the beginning of this chapter, it was necessary to examine differences in appearance and content of ads as a function of the racial orientation of the magazines in which they appeared. The following sections provide further analysis.

4.4.1 Differences in Appearance

RQs 5 and 6 relate to differences in the race of models used in DTCA placed in black-oriented women's magazines versus white-oriented women's magazines before and after the 2009 FDA report. RQ5 asks whether the race of the models used in DTCA varies based on the racial orientation of the magazine, and RQ6 questions whether the number of advertisements featuring black models increased after publication of the FDA report in 2009. To answer these questions, data were first filtered by whether the advertisement included a human model or likeness. Those ads that did feature a human model or likeness were then filtered by magazine genre and publication date.

To address RQ5, Table 4-5 looks at the race of the primary model used in DTCA placed in different magazine genres. The number of ads in which the primary model is either Black or White is reported. From this table we can see that the race of the models used in pharmaceutical advertising is positively associated with the racial orientation of the magazine in which it appears (χ^2 (2, n=348) = 103.8, $p < .001$). Over 70 percent of the ads appearing in black-oriented magazines featured black models. Similarly, over 80 percent of the ads appearing in white-oriented magazines featured white models.

Table 4-5: Race of primary model by magazine genre

Magazine Genre	Primary Model Race		Total
	Black	White	
White-Oriented			
N	33	207	240
%	13.8	86.3	100.0
Black-Oriented			
N	52	16	68
%	76.5	23.5	100.0
Crossover			
N	12	28	40
%	30.0	70.0	100.0
Total	97	251	348
%	27.9	72.1	100.0

χ^2 (2, n=348) = 103.8, p < .001

This trend was present regardless of when the ad was published. Tables 4-6 and 4-7 compare the frequency with which model race aligned with magazine genre in DTCA published before and after the 2009 FDA report. The number of ads in which the primary model is either Black, White, or another identifiable race or ethnicity (e.g., Hispanic, Asian, or Indian) is reported. A Chi-square test confirms the statistical significance of this trend for both time periods examined (pre-FDA report publication: χ^2 (4, n=150) = 56.47, p < .001; post-FDA report publication: χ^2 (4, n=216) = 60.41, p < .001).

The results for the crossover magazine are interesting. In the time period before publication of the FDA report, DTCA placed in the crossover magazine, *O, The Oprah Magazine,* included a similar number of ads featuring either a black or white model (7 and 10, respectively). However, in the time period following publication of the FDA report, this proportion shifted dramatically. Twenty-one ads published between 2011 and 2012 featured white models, while only two ads featured black models. Statistical testing for significant difference between two proportions revealed that the decrease in the

number of ads featuring black models found in *O, The Oprah Magazine* over time was statistically significant at the 95 percent confidence level.

Table 4-6: Race of models appearing in DTCA by magazine genre before FDA report

	Race of Primary Model			
Magazine Genre	White	Black	Other	Total
White				
N	84	9	1	94
%	89.4	9.6	1.1	100.0
Black				
N	11	28	0	39
%	28.2	71.8	0.0	100.0
Crossover				
N	7	10	0	17
%	41.2	58.8	0.0	100.0
Total	102	47	1	156
%	68.0	31.3	0.7	100.0

χ^2 (4, n=150) = 56.47, p < .001

Table 4-7: Race of models appearing in DTCA by magazine genre after FDA report

	Race of Primary Model			
Magazine Genre	White	Black	Other	Total
White				
N	123	24	11	158
%	77.8	15.2	7.0	100.0
Black				
N	5	24	3	32
%	15.6	75.0	9.4	100.0
Crossover				
N	21	2	3	26
%	80.8	7.7	11.5	100.0
Total	149	50	17	216
%	69.0	23.1	7.9	100.0

χ^2 (4, n=216) = 60.41, $p < .001$

Figure 4-5 and Table 4-8 help us to answer RQ6, which asks whether the percentage of advertisements featuring black models increased following the 2009 FDA report. Figure 4-5 illustrates the distribution of model race by time period.

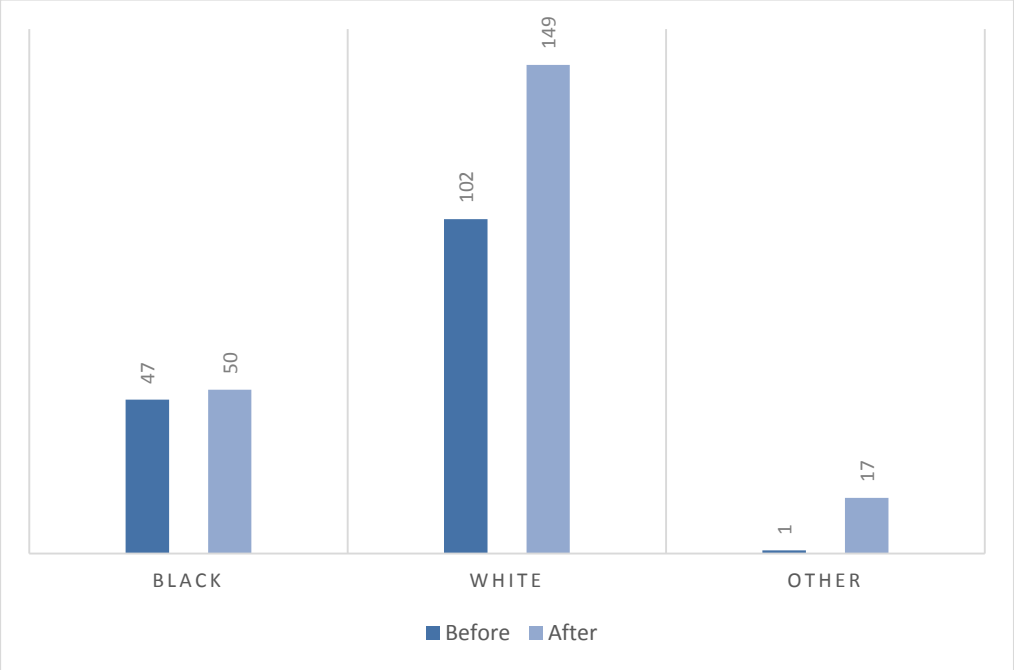


Figure 4-5: Frequency of model race appearing in DTCA published before and after FDA report

As one can see, the race of the majority of the models used was White, followed by Black. The number of ads featuring black models remained relatively unchanged over time (47 versus 50), while the number of ads featuring white models and models that were neither Black nor White increased. From Table 4-8, which presents the results of a Chi-square test for independence, we can see that the association between the race of the primary model used in advertisements and the racial orientation of the magazine in which they appear remains significant over time (χ^2 (3, n=372) = 19.96, p < .001).

Table 4-8: Race of primary model appearing in DTCA published before and after FDA report

Primary Model Race	Before	After	Total
White			
N	102	149	251
%	40.6	59.4	100.0
Black			
N	47	50	97
%	48.5	51.5	100.0
Other			
N	1	17	18
%	5.6	94.4	100.0
Total	150	216	366
%	41.9	58.1	100.0

χ^2 (2, n=366) = 11.59, p=.003

In terms of whether the percentage of advertisements featuring black models increased following the FDA report, it appears that the percentage decreased from 31.3 percent (see Table 4-6) in the 2008/2009 timeframe to 23.1 percent (see Table 4-7) in the 2011/2012 timeframe. However, if we look only at the difference in the percentage of ads featuring black models that appeared in black-oriented magazines, we find a slight increase from 71.8 percent (see Table 4-6) of ads published in the 2008/2009 timeframe to 75.0 (see Table 4-7) of ads published in the 2011/2012 timeframe. Neither of these percentage differences are statistically significant at the 95 percent confidence level.

The relationship between the type of drug advertised, model race, and magazine genre was also explored. Tables 4-9 and 4-10 examine the association between the race of the primary model used in an advertisement and the disease category in which the advertised medication falls. Table 4-9 provides these data for ads published in the 2008/2009 timeframe, and Table 4-10 provides these data for ads published in the 2011/2012 timeframe. As can be seen, the majority of ads in all disease categories but

one feature white models. Diabetes is the only disease category in which a preponderance of ads for medications to treat this disease feature black models. In the 2008/2009 timeframe, 19 of the 24 ads (79.2 percent) for diabetes medications featured a black model. In the 2011/2012 timeframe, 21 of the 29 ads (72.4 percent) for this drug type feature a black model. A Chi-square test for independence indicates that the association between the race of the primary model featured in an ad and the medication that is advertised is statistically significant for both time periods studied: (pre-FDA report: χ^2 (8, n=150) = 39.78, p < .001; post-FDA report: χ^2 (8, n=216) = 53.65, p < .001).

Table 4-9: Race of primary model in DTCA published before the FDA report by disease category

	Race of Primary Model			
Disease Category	White	Black	Other	Total
Alzheimer's				
N	0	0	0	0
%	0.0	0.0	0.0	100.0
Cancer				
N	1	1	0	2
%	50.0	50.0	0.0	100.0
Cardiovascular				
N	46	5	1	52
%	88.5	9.6	1.9	100.0
Depression				
N	25	14	0	39
%	64.1	35.9	0.0	100.0
Diabetes				
N	5	19	0	24
%	20.8	79.2	0.0	100.0
Respiratory				
N	25	8	0	33
%	75.8	24.2	0.0	100.0
Total	102	47	1	150
%	68.0	31.3	0.7	100.0

χ^2 (8, n=150) = 39.78, p < .001

Table 4-10: Race of primary model in DTCA published after the FDA report by disease category

	Race of Primary Model			
Disease Category	White	Black	Other	Total
Alzheimer's				
N	11	6	0	17
%	64.7	35.3	0.0	100.0
Cancer				
N	0	0	0	0
%	0.0	0.0	0.0	100.0
Cardiovascular				
N	25	2	4	31
%	80.6	6.5	12.9	100.0
Depression				
N	69	16	8	93
%	74.2	17.2	8.6	100.0
Diabetes				
N	8	21	0	29
%	27.6	72.4	0.0	100.0
Respiratory				
N	36	5	5	46
%	78.3	10.9	10.9	100.0
Total	149	50	17	216
%	69.0	23.1	7.9	100.0

χ^2 (8, n=216) = 53.65, p < .001

As discussed in the previous chapter, the types of drugs advertised varied by the racial orientation of the magazine. Chapter 3 provided information for drugs advertised in all disease categories. Since the focus of this chapter is on drugs used to treat life-threatening conditions, the data presented in the following figures and table represent only the six disease categories of interest in the second phase of analysis. Figures 4-6 and 4-7 illustrate the distribution of advertisements by disease category as a function of magazine genre. Figure 4-6 provides this information for ads published before the 2009 FDA report; Figure 4-7 provides this information for ads published after the report. As noted previously, drugs used to treat diabetes were most likely to be found in magazines

read by a predominantly black audience, regardless of publication date. Cardiovascular drugs were advertised in all magazine genres studied with publication dates in either 2008 or 2009; however, no cardiovascular drugs were advertised in either *Ebony* or *Essence* in 2011 or 2012. Antidepressant drugs were more likely to be advertised in magazines read by a predominantly white audience in both time periods studied, although the number of ads for these types of drugs that appeared in *O, The Oprah Magazine* (i.e., the crossover magazine) more than doubled between 2008 and 2012 (from 10 to 22).

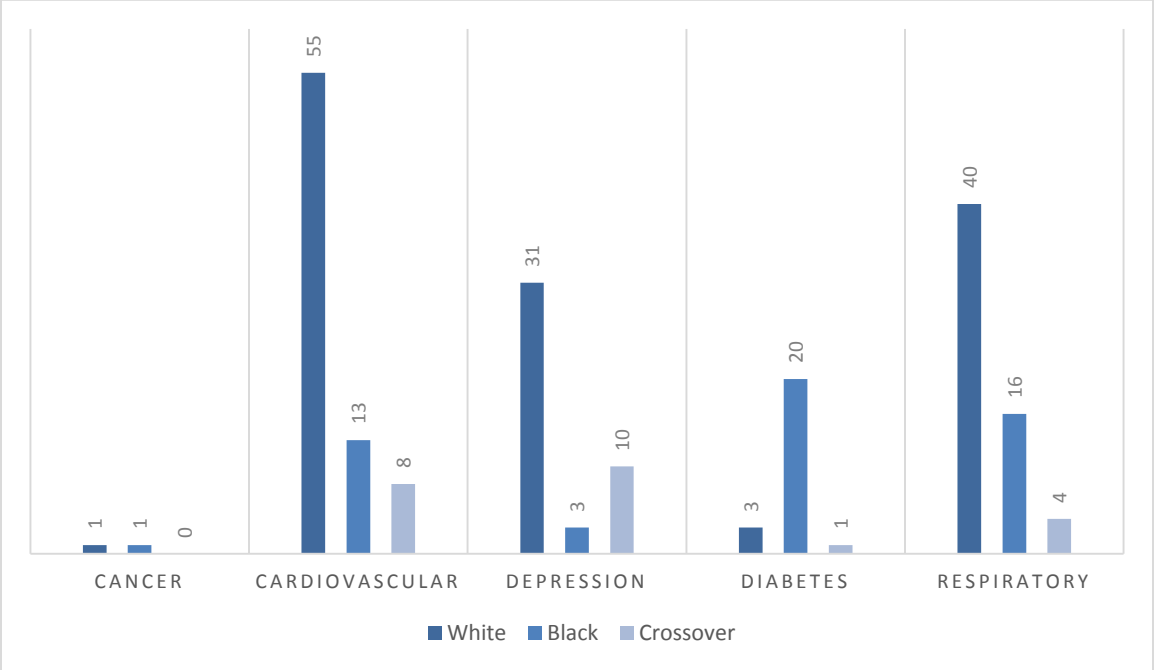


Figure 4-6: Frequency of DTCA published before FDA report by disease category

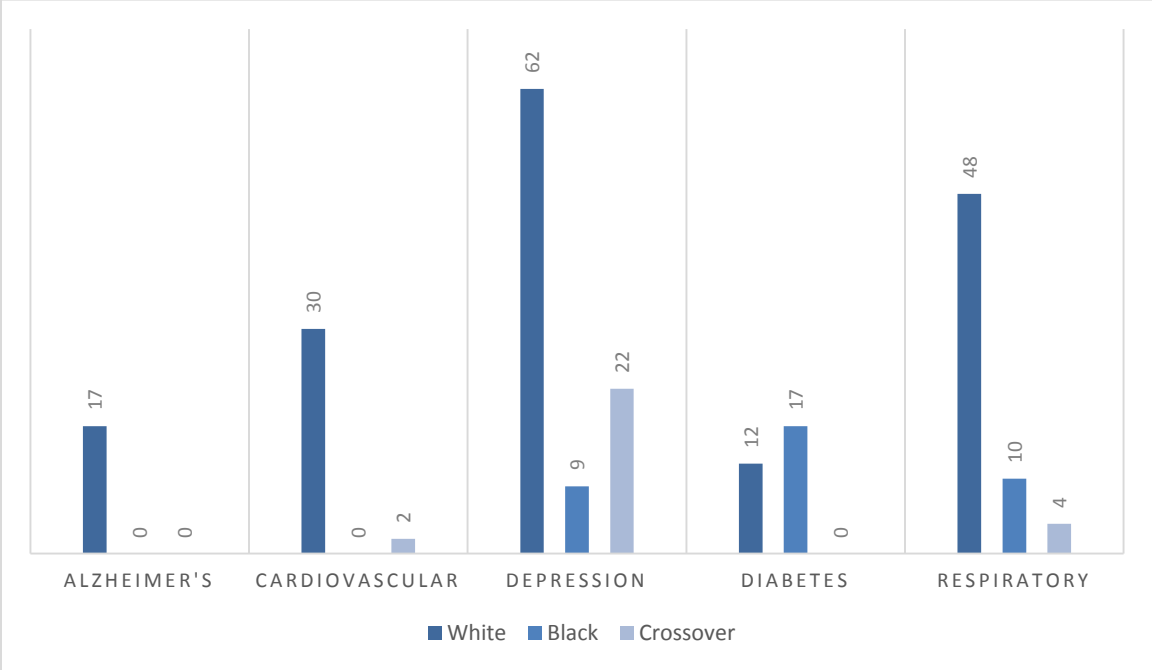


Figure 4-7: Frequency of DTCA published after FDA report by disease category

Looking solely at the number of ads published may be misleading given the disparity in the amount of DTCA appearing in *Family Circle* and *Good Housekeeping* relative to the other magazine titles studied. Table 4-11 presents the percentage of ads published both before and after the FDA report by the six disease categories of interest as a function of magazine genre. The greatest percentage of ads within these six disease categories published in *Family Circle* and *Good Housekeeping* prior to the FDA report promoted drugs to treat cardiovascular disease (42.3 percent) and respiratory illness (30.8 percent). After the report, the majority of ads promoted drugs to treat depression (46.0 percent) and respiratory illness (28.4 percent). Regardless of publication date, the greatest percentage of ads within the six disease categories of interest that were published in *Ebony* and *Essence* during the time period studied promoted drugs used to treat diabetes (37.7 percent and 47.0 percent, respectively) and respiratory illness (30.2 percent

and 27.8 percent, respectively). Similarly, the greatest percentage of ads within the six disease categories of interest published in *O, The Oprah Magazine* promoted drugs used to treat depression (43.5 percent and 79.6 percent, respectively).

Table 4-11: Percent of DTCA published before and after FDA report by disease category as a function of magazine genre

	BEFORE			AFTER		
Disease Category	Magazine Genre			Magazine Genre		
	White	Black	Crossover	White	Black	Crossover
Alzheimer's	N/A	N/A	N/A	10.1 (n=17)	N/A	N/A
Cancer	0.8 (n=1)	1.9 (n=1)	N/A	N/A	N/A	N/A
Cardiovascular	42.3 (n=55)	24.5 (n=13)	34.8 (n=8)	17.8 (n=30)	N/A	7.1 (n=2)
Depression	23.8 (n=31)	5.7 (n=3)	43.5 (n=10)	46.0 (n=68)	25.0 (n=9)	79.6 (n=22)
Diabetes	2.3 (n=3)	37.7 (n=20)	4.5 (n=1)	7.1 (n=12)	47.0 (n=17)	N/A
Respiratory	30.8 (n=40)	30.2 (n=16)	17.4 (n=4)	28.4 (n=48)	27.8 (n=10)	14.3 (n=4)

N/A indicates that no ads for drugs in this disease category appeared during the time period studied.

4.3.2 Differences in Content

The second phase of analysis examined the differences in the content of DTCA found in black-oriented women's magazines versus white-oriented women's magazines before and after the 2009 FDA report. For the purposes of this study, content refers to the type of appeal used in an advertisement, as well as the type of information provided, particularly information about financial assistance and nondrug interventions. The 2009 FDA report specifically recommends that DTCA include such information.

The first step of this analysis looked at whether the type of appeal varied as a function of the racial orientation of the magazine. A Chi-square test for independence

found that ads using a rational appeal were just as likely to be found in a white-oriented magazine as in the black-oriented or crossover magazines (χ^2 (2, n=439) = 1.41, p=.493). This was also true of DTCA using an emotional appeal (χ^2 (2, n=439) = .777, p=.678) (see Tables D-1 and D-2). However, as Tables 4-12 and 4-13 demonstrate, the type of appeal used in an advertisement is associated with the disease category of the advertised drug.

Table 4-12: DTCA using a rational appeal by disease category

	Rational Appeal?		
Disease Category	No	Yes	Total
Alzheimer's			
N	0	17	17
%	0.0	100.0	100.0
Cancer			
N	0	2	2
%	0.0	100.0	100.0
Cardiovascular			
N	0	108	108
%	0.0	100.0	100.0
Depression			
N	0	137	137
%	0.0	100.0	100.0
Diabetes			
N	3	50	53
%	5.7	94.3	100.0
Respiratory			
N	0	122	122
%	0.0	100.0	100.0
Total	3	439	439
%	0.7	99.3	100.0

χ^2 (5, n=439) = 22.00, p=.001

Table 4-13: DTCA using an emotional appeal by disease category

	Emotional Appeal?		
Disease Category	No	Yes	Total
Alzheimer's			
N	0	17	17
%	0.0	100.0	100.0
Cancer			
N	0	2	2
%	0.0	100.0	100.0
Cardiovascular			
N	21	87	108
%	19.4	80.6	100.0
Depression			
N	12	125	137
%	8.6	91.3	100.0
Diabetes			
N	0	53	53
%	0.0	100.0	100.0
Respiratory			
N	27	95	122
%	22.1	77.9	100.0
Total	60	379	439
%	13.7	86.3	100.0

χ^2 (5, n=439) = 24.66, p < .001

Virtually all advertisements (99.3 percent) made some sort of rational appeal. Only three ads for a diabetic drug did not. These ads were for the diabetes drug, Victoza, and focused on a patient support program that the manufacturer, novo nordisk, had initiated with celebrity spokesperson, Paula Deen.

A majority of ads (86.3 percent) also included some type of emotional appeal. Some ads for cardiovascular and respiratory drugs provided only a rational appeal, preferring to state facts and figures about the drugs' effectiveness and the extent of its use. For example, the advertisement for Zetia (see Figure 4-1), states, "If you diet and take a statin, ZETIA can help lower LDL (bad) cholesterol even more." This is followed by a series of statements explaining how Zetia works and why it is unique. An ad for

Advair Diskus, used to treat asthma and COPD, simply directs the reader to talk to his or her doctor about Advair. Table 4-13 also indicates that about 9 percent of the ads for drugs used to treat depression did not include an emotional appeal. A version of an ad for Abilify published in 2009 features a series of medicine bottles labeled with the names of common antidepressants, such as Lexapro, Zoloft, and Prozac. The tag line reads, "Talk to your doctor. Adding Abilify to an antidepressant such as one of these can help treat unresolved symptoms of depression." As noted earlier, many ads contained both a rational and an emotional appeal.

Because the type of appeal used is positively associated with the drug advertised, rather than with the magazine genre in which the advertisement appeared, several research questions probing the general differences in ad content used over time were reconsidered. These original research questions were replaced with RQs 7–10, which focus on whether an ad provided information on nondrug interventions and financial assistance, as recommended in the 2009 FDA report. While no longer central to the primary purpose of this study, Appendix D does report the frequency of ads using various types of rational and emotional appeals as a function of time and magazine genre.

Advertisements were also coded for their inclusion of more general information, Table 4-14 summarizes these data. Most of the content remained the same between the two study periods. For example, all advertisements, regardless of their publication date referred the reader to a Web site where he or she could obtain additional information. Nearly all encouraged readers to talk to their doctor or healthcare provider about the advertised medication. The percentage of ads offering patient support services and financial assistance remained relatively unchanged between the two study periods, with

few (14–15 percent) offering patient support services and most (87–88 percent) offering financial assistance. The percentage of ads providing a telephone number declined over the two periods studied, although over three-quarters of the DTCA reviewed did offer one. The most noticeable differences were in the percentage of ads recommending alternative therapies, such as diet and exercise, and the percentage of ads that encouraged consumers to report negative side effects of prescription drugs to the FDA. In the first case, the percentage declined from 44.4 percent to 38.1 percent; in the second case, the percentage increased from 82.4 percent to 99.6 percent (see Table 4-14). The increase in the number of ads encouraging consumers to report negative side effects would be expected given the regulatory requirement to do so promulgated as a result of the FDAAA. However, a difference in proportion test suggests that none of the differences are statistically significant at the 95 percent confidence level.[10]

Table 4-14: Other content included in DTCA published before and after FDA report

	BEFORE		AFTER	
Content	Frequency	Percent	Frequency	Percent
Support Services	31	15.0	34	14.6
Web Site	206	100.0	233	100.0
Telephone Number	171	83.0	180	77.3
Healthcare Provider	204	99.0	229	98.3
Financial Assistance	180	87.4	206	88.4
Nondrug Interventions	91	44.2	88	37.8
Side Effects to FDA	170	82.5	232	99.6

[10] A difference in proportions test could not be conducted for the variable, "Side Effects to FDA," because the values violated the requirements of the test. However, the fact that nearly 100 percent of ads now include this requirement is noteworthy, if not statistically significant.

Table 4-15 looks at these data by magazine genre. A lower percentage of ads published before the FDA report that appeared in black-oriented magazines included information about patient support services (7.5 percent versus 18.5 percent of ads appearing in white-oriented magazines and 13.0 percent of ads appearing in the crossover magazine). This difference reversed itself in ads published after the FDA report, with a greater percentage of ads appearing in black-oriented magazines containing such information (27.8 percent versus 12.4 percent of ads appearing in white-oriented magazines and 10.7 percent of ads appearing in the crossover magazine). A difference in proportions test reveals that the change in the percent of ads offering patient support services that appeared in black-oriented magazines over time is statistically significant at the 95 percent confidence level.

Table 4-15: Percent of DTCA published before and after FDA report that includes other content

	BEFORE			AFTER		
Content	Magazine Genre			Magazine Genre		
	White	Black	Crossover	White	Black	Crossover
Support Services	18.5 (n=24)	7.5 (n=4)	13.0 (n=3)	12.4 (n=21)	27.8 (n=10)	10.7 (n=3)
Web Site	100.0 (n=130)	100.0 (n=53)	100.0 (n=23)	100.0 (n=169)	100.0 (n=36)	100.0 (n=28)
Telephone Number	83.1 (n=108)	86.8 (n=46)	73.9 (n=17)	84.0 (n=142)	44.4 (n=16)	78.6 (n=22)
Healthcare Provider	98.5 (n=128)	100.0 (n=53)	100.0 (n=23)	97.6 (n=165)	100.0 (n=36)	100.0 (n=28)
Financial Assistance	87.7 (n=114)	83.0 (n=44)	95.7 (n=22)	87.6 (n=148)	97.2 (n=35)	82.1 (n=23)
Nondrug Interventions	42.3 (n=55)	49.1 (n=26)	43.5 (n=10)	35.5 (n=60)	52.8 (n=19)	32.1 (n=9)
Side Effects to FDA	83.8 (n=109)	79.2 (n=42)	82.6 (n=19)	99.4 (n=168)	100.0 (n=36)	100.0 (n=28)

While all ads included a Web site address, the number offering a telephone number ranged from about 74 to 87 percent in ads published in the 2008/2009 timeframe, depending on magazine genre. In the timeframe after the FDA report was published (i.e., 2011/2012), the percentage ranged from about 44 to 84 percent. The greatest decrease occurred in ads published in black-oriented magazines. The decline from 86.8 percent of ads published in 2008/2009 to 44.4 percent of ads published in 2011/2012 was found to be statistically significant at the 95 percent confidence level using a difference in proportions test.

The number of ads referring readers to their health care provider remained at or close to 100 percent over time for all magazine genres. In terms of offers for financial assistance, the number of ads providing such offers placed in black-oriented magazines increased over time (83.0 percent to 97.2 percent), while the number of such ads placed in the crossover magazine decreased over time (95.7 percent to 82.1 percent). The observed differences are statistically significant at the 95 percent confidence level.

The percentage of ads that included information about nondrug interventions declined in the period following the FDA report for the white-oriented and crossover magazines (42.3 percent versus 35.5 percent and 43.5 percent versus 32.1 percent, respectively). However, the percentage of ads that included this information increased slightly (49.1 percent versus 52.8 percent) in black-oriented magazines. The decline in ads placed in the crossover magazine that provided information on nondrug interventions was statistically significant at the 95 percent confidence level.

4.5 Discussion

The results reported in this chapter provide additional insight into the potential for DTCA to narrow health disparities by educating and motivating consumers, particularly black consumers, to seek additional information from their physicians. Recall that both the health belief model and social cognitive theory identify information as a key motivator in changing behavior. The study updates previous research regarding the appearance and content of DTCA and identifies interesting trends in terms of the race of human models used, the types of appeals made, and the information provided in pharmaceutical advertising. The impact of the FDA report recommendations on each of these aspects of DTCA was explored in depth and the results are discussed in the following sections. Section 4.5.1 addresses RQ5 and RQ6 as they relate to the use of black models in DTCA. Section 4.5.2 addresses RQs 7–10 as they relate to the type of information provided in the promotional content of DTCA. To delve deeper into potential differences between DTCA place in white-oriented versus black-oriented magazines, Section 4.5.3 qualitatively explores differences in advertisements for the same drug published in the same month and year in magazines of differing racial orientation. Section 4.5.4 notes the limitations of the current study.

4.5.1 Model Race

The study results confirm the work of earlier researchers. Both Mastin et al. (2007) and Kean and Prividera (2007) found that black models were more likely to appear in advertisements placed in magazines read by predominantly black audiences. From Table 4-6, we see that over 70 percent of advertisements appearing in black-oriented magazines published prior to the FDA report featured black models; this

percentage rose slightly to 75 percent in ads published after the FDA report (see Table 4-7). Nearly 89 percent of the ads appearing in white-oriented magazines published before the FDA report featured white models; after publication of the FDA report, this percentage fell to 77.8 (see Tables 4-6 and 4-7). As noted earlier, the decrease over time in the percentage of ads featuring black models placed in *O, The Oprah Magazine* (from 58.8 percent to 7.7 percent), a magazine read by both black and white women, was statistically significant at the 95 percent confidence level.

Tables 4-6 and 4-7 also reveal that the percentage of ads featuring black models that appeared in white-oriented magazines increased over time. In white-oriented magazines published before the FDA report, only 10 percent of the ads featured black models. After the report, this percentage increased to 15.2 percent. The difference between these two values is statistically significant at the 95 percent confidence level. While this change is certainly a positive trend, it may have little value with regard to the larger question of health disparities because only a small percentage of black women read *Family Circle* or *Good Housekeeping* (9 percent and 11 percent, respectively (see Table 3-1)).

Another potentially positive trend is the increase in DTCA that features models that are neither Black nor White. Looking at Figure 4-5, we see that, of the 206 ads published before the FDA report, only one featured a model that could be identified as either Hispanic, Asian, or Indian. After the FDA report, that number rose to 17 of the 233 ads published, an increase of nearly 1,500 percent. Increasing the use of a broader range of nonwhite models may have important policy implications, especially if women of color identify with any nonwhite model.

These results confirm that the race of models used in DTCA does vary based on the racial orientation of the magazine (RQ5) and that the race of models used in DTCA is positively associated (χ^2 (6, n=348) = 103.8, $p < .001$). In other words, white models are more likely to be used in DTCA appearing in white-oriented magazines and black models are more likely to be used in DTCA appearing in black-oriented magazines. However, before we can conclude that the racial orientation of a magazine drives the race of models used in its advertising, we must consider the possibility that the product advertised might drive the race of models used to promote it.

Cline and Young (2004) found differences in the race of models used to advertise certain drugs. Black models did not appear in advertisements for drugs used to treat cardiovascular disease or cancer, although they were featured prominently in ads promoting HIV/AIDs drugs. Unlike those of Cline and Young (2004), the results of this study show that black models were used to promote medications in all disease categories (see Tables 4-9 and 4-10). However, fewer ads, as well as a smaller percentage of ads, featured black models versus white models in all disease categories but one (diabetes). Figures 4-6 and 4-7 illustrate the frequency of DTCA published before and after the FDA report by disease category. From Figure 4-6, we see that the greatest number of ads placed in black-oriented magazines promoted drugs used to treat diabetes. Figure 4-7 shows this same trend. From Table 4-10, we see that ads for diabetes drugs are more likely to feature a black model than a white model. This is a notable finding, given that African Americans have twice the risk of non-Hispanic Whites of being diagnosed with diabetes (CDC, 2012). Based on social cognitive theory, black readers are more likely to self-identify with ads featuring a black model than a white model. Consequently, a

diabetes ad featuring a black model may be more likely to encourage a black reader to take a more proactive role in his or her health care than an ad featuring a white model.

Ads for diabetes ads were the only ads that consistently featured black models. Drugs to treat cardiovascular disease, another illness to which Blacks are more susceptible than Whites (CDC, 2011), were more likely to feature white models (see Table 4-6). In fact, ads used to treat all other disease categories were more likely to feature white models than black models.

RQ6 asks whether there has been an increase in the number of advertisements featuring black models following publication of the 2009 FDA report. Figure 4-5 reveals that the number of ads featuring black models rose slightly, from 47 to 50, after publication of the FDA report. However, on a percentage basis, the amount of advertising in the six disease categories of interest actually declined, from 23 percent to 21.5 percent (although this decline was not statistically significant). Looking more closely at the results for the individual disease categories reported in Tables 4-9 and 4-10, we find that both the number and percentage of ads featuring black models declined over time in three categories: cardiovascular disease, cancer, and respiratory illness. The number and percentage of ads increased in three categories over time: Alzheimer's disease, depression, and diabetes. Interestingly, although 6 of the 17 ads for drugs used to treat Alzheimer's disease featured black models, none of these ads appeared in a black-oriented magazine (see Table 4-11). Thus the use of black models in these ads may be of dubious educational value to the target population if they are not seen by black readers.

These results do not suggest that pharmaceutical manufacturers have heeded the FDA recommendations and increased their outreach to black consumers. While the number of ads for drugs used to treat life-threatening conditions increased over time, the number of those ads that appeared in black-oriented magazines decreased from 53 to 36 (see Figures 4-6 and 4-7). Particularly troubling is the decline in advertising for conditions of great concern to the African American community, such as cardiovascular disease and asthma. The one disease category in which the ads consistently featured black models was diabetes. However, of the 40 ads that featured black models, 30 were for a single drug, Januvia, which is used to treat diabetes (see Table C-1). The other ads included in this category used both white and black models in relatively equal proportions.

Furthermore, not all ads that featured black models were found in black-oriented magazines (see Tables 4-9 and 4-10). Ads for drugs to treat Alzheimer's disease, which were introduced after the FDA report was published did feature black models, but the ads did not appear in black-oriented magazines. This is also true of ads for antidepressant drugs. Of the 132 ads for antidepressants identified, 30 featured a black model. However, only 6 of those 30 ads were placed in black-oriented magazines (17 were placed in white-oriented magazines and 7 were placed in the crossover magazine). Three were placed in black-oriented magazines published prior to the FDA report and three were placed in black-oriented magazines published after the report.

4.5.2 Advertising Appeals and Information Provided

As could be expected, appeals used in the DTCA evaluated were positively associated with the type of drug advertised (see Tables 4-12 and 4-13). Nearly every ad

included some type of rational appeal—most often claims about the drug's effectiveness (see Tables D-3 and D-4). The majority of ads (see Table D-5) also included emotional appeals (over 80 percent in ads published before the FDA report and 91 percent of ads published after the report). Because the type of appeal used in an advertisement is dependent on the drug being advertised, further analysis of appeal type as a function of magazine genre and publication date is less important than originally thought. Thus, the results of these analysis can be found in Appendix D. However, a brief discussion of the trends in these data follows.

Positive appeals were found in nearly 50 percent of the ads published before the FDA report and in nearly 63 percent of the ads published after the report (see Table D-6). Negative appeals were used in 60 percent of ads published before the report and 65 percent of ads published after the report (see Table D-6). The increase in positive and negative appeals can likely be explained by the more than doubling in the number of ads for antidepressant drugs that occurred over the time period studied. These ads often used both a positive and negative appeal. Relatively few ads featured either a humorous or nostalgic appeal, perhaps because of the seriousness of disease categories included in the subset of ads used in this phase of the analysis.

Ads placed in white-oriented magazines used a broader range of emotional appeals (see Table D-7). At least one ad used either a humorous or nostalgic appeal, in addition to a positive and/or negative appeal. Ads that appeared in black-oriented magazines used either a positive or negative appeal or both. Ads that appeared in the crossover magazine included positive, negative, and humorous appeals, but not nostalgic appeals. However, the vast majority of all ads (at least 95 percent) appearing in *O, The*

Oprah Magazine included a negative appeal. As discussed earlier, this observation can be explained by the types of drugs advertised. Most of the drugs advertised in *O, The Oprah Magazine* during the time period studied are used to treat cardiovascular disease or depression. Advertisements for these types of drug tend to use negative appeals more frequently than drugs used to treat other diseases.

Few changes were observed in the type of information provided in the DTCA evaluated over time. As reported in Table 4-14, the majority of ads, both pre- and post-publication of the FDA report, included a Web site address and telephone number. Virtually all ads recommended talking with a doctor or other healthcare provider. A minority of ads provided information about patient support services, and the proportion of those doing so did not change over time (15.0 and 14.6 percent pre- and post-FDA report).

RQs 7–10 address the FDA recommendations concerning the provision of information about nondrug interventions and financial assistance. The PhRMA DTC Guiding Principles also recommend that its members include this information in their advertisements (as quoted in Arnold & Oakley, 2013). Therefore, we would expect that a significant proportion of ads would comply with these recommendations. RQs 7 and 8 ask whether the provision of information about nondrug interventions varies with magazine genre and whether the percentage of ads offering such information increased following the 2009 FDA report. From Table 4-14 we can see that less than half the ads published during the study period discussed nondrug interventions. From Table 4-15, we see that the provision of this information did not vary as a function of the racial orientation of the magazine and that differences between the two study periods were not

statistically significant. A Chi-square test for independence suggests that the provision of information about nondrug interventions was positively associated with the type of drug advertised (χ^2 (5, n=439) = 150.79, p < .001) rather than the genre of the magazine in which the drug appeared (χ^2 (2, n=439) = 4.45, p=.0108).

RQs 9 and 10 relate to the provision of information about available discounts or patient assistance programs. Table 4-14 reports that nearly 90 percent of the ads evaluated offered some sort of financial assistance, such as a free trial or a discounted prescription rate. RQ 9 asks whether offers of financial assistance varied by the racial orientation of the magazine. From Table 4-15, we see that a high percentage of ads, regardless of when and where they were published, included this information. Differences in the percentage of ads placed among the three magazine genres were not statistically significant. RQ 10 asks whether the percentage of ads that offered some sort of financial assistance increased following the 2009 FDA report. Looking again at Table 4-15, we see that the percentage of ads offering financial assistance placed in black-oriented magazines increased from 83.0 percent to 97.2 percent over time. Ads appearing in the white-oriented or crossover magazines did not experience comparable increases. A difference in proportions test indicated that this increase was statistically significant. To confirm that the provision of financial assistance was not dependent on the drug advertised, a Chi-square test for independence was conducted. A positive association was not found between the offer of financial assistance and the drug advertised (χ^2 (5, n=439) = 11.04, p=.051), although future research should explore the relationship between offers of financial assistance and the length of time the advertised drug has been on the market.

Table 4-15 reports some additional results worth noting. If we focus on changes in the information provided in ads placed in black-oriented magazines before and after publication of the FDA report, we can see some statistically significant trends. The percentage of ads offering patient support services increased from 7.5 percent to 27.8 percent. This change was statistically significant at the 95 percent confidence level. However, the percentage of ads appearing in black-oriented magazines that provided a telephone number by which the consumer could gain additional information declined from 86.8 to 44.4 percent. This change was statistically significant at the 95 percent confidence level. This could be a problematic trend if it were to continue. Consumers without access to a computer would have a limited ability to gain further information about an advertised drug. This is more likely to be a barrier for ethnic and minority households than for non-Hispanic white households (U.S. Census Bureau, 2013).

The most notable difference in ad content was in the percentage of ads advising consumers to report adverse side effects to the FDA. About 80 percent of ads published in 2008/2009 included this advice; by 2011/2012, nearly 100 percent contained language to this effect. The reason for this change is clear. The FDAAA of 2007 mandated that print ads include the statement, "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch, or call 1-800-FDA-1088" (FDA, 2012b).

Overall, the DTCA evaluated did a good job in providing consumers with access to additional information via a Web site or telephone number (with the exception noted above) and encouraging them to discuss their symptoms with a healthcare provider. The vast majority of ads offered consumers a means of obtaining financial assistance in

acquiring their prescription drugs. Information about support services and nondrug interventions was dependent on the drug advertised. For example, an advertisement for the Exelon Patch lets consumers know that, "[t]he makers of Exelon Patch also offer tools to help you handle the challenges of caregiving," and encourages them "to explore all the patient and caregiver resources on exelonpatch.com." An ad for Victoza, a diabetes drug, features Paula Deen encouraging readers to exercise every day and eat smaller portions. This ad also refers consumers to a Web site to learn more about making positive lifestyle changes. However, there was no real discernable in the number of ads offering such information pre- and post-publication of the FDA report, despite the report's express recommendation to do so.

On the other hand, pharmaceutical manufacturers did respond to the regulatory requirement to advise patients to report negative side effects to the FDA. The percentage of ads that included the required statement increased from just over 80 percent in 2008/2009 to nearly 100 percent by 2012. This finding suggests that regulatory action may be necessary if FDA is interested in leveraging DTCA as a means of improving health information access and reducing health disparities.

4.5.3 Same Drug—Different Magazine Genre

A final step in the analysis was to qualitatively review advertisements for the same drug placed in different magazine genres during the same month and year. While not a formal research question, it was thought that such a comparison might reveal differences in the approach used to advertise a drug in magazines with different target audiences. Particular attention was paid to the race of the featured models used in the ad as differences in this variable might suggest a more focused attempt on the part of the

pharmaceutical companies to appeal to the magazine's targeted audience. Four of the six disease categories (Cardiovascular, Diabetes, Depression, and Respiratory) included advertisements that met the criteria. A total of 10 drugs were advertised in both black-oriented and white-oriented magazines during the same month and year. (Drug ads that appeared in the crossover magazine were omitted from this phase of the analysis since its target audience is less defined.) Twenty-seven ad versions were evaluated.

Only 2 of the 10 drugs advertised to treat cardiovascular disease met the selection criteria (i.e., advertisements for these drugs appeared during the same month and year in magazines of differing racial orientation). Identical versions of ads for Caduet were placed in the July and September 2009 issues of *Ebony* and *Family Circle*. Identical versions of ads for Plavix were published in the May 2008 issues of *Ebony* and *Family Circle* and the February 2008 issues of *Ebony* and *Good Housekeeping*. Different ads for Plavix were found in the May 2009 issues of *Ebony* and *Family Circle* and in the February 2009 issues of *Good Housekeeping* and *Ebony*. The February 2009 Plavix ad published in *Good Housekeeping* did not include a human model or likeness and focused on the life-saving advantages for those who have had a heart attack of used Plavix to prevent clots. The February 2009 Plavix ad that appeared in *Ebony* featured two white models and promoted Plavix as a treatment for peripheral artery disease. This same ad version was published in the May 2009 issue of *Family Circle*. That same month (i.e., May 2009), another version of a Plavix ad appeared in *Ebony* magazine. It too featured white models but targeted those who had experienced a heart attack rather than those with peripheral artery disease.

A total of four drugs used to treat depression or bipolar disorder were advertised during the study period. Advertisements for two of these drugs, Cymbalta and Pristiq, were placed in the same month and year in both black-oriented and white-oriented magazines. Identical versions of a Pristiq ad were found in the November 2011 issues of *Essence* and *Family Circle*; the December 2011 issues of *Ebony* and *Family Circle*; the October 2011 issues of *Essence* and *Family Circle*, and the February 2012 issues of *Essence* and *Good Housekeeping*. Different versions of an ad for Cymbalta were placed in the June 2008 issues of *Ebony* and *Family Circle*. The ad that appeared in *Ebony* featured a black model, while the ad that appeared in *Family Circle* featured a white model.

Advertisements for two of the four drugs used to treat diabetes met the selection criteria. Identical ads for Victoza appeared in the February 2011 issues of *Family Circle* and *Ebony*. Different ad versions for Januvia appeared in the June 2008 issues of *Ebony*/*Essence*[11] and *Good Housekeeping*. In the version of the ad that appeared in *Ebony* and *Essence*, the featured model was Black. In the version that appeared in *Good Housekeeping*, the featured model was White.

In the Respiratory category, four drugs were advertised in the same month and year in both white-oriented and black-oriented magazines. Identical ads for Symbicort were found in the April 2012 issues of *Ebony* and *Good Housekeeping*. Somewhat different ads for Symbicort appeared in the October 2012 issues of *Ebony* and *Good Housekeeping*. Both included a human model whose race was neither Black nor White. The difference in the ad versions was associated with the placement of an offer for a free

[11] The same ad version appeared in both *Ebony* and *Essence* in June 2008.

month's prescription—in one version, the offer was placed on the opposing page; in the other version, it was placed on the same page.

Identical ads for Advair Diskus were found in the October 2008 issues of *Good Housekeeping* and *Essence* and the May 2009 issues of *Ebony*, *Essence*, and *Family Circle*. Differing versions of Advair ads appeared in the July 2008 issues of *Ebony* and *Good Housekeeping*; the December 2009 issues of *Ebony*/*Essence*[12] and *Family Circle*; and the May 2011 issues of *Essence* and *Good Housekeeping*. Neither the July 2008 nor the December 2009 ads for Advair featured a human model of likeness. The Advair ad published in the May 2011 issue of *Good Housekeeping* featured two human models, both of whom were White. The version of the Advair ad that appeared in *Essence* that same month did not include a human model or likeness.

In only two cases (the June 2008 ads for Cymbalta and the June 2008 ads for Januvia) did ads for the same drug published in the same month and year appear to target the race of a magazine's primary audience through their choice of human models. (Although these ads happened be published in the same month and year, we have to assume a coincidence since the drugs advertised have different manufacturers and different purposes.) A closer examination of these ads, found in Figures 4-8 and 4-9 at the end of this chapter, reveals more subtle differences. Figure 4-8 presents two advertisements for the diabetes drug, Januvia: Figure 4-8a appeared in the June 2008 issue of *Ebony* magazine, and Figure 4-8b appeared in the June 2008 issue of *Good Housekeeping*. The most prominent difference in these two ads is the race of the models

[12] The Advair ads that appeared in the December 2009 issues of *Ebony* and *Essence* differed in appearance, but neither featured a human model of likeness. The version of the ad that appeared in *Ebony* also appeared in *Family Circle*.

used. In the ad appearing in *Ebony*, the race of the primary model is Black. Interestingly, his two lunch companions are White. They are all male and they all appear to be middle-aged. In the ad that appeared in *Good Housekeeping*, the primary model is a White, middle-aged woman. She is joined at lunch by two adult female companions, one of whom is White and one of whom is Black. The ages of these women is less identifiable.

The layout of the ads is identical, as well as the majority of the text. The key difference in text is the type of meal chosen. In the ad that appeared in *Ebony*, the primary is eating a salad, and the tag line states, "Today, I chose salad and talked to my doctor." In the ad that appeared in *Good Housekeeping*, the primary model is eating fish, and the tag line states, "Today, I chose salmon and talked to my doctor." Note that in both ads, the lunch companions are eating high fat, high calorie meals thereby highlighting the primary models' determination to eat more healthfully.

Figures 4-9a and 4-9b are advertisements for the antidepressant drug, Cymbalta. The ads are virtually identical, with the exception of the age and race of the model used. In the ad that appeared in the June 2008 issue of *Family Circle*, the model is an older white woman. A younger, black woman is used in the ad version that appeared in the June 2008 issue of *Ebony*. Most of the text is the same, although the ad appearing in *Family Circle* directs people to inform their doctors if they use nonsteroidal anti-inflammatory drugs (NSAID) pain relievers, aspirin, or blood thinners as they may lead to an increase in bleeding risk. It is beyond the scope of this study to evaluate why this caution is included in one ad and not the other, but exploring such differences could be the focus of future research.

This phase of the analysis was strictly exploratory. Since no previous researcher had evaluated ads for the same drug placed in magazines of differing racial orientation, the methodology used was developed solely for this study. Although limited to just a few advertisements, the results do suggest that drug companies tailor certain ads for their intended audience. Future research will look at a larger variety of drug ads as well as expand the comparison period beyond a month.

4.5.4 Limitations

Many of the limitations of this phase of the analysis are the same as those described in Chapter 3. The study was limited to five magazine titles and four publication years. The final publication year reviewed was 2012; it is possible that reviewing magazine issues published more recently would yield different results.

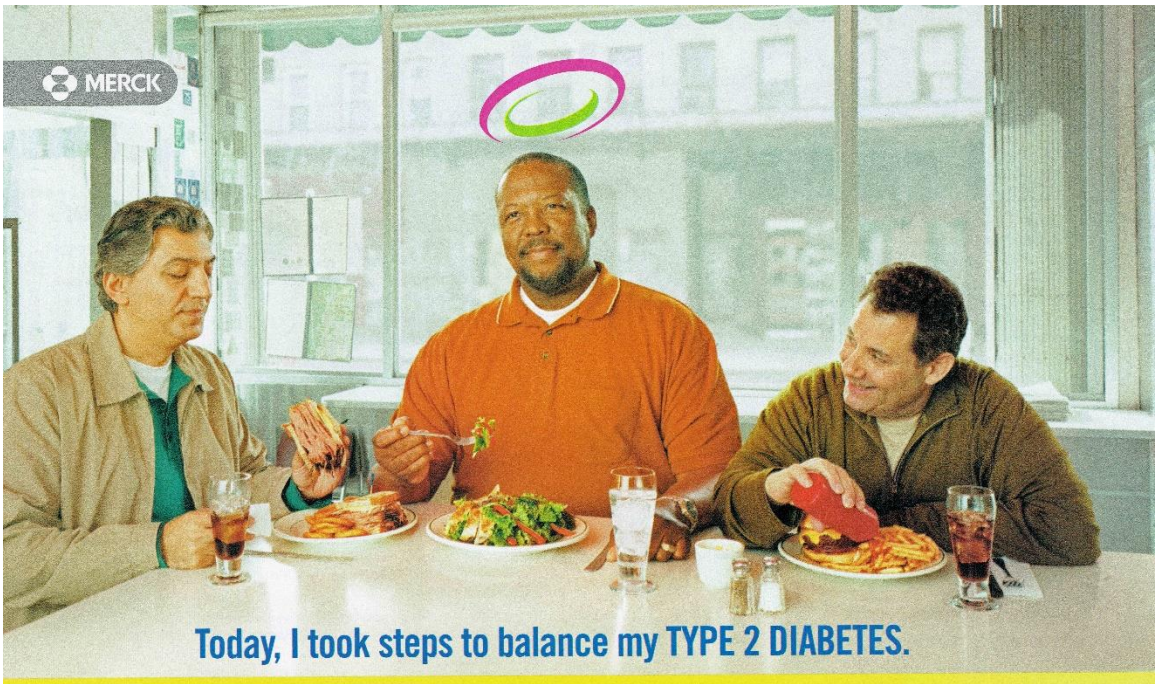
The study only looked at women's magazines and focused on a single minority (Blacks). Therefore, the findings cannot be generalized to other minorities or other magazine genres. The study also only evaluated print advertisements. No attempt was made to evaluate the appearance or content of DTCA that appeared on television or the World Wide Web. Pharmaceutical advertising using these media outlets could be more targeted to the anticipated audience than that appearing in the magazine titles selected for review.

Establishing causality between the advertisements reviewed and the magazines in which they appeared was impossible. While many of the ads that appeared in the black-oriented magazines featured black models, a number of ads that featured black models appeared only in white-oriented magazines and a number of ads that appeared in black-oriented magazines featured white models. Although certain advertising

campaigns appeared to be targeted to black consumers, many did not. Hence, it is possible, and perhaps even likely, that the appearance and content of a particular advertisement appearing in a specific magazine has more to do with the medication advertised than with the demographics of the magazine's readership. Thus, differences in ad appearance and content pre- and post-publication of the FDA may have more to do with the introduction of new drugs than with any other factor.

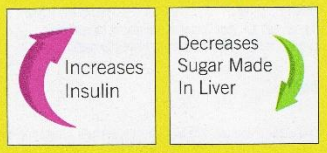
A limitation unique to this phase of the study is the use of subjective judgments inherent to any content analysis. Although each unique ad was coded using an explicit code sheet and coding differences were settled by a third party, it is possible that some bias occurred. However, the code sheet used was extremely detailed and provided specific examples of text that should be coded in a certain way to limit potential bias.

Finally, the number of unique ads coded (158) was relatively small compared to the entire universe of ads identified (1,090) (about 15 percent). An ad was considered unique if it differed in any of its visual or textual elements or if it included a post card of other tear out that the reader could use to obtain additional information. Limiting the number of ads to those promoting medications used to treat life-threatening conditions could skew the results in one direction or another. On the other hand, the focus of this study is on the possible impact of DTCA on health disparities so it is less important that advertisements promoting contraceptives feature black models than advertisements promoting drugs used to treat cardiovascular disease. In addition, certain ad versions appeared only once during the timeframe studied, while others appeared numerous times. Thus, a single ad version could bias a particular variable. A larger number of ads would reduce the effect of an individual ad version on the overall results.



Today, I chose salad and talked to my doctor.

JANUVIA works differently to lower blood sugar in 2 ways. Talk to your doctor about JANUVIA today.



- It's a once-daily prescription pill that helps your body increase the insulin made in your pancreas and decrease the sugar made in your liver.
- Along with diet and exercise, JANUVIA helps lower blood sugar levels in people with type 2 diabetes.
- JANUVIA is not likely to cause weight gain.

Important Information: JANUVIA has not been studied with insulin and should not be used to treat patients with type 1 diabetes or diabetic ketoacidosis (increased ketones in the blood or urine) or used if you are allergic to JANUVIA. Your doctor may perform blood tests from time to time to measure how well your kidneys are working. If you have kidney problems, your doctor may prescribe lower doses of JANUVIA. When JANUVIA is used with a sulfonylurea, low blood sugar (hypoglycemia) can occur. To avoid this risk, your doctor may prescribe lower doses of the sulfonylurea. Allergic reactions, which may be serious, including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty breathing or swallowing, can occur. If you have an allergic reaction, stop taking JANUVIA and call your doctor right away. The most common side effects include upper respiratory tract infection, stuffy or runny nose and sore throat, and headache.

Call 1-888-JANUVIA or visit Januvia.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the Patient Information on the next page and discuss it with your doctor.

MERCK patient assistance program

This product is available through the Merck Patient Assistance Program. To find out if you qualify, call 1-800-727-5400.

A different way.™

Januvia™

(sitagliptin) tablets

Figure 4-8a: Advertisement for Januvia (*Ebony*, June 2008)

Figure 4-8b: Advertisement for Januvia (*Good Housekeeping*, June 2008)

You might feel sad or maybe you've lost interest in things you once enjoyed. You could have aches and pains or always feel tired. Or maybe you're sleeping too much. Or not at all. Many people wouldn't think these could all be symptoms of depression. But they can be. Cymbalta is a prescription medication that treats many symptoms of depression.

There are many paths to take in the treatment of depression, including talk therapy, diet, and exercise. You and your doctor or healthcare provider can decide on the right path. Remember, only your doctor can determine if Cymbalta or other treatments are right for you. You deserve every chance to feel the way you want to feel.

Learn more by calling 877-CYMBALTA or visiting www.cymbalta.com, where you can also find the personal stories of people who have been treated with Cymbalta. Results may vary.

Antidepressants can increase suicidal thoughts and behaviors in children, teens, and young adults. Call your doctor right away if you have new or worsening depression symptoms, unusual changes in behavior or thoughts of suicide. Be especially observant within the first few months of treatment or after a change in dose. Approved only for adults 18 and over.

Cymbalta is not for everyone. Do not take Cymbalta if you have recently taken a type of antidepressant called an MAOI or Mellaril® (thioridazine) or have uncontrolled glaucoma. Talk to your doctor before stopping Cymbalta or changing your dose; about all your medicines, including those for migraine, to avoid a potentially life-threatening condition; about use of NSAID pain relievers, aspirin, or blood thinners with Cymbalta, which may increase bleeding risk. Tell your doctor about your alcohol consumption and about all your medical conditions, including liver or kidney problems, glaucoma or diabetes. Dizziness or fainting may occur upon standing. The most common side effects include nausea, dry mouth and constipation. This is not a complete list of side effects.

Please see back page for additional important safety information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Partnership for Prescription Assistance

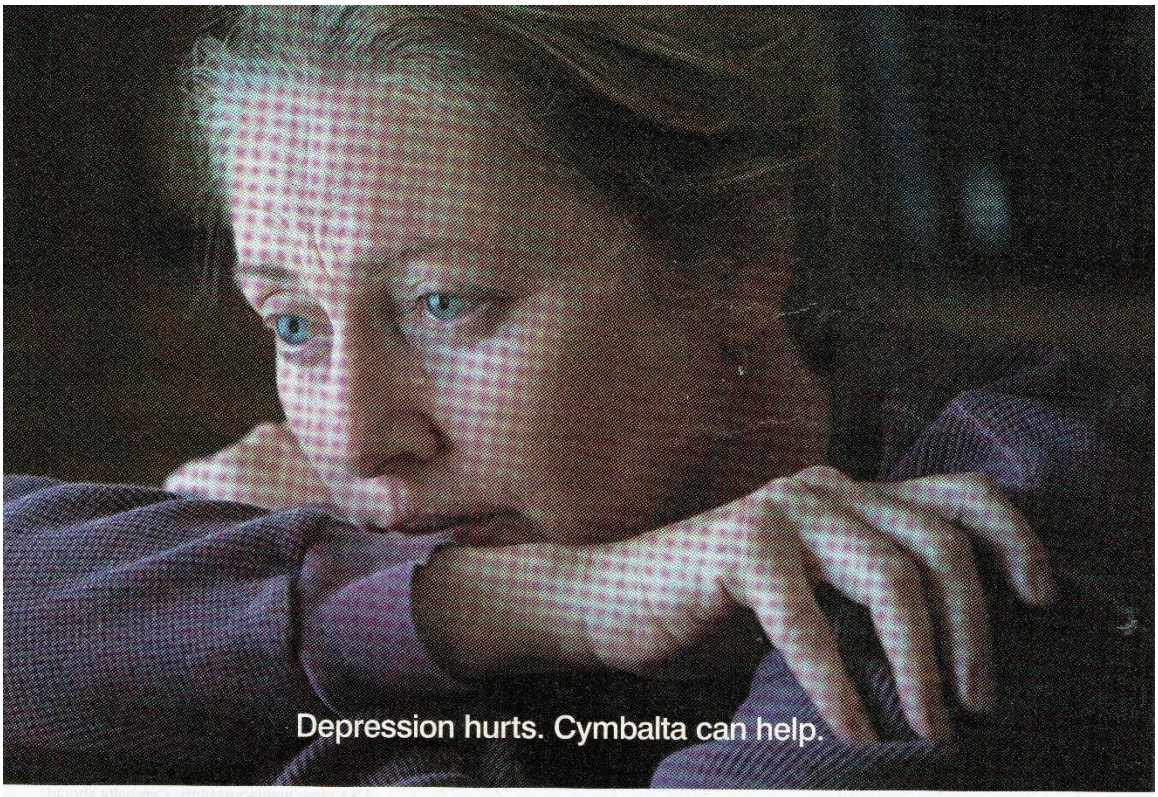
If you need assistance with prescription costs, help may be available. Visit www.pparx.org or call 1-888-4PPA-NOW.

Cymbalta® DELAYED RELEASE CAPSULES
duloxetine HCl

because depression hurts

Lilly

Figure 4-9a: Advertisement for Cymbalta (*Ebony*, June 2008)



You might feel sad or maybe you've lost interest in things you once enjoyed. You could have aches and pains or always feel tired. Or maybe you're sleeping too much. Or not at all. Many people wouldn't think these could all be symptoms of depression. But they can be. Cymbalta is a prescription medication that treats many symptoms of depression.

There are many paths to take in the treatment of depression, including talk therapy, diet, and exercise. You and your doctor or healthcare provider can decide on the right path. Remember, only your doctor can determine if Cymbalta or other treatments are right for you. You deserve every chance to feel the way you want to feel.

Learn more by calling 877-CYMBALTA or visiting www.cymbalta.com, where you can also find the personal stories of people who have been treated with Cymbalta. Results may vary.

Antidepressants can increase suicidal thoughts and behaviors in children, teens, and young adults. Call your doctor right away if you have new or worsening depression symptoms, unusual changes in behavior or thoughts of suicide. Be especially observant within the first few months of treatment or after a change in dose. Approved only for adults 18 and over.

Cymbalta is not for everyone. Do not take Cymbalta if you have recently taken a type of antidepressant called an MAOI or Mellaril® (thioridazine) or have uncontrolled glaucoma. Talk to your doctor before stopping Cymbalta or changing your dose; about all your medicines, including those for migraine, to avoid a potentially life-threatening condition; about use of NSAID pain relievers, aspirin, or blood thinners with Cymbalta, which may increase bleeding risk. Tell your doctor about your alcohol consumption and about all your medical conditions, including liver or kidney problems, glaucoma or diabetes. Dizziness or fainting may occur upon standing. The most common side effects include nausea, dry mouth and constipation. This is not a complete list of side effects.

Please see back page for additional important safety information.

Partnership for Prescription Assistance

If you need assistance with prescription costs, help may be available. Visit www.pparx.org or call 1-888-4PPA-NOW.

Cymbalta® DELAYED RELEASE CAPSULES
duloxetine HCl

because depression hurts

Lilly

Figure 4-9b: Advertisement for Cymbalta (*Family Circle*, June, 2008)

4.6 Conclusions

This chapter opened with a discussion of the theory that frames DTCA as a potential health promotion tool. Social cognitive theory suggests that models used in advertising should reflect the appearance of those who the advertiser wishes to persuade. The results of this study indicate that pharmaceutical companies are continuing to do a good job aligning model race with the racial orientation of the magazines in which their ads are placed. As found in previous research, black models are more likely to be featured in ads placed in black-oriented magazines, and white models are more likely to be used in ads placed in white-oriented magazines. However, drug companies are missing an opportunity to positively impact the health of black Americans by limiting the amount of advertising for drugs to treat life-threatening conditions that they place in black-oriented magazines. Although this study, unlike previous research, found that black models were used to advertise drugs in all disease categories of interest, ads for certain types of drugs, such as cardiovascular disease, did not appear in black-oriented magazines published in 2011 or 2012 (i.e., after publication of the FDA report).

The health belief model tells us that people will take action if they believe that they are susceptible to a condition and that ignoring the condition will lead to serious consequences. DTCA commonly identifies symptoms that the advertised drug is intended to treat and often indicates relief from these symptoms once the drug is taken. This information can serve to educate consumers and motivate them to seek out their health care professional (Mackert & Love, 2011). Therefore, it is important that ads for drugs used to treat serious medication conditions be seen by those at risk.

The health belief model also tells us that people will pursue a course of action if they believe "that the anticipated barriers (or cost of) taking action are outweighed by the benefits" (Glantz et al., 2002, p. 48). Thus information about nondrug interventions and financial assistance may facilitate behavior change. Ads that omit this information are less likely to fulfill their health promotion potential.

The results of this study indicate that, in most cases, the content of the ad did not vary as a function of magazine genre or publication date. Virtually all ads used a rational appeal, claiming the drug's effectiveness in particular. Most ads also made some sort of emotional appeal, either positive or negative or both. The type of appeal used in an ad was found to be positively associated with the drug advertised rather than with either magazine genre or publication date.

Almost all ads provided a telephone or Web site address, encouraged readers to talk to their healthcare providers about their symptoms, and offered financial assistance. Offers of patient support services and recommendations of alternative therapies were dependent on the drug advertised. For example, the ad for the Exelon Patch, which is used to treat Alzheimer's disease offered a Web site address to obtain additional caregiver resources; the ad for Aricept, another drug used to treat Alzheimer's disease, did not. Similarly, advertisements for Pristiq, a drug used to treat depression, were the only ones in this disease category to offer patient support services. Nondrug interventions were mentioned in the majority of advertisements for drugs used to treat diabetes and cardiovascular disease, especially those used to treat high cholesterol, but in relatively few ads for drugs used to treat other medical conditions.

The most noteworthy conclusion that can be drawn from this phase of the analysis relates to the impact of a regulatory requirement on ad content. Although most ads published in 2008 and 2009 encouraged consumers to report negative side effects to the FDA, it was not until the FDA required pharmaceutical manufacturers to do so did a statement to this effect appear in nearly 100 percent of the ads evaluated. This finding has important policy implications if DTCA is ever to be used effectively as a means to increase access to health information and reduce health disparities among minority and disadvantaged populations.

To further highlight the difference in responsiveness of pharmaceutical companies to a regulatory requirement versus a voluntary recommendation, let us contrast the number of ads that included a statement regarding the reporting of negative side effects to those suggesting alternative therapies. The former was a requirement of the FDAAA of 2007; the latter a recommendation in the 2009 report issued as a result of the FDAAA. As mentioned above, virtually 100 percent of the ads published in 2011 and 2012 included the negative side effects statement. In contrast, the number of ads placed in the white-oriented and crossover magazines that recommended alternative therapies actually declined over time, and the number of ads placed in black-magazines that included this information rose only slightly. In any case, the percentage of ads that recommended alternative therapies was never greater than 55 percent, despite the fact that the PhRMA DTC Guiding Principles encourage pharmaceutical manufacturers to "include information about the availability of other options such as diet and lifestyle changes where appropriate for the advertised condition" (as quoted in Arnold & Oakley, 2013, p. 510).

Based on these results, we must conclude that the FDA report had no impact on the advertising decisions made by pharmaceutical companies in terms of the appearance or content of the ads placed in magazine read by black women, with one notable exception as discussed above. Enhancing the educational and motivational value of DTCA, while a laudable goal, will require more than a set of recommendations in a report submitted to Congress. Regulatory action may be the only way possible to assure that pharmaceutical manufacturers develop advertising campaigns that not only promote their product, but also positively impact the health outcomes of those who read their ads.

CHAPTER 5: CONCLUSIONS

Disparities in health outcomes among various racial and ethnic groups persist in the United States. While a myriad of reasons have been advanced to explain these differences, this dissertation focused on one—differences in access to health information delivered via DTCA placed in popular women's magazines. Pharmaceutical advertising offers a "vehicle that can provide important information in a pithy and purposive way to patients" (Kontos & Viswanath, 2011, p. 142). Along with a high degree of awareness (Bell, Kravitz, & Wilkes, 1999; Weissman et al., 2003) comes the potential for DTCA to have a tremendous effect on its target audience (Kontos & Viswanath, 2011). Recognizing the health promotion possibilities of DTCA, the FDA issued a series of recommendations in a 2009 report to Congress aimed at enhancing the ability of these ads to reach disadvantaged populations. This dissertation examined differences in pharmaceutical advertising published before and after these recommendations in terms of its frequency, appearance, and content.

Within the constructs of the health belief model and social cognitive theory, well-designed pharmaceutical advertising can serve a health promotion function. Typical ads include information designed to change individual perceptions about their susceptibility to a particular disease and the consequences of inaction. Through various cues to action embedded within the ad (such as a tag line from a 2008 ad for Singulair which reads, "Is your asthma really under control or do you just think it is?"), as well as

the repetitive nature of DTCA, consumers be compelled to seek out their health care providers. Pharmaceutical companies further reinforce their messages by aligning the race of models used in their ads with the race of their intended audience. Thus, ads appearing in magazines read predominantly by black women are more likely to feature black models than magazines read by white women (Mastin et al., 2007). Advocates of DTCA highlight its potential to reduce the underdiagnosis and undertreatment of serious medical conditions (Ventola, 2011), while critics claim that, at a minimum, it manipulates consumers into seeking treatment for diseases they do not have (Finlayson & Mullner, 2005). At its worst, DTCA creates illnesses solely for the purpose of selling more pills (Moynihan & Henry, 2006). While such concerns cannot be dismissed, this dissertation focuses on the potential of DTCA to improve health outcomes.

The results of my research indicate that the pharmaceutical industry has yet to embrace the FDA recommendations. Differences in advertising frequency between black- and white-oriented magazines persist. Far more DTCA was placed in white-oriented magazines than in black-oriented magazines. The amount of DTCA placed in *O, The Oprah Magazine* was more than in the black-oriented magazines, but less than in the white-oriented magazines. Furthermore, there was little difference in the amount of advertising placed in black-oriented magazines published before the FDA report than after the report.

The types of drugs advertised and the medical conditions they treat were found to vary based on the racial orientation of the magazine. Drugs that were advertised in both white-oriented and black-oriented magazines were more likely to treat serious medical conditions than previously reported. However, only a small percentage of drugs

advertised are used to treat life-threatening conditions. While the most prevalent drug advertised in the black-oriented magazines is used to treat diabetes (a disease that disproportionately affects black Americans), far fewer ads for cardiovascular drugs (another disease of particular concern for the black community) appeared in black-oriented magazines than in white-oriented magazines. More troubling was the fact that no cardiovascular drug was advertised in black-oriented magazines in either 2011 or 2012.

Pharmaceutical companies are continuing to do a good job aligning the race of models used in their ads with the race of a magazine's primary audience. Black models were more likely to be featured in ads placed in black-oriented magazines and white models were more likely to be used in ads placed in white-oriented magazines. However, a number of ads that featured black models did not appear in black-oriented magazines. On the other hand, there was an increase in the number of ads that featured models that were either Hispanic, Asian, or Indian. This is a positive trend, particularly if women of color identify with any nonwhite model.

Advertising appeals were dependent on the type of drug advertised rather than where the ad was place or the year in which it was published. Virtually all ads included a rational appeal, most often touting the drug's effectiveness. The use of emotional appeals increased pre- and post-FDA report, but a closer examination of the data tied that increase to a rise in the number of antidepressant drugs advertised. Ads for such drugs always included some sort of emotional appeal.

Few differences were observed in the other information contained within the pharmaceutical advertisements evaluated, regardless of magazine genre or publication

date. The majority of ads included a Web site address, telephone number, and information concerning patient discounts or other financial assistance. Virtually all ads recommended talking with a doctor or other healthcare provider, but only 40 percent suggested nondrug interventions. A minority of ads provided information about patient support services. Information about nondrug therapies and patient support services were dependent on the type of drug advertised.

The most significant difference in ad content was in the percentage of ads advising consumers to report adverse side effects to the FDA. About 80 percent of ads published in 2008/2009 included this advice; by 2011/2012, nearly 100 percent contained language to this effect. The reason for this change is clear. The FDAAA of 2007 mandated that print ads include the statement, "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch, or call 1-800-FDA-1088" (FDA, 2012b).

Table 5-1, which appears at the end of this chapter, summarizes the research findings. From a health policy perspective, the results are disappointing. The FDA report recommendations had no impact on the advertising decisions made by pharmaceutical companies in terms of the frequency or content of DTCA. While the industry does tend to use black models to advertise in black-oriented magazines, it has not increased the amount of advertising it does in these magazines and, in fact, has cut back on the number of ads it places that promote drugs used to treat the health issues of most concern to the black community. Enhancing the educational and motivational value of DTCA, while a laudable goal, will require more than a set of recommendations in a report submitted to Congress. The following section presents a series of policy remedies

that the FDA should consider if it is serious in its intent to shape DTCA in such a way that it can increase access to health information and decrease health disparities among racial and ethnic minority groups.

5.1 Policy Recommendations

To date, the FDA has combined the typical command and control regulatory approach with "soft" regulations in the form of various guidance documents as a means of monitoring pharmaceutical advertising in this country. The intent of these regulations is to ensure that pharmaceutical companies, in their efforts to promote their products, do not cause harm (Handlin, Mosca, Forgione, & Pitta, 2003). Thus, the FDA requires that ads present both the benefits and risks of a drug in a balanced manner. Ads may only state the FDA-approved use for the drug and may only make claims that are substantiated by scientific evidence or clinical experience. And, as a result of the FDAAA of 2007, print ads must also include a statement encouraging consumers to report negative side effects to the FDA (FDA, 2012b).

The pharmaceutical industry has adopted a strategy of self-regulation when it comes to DTCA. The Pharmaceutical Research and Manufacturers of America has adopted a series of guiding principles for DTCA consistent with FDA requirements. PhRMA member companies not only pledge to adhere to these principles, but also must certify their compliance (Arnold & Oakley, 2013). Like the FDA regulations, the PhRMA guiding principles also require that DTCA clearly state the intended use of the medication, include a balanced presentation of its risks and benefits, and make only claims that are supported by a significant amount of evidence (Arnold & Oakley, 2013). Ads should also include information "about the availability of other options such as diet

and lifestyle changes where appropriate for the advertised condition", and "include information…about help for the uninsured and underinsured" (as quoted in Arnold & Oakley, 2013, pp. 510–511).

Critics claim that the current regulatory approach, which relies in large part on the industry's willingness to police itself, is not working (Government Accountability Office (GAO), 2006; Arnold & Oakley, 2013). Despite evidence of regulatory violations, FDA issues few enforcement letters. Those that are issued are often the result of months of internal agency deliberations. In the meantime, the offending advertisement continues to run (GAO, 2006). Similarly, Arnold and Oakley (2013) found numerous violations of the PhRMA guiding principles in their 4-year study of advertising for erectile dysfunction drugs. Thus, neither formal agency regulations nor voluntary industry guidelines appear to exact responsible pharmaceutical advertising on a consistent basis.

The results of the current study shed additional light on the industry's compliance with both hard and soft regulations. Information that is not required by regulation, such as information about nondrug interventions, appeared in less than 50 percent of the ads evaluated. Arnold and Oakley (2013) found that no ad in their study provided information about nondrug options for erectile dysfunction. The number of ads that included a telephone number also declined significantly over time. On the other hand, the number of ads compliant with the FDA's requirement to include a statement encouraging consumers to report negative side effect increased to nearly 100 percent in ads published in 2011 and 2012. This result suggests that regulatory action may be necessary to ensure that pharmaceutical manufacturers develop advertising campaigns

that not only promote their product, but also positively impact the health outcomes of those who read their ads.

Rather than recommending a strict command and control regulatory approach, I believe that the FDA should establish a program of voluntary agreements with pharmaceutical companies to increase their use of help-seeking advertising campaigns and to enhance the educational value of their product claim advertising. These collaborative agreements between regulatory agencies and private companies have been used by the U.S. Environmental Protection Agency (EPA) to reduce the release of toxic chemicals and greenhouse gas emissions (Delmas & Terlaak, 2001). Participating companies submit plans to their state regulators and the EPA based on their own pollution reduction targets; regulators offer these firms financial support and technical assistance. The advantage to the private sector of these agreements is less regulatory burden; the advantage to public sector is a less confrontational and less costly way of achieving its goals (Delmas & Terlaak, 2001).

While certain enhancements to DTCA could and should be achieved through regulation (such as the provision of a telephone number, information about nondrug interventions, and offers of financial assistance), mandating too many specifics may not be practical given the dependence of ad content on the unique attributes of the drug being advertised. In addition, the FDA cannot insert itself into the advertising practices of a pharmaceutical company lest it be accused of endorsing one drug over another. A key role of the FDA is to ensure the drug safety; it cannot be seen as colluding with industry to promote their products. However, the FDA could work actively and collaboratively with drug companies to improve the health literacy aspects of DTCA rather than relying

on the industry to voluntarily adopt agency guidelines and recommendations into their advertising campaigns. To better reach disadvantaged populations, the FDA could assist companies in developing help-seeking advertisements that provide valuable information about medical conditions of particular importance to the targeted community. The industry could commit to targeting a certain percentage of both their help-seeking and product claim ads to at-risk populations, which would likely result in less criticism of their motives and advertising practices. Rather than using its self-regulation strategy as a means of blocking more stringent regulatory action (Arnold & Oakley, 2013), the industry should demand more of its members and aggressively promote high-quality, responsible advertising that provides valuable health information to consumers.

5.2 Study Limitations

The current study has several limitations. Only five magazine titles and four years were selected for review. A lag period of 15 months between the publication of the FDA report in September 2009 and the first magazine issue considered post-publication of the FDA report was considered adequate. It is possible that pharmaceutical companies were adjusting their ongoing ad campaigns well into 2011 and that reviewing magazine issues published in 2013 would have yielded different results.

The study focused on a single minority (Blacks) and evaluated only magazines read by women. Therefore, the findings cannot be generalized to other minorities, such as Hispanics and Asians, or to other magazine genres, such as entertainment or news. It is possible that pharmaceutical companies place much of their advertising directed to black readers in magazines other than *Ebony* and *Essence*, although circulation figures and previous research would not suggest this. Furthermore, because this study only

evaluated print ads, pharmaceutical companies may have increased their advertising to minority populations after publication of the FDA report using other media outlets, such as television or the Internet.

While the analysis discusses results in the context of pre- and post-FDA report publication, causality between the report and any decrease in advertising frequency or seemingly negative changes in advertising content (e.g., the lack of cardiovascular ads in black-oriented magazines published in 2011 and 2012) is not presumed. Companies make advertising decisions for a variety of reasons. To some extent, the data collected represent the natural ebb and flow of advertising—advertising shifts away from older drugs as new drugs enter the market. Therefore, it is important not to construe the lack of change in DTCA frequency, appearance, and content as an intentional rejection of the report's recommendations.

Finally, the focus of the study is on the appearance and content of the advertisement, rather than on its effects. No attempt was made to evaluate the effectiveness of the advertisement in motivating consumer behavior, the appropriateness of the information conveyed in the advertisement, or how that information is understood by the consumer.

5.3 Next Steps

This study represents the most recent compilation of data on the frequency and content of pharmaceutical advertising. The data set developed is larger than most used by previous researchers, both in terms of the number of magazine issues reviewed and the amount of advertisements identified. Furthermore, it is the only data set that compiles data on not only ad placement, but also on the visual and written characteristics of the

individual ads. Thus, it is a rich data set that can be used to examine multiple dimensions of the DTCA included.

In doing my analysis, I noticed a number of interesting trends in the data that are worthy of further research. For example, no advertisements for drugs to treat overactive bladder appeared in any of the 96 issues of *Ebony* or *Essence* reviewed, although ads for these types of drugs appeared frequently in *Family Circle* and *Good Housekeeping*. Given that overactive bladder may be considered a medicalized condition, it would be interesting to determine whether advertising for other medicalized conditions vary based on the racial orientation of the magazine in which it appears. And if it does, what are the policy implications of such a finding?

Two models underpin this and previous studies of DTCA. The health belief model and social cognitive theory each have elements that can be used to explain the health promotion potential of DTCA. While working on this dissertation, I began to develop a new model that synthesized various aspects of these two models into a single, innovative framework to better explain the interaction of DTCA and consumer behavior. Further research would look at ways to test and refine this model with the goal of one day creating a model that could be used as a basis for future studies.

I also intended to look at the health literacy aspects of DTCA. As I conducted my literature review, I found numerous studies that had evaluated the health literacy demands of DTCA, all of which concluded that much of the information provided in these ads is well beyond the ability of most consumers to understand. I quickly realized that I would not be able to contribute to the literature in this area within the scope of the current study. However, I envision a future study using the same database that focuses exclusively on

health literacy and evaluates the use of visual cues, such as inanimate objects, font size, and color selection, and written cues in the form of tag lines and slogans, to communicate information in a more user-friendly manner.

DTCA is embedded in our culture. Further research should focus more on ways to improve its value as a health promotion tool and less on its shortcomings in an effort to curtail its use. The potential is there—one only has to determine ways to marry the financial interests of the pharmaceutical industry with the broader healthcare goals of the policymakers.

Table 5-1: Summary of Research Findings

Research Question	Findings	Policy Recommendations
RQ1: Does the frequency of pharmaceutical advertising vary based on the racial orientation of the magazine?	The amount of DTCA in white-oriented magazines is significantly greater than in black-oriented magazines.	Despite the FDA recommendations, the pharmaceutical industry has not increased its outreach to readers of black-oriented magazines. The lack of DTCA in black-oriented magazines perpetuates disparities in access to health information. The FDA should enter into voluntary agreements with pharmaceutical companies to increase the number of help-seeking ads placed in black-oriented magazines.
RQ2: Did the frequency of pharmaceutical advertising appearing in black-oriented women's magazine increase following the 2009 FDA report?	The amount of DTCA in black-oriented women's magazines did not increase significantly following the 2009 FDA report.	

Table 5-1: (continued)

Research Question	Findings	Policy Recommendations
RQ3: Do the types of drugs advertised vary by the racial orientation of the magazine?	The types of drugs advertised varied by the racial orientation of the magazine. The drugs advertised most prevalently in black-oriented magazines are used to treat diabetes, depression, and asthma. The most popular drugs advertised in white-oriented magazines are used to treat ADHD, asthma, depression, postmenopausal osteoporosis, and vaginal dryness.	The most frequently advertised drugs in black-oriented magazines are used to treat significant health risks. This finding differs from the work of previous researchers and represents a positive trend. However, the observed reduction in the amount of advertising for drugs used to treat medical conditions of particular concern to black Americans (such as cardiovascular disease) could negatively impact the health outcomes of ethnic and racial minorities. The FDA should enter into voluntary agreements with pharmaceutical companies to develop and implement help-seeking ad campaigns for medical conditions of particular concern to black Americans.
RQ4: Have the types of drugs advertised become more concordant with the health risks of the race of the magazine's readers following the 2009 FDA report?	DTCA published after the 2009 FDA report was less concordant with the race of the magazine's readers than DTCA published before the report. In particular, cardiovascular drugs, which were the third most common drug advertised in black-oriented magazines published before the 2009 FDA report, were not advertised in any issue of the black-oriented magazines published in either 2011 or 2012.	

Table 5-1: (continued)

Research Question	Findings	Policy Recommendations
RQ5: Does the race of the models used in DTCA vary based on the racial orientation of the magazine?	The race of the models used in DTCA varies based on the racial orientation of the magazine. White models were more likely to be featured in ads placed in white-oriented magazines, and black models were more likely to be featured in ads placed in black-oriented magazines.	Social cognitive theory suggests that consumers are more likely to positively react to ads that feature models of the same race. Thus, seeing a drug ad that features a black model is more likely to motivate a black reader to seek treatment than an ad featuring a white model, all else being equal. Positive alignment between model ads and the race of a magazine's readers may reduce health disparities. No change in policy is needed.
RQ6: Did the percentage of advertisements featuring black models increase following the FDA report?	No statistically significant change in the percentage of ads featuring black models was detected in DTCA published before the FDA report versus that published after the report.	It appears that the pharmaceutical industry has not increased its outreach to black readers of women's magazines, regardless of their racial orientation. The FDA should implement voluntary agreements with the pharmaceutical industry to increase its outreach to black Americans. These agreements could include a commitment to increase the use of black models in ad campaigns.

Table 5-1: (continued)

Research Question	Findings	Policy Recommendations
RQ7: Does the provision of information about nondrug interventions vary based on the racial orientation of the magazine?	Fewer than 50 percent of the ads reviewed included information about nondrug interventions. The provision of this information varied based on the type of drug advertised rather than the racial orientation of the magazine in which the drug appeared. Ads for drugs used to treat high cholesterol, diabetes, and depression were more likely to include this information than ads for other types of drugs. However, this information was not consistently provided—an ad for one antidepressant medication mentioned nondrug therapies while an ad for another did not.	Despite the FDA recommendation to include this information, as well its own guiding principles, the industry has not been successful in alerting consumers to possible nondrug interventions in its advertising. Such information can be an important cue to action and has important educational value. The FDA should mandate that this information be included in all pharmaceutical advertising.
RQ8: Did the percentage of advertisements that include information about nondrug interventions increase following the 2009 FDA study?	No statistically significant increase in the percentage of advertisements including information about nondrug interventions was detected.	

Table 5-1: (continued)

Research Question	Findings	Policy Recommendations
RQ9: Does the provision of information about available discounts or patient assistance programs vary based on the racial orientation of the magazine?	The majority of ads evaluated included some form of discount or patient assistance program, whether it be a free trial, a discounted prescription rate, or referral to a program to assist low income or uninsured individuals in getting their medications. The provision of this information did not vary based on the racial orientation of the magazine.	These findings suggest that the pharmaceutical industry has is following both the FDA recommendations and its own guiding principles in with regard to this information. In addition, it appears that the industry has increased its outreach to readers of black-oriented magazines through prescription discounts and other financial assistance. However, it is impossible to conclude whether this finding represents an intended effort to make drugs more accessible to these readers or a tool to promote a particular drug. Lack of financial resources can be a key barrier in obtaining medication and continuing a medication regime. The FDA should mandate that drug ads include information to assist low-income individuals in obtaining their prescribed medications.
RQ10: Did the percentage of advertisements that include information about available discounts or patient assistance programs increase following the 2009 FDA study	A statistically significant increase in the number of advertisements placed in black-oriented magazines that offered financial assistance was observed over time.	

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APPENDIX A: CODE SHEETS

MAGAZINE CODE SHEET

ID #: _____

Magazine Name: _____

Publication Date: _____

Number of Pages: _____

Number of Advertising Pages: _____

Number of DTCA Pages:_____

Percent of Advertising Pages: _____

Percent of DTCA: _____

NON-DTCA ADVERTISING

Full Page Half Page

DTCA ADVERTISING

Full Page Half Page

ADVERTISEMENT CODE SHEET

Coder Name: _____

Advertisement ID # _____

TYPE OF DRUG

Drug Name: _____

Medical Condition Used to Treat: _____

Manufacturer: _____

SIZE OF AD

Pages (Promotional):_____

Pages (Brief Summary):_____

AD APPEARANCE

Does the ad use human models?

Y N

Does the ad use a cartoon character?

Y N

Does the ad use an inanimate object?

Y N

ADVERTISEMENT CODE SHEET (continued)

DEMOGRAPHICS OF HUMAN MODELS

How many human models does the ad feature: _____

Is the race of the models distinguishable?

Y N

For each model used, identify the race, gender, and approximate age in the table below. Code models from left to right. Circle the number of the primary model used in the ad.

Model	Race			Gender		Age		
	W	B	O	M	F	Child	Adult	Senior
1								
2								
3								
4								

W = White
B = Black
O = Other
U = Unknown

M = Male
F = Female
U = Unknown

Child = < 18 years of age
Adult = 18 to 64 years of age
Senior = 65+ year of age

ADVERTISEMENT CODE SHEET (continued)

AD APPEALS

Is there a rational appeal (e.g., does the ad describe how the drug is to be used, does the ad list the drugs benefits, does the ad compare one drug to another, does the ad include statistics)?

Y N

Using the following taxonomy, identify the types of rational appeals used based on the words that appear in the ad:

Claimed Attribute	Description of Drug	Yes	No
Effectiveness			
Effective	"effective," has a "proven" therapeutic benefit, "works"		
Cure	Provides a "cure" for condition		
Dependable	"reliable," "dependable"		
Innovative	"advancement," "breakthrough," "a first," "new," "novel," "only" drug of kind, "innovative"		
Powerful	"potent," "powerful," "strong"		
Prevention	"prevents," offers "prevention of" condition		
Reduced mortality	"prolongs life," "saves lives," "prevents death"		
Symptom control	"controls" or "manages" symptoms, brings symptoms "under control"		
Social-Psychological Enhancements			
Lifestyle	Allows for a more "active," "regular," "normal," "free," or "flexible" life		
Psychological	Increases feelings of "confidence," "sureness," "happiness," "hope," "relieves fears"		
Social	Enhances the "attractiveness" or "appearance" of the user		
Ease of Use			
Convenience	"convenient," "easy," "simple" to use, "infrequent" dosage or "short-term" use required		
Easy on system	"gentle" on the user, "good tasting"		
Economical	"economical," "cost-beneficial," or "saves money"		
Quick acting	works "quickly," "fast," "rapidly," "speedily"		
Safety			
Safe	"safe," leaves the system quickly, is a "reversible" treatment, "approved," "FDA-approved"		
Natural	Works "naturally," works like your own body does, made of natural agents		
Nonaddictive	"nonhabit forming" or "nonaddictive"		
Nonmedicated	Does not make one feel "drowsy," "sleepy," "medicated," "drugged," or "spacey		

ADVERTISEMENT CODE SHEET (continued)

Is there a positive appeal (e.g., does the ad convey a sense of happiness, warmth, pride, joy, caring, humor, sex, fantasy, or nostalgia)?

Y N

Is there a humor appeal (e.g., does the ad use puns or satire)?

Y N

Is there a nostalgic appeal (e.g., does the ad include images from earlier time periods, is the ad printed in black or white or use sepia tones)?

Y N

Is there sex appeal (e.g., are the characters portrayed in an intimate encounter, scantily clad, wearing revealing clothing, or using provocative gestures?

Y N

Is there a negative appeal (e.g., does the ad invoke a sense of fear, anger, regret, sadness, guilt, or shame?

Y N

ADVERTISEMENT CODE SHEET (continued)

OTHER INFORMATION

Is the reader offered help in finding patient support services?

Y N

Is the reader referred to a Web site for additional information?

Y N

Is the reader given a telephone contact for additional information?

Y N

Is the reader encouraged to talk with a doctor or another individual?

Y N

Is the reader offered monetary incentives or other financial support?

Y N

Is the reader informed of nondrug interventions, such as diet and exercise, which might be helpful?

Y N

Does the ad encourage the reader to report negative side effects of prescription drugs to the FDA?

Y N

APPENDIX B: SUMMARY OF PREVIOUS CONTENT ANALYSES OF DIRECT-TO-CONSUMER ADVERTISING IN MAGAZINES

This appendix summarizes the work of previous researchers that contributed to the design of the study reported in this dissertation. With one exception (Kean & Prividera, 2007), this research examined direct-to-consumer advertising (DTCA) found in a broad range of magazine genres. These studies evaluated the content of the advertisements and compared differences in their appearance, the types of drugs advertised, and the kinds appeals used. Some studies specifically compared ads based on the racial orientation of the magazine, while others made more general comparisons. Taken together, these studies reveal trends in DTCA over a period of nearly 20 years.

The following paragraphs provide a brief overview of each study. Table B-1 includes more detailed information about the sample size, methods used, and conclusions reached.

Abel, Lee, and Weeks (2007): This study focused on the advertising of pharmaceuticals to treat cancer or the effects of chemotherapy in both patient-oriented oncology magazines, as well as the popular press. Selected issues of 10 popular magazines and all issues of four cancer magazines published between January 2003 and January 2006 were reviewed. Researchers looked at not only the advertising prevalence of cancer-related drugs, but also the readability of such advertisements. Not surprisingly, fewer advertisements for cancer-related drugs appeared in the popular press than in the patient-oriented oncology magazines, and the ads that did appear tended to be placed in women's magazines. Abel et al. also found that all of the information provided in the advertisements was hard to understand. While other researchers have considered this to

be a net negative of DTCA, Abel et al. advance the idea that such intelligibility could be considered an asset by encouraging patients to discuss more fully the advantages and disadvantages of certain treatment options.

Bell, Kravitz, and Wilkes (2000): This early content analysis reviewed DTCA in 13 magazine categories, as well as five publications targeted to a particular population based on ethnicity, age, and sexual orientation. Advertisements appearing in these magazines between the years 1989 and 1998 were evaluated for trends in the drugs advertised, inducements offered, and appeals used. Not surprisingly, the researchers found a dramatic increase in the amount of advertising over the study period. Nearly a third of the ads were for drugs used to treat life-threatening conditions, and the vast majority of ads were aimed at the potential user of the drug, rather than a parent, spouse, or adult child. Nearly a quarter of the ads were directed at women exclusively. Most advertisements offered additional information, and a few offered monetary incentives. In terms of appeals used, two-fifths of the ads characterized the product as innovative, while the notion of cost savings was rarely mentioned.

Cline and Young (2004): This study focused on the visual cues found in print advertisements placed in 18 popular magazines during the two-year period between January 1998 and December 1999. Variables included the presence or absence of people; the number of people depicted; the age, ethnicity, and gender of each person depicted; the way in which people were depicted—either in a photograph or as a drawing or cartoon figure; whether the person appeared friendly, healthy, or active, and the social and relational context of the people depicted. The researchers found that the models used in advertising were likely to appear active, healthy, and friendly. They also found that the

advertisements reinforced gender stereotypes, with half the ads focusing on a woman's reproductive capacity. Advertisements for psychiatric products also tended to feature women. African Americans did not appear in ads for drugs to treat cancer- and cardiovascular-related conditions, respiratory ailments, or psychiatric-neurological illnesses. They also did not appear in ads promoting smoking cessation products. On the other hand, ads for HIV/AIDS drugs more often than not featured African American or Hispanic models. Few ads featured older people. These results led the researchers to conclude that the visual cues in DTCA may perpetuate existing disparities in access to health care and health information.

Crawley, Hisaw, and Illes (2009): In this study, the researchers examined six magazines, representing three genres, for a six-month period between September 2005 and February 2006. Magazines in each genre were matched in terms of their target audience: general audience versus African American audience. The analysis included both prescription drug and over-the-counter product advertisements. Variables included magazine genre, magazine racial/ethnic orientation, medical condition, advertisement type, FDA regulatory designation, and ad size. A multiple correspondence analysis was used to explore placement patterns of advertising between the general audience and African American magazines. Crawley, Hisaw, and Illes found little difference between the two magazine groups in terms of the total volume of advertisements placed. However, they did find significant differences in the types of products advertised, with drugs for mental health conditions and serious life-threatening conditions corresponding to the general audience magazines while drugs for chronic non-life-threatening conditions and infectious disease corresponding to the African American magazines.

Duerksen et al. (2005): In this study, Duerksen et al. examined the health-related advertising that appeared in the June, July, and August 2002 issues of 12 separate women's magazines. Advertisements were grouped into 48 categories, including health promotion products, products that could negatively affect health, food and nonalcoholic beverages, and products with mixed health impact. The race/ethnicity of the models appearing in each advertisement was noted. The study found that magazines targeted to African American or Hispanic audiences included more ads promoting products with potentially negative health consequences (i.e., health-diminishing products) than did magazines targeted to a more general audience. Furthermore, ads promoting such products were more likely to use African American models than Caucasian models. In contrast, general audience magazines included more advertisements for health-promoting products than for health-diminishing products, and health-promoting products were more likely to be advertised using Caucasian models.

Kean and Prividera (2007): This study did not evaluate DTCA, but instead compared advertisements for consumables, such as food, drink, vitamins, and supplements, found in two selected magazine titles: one targeted to an African American audience and one targeted to a more general readership. The researchers evaluated all issues of these two magazines published between January 2004 and December 2004. Kean and Prividera were particularly interested in the types of products advertised, the product claims made, and the appearance of the models used in the ads. They found differences in the types of products advertised (more fast food ads appeared in the African American audience magazine), the claims made (a greater number of advertisements for weight loss products or making weight loss claims appeared in the magazine aimed at a more general

readership), and models used (the advertisements placed in the magazine targeted to an African American audience included more African American models while advertisements appearing in the magazine aimed at a more general readership included more Caucasian models).

Mackert and Love (2011): In this study, Mackert and Love investigated the content of DTCA within the context of the health belief model and evaluated the challenges to health literacy posed by such content. Twenty magazines, representing a broad range of topic areas and target audiences, were chosen, and the issues of those magazines published between January and March 2007 were examined. Although this study did not look specifically at racial disparities in advertising, the researchers did note that nearly half the advertisements featured Caucasian models, while only 20 percent featured African American models. The researchers also found that the messages included in the advertisements reviewed did provide valuable medical and social information, but lacked some equally important information, such as statements regarding disease prevalence. However, Mackert and Love raised a concern regarding the ability of low literacy audiences to fully understand an advertisement's intended message, but offered strategies for increasing the educational potential of DTCA.

Main, Argo, and Huhmann (2004): This study focused on the types of appeal and the appearance of the models used in DTCA, as well as advertisements for over-the-counter remedies and dietary supplements. Magazines from seven different categories were selected (for a total of 30 magazines), and the December issues for years 1998, 1999, and 2000 were chosen for study. In examining the visual images and headline of each advertisement, the researchers found that most DTCA relies on an emotional appeal

rather than a rational appeal. They also found that the DTCA evaluated featured fewer women, more children, and more white models than the nonpharmaceutical advertising.

Mastin, Andsager, Choi, and Lee (2007): This study looked specifically at how DTCA targets particular audiences by evaluating pharmaceutical advertisements placed in four magazine genres (African American, entertainment, news, and women's) published during the period 1992 to 2002. Variables included drug purpose, model race/ethnicity, and model gender. The researchers found that most of the ads featured Caucasian models only; however, those ads placed in African American magazines were more likely to feature African American models. They also discovered that while DTCA increased dramatically during the time period, the vast majority of the increase was found in those magazines targeted to African Americans and women. In terms of the types of drugs advertised, Mastin et al. found little connection between the products promoted and the conditions likely to be a concern for the targeted population. For example, African Americans are more likely to die from heart disease than Caucasians, but there were far fewer ads for heart medication in the magazines aimed at an African American audience than there were in those magazines targeted at women.

Omonuwa (2001): Omonuwa evaluated the DTC advertising in 10 popular magazines during the period of June to August 2000. Five of the magazines were oriented to African American audiences and five were oriented to white audiences. Omonuwa found a significant difference in the number of DTC advertisements between the two sets of magazines. Those magazines oriented to white audiences contained four to eight times more DTC advertisements than magazines oriented to black audiences.

Pinto (2000): Another early content analysis of DTCA, this study examined the type of appeals used in DTCA found in a random sample of magazine issues published between March 1996 and February 1998. Twenty-four popular magazines, representing 12 publication categories, were included in the study. Pinto found that DTCA uses all types of appeal (fear, humor, guilt, sex, relational, and information), and many ads rely on both informational and emotional appeals. Furthermore, the type of appeal did not vary with the type of drug being advertised.

Sokol, Wackowski, and Lewis (2010): This study reviewed the monthly issues of five popular women's magazines published between July 2005 and June 2006. Variables were related to the target audience of the magazine (in terms of age), the type of advertisement (product claim, help seeking, or reminder), the health condition for which the advertised drug was intended, the type of appeal used in the advertisement (logic, fear, emotion, humor), the type of evidence presented (testimonials, quantitative or narrative information, and eyewitness statements), and the characteristics of the models used in the advertisement. The researchers found that the frequency of advertising, the types of drugs advertised, and the types of appeals and information presented varied depending on whether the magazine was aimed at an older or younger audience. Sokol et al. also found that those magazines targeted at an older audience included advertisements for medications to address not only women's health conditions, but although those more common to men and children.

Woloshin, Schwartz, Tremmel, and Welch (2001): This early content analysis of DTCA reviewed DTCA in a total of 10 magazines within three categories of readers: men, women, and the general population. Seven issues of each magazine title were evaluated.

Publication dates ranges from July 1998 to July 1999. The study looked at both advertisement frequency and advertisement content. Researchers found that DTCA was least common in men's magazines and most common in women's magazines. The types of products advertised also varied by magazine genre, with hair products advertised most frequently is men's magazines and medications to relieve allergy symptoms advertised most often in women's magazines and magazines with a general readership. In terms of content, much of the DTCA evaluated provided quantitative data on a drug's possible side effects, but very little provided quantitative data on a drug's benefits.

Table B-1: Summary of Previous Content Analyses of DTCA

Author	Sample	Method	Discussion
Abel, Lee, and Weeks (2007)	Oncology-related DTCA in 3 patient-focused cancer magazines (all issues) and 10 popular magazines (January & June issues) *** January 2003–June 2006 *** Reminder and product-specific ads *** 136 magazine issues and 284 oncology-related DTCA identified; 49 unique ads for 22 products analyzed	Designated each sentence as either a benefit, a risk/adverse effect, or neither. *** Analyzed proportion, placement, and font size of each type of statement. *** Assessed readability (Flesch reading ease score). *** Evaluated nature of appeals. *** Assessed content of appeals using methods of Bell, Kravitz, and Wilkes (2000).	• Oncology-related DTCA is common in patient-directed cancer magazines. • Oncology-related DTCA is not common in popular magazines. • Oncology-related DTCA is more likely to appear in popular magazines targeted to women. • Oncology-related DTCA is difficult to read. • Medication effectiveness was the most common appeal.
Bell, Kravitz, and Wilkes (2000)	DTCA in 18 popular magazines; 5 of which were targeted to a particular audience *** January 1989–December1998 *** Product-specific ads 320 distinct ads, 101 brands, and 14 categories of medical conditions	Classified each drug based on medical condition. *** Determined the presence or absence of inducements. *** Evaluated the content of appeals.	• The number of ads and the brands advertised increased significantly over study period. • Drugs used to treat dermatologic conditions, HIV/AIDS, and OB/GYN conditions were most common. • Almost all ads targeted the potential user. • Women were likely targeted than men. • Less than 20 percent of ads offered a financial incentive; one-third offered additional information. • Convenience, effectiveness, innovativeness, and symptom control were the most common appeals.

Table B-1: (continued)

Author	Sample	Method	Discussion
Cline and Young (2004)	18 popular magazines, 5 of which targeted specific populations *** January 1998–December 1999 *** 684 magazine issues *** All pharmaceutical advertisements *** 994 pharmaceutical ads for 83 drugs addressing 15 types of medical conditions	Identified model characteristics. *** Identified identity rewards (healthy, active, friendly). *** Identified relational rewards (social context, relational context).	• DTCA includes a variety of visual models with positive characteristics. • Nearly 40 percent of the ads included the appearance of relational rewards. • DTCA promoted the message that taking the advertised drug will lead to the consumer being healthy looking and active. Thus, visual cues in DTCA may be misleading. • DTCA reinforced gender stereotypes; nearly two-thirds of the ads for cardiovascular drugs depicted men only (cardiovascular disease is the number one killer of both men and women). African Americans did not appear in ads for cancer- or cardiovascular-related products, but dominated ads for HIV/AIDS medications.
Crawley, Hisaw, and Illes (2009)	Matched 3 magazines targeted to African American audiences to 3 magazines targeted to a general audience by genre *** September 2005–February 2006 *** All health-related ads, including OTC and prescription drugs, and ads with health messages *** 262 ads in 6 magazines; 70 distinct products and 30 distinct messages	Evaluated frequency of ads in terms of volume of ads by magazine genre. *** Compared types of products advertised and health messages given as a function of magazine audience (African American or general). *** Used multiple correspondence analysis to assess the relationship of ad characteristics to the magazine audience.	• Total volume of ads did not vary as a function of magazine audience. • Racial differences existed in types of drugs advertised. • General audience magazines were more likely to include ads for prescription drugs used to treat life-threatening conditions and mental health conditions. • African American magazines were more likely to include ads for products to treat colds and allergies and chronic, non-life-threatening conditions.

Table B-1: (continued)

Author	Sample	Method	Discussion
Duerksen et al. (2005)	12 women's magazines— 4 targeted to African Americans 4 targeted to Hispanics 4 targeted to the mainstream (predominantly Caucasian readership) *** June, July, and August 2002 *** 10 issues of African American magazines 14 issues of Hispanic magazines 12 issues of mainstream magazines *** All health-related ads *** 140 ads in African American magazines 110 ads in Hispanic magazines 470 ads in mainstream magazines	Evaluated ad content, categorizing each ad as either health promoting medical treatment or products, products with potentially negative health consequences, and food and nonalcoholic beverages with either healthy impact, unhealthy impact, or mixed health impact. *** Noted the race/ethnicity of models used in ads. *** Compared the relative and absolute amount of health-related advertising as a function of magazine audience.	• Women's magazines targeted to African American and Hispanic audiences contained more health diminishing advertising and less health-promoting advertising than mainstream magazines. • In African American magazines, advertisements promoting health-diminishing products were more likely to include an African American model than a Caucasian model. • Caucasian models were rarely used to promote health-diminishing products, but were frequently used to advertise health-promoting products.

Table B-1: (continued)

Author	Sample	Method	Discussion
Kean and Prividera (2007)	One magazine targeted to an African American audience matched to one general readership (mainstream) magazine *** Only advertisements for consumption products considered *** January 2004–December 2004 *** 141 ads in the African American magazine 215 ads in the mainstream magazine	Assessed the type of product advertised and the claims made about the product. *** Evaluated the characteristics of the most prominent model used in the ad.	• More fast food ads appeared in the African American magazine than in the mainstream magazine. • More alcohol ads appeared in the mainstream magazine than in the African American magazine; alcohol was the product most advertised in the mainstream magazine. • No ads for weight loss supplements or products appeared in the African American magazine. • One-third of ads in the African American magazine made health claims as compared to 41% of ads in the mainstream magazine.

Table B-1: (continued)

Author	Sample	Method	Discussion
Mackert and Love (2011)	10 popular magazines; 10 culturally focused and other specialty magazines *** January 2007–March 2007 *** 82 unique pharmaceutical advertisements	Analyzed ad content for the presence or absence of information regarding a condition's prevalence, medical and social benefits, barriers to use, and symptoms. *** Evaluated the health literacy of the ad in terms of fonts used, information regarding research or clinical trials, and the appearance of the models used (cultural literacy).	• Many ads lacked information about a condition's prevalence. • Virtually all information contained information about medical benefits; about 40 percent included information about social benefits. • Most of the ads included information about potential side effects and contraindications. • More than half of the ads provided information about financial assistance. • Less than half of the ads included information about symptoms. • Most ads used nonstandard text formatting. • Nearly half the ads featured Caucasian models; African American models appeared in about 20 percent of the ads and Hispanic models appeared in less than 10 percent.

Table B-1: (continued)

Author	Sample	Method	Discussion
Mastin et al. (2007)	Four magazine genres *** 1992–2002 *** All DTCA for prescription drugs *** 132 magazines; 282 advertisements	Identified the purpose of the drug, the race/ethnicity of the models, and the gender of the models. *** Compared the race/ethnicity of models as a function of magazine genre. *** Compared the purpose of the drug advertised as a function of magazine genre. *** Compared the purpose of the drug advertised in African American and women's magazines over the study period.	• The amount of DTCA increased over the study period. The largest increase in DTCA occurred in magazines targeted to African Americans and women. • Three–fourths of the ads in African American magazines used African American models; few ads in African American magazines featured Caucasian models while nearly all ads placed in other magazines feature Caucasian models only. • The types of drugs advertised varied by magazine genre. DTCA for drugs to treat women's health issues, as well as sexually transmitted diseases, were more likely to appear in magazines targeted to African Americans. • The types of drugs advertised were not consistent with risk of illness associated with the magazine's intended audience. For example, the ratio of ads for heart medication was 1:4 in African American magazines versus women's magazines although African Americans are more likely to die from heart disease than are Caucasians.

Table B-1: (continued)

Author	Sample	Method	Discussion
Main, Argo, and Huhmann (2004)	30 popular magazines representing seven categories *** December 1998, 1999, and 2000 *** All prescription and nonprescription medications (OTC remedies and dietary supplements) ads *** 365 advertisements—195 for prescription drugs, 137 for OTC remedies, and 33 for dietary supplements	Determined the type of appeal used. *** Evaluated the demographic characteristics of the models used. *** Compared the type of appeal used and the appearance of the models used in prescription drug ads to those used in nonprescription drug ads.	• DTCA does include information about the drug, the disease, and the risks and benefits. • The promotional part of the ads relies on an emotional rather than a rational appeal. • Emotional appeals can be both positive and negative. • Prescription drug ads featured fewer women, more children, and more Whites.

Table B-1: (continued)

Author	Sample	Method	Discussion
Omonuwa (2001)	5 black-oriented magazines; 5 white-oriented magazines *** June 2000–August 2000 *** All DTCA for prescription drugs	Compared the number and type of DTCA appearing black-oriented magazines versus white-oriented magazines.	• The amount of DTCA was substantially greater (four to eight times) in white-oriented magazines than in black-oriented magazines. • The types of drugs advertised varied between white-oriented magazines and black-oriented magazines. • No ads appeared in white-oriented magazines for oral contraception or HIV/AIDS. • No ads appeared in black-oriented magazines for cholinesterase inhibitors (for the treatment of dementia), calcium supplements, COX-II inhibitors (pain relief), intranasal steroids, anorexiants (appetite suppression), proton pump inhibitors (reduction of gastric acid production), and smoking deterrent agents.
Pinto (2000)	24 popular magazines representing 12 categories *** March 1996–February 1998 *** 48 magazine issues randomly selected *** All DTCA of at least one-half page in size *** 58 unique pharmaceutical advertisements	Categorized drugs advertised within six categories. *** Evaluated the type of appeal used in each ad (fear, humor, guilt, sex, relational, and information). Compared the type of appeal as a function of drug category.	• All magazine categories contained at least one drug ad, although the number of ads varied substantially even between magazines within the same category. • DTCA used all types of appeals, with many ads employing both emotional and information appeals. • The type of appeal did not vary with the type of drug advertised.

Table B-1: (continued)

Author	Sample	Method	Discussion
Sokol et al.	5 popular women's magazines *** July 2005–June 2006 *** 60 magazine issues All pharmaceutical advertisements *** 139 unique pharmaceutical advertisements addressing 36 different medical conditions	Identified the type of advertisement according to FDA guidelines. *** Organized the conditions treated by the advertised drugs into six categories. *** Classified each ad's intended audience by considering the presence, number, and gender of models. *** Identified the type of appeal used and the type of evidence presented. *** Investigated differences among the five magazines selected.	• DTCA varied by the age of the magazine's intended audience. • The magazines intended for an older audience contained the largest amount of DTCA. These magazines were also more likely to advertise medications for use by men and children rather than for women's personal use. • A greater number of ads for cardiovascular and chronic conditions appeared in the older audience magazines. • Lifestyle-type drugs were more likely to be advertised in magazines appealing to younger women. • Drugs to treat mental health condition were advertised significantly more often in magazines appeal to younger women.

Table B-1: (continued)

Author	Sample	Method	Discussion
Woloshin et al. (2001)	10 popular magazines **** 7 magazine issues of each title, published between July 1998 and July 1999 **** 211 pharmaceutical ads of which 67 were unique	Evaluated the frequency of advertisements intended to relieve symptoms, treat disease, and prevent disease. **** Evaluated the description of side effects and benefits, particularly the use of qualitative versus quantitative statements. **** Also evaluated whether ad included an emotional appeal, encouraged self-diagnosis, or mentioned drug cost or offered a free trial or rebate.	• Most DTCA appeared in women's magazines. • Most advertisements were for drugs to treat allergies or menopause symptoms. • Most advertisements described benefits in vague terms, but were quite explicit about the side effects. • The most common emotional appeal was a desire to "get back to normal" (p. 1144). • No ad mentioned drug cost, few offered free trials. A rebate was offered in 24 percent of the ads.

APPENDIX C: FREQUENCY OF INDIVIDUAL DRUG ADVERTISEMENTS BY MAGAZINE GENRE AND PUBLICATION DATE

The following table provides a complete inventory of the 1,090 product claim advertisements found in the five magazines providing data for this research. Individual drugs are grouped within 16 categories: Allergies, Cancer, Cardiovascular, Cosmetic, Dermatologic, Diabetes, Gastrointestinal/Nutritional, Infectious (Non-HIV), Musculoskeletal, Obstetric/Gynecological, Ophthalmological, Psychiatric/Neurologic, Respiratory, Tobacco Addiction, and Urological (e.g., the category "Allergies" includes the drugs EpiPen and Singulair). The number of ads for each drug is reported, as well as the relative percentage within a given category. For example, 13 ads for cardiovascular drugs appeared in black-oriented magazines published before the 2009 FDA report. Five of these ads (or 38.5 percent) were for Caduet and eight (or 61.5 percent) were for Plavix.

Table C-1: Name of Drug Advertised by Racial Orientation of Magazine
(No. of Ads/Percent of Disease Category)

DRUG NAME	BEFORE			AFTER		
	Black	White	Cross-over	Black	White	Cross-over
Allergies	---	1/100.0	---	---	3/100.0	---
EpiPen	---	---	---	---	3/100.0	---
Singulair	---	1/100.0	---	---	---	---
Cancer	1/100.0	1/100.0	---	---	---	---
Arimidex	---	1/100.0	---	---	---	---
Femara	1/100.0	---	---	---	---	---
Cardiovascular	13/100.0	56/100.0	8/100.0	---	30/100.0	2/100.0
Caduet	5/38.5	5/8.9	---	---	---	---
Crestor	---	12/21.4	4/50.0	---	---	---
Lipitor	---	4/7.1	---	---	3/10.0	2/100.0
Livalo	---	---	---	---	8/26.7	---
Lovaza	---	2/3.6	---	---	1/.33	---
Niaspan	---	2/3.6	---	---	2/6.7	---
Plavix	8/61.5	13/23.2	4/50.0	---	---	---
Pradaxa	---	---	---	---	12/40.0	---
TriCor	---	2/3.6	---	---	---	---
Vytorin	---	5/8.9	---	---	---	---
Xarelto	---	---	---	---	2/6.7	---
Zetia	---	11/19.6	---		2/6.7	---
Cosmetic	---	---	17/100.0	---	8/100.0	13/100.0
ArteFill	---	---	2/11.8	---	---	---
Botox Cosmetic	---	---	3/17.7	---	3/37.5	6/46.2
Dysport	---	---	1/5.9	---	---	---
Juvederm	---	---	3/17/7	---	---	3/23.1
Latisse	---	---	3/17.7	---	5/62.5	3/23.1
Restylane	---	---	3/17.7	---	---	---
SculptraAesthetic	---	---	---	---	---	1/7.7
Vivite	---	---	2/11.8	---	---	---

Table C-1: (continued)

DRUG NAME	BEFORE			AFTER		
	Black	White	Cross-over	Black	White	Cross-over
Dermatologic	---	6/100.0	3/100.0	---	3/100.0	11/100.0
Asclera	---	---	---	---	---	5/45.5
Enbrel	---	3/50.0	---	---	---	---
Humira	---	---	---	---	3/100.0	3/27.3
Oracea	---	3/50.0	---	---	---	3/27.3
Diabetes	20/100.0	3/100.0	1/100.0	17/100.0	12/100.0	---
FlexPen	2/10.0	---	---	---	---	---
Januvia	16/80.0	2/66.7	1/100.0	14/82.4	---	---
Lantus	2/20.0	1/33.3	---	---	1/8.3	--
Victoza	---	---	---	3/17.6	11/91.7	---
Gastrointestinal/ Nutritional	---	17/100.0	2/100.0	---	---	---
AcipHex	---	11/64.7	---	---	---	---
Amitiza	---	4/23.5	---	---	---	---
Transderm Scop	---	2/11.8	2/100.0	---	---	---
Infectious (Non-HIV)	5/100.0	17/100.0	6/100.0	20/100.0	20/100.0	---
FluMist	---	---	---	---	3/15.0	---
FluZone	---	---	---	---	2/10.0	---
Gardasil	2/40.0	10/58.8	6/100.0	12/60.0	8/40.0	---
Incivek	---	---	---	3/15.0	---	---
Prevnar 13	---	---	---	5/25.0	2/10.0	---
Tamiflu	---	---	---	---	2/10.0	---
Valtrex	3/100.0	---	---	---	---	---
Zostavax	---	7/41.2	---	---	3/15.0	---

Table C-1: (continued)

DRUG NAME	BEFORE			AFTER		
	Black	White	Cross-over	Black	White	Cross-over
Musculoskeletal	8/100.0	76/100.0	13/100.0	5/100.0	79/100.0	7/100.0
Actonel	---	22/29.0	---	---	---	---
Boniva	---	11/14.5	3/23.1	---	11/13.9	---
Celebrex	---	8/10.5	---	---	7/8.9	---
Cimzia	---	---	---	---	8/10.1	---
Enbrel	---	---	---	---	2/2.5	---
Evista	---	11/14.5	4/30.8	---	4/5.1	---
Humira	---	1/1.3	---	---	4/5.1	---
Orencia	8/100.0	8/10.5	3/23.1	5/100.0	6/7.6	3/42.9
Prolia	---	---	---	---	14/17.7	---
Reclast	---	13/17.1	3/23.1	---	5/6.3	---
Remicade	---	1/1.3	---	---	---	---
Simponi	---	---	---	---	6/7.6	---
Synvisc-One	---	1/1.3	---	---	2/2.5	---
Vimovo	---	---	---	---	10/12.7	4/57.1
Obstetric/ Gynecological	11/100.0	7/100.0	2/100.0	5/100.0	18/100.0	8/100.0
Estring	---	---	---	---	1/5.6	---
Mirena	1/9.1	---	2/100.0	---	---	---
NuvaRing	---	---	---	5/100.0	---	---
Plan B	2/18.2	---	---	---	---	---
Premarin Vaginal Cream	---	7/100.0	---	---	17/94.4	7/87.5
VagiFem	---	---	---	---	---	1/12.5
Yaz	8/72.7	---	---	---	---	---
Ophthalmological	---	---	---	---	8/100.0	6/100.0
Restasis	---	---	---		8/100.0	6/100.0

Table C-1: (continued)

DRUG NAME	BEFORE			AFTER		
	Black	White	Cross-over	Black	White	Cross-over
Psychiatric/ Neurologic	22/100.0	125/100.0	25/100.0	18/100.00	109/100.0	33/100.0
Abilify	---	17/13.6	6/24.0	---	14/12.8	11/33.3
AmbienCR	1/4.5	11/8.8	---	---	---	---
Aricept	---	---	---	---	11/10.1	---
Botox	---	---	---	---	4/3.7	3/9.1
Concerta	---	8/6.4	1/4.0	---	---	---
Cymbalta	3/13.6	18/14.4	8/32.0	---	29/26.6	5/15.2
Exelon Patch	---	---	---	---	6/5.5	---
Horizant	---	---	---	---	1/0.9	---
Keppra	---	4/3.2	---	---	---	---
Lunesta	---	2/1.6	---	---	3/2.6	---
Lyrica	11/50.0	11/8.8	6/24.0	9/50.0	16/14.7	8/24.2
Mirapex	---	2/1.6	---	---	---	---
Nuedexta	---	---	---	---	1/0.9	---
Pristiq	---	6/4.8	---	9/50.0	13/11.9	3/9.1
Provigil	---	1/0.8	---	---	---	---
Rozerem	---	1/0.8	1/4.0	---	---	---
Seroquel XR	---	---	---	---	11/10.1	3/9.1
Topamax	---	3/2.4	3/12.0	---	---	---
Treximet	---	8/6.4	---	---	---	---
Ultram ER	---	1/0.8	---	---	---	---
Vyvanse	7/31.8	32/25.6	---	---	---	---
Respiratory	16/100.0	41/100.0	4/100.0	10/100.0	48/100.0	4/100.0
Advair Diskus	9/56.3	17/41.5	---	2/20.0	18/37.5	1/25.0
Dulera	---	---	---	---	12/25.0	---
Flovent Diskus	---	---	---	4/40.0	2/4.2	1/25.0
Pulmicort Respules	3/18.8	1/2.4	4/100.0	---	---	---
Singulair	---	7/17.1	---	---	---	---
Spiriva HandiHaler	4/25.0	4/9.8	---	---	7/14.6	---
Symbicort	---	12/29.3	---	4/40.0	9/18.8	2/50.0
Tobacco Addiction	---	7/100	---	---	---	---
Chantix	---	7/100	---	---	---	---

Table C-1: (continued)

DRUG NAME	BEFORE			AFTER		
	Black	White	Cross-over	Black	White	Cross-over
Urological	---	40/100.0	2/100.0	---	13/100.0	4/100.0
Detrol LA	---	11/27.5	---	---	---	---
Enablex	---	17/42.5	---	---	---	---
Toviaz	---	4/10.0	2/100.0	---	9/69.2	4/100
VESIcare	---	8/20.0	---	---	4/30.8	---

APPENDIX D: ANALYSIS OF APPEALS USED IN DIRECT-TO-CONSUMER ADVERTISING

The following analysis examines the type of appeals used in DTCA as a function of magazine genre and time. As discussed in Chapter 4, the primary driver behind the type of appeal used in DTCA is the actual drug advertised and not the magazine in which the ad appeared (see Tables D-1 and D-2). Hence, the data reported in this appendix should be considered with this in mind. There is no evidence to suggest that pharmaceutical manufacturers altered the appeals used in their advertising based either on magazine genre or publication date.

Virtually all DTCA examined used a rational appeal (less than 1 percent did not). Nearly all ads made a claim about their effectiveness; roughly one-third claimed some sort of social or psychological enhancement, such as allowing the user to lead a more active lifestyle. Between 30 and 45 percent of ads claimed to be easy to use and safe. There was some variation in these latter two attributes between the two time periods studied, with the number of ads claiming to be easy to use decreasing over time and the number of ads claiming to be safe increasing. Table D-3 presents these results.

Table D-1: Relationship of ads using a rational appeal to magazine genre

	Rational Appeal?		
Magazine Genre	Yes	No	Total
White			
N	296	3	299
%	99.0	1.0	100.0
Black			
N	89	0	89
%	100.0	0.0	100.0
Crossover			
N	51	0	51
%	100.0	0.0	100.0
Total	436	3	439
%	99.3	0.7	100.0

χ^2 (2, n=439) = 1.41, p=.493

Table D-2: Relationship of ads using an emotional appeal to magazine genre

	Emotional Appeal?		
Magazine Genre	Yes	No	Total
White			
N	256	43	299
%	85.6	14.4	100.0
Black			
N	77	12	89
%	86.5	13.5	100.0
Crossover			
N	46	5	51
%	90.2	9.8	100.0
Total	379	60	439
%	86.3	13.7	100.0

χ^2 (2, n=439) = .777, p=.678

Table D-3: Distribution of rational appeal claims in DTCA published before and after FDA report

	BEFORE		AFTER	
Attribute	Frequency	Percent	Frequency	Percent
Effectiveness	198	96.1	230	98.7
Social-Psychological Enhancement	68	33.0	79	34.6
Ease of Use	83	40.3	78	34.2
Safety	71	34.5	99	43.4

Table D-4 reports the percentage of ads using a rational appeal as a function of magazine genre for both time periods studied. Claims about a drug's effectiveness were by far the most common rational appeal used regardless of magazine genre or publication date. A greater proportion of ads appearing in the black-oriented magazines than in the white-oriented magazines claimed a social-psychological enhancement, such as weight loss, or advertised its product as being easy to use. This was true for all publication dates studied. For example, 29.2 percent of ads appearing in white-oriented magazines published before the FDA report claimed some sort of social-psychological enhancement. During this same time period, 50.9 percent of ads appearing in black-oriented magazines made such a claim. Besides being effective, the most likely product claim made by medications advertised in the crossover magazine was safety (65.2 percent of ads published before the FDA report and 50.0 percent of ads published after the FDA report made such a claim).

Table D-4: Percent of DTCA published before and after FDA report using rational appeals as a function of magazine genre

	BEFORE			AFTER		
Rational Appeal	Magazine Genre			Magazine Genre		
	White	Black	Crossover	White	Black	Crossover
Effectiveness	97.7 (n=127)	96.2 (n=51)	87.0 (n=20)	97.0 (n=161)	100.0 (n=36)	96.4 (n=27)
Social-Psychological Enhancement	29.2 (n=38)	50.9 (n=27)	13.0 (n=3)	33.7 (n=56)	61.1 (n=22)	3.6 (n=1)
Ease of Use	30.8 (n=40)	64.2 (n=34)	39.1 (n=9)	32.5 (n=54)	50.0 (n=18)	25.0 (n=7)
Safety	23.8 (n=31)	20.8 (n=11)	65.2 (n=15)	44.0 (n=73)	36.1 (n=13)	50.0 (n=14)

The use of product claims varied depending on the type of drug advertised as illustrated in Table D-5. This table reports the distribution of ads using rational appeals across the six disease categories of interest for all magazines and both time periods studied. From this table, we can see that nearly 61 percent of the ads for drugs used to treat respiratory illness claimed a social-psychological enhancement and nearly 33 percent claimed to be safe. As an example, an advertisement for Advair, used to treat asthma, claimed that the drug would help you "breathe better" (social-psychological enhancement) and promised symptom control for up to "24 hours" (easy to use). Lipitor, a drug used to lower cholesterol, touted the results of clinical trials (effectiveness) and noted that it had been "extensively studied with over 18 years of research…backed by over 400 ongoing or completed clinical trials" (safety). One hundred percent of ads for cardiovascular drugs claimed to be effective. Most of the DTCA in the diabetes drugs were for injection pens, hence the large percentage (94.3%) of ads claiming ease of use.

Table D-5: The distribution of DTCA using rational appeals by disease category

Disease Category	Type of Rational Appeal			
	Effectiveness	Enhancement	Easy to Use	Safety
Alzheimer's	17 (100.0%)	6 (35.3%)	6 (35.3%)	4 (23.5%)
Cancer	2 (100.0%)	0 (0.0%)	1 (50.0%)	2 (100.0%)
Cardiovascular	108 (100.0%)	20 (18.5%)	33 (30.6%)	29 (26.9%)
Depression	126 (92.0%)	4 (2.9%)	30 (21.9%)	92 (67.5%)
Diabetes	48 (90.6%)	43 (81.1%)	50 (94.3%)	4 (7.6%)
Respiratory	121 (99.2%)	74 (60.6%)	42 (34.4%)	40 (32.8%)

In the ads published before the FDA report, 81 percent (n=166) included an emotional appeal. For ads published after the FDA report, that proportion increased to 91 percent (n=213). Of the 166 ads published before the 2009 FDA report, nearly 50 percent included a positive appeal. That percentage increased to over 60 percent in ads published after the FDA report. Only one ad published in 2008 and 2009 included a humorous appeal; that number rose to 33 in the 2011/2012 timeframe. Less than 10 percent of the ads examined included a nostalgic appeal. A negative appeal was used in just over 60 percent of the ads published in 2008 and 2009; this proportion rose to 65 percent in ads published in 2011 and 2012. Some ads included both a positive and negative appeal. (Recall the tag line for the Cymbalta ad in Figure 4-3—"Depression Hurts. Cymbalta can help.") Table D-6 summarizes these results.

Table D-6: Distribution of emotional appeals in DTCA published before and after FDA report

	BEFORE		AFTER	
Type of Appeal	Frequency	Percent	Frequency	Percent
Positive	81	48.8	134	62.9
Humorous	1	0.6	33	15.4
Nostalgic	12	7.2	18	8.5
Negative	101	60.8	138	64.8

Table D-7 reports the percentage of ads using an emotional appeal as a function of magazine genre for both time periods studied. The most common types of emotional appeal were either a positive appeal or negative appeal. Few ads took a humorous approach and those that did often coupled it with a negative appeal. For example, an ad for Spiriva, a medication used to treat COPD, shows an elephant sitting on a woman's chest. While the graphic image could be considered humorous, the tag line is not: "Does Breathing With COPD Weigh You Down?" Nostalgic appeals were prompted by images, such as photos of the ad's model at an earlier period of life, and the use of tag lines such as this: "throughout my life, mom has always been there for me, now it's my turn," found in an ad for the Exelon Patch used to treat Alzheimer's disease.

Table D-7: Percent of DTCA published before and after FDA report using emotional appeals as a function of magazine genre

	BEFORE			AFTER		
Emotional Appeal	Magazine Genre			Magazine Genre		
	White	Black	Crossover	White	Black	Crossover
Positive	46.5 (n=47)	64.4 (n=29)	25.0 (n=5)	57.4 (n=89)	93.8 (n=30)	42.3 (n=11)
Humorous	1.0 (n=1)	0.0 (n=0)	0.0 (n=0)	14.8 (n=23)	0.0 (n=0)	38.5 (n=10)
Nostalgic	8.9 (n=9)	0.0 (n=0)	15.0 (n=3)	11.6 (n=18)	0.0 (n=0)	0.0 (n=0)
Negative	65.3 (n=66)	35.6 (n=10)	95.0 (n=19)	63.2 (n=98)	46.9 (n=15)	96.2 (n=25)

It is important to note that many ads used both a positive and negative appeal. Therefore, caution should be exercised in interpreting the results reported in Table D-7. For example, it would not be correct to conclude that ads placed in black-oriented magazines were more likely to use a positive appeal than ads place in white-oriented magazines or that ads placed in white-oriented magazines were more likely to use a negative appeal than ads placed in black-oriented magazines.

However, it is interesting that the overwhelming majority of DTCA found in *O, The Oprah Magazine* (95.0 percent of ads published before the FDA report and 96.2 percent of ads published after the report) used a negative appeal. Looking more closely at the data revealed that 39 of the 46 ads (approximately 85 percent) that appeared in the magazine during the study period promoted drugs used to treat either depression or cardiovascular disease. Drugs in both of these disease categories tend to use negative appeals, such as the ad for Crestor which uses the tag line: "While you've been building your life, plaque may have been building in your arteries." This trend can be seen in Table D-8 which reports the distribution of ads using emotional appeals across the six disease categories of interest for all magazines and both time periods studied. For example, 86.1 percent of ads for antidepressant medications and 65.7 percent of ads for cardiovascular medications used a negative emotional appeal.

Table D-8: The distribution of DTCA using emotional appeals by disease category

Disease Category	Type of Emotional Appeal			
	Positive	Humorous	Nostalgic	Negative
Alzheimer's	0 (0.0%)	0 (0.0%)	17 (100.0%)	0 (0.0%)
Cancer	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular	43 (39.8%)	1 (0.9%)	13 (12.0%)	71 (65.7%)
Depression	37 (27.0%)	21 (15.3%)	0 (0.0%)	118 (86.1%)
Diabetes	53 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Respiratory	59 (48.4%)	12 (9.8%)	0 (0.0%)	33 (27.1%)