Ethical Strategies that Make 'Good' Business Sense: Direct-to-Consumer Advertising of Prescription Products

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ETHICAL STRATEGIES THAT MAKE “GOOD” BUSINESS SENSE: DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION PRODUCTS

A Thesis
Presented to
the Graduate School of
Clemson University

In Partial Fulfillment
of the Requirements for the Degree
Master of Arts
Professional Communications

by
Bambi Michelle Thompson
May 2007

Accepted by:
Dr. Barbara Heifferon, Committee Chair
Dr. Steven Katz
Dr. Joseph Sample
The increased use of direct-to-consumer (DTC) advertising of prescription pharmaceuticals has caused everyone from physicians and patients to congressmen and professionals to question the ethics of the practice. Although the Federal Drug Administration (FDA) regulates advertising content, healthcare professionals often criticize the practice on the basis of weakening the doctor-patient relationship and jeopardizing patient well-being. Pharmaceutical companies have found print and broadcast ads in DTC campaigns to greatly increase the sales of their products. However, because of the impact of DTC on patient lives and health, the ethics of the practice need examination.

The purpose of this thesis is to determine whether current DTC efforts are ethical and to create a model for ethical decision-making within the industry. In order to provide an effective model that satisfies ethical boundaries as well as corporate financial goals, I create a synthesis employing a normative approach with stakeholder theory from business ethics so that the large number of groups affected by DTC campaigns can have their needs appropriately addressed. Once an ethical model has been outlined, I analyze the visual and linguistic features of DTC advertisements to determine areas for
ethical revision. I conclude with strategies for DTC decision-makers that satisfy ethical parameters while also enhancing the reputation and, thus, the success of pharmaceutical companies that utilize DTC campaigns.
DEDICATION

I dedicate this thesis to my wonderful parents Billy and Sherry Thompson. Without their love, advice, and boundless support, I would not be who I am today.
ACKNOWLEDGEMENTS

First and foremost, I would like to thank Dr. Barbara Heifferon for her dedication and guidance throughout this journey. Her kind words, endless knowledge, and tireless enthusiasm were an invaluable aid in the completion of this thesis.

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Finally, I would like to extend a very special thank you to my family, especially my parents, for always pushing me to follow my dreams. Their senses of humor, constant encouragement, and unconditional love have kept me going.
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CHAPTER 1
INTRODUCTION

In the past fifteen years, the pharmaceutical industry has significantly increased the amount of direct-to-consumer (DTC) advertising used to promote prescription products to a diverse audience, thus significantly increasing product sales. Patients become aware of prescription medications through television commercials and magazine advertisements, often leading them to self-diagnose or to request a particular prescription from their physician. While the US Food and Drug Administration (FDA) has developed a set of regulations for drug advertisements, many physicians worry that marketing prescription products to an audience with little medical knowledge leads to problematic patient self-diagnosis and possible dangerous effects. This concern may be attributed to the way in which information is supplied in ads and the ethical implications of current corporate goals to both provide valid product information and to increase company profits. The FDA mandates that ads give a brief summary of the benefits and possible side effects of the product in question; however, DTC ads are geared more towards product sales than patient education, thus the language used and message conveyed in the ads is often biased towards pharmaceutical sales.
Advertising executives who create DTC campaigns could be put into an ethical dilemma if their personal ethics do not coincide with the moral and financial objectives of their company. By analyzing the practices of both individuals and corporate entities that have a stake in DTC advertising, ethical roadblocks can be determined though a solution may be more difficult to achieve. The purpose of this thesis is to examine the current ethical problems that exist within pharmaceutical advertising both on an individual and corporate basis, and to prescribe possible ethical strategies to accomplish corporate goals of increased sales as well as keep patients safe. In order to focus this thesis, I will not examine all DTC advertisements, but instead make suggestions tailored towards the largest therapeutic area within pharmaceutical marketing: statins.

Statins are prescription medications approved by the FDA to reduce or prevent high cholesterol levels in patients. First created in 1987, statins quickly became the fastest growing therapeutic area in pharmaceutical history. In recent years, nations across the globe have spent more money on statins than on any other medication, “generat[ing] revenues of more than $25 billion a year for their manufacturers” (Moynihan and Cassels 1). Although statins have improved the health of many patients, some physicians are concerned that marketing efforts have generated a false sense of need with the patient population. Since statins corner such a large percentage of the prescription
market, it is not surprising that DTC advertisements for the drugs can be found throughout popular magazines and during high traffic time slots on television. This thesis focuses primarily on statins because they are the largest therapeutic area in the world, affecting the largest number of both potential and current patients.

The target audience customers for pharmaceuticals vary greatly across national and international boundaries, thus this thesis will only pertain to the use of DTC advertisements in the U.S., as this is the only country that promotes prescription pharmaceuticals to the general public ("New Zealand"). Although most marketing materials are produced through a collaborative effort, it is important to analyze the ethical practices of individuals in relation to group ethics. Many of the issues that I will assess in this thesis pertain to all professional practices; however, the promotion of healthcare products brings ethics to the forefront of professional goals because the end result impacts the physical wellbeing of an individual. Since preventative medications, such as statins, are becoming the largest sector of the pharmaceutical industry, it is necessary to establish ethical strategies within the corporation for DTC promotional efforts that will improve moral decision-making and, in turn, help the business.

The primary purpose of this thesis is to determine ethical strategies for DTC advertisements that will benefit all stakeholders from the corporation to
the consumer. In the remainder of this chapter, I will discuss the scope of DTC advertising in order to emphasize the impact this marketing tactic can have on the general public. In Chapter 2, I will provide an overview of the FDA regulations for DTC advertisements and will introduce readers to the verbal and visual rhetoric behind statin ads in order to provide readers with a basic understanding of the legal implications and formal layout of DTC advertisements in the referenced market. Chapter 3 emphasizes the role of ethics in business, in marketing, and in the medical field. Here, I will form the foundation of what is considered ethical in different professional settings so that the fusion between DTC advertisements and ethics, the purpose of Chapter 4, can lend itself to an analysis of ethical and non-ethical practices within the promotional efforts of statins. In Chapter 5, I will present ethical strategies for DTC campaigns that will make “good” business sense to decision-makers in the pharmaceutical industry while also satisfying ethical goals of physicians, consumers, the FDA, and all other stakeholders. The thesis concludes with a brief discussion concerning the future of statins and new advertising technologies.

**History of DTC Advertising**

Direct to consumer (DTC) advertising has become one of the most effective ways pharmaceutical companies increase the sale of their products. A 1992 study of the frequency of particular advertisements during prime time
television indicated that no ads were displayed for prescription pharmaceutical products; however, in just six years, an average of four prescription ads were visible during the same time slot and on the same channels (Byrd-Bredbenner and Grasso 63). The presence of DTC ads has grown within the industry since that 1992 study with pharmaceutical companies spending around $2.7 billion in 2001 (Rados). A study conducted between 1999 and 2000 by the Kaiser Family Foundation, a national health philanthropy, found that DTC ads accounted for 14% of spending by pharmaceutical companies, which translated into $4.20 in additional sales that year for each dollar spent (“Impact of Direct”). These are significant figures considering the billions of dollars pharmaceutical companies make each year and the significant rise in the cost of healthcare coverage over the past decade. With such an increase in the number of ads and in the price of medications, many consumers and physicians have begun to debate the safety and educational value of DTC advertising.

Some physicians ridicule DTC ads claiming that they present biased and inaccurate medical information and that patients can obtain a false sense of need for a medication because they are not fully educated about the product. These physicians feel that the ads often present misleading information and cause patients to self diagnose an otherwise non-existent ailment (“Impact of Direct”). The argument goes along with the notion that
the concise form of a DTC advertisement cannot educate a consumer, but rather, it can only provide condensed slices of information. This contention raises an important distinction between *educating* a consumer (i.e., providing them with enough information to make informed decisions) and *informing* consumers of product features. Theorists such as Steven Katz might go further to assert that words such as *educate* and *inform* all “reflect a view of communication as a one-way process—from expert (scientist, industry rep, government official) to public” (Katz 5). In this sense, advertising is not a two-way system where the audience has the opportunity to ask questions, offer opinions, and actively construct knowledge; rather, the audience is educated-informed-about product features. Although the conversation between patients and physicians that DTC advertising encourages can be viewed as two-way communication, the DTC advertisements may be perceived as a one-way transmission from the pharmaceutical company to consumers. Unless specifically noted, the use of “educate” and “inform” or “education” and “information” will only refer to the message conveyed by DTC advertisements, which is the way pharmaceutical companies and businesses in general use the terms. Physicians are not all in agreement over the use of DTC campaigns, with some arguing that advertisements can misrepresent the medical conditions by selective editing of the number and types of symptoms that are presented to the general public (“Impact of Direct”). Opponents of DTC
advertisements further contend that because the ads present such convincing arguments, many patients are convinced that they have an illness, sometimes causing them to get second and even third opinions when their family doctor will not prescribe the marketed medication (“Impact of Direct”). Not only do the ads convince patients that they suffer from the advertised condition, but ads also cause some patients to pressure doctors to prescribe the medication when they otherwise would not. According to the FDA’s 2002 survey of 500 physicians, 28 percent felt at least “somewhat pressured to prescribe the specific name brand drug when the patient asked the physician to do so” (Woodcock), meaning that over one quarter of the physicians surveyed acknowledged that patient questioning plays a role in their prescribing habits, thus stressing the impact an ad campaign can have on a person’s health.

Proponents of DTC pharmaceutical advertising are not just pharmaceutical companies and a few physicians; the FDA also supports the educational and health values that the ads provide, but for different reasons. Advocates of prescription DTC ads argue that the campaigns encourage patient awareness of medical ailments, sometimes helping them discover illnesses at an early stage and often bringing an illness to the attention of their physician (Rados). Recent research conducted by Kimberly Emmons of Case Western Reserve University, indicates that the rhetorical discourse of DTC ads has significantly changed the relationships between patients, physicians, and
pharmaceutical companies. Emmons asserts that the new discourse generated by the ads, places the consumer and the pharmaceutical company in the role of healthcare decision-makers (Emmons). The validity of this assertion is further supported by FDA research findings: a 2002 FDA survey of 500 physicians mentioned earlier: “forty percent of physicians believe that patients understood well the possible risks and negative effects of an advertised drug from the DTC ad alone” (Woodcock). Based on this survey and other studies, the FDA concludes that “accurate” DTC campaigns “can lead to significant increases in the detection of under-treated conditions such as high blood pressure, diabetes, and depression, with consequent health benefits for Americans” (Woodcock). With proponents of DTC campaigns asserting that promotional efforts are an effective form of patient awareness, the FDA serves to monitor the way in which a pharmaceutical company presents product information to an audience that often does not fully understand the illness that needs to be treated.

**Current State of Direct-to-Consumer Advertisements**

Advertisements have been used by corporations for decades to encourage consumers to buy products ranging from bubble gum and snack food to cough syrup and toothpaste. Over the years, television and print media, especially magazines and newspapers, have become the most prominent places advertisers use to promote their products. Although these
media have traditionally been used to market everyday products to consumers, the past decade has introduced a new range of products for consumers to consider, prescription medications. In the past, pharmaceutical companies marketed their products primarily to physicians and pharmacists in an attempt to increase product sales, but now direct-to-consumer advertising is commonplace and has hit the market with a surge in pharmaceutical sales (Buckley 5). As mentioned earlier, the introduction of prescription products to consumers with little to no medical background raises many questions as to the safety and efficacy of such marketing campaigns.

Within DTC campaigns of prescription medication, consumers are often provided with a series of questions that relate to a sampling of characteristics associated with medical problems such as high cholesterol, depression, overactive bladder, and a variety of other health issues (see Figure 1.1). While print ads are often accompanied by a copy of a package insert (PI), which provides FDA approved medical information about the product (see Figure 1.2); television ads rarely contain such information. DTC ads often encourage consumers to consult their physician to see if they need a prescription for the product being marketed, creating questions as to the educational value of the ads.
At your age, with your high cholesterol, what’s your risk of a first heart attack?

If you have high cholesterol, figure your risk of a first heart attack.

- **Age Mens**
  - 0 pts: Less than 35
  - 1 pt: 35 to 64
  - 2 pts: 65 to 75
  - 3 pts: 76 to 84
  - 4 pts: 85 to 99

- **Women**
  - 0 pts: Less than 46
  - 1 pt: 46 to 56
  - 2 pts: 57 to 74
  - 3 pts: 75 to 84
  - 4 pts: 85 to 99

- **Total Cholesterol Level**
  - 0 pts: Less than 200 mg/dL
  - 1 pt: 201 to 239 mg/dL
  - 2 pts: 240 to 259 mg/dL
  - 3 pts: 260 to 279 mg/dL
  - 4 pts: 280 mg/dL and above

- **HDL (good) cholesterol**
  - 0 pts: Less than 40 mg/dL
  - 1 pt: 41 to 50 mg/dL
  - 2 pts: 51 to 60 mg/dL
  - 3 pts: 61 to 70 mg/dL
  - 4 pts: 71 mg/dL and above

- **Family History**
  - 0 pts: My family has history of heart disease before the age of 60
  - 1 pt: 60 to 69
  - 2 pts: 70 to 74
  - 3 pts: 75 to 79
  - 4 pts: 80 years and older

- **Inactive Lifestyle**
  - 0 pts: Exercise regularly
  - 1 pt: Don’t exercise or do anything physically demanding

- **Weight**
  - 0 pts: More than 30 lbs. over ideal weight
  - 1 pt: 10 to 29 lbs. over ideal weight
  - 2 pts: 5 to 9 lbs. over ideal weight
  - 3 pts: 0 to 4 lbs. over ideal weight

- **Smoking**
  - 0 pts: Non-smoker
  - 1 pt: Smoker

- **Diabetes**
  - 0 pts: No
  - 1 pt: 1 (Diabetic)
  - 2 pts: 2 or more diabetes

**Total Points**

Based on the points you scored, your risk of a first heart attack compared to the general adult population. The lower your score, the lower your risk.

---

**PRAVACHOL**

*Proven to help prevent first heart attacks in people with high cholesterol.*

PRAVACHOL is the only cholesterol-lowering drug of its kind proven to help prevent first heart attacks. Ask your doctor about PRAVACHOL. It can help reduce the risk of a first heart attack and the need for surgery to clear blocked coronary arteries. PRAVACHOL has been prescribed by doctors for millions of men and women worldwide. It could help you live a longer, healthier life.

Ask your doctor about PRAVACHOL,

[Contact information]

[Website]

PRAVACHOL is prescribed by your doctor in combination with diet, exercise, weight loss, and changes in lifestyle. Because PRAVACHOL is a prescription drug, you should ask your doctor if the dosage is right for you. You should also check the blood pressure and other information on the prescribing information on the back cover of this package insert. If the blood pressure is not within the range of 120/80 millimeters of mercury or if you experience dizziness, lightheadedness, or any symptoms of joint pain, muscle weakness, or unusual tiredness, then you should consult your doctor.

**American Heart Association**

[Website]

**PRAVACHOL pravastatin sodium**

Proven to help prevent first heart attacks.

![Pravachol Advertisement](image)

Figure 1.2. PI Information Found on the Reverse Side of the Same Advertisement, Pravachol. Advertisement. *Prevention.* January 1998.
The DTC Debate

Direct-to-consumer advertising of prescription pharmaceuticals is not a new thing. Although the advertising of pharmaceuticals began as an effort directed at physicians, the practice became less successful in the early 1980s as the competition among pharmaceutical companies rose and scores of “me-too” products were launched into the market (White 232). When DTC advertising of prescription products began in the early 1980s, the FDA had very few restrictions on the ads; however, as marketing expanded and the debate over the ethics and educational value of the ads increased, the FDA was forced to create detailed restrictions on DTC efforts (Jaramillo 267). Traditionally, the Federal Trade Commission (FTC) was the government agency in charge of monitoring all advertisements, but pharmaceutical ads posed a new challenge. Since the advertisements deal with health related products, the FDA was put in charge of all pharmaceutical product labeling and advertising (Jaramillo 267).

The FDA has been presented with a unique challenge because the targeted audience of prescription products is much more elaborate than that of traditional consumer goods. While many products in the world market are targeted towards specific ages, genders, races, etc., prescription pharmaceuticals are often targeted towards a more all-encompassing audience. When drug companies first started to market their products after the
introduction of penicillin in 1945, physicians were the only targeted individuals for promotional campaigns. Now, companies struggle to meet the expectations of a range of stakeholders: physicians, nurses, pharmacists, “payers,” and patients (Wadman and Hutt). The expansion of marketing targets introduces a problem for strategists because each group of stakeholders typically prefers to hear about specific features and benefits of a product based on their cultural needs. This shift within the past few years makes creating a promotional strategy for even a small, localized group a difficult task because of the diversity of groups affected.

The United States has not always been the only country to allow DTC pharmaceutical advertisements. New Zealand, Canada, and parts of Europe allowed these marketing campaigns in the past, but the presence of this marketing tactic has incurred a flood of criticism from the medical community and reduced its presence worldwide. Healthcare professionals fall on both side of the debate, with patient education being the foremost issue. Few people argue that DTC pharmaceutical advertisements have not been successful, because corporate profits have surged since the ads hit the market and advertising budgets have skyrocketed. Pharmaceutical companies have always spent a great deal to market their products to the healthcare community and the budget continues to rise with total DTC spending amounting to $4 billion in 2004 alone (White 232). The controversy surrounding the use of DTC
tactics is centered upon whether or not the advertisements educate patients about the use and risks of a medication and the illness it can treat.

Proponents of DTC advertising such as Pharmaceutical Research and Manufacturers of America (PhRMA), an organization that represents leading pharmaceutical research and biotechnology companies, argue that advertising prescription products directly to the consumer is beneficial because it informs people about illnesses and remedies that they may not have previously been aware (Buckley 4). The assertion is that advertisements provide consumers with a basic understanding of the illness as well as a course of action to prevent or treat the ailment. In this scenario, the general public understands the risks and side effects of a product after reading or watching the ad and is, in turn, encouraged to seek further information by consulting their personal physician. Not surprisingly, pharmaceutical giants such as Pfizer, the largest pharmaceutical company in the world, assert that the ads strengthen doctor-patient relationships. Corporations are prepared for the debate, even including their “policy” on DTC advertising on the company website such as Pfizer’s stance on the ads:

Pfizer believes that patients benefit from information about diseases and medical treatment options because when they learn about symptoms and therapies, they can engage in a more informed discussion with their healthcare provider. One way that disease and treatment information is made available is through advertising. (“Access and Affordability: Advertising and Promotion”)
It is interesting to note that Pfizer’s statement does not acknowledge persuasive tactics presented in DTC efforts, but rather, the transmission of information is at the heart of their defense of the advertisements. The statement above asserts that the advertisements encourage the doctor-patient relationship by allowing for a more “informed discussion,” but the extent of the patient’s knowledge of the drug is not considered. Proponents of DTC campaigns rely on this contention that the ads facilitate two-way communication between an “informed” patient and their physician; however, it is unclear whether the patients are simply made aware of an illness or if they are, in fact, informed of the condition by ads. Despite this distinction, the FDA agrees with proponents of DTC ads and contends that the marketing tactic is educational for patients and, thus, is beneficial.

Opponents of the marketing strategy assert that the advertisements go against the idea that prescription products are made available to consumers through medical specialists who have a thorough understanding of their patient’s medical history and of the affect the drug will (or should) have on the patient (Wilkes et. al.). Some worry that DTC ads encourage patients to self-diagnose an illness and then put pressure on their physician to prescribe the product. This may be the case with a 1998 study by Prevention magazine showing that, “15.1 million U.S. consumers asked their physician for a medication they saw advertised, and that physicians honoured those requests
eighty percent of the time, which translates into 12.1 million prescriptions generated by advertising” (Buckley 6). These are staggering figures considering that DTC spending just one year later, in 1999, totaled $1.824 billion and that number has more than doubled today (Jaramillo 271).

The debate over the effectiveness of DTC pharmaceutical advertisements continues to be a hot topic both within the healthcare community, within Congress, and within the FDA, the organization in charge of regulating all promotional activities conducted by pharmaceutical companies. In order to make sure that DTC pharmaceutical advertisements were considered beneficial by a majority of physicians and potential consumers, the FDA conducted three primary studies over the course of the past fifteen years in order to determine whether or not the campaigns are effective in patient education. The results of the two most recent studies were published by the FDA in January of 2003 in a report entitled, Assessment of Physician Attitudes Toward Direct-to-Consumer Promotion of Prescription Products. The report describes the methodology and results of two national surveys conducted by the FDA in 1999 and 2002. In each study, a random sample of roughly 1000 participants who had visited a physician within the past three months were selected to complete a sixty-five question survey consisting of solely quantitative questions (Patient and Physician Attitudes “Appendix B.2”). The questions ranged from a “yes or no” format to a Likert
scale and covered areas such as why the patient went to the doctor, whether or not they visited because of an advertisement, and whether or not they agree that prescription advertisements make them want a specific drug. The same format of questioning was followed for physicians, including questions such as how many patients they see in a week, whether or not a patient mentioned an advertisement during their visit, and if so, did the ad cause any problems during the visit (Patient and Physician Attitudes “Appendix B.3”).

The surveys were conducted by means of recorded interviews and researchers maintained certain qualifications for participants. For example, the patient survey indicated that the only qualifications of a participant were that they must be at least eighteen years of age and must have visited their physician within the past three months. To qualify as a participant, physicians only had to be actively seeing patients within the past three months (Patient and Physician Attitudes “Appendix B.2”). This allowed the patient sampling to be broad and not focused on a specific age, race, or educational status.

The researchers determined that 88% of the patients, who asked their doctor about a prescription ad they saw, actually had the illness (Rados). Of the patients surveyed, 90% could remember the benefits of the drug being marketed and its side effects and 89% could recall who should not take the medication (Rados). A majority of the physicians surveyed, 53%, admitted that DTC campaigns led to better discussions with their patients and 42% felt
the patients were more aware of treatments (Rados). Although a majority of physicians agreed that the ads aided in discussion with their patients, only 10% of the physicians felt that DTC advertisements informed or educated their patients (Rados). Based on these figures, the FDA concluded that DTC campaigns effectively educate patients enough to encourage them to seek the opinion of a doctor. Although the results of the studies reveal DTC advertising to be educational and beneficial to patients, the debate over DTC ads has also prompted more detailed regulations for the ads as will be discussed in the next chapter.
CHAPTER 2

TYPES OF DTC ADVERTISEMENTS AND FDA REGULATIONS

The purpose of this chapter is to identify DTC advertising classifications and to outline the rules and regulations set forth by the FDA to govern ad content. Here, I hope to provide the FDA regulations for print and broadcast ads and to discuss the procedures the FDA uses to reprimand pharmaceutical companies that do not follow protocol. Since the FDA is in charge of monitoring the advertisements created and distributed by pharmaceutical companies, officials have created specific regulations for print media, television and broadcast commercials, and Internet marketing. Each medium reaches staggering numbers of consumers with print and television ads comprising the greatest consumer reach. Print advertisements for pharmaceuticals can be found in virtually every type of magazine from Reader’s Digest and Good Housekeeping to Health and Prevention. Broadcast commercials are even more visible. A 2003 survey indicated that 86% of all consumers either saw or heard a television advertisement for a prescription drug (Bodenheimer W3-114). Not to be outdone, the Internet is used to market pharmaceutical products to millions of consumers through product
informational websites, company websites, and product advertisements which are placed on every type of webpage imaginable. Although the Internet is the one of the newest mediums for DTC advertising, it may soon become the frontrunner with “nearly 100 million Americans [using] the Internet to find health information” between September 2005 and September 2006 (“Pharma Companies’ Internet Marketing”). The scope of DTC pharmaceutical ads is undoubtedly increasing at a tremendous rate with the increase in marketing efforts on the Internet alone, thus calling for a revision of current FDA regulations.

The regulations surrounding DTC pharmaceutical advertisements have been revised many times since the ads started to become a more popular marketing tactic and restrictions were imposed in the early 1980s. The rules and regulations were only slightly revised over the next fifteen years, but the introduction of the FDA’s Modernization Act in 1997, brought forth more freedom for pharmaceutical companies that wanted to take advantage of DTC efforts. Rules and regulations were relaxed and the market experienced a DTC surge that resulted in enormous profits for drug makers (White 232). The increased presence of pharmaceutical ads re-fueled debate over the ethics and educational value of their use. In order to determine the best regulatory response, the FDA initiated the three studies mentioned in Chapter 1 in order to determine whether or not the ads should continue. The results prompted
the FDA to consider DTC ads not only educational, but also a good preventative tactic for everyday citizens. The FDA asserts that drug ads are beneficial to the public, as long as certain requirements are fulfilled, “for such promotion to have this beneficial effect, it must be truthful, non-misleading, and scientifically substantiated” (Guidance for Industry...Print Advertisements). Despite the research and data used to support this view, the debate over the effectiveness in patient education persists and the FDA continues to revise its regulations with more amendments promised very soon.

Pharmaceutical companies in the United States rely on the ability to market their products to consumers who will often pay a hefty price for a healthy lifestyle. Although companies spend a great deal of money to employ a sales force that markets products to physicians and pharmacists around the country, the primary target audience for US pharmaceuticals is citizens. The industry spends enormous amounts of money on DTC advertising, allocating $1.9 billion dollars for the first five months of 2004 alone (“Drug Makers are Changing”). Not only does the FDA regulate the entrance of new drugs into the market, it also provides rules for promotional efforts within the United States. Although the FDA provides regulations for DTC advertisements, pharmaceutical companies are not required to submit ads to the FDA prior to their public release. In fact, the FDA’s review process can take so long, that ads have often finished running on television or in print media before they are
even reviewed. After the review process, the FDA issues warning letters to
pharmaceutical companies that “misrepresent” their product in
advertisements, often leading to legal action against the company (Jaramillo
277). Since regulatory action taken by the FDA can often lead to such legal
matters, companies are encouraged to abide by current regulations.

**DTC Advertisement Types**

According to the FDA, there are three main types of DTC
advertisements: product claim, reminder, and help-seeking. The most
prevalent of these ads is product claim, where both the name of the product
and an explanation of its use are provided to consumers (Figure 2.1). The FDA
requires that “claims of drug benefits, such as safety and effectiveness, must be
balanced with relevant disclosures of risks and limitations of efficacy”
(Woodcock). If the information is in print form, companies must provide a
“brief summary” of risk information that can typically be found in a product’s
package insert (PI) (Figure 2.2). This data, according to advertising regulations
set forth in the Federal Food, Drug, and Cosmetic Act, includes all risk factors,
contraindications, FDA approved medical studies concerning the medication,
and side effects in addition to directions for use and product benefits
(*Guidance for Industry…Print Advertisements*). Anyone familiar with print
pharmaceutical ads has seen this information on the reverse side of the ad as it
is often printed in miniscule text and is packed with industry specific
language. Companies that use television commercials are required to provide a web address or phone number where consumers can obtain the same information (Woodcock). The product claim advertising method usually reaches consumers in a very persuasive context that relies heavily on emotional appeals to promote the effectiveness of a product. This strategy is often ridiculed because the advertisements print the side effects and potential risks associated with the drug in very small text sizes that are easily overlooked.

![Figure 2.1. Example of a Product Claim Advertisement, Crestor. Advertisement. Prevention. June 2006.](image-url)
The second type of pharmaceutical advertisement, the reminder ad, can mention the product name and “dosage form” (i.e., tablet, capsule, etc), but cannot provide any information as to what the product does (product indication) or when to use it (Figure 2.3). Traditionally, reminder ads were directed towards physicians who already knew the name of the product and its recommended uses (Woodcock); however, the ads are now presented in magazines and on television where a general audience can be persuaded. Reminder ads cause a great deal of confusion amongst consumers since they provide very little information (Byrd-Bredbenner and Grasso). Consumers
often determine the use of the drug based on visual cues that are present in the ads which can (and often do) lead to misinterpretation of the product’s intended use. In turn, each member of the intended audience creates their own impression of the drug’s function which increases sales based on socially constructed ideologies.

Figure 2.3: Example of a Reminder Advertisement Starring Dorothy Hamill, Vioxx. Advertisement. *Prevention*. January 2003.
Although there are three types of drug ads, the FDA only regulates two: product claim and reminder. The third type, help-seeking, does not name a particular product, rather it briefly explains a disease or condition and encourages the audience to consult their physician for treatment or further information (Figure 2.4). Recent examples include commercials for erectile dysfunction or overactive bladder problems (Byrd-Bredbenner and Grasso). According to Janet Woodcock, Director for the Center for Drug Evaluation and Research (a branch of the FDA), “because no drug product is mentioned or implied, this type of ad is not considered to be a drug ad and is not regulated by [the] FDA” (Woodcock). Although help-seeking advertisements do not provide product names, the company who sponsors the ad is often listed or mentioned, thus pointing the consumer towards a company and its marketing goal.
Although these restrictions seem easy enough to follow, many healthcare professionals argue that the ads are deceiving and that they misguide patients, particularly older patients, into believing that they suffer from an ailment when, in fact, they may not. DTC marketing techniques pull in a lot of money for the pharmaceutical industry in the United States and the FDA has firmly established rules that corporations must follow in order to advertise their products; however, since the FDA does not review the ads until
after they have already been released to the public, patients can suffer. This has caused several prominent drug campaigns to be stripped from magazines and television slots after brief exposure, but those that gain approval stay firmly in place, influencing an audience that often does not understand the medical jargon being thrown their way.

**FDA Regulations**

The FDA places DTC advertisements into the categories of product claim, reminder ad, or help-seeking in an effort to establish precise rules and regulations for companies to follow. Although grouping ads into such categories can help build an umbrella of guidelines for similar promotional tactics, regulating prescription products constitutes much more specific rules for the industry. FDA rules and regulations can be categorized as follows: acts, code of federal regulations, guidance documents, and enforcement actions. Each category carries different legal limitations, thus some regulations carry legally binding guidelines and others do not. For example, an act is a piece of legislation that has been made into a law (“Act” def. Legislative act), whereas; a code of federal regulation (CFR) refers to “the general body of regulatory laws governing practice and procedure before federal administrative agencies (“Code of Federal Regulations” def.). In the case of DTC advertising, legally binding regulations are primarily contained within the Federal Food, Drug and Cosmetic Act and 21 CFR 202. Some of the most specific guidelines for DTC
advertising can be found in the FDA’s guidance documents, which are not legally binding. In fact, the FDA specifically states that the documents “do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both” (Guidance Documents-About). The Center for Devices and Radiological Health’s Division of Drug Marketing, Advertising, and Communications (DDMAC) works with “involved parties” to draft guidance documents in an effort to constrain DTC advertising with the most current goal being, to “[examine] whether the current advertising and labeling regulations should continue to apply to promotion directed to consumers, or whether there should be changes made in the requirements for this type of promotion” (Policy Development and Guidance). Although guidance documents are not legally binding, pharmaceutical companies are encouraged to follow the guidelines in order to craft promotional materials that accomplish corporate objectives as well as federal objectives that are in place to protect the consumer. Companies that violate the CFR or the Cosmetic Act receive warning letters from the Center for Drug Evaluation and Research (CDER), a branch of the FDA, as an enforcement action.

Although, I will more specifically address the compliance (or lack thereof) of DTC campaigns of statins with the range of FDA guidelines and
regulations in Chapter 4, I will now provide a glimpse into the language and specificity of guidance documents in order to provide readers with a basis of the language used to control DTC advertising. The FDA differentiates between print and broadcast advertisements with the understanding of the impact each medium can have on a consumer audience. According to the FDA’s most recent “Industry Guidance” draft for print advertisements proposed in January of 2004, all DTC ads, regardless of type, should contain a brief summary of the product’s side effects and contraindications. Known in the industry as the brief summary requirement, these guidelines provide the following options:

(1) Present[ing] all risk information from the FDA-approved professional labeling; (2) reproduce FDA-approved patient labeling, either in its entirety or as modified to omit less important risk information; or (3) provide the risk information that would be appropriate for FDA-approved Highlights. (Guidance for Industry…Print Advertisements)

The first and second options refer primarily to the information that is included in package inserts that have been approved for either patients or healthcare professionals. The third option, however, refers to a patient-friendly version of the same information, which alters industry specific language into a format more appropriate for the consumer as the audience. Although the guidance document is not legally binding, pharmaceutical companies that wish to pursue an approach outside the scope of these suggestions are encouraged, but
not required, to submit alternative suggestions to the FDA before distributing the ads to the public (Guidance for Industry…Print Advertisements).

**Corporate Strategies and Implementation of Statins**

Up to this point, I have discussed the debate surrounding DTC advertisements in the US and have provided a basic foundation of FDA regulations of consumer promotional efforts in the drug industry. To put this information into perspective, a single product line within the pharmaceutical industry will be examined. Statins, commonly known as cholesterol-lowering agents, are the largest selling prescription drug type in the world. Although statins have been around since 1987, researchers continue to praise the affects of the drug, with Pfizer's Lipitor leading the market. Statins continue to be promoted to consumers through DTC advertising efforts, but the FDA does not have regulations specific to therapeutic areas. All FDA DTC regulations are standard for every prescription product, regardless of type. The uniformity of FDA regulations is an important fact to remember as the ethical analysis of DTC statin promotion is discussed in Chapter 4.

Pfizer's atorvastatin, commonly known as Lipitor, was not always the leading statin in the cholesterol drug market. Merck is credited with creating statins with the invention of lovastatin, commonly known as Mevacor, in 1987. This product line was created to battle high cholesterol levels in patients in order to help prevent heart disease. Researchers and physicians
have identified several primary risk factors that can contribute to heart
disease: age, gender, heredity, diet, smoking, weight, and diabetes. In order to
determine whether or not a patient is at risk of heart disease, physicians use a
test created by the US National Cholesterol Education Program (NCEP) that
ranks individuals according to these risk factors. For example, a man who is
over the age of 45 is considered to be at risk for heart disease; however, a man
of the same age who smokes and is diabetic has a much higher risk of heart
disease and will most likely be encouraged to start taking a statin to help
reduce or maintain lower cholesterol levels. In addition to analyzing risk
factors, doctors examine the levels of high density lipoproteins (HDL), or good
cholesterol; low density lipoproteins (LDL), or bad cholesterol; and
triglycerides (TG), a type of fat that is carried in the blood, to calculate a
person’s current cholesterol level (Haines). Generally, doctors recommend
that a person maintain cholesterol levels below 200; however, a person with a
high number of risk factors is often encouraged to maintain even lower levels.
Although there are several options to treat high cholesterol, statins have
become the drug of choice since they often lower LDL levels and increase
HDL levels with a reduced chance of side effects than other treatment options.

Cholesterol drugs account for more consumer spending across the globe
than any other prescription medication with revenues of over $25 billion per
year for the corporations that produce them (Moynihan and Cassels 1).
Although Merck invented the first statin, Mevacor in 1987, and they introduced a second option, Zocor in the early 1990s, they were unable to maintain the rank of highest producer shortly after Pfizer launched Lipitor into the market in 1997 (Simons). Pfizer exploded onto the market with a superior marketing tactic that included a lower cost and a centralized strategy that emphasized higher results with a lower dosage, a message that pleased physicians who were still hesitant to use high doses of a new medication. Lipitor became the second highest prescribed statin on the market, but Pfizer wanted to be number one. In 1999, the company spent $55.5 million on DTC advertising resulting in a 40% increase in Lipitor sales in the first half of 2000 alone (Posey). Pfizer is now the nation’s fourth largest advertiser (Thomaselli and Sanders) and Lipitor is the world’s highest selling prescription drug ever, totaling yearly sales of over $10 billion (Moynihan and Cassels 3).

In 2005, Pfizer launched a new layout for product risk information that was intended to be more consumer-friendly because it reduced the amount of industry specific language commonly included in the package insert format and presented the information in a visually simplified manner (Figure 2.5). The changes were introduced to the DTC marketplace through the company’s most prominent product, Lipitor, “featur[ing] the prominent presentation of risk information [and] promot[ing] the drug as one of several treatment options including diet and exercise” (McGuire 30). Since Pfizer’s
brief summary was introduced, many pharmaceutical companies have followed suit, using a similar format to provide consumers with product information and potential risks in a manner that is easier for everyday consumers to understand. Pfizer’s format for providing risk assessment to consumers has been a breakthrough for DTC ads since medical jargon is presented in a reader-friendly format, a testament to Pfizer’s new mission to “support a productive patient-healthcare provider dialogue” (Arnold 30).

Figure 2.5. New Format for Product Information as Seen on the Reverse Side of a Recent DTC Ad, Lipitor. Advertisement. “USA Weekend.” The Greenville News. 2-4 February 2007, 11-12.
Much like other companies that promote statins, Pfizer has centered advertising efforts on product claim and reminder ads; however, as the most marketed product in pharmaceutical history, Lipitor has benefited from DTC campaigns with a primary focus on product claim advertisements. The most recent campaign is recognized as the first time a physician has been used to promote a drug with Dr. Robert Jarvik, inventor of the artificial heart, appearing as the new spokesperson for Lipitor (Figure 2.6).

As of late November 2006, Pfizer spent an estimated $55 million on the Jarvik campaign (Schupak 52), a move that is credited with a 15 percent increase in Lipitor sales over the previous year (Bazell). This is a profoundly effective endorsement as Dr. Jarvik is a familiar name in medical innovation. Examples of this DTC campaign can be found everywhere from popular magazines and newspapers to high traffic television spots. Although many of the print versions portray Jarvik as a serious physician in his lab coat, the television commercial shows Dr. Jarvik rowing a kayak and sitting on the banks of a picturesque lake as he promotes Pfizer’s product with the words, “more cardiologists surveyed said they’d prescribe Lipitor for their own families than any other cholesterol brand” (qtd. in Arnold 30). With groundbreaking DTC tactics including the utilization of a celebrity physician and a redesign of the product brief summary requirement, Pfizer continues to place itself at the top of the industry.

The success of Lipitor is an indication of the significant impact that DTC campaigns can have on a drug class. It is easy to assume that medications that are promoted to consumers will enjoy higher sales than those that are not, especially when patients begin to ask their doctor for a prescription of a specific product, but the impact of DTC advertisements is much greater than one might assume. When Pfizer invested a significant budget to DTC advertising of Lipitor in 1999, the sales of the product significantly increased.
Coincidentally, “between 1999 and 2000 the number of prescriptions dispensed for the fifty most heavily advertised drugs rose 25 percent, but the number dispensed for drugs that were not heavily advertised increased only 4 percent” (Gahart et. al.). DTC advertisements have a significant impact on the prescription habits of physicians as well as patient education. Although the debate over the existence of DTC campaigns in the US continues to rage, pharmaceutical companies and the FDA must work to determine ethical strategies for DTC campaigns.
CHAPTER 3

ETHICAL PARAMETERS OF PRESCRIPTION PHARMACEUTICALS

The purpose of this chapter is to lay the groundwork for an analysis of the ethics surrounding DTC advertisements of pharmaceutical products. Scholars and theorists have attempted to define and set parameters for ethical decision making since the time of Aristotle and Plato and before, so establishing an ethical framework for the promotional efforts of the pharmaceutical industry is no easy task. In order to assess the current ethical situation of DTC advertising, the parameters of business and advertising ethics must first be established. The scope of the study of ethics is so broad that it would be overwhelming to discuss them all with relation to DTC efforts, let alone the pharmaceutical marketplace; therefore, this chapter will assess the most relevant concepts of ethics in relation to the referenced market in order to establish a list of norms for the purpose of this discussion. Marketing pharmaceutical products is vastly different from promoting an everyday product such as chewing gum or laundry detergent because pharmaceuticals incorporate a more complex web of stakeholders. In creating ethical parameters for marketing decision-makers in the pharmaceutical industry, this
chapter will lead to an assessment of current ethical trends within DTC advertising in Chapter 4, which will then turn to a proposal of changes in the creation of the ads in order to best achieve ethical codes of practice within the industry. The overall goal of this chapter is to introduce the main overall concepts behind business ethics and then, to collapse these theories by relating them to the practice of DTC in the pharmaceutical industry. Hopefully, this will make the ethics surrounding the ads easier to understand before a thorough analysis of the medical ethics of ads are cast into the mix. By the end of this chapter, readers should understand the inner-workings of normative ethics as they pertain to prescription advertisements so that an ethical case study of statin advertisements, the purpose of chapter 4, makes sense.

Although the FDA has regulations for DTC advertising in place, decisions as to the use of language and the manner in which the marketing message is conveyed are the responsibility of a range of entities both inside and outside the sponsoring organization. The overall goal of advertising is to encourage the audience to buy the marketed product; therefore, pharmaceutical ads are not just a form of public information. DTC decision-makers find themselves in an ethical dilemma: either provide a truly fair and balanced message that a varied audience can interpret and comprehend or cloud the message with medical terminology and persuasive strategies that
may encourage the audience to want a product without fully understanding its purpose. Rhetorical theory can help determine ethics for DTC campaigns.

Determining ethical business decisions is not an easy task. Ethics themselves are primarily social constructions that are based on an array of personal and professional ideals. Professionals are faced with numerous ethical decisions within the corporate environment, not the least of which is determining the choice of language they will use when crafting a marketing message. According to Mary Beth Debs and Kathryn Rentz, “to use language is to influence another person’s perceptions and values,” thus communication in any form is an ethical act (Rentz and Debs 37). They argue that a flaw in business ethics is that it is often more concerned with how to act “ethically” rather than the audience’s perception of language. Professionals have an “ethical responsibility” to control their use of language since their words will generate perceptions of the writer, in this case the pharmaceutical company and its products, and her message (Rentz and Debs 39).

DTC advertising is a rhetorical tool used by pharmaceutical companies to increase the sale of their products through persuasive techniques. This goal coincides with the goals of a majority of technical communicators which Ornatowski asserts, have taken on a role of “irresponsibility” (Ornatowski 93) because a neutral, unbiased message cannot be created. A DTC campaign cannot be created without placing greater emphasis on the interest of either
the consumer or the pharmaceutical company and, thus the question arises: how can an ethical advertising campaign be ethical? Ornatowski uses the example of an aerospace engineer’s dilemma in reporting on the operation of an aircraft engine in accordance with environmental rules and regulations. While composing the technical report, the engineer must carefully evaluate language choice so that she truthfully reports malfunctions of the engine, while still protecting the interest of her employer (i.e., word the report in such a way that the malfunction is reported to customers, yet her employers will not fire her). The engineer uses what Ornatowski calls “selective emphasis” (97), which is comparable to media spin, meaning that negative information is worded so that it does not sound as bad and vice versa. The decisions of some DTC professionals to include selective emphasis in the campaigns are based upon their ideological relationship with pharmaceutical companies.

Ideologies held by executives in the DTC scenario are not the same for each employee or each corporation because, as Mary Beth Debs argues, “the society we participate in is made up of a proliferation of organizations, and part of the way in which we identify ourselves is made up of the multiple, often embedded, memberships we each hold” (Debs 161). This is illustrated through the way companies dictate corporate authorship. The person who writes a text is rarely identified as the author; instead the corporate logo takes ownership of the text. If this is the case, then the person (or persons) who
create(s) an advertisement for a DTC campaign would not be viewed as the ethical decision-maker by consumers; instead the parent company would take the credit or blame. Corporate authorship, which is commonly collaborative because of formatting suggestions and management revisions, is constructed in such a way that employees often do not realize that collaboration occurs: a situation that Bloom calls “anxiety of influence” (160). Debs goes on to add an additional component to the traditional rhetorical situation (purpose, writer, audience) by distinguishing between “the corporation” and “the executive” as separate writers that are bound together through collaborative efforts (164). Although a marketing representative might compose a promotional piece, she must also gain approval from a manager or higher authority. The writer must combine her own ideas and ethics with that of upper management and corporate goals. Adding this extra component to the rhetorical situation makes the writer more of a “spokesperson.” Since employees, and thus spokespersons, change in an organization, companies condition new hires to operate within the same constraints as the previous employee so that the audience does not have to adapt to changes.

In his analysis of ethics, Stuart Brown agrees with Henry Johnstone’s assertion that “most communication involves a social contract, one between an advocate and an audience” (qtd. in Brown 194). Audience analysis is a vital component of any marketing campaign because companies want to make sure
that consumers will discover a need for the product through promotional efforts. Ethics complicate the achievement of these goals and Johnstone’s statement further asserts that social construction is a factor in the determination of ethics. He goes on to provide three requirements for ethical communication: “First, the advocate or writer must assume that audiences are beyond control...Second, both the writer and the audience must be open-minded. Third, both parties involved in the exchange must have a genuine interest in the outcome or the solution to the problem” (qtd. in Brown 194). Consumers for pharmaceutical products do have a “genuine interest in the outcome” as it pertains directly to their wellbeing (i.e., their health); but do pharmaceutical companies share this interest? Of course the companies do want to help improve the health of customers, but money is usually the bottom-line. Johnstone’s model of ethical communication may pose the biggest problem for companies that support DTC advertising of prescription drugs, especially in the eyes of physicians who are opposed to such efforts.

The impact that DTC advertising has had on the success of the pharmaceutical marketplace is undeniable. With profound increases in sales since DTC ads were introduced into the prescription marketplace, it is evident that the campaigns work and continue to increase the number of consumers who are aware of medical ailments and possible treatments. As discussed in the last two chapters, DTC advertising has endured escalating debate over the
past fifteen years with proponents advocating the increased consumer awareness generated by the ads and opponents insisting that the practice is of questionable ethics since the products are being promoted for profit. The debate surrounding DTC campaigns raises a distinction between the pathos used in ads to increase company profits and the question of whether or not the advertisements include an element of logos that goes beyond patient awareness. If DTC advertisements are meant to be a two-way mode of communication that encourage an increased knowledge of consumer healthcare awareness, then the ethical practice and nature of the ads needs to be discussed.

**Normative Business Ethics**

When attempting to make ethical decisions in business, managers are faced with a wide range of ethical theories to dictate their course of action. For the purpose of this discussion of business ethics, only types of normative ethics (virtue, utilitarian, and deontology), which are centered on establishing rules or codes of conduct (Boylan 26), will be addressed. Broadly speaking, each type of theory classifies the overall goal of the business that wants to make an ethical decision and proposes a solution; however, as will be illustrated in the following pages, each of the three categories of ethical theory can be broken down into more specific theoretical study and, not surprisingly,
theories are often combined in order to achieve what a corporation believes is the most ethical decision making procedure.

In order to provide a consistent foundation for normative ethics, I draw the primary defining characteristics of virtue ethics, utilitarianism, and deontology from the works of Patrick Murphy and Joseph DesJardins. Murphy has conducted extensive research within business ethics and has received notoriety as a top marketing researcher, even serving as the marketing section editor of *Business Ethics Quarterly*. He is also the co-director of the Institute for Ethical Business Worldwide at Notre Dame University. Murphy’s writings are used at universities all over the country in the teaching of marketing ethics. DesJardins is the executive director for the Society for Business Ethics and has written a number of books that are used to teach the fundamentals of business and environmental ethics. While I utilize the parameters of normative ethics as discussed by Murphy and DesJardins, I also reference a few other theorists throughout this discussion of normative ethics in order to establish a solid foundation of theory.

**Virtue Ethics**

Aristotle is credited as being one of the first authors of virtue ethics as an important model of moral decision-making, basing his argument on the idea of ethos. Aristotle centered his study upon *how* individuals should live rather than *what* is considered a moral action (van Hooft 50). He believed that
people cannot learn to be virtuous in the textbook sense, rather, they become virtuous through practice. Every individual has ability to be virtuous, but each person must want to be virtuous in order to be so (van Hooft 58). Rather than asking what can an individual do to be ethical, this theory encourages people to ask themselves how they should act (DesJardins and McCall 25). A basic explanation of virtue ethics asserts that the values of the individual outweigh the values of the corporation when making moral judgments. Three main elements guide the theory behind virtue ethics: 1) virtues are good habits and in order for them to work, they must be practiced and learned by everyone in the organization; 2) people learn to make admirable decisions because they witness others doing so; and 3) there must be a balance of virtuous practice (i.e., if someone is too truthful, they can be perceived as boastful) (Murphy and Laczniak 26-27). Professionals should work on defining how to best apply this theory within a corporation, possibly even examining other companies that are considered to have high ethical standards.

Johnson and Johnson is considered to be a pharmaceutical company with high ethical standards (Murphy and Laczniak). This may be attributed to the way in which executives handled crisis management fifteen years ago, when the company voluntarily recalled all Tylenol capsules from pharmacy shelves nationwide after a small number of consumers in the Chicago area were fatally poisoned through bottles of the product that had been illegally
tampered with (Blackwell 21). Advertising campaigns were launched to increase public awareness and Johnson & Johnson destroyed their entire stock of tablets to promote good will and to show consumers that they were prepared to sacrifice their finances if it were in the best interest of the public. Despite their best efforts, the company did not avoid nationwide panic concerning the capsules, so they opened up a toll-free number service to help field calls from nervous consumers. By the end of the first week, over 90 percent of the American population had heard of the Tylenol poisonings (Blackwell 23). Just a few years later, a similar incident happened and Johnson and Johnson was again credited as handling the situation in an ethical manner. Since the company reacted in such a manner, it is often cited as one of the most ethical pharmaceutical companies (Murphy and Lacziak; DesJardins and McCall; Gibson).

Theorists argue that it is the responsibility of the company to instill virtue ethics in employees. Companies such as Johnson and Johnson have tackled this challenge by laying out values statements (not to be confused with a code of conduct) that outline the values of the company. Johnson and Johnson may be successful in this model because the founders of the company instilled their values in the corporation from its inception and, thus, the practice of the values has been passed down throughout the years (Murphy and Lacziak). The practice of virtue ethics within the corporate system could
be problematic in that it is difficult to establish or define what is good when the decision impacts an array of cultural backgrounds that may provide different definitions of what “good” is.

This is further complicated by the notion that not all individuals have the desire to be virtuous, so achieving common ground may be impossible. As with all ethical questions both the individual and corporation must choose between taking the “ethical” route or indulging in her or its own self interest. Virtue ethics proposes a solution to this dilemma: “Either we accept the inevitability of self interest and try to find ways to regulate it, or we look for ways to turn selfish interests into ethical interests” (DesJardins and McCall 25). The virtuous professional would have a desire to live ethically and, thus, would choose the latter approach. The theory also poses a problem in that a virtuous practice is most often described as “for the good of the community” rather than singling out self interest (Murphy and Laczniak), thus, discouraging capitalist ventures where money is often the bottom line (Evan and Freeman). Many businesses, Johnson and Johnson being a prime example, have incorporated virtue into their corporate strategy through the introduction and continued use of values statements which are meant to shape corporate culture towards ethical production.
Utilitarian Ethics

Although virtue ethics pose a valid normative ethical solution within the workplace, utilitarianism theory advances another option. The primary premise for utilitarianism is the idea that decisions should be based on the consequences of actions; the best solution is the one which has the potential to produce the greatest good for *all* stakeholders. A defining characteristic of utilitarian theory is that the consequences of an action must be able to be calculated, measured, and compared in order to assess possible positive and negative consequences (DesJardins and McCall), a task that is not always possible for every corporate decision. One of the problems that surfaces with this theory is the lack of emphasis on the individual. This theory leads to decisions which are based on the greater good rather than what is best for a single person. When determining ethical solutions to business problems, companies typically encourage employees to make decisions that will emphasize the bottom line or financial gain of the organization. This encouragement presents a dilemma because to achieve that objective places the goals of the company over an individual’s personal goals or ethics.

In an effort to avoid such dilemmas, some theorists assert that social scientists, who are trained in specialty areas such as medicine, law, science, and education, should be in charge of analyzing whether or not a decision is ethical when defining public policy (DesJardins and McCall 28). For example,
within the scope of pharmaceutical DTC campaigns, a utilitarian perspective might mean that officials from the FDA and leading physicians should be the only voice in the ethical debate over advertisements because they have a specified knowledge of the industry and the effect of the ads. This contention can be problematic because of the complexity of relationships among stakeholder groups in the pharmaceutical industry. Physicians, for instance, overlap stakeholder groups including FDA officials, corporate board members and advisors, and healthcare providers, thus; if doctors are decision-makers operating under the utilitarian perspective, conflicts of interest may arise which in actuality could prevent the greatest good from prevailing because the doctor may have to choose between the greatest good for his patients versus that of his ties to other stakeholder groups.

**Deontology**

A contrasting theoretical perspective is represented by deontology, which places no emphasis on the consequences of an action, but encourages decision-makers to implement a set of universal rules that should be followed by *all* stakeholders (Boylan). This perspective relies more on the logos, or the logic, behind ethical decisions rather than the ethos of virtue ethics or the consequences of utilitarianism. In this sense, individual rights are the focus of this theory because the rights of others should always be respected (DesJardins and McCall 31). Deontology posits that certain actions are inherently “good”
and the intentional ethics behind the decision is what should be considered rather than the consequences. Russian philosopher Immanuel Kant, a leading proponent of deontology, is credited with developing three main characteristics that determine “appropriate” behavior in all situations:

1. Act only on maxims that you can will to be universal laws of nature. (universality)
2. Always treat the humanity in a person as an end and never merely as means. (never treat people as a means to an end)
3. Act as if you were a member of an ideal kingdom of ends in which you were both subject and sovereign at the same time. (moral community) (qtd. in Murphy and Laczniak 21)

Kant contends that there are universal standards for ethical behavior; thus, and that the individuality of stakeholders should not be questioned per se because universal morality determines their ethics. This approach differs greatly from the utilitarian view where stakeholders are seen more as tools in completing ethical tasks rather than as individual persons. Kant also asserts that every rational human being, “exists as an end in itself, not merely as a means to be used by this or that will at its discretion; instead he must in all his actions, whether directed to himself or also to all other rational beings, always be regarded at the same time as an end” (Kant 18). Even though this theory places more emphasis on the individual, it also proposes universal rules of conduct, which are difficult to establish when the stakeholder range is broad. Deontological ethics can be broken down into a vast number of categories ranging from religious affiliation to natural law; however, the role of
individual rights is most pertinent to the current discussion of business ethics because it falls in line with stakeholder theory (DesJardins and McCall 31).

**The Role of Stakeholder Theory**

The normative ethical practices of virtue ethics, utilitarianism, and deontology provide different moral models for business decision-making in a general sense, but in order for managers to determine ethical strategies for their companies, ethical parameters must be further narrowed. Up to this point, the term stakeholder has been used in a general sense, but business ethics call for a more articulated distinction between stakeholders and shareholders in order to define the basis for stakeholder theory. In general, shareholders, also referred to as stockholders, are the individuals who stand to financially benefit from an investment in an organization (i.e., the owners). The scope of a stakeholder expands from the narrow shareholder view where the only thing that matters is increasing financial gain for those with a financial stake in the company, to an all encompassing group that includes, as defined by R. Edward Freeman, “any group or individual who can affect or is affected by the achievement of the organizations’ objectives” (qtd. in Goodpaster 230). Stakeholders can be further classified into two groups: 1) primary, which includes owners, employees, consumers, and affiliates such as suppliers; and 2) secondary, which includes the government, general public, competitors, and anyone else who may be affected by the actions and decisions
of the corporation (Boylan 79). Primary stakeholders usually make a greater impact in decision-making since they have a more formal relationship to the company; however, secondary stakeholders also should also be considered when ethical decisions are in question (Figure 3.1).

![Diagram of Primary Stakeholder Groups in a Large Corporation](image)


The primary stakeholder groups depicted above offer a simplified grid of the relationships of different discourse communities within a generalized organization. Identifying the stakeholder groups in pharmaceutical companies is more complex than the traditional model because so many people are affected by the products produced. Where traditional stakeholder groups are classified into groups of primary and secondary in the traditional model,
pharmaceuticals often fuse the groups together because stakeholder communities often overlap. Governing bodies such as the FDA will fit into primary stakeholder groups because the rules and regulations governing DTC advertising must be followed and adapted to best suit the so-called educational needs of consumers. Competitors may fall into the primary category because the innovations of one pharmaceutical company may lead to advances by another, or discoveries may lead to product withdrawals if necessary. The affects of these stakeholder groups change the dimensions of stakeholder theory for pharmaceutical companies because everyone is a potential consumer. The products promoted by DTC campaigns are products that might be needed by consumers, rather than commercialized products such as clothing or household items that merely might be wanted by the audience. To further elaborate, doctors join consumers as stakeholder groups that bisect all groups in the organization because these professionals often make up advisory committees as employees, regulation consultants in FDA hearings, partial owners, company managers, or even paid speakers by competitors (Figure 3.2).
Recognizing the difference between shareholders and stakeholders is at the forefront of stakeholder theory where the ethical business manager is encouraged to recognize the impact of her decisions on all groups. The theory is further complicated because individuals can fit into more than one group entity. For example, a marketing manager for Pfizer who has been prescribed Lipitor to help lower her cholesterol will fit into both the employee and consumer groups. Much like other ethical theories, stakeholder theory can be further broken down, in this case, into three main ideologies: descriptive, instrumental, and normative. As stated earlier, this discussion is focused on...
normative strategies, so I will rely on a normative stakeholder approach which analyzes the *reasons* stakeholder claims *should* be considered in business decisions for moral reasons regardless of potential benefits to the company (R. Phillips 66-67). Although normative stakeholder theory is the focus here, it is important to note that descriptive strategies focus on whether or not the claims of stakeholders are *considered* in business decisions, whereas instrumental approaches concentrate on the *impact* stakeholders can have on attaining business goals without emphasis on the morality of decisions (R. Phillips 66-67). Since this discussion will rely on normative stakeholder theory, the normative strategies mentioned earlier in this chapter will now be collapsed into the stakeholder theory of marketing ethics in order to establish boundaries for the discussion of ethics within DTC advertising.

The normative approach to stakeholder theory relies heavily upon the deontological model of business ethics discussed earlier, thus encouraging businesses to avoid treating individuals as tools, or as a means to an ends. Deontology theorists, such as Immanuel Kant, assert that people have the ability to distinguish between right and wrong and that the moral duty is to treat others as you would want to be treated (Murphy and Lacznia 21), much like the Golden Rule of childhood. Stakeholder theory provides managers with a framework for decision-making that takes the moral standpoint of affected groups into consideration. Deontology shapes stakeholder theory in
three main ways: “i.) Businesses have positive duties to stakeholders based on stakeholder interests; ii.) Stakeholder groups are distinct from individuals; and iii.) Duties are owed to stakeholders equally” (Gibson 249). The first assertion points to the fact that all groups have different interests in relation to business actions; however, not all claims warrant action by the company. For example, customers want products that are of high quality and low cost, but managers may recognize that creating a product of high quality may not be feasible at a low price. This concept points to an important distinction between what is a moral right versus a personal want. Businesses have a moral obligation to stakeholders to consider their claims, but not all claims warrant moral action.

The second deontological basis for stakeholder theory posits that groups are composed of individuals, an assertion that can complicate the ethical model, especially if individuals are members of more than one group. This can lead to problems in distinguishing between ethical claims of an individual versus that of a stakeholder group. Stakeholder theory combats this notion through the contention that, “for a group to have moral standing…it needs to have a culture which will survive the coming and going of any one person, and whether written or not, there will be a continuing ‘spirit,’ or set of shared understandings, which identify the group” (Gibson 252).

The final deontological approach to stakeholder theory brings the concept of authority or partiality into ethical consideration. Stakeholder
theory is considered neutral because it does not place emphasis on one group of stakeholders over another; the values and perceptions of every group should be considered equally. Where stockholder theories place emphasis on the maximization of company profits with little regard to social or moral obligations, stakeholder theory envisions business managers as monitors of the “health of the organization” who must balance sometimes conflicting views of stakeholders in order to achieve a decision that is both ethical and non-detrimental to the company itself (Evan and Freeman 81). If no emphasis is placed on one stakeholder group over another, then managers are placed in a dilemma when making decisions where groups have conflicting claims. Known as the stakeholder paradox, this concept questions whether it is more ethical to ignore stakeholder claims and advance the financial maximization of stockholders or to acknowledge all stakeholders since managers are faced with an impossible task of balancing the value of all claims (Goodpaster 240). To subvert this contention, theorists emphasize the importance of the fiduciary obligation businesses have to protect the well-being of the company, and thus the stockholders, while also working to protect the rights of stakeholders. Theorists assert that it is natural for human beings to have feelings of obligation (such as justice, gratitude, and indebtedness) towards others and such notions can be described as moral agents (Gibson 254). If this is the case, then managers may have a hard time balancing the claims of competing
stakeholder groups in order to determine an ethical course of action because the viewpoint of one group does not necessarily outweigh the viewpoint of a different group.

Stakeholder theory is an effective model for decision-makers in business to follow in an effort to set a moral framework for their company. In order to implement this strategy, professionals are encouraged to take the following steps:

1. Establish a list of stakeholders
2. Classify stakeholders into primary and secondary distinctions and determine the stakes each group has within the company
3. Determine the responsibilities the organization has to each stakeholder group (legal, economic, ethical)
4. Identify conflicts between stakeholder values
5. Determine the best response to the benefits and risks in the stakeholder claims with emphasis on compromise (Murphy and Laczniak 7)

Although ethical decisions are not guaranteed if stakeholder theory is implemented, this is a step in the right direction. The theory should be applied in all levels of the organization, not just on a corporate level. Thus, stakeholder theory is an effective framework for decision-makers in the marketing profession as well. As previously mentioned, within the DTC pharmaceutical marketplace, the stakeholder range is much more complicated than in many other business scenarios because the products being marketed affect the health or well-being of an individual. DTC campaigns reach a much more complex web of stakeholders because the specialists that might
recommend an ethical strategy can take on the role of specialist and consumer.

Stockholders, managers, and employees of a pharmaceutical company also may be consumers of the product. Physicians and pharmacists that make up specialty boards in the FDA can also serve on boards of pharmaceutical companies in addition to undertaking the role of healthcare provider for patients. The wide range of stakeholders in the pharmaceutical industry further complicates the ability to make sound ethical decisions for DTC pharmaceutical ads.

**Ethical Advertising Decisions**

Normative ethics and stakeholder theory propose solutions for decision-makers to make moral judgments for a company in general, but decisions can be further complicated when the business is examined in a more segmented manner. In this respect, adding advertising into the discussion will introduce a range of factors that advertising (and often, marketing) managers must consider within their field. While ethical decisions may or may not come up that often in a normal business setting, ethics enters the discussion almost daily in the advertising sector (Drumwright 608). Ethics enters the advertising workplace in such a dramatic way, that advertising itself has been criticized as being unethical, regardless of the product being promoted. Ethicists have debated the morality of advertising for years, but whether or not advertising should exist as a practice is not the point of this discussion.
The focus here, rather, is to analyze the practice of advertising to consumers in the pharmaceutical marketplace in order to determine whether or not DTC campaigns are ethical promotional strategies. The question is not whether or not businesses should be able to advertise their products, but whether or not \textit{pharmaceutical} products can ethically be advertised and, if so, what strategies drug companies should adopt in order to ethically promote their products. In order to further establish parameters of ethics within the discussion of advertising, factors such as puffery, legal discourse, endorsements, and deception will be placed at the forefront of the conversation.

Since their conception, advertisements have been criticized as containing misleading or deceptive messages that can create a sense of false need within audience members and can lead to sometimes harmful demand (Drumwright 619)--a claim that parallels the debate over DTC pharmaceutical efforts. Advertising has an uncontested affect on society’s perception of reality (though the type and quantity of the affect is debated), influencing culture beyond the influence ads have over buying habits (B. Phillips 111). Promotional campaigns socially construct norms in society that can be seen in everything from language use and fashion sense to the perception of cleanliness and beauty. The impact of such messages on society has caused ethicists to question the morality of advertising campaigns through the distinction between behavior and desire as motivators. Ads that are not
deceptive in nature serve the purpose of increasing the desire for a certain lifestyle and proposing a way of soothing that desire. In this case, the consumer already has a certain amount of desire for the lifestyle in question whether they realize it or not (DesJardins and McCall 326).

This proves to be an interesting notion because it places less emphasis on the behavior of the consumer (i.e., whether they buy the product being promoted) and refocuses attention on the ability of advertisements to create socially constructed norms. The idea that advertisements mold the psychological desires and lifestyles of consumers introduces an interesting notion into the ethical debate because the goal of advertising would then be to increase consumer demand for a lifestyle, not a specific product. If this were the case, competing companies that market a similar product could join together to promote a certain lifestyle and product names would be irrelevant because the desire for the product type would exist. It is important to establish the purpose of advertising campaigns in order to determine whether messages are meant to control the behavior of consumers or to encourage desire, thus introducing the concept of deception. Although deception can be unintentional, theorists argue that this does not decrease the impact or morality of messages.

The dichotomy between consumer behaviors versus desire poses an interesting ethical dilemma within the advertising profession, but it hinges
upon the notion of non-deceptive ad campaigns. One of the primary ethical debates within the industry is that deceptive advertising is not easily identified. In fact, scholars such as Daniel Attas make a distinction between deception and lying, asserting that deception can come to fruition through both visual and verbal means, whereas, lying is achieved only through language (Attas 50). Furthermore, deception is a *successful* attempt to mislead the audience, but lying is *merely an attempt* to do so (Attas 50). The Federal Trade Commission (FTC), the government body that typically regulates advertisements (except DTC ads which, as previously mentioned, are regulated by the FDA) classifies ads as deceptive when they include, “false representations, material omissions, and other deceptive acts or practices” (Drumwright 610). Deceptive ads are discouraged in an effort to promote non-misleading information transfer to consumers; however, deception and persuasion are two different things.

For example, diet-conscious consumers might be familiar with the deceptive powers of food labels that include: “light” or “reduced fat” qualifiers but, in fact, are not healthy food options. This advertising tactic was discouraged by the Nutritional Education and Labeling Act of 1990, which forced companies to include nutrition information on all food products (Weiss 175). The FDA attempts to regulate deceptive advertising through regulations such as the brief summary requirement mentioned in Chapter 2. Many
scholars and leaders within the advertising industry acknowledge that everyone expects ads to be somewhat misleading or deceptive; however, this does not acknowledge the contention that ads are of questionable ethics (McCall 334). The morality of advertising campaigns lies in the “fact of generally practiced or tolerated negligence in conveying information in advertising that has harmful consequences” (Attas 56), rather than the perception of the audience. Thus, the intention of the company that generates an advertising campaign is key.

Intentionality of companies is another aspect of advertising ethics that is often difficult to pinpoint, especially when marketing tactics such as expert or celebrity endorsements and puffery are accepted practices. Ethics are questioned in endorsements when it is not clear if the spokesperson really does use the marketed product, a requirement that is sometimes difficult for regulating bodies to determine (Drumwright 615). As will be discussed in Chapter 4, the use of experts to promote prescription products is a current marketing trend that is receiving criticism due to the intention of pharmaceutical companies to persuade consumers and possible conflicts of interest between the experts in advertisements and the messages they provide. Regardless, it is important to note the questionable morality of using celebrities or experts to endorse a product; however, the use of puffery in
advertising campaigns has incurred higher levels of criticism because of the difficulty in determining the intention to deceive.

As defined by Ivan Preston in his analysis of puffery, the concept is the presentation of information in advertisements that depict a product in a positive light using “subjective opinions, superlatives, or exaggerations, vaguely and generally, stating no specific facts” (qtd. in Drumwright 611). Messages that utilize puffery contain true statements that are over exaggerated in an effort to maximize the impact of the ad campaign: for example, Merck’s used the tag line: “It’s Your Future. Be There.” to promote Zocor throughout part of 2005 (Zocor). No facts are stated in this claim, but the consumer is presented with the idea that if they do not use Zocor to lower their cholesterol, they may not be alive to witness their future. Critics of the advertising strategy assert that overstated claims do not present an accurate portrait of a product because they cloud relevant information, and thus alter logical buying decisions (Drumwright 611). The FTC contends that the practice is legal on the basis of caveat emptor (Let the buyer beware). This notion is defended on the grounds that “reasonable” buyers do not rely on persuasive statements from the company selling a product; therefore, they are not deceived (Drumwright 611). Advertising executives conduct in-depth research to determine the social wants and needs of consumers in order to develop ads that will respond to these desires (Arrington 349). Puffery plays
into this by embellishing the desired lifestyle and asserting that a specific product is the key to achieving the best life. Images are repeated over and over through television and print ads, causing consumers to confuse *desire* with *need*.

Analyzing the question of ethics within the advertising industry is a difficult task in and of itself, but adding the complexity of the pharmaceutical industry and all of the stakeholders involved further complicates the ability to make moral marketing decisions in DTC campaigns. The purpose of this chapter was to introduce readers to the impact of normative ethics on business decisions, then to collapse those ideologies into the stakeholder theory of marketing ethics in an attempt to establish boundaries for the application of ethics within DTC statin advertising. After receiving a brief foundation in the ethical considerations within advertising itself, readers should now be prepared for the deconstruction of DTC statin campaigns in Chapter 4.
CHAPTER 4

THE IMPACT OF STATIN PROMOTION IN ETHICAL DECISION-MAKING

With so many ethical questions affecting the decisions of marketing managers, it is not surprising that executives who create DTC campaigns for pharmaceutical products are faced with so many challenges. Determining the normative approach to business decisions can be complicated because professionals often follow a combination of theories; however, adding such a complex and overlapping range of stakeholders into the equation (doctors, consumers, managers, employees, etc) further complicates the ethics behind DTC advertisements because decisions must in addition to all the stakeholders, consider the medical implications of products. For example, physicians must apply the ethical requirements of the Hippocratic Oath, a set of universal duties for doctors, to every interaction with a patient (Cornelius 103). The mandatory application of these rules sets boundaries for individual decision-making by binding physicians together as a group. Thus, marketing managers might assume that physicians, as a group, hold the same opinion of DTC campaigns; however, each individual doctor may have a different interpretation of the Hippocratic Oath. Differences in the application of
universal rules such as the Hippocratic Oath further complicate marketing managers’ ability to determine the standpoint of stakeholders as group entities.

In order to provide the best analysis of DTC statin campaigns, I will utilize stakeholder theory as an umbrella for analyzing ethics in statin advertisements since the ads affect such a wide and complex web of stakeholder groups as discussed in Chapter 3. It is also important to note that normative ethics cannot be cast aside because there are important factors that each type of normative ethics introduces into the discussion. For example, stakeholder theory relies heavily on deontology by acknowledging the ethics of individual groups; however, each individual stakeholder group is comprised of *individuals* who will bring different standpoints to the issue, thus virtue ethics will come into play. Conflicts of interest within the industry are an important issue in this respect. Since this chapter will fuse the practice of DTC advertising with the aforementioned ethical parameters, I will provide a framework by analyzing the following features of the ads: language use, visual rhetoric, approval and distribution issues, and conflicts of interest.

Although I have not dedicated a significant portion of the thesis to a direct discussion of medical ethics per se, this topic needs consideration and will also be woven through this chapter. It is important to note that the constraints of DTC campaigns are distinct from other advertising efforts because they bring the dissemination of medical information to the forefront
of the discussion. As previously mentioned, prescription products affect the personal health of consumers, a factor that is not usually associated with common consumer products such as cleaning supplies or clothing. Thus, using business and advertising ethics to qualify DTC content is not enough for corporate decision-makers. Medical ethics touch every stakeholder group affected by DTC campaigns, creating a further need for ad analysis. Because medical ethics is such a large issue, encompassing much more than just the impact of DTC efforts, I will discuss several components that are most germane to this discussion. Ethics specific to medicine that I am considering in this chapter include: conflict of interest among stakeholder groups, the use of medical language that is targeted to a general audience rather than healthcare providers, and the implications of corporate codes of conduct in combination with a physician’s obligation to uphold the Hippocratic Oath.

In general, ethical reasoning is the process by which decision-makers should analyze an ethical issue in order to produce a morally sound result. Marketing managers are often encouraged to use the following three steps in order to come up with an ethically reasoned decision: 1.) Determine the ethical implications that are in question by determining the causes and effects of actions; 2.) Establish the parameters of ethical standards (i.e., choose which ethical theories will shape the moral judgment); and 3.) Apply the ethical standards to the ethical dilemma in question (Murphy and Laczniak 14). Up to
this point in the discussion, I have provided readers with both the moral implications of DTC advertising and the ethical parameters by which I will analyze the dilemma. The purpose of this chapter is to critique the construction and dissemination of statin ads using normative and stakeholder theories in order to promote ethical reasoning, thus determining which aspects of the campaigns are ethical and which are not. Once the problem areas are established, I will then propose strategies to remedy ethical conflicts in Chapter 5.

**Impact of Language in DTC Advertisements**

The effectiveness of DTC statin advertisements has undoubtedly helped generate the worldwide, blockbuster success of the drug class. With the most recent Lipitor campaign totaling an estimated $55 million (Schupak 52), it is evident that pharmaceutical companies recognize ads as a stimulus to increase profits. Analyzing the content of such marketing efforts is no easy task. Each ad crosses the desk of a wide range of professionals from marketing executives to FDA regulatory members. Each stakeholder brings a different purpose and interpretation to the DTC ad, thus complicating the ability to determine the educational content and the persuasive nature of the text. Put simply, DTC advertisements are a form of communication that are intended to persuade a designated audience (which includes members of each stakeholder group) to act in a certain way by purchasing a specific product.
The use and manipulation of language is at the heart of this discussion because the words used in an ad, which can be interpreted differently by stakeholder groups, comprise much of the ethical basis of the text. Rhetorical theory posits that language and ethics are tied together or, in the words of Paul Dombrowski, “Contemporary rhetorical theory holds that language, and all knowledge constituted and mediated by language, always inescapably embodies, represents, and propagates a world view and therefore a system of values” (qtd. in Markel 17). Because of the influence language has on the determination of ethics, I first want to discuss the verbal appeals of statin ads.

As mentioned at the end of Chapter 3, promotional campaigns have a profound impact on the lifestyle of citizens in society. Consumers digest the information and images created by ads and, in turn, want to achieve the healthy lifestyle promoted in the campaigns. Evidence of this desire can be found within the increasing number of prescriptions for statins that are written each year, that is, rhetorically, the actual medical or physical actions of the drug on a body part or system have been erased by a larger construct: one’s *lifestyle*. As the number of DTC ads have increased, so have the number of prescriptions written. Many physicians criticize this increase in demand for the drug, asserting that patients see an ad on television or in a magazine and turn to their doctors to request a statin to prevent high cholesterol rather than trying other treatment options. While preventative measures such as an
improved diet, regular exercise, and stopping smoking are proven to be cheaper, safe, and effective non-drug interventions for patients, the availability of DTC ads and increased consumer awareness have made it possible for statins to be sold to everyone (Moynihan and Cassels 2-3).

Marketers have a huge responsibility to deliver an effective sales message that will satisfy corporate goals as well as achieve ethical standards since over 80 percent of physicians are willing to prescribe the specific medication asked for (as long as no apparent medical risks are present) (Callahan and Wasunna 170). I have previously shown that statin advertisements have successfully increased the number of prescriptions written for the drug class. Since ads are proven to have an impact on consumer desire for a particular lifestyle, it is safe to say that DTC statin campaigns have effectively increased consumer desire for a “healthy” cholesterol level. The success of statins have more than likely satisfied the financial goals of pharmaceutical shareholders (as least in the sense that profits continue to increase each year), but does the lifestyle portrayed in DTC efforts achieve the same success in relation to ethics? I will now attempt to answer this question by analyzing the linguistic affect of rhetorical appeals found in statin advertisements, most specifically, the language used to attain the audience’s attention and to explain the benefits and risks of products.
Interpretation of Language and Healthcare Models

Regardless of the product being promoted, deception is an issue that is often associated with the message conveyed and lifestyle portrayed in an advertisement. Statin campaigns often use language that could be deemed as deceptive or inappropriate to generate a fear of death within the audience in order to push consumers to seek treatment or prevention (Moynihan and Cassels 14). For example, a 2005 Zocor advertisement in *Prevention* (Figure 4.1) depicts a middle-aged woman walking in the rain and using an umbrella, rain hat, waterproof boots, and a rain coat to protect her from the weather. The top of the following page proclaims in bold text, “Every day you protect yourself. Are you doing enough to protect your heart?” (Zocor, Feb. 2005). The ad then presents several selling points concerning Zocor, starting with the assertion, “Heart disease is the #1 cause of death in women” (Zocor, Feb. 2005). The product claim ad does comply with FDA guidelines by presenting safety and benefit factors in balance with potential risk considerations as well as mandatory PI information, which is included on the reverse side of the advertisement (Figure 4.2). Consumers are directed to further information via the Zocor website, a help line, and the advice of the patient’s physician. So, does this DTC advertisement possibly breech any ethical stances? Is it deceptive?
Figure 4.1. Advertisement That Utilizes Language to Create a Fear of Death From Heart Disease, Zocor. Advertisement. *Prevention.* February 2005.
Figure 4.2. Reverse Side of Same Advertisement, Zocor. Advertisement. Prevention. February 2005.
First, the ad attempts to appeal to the conscience of consumers by insinuating that people often take precautions for daily activities as simple as a rainstorm, but not for issues as important as cardiovascular health. As soon as doubt is introduced to the audience, the ad goes further to use the fear-of-mortality strategy by providing a statistic that links heart disease to women, then to death. Research indicates that fear appeals are an effective advertising strategy that can increase the pathos and persuasive nature of an ad, while also increasing the audience’s ability to recall the main ideas of the advertisement (Snipes et. al. 273). DTC campaigns are well known for using emotional appeals to help persuade patient action, but does the use of fear appeals really allow the patient to come away from an ad with adequate medical information? The use of this type of pathos may make the consumer aware of the ailment, but it may not facilitate a two-way communication where the patient actively participates in constructing knowledge from ad material. Thus, the emotional appeals of the ads are evident but whether or not the language present in the advertisement actually educates consumers rather than just increasing awareness is a big question. So, is it ethical to use emotional appeals when the advertisements are often defended by pharmaceutical companies, the FDA, and some physicians on the basis of patient education or on logos?
Stakeholder theory requires that the ethical decision-maker analyze the impact of her decisions on all groups affected, in this case: physicians, patients, marketing managers and employees, owners, and the FDA. The Zocor ad above complied with FDA regulations and also did not receive any warning letters from the regulatory group. As discussed in Chapter 2, the FDA has conducted several studies to test the effectiveness and informational value of DTC campaigns, thus concluding that the efforts are worthwhile and beneficial to patients as long as regulations and guidelines are followed. Since the ad in question did not violate any of these boundaries, it is safe to say that the FDA, as a stakeholder group, would most likely consider the ad to be ethical. Marketing managers, owners, and employees would find that the ad is ethical for the same reasons with the additional assertion that market share increased. Thus, Merck not only increased patient awareness, but also increased company profits.

So far, all stakeholder groups are probably in agreement that the DTC ad is both ethical and effective; however, conflicting viewpoints might present themselves when physicians and patient stakeholder groups are taken into consideration because the individuals within each group will have a range of interpretations and opinions. The introduction of differing opinions complicates the ethical decision-maker’s assessment of the problem if they choose to follow stakeholder theory.
Stakeholder theory relies on the classification of individuals into groups based on their social relationships and status in relation to the company in question, in this case, the pharmaceutical corporation. Classifying people into groups, such as physicians and patients, allows the marketing manager to try to determine the ethical position of each group through conducting studies or by consulting a panel comprised of members of each stakeholder group. Although each group is represented in this scenario, little is said about how decisions are reached within the stakeholder group itself. It is unlikely that everyday citizens are well versed in theories of ethics and that each individual has chosen a specific theory by which to live their lives. In this respect, ethical theorists Reidenbach and Robin have introduced the notion that “individuals do not use the clearly defined concepts of ethical philosophies in making specific ethical evaluations, but that a mixing or combining of these philosophies is the norm” (Snipes et. al. 274). Thus, in order to determine whether or not physicians and patients (as stakeholder groups) consider fear appeals to be deceptive or unethical advertising, normative ethics must be addressed.

When assessing the value of normative business ethics in relation to DTC advertising of statins, it is important to note that ethical strategies are complicated by the dynamics of the healthcare system. The three primary types of normative ethics as described in Chapter 3 included: virtue ethics,
utilitarianism, and deontology. While virtue ethics are centered upon the individual’s quest to determine what is “good,” deontology and utilitarianism go beyond the individual and center attention on the organization. Within the healthcare system, there are two primary structural models: 1.) physician-focused, in which product information is provided to doctors who, in turn, run medical exams and tests for the basis of interaction with the patient; and 2.) patient-focused, in which the patient receives all information and has a greater role in healthcare decisions; the doctor exists to please the patient (Parker and Pettijohn 282). These two structural models of healthcare also represent a valid parallel between healthcare professionals who adopt deontological standpoints versus those who prefer utilitarian strategies.

For instance, a deontological perspective centers on the physician’s duty to her individual patient to provide ethical healthcare, whereas, the utilitarian perspective re-centers focus on the greatest good for the largest number of patients. The deontological approach parallels the physician-model of healthcare because doctors uphold universal rules such as the Hippocratic Oath in an effort to facilitate trust within the doctor-patient relationship, thus becoming “the patient’s advocate, with the patient’s health being the physician’s primary concern” (Cornelius 103). In this respect, some physicians may disagree with the use of fear appeals in statin (or any DTC) advertisements because the solution proposed by the ad is to prevent heart
problems by taking a specific cholesterol-lowering agent, in this case, Zocor. Here, the physician-patient relationship shifts more towards the patient, which is in contrast to this healthcare model.

In fact, a study conducted in 1999, indicates that both physicians and patients “contend that DTC [advertising] alters consumers’ communication behavior, and, ultimately, relationships with physicians, by encouraging greater patient participation and control” (Cline and Young 1050). In this respect, those who utilize a physician-model of healthcare would most likely discourage not only fear tactics such as the one referenced in the Zocor advertisement, but also the ad’s push to “Ask your doctor if Zocor is right for you” (Zocor. February 2005). Even though the doctor-patient relationship is encouraged here, the rhetoric of the advertisement encourages the patient to initiate the medical discussion rather than the physician. Thus, proponents of the deontological, physician-centered, healthcare model would most likely consider the linguistic strategies used to be unethical even if an ad causes a patient who “needs” the drug to consult their physician. Since this healthcare model relies on a deontological approach, the consequences of an action (in this case, the patient’s response to the DTC ad) are not judged, but rather, the action itself is what matters (i.e., shifting responsibility from the physician to the patient is considered unethical).
Advocates of the patient-centered healthcare model fall under a more utilitarian perspective which would tend to see the consequences of fear tactics as a positive effect. Under this framework, the greatest good is considered to be the most ethical standpoint and patients have greater control over their medical treatment in that they receive information on treatment options, and then they consult their physician. In patient-centered healthcare, the doctor exists to please the patient, though they must still uphold standards such as the Hippocratic Oath. In this system, physicians would judge the ethics of fear appeals in statin advertisements by examining the consequences of the ads on all patients as a group rather than an individual basis (Cornelius 105). Although the patient-centered model appears to suggest greater focus on the individual, decisions are still based upon utilitarian cost and benefit analysis to determine the greater good (Cornelius 105), so if patients consult their physician about an ailment (or product) mentioned in an ad, they have the potential to benefit from the medication if it is needed. Without DTC efforts, some patients may not become aware of medical conditions and, thus, might not ask for treatment. Because patients have the potential to medically benefit from DTC ads (through awareness), advocates of the patient-focused healthcare model might contend that the ads are beneficial.

If decisions are created for patients as a group rather than on an individual basis, both the physician and the patient are put into a difficult
position. As discussed in Chapter 1, 2002 FDA studies indicated that at least
28 percent of physicians felt at least somewhat pressured to prescribe a specific
drug when asked to do so (Woodcock). More recent numbers indicate an
increase to 80 percent of physicians who are willing to prescribe a specific
medication requested by a patient, suggesting that physician compliance to
patient demands is on the rise (Callahan and Wasunna 170). With so many
physicians prescribing the desired medications of their patients, it can be
argued that DTC advertisements allow patients to become aware of ailment
and treatment options and, in turn, patients can take charge of their health by
asking for preventative measures. In fact, DTC advocates assert that
“consumers can engage in more equitable relationships with healthcare
providers and become partners in their own healthcare as a result of DTC
[advertising]” (Buckley 5), which coincides with the goals of the utilitarian
patient-centered healthcare model. Some might argue that patients are tools
of the pharmaceutical industry because they are persuaded by fear appeals and
the healthy lifestyle presented in DTC ads to ask for a specific medication, a
utilitarian perspective would probably assert that the patients who benefit
from the ads promote the greatest good scenario. Statin ads, such as the Zocor
piece above, use fear appeals as a stimulus to push consumers to consult their
physician about cholesterol problems, a tactic that increases patient education
and thus could be deemed ethical from a patient-focused healthcare approach.
Based on the current analysis of fear tactics in DTC statin advertisements, the practice will most likely be deemed as ethical by all stakeholder groups except physicians in the physician-centered or deontological healthcare model. Since evidence shows that fear appeals increase interest in the product advertised without introducing deception, the tactic proves ethical and beneficial in the eyes of the FDA, members within the pharmaceutical corporation, and to consumers (especially since the drugs are prescription products, thus, professional medical advice and support is needed). Even though the practice is ethical in the eyes of a majority of stakeholders, ethical decision-makers who wish to follow the stakeholder theory of ethics are now caught in the paradox, with no clear solution because all stakeholders are not in agreement.

**Package Insert (PI) Information**

Fear tactics and deception are only two of a wealth of rhetorical strategies used by marketing managers to utilize language in DTC advertisements. Although these are typically the most controversial measures, it is also important to discuss the use of medical language in the ads in relation to audience perception. DTC campaigns utilize the persuasive nature of language beyond the obvious sales message of an advertisement. PI information must be provided for every product claim ad. Here, I will examine the difference in comprehension between the linguistic rhetoric of
traditional PI information provided in DTC statin advertisements versus the new format created by Pfizer in 2005. In the next section, I will discuss differences in visual context.

The traditional PI model provides prescribing information that is approved by the FDA before a drug is launched. The information included is directed at a range of individuals including: prescribing physicians and pharmacists who will use the text to educate themselves on the features, benefits, and risks of the drug; patients who will use the information to learn about a product they have been prescribed; and consumers who see the information on the reverse side of DTC advertisements. The text is divided into several headings including (in this order): “Contraindications,” “Warnings,” “Precautions,” “Adverse Reactions,” and “Overdosage.” The traditional PI is often disbursed with prescriptions and was used years before DTC advertisements of prescription products entered the market thus originally, the general public was not the intended audience for package inserts. Conversely, Pfizer’s new PI information is geared towards a general audience and was constructed solely for use in advertisements. This distinction is made clear since the document is titled “Important Facts” rather than “Prescribing Information.” The major headings of this PI include (in this order): “Lowering your Cholesterol,” “Who is Lipitor For,” “Before you Start Lipitor,” “About Lipitor,” “Possible Side Effects of Lipitor,” “How to Take
Lipitor,” and “Need More Information.” A comparison of the PI headings alone proves that the new model includes much more simplified language that can be understood and utilized by everyday consumers. The new format is much more user-friendly and provides information in a way that is fairly clear to a general audience; however, it is important to note that the PI may not fully educate consumers but, rather, it provides information in more accessible language for the target audience. Although Pfizer launched this new format for product information, other pharmaceutical companies are now following a similar format. Which model should marketing managers choose to implement?

In order to determine the ethics of disseminating medical information through PIs, medical rhetoric and the complexities of language must be examined. Medical language is often difficult for the public to decipher, even prescription drug labels. A recent study shows that “only 34.7 percent of the people with lower literacy, grade level or below…could determine the number of pills to take daily when faced with ‘take two tablets by mouth twice daily’” (Edelson “Prescription”). The study went further to assert that many people with higher literacy, including individuals with college degrees, have trouble understanding such instructions (Edelson “Prescription”). If the public has this much trouble understanding directions on how to take a medication, what
does that say for the contention that patients can educate themselves from DTC advertisements?

When comparing the two types of PIs, it is evident that the new version is much more reader-friendly. For example, one of the possible side effects of Lipitor is worded, “Muscle problems that can lead to kidney problems, including kidney failure. Your chances of muscle problems is higher if you take certain other medicines with LIPITOR” (Lipitor Greenville News). By using simple language and avoiding high levels of industry specific language, the PI delivers a message that should be clear to most audience members. Although the same information is included in the traditional PI, it is scattered throughout the text and is stated in much more scientific language. For example, the same side effects are listed under “Adverse Reactions” and further categorized as “Urogenital System.” Instead of using simple sentences and language to inform consumers that kidney problems may arise with the use of Lipitor, the traditional PI lists possible kidney problems among other potential issues within the urogenital system, “Urinary tract infection, urinary frequency, cystitis, hematuria, impotence, dysuria, kidney calculus, nocturia, [etc.]” (Lipitor Prevention). The difference between the two types of package insert can be simplified into the concept of audience. The traditional model is targeted towards people in the healthcare industry who have a heightened understanding of medical language, so they have the ability to respond to the
text where consumers do not. The new PI simplifies language into a more accessible format that allows anyone to fit into the audience label even though true patient education may not arise. Going further, the traditional model uses scientific language to convey very precise, logical, and accurate prescribing information; however, professionals write this text for the FDA before the drug is even launched. A single, traditional PI is written for the FDA and is not altered for a more diverse audience after FDA approval is received, a “rhetorical constraint” that is now conquered through the availability and use of the new PI (Bell, Walch, and Katz 252). Given the range of audience members that can use the new PI format versus the narrow window of comprehension for the traditional version, it is safe to say that all stakeholder groups would assert that the new model is the most rhetorically ethical for use in DTC efforts.

**Visual Rhetoric**

Language use is an important element in DTC advertisements because marketers carefully choose words to convey a specific message to consumers. While the ethical implications of language use is key in analyzing DTC statin campaigns, visual rhetoric also plays a very important part in determining the intentions of promotional efforts. In a general sense, ad campaigns are considered effective (in the eyes of shareholders and the advertising industry) if they successfully persuade an audience to buy a specific product by creating
a message that is meaningful to the audience, creating a lasting image.

Advertisements do so through impacting the audience, “by achiev[ing] the appropriate synthesis of primary visual and secondary verbal elements mutually reinforcing one another; the perceptual reception of the message is determined by the set of thoughts and emotions that are part of the consumer” (Barry 254). The audience sees the visual aspects of an ad before they begin to digest any verbal messages; thus the visual impact of DTC statin advertisements is a critical element in the discussion of ethics. Marketing executives consider every visual component of an advertisement; therefore, every aspect of an image is “intentional” (Barthes 152). In order to keep the scope of the discussion of ethics within DTC statin campaigns at a reasonable level, I will now analyze the use of graphs and charts, font size and placement, pictures, and celebrity or expert endorsements within DTC ads.

**Font Size and Placement**

Consumers are often encouraged to read the small print when assessing the validity of a contract; the same is true for the validity of claims presented in a DTC ad. Very often, pharmaceutical marketers satisfy the FDA’s brief summary requirement (that must provide risk information) by printing the information in very small typeface. Although many ads mention a couple of risk factors on the first page (of a print ad) or in small text at the bottom of the screen (for a television ad), most of the mandatory risk information is
presented in the PI. As previously mentioned, the new format for PIs is much easier for consumers to understand because the complexity of medical rhetoric has been simplified for a general audience. The same is true for the format of the new PI. The original format for PI information consisted of extremely small text with little or no format changes to denote sections of information such as side effects, indications, dosage forms, etc (Figure 4.3). The new format utilizes varied text sizes with the smallest still being large enough to read (Figure 4.4).

Figure 4.3. Actual Size of a Portion of Traditional PI Information on the Reverse Side of an Advertisement, Lipitor. Advertisement. *Time.* 5 August 2002.
In addition, sections of information are clearly separated and main points are denoted by bullet points. Instead of a white background with black text, the new format also uses grey and bubbles to separate information, thus making the material more reader-friendly. It is likely that more consumers will read the new format because of the stylistic changes, whereas, the traditional model might be skipped because the text is so small. Pfizer, creator of the new format, asserts that visual and textual changes “make its ads more effective at communicating risk and benefit information and reinforcing doctor/patient relationships” (McGuire 30). Some stakeholder groups might
disagree by asserting that the simplification of product information may not necessarily be ethical because all possible risks and side effects of drugs are not listed regardless of the visual simplicity of the text; however, analyzing the ethics of DTC ads through a visual lens goes beyond the words on a page and brings forth the initial response of a potential reader of the text. That is to say, consumers do not have the potential to benefit from package insert information if they do not read it, and they will not read it if they do not respond to the visual composition of the text. John Trimbur, a scholar in cultural literacy, asserts that the key to this response is in the typography of a text which, “call[s] attention to how the look of a page communicates meaning by treating text as a visual element that can be combined with images and other nonverbal forms to produce a unit of discourse” (Trimbur 267). Thus, the new format of the PI has a greater chance of opening a discourse between the reader and the text of the statin advertisement because the larger typeface and clear layout is more visually appealing. Engaging the text allows consumers to be more informed, while also facilitating further discussions with their physician; therefore, both the patient and physician models of healthcare should be satisfied, making it more likely that all affected stakeholder groups will deem this change as a step in the ethical direction.
Charts and Graphs

Many DTC statin advertisements also use the visual rhetoric of graphs and charts in order to illustrate the efficacy and superiority of a drug. The use of graphs and charts to present scientific information is a common rhetorical strategy used to instill confidence in the information being presented. In his case studies of the cholera epidemic and the Challenger disaster, Edward Tufte asserts that graphs and charts present a visual representation of information that can be misleading if the logic of the design behind the graph does not coincide with the logic of the quantitative data (Tufte 53). He goes further to claim that appropriate cause and effect relationships as well as appropriate comparisons must be present in the design of graphs in order for the message to be clear and useful (Tufte 53). DTC advertisements are known for using graphs or charts to present benefits over competitors or even to downplay the potential risks of a drug. This advertising strategy is credited with instilling credibility in the audience, “and based on the perceived scientific precision of an abundance of charts and graphs included, [consumers] assume a far less skeptical orientation toward such information-rich advertising” (Beltramini 334). For example, the most recent statin to hit the market, Crestor, utilizes a graph to illustrate the results of a clinical study that proved that a 10mg dose of Crestor lowered LDL (bad cholesterol) levels at least 9 percent more than competing products (Figure 4.5).
At first glance, the graph clearly proves that Crestor is the most effective statin on the market; however, the ad does not distinguish between statin and superstatin, leading consumers to believe that Crestor is the same type of drug as Lipitor, Zocor, and Pravachol. The picture indicates that the 10mg dose of Crestor reduces LDL levels 9 percent more than the same dosage of Lipitor, the most prescribed and recognized statin on the market. What the graph fails to mention is that the superstatin status of Crestor means that “its
lower doses have the pharmacologic effect of the midrange doses of market leader atorvastatin (Lipitor-Pfizer)” (Bennett). To an audience with a limited knowledge of statins, this point may not mean much (and might even be taken as an uncontested positive feature of the drug); however, the distinction between statin and superstain is a big one to healthcare professionals because the latter is a relatively new form of a statin that has drawn consistent safety concerns.

In 2005, the American Heart Association released information claiming that Crestor had a higher rate of adverse side effects than other statins on the market (Edelson “Crestor”). While cardiologists assert that the drug is still safe, some assert that “it might be preferable” to try to lower cholesterol levels with traditional statins first and use superstain Crestor when patient LDL levels are not efficiently reduced (Edelson “Crestor”). Patients who are treated with statins are often prescribed a low dose with the potential to increase the dosage if a physician is not satisfied with the lowering of LDL levels. Since some cardiologists encourage colleagues to prescribe the superstain if a statin does not work, it is clear that the low dose of Crestor presented in the graph above is, in fact, not comparable to the lowest dose of Lipitor. Although the graph in the Crestor ad above does present the findings of a scientific study, the information misleads consumers into trusting that the product is superior to other drugs in the same class.
If the primary goal of a DTC statin advertisement is to encourage patients to be aware of the dangers of high cholesterol and the possible prescription treatments available, the Crestor graph appears to satisfy the goal by showing results for each brand. In light of this point, some physician and consumer groups will probably consider the use of graphs and charts to be ethical since the data shows the range of LDL reduction for starting doses of prescription treatment options. The FDA did not issue a warning letter for this advertisement and, thus, did not consider the information to be deceptive. However, the ad is somewhat deceptive because it leaves out the difference between statins and superstatins. Although the text above the ad which states, “Cholesterol high? Trouble getting it low? Perhaps your answer is right here, below.” does suggest an alternative prescription for patients who are already working to lower their cholesterol (Crestor), the combination of verbal and visual text presents a heightened argument for patients to alter current treatment to a different product, a persuasive strategy that could be deemed as unethical by some individual stakeholder members, especially those who ascribe to the physician-focused healthcare model.

**Celebrity Endorsements**

A final visual component that is of importance in statin ads is the use of celebrity or expert endorsements. Statin advertisements have included a range of celebrity endorsements to appeal to various audience types including a 1999
campaign by Zocor which used NFL coach Dan Reeves (Henderson). Silvia Bonaccorso and Jeffery Sturchio of the British Medical Journal assert that consumers are well aware of the persuasive nature of DTC advertisements, “But it seems condescending to assume that consumers have no consciousness of these mixed motives and that their skepticism will be dissolved in their anxieties about health and illness” (qtd. in Segal 34). While consumers might already be wary of a celebrity endorsement, expert endorsements can still be more deceptive. Advertising ethics require that expert endorsements must “be based on the actual use of the expert’s knowledge” and that the product points being delivered “must be within the endorser’s expertise” (Drumwright 616).

Take for example, the most recent Lipitor advertising campaign in which Dr. Robert Jarvik, who is credited with inventing the artificial heart, encourages people to ask their doctor about the statin (Figure 4.6). The argument is compelling; a well-known physician who significantly advanced cardiovascular medical technology by developing the artificial heart is bound to satisfy the credibility test of even the most cynical critic. A closer look at the CV of this industry leader introduces some interesting points. Dr. Robert Jarvik did not take the traditional route to earn his medical degree. He earned his bachelors degree from Syracuse University, but his poor grades kept him from going to medical school, so he ended up graduating from New York University with a master’s degree in medical engineering (Bazell). Upon
graduating, Jarvik began working with Dr. William Kolff, inventor of the first
dialysis machine, who also happened to be working on an artificial heart
(Bazell). Jarvik used his engineering knowledge to alter the design of the
heart, creating a device that lasted a record three weeks (Teague 61). With
groundbreaking medical technology on his side, Jarvik was finally accepted
into medical school and he earned his medical degree in 1976 from the
University of Utah (Bazell). After receiving his medical degree, Jarvik
continued to work on mechanical heart pumps under the supervision of Dr.
Kolff, rather than practicing medicine (Bazell). In fact, Jarvik has never taken
an internship or practiced medicine (Bazell). Instead, he continues to advance
research in the use of the artificial heart with the hope for eventual FDA
approval. Jarvik credits this focus on invention to biomechanical leader Dr.
Robert Fusom, “He became my role model for a physician who could devote
his professional life to industry rather than clinical practice” (qtd. in Teague
61). Since earning his MD, Jarvik has continued to advance the success of the
artificial heart with his most recent model, the Jarvik 2000, still in clinical
trials.
Although consumers are typically hesitant to believe everything they see and hear in a DTC advertisement, the notoriety of Dr. Jarvik packs an effective punch. The ads have been so effective, that Pfizer saw a 15 percent increase in sales of Lipitor versus the figures from the same quarter a year before (Bazell). The ethical dilemma that arises in using Dr. Jarvik is one of perceived credibility. Although he undoubtedly has a superior understanding of the cardiovascular system, he does not have the same experience with patients that a cardiologist has. Physicians who frequently interact with patients will have a better idea of how a drug will affect different patient types. They will know what treatment options work best and will, most likely, have a better understanding of the common day-to-day health obstacles that face a patient. While Dr. Jarvik undoubtedly has a superior knowledge of
the workings of the heart, his lack of clinical practice experience tarnishes his credibility as a physician promoting a statin to patients because he does not have the same doctor-patient relationship as a practicing physician.

Despite the ethical problems with using Dr. Jarvik as a sponsor for Lipitor, the notion of the celebrity doctor poses another threat. Medical ethicist Katie Watson of Northwestern University asserts, “The danger of celebrity physician ads is that it creates a physician figure that is in competition with my physician” (qtd. in Schupak 52). In this respect, the word of one physician may be valued over another, a problem that could cause some patients to value celebrity advice over that of their own physician, who knows them and their medical history well. Although corporate stakeholder groups and some physicians will see the use of medical celebrities as beneficial, the practice has definite ethical problems.

**Ethical Challenges within the FDA Approval Process**

Now that I have analyzed some of the visual and verbal aspects of DTC statin campaigns, I will now discuss the FDA approval process that each campaign goes through. As is explained in Chapter 2, the FDA is in charge of regulating DTC advertisements within the pharmaceutical industry. Regulations and guidelines are established in an effort to control the persuasive tactics used by pharmaceutical companies and to promote patient education. If the regulations are not met, then the FDA issues a warning letter
to the offending corporation encouraging corrective action. Technically, if corrective action is not achieved, the FDA has the right to cease the dissemination of the drug and to ban it from the market. Although the FDA claims that all warning letters have been complied with to date (Gahart et.al.), several ethical dilemmas arise from this system. First, DTC advertisements are not assessed until after they are already on the market and the FDA regulatory process takes so long that the ads have often run their course before corrective action is suggested. This means that the FDA process takes so long, that by the time regulatory officials recognize that action is needed, the pharmaceutical company has already launched a new ad campaign (Pear).

The fact that DTC advertisements are not reviewed until after they are viewed by consumers introduces an ethical problem that is in dire need of a solution. From a stakeholder standpoint, the risk involved in exposing consumers to ads for prescription products such as statins is alarming. As previously mentioned, the linguistic and visual rhetoric presented in ads that pass regulations can still be of questionable intent such as the use of celebrity doctor endorsements, charts and graphs, or even fear appeals and deception. DTC advertisements deal with products that can have an adverse affect on a person’s health, thus a clear and ethical message is imperative. Corporate pharmaceutical executives and owners might contend that any breach in FDA regulations was unintentional which, even if true, does still not compensate
for any damage already done. Physician stakeholders might contend that misleading advertisements cause consumer panic or self diagnosis, thus further proving that regulations must be observed. With the increased number and methods of DTC pharmaceutical advertising, it is quite possible that the FDA does not have enough resources (including employees) to review ads; however, this does not make current procedures ethical. So how do stakeholder positions break down on a normative scale?

Individuals within stakeholder groups who lean more towards the utilitarian perspective would question the FDA timeline in terms of the greater good; however, it would be very difficult (if not impossible) to calculate whether or not specific patients were negatively affected by a specific deceptive advertisement. Deontologists on the other hand, would assert that disseminating DTC advertisements, which are already a topic of questionable ethics, to the public is an unethical action regardless of the positive or negative consequences which may ensue. Although no specific figures are available for the impact of the FDA ad review process of statins, 88 warning letters were issued by the FDA between August 1997 to August 2002 for prescription DTC advertisements (Pear).

Although the number of warning letters issued over a five-year period is small in relation to the number of DTC ads that run each year, it is also important to note that the FDA has no way of insuring or verifying that it
receives and reviews all new drug advertisements (Gahart et. al.). In a system that relies on the FDA to regulate the content of all advertisements, this lapse opens the door to ethics problems in DTC advertising. If the ad is reviewed and gets a warning, the drug can be stripped from the market if the parent company does not comply with corrective action. This action creates another ethical issue. The FDA could find itself in a dilemma because if the drug is stripped from the market, it is very likely that patients could suffer physical harm and even death. For example, a Lipitor ad dispersed in 2002 received a warning letter stating that it “inaccurately claimed that Lipitor may not have the side effects of other statins” (Simons 61). Although Pfizer did take corrective action by changing the wording of the ad, if they had not, then the FDA had the right to strip Lipitor from the market. What impact could this have had? Although the FDA claims that all warning letters issued on behalf of DTC problems have been successfully addressed, the organization may not see the benefit in taking corrective action against a company such as Pfizer because the company funds a great deal of research in the statin market. Stripping a product such as Lipitor from the marketplace could also halt research that could benefit a wealth of patients. Thus, utilitarian ethicists would assert that the most ethical choice is that which will benefit the masses. That is to say, if a small handful of consumers are deceived by the ads, then that is a smaller price to pay than punishing many by stripping Lipitor from
the market because of deceitful language use in an ad. In this respect, pharmaceutical companies have the advantage because they know that the repercussions will only be a slap on the wrist.

Conflicts of Interest

Up to this point in the chapter, I have analyzed DTC statin ads and their review process in relation to stakeholder theory while looking at the effect normative strategies impose on individual decisions. Now, I will briefly discuss the impact that conflicts of interest can have on DTC campaigns, as this is a relevant point for ethical determinations within the industry. As I mentioned in Chapter 3, stakeholder theory is an excellent decision-making strategy; however, it does have its challenges when all stakeholder groups do not share the same ethical point of view as is the case in many ethical issues concerning DTC campaigns. This paradox is further complicated in the pharmaceutical industry because so many of the stakeholders fit into more than one category. For example, many physicians are also employed as speakers by the pharmaceutical company and/or the FDA with “eight of the nine experts who wrote the latest cholesterol guidelines also serv[ing] as paid speakers (Moynihan and Cassels 4).

In addition, all stakeholders have the potential to become (if they are not already) consumers since statins are medical treatments. Even promotional grassroots campaigns that exist to increase consumer awareness of
the definition and nature of cholesterol are often funded by pharmaceutical companies. For example, a 2004 grassroots campaign by the Boomer Coalition was launched to advise consumers of the risks of heart disease and possible treatment and prevention options including the monitoring of cholesterol levels. The campaign was funded by Pfizer (Moynihan and Cassels 9). Even more surprising, over half of the FDA regulatory budget is funded by pharmaceutical companies (Moynihan and Cassels 19). A complex web exists within the pharmaceutical industry making it virtually impossible to get a fair and balanced perspective, which is perhaps the largest ethical problem within the DTC advertising of pharmaceutical products, let alone statins.

Conflicts of interest are everywhere in the pharmaceutical industry, usually affecting the efficiency of marketing efforts. Research conducted by Dr. Jerome Kassirer of Tufts University School of Medicine concludes:

Pharmaceutical marketing involves advertisements directed at physicians and the lay public, face-to-face encounters between drug salesmen and doctors, gifts to physicians, and engagement of physicians in the industry’s activities. These activities include clinical and basic research, physician education, and product promotion. In virtually all of these activities, physicians have financial arrangements with pharmaceutical companies that have certain value in themselves (for example, they provide education), but they also foster the companies’ marketing goals. (Kassirer 134).

From a stakeholder standpoint, the levels of conflicting interest presented here lead to an advanced form of the stakeholder paradox because the ethical
stances of stakeholder groups will most likely not be consistent. *Individual* members of a stakeholder group will bring forth different perceptions of ethically right and wrong, making a single standpoint for the *group* impossible. For example, healthcare professionals who adopt the utilitarian, patient-focused model of healthcare may downplay potential negative of deceptive qualities of DTC efforts because quantitative research points to both corporate financial success and patient benefit from statin campaigns. Thus, a physician who is a paid speaker for Pfizer will benefit financially from the drug’s success and most of her patients can benefit from the information they attain from the ads. From a utilitarian standpoint, the DTC ad produces the greatest good for the largest number of people. On the other hand, a physician in the same scenario but that advocates a deontological, physician-focused healthcare model, might assert that the financial and statistical consequences of DTC statin efforts do not matter. The deontological physician would posit that the ethics of DTC ads lie within the physician’s duty to the patient. Each of these scenarios poses a simple solution based on normative strategies; however, not all individuals will make ethical decisions so easily, nor will they be able to separate their role in each stakeholder group to come to an all-encompassing, ethical solution.
CHAPTER 5

ETHICAL PRESCRIPTION FOR DTC

Although some individuals will assert that DTC statin efforts can be deemed as ethical from a normative perspective, changes need to be made to the system in order to work towards a more ethical model supported by stakeholder theory. Is it possible to create an ethical model for decision-makers that will accomplish moral objectives yet still insure the existence and success of capitalism within the pharmaceutical industry? The answer is simple: yes; however, the solution is much more complex. Throughout this thesis, I have argued for the utilization and implementation of the stakeholder theory of ethics for decision-makers within pharmaceutical DTC efforts. Based on the analysis of statin advertisements in the last chapter, it is evident that several obstacles present themselves in relation to this theory:

- Disagreement among *individuals* that comprise a stakeholder group. For example, the sometimes conflicting views of the patient-focused versus the physician-focused healthcare models.
- Disagreement between stakeholder *groups*.
- Conflicts of interest.
- FDA regulatory process is too long and takes place after the public is exposed to an ad.
- Persuasive techniques used in DTC advertisements such as verbal and visual rhetoric, use of endorsements, and dissemination of information can be misleading.
Although these challenges complicate an ethical framework for DTC decision-makers, a solution is possible.

The goal of this chapter is to provide suggestions for changes within the creation, regulation, and distribution of DTC statin campaigns. I will present this information through the window of stakeholder theory, but with extra attention to the individual impact of normative ethics. The suggestions put forth in this chapter are meant to help decision-makers in the DTC process, so it is important to articulate strategies that are ethical and that make “good” business sense. In order to present these ideas, I will provide suggestions for decision-makers to determine an ethical course of action as well as introduce a few changes in the way DTC advertisements are designed and regulated. The chapter will conclude with a projection of changes within the statin industry that are currently underway.

**Including Stakeholder Theory**

Stakeholder theory is a valid solution to ethical obstacles within the DTC marketplace because the viewpoints of all affected groups must be taken into consideration. In order to implement this process, pharmaceutical companies should heed the advice of William Evan and R. Edward Freeman by creating a Board of Directors that is comprised of members from each stakeholder group (Evan and Freeman 82). In relation to DTC campaigns, this Board of Directors would include representatives from the following
stakeholder entities: marketing managers, employees, physicians and other healthcare professionals (with representative from both the physician-focused and patient-focused healthcare models), the general public, current patients, and the FDA. Evan and Freeman also suggest that a “metaphysical director,” or representative of the corporation, be unanimously elected by members of the board to “convince both stakeholders and management that a certain course of action was in the interests of the long-term health of the corporation” (Evan and Freeman 82-83). The director should function to negotiate the delicate balance between ethical and business decisions, that is, she will work as a mediator between the Board of Directors and shareholders of the company.

Representatives who serve on the board should be screened in order to prevent individuals who may have potential conflicts of interest from impacting decisions. For example, a physician would only be allowed to serve if she did not have an affiliation with any other stakeholder group. Since any individual has the potential to become a consumer of DTC products, board members should voluntarily step down from their position if they were prescribed a product of the parent company. I would also recommend that stakeholder representatives from the following groups: physicians and healthcare professionals, the general public, current patients, and the FDA, serve on the board on a voluntary basis rather than as a “working”
responsibility in order to avoid another possible conflict of interest. In a similar respect, board members who represent groups affiliated directly with the pharmaceutical company should not be compensated for their service.

Once a Board of Directors is created, the pharmaceutical company in question will need to determine how the board will effect corporate decisions concerning DTC advertisements. Decision-makers for DTC efforts may schedule regular meetings with the board in which problems with no clear ethical solution are explained. The Board of Directors would then have the responsibility of analyzing potential solutions to the problem. Although some decisions might be satisfied by a unanimous vote, it is likely that all stakeholder groups will not agree on most issues. This disagreement poses the stakeholder paradox, thus a system for weighing the viewpoint of each stakeholder group would need to be created. Regardless, the creation of a Board of Directors would insure that each stakeholder group has a voice in the creation and dissemination of DTC campaigns and the ethical implications that arise within them.

**Inclusion of Normative Ethics**

Stakeholder theory poses a valid solution to avoiding conflicts of interest and determining ethical strategies for decision-makers; however, stakeholder groups are comprised of individuals, thus normative ethics will also come into play on an *individual* basis. For example, advocates of the
physician-focused healthcare model will prescribe to a deontological emphasis of duty; whereas proponents of the patient-focused model will advocate a more utilitarian emphasis on the greater good. Normative ethics will also impact a DTC campaign through all of the individuals who work to create, review, and distribute an ad. Thus, while the Board of Directors may be consulted for major decisions, they will probably not impact every choice made by an individual stakeholder. Some companies such as Johnson and Johnson use values statements to encourage ethical behavior by employees; however, handing an employee a copy of corporate codes of conduct or values statements are only effective if the individual reads, comprehends, and implements the values presented.

By mandating an ethics workshop for all employees, pharmaceutical companies could ensure that each individual within the corporation is not only familiar with the organization’s values statement or code of conduct, but that they understand the moral value of such statements. While it is impossible to ensure that each employee has a desire to be ethical, workshops would at least promote ethical decision-making. As is mentioned in Chapter 4, most people are not familiar with the technicalities of ethics; therefore, employees that attend a basic ethics workshop may be overwhelmed with the specifics of normative ethics. In order to avoid this problem, ethics should be introduced in a simplified manner such as a fundamental list of things to
consider before taking action. For example, an introduction to marketing ethics might include the following parameters:

- The Golden Rule – Treat others as you would want to be treated.
- Professional Ethic – Actions should be acceptable by an “objective panel” of professional peers.
- TV or Newspaper Test – Would you be able to explain your actions via television or national news without guilt?
- Never Intentionally do Harm
- If in Doubt, Do not Act (Murphy and Laczniak 11)

If employees are trained to think of the consequences of or at least the motivation behind their actions, then they begin to think about ethical implications in an elementary sense. Ethics workshops could go further to explain the central concepts behind normative ethics and their application in business decisions, in this case, the creation and distribution of DTC campaigns. Introducing general guidelines such as these to employees will help individuals determine what they deem to be morally sound and what they do not. Although consensus among all individuals is still unlikely, it is important for pharmaceutical corporations to shape ethics into their corporate culture through an emphasis on ethical action.

**Shift to More Help Seeking Ads**

As previously mentioned, evidence shows that advertisements are effective sales tools because they create a desire for a certain lifestyle. In fact, the brand mentioned is not always the most important aspect of the ad, but
rather, it functions to create a visual representation of what is desired by consumers. Currently, most DTC statin efforts are product claim ads which discuss the features and benefits of a specific statin. DTC campaigns should shift focus to more help-seeking ads which will benefit not only the consumer, but also the pharmaceutical company itself. That is to say, a help-seeking ad that explains the risks associated with high cholesterol might ignite a consumer’s desire to lower her cholesterol levels, thus driving her to seek the advice of her physician. The physician would then be in charge of determining the specific statin brand to prescribe based on the needs and health history of the patient. The doctor would not feel pressured to prescribe a specific drug because the patient is seeking help based on symptoms rather than a product name.

Some members of the pharmaceutical industry, especially shareholders, may have a problem with this DTC strategy because the brand name is not mentioned in the ad. However, a closer look at the range of marketing efforts for statins reveals plenty of opportunities for a specific product name to be emphasized. DTC efforts are just one of many different marketing tools used by pharmaceutical companies. Sales representatives visit physicians on a daily basis, advertisements in academic journals are geared towards physicians, and scientific studies are sponsored by the makers of specific drugs in order to prove safety and efficacy. Help-seeking advertisements can create consumer
awareness of high cholesterol risks and increase the appeal of a healthy lifestyle. Marketing efforts targeted at healthcare professionals can then work to persuade physicians to prescribe a specific statin.

An increased use of help seeking advertisements also accommodates the two different models of healthcare in that physicians still conduct tests to determine patient ailments and they are still in charge of advocating appropriate treatment options. The patient-focused healthcare model still thrives because consumers are informed by help seeking ads and might be further encouraged to increase their education by visiting legitimate websites and/or consulting their physician. Patients can seek treatment or preventative measures, but the doctor will determine the specific treatment track. Thus, shifting to more help-seeking ads will accomplish the goal of alleviating symptoms and creating a desire for a healthy lifestyle and consumers educating themselves about treatment options and ailments. Consumers will still be persuaded to consult their physician about possible diseases or illnesses, but instead of asking for a specific drug, patients will ask for treatment options. It is then up to the physician to determine which specific statin she will prescribe. This accomplishes the ethical goals of all stakeholder groups including drug companies’ intent to make profits.
Changes in the FDA Regulatory Process

Since the FDA does not regulate help seeking advertisements, an increased use in the marketing tactic would decrease the number of ads that must be reviewed by the governing organization, thus allowing more time to conduct a more thorough investigation of other DTC efforts that will reach the public. One problem with the current system is that it takes too long and, as I discussed in Chapter 4, the FDA has no way of knowing if all DTC ads are reviewed. This system of governance allows the public to be exposed to ad content that may violate FDA regulations and guidelines. In order to avert the problems that can arise in such a system, changes must be made.

A certain number of FDA regulatory members should be assigned to each pharmaceutical company that distributes DTC advertisements. In this scenario, the FDA could become the final step in the ad process from creation to distribution. For example, once a Lipitor advertisement gets to the stage where it is ready to be disseminated to the public, the ad should be sent to the FDA group that works with Pfizer before it appears in print or broadcast media. This way, corrective action can be taken by Pfizer before the message in the DTC campaign has the potential to present incorrect or misleading information to the public. Implementing this system of FDA regulation would ensure that all ads are reviewed prior to circulation. Assigning a specific number of FDA officials to each pharmaceutical company should also speed up
the review process thus eliminating another problem with the current regulatory process.

In the event that these changes are too expensive or are not feasible to implement, the FDA should then consider an alternate plan to change the way warning letters are handled. As is discussed in Chapters 2 and 4, the FDA uses warning letters to require corrective action for DTC advertisements that do not follow guidelines. Instead of just sending a letter, the FDA should impose a financial penalty to go along with the letters. Pharmaceutical companies, like most other companies, are in business to make the greatest profit possible. If a financial penalty accommodates each warning letter received for DTC corrective action, the creators of the campaign will be further encouraged to compose advertisements that do not go against FDA regulations.

**DTC Advertising Specifics**

Up to this point in this chapter, I have proposed changes in the regulatory and decision-making strategies of the DTC process. Now, I make further suggestions dealing with specific advertisement content such as a verbal and visual balance of content and the constraints of celebrity endorsements. While regulatory and decision-making strategies will help facilitate a more ethical environment within pharmaceutical companies, the direction of specific ad content must also be modified in order to present a DTC campaign that accomplishes the goals of all stakeholder groups.
As is discussed in Chapter 4, the verbal and visual content in a DTC statin advertisement can present misleading information even if the ad is within FDA regulations. Visual and verbal cues work together to deliver a message to consumers about a specific product. They also work to create a desire for a certain lifestyle, in this case, a healthy lifestyle. If DTC campaigns are permitted because they have the potential to educate patients about the symptoms, risks, and benefits of a specific medication, then the verbal and visual text within the ad must be clear. For this reason, all DTC advertisements should use the new PI format that was created by Pfizer. As is illustrated in Chapter 4, the traditional format relies on medical terminology that is not clear to a general audience. The new format provides information through the use of simplified language that can, more likely, be understood by the general public. In addition, the new PI is more visually appealing because, in this case, statin information is divided into clearly labeled sections and bullet points further break down the material presented. The traditional PI information in DTC ads is not laid out in a visually-friendly way since font size is miniscule and bold text is the only divider of information. Thus, pharmaceutical companies should switch to the new PI format to achieve higher consumer understanding and response to the information.

Another DTC ad component that needs special attention is the use of celebrity endorsements. As is discussed in Chapters 3 and 4, most consumers
do not put full faith in the advice of celebrities such as sports figures or actors in relation to prescription drugs. However, the recent use of Dr. Jarvik to promote Lipitor has called into question the distinction between celebrity and expert endorsement. This is an important distinction because, as is noted by medical ethicist Katie Watson, the introduction of expert endorsements within the DTC environment could lead to conflicting claims between the person endorsing a product and a patient’s physician (Schupak 52). Regardless of the questionable credibility of Dr. Jarvik’s endorsement of a cardiac medication (mentioned in Chapter 4), the contention that his expert endorsement may negatively impact the doctor-patient relationship holds strong ethical implications. Consumers may be hesitant to accept the medical advice of an athlete, but they may take the “expert” advice of a physician in a commercial much more seriously. Although expert endorsements may effectively increase company revenue, the assertion that they have the potential to harm the doctor-patient relationship is reason enough to ban the practice. Going further, this particular DTC strategy is of questionable ethics because a physician in an advertisement is also an employee of the pharmaceutical company; a conflict of interest ensues.

**Looking Forward**

Pharmaceutical companies that encourage DTC decision-makers to implement the stakeholder theory of ethics will benefit ethically as well as
financially from the recommendations posed in this chapter. Throughout this thesis, I have worked to establish a theoretical framework of ethics in relation to DTC advertisements, particularly those in the statin marketplace. My analysis of statin DTC campaigns exposed problems that exist within stakeholder groups, such as the ethical differences between a physician-focused and patient-focused healthcare model. Further, my deconstruction of statin advertisements revealed implications that can arise within visual and textual elements of ads. Although the FDA works to regulate the content of DTC campaigns, many problems exist within the current regulatory process that must also be addressed. Pharmaceutical companies that choose to market their prescription products through the use of DTC advertising should follow a stakeholder theory approach to decision-making, while still acknowledging the impact that individual normative ethics can have on marketing decisions. Implementing the above suggestions will push drug companies closer to ethical advertising practices without sacrificing the financial emphasis of the company. The strategies will help facilitate effective communication between all stakeholder groups in order to achieve an advertising message that increases company profits, advances the reputation of the company as an “ethical” choice, and satisfies government regulations thus, a good business decision.

While the suggestions posed herein are centered on print and broadcast DTC efforts, it is important to note that advancing technologies allow for a
more diverse and far reaching effect of DTC campaigns. For example, pharmaceutical companies also advance advertising measures through the use of product websites, cell phone text messages (Mehta 82), and even taxi receipts (Dickersin and Goodman 656). Broadcast and print media have been the traditional methods pharmaceutical companies use to reach the consumer; however, it is likely that the focus will shift if these newer DTC opportunities prove to reach a greater audience. New technologies are sure to introduce new ethical questions into the DTC debate.

In addition to new outlets for DTC advertisements, decision-makers must also recognize the ever-changing environment of the pharmaceutical industry. I have centered my discussion of DTC campaigns upon statins, but this drug class may not always require a prescription. In fact, the makers of Zocor and Pravachol have already requested FDA permission to sell the statins over-the-counter (OTC), which means consumers would not need a prescription to take a statin (McCain 47). Although the drug makers have not yet received permission in the US, statins were made available OTC in the UK in late 2004, though the decision has incurred a great amount of debate (Ross 1543). If statins do become OTC products in the US, then the DTC issues I discuss will change. However, although I encourage pharmaceutical decision-makers who promote *statins* to implement the ethical strategies in this
chapter, the theories behind my recommendations can apply to DTC campaigns of many prescription products.
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