Direct-to-Consumer Advertising of Prescription Drugs:

An Ethical Assessment

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Introduction

Direct-to-consumer advertising (DTCA) of prescription drugs is a very prominent component of the pharmaceutical industry’s marketing strategy in the U.S. Out of approximately 200 countries in the world, only the U.S and New Zealand allow this method of advertising (Frosch 2007, p. 6). It is debated whether DTCA benefits the consumer or is primarily an advertising tool for corporations. It is important that we not only look at this debate from a business or societal standpoint, but also from an ethical standpoint. I will examine DTCA from an ethical perspective and assess its ethical status. I will argue that DTCA is not ethically justifiable.

I will provide my interpretation of DTCA as follows. Direct-to-consumer advertising, or DTCA, is the promotion and marketing done by the pharmaceutical companies for their brand name drugs that cannot be purchased without a visit to the doctor who has the authority to write a prescription for that medication, based on the patient's condition and health. The advertising is conducted by targeting the consumers directly in order to inform them about the availability of certain prescription drugs through consultation with their physician. This form of advertising is done through the media through televised commercials, print advertisements, online advertisements and radio advertisements. Since the target of these advertisements is the patient, this information is made available to this group of consumers without the need to hear about them through their personal physician who may or may not volunteer that information to the patient.

To illustrate the magnitude of the spending on DTCA, I will present some facts below. Ever since the U.S. Food and Drug Administration (FDA) expanded the use of multi-media advertisements by drug manufacturers in 1997 to promote the sales of their products, DTCA has been used extensively by the industry. The rapid rise of health care costs in the U.S. over the years has been staggering with a total cost of $2.5 trillion in 2009, or approximately 18% of the Gross Domestic Product (GDP) (DHHS, 2009). The prescription drug component of the expenditure is about 10% of the annual cost. Such high sales revenues could not be possible without a calculated and aggressive marketing strategy and without an enormous amount of money spent on DTCA by the pharmaceutical industry which was $2.5 billion in 2008 (Hanson, 2011). With these significant levels of expenditure by this industry in trying to attract
the public attention, it is my intention to weigh both sides of the arguments for a balanced analysis of the advantages and drawbacks of DTCA.

In Chapter 1, I will go into the background of DTCA and give relevant information to provide a better understanding of the arguments presented in Chapters 2 and 3. In Chapter 2, I will present, analyze, and assess the arguments in favor of DTCA from an ethical perspective. Although not a sufficient argument to conclude that DTCA should be allowed, I will argue that DTCA does not violate the rights of others. Proponents argue that by allowing DTCA, there is great competition between the pharmaceutical companies which is what causes the prices of prescription drugs to be low. Proponents’ also contend that DTCA is creating awareness amongst consumers and educating them on medical matters. This in turn leads to the proponents’ claim that DTCA is what has given patient’s more autonomy and empowerment when it comes to their health. In Chapter 3, I will present, analyze, and evaluate the arguments against DTCA through the lens of normative ethical principles. I will argue that DTCA is more of an advertising tool than a means of educating the public. I argue that this form of advertising leads patients to believing that they have increased autonomy when they are merely consumers. This new found autonomy of the patient plays a part in my argument that the doctor patient relationship has been damaged due to DTCA. I refute the argument in favor of DTCA regarding the price drop due to competition with evidence that proves otherwise. I also argue that DTCA has led to pharmaceutical companies using consumers as means to an end with the end being their high profits. Finally, in Chapter 4, using Rawls’ difference principle as a guide, I will summarize my findings based on the validity of the ethical arguments that I have presented on behalf of both sides and conclude that the arguments against DTCA are stronger than the arguments in favor.
1. Background on DTCA

The Food and Drug Administration (FDA) is part of the U.S. Department of Health and Human Services with responsibilities for the protection of public health by ensuring, among other things, the efficacy of drugs sold to the public (FDA). Among these responsibilities are the requirements that the drugs be safer, more affordable and that the public can have access to “accurate and science-based information” about the use of medicines (Ibid). Based on this authority, the regulation of DTCA has been the responsibility of the FDA.

In 1997 the FDA made minor changes to the “Guidance for Industry” document which required drug advertisements not to be deceptive. To the industry’s relief, it was no longer required to provide a “brief summary” to accompany broadcast ads (Schwartz et al 2009, p. 345). This, as we shall see in a later chapter, was a source of controversy since complete information was not made available to the public. The “brief summary” required the advertisement to indicate the proper use for the drug, the possible side effects involved, contraindications, and warnings (Palumbo et al, 2002, p. 428). Giving a “brief summary” of the drug being advertised was not possible during the short time-slots over the air so print media was the most popular form of advertising initially (Donohue 2006, p. 674). However, the advertisements still must contain a “fair balance”, meaning that it needs to have an even amount of risks presented as there are benefits for the particular drug to avoid being misleading (Palumbo et al, 2002, p. 428). In order for consumers to obtain more detailed information about the drug, the FDA requires that commercials provide a toll-free number, a website for reference and a recommendation for the patients to consult their doctors (Schwartz et al 2009, p 345). In essence, the industry was only required to provide the most critical information over the broadcast while the rest of the information could be available only upon request by the patient.

The skyrocketing rise in DTCA by the pharmaceutical industry also commenced in 1997 following the relaxation of the rules by the FDA, which remains in effect today (Calfee 2002, p. 3). To bring some perspective to this rapid growth, we can compare DTCA spending in the years preceding 1997 and post-1997. In 1993 these spendings were $150 million, whereas in 2005 it was $2.24 billion (Dhaval et al, 2010, p. 1). During the early years of its introduction, DTCA’s annual growth rate
was 33%, while during the same years direct-to-physician advertising, also known as “detailing”, grew at a rate of about 12-13% (Ibid, p. 4). The way DTCA works is by exposing the consumer to a patented drug that is on the market but not available without a prescription. Through encouragement and persuasion, DTCA opens the possibility of doctor visits by the consumers to discuss their medical problems. This would eventually lead to prescribing and the sale of the drug being marketed. The moral implications of this alleged economic objective of the industry as well as benefits to the consumer will be evaluated in the following chapters.

Another area of DTCA that also took off at a rapid pace was advertisements through the internet that catered directly to the consumers seeking information. Reference information can now be found easily on any health related issues including prescription drugs on websites such as WebMD whose advertising slogan is “Better information. Better health” (WebMD). The print media has been widely used as a place for advertisements either directly to physicians or the lay public. Ads that are directed to the health professionals appear in scientific journals while ads directed to the common consumer, or DTCA, can be found in every magazine category (Mehta et al, 2003, p. 197). Some popular magazine categories include news magazines, fashion magazines, health magazines, sports magazines and the numerous home improvement journals targeting both men and women.

With this multi-faceted outreach, the pharmaceutical industry has submersed itself in one form of DTCA or another in most media outlets to get the message about its brand name prescription drugs out to the public. Although most scholarly research found in the literature on DTCA has delved in its impact on society from the economic, social and health perspectives, few have tied the arguments to the ethical principles of philosophers whose work can be used for the moral interpretation of the effects of DTCA on society which I will do in Chapters 2 and 3.
2. Arguments in Favor of DTCA

The pharmaceutical industry’s existence is essential to the continued health and minimization of suffering for millions of people through the manufacture of drugs. However, society has questioned the conflict between this industry’s commercial interest and the requirement to follow ethical principles and guidelines when it comes to their use of DTCA. In this chapter, I will discuss several arguments in favor of direct-to-consumer advertising.

2.1 Property Rights and Moral Rights

The pharmaceutical industry is the owner and patent holder of prescription drugs. Because of this ownership of property, it possesses certain rights and privileges. Among those is the right to advertise directly to the consumer. In this first argument, I will show that the rights argument supports the moral legitimacy of DTCA as long as they are not violating others’ rights.

Modern day libertarians derive some of their theories from one of the twentieth century contemporary philosophers, Robert Nozick (Arnold 2003, p. 156). They believe that individuals should be free to decide what is good for them as long as they respect similar freedom for others. Nozick’s ‘entitlement theory’ claims that if people are entitled to the goods that are currently in their possession, any distribution of those goods that is conducted in a free manner is considered morally just (Kymlicka 2002, p. 103). As a property owner, people have the prerogative to do whatever they think is fit when it concerns their personal holdings. Drugs are the property of the pharmaceutical industry because they are produced by their talents and labor. If they wish to give them away for free or set a high price for them, as the rightful owner of that property, they have the right to do so. By extension of these rights, they may also use any means that they can think of to sell their goods to whomever these please. If they target the rich or the middle class, that is also their right. DTCA is one way to get the attention of the buyers and they are entitled to use this method of advertising as a way to market and sell the products. Kymlicka further argues that, “Once people have appropriated private property, a free market in capital and labour is morally required” (Ibid, p. 116). With respect to corporations,
libertarians’ viewpoint is that it is the responsibility of these business entities to make profits for their shareholders as long as they are working within a simple framework of not violating other’s rights. DTCA abides by these rules.

Libertarians also subscribe to the philosophy of free markets with minimal government intervention, which brings us to ‘negative rights’. Negative rights are defended by libertarians and they use these as common ground for their view. They perceive property rights from two distinct categories, namely positive rights and negative rights (Arnold 2003, p. 157). “Negative rights constitute shields against the unjust violation of individual freedom. Positive rights on the other hand constitute entitlements to things that are necessary for the exercise of individual freedom” (Ibid). Arnold also asserts that corporations have the duty to respect the basic rights that are part of the foundation of societies. In return, their actions are morally permissible if they do not violate the basic rights of society. Practice of DTCA is considered a negative right. When pharmaceutical companies conduct DTCA campaigns, their negative rights are what protect them from violations of their freedom to advertise. They are, therefore, acting within their moral rights.

Libertarians, furthermore, believe that the main reason for having a government is that it will ensure that the rights of individuals with respect to their properties are protected (Garland 2007, pp. 72-73). Along the same line of reasoning, Robert Nozick also added that as far as these individual rights are concerned, no person, group, or government may do any harm to them (Kymlicka 2002, p. 103). Therefore, not only does DTCA not violate anyone else’s rights, but society should also protect from others who wish to violate the industry’s right to advertise. As a property owner, the pharmaceutical industry’s practice of DTCA is morally acceptable.

2.2 Competition Benefits Cost of Drugs

The pharmaceutical industry is an extensively competitive industry that needs advertisements as a major component of its business strategy for its growth and expansion. DTCA has been argued by the proponents as the reason for keeping drug prices low. The existence of competition between the pharmaceutical companies, made available through DTCA, has been a contributing factor (van de Pol et al 2010, p. 215). Proponents of DTCA have also argued that there would be serious drawbacks
if this form of advertising was not allowed, as it would drive the prices up. A competing new drug on the market would have to ensure that it is of a higher quality and a lower price than available alternative drugs for it to survive, all of which results in a great advantage to the consumer. It has also been pointed out that if the drug is effective in curing a costly disease, or preventing other expensive medical complications and surgeries, it might be a bargain even if the price is high.

As with the products of any industry, competition results in the overall reduction of drug costs. Research conducted by the American Enterprise Institute has also found that because of competitive forces in the market brought about by advertising, there is a reduction in the cost of drugs (Calfee 2002, p. 179). This satisfies Rawls’ difference principle (Rawls 2001, p. 43) from the standpoint that the inequalities realized through the higher profits made by drug companies do serve a useful purpose by the competitive environment that DTCA provides to the general public. Low prices are considered to be of high value. Since DTCA helps in achieving this outcome, it is morally justified.

2.3 Patient Autonomy

To be considered autonomous, an individual should be directed by one’s own desires, situations and considerations without any form of imposition or domination by others (Christman, 2011). Immanuel Kant has a great deal of work devoted to moral philosophy and, in particular, to the subject of autonomy. In this thesis the Kantian meaning of autonomy that suggests that all “rational human wills are autonomous” will be the basis of our understanding of patient autonomy (Johnson, 2010). Kant further considered freedom to be an intrinsic part of autonomy. A similar view of autonomy is shared by John Locke who believed that people have to be able to make rational decisions for themselves in order to be part of a well-ordered society (Engelhardt 2001, p. 286).

An essential role of DTCA is to provide awareness and access to educational information on medicines. DTCA is educating the public on medical matters by giving them information on conditions and on treatments in the form of prescription drugs. Proponents have successfully argued that DTCA results in increased awareness which could lead to detecting a potential disease, diagnosing it and eventually treating
it with proper medication (Dubois 2003, p. 2). Increased awareness is beneficial for both the patients and doctors since the patients can now come to their doctors with advanced preparation and some knowledge about their health issues. This enhanced awareness encourages the patient to exercise his or her autonomy. Having such knowledge is very helpful in conducting a meaningful conversation instead of a one-sided conversation with the doctor in regards to the patient’s ailments. Greater consumer involvement in their own healthcare can be seen as a very positive development that should be credited to DTCA (van de Pol et al 2010, p. 215).

Patient education through the use of DTCA has been an educational tool, as seen in this confirmation. Five years after DTC advertisement regulations were relaxed by the FDA, the National Health Council, which is an organization of over eighty health and medical specialty associations (e.g., American Heart Association, the American Medical Association and the pharmaceutical trade associations) unanimously agreed to a statement that “…DTC advertising was an effective tool for educating consumers and patients about health conditions and possible treatment” (Calfee 2002, p. 8). Patients do not have the same level of information as their physicians and unless they take a proactive role in learning more about the availability of new prescription drugs, very important medical conditions might remain undiagnosed. These include treatable conditions of depression, diabetes and osteoporosis (Ibid, p. 12). DTCA now provides that educational opportunity that did not exist before.

Since educating the public is conducive to greater autonomy, the most prominent argument by proponents of DTCA is that it promotes patient autonomy. This moral argument is the backbone of DTC advertising and one that the pharmaceutical industry has been aggressively promoting. For more than a decade, patients have been involved to a greater degree in voicing their opinion when consulting with their physicians and playing an active role in the choice of their treatment. Armed with the knowledge they have acquired from broadcast, online or print media, they now have some input in their treatment process and the medication being prescribed to them. DTCA has increased patient autonomy by giving them the opportunity to have some contribution in their personal health treatment process. They are no longer “passive recipients of information that [has been] filtered and dispensed by health care providers” (Jacobson 2007, p. 3).
Once the patient becomes more autonomous through exposure to DTCA, it inherently leads to empowerment which is different from autonomy. Empowerment is a process of increasing the capacity of individuals by giving them power to act on things that are important to them (Page, 1999). Access to information has given rise to patient empowerment which is a term used to describe patients’ direct involvement in the decision-making process that used to be the domain of the physician (Jacobson 2007, p. 3). They are taking charge of their own health issues and discovering what the best possible solution is for them. This acquisition of empowerment is a positive achievement that must be attributed to DTCA. In the doctor-patient relationship, some information can now be equally shared between the patient and the physician. Empowered patients are able to manage their health care better than those who play a passive role in the relationship with their doctors. The hierarchy in medical care has been impacted as a result of patient autonomy and empowerment.

Better earlier diagnosis is also one of the favored outcomes of DTCA. The treatment of cholesterol is a good example of a condition that can remain undetected unless the patient is made aware of it through proper screening. Calfee’s research presents evidence that increased pharmaceutical drug consumption, resulting from DTCA, has lowered the overall healthcare costs, especially for HIV/AIDS and ulcers (Calfee 2002, p. 10). DTCA has been credited for this awareness with subsequent improvement in patients’ health through doctor visits and medication.

Depression cases are highly prevalent in the U.S. and, therefore, a good market for DTCA (Donahue et al, 2004, p. 116). A study in the early 2000’s unveiled that as much as fifty percent of people with depression received no treatment at all. Patients who were treated for depression and received medication grew from about 37% in 1987 to almost 75% in 1998. Besides mental health, undiagnosed and untreated depression can impact society economically. Increased awareness has benefited this group of patients who have sought medical help and improved their quality of life substantially.

DTCA encourages patients to exercise their rights to autonomy by asking their doctors specific questions about their health. The medical care system now sees the patient, not the doctor, as the center point (Parker 2003, p. 282). This is a great stride in the progress toward patient autonomy because DTCA conforms with Kantian moral principles that advocate the establishment of these rights for all people.
Having presented the proponents’ point of view in this chapter, I will present arguments from the opponent’s standpoint in the next chapter to lay the groundwork for a fair and objective assessment of the advantages and the disadvantages of DTCA. I will then formulate my position on the effectiveness of DTCA, based on applicable ethical principles in the final chapter.

2.4 Summary of Chapter 2

In this chapter I have described the libertarian views of property rights. Using these rights as the basis of the argument, I have shown how the drug industry’s practice of DTCA does not violate the rights of others and, is therefore, morally acceptable. I have explained how competition among the pharmaceutical companies is helpful in lowering drug costs, as claimed by proponents. Patient autonomy is the cornerstone of the benefits claimed by the proponents. I have assessed their arguments in a logical manner by showing how DTCA starts with educating the public about drugs. This education leads to autonomy which, in turn, leads to patient empowerment. As a result, there is a new patient-doctor relationship established which looks at the patient as the focal point of the health care system. Patients get a chance to obtain earlier diagnosis that, in the long run, lowers the cost of patient health care.

3. Arguments against DTCA

According to a report by the Kaiser Family Foundation, total prescription drug sales in the U.S. topped $300 billion in 2009 compared to $40 billion in 1990 and $234 billion in 2008 (Kaiser 2010, pp. 1-4). This did not happen by chance. As stated by IMS Health (an entity that collects pharmaceutical sales and prescription drug data throughout the world), the growth was due to the stronger demand for prescription drugs. This unusual increase in revenue was during a period when the U.S. was going through an economic recession. The contributing factor to this dramatic rise is the power of DTCA expenditure by the pharmaceutical industry which, in 2009 reached $4.3 billion compared to $1.8 billion in 1999. In this chapter I will delve into some of the ethical principles underlying the opponent’s point of view that demonstrate a completely different perspective on the same subject and show that this method of advertising does not benefit a large segment of patients and consumers. I will draw
from Rawls’ theory of justice to analyze whether or not the benefits of DTCA reach the least advantaged. The opponents consider the misleading educational benefits as the core argument against DTCA. With due considerations to this argument I will, however, refer to Rawls’ difference principle as my main argument that DTCA’s benefits do not reach the least advantaged member of society. I will also shed light on several other arguments such as misrepresentation of autonomy, ineffectiveness of competition between pharmaceutical companies, doctor-patient relationship, and how the end does not justify the means, all of which strengthen the claims of the opponents.

3.1 Patient Autonomy versus Consumerism

Patient autonomy and empowerment have been some of the main discussion points used by the industry in support of DTCA. Opponents point out that the industry has successfully used the empowerment discourse to achieve its own end very successfully (Fisher et al, 2008, p. 1). They argue that under the guise of autonomy, patients have been led to become consumers of goods. An autonomous customer is not the same as an autonomous patient. Autonomy as applied to consumerism is associated with making irrational preferences and desires rather than informed and rational choices. This perceived power brings with it all the benefits and behaviors associated with consumerism mentality which means that, as a buyer, the patient has the right to selectively choose the product of his or her preference. They feel that they have the right to buy prescription drugs based on their personal preferences as well, which may not be in their best interest.

The pharmaceutical companies were bolstered by the reform movements during the last decades of the late 20th century by the socially conscious citizens demanding greater autonomy in health care, mostly related to HIV/AIDS drugs (Donohue 2006, p. 681). The debate over consumer autonomy has been misused by advertisers of medicine who try to convey the message that the patients’ choice in the selection of drugs should be respected. This is being accomplished by stirring the emotions of the consumers with highly optimistic ads while understating the potentially harmful side-effects. Some of the risks that go undetected during pre-market trials may cause harm before the problem is recognized (Vogt 2005, p. 6). In
reality, the principle of autonomy is no longer valid when the consumer is only equipped with partial information or has been misled by DTCA into thinking that the advertised product must be good for his or her use. As one researcher has pointed out, “To be autonomous requires at least the capacity to understand intellectually […] what is at stake” (Englehardt 2001, p. 286).

The benefits of the drugs that the consumers wish to purchase are usually overstated or the risks and side-effects may be omitted or minimized (Hoek 2007, p. 1). The drugs may be inappropriate for the treatment of the disease, especially in cases where the patient is self-diagnosing. DTCA has transformed the patient into a consumer of goods which is good for the economy, but may not be good for the patient. If this is true, opponents argue, patient autonomy has been misused to open a new path to consumerism, a path that is not beneficial to the well-being of the patient but one that has much appeal to the pharmaceutical industry (Fisher et al, 2008, p. 3). Granted that the patient feels more in control and autonomous but, as pointed out earlier, the risks and rewards should be weighed carefully.

The majority of the advertisements are for the patent-protected, brand name prescription drugs that are the best selling drugs on the market, also known as “blockbuster” drugs (Findlay 2002, p. 4). The patients who have seen the advertisements arm themselves with the brief information they have received and approach their doctors for prescriptions. There are also visits made by the representatives of drug manufacturers to doctors’ offices to push their products. They provide free samples for the physicians to try the new products on their patients (Parker 2003, p. 282). These are medicines that could be potentially harmful if taken inappropriately. With these two forces at work, namely the patient coming in with a predetermined choice based on the consumer mentality, coupled with the representatives pressuring doctors to prescribe their products, a risk is that the patient can be given a prescription that is not necessarily the one that the doctor would have preferred. The doctors are the ones caught in the middle with much reduced authority in how the treatment should proceed. As pointed out in the previous chapter, proponents claim that autonomy has made patients, not the doctors, the focal point of the health care system as a result of DTCA. We see, however, that patient autonomy is not well-served here because the patient leaves the doctor’s office falsely thinking that he or she has had direct a contribution in the treatment procedure whereas, in reality, it is the consumer behavior that has dominated the process. For the doctors,
this double pressure from both sides is not ethical since it sends a message that the patient’s well-being and speedy recovery are no longer the intent of the therapy, but the sale of brand name drugs are. Patient autonomy has been misrepresented by DTCA.

3.2 Drug Prices and Competition

Pharmaceutical companies claim that their competition brings the prices down, but the prices of these drugs are nowhere near being affordable for everyone. Opponents argue that there are no visible advantages of competition between pharmaceutical companies associated with DTCA that benefit the consumer. The high costs related to this form of advertising are what contribute to the higher cost of drugs (van de Pol et al, p. 215). New competitors also find it extremely difficult to gain a foothold in the market due to the high-entry barrier of the drug industry. This barrier is due to the soaring expenses of DTCA. By the time the costs of DTCA are included in the price of the prescription drug, it becomes even more out of reach for many in the U.S.

As an example, research conducted by the American Medical Association published in the Archives of Internal Medicine in 2009, found that Clopidogrel, a medicine used for the prevention of heart attacks and strokes, increased in cost by 12% immediately after DTCA campaign commenced (Law 2009, p. 1971). The same study found that the trend over the following years did not change appreciably and there was no reduction in cost over the years after initial introduction through the period of study, 2001-2005. This refutes the proponents’ claim that DTCA creates a competitive environment that results in the lowering of drug prices for the consumer. Rawls’ difference principle guides us by suggesting that economic inequalities are justified as long as they also provide the maximum benefit to the least advantaged in society (Rawls 2001, pp. 42-43). This principle that allows limited inequality for the well-off seems to have been misused here by the people who are benefiting from the higher prices but, simultaneously, making it more unreachable for the poor and the disadvantaged.

Instead of spending on DTCA, the same expenditure could be used to bring down the cost of drugs for all layers of society. In 2009, statistics show that 50 million people in the U.S. did not have health insurance (Kaiser, 2010). The ads placed by the
industry on broadcast and print media are equally accessible to all people regardless of their income level. If drug costs are so high that only people with insurance have access to it by requesting their doctors for a prescription, the disadvantaged are left out with no benefits trickling down to their level. This argument also shows that DTCA does not benefit all levels of society.

3.3 Rawls’ Theory of Justice

John Rawls has given us two important principles of justice that enable us to find our way through the ethical maze of theories that lead us to live cooperative lives (Rawls 2001, p. 42). This is part of Rawls’ idea of a social contract. This is also my interpretation of Rawls’ theory of justice and I chose to use his principle because it is intuitively appealing. The first principle is that of “equal basic liberties” which includes “freedom of thought, liberty of conscience, political liberties […] and the rights and liberties covered by rule of law” (Ibid, p. 44). Social justice would not be possible without equal basic liberties and is a precondition to the second principle (Ibid, p. 42). The second principle states that inequalities are acceptable as long as they also result in the greatest benefit for the least advantaged in society. This is also known as the difference principle. The first principle of equal basic liberties, also known as the principle of equality, has broad support (Resnik 2004, p. 99). The interpretation of the second principle, the difference principle, is important in the understanding of the moral arguments related to justice and fairness in society. His second principle is appealing as it can be related to the disadvantaged people who do not benefit from DTCA. As Rawls states more clearly:

The difference principle expresses the idea that, starting from equal division, the more advantaged are not to be better off at any point to the detriment of the less well off. But since the difference principle applies to the basic structure, a deeper idea of reciprocity implicit in it is that social institutions are not to take advantage of contingencies […] except in ways that benefit everyone, including the least favored. (Rawls 2001, p. 124)

Returning to our discussion on DTCA, I argue that this form of advertisement does not benefit the least advantaged. Now, let us examine who are the more advantaged
and who are the least advantaged in today’s society. Again, this is my interpretation of Rawls’ theory of justice as it is related to the people who cannot afford prescription drugs. The powerful pharmaceutical industry has a greater advantage due to the fact that it has vast financial resources, vast intellectual know-how in the field of medicine, vast talent in business management and, most importantly, it is the owner of the property known as drugs that have propelled it to such a high position in society. The least advantaged, on the other hand, are people who are at the bottom of the social strata who may either be unemployed, or who may have an income that is below the poverty level with no medical insurance to cover the cost of their health care, doctor visits or medicine.

Rawls has respect for owning and holding property for one’s exclusive use (Ibid, p. 114). He believes that ownership of a property gives a sense of independence and self-respect, both of which are essential for moral power. However, this limited interpretation does not mean that those without property should be deprived of the feeling of independence and self-respect. Rawls’ principles allow for these contingencies without diminishing the worth of people who are not well off. In a parallel manner, the drug industry, as the owner of the property, may have exclusive rights and all the privileges that come with that ownership. However, when it spends billions of dollars marketing its property or commodity directly to the consumer, the industry immediately builds a barrier to exclude those who cannot afford the drug but who are nonetheless, subject to constant barrages of advertisements, especially TV broadcasts, on a daily basis. Proponents might claim that in due course the prices may drop as a result of DTCA, but as discussed in section 3.2 of this thesis, (Drug Prices and Competition) this price reduction does not materialize. The prices maintain the same trajectory as before initiation of DTCA. As most of the advertised drugs are usually more expensive, the disadvantaged members of society are the ones who do not see any of the benefits. This supports the argument that the inequality that benefits the rich but not the least advantaged, which is a result of DTCA, is unacceptable.

Rawls’ theory is also related to DTCA from the standpoint that money is an “incentive” that allows pharmaceutical companies to develop better drugs which are supposed to benefit the least advantaged. The main role of incentives, according to Rawls, is to ensure that there is increased productivity that benefits everyone in one form or another (Ferrero, p. 3). This can be brought about by either encouraging
people to work harder or be involved in work that makes use of their special talents and skills.

In the case of the pharmaceutical industry, incentives are the above-average profits made by them through their DTCA campaigns. Even though Rawls would accept the incentive argument on the basis that it produces more goods, his reasoning about the difference principle is valid when applied to DTCA because it exposes the fact that the disadvantaged receive no benefits from the inequalities. The billions of dollars of revenue the drug industry makes from sales do not trickle down to the poor. If the industry did not take the incentives, and worked for the compensations they would normally receive, the disadvantaged, especially, would gain incrementally more.

The consequence of not getting incentives does not mean that the drug companies will not be making a profit. They would be making very reasonable profits even without the incentives as compared to the meager gains received by the least well-off. Therefore, one way that the disadvantaged can receive benefits would be for the drug companies to not take advantage of the inequalities provided in Rawls’ argument and return the incentives. Gerald Cohen, a contemporary Marxist philosopher, also has the point of view that differential incentives are not needed to increase productivity (Cohen 2001, p. 265). He asserts that the well-off or the talented do not need the incentives to work harder to benefit the worst-off. Instead, the talented should work harder without any incentives if they really cared for justice because, by doing so, they would benefit the disadvantaged even more. Cohen’s reasoning as applied to DTCA would be that the drug companies should work hard for the benefit of mankind. In reality, incentives are what drive mankind to strive harder for higher goals and greater achievements, however there are many people who are passionate about what they do and do not need an incentive to work to their full capacity. Furthermore, there actually is a different non-monetary incentive for the drug industry; they are able to have the opportunity to give a helping hand to the least advantaged.

DTCA, as we have seen, does not satisfy Rawls’ difference principle. It provides excessive profits to the drug companies but does not reciprocate by making the lives of the needy better. In addition, Cohen’s philosophy also weighs in against incentives. Since the inequalities and incentives received by the drug companies do not benefit the disadvantaged, DTCA is not morally acceptable.
3.4 Educating versus Advertising

Opponents of DTCA disagree with the claim that giving partial information through broadcast or the internet is patient education. They have argued that it is no more than advertising to gain greater market share. As the baby boom generation (those born between 1946 and 1964) is going through its life cycle with increased consciousness about health issues, there has been an ever increasing demand for information. It is not surprising, therefore, that the internet has become a source of abundant health-related information that is very easily accessible by anyone who wishes to research any subject (Parker 2003, p. 279). Pharmaceutical companies have taken advantage of this new marketing media to sell their products to this large audience looking for cures of their ailments. The baby boom generation is reaching the age of retirement which is normally associated with increased medical needs. Other middle-aged people are also not far behind. In this new era of the internet, even people who are not expert users of communication technologies can receive reasonable amount of information via this medium. With such a vast number of citizens seeking information for answers on the internet, the likelihood of being influenced by the relentless advertisements that now dominate the Web is very high. The ethical problem here is whether or not it is morally acceptable for these companies to advertise medicinal products to people who are not medically trained professionals and, therefore, do not have the ability to distinguish between true and false statements or misrepresentation by the industry. Making decisions based on fully informed and complete knowledge of the product is the appropriate and ethical way of judging the claims of the drug industry. Limited information that uses medical terminologies not understandable by the lay person will not suffice. DTCA fails to meet the ideals of patient education.

In an article in the online journal of the American Association of Orthopedic Surgeons, several physicians have disputed the claims that DTCA is an important source of educational material on diseases and potential treatments (Kusuma et al, 2007). Such patient education, theoretically, encourages patients to obtain treatments for problems that were left untreated with the net result that the overall public health is improved. These doctors contend that the information provided to the public via DTCA is biased “education” because they are incomplete, vague, and not supported by medically researched data. They further bring attention to the fact that DTCA on television expresses the benefits of the drugs at a twelve-year-old reading level so that
most people will comprehend. However, the risks are presented at a higher comprehension level. They conclude that such misrepresentation of information is an indication that the pharmaceutical companies are not interested in patient education through DTCA.

Television advertisements for drugs in the U.S. have dominated the prime time hours (18:00-23:00). The ads range from medications for heartburn to Alzheimer to depression. There is one message common in all the advertisements. Instead of suggesting that the patients consult with their doctors, they encourage the patients to “ask” their doctors for the particular brand name of drugs being advertised (Hoffman 1999, p. 1301). The people who are the subject of Rawls’ difference principle, i.e. the disadvantaged, have been left out completely because they see or read the same ads yet cannot afford to go see a doctor, let alone ask for a specific drug. Researchers have found that people who have insurance respond more positively to ads since the majority of them do not have to pay the full cost of the visit to the doctor’s office, including the cost of prescribed medications (Iizuka et al, 2003, p. 4).

Does direct-to-consumer advertisement increase the flow of patients to see their doctors? This indeed has happened as the following records show (Parker 2003, p. 280). During the period between 1990 and 1998, the annual number of people who visited their doctors for allergies remained at a constant annual steady pace. In 1999, not long after FDA relaxed the requirements for DTCA, visit to the doctor’s office for the same symptoms increased by 4 million patients in the U.S. Although this boom in business was good for doctors, perhaps not all visits were absolutely necessary.

The argument that advertising is a form of patient education is not convincing because DTCA is designed by advertising agencies whose job is to excite the emotions of people to buy new products even though they are unaware of the risks involved. DTCA is giving the illusion that they are educating the public about their health, but their main concern is actually the advertising end of DTCA to create astronomical profits as we have seen earlier. By not having the well-being of the patient as the highest priority, the pharmaceutical companies are opening the door to potential health risks of the patients.
3.5 Doctor-Patient Relationship Damaged

One of the adverse effects of DTCA, as argued by its opponents, has been the lowering of the authority doctors have had on the treatment of their patients (ACP 2005, p. 5). This ethical problem has been a source of great concern to the medical profession. In a survey conducted by the World Health Organization (WHO), 89% of the doctors said that DTCA did not enhance doctor-patient relationship (Norris et al, 2005, p. 18). Proponents of DTCA may not consider this a serious issue but, nonetheless, it does harm the mutually cordial relationship. The profession of physicians is one of the most demanding curriculums at any academic institution. Assuming that the patient visits a doctor who is a specialist in a particular field of medicine, the knowledge of the specialist in that area of expertise would be greater than that of the patient. Similar arguments can be made about the knowledge of the pharmacists compared to that of a lay person. Prescription drugs, by their very nature, require the skills of a highly trained professional to correctly prescribe the medication to patients.

The pharmaceutical industry, through the medium of DTCA, has empowered the patient to discuss the choice of medication with his or her doctor and, quite often, even convince the doctor to prescribe a medicine of the patient’s choice (Fisher 2008, p. 7). There is a sense of autonomy, discussed in an earlier section that the patient would like to preserve as a result of the increased openness offered by DTCA, which is understandable. However, this privilege of autonomy should be seriously weighed against the risks involved in insisting on a preferred choice of medication. Even though a patient may insist on a certain medication, they may not understand that that particular medication might not be the right one for them due to their specific condition or health. Also, the patient may be on other medications that cannot be taken with the one that they are requesting because it puts their health at risk. The welfare of the patient should be taken into consideration and if the prescription they desire can potentially threaten the patient’s welfare, then autonomy plays a lesser role. Unless the patient has thoroughly researched and educated him or herself to know every detail about the medicine, the risks may outweigh the benefits of autonomy.

One would not compare a lay person who has received fragments of information about a particular drug with a doctor, just like it is improper to compare a
lay person and an architect who designs skyscrapers. Even if that lay person plans to live in the skyscraper, he or she has no say in the design and construction of that structure. Why then should the pharmaceutical industry give such importance and equal voice to the views and desires of the patients when their level of expertise cannot compare to that of the doctors? This lowering of the doctor’s authority may impact his or her self-respect. As long as this does not hinder the treatment process, there is no major issue. As far as the patient’s self-respect is concerned, the best conduct of preserving it would be to educate themselves by doing some research before visiting the doctor’s office so that an educated exchange of information takes place and the patient returns home satisfied. This minor step on the part of the patient would go a long way in the enhancement of mutual self-respect between the doctor and the patient. The doctor would be pleased to discuss the medical information with a knowledgeable patient. The patient would perhaps even gain an additional understanding about the drug and the course of treatment.

Doctors often spend a lot of time discussing the appropriateness of drugs advertised with their patients seeking those options (ACP 2005, p. 1). If the patients do not get what they want, it may lead to mistrust resulting in some degree of degradation in the doctor-patient relationship. Other researchers have found that DTC ads also affect the patients’ relationship and attitude towards their doctors (Royne et al, 2008, p. 67). Their study found that a great number of patients said that they would react adversely if their doctor did not honor their request for a certain advertised drug. Approximately half of the people surveyed said that they would be disappointed and about one quarter indicated that they would change physicians if their expectations were not met. DTC ads are not in the interest of either the patient or the doctor. Based on reasons cited above, opponents argue that it is ethically wrong for pharmaceutical companies to intervene and ruin the sacred trust that has long existed between doctors and patients.

3.6 DTCA – Does the End Justify the Means?

One of Kant’s categorical imperatives with regards to our treatment of other human beings states that, “Act in such a way that you always treat humanity, whether in your own person or in the person of any other, never as a means, but always at the same
time as an end” (Borowski 1998, p. 1627). Because every human being is a rational creature, Kant believes that we should all be treated with respect and dignity, never only as means but always as an end. When we respect humanity in others, it follows that we should not engage in deceptive, misleading, or manipulative acts because such behavior would take away the other person’s ability to make rational choices. This would be similar to imposing our will on another person. I argue that DTCA is using patients as a means by putting their well-being in danger with drugs they might not need in order to reach the pharmaceutical companies’ end which is their astronomically high profits.

Are DTC advertisements misleading, deceptive and manipulative? It has been pointed out by researchers on this subject that information given through DTCA could be biased and not suitable for use by people without suitable training, such as physicians (van de Pol et al, 2010, p. 215). Other authors have also shown that DTCA encourages the use of drugs by skewing research priorities to market products that have consumer appeal (Fisher et al, 2008, p. 3). Although not directly related to promotion of medicine, a television ad promoting a coronary stent used by cardiologists to open a clogged artery was criticized by physicians in the New England Journal of Medicine for not being fair and balanced because the ad only touted the benefits and not the serious side-effects (Boden et al, 2008, p. 2197). As pointed out earlier in this chapter, the argument that DTCA provides autonomy is a misrepresentation by the industry. While not outright deceptive, the examples of DTCA described above show that, at minimum, people are being misled by the pharmaceutical industry to consume drugs that they may not need, or ask for procedures that they may know little about. This behavior can be construed as a violation of Kant’s categorical imperative that people should not be used as a means to achieve other’s ends. But what does it mean to treat a person as an end in themselves? If they are their own person, they should be able to make their own autonomous decisions. By using DTCA as a way to create interest in patient’s to purchase prescription drugs that are possibly unsuitable for their health or condition as a means to create profit for the pharmaceutical companies is a violation of Kant’s principle. One can object that banning DTCA would not be allowing people to decide for themselves therefore treating them as ends, but I suggest that if DTCA was used exclusively for its educational benefits, then only we could postulate that people were indeed the ends and not the means.
For the opponents it is a moral dilemma that an industry which plays such a crucial role in the prevention and cure of hundreds of diseases should place profits at the top of its business objectives. This behavior, to the critics of DTCA is a confirmation that human beings are being used to serve someone else’s end. A more humane approach would be to maintain a healthy balance between societal needs and the financial goals of the industry.

Research and development (R&D) is a major function in the pharmaceutical industry where billions of dollars are spent each year in pursuit of new drugs with the hope that the rewards would be well worth the investment (DiMasi et al, 2003, p. 152). The industry contends that getting drugs to the market is a very long and costly process that may or may not bear fruit. There are several phases involved, starting from the pre-clinical phase, to the several stages of clinical phases. The final phase 3 involves testing on thousands of people to determine the efficacy of the drug. After the completion of these phases, the manufacturer submits a new drug application to the FDA for approval (Resnik 2004, p. 96). For the industry, the decisions made to invest in R&D have to be carefully analyzed because of the long-term ramifications. As opponents have pointed out, most R&D efforts in the U.S., however, are subsidized by the government. Therefore, the benefits should reach all level of society including the poor, as required by Rawls’ second principle. The real outcome, however, is that those who cannot afford medical coverage do not benefit from the outcome of research.

Opponents have also argued that the high cost of DTCA takes away the much needed financial resources from R&D (van de Pol et al, 2010, p. 212). According to a report by the U.S. Government Accountability Office (GAO), drug companies’ spending on DTC advertising grew twice as fast as on research and development (GAO 2005, p. 12). Among all the industries in the U.S., the pharmaceutical industry is the most research-intensive (Scherer 2004, p. 927). With such a high interest in R&D, it is somewhat unusual that it spends a large portion of its budget, $4.3 billion in 2009, on DTCA. It would appear intuitive that a good portion of this extraordinary amount of its budget should be diverted to R&D if finding cure for diseases was the highest priority. Research conducted by the Alliance of Retired Americans Educational Fund found that the drug industry claims that it takes an average of about $800 million in R&D costs to develop one drug and get it to the market (ARA 2007, p. 16). This figure is refuted by the ARA which counters that the real expenditure is
less than half of that amount (Ibid, p. 17). Whatever the correct figure happens to be, its relevance to DTCA expenditure is critical from the standpoint of the moral high ground the industry claims in serving human welfare. By rapidly expanding expenditure in this area of advertising, the pharmaceutical industry has discovered that the return on investment in DTCA is as or even more important as investing in R&D.

In 2009, the sales of prescription drugs in the U.S. amounted to $300.3 billion (Kaiser 2010, p. 4). IMS Health predicts that in 2014, sales will soar upwards to approximately $360-390 billion. With such staggering amounts of profits made by the pharmaceutical industry that happens to be among the highest profitable industries in the U.S., it is surprising that they do not make prescription drugs more affordable to those that need them but are financially unable to purchase them. As mentioned earlier, there are about 50 million people who do not have health care in the U.S. The pharmaceutical industry is more than financially capable of making drugs more accessible to the least advantaged. If they were actually more interested in the well-being of patients instead of profits, there is no doubt that the drug industry could reach a helping hand to those in need. If they wanted to, they could make drugs available free of charge to the majority of the poor in the world, or at least the people who are in need of them in the U.S. Clearly, this is not the situation. The pharmaceutical industry is not more interested in the well-being of others than making profits. What is unacceptable is that they are using people as a means to their end.

3.7 Summary of Chapter 3

I began this chapter by describing how the drug industry promotes consumerism in the guise of autonomy. The patients feel empowered by autonomy but in reality they treat medicines as if they are consumer goods and not drugs that could be potentially harmful. I explained how advertising is being used for purely commercial advantages but touted as a means of educating the public. I brought attention to the fact that drug price reduction through competition among pharmaceutical companies did not materialize as a result of DTCA. The long-established doctor-patient relationship has been harmed to some extent as a result of patients insisting on getting prescriptions for drugs that they have seen advertised, which may be dangerous for some patients.
depending on their health. I have argued that the disproportionately high inequalities received by the drug industry do not trickle down in any form for of benefits to the least advantaged. Finally, I have argued that patients have been used as a means to reach the drug industry’s end which is to make above normal profits.
4. Conclusion

The debate over the benefits and drawbacks of DTCA has been going on for more than a decade with no end in sight. As we have seen through the arguments presented in Chapters 2 and 3, both sides of the controversy have very little likelihood of accepting each other’s point of view. There is no doubt this is due to the vast variation in the interpretation of the benefits of DTCA, depending on whether we are looking through the lens of the pharmaceutical industry or that of the consumers at large. In this work, I have used ethical arguments based on Immanuel Kant’s categorical imperative and John Rawls’ difference principle to look at the claims made by the industry and its proponents as well as the claims made by the opponents. The conclusion I have reached is that the moral arguments against DTCA are stronger than that of the proponents and therefore tilt in this direction.

Rawls second principle accepts economic and social inequalities provided that these inequalities result in some form of benefit to the least advantaged in society and not be channeled only to the top. Unfortunately, this has not happened despite claims by the proponents to the contrary. There are gross inequalities when we see how DTCA has mainly promoted “blockbuster” drugs that bring in billions of dollars in sales. This further exacerbates the situation of the least advantaged, who do not gain any benefits from these inequalities. DTCA has been misrepresented as an educational tool when, in reality, it was only a marketing tool used to bring enormous profits. This is a very clear violation of the Kantian principle of not using others as a means to an end and that every human being should be treated as an end irrespective of other business or personal objectives.

In conclusion, even though DTCA has had some beneficial effects, the drawbacks far outweigh the advantages received by the consumer, the patient, or society. An industry whose primary business ought to be improving the health care of the people should not expend great resources on promoting drugs that are of commercial interest while putting the health of patients at risk. The patient’s welfare is clearly compromised. This surely was not the purpose behind Rawls’ difference principle where a limited amount of inequality could be justified. The high level of incentives given to the drug manufacturers would not be achievable without aggressive DTCA campaigns.
My conclusion is that DTCA should be banned. However, since this is an unlikely possibility, especially in the U.S.’s capitalistic economy in an industry where billions of dollars are at stake, other compromising settlements should be pursued. I suggest that improvements should be made in areas where DTCA provides no benefit to the millions who cannot afford the high-priced advertised drugs. Here are two proposed solutions:

(1) Legislation should be enacted through Congress with the unified support of several powerful organizations in the country such as the American Civil Liberties Union, the American Medical Association, the health insurance industry and the American Association of Retired People to introduce a special tax for the unusually high profits made through certain types of blockbuster drugs that are the main focus of DTCA campaigns. Revenues thus collected could be used by the government to subsidize the purchase of drugs by the poor and the elderly with very limited income resources. This step would restore Rawls’ second principle the way it ought to benefit society.

(2) Additional legislation should be introduced to ensure that advertisements are strictly educational in nature and sanctioned by an impartial third party composed of medical professionals who do not have any private gain on the matter. Advertising agencies should not be permitted to design the contents of the ads, especially ones broadcast on the radio or shown on television. This step would restore the educational objectives of the ads without any misrepresentation.
References


