Direct to Consumer Advertising in the United States: A Controversial Debate

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Living in an American household today, one may sit down to watch any commercial television program and chances are highly likely to be exposed to an advertisement for a prescription medication. This paradigm of prescription drug advertising has shifted significantly from being directed at the healthcare providers who typically made the sole decisions over to the patients and consumers. The pharmaceutical companies now are directly targeting the patient population as opposed to the healthcare providers. The controversial and ethical issues that accompany this topic have been and currently are being argued today, many people believe that direct to consumer advertising (DTCA) should be banned in the United States. The only other country that allows DTCA over broadcast television and media is New Zealand; for this matter, I would have to question why only two countries have legalized this process if indeed it has the benefits that proponents say that it does. In order to determine an ethical stance on this issue, one must have a thorough understanding of the history and development of DTCA, the pros and cons of the issue, the impact DTCA has had on the healthcare system financially, the impact on the patients and the healthcare providers, and finally in what direction DTCA is heading in the future.

Taking a look at the historical evolution of prescription drug advertising in the United States, the first federal legislation regulating food and drugs was the Pure Food and Drugs Act of 1906, or the Wiley Act. The Wiley Act was merely geared towards product labeling and did not contain any restrictions concerning advertising. A product was only labeled as misbranded if the label contained false statements about the ingredients or therapeutic effects; therefore, any false claims that were not on the label were not prohibited thus creating a loophole.
In 1938, following the Wiley Act, the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) was enacted. At this time, advertising for food, drugs, and cosmetics had grown tremendously since 1906, creating a demand for this new legislation. Many of the main concerns in creating the new legislation were the dangerous products on the market as well as false marketing claims. Congress granted the FDA jurisdiction over the labeling of all drugs; however, the jurisdiction over drug advertising was in the hands of the Federal Trade Commission (FTC).

Prior to 1951, there was no distinction between prescription drugs and over the counter (OTC) drugs. A prescription was not required by law, except for narcotics. Therefore, in 1951 we saw the development of the Durham-Humphrey Amendments to the FDCA that required that drugs must be dispensed only by a prescription from a licensed healthcare provider. The goals of these amendments were to protect the public from abusing prescription drugs and to relieve pharmacists and consumers from restrictions on dispensing medications that can be taken safely without a prescription.

Almost 30 years after the FDCA was enacted, in 1962 the Kefauver-Harris Drug Amendments granted prescription drug advertising regulations to the FDA; however, the FTC retained regulatory authority over OTC advertising. A near twenty years later, in 1981, the first U.S. prescription drug advertisement was made by Boots Pharmaceuticals for the ibuprofen product, Rufen. Following four years later in 1985, the FDA issued the regulation of direct to consumer advertising. In August 1997, the FDA issued the “Draft Guidance for Industry, Consumer-Directed Broadcast Advertisements” allowing DTC advertisements on broadcast media; the Draft Guidance was finalized in 1999 and DTCA has since grown tremendously over the past decade.
Currently, drug advertising within the FDA is regulated by the Division of Drug and Marketing, Advertising, and Communications (DDMAC), under the Center for Drug Evaluation and Research (CDER). The regulatory actions by the FDA concerning advertising under the FDCA require that the advertisements include the drug’s generic name and formula and a brief summary describing the efficacy and risks. The FDA has developed two major requirements based on this provision in the FDCA. First, the “brief summary” must have the drug’s side effects, contraindications, warnings, precautions, and indication for use. Specifically, for broadcast advertisements there are “adequate provisions” instead of a brief summary and a “major statement” of risks. For the adequate provision there must be information provided to the consumer such as a telephone number to get more information or in an internet web site because all of the brief summary information can not be provided in a 30 second commercial. Secondly, the fair balance doctrine states that the advertisement must have a balanced representation of all clinically relevant information. For example, it must accurately present the risks so that the benefits are not over-emphasized.

There are three types of prescription drug advertisements which have different regulations: 1) reminder advertisements, 2) help-seeking advertisements, and 3) product-claim advertisements. The first type, reminder advertisements, merely calls attention to the name of the product, but does not include any information about the product. For example, the over abundance of pens and notepads advertising medications would be a type of reminder advertisement. The help seeking ads will describe the symptoms of a disease state and encourage patients to contact their physician for more information; this type of ad does not mention the drug’s name. Both of the aforementioned types of ads are not required to have the “brief summary” or fair balance requirements because there is no information pertaining to how
effective the medication is. Thirdly, the product-claim ads give the drug name and indication and are therefore, required to have the brief summary and maintain fair balance of information. Despite these regulations that are in place by the FDA, there are still arguments as to whether many medications are represented accurately and if the risks and benefits are both equally represented to the patients. The DDMAC does have a monitoring program in place to ensure that the advertising regulations and laws are being met. However, the FDA oversight of the DTC advertisements is questionable. If the promotional advertisement is in violation, the FDA will send a violation letter if it is a minor violation or a warning letter for more serious incidents. The letters the FDA sends to the companies are posted on the CDER website. Typically, the company in violation is asked to discontinue the advertisement. The number of violation letters that the FDA has sent since 1997 has declined greatly; this could be attributed to the companies increasing compliance or from the FDA’s loss of oversight.

In a recent article by Donahue et al. in the New England Journal of Medicine looking at the past decade of direct to consumer advertising, one of the objectives was to look at the trends in the FDA’s regulation of drug advertising. In 1997, the FDA sent 142 violation letters for prescription drug ads and that number dropped to only 21 in 2006. However, one third of the letters sent in 2006 were citing problems with DTCA as opposed to promotional material aimed at health professionals. The majority of the letters from 1997 to 2006, or 84%, cited the advertisements for either minimizing risks or exaggerating effectiveness. In one case, the FDA cited Pfizer’s print advertisement of Zoloft (sertraline) stating that it was misleading because it omitted pertinent information relating to the risk of suicide in patients. Zoloft became a very popular drug very quickly, it was the drug to make everyone happy and one can see where this
would be a big issue not clarifying the significant risks that are associated with this class of medication, or any other medication for that matter.

The authors of this article found compelling indication showing that the FDA’s oversight has worsened over the years. The FDA requires all of the regulatory letters to be reviewed by the Office of Chief Counsel before they are issued and often the letters are not sent out until after the advertisement has ran for a period of time. There is also a shortage of staffing, the number of people who reviewed these advertisements was 3 in 2002 and in 2004 jumped up to 4 staff members; however, the spending on these advertisements increased from $2.9 billion to $4.2 billion in these two years which would indicate a need for significantly more staff to oversee the advertisements. Furthermore, the number of advertisements that were reviewed by the FDA before being broadcasted decreased from 64% in 1999 to only 32% in 2004. All of these factors contribute to the issue of whether or not the regulations on prescription drugs are being enforced like they should be and what messages the pharmaceutical companies are sending to consumers when advertising prescription medications.

In response to the large demand and concern about DTCA, the Pharmaceutical Research and Manufacturers of America (PhRMA), which represent America’s leading pharmaceutical and biotechnology research companies, developed a set of fifteen voluntary guiding principles about prescription medications that meet the FDA regulations so that the companies will release advertisements that are consistent with these principles. The main concern is that the pharmaceutical industry is compliant with DTC communications being accurate, fairly balanced, and meeting all legal requirements. These guiding principles are another step to ensure that DTCA is delivering messages that educate patients and encourage them to seek advice from their healthcare providers.
After understanding the historical development and regulatory actions that impact DTCA, there are differing viewpoints to consider on whether or not DTCA should be legal in the United States. Some of the arguments for DTCA that proponents make include: increasing patient awareness and empowering the patient, motivating the patient about health concerns and improving patient/physician relationships, improving treatment for under-diagnosed conditions such as hypertension and hypercholesterolemia, and increasing patient adherence. On the contrary, the arguments against DTCA include: increasing healthcare costs, overuse of inappropriate or unnecessary medications, that the advertisements are false or misleading, the benefits and risks are not accurately represented and conveyed to the patient, and most importantly that most of the newly approved medications are advertised to the mass public within a year of being available on the market.

In 2002, the FDA conducted a survey to 459 physicians randomly chosen from the American Medical Association master file in order to evaluate the impact of direct to consumer advertising on their patient interactions. When looking at the beneficial effects of the interaction after seeing an advertisement for a medication, 59% of the physicians stated there was no beneficial effect. The 41% that reported there were beneficial effects, stated that the majority of the benefits were seen in the discussion with the patient (53%) and that the patients were more aware of treatments (42%). However, 82% reported that there were no problems that were created by the patient being exposed to the advertisement. Furthermore, 86% reported that the patients asked for a specific drug by brand name and of those that asked 88% of the patients had the condition that the drug treats. As far as any problems DTCA created for the patients, the majority of physicians reported that the benefits were exaggerated and the patients were confused about the risks and benefits. Also, most of the patients think that the drug works better.
than it does after seeing the advertisement. When looking at the overall impact of DTCA, 37% reported that DTCA somewhat positively affected their patients, 28% reported it did not affect them at all, and 27% reported that it somewhat negatively affected the patients. The results of this survey show, once again, differing views about DTCA with a little more than one third of physicians stating there is a positive effect and a little less than one third stating there is an overall negative effect.

In an executive summary released from the FDA in 2004 that includes information from the aforementioned survey as well as from two patient surveys (one conducted in 1999 and one in 2002) provides important information concerning the patient attitudes and behaviors associated with DTCA. The patients in the surveys were limited to patients who had seen a physician in the past three months. The findings showed that 81% reported exposure to broadcast or printed promotions in 2002 which was an increase from 72% in 1999. A large percentage of patients were found to be seeking information about a drug seen in an advertisement; 89% retrieved information from their physicians and 51% obtained information from their pharmacists. A large portion of the patients agreed that DTCA increases awareness (77%), while 73% also reported that they do not feel the ads minimize the role of the physician. One third of the patients felt the ads helped them make better health decisions and 18% agreed that seeing the ads reminded them to take their medication. In general, one third of the patients reported that they liked seeing the advertisements in 2002 which represents a decline from the 52% in 1999 that reported they liked seeing the advertisements. From the results of this survey, it is apparent that the number of people being exposed to DTCA is increasing tremendously and most patients agree that it is increasing awareness and patient/physician interaction; however less people are enjoying seeing the ads. Although there is limited information pertaining to patients’
behaviors and attitudes, there needs to be more primary research conducted in order to evaluate the direct benefit or disservice that DTCA imparts on consumers.

Almost all of the DTCA advertisements create an environment that is very inviting to consumers. There is always a beautiful scene with someone throwing a football, the sun is shining, or an old man is rowing in a canoe; it creates a setting that everyone wants to be a part of using emotional response. The images and music used in these advertisements do not coincide with the audio information that is being communicated such as the adverse effects. In August 2007, the U.S. Food and Drug Administration (USDA) announced that it will study whether the DTC ads distract the consumers from looking at the risk information. Some of the goals of the study are to assess how the images used in the ads affect the consumers and how the text and music can divert attention from the audio warnings. The FDA is also concerned that the ambience portrayed such as the relaxing, upbeat images and text directing consumers to the website can also distract from the important audio side effects that are being communicated in the advertisement.

A study published in the Annals of Family Medicine by Frosch et al evaluated a content analysis of television direct to consumer advertising. This is an important analysis because it shows the techniques that the companies use to persuade the consumer about the use of a medication and ultimately the impact that DTCA has on the patients. The majority of expenditures for pharmaceutical companies related to DTCA are now devoted to television advertising as opposed to print ads, journals, etc. The average American will see 16 hours of prescription drug advertisements yearly, which definitely exceeds the time that anyone spends with a primary care physician in one year. There has been previous research that looked at print ads; however, television ads combine visual images, music, and spoken words to create a story
can provide emotional appeal to a larger number of people. The goal of this study was to analyze the content of DTCA messages in order to be able to project in the future how this type of advertising is affecting people’s health-related behaviors and beliefs.

This study looked specifically at ads shown during prime time from 8:00-11:00 PM and on the channels with the most viewers including ABC, CBS, NBC, and Fox. The programming was recorded for four weeks and each day a different channel was selected randomly. The sample they obtained captured a total of 103 ads consisting of 31 unique product claim ads and 7 reminder ads. The results found that the average ad length was almost 45 seconds; the reminder ads were significantly shorter because they do not contain as much information. The focus was on the product claim ads because the reminder ads do not represent any factual information.

Pertaining to the factual claims about the condition, most of the ads made a factual claim about the target condition by mentioning the symptoms. This way the patients can identify with those symptoms and therefore might persuade them to ask for the medication. Only 26% of the ads made claims about the risk factors or causes of the condition and many of the ads used the term “millions” whereas 8% of the ads identified specific populations at increased risk for having the condition.

Abiding by the FDA regulations, all of the product claim ads used rational appeal by describing the product indication and almost 95% of the product claim ads and 100% of the reminder ads used positive emotional appeals, often the happy character that we see on the television taking the medication. Some of the ads also used negative emotional appeals showing a person in a fearful state before taking the medication and then in the land of the happy after taking the medication. Control is also a big factor that is used in these advertisements to gain the attention of the consumers; 85% of the ads showed the characters regaining control of the
situation in their life as a result of taking the product in the ad. Also, almost 80% showed social approval as a result of the product use; for example, Joe (the character) is now taking his Crestor and enters into happy, sunny suburbia in the land of success where his neighbor is smiling and waving and he happily jogs home to have a picnic with his smiling family. The themes used in these advertisements create an environment that makes the consumers want to purchase the product via social and emotional appeals. However, these advertisements do not advocate the importance of behavior modification and many times suggest that the only improvement comes from taking the medication alone or in combination with healthy activities.

This content analysis shows that although PhRMA has issued guidelines for DTCA; they may be somewhat vague in what the guidelines allow and also because the guidelines are voluntary, one alternative would be for congress to pass legislation which would require specific content in the pharmaceutical ads. Furthermore, DTCA can persuade the viewers on grounds other than rational consideration of medical costs and benefits by using emotional and social product appeals. Picking which shampoo to buy or which ice cream sounds the most appealing does not have the same ramifications as picking a medication based on the television ad appeals.

One hard and fast piece of evidence that the proponents against DTCA have is the fact that the costs have risen significantly over the past ten years and are continuing to rise. Many believe that DTCA is fueling the skyrocketing drug costs in the United States. The amount of money spent on DTCA annually in 1996 was close to 1 billion dollars and in 2006 the numbers were nearing 5 billion dollars which is a phenomenal increase.

The Government Accountability Office (GAO) released a report in 2002 to congress that contains a great deal of information concerning the cost of prescription drugs. The main goals of the report were to assess the trends in spending on DTCA, to look at overall promotion, and
research and development. Much of the controversy surrounding this topic leads to the issue of how the pharmaceutical companies are spending their money. Are they spending most of their money on promoting the drugs or on the research and development of these potentially dangerous medications?

According to the industry analyses that GAO reported, pharmaceutical companies still spend more on research and development than on DTCA or all promotion combined. However, DTCA has had the biggest and fastest increase. Looking at the overall picture, in 2001, pharmaceutical companies spent $30 billion on research and development, and $19 billion on all promotional activities which includes $2.7 billion on DTCA. However, the growth rate of spending on DTCA is higher than the rate of increase on total promotional spending or research and development. From 1997 to 2001, the amount of spending on DTCA increased by an astounding 145%, followed by a 74% increase on total promotional spending, and a 59% increase on research and development. These numbers are from 6 years ago and now we have seen that the total amount spent on DTCA has risen to almost $5 billion. In a more recent report by the GAO released in December 2006, the percentage increase in spending on DTCA from 1997 to 2005 is up to 297% compared with 103% for research and development. Although the pharmaceutical companies are still spending more money on research and development at this point, the rate of increase in spending on DTCA is far surpassing the increases for research and development. It wouldn’t be surprising if in the near future there is a great deal more being spent on drug advertising as opposed to actually researching and developing a safe and effective medication.

The study conducted by Donahue et al. looked at three major components of spending on promotion to professionals: visits of pharmaceutical sales representatives to physicians’ offices
(“detailing”), free samples dispensed to physicians, and advertising in professional journals as well as looking at direct to consumer advertising spending. The results showed that spending on promotion grew from $11.4 billion in 1996 to almost $30 billion in 2005. Also in the previous 9 years, spending on DTCA and free samples has risen as a share of total promotion, while numbers in detailing and advertising in journals have decreased as a share of the total. This study shows a 330% increase in spending on DTCA from 1996 to 2005; however, the promotion to professionals still outweighs the spending on DTCA. In 2005, only 14% of the total industry expenditures were spent on DTCA. One concern is that consumers are bearing the increasing costs in the form of higher prices for medications; however, evidence suggests that changes in marketing costs are unlikely to have a direct effect on pharmaceutical prices.

Some of the top DTCA drugs in 2005 include: Lunesta, Nexium, Vytorin, Crestor, Advair, and Lamisil. The amount of money spent on promoting these medications range from the low end at $126 million/year up to $227 million/year for Lunesta. Again, many of these medications are for diagnoses that patients can recognize for themselves and almost self-diagnose or they are for under-diagnosed conditions. Due to the fact that most of these medications are highly advertised to millions of consumers within one year of making it to the public, Senator William Frist’s thought is that pharmaceutical companies should have to comply with a two-year moratorium before advertising new drugs. This delay would allow the medication to be used by healthcare providers and patients and would allow for some of the rare but significant adverse effects to be recognized that may have not been discovered in the trials. In an attempt to comply with the DTCA regulations, Bristol-Myers Squibb set its own voluntary one year moratorium on new drug ads. However, the downside of this moratorium would be that the pharmaceutical company just spent billions of dollars as well as several years developing a
medication that can not be advertised as widely to the public to increase the sales and revenue and that is also chipping away at the patent time on the medication.

DTCA has been around for several years and the controversy and debates surrounding this topic continue to expand. I conducted a survey to the first through third year pharmacy students at Wayne State University as well as to several faculty members. The survey was distributed via an internet survey site, it was voluntary and the participants’ names were kept anonymous. The goal of the survey was to assess the opinions of future pharmacists and current pharmacists regarding some of the issues surrounding the DTCA controversy.

The results of the survey showed that 76 people filled out the survey completely; there is no way to distinguish which of the 76 were students and which were pharmacists and professors. According to the survey, almost 50% believe that DTCA should be legal in the United States. Therefore, the 30% who believe it should be illegal take the opposite stance; the other 20% stated they were unsure about the issue. Once again, we see almost an even divide on whether or not this should be allowed in the United States.

A little over half of the respondents believe that DTCA is beneficial for patients with under-diagnosed conditions such as hypertension and hypercholesterolemia; however, a large majority (83%) stated that they agreed that the DTC ads do not accurately represent the benefits and risks of the product. This seems to be a common trend that many are against this because of the misrepresentation of the effects of the medications. Almost 72% also agreed that DTCA increases patients’ education and awareness about the medications and about 2/3 of the responses indicated that DTCA is increasing healthcare costs in the United States. When asked how many DTC ads they were exposed to in the past week 37% stated 5-10, 26% 0-5, and 22% 15-20. Interestingly, 61% disagreed that the patients would be more adherent with taking their
medications as a result of DTCA. Finally, at the end of the survey I stated the point that DTCA is only legal in one other country, New Zealand, and I asked if it should still be legal. The 50% that thought DTCA should be legal in the beginning of the survey dropped to 40% at the end with 25% still unsure about the issue. The results of this survey still support the fact that there are pros and cons, advantages and disadvantages to DTCA in the United States.

Pharmacists can play a vital role in this arena in addition to the physicians and the patients. Pharmacists are the most accessible healthcare professional and many patients will come in asking questions about a certain medications that they saw on television. Pharmacists need to be prepared and aware of the advertisements and claims that are being made and more importantly, need to be able to explain to the patient if there is a need for the medication or if there is a therapeutically equivalent medication that is less expensive or that has fewer risks for that specific patient.

At this point, there is not talk about banning DTCA in the United States which appears to be growing exponentially. There needs to be continued regulatory actions for these advertisements to ensure that they are communicating safe messages to the consumers. The future of DTCA laws and current regulations is held by the FDA; it seems that they need to increase their staff in order to properly oversee such an important matter. Currently, in New Zealand there has been much talk of banning DTCA.

As with any ethical issue, there is no right or wrong answer. There are many facts and opinions surrounding this issue and it is up to each person individually to make an informed decision on this topic. Furthermore, it is equally important for healthcare providers, including pharmacists, to play a proactive role in staying current with this issue and having the ability to answer any questions the patients may have as well as correct any misconceptions.
In conclusion, DTCA is here to stay for the time being; it definitely offers substantial benefits to the patients and at the same time can also be detrimental to their healthcare choices and behaviors. Hopefully, in the future we will see more studies and concrete evidence supporting whether or not DTCA is beneficial and whether it should or should not be legal in the United States.


