Direct-to-Consumer Advertising
by Pharmaceutical Manufacturers and Healthcare Systems

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Choosing a hospital could be the most important decision of your life. Do you have a Beaumont doctor? Viva Viagra! Ever heard of Dr. Robert Jarvik, the inventor of the Jarvik artificial heart who advertises for Lipitor? Nexium, the healing purple pill. Do these advertisements sound familiar? Consumers are constantly being bombarded with health information through magazine advertisements, television commercials, and billboards. One cannot watch a television show without seeing a commercial for a prescription medication. Direct-to-consumer (DTC) advertising has become a major approach pharmaceutical companies use to promote their drugs to consumers. More recently, healthcare systems have begun using the media to attract patients to their hospitals. The consumer is left with a wealth of information from these advertisements to sort through. DTC advertising has a dramatic effect not only on patients but also on physicians and healthcare systems. Patients are going to their physician to request medications for which they have seen in advertisements. Similarly, healthcare systems are competing against one another in order to attract the most patients to their hospital. DTC advertising has many implications which need to be analyzed to determine the overall effect advertising has on healthcare.

Pharmaceutical companies have not always been allowed to advertise through the media to consumers. The advertising of prescription drugs was once limited only to medical journals and publications for physicians. A series of laws have since changed the way the pharmaceutical industry can advertise their products. It all began in 1981 when pharmaceutical companies
brought forth the idea of direct-to-consumer advertising. A moratorium was issued in 1983 in order to allow the Food and Drug Administration (FDA) and other interest groups time to research public demand and the effect advertising would have on the healthcare industry. In 1985, the FDA lifted the moratorium by publishing a *Federal Register* notice indicating that existing standards to regulate advertisements to physicians must be followed in DTC advertising. By lifting the moratorium, the FDA asserted its authority to regulate DTC advertising. Although, the FDA already had jurisdiction to control prescription drug advertising according to the Kefauver Harris Drug Amendment passed in 1962. “Under FDA regulations, advertisements that mentioned a product’s name and indication are required to include a “brief summary” of the drug’s adverse effects, contraindications, and effectiveness.” In order to further clarify how manufacturers can meet the requirement to allow a diverse audience to receive the advertised product’s approved labeling for broadcast advertisements the FDA published the *Guidance for Industry-Consumer-Directed Broadcast Advertisements* in August 1999. The history of regulating DTC advertising by the government provides a framework for how it is regulated and lets manufacturers know the rules they must follow in order to advertise to consumers.

The drug industry spent $791 million on DTC advertising in 1996 versus $3.2 billion in 2003. In 2003, 13% of promotional spending by pharmaceutical companies was spent on DTC advertising. These statistics have continued to increase since 2003. One can clearly see that a large portion of money spent by manufacturers is spent on advertising their products. Merck spent a total of $296 million dollars to promote Vioxx (rofexcoxib) from 2000 to 2001 which was ultimately later taken off the market. One magazine, *Advertising Age*, even rewarded Merck for this by announcing Vioxx as one of the top brands recognized by consumers. In 2003, the
Kaiser Family Foundation announced a report declaring for every $1 spent on promotion, manufacturers gained $4.20 in revenue. Overall, pharmaceutical companies are increasingly spending more money on advertising and with the increased amount of advertisements consumers are recognizing more and more of the drugs advertised. This increased spending has tremendous implications on the cost of healthcare for consumers.

Proponents of DTC advertising argue that advertisements are a good source of information for patients and increase health awareness. The advertisements encourage patients to see their physicians and seek a more active role in deciding on treatment options. Proponents also argue DTC advertising increases patients awareness of “silent diseases” such as hypertension.

Critics of DTC advertising have many more reasons of why the advertising is harmful to patients. In fact, only two developed countries, New Zealand and the United States, allow DTC advertising. Interestingly, New Zealand is working very hard to ban the advertising in its county. Opponents argue advertisements are a biased opinion set forth by the manufacturer. The advertisements create an increased demand for prescriptions which may not be medically necessary. Doctors may feel pressured to prescribe medications when patients come into their office requesting a medication they saw advertised on television. DTC advertising therefore has a tremendous impact on quality patient care.

First of all, the impact DTC advertising has on influencing physician prescribing will be analyzed. In the study, “How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA”, researchers analyzed prescribing by primary care physicians practicing in Sacramento, California, Vancouver, and British Columbia. In Vancouver, prescription advertising is illegal, although manufacturers are
allowed to advertise for over-the-counter products. Prior to seeing their physician, pre-selected patients were asked to fill out a questionnaire. Immediately following the patient visit, the physician was asked to fill out a questionnaire. By pairing responses, researchers were able to determine how many patients had been exposed to DTC advertising, the frequency of patients’ requests for prescriptions advertised, and the frequency of prescriptions prescribed which were stimulated by the patients’ requests. The results showed Sacramento patients were twice as more likely to request medications and twice as likely to request advertised medications versus Vancouver patients. DTC advertising also appeared to affect both prescribing volume as well as medication choice. Patients who requested an advertised drug were 17 times more likely to receive 1 or more new prescriptions as patients who did not request any medications. The study also determined that 9 out of 10 patients who requested an advertised medication received the medication or an alternative.4

Patients’ requests for advertised medications could lead to improved health benefits if patients seek care at an earlier stage thus avoiding disease complications and hospital admissions. Though, many of the requested advertised products in the previous study were “lifestyle drugs” or medications for symptomatic treatment. These therapies may lessen discomfort but are unlikely to prevent hospital admissions or morbidity.4

In another randomized controlled study, “Influence of patients’ requests for direct-to-consumer advertised antidepressants”, researchers analyzed the effects of patients’ DTC requests on physicians’ initial treatment decisions in patients with depressive symptoms. Standardized patients were used with two conditions (major depression or adjustment disorder with depressed mood) with three medication request types (brand-specific, general, or none). The patients were randomly assigned to visit recruited family physicians and general internists so each physician
saw one patient with major depression and one with adjustment disorder. The results showed in major depression, rates of antidepressant prescribing were 53%, 76%, and 31% for patients making brand-specific, general, and no requests respectively. With adjustment disorder, antidepressants prescribing rates were 55%, 39%, and 10% respectively. This study clearly showed that patients have a profound effect on physician prescribing. While patient requests were effective methods of preventing undertreatment of depression, at the same time patient requests led to overprescribing by physicians.\textsuperscript{5}

Next, how patients and physicians feel about DTC advertising will be analyzed. The FDA conducted two national patient telephone surveys, in 1999 and 2002, to determine how patients felt about DTC advertising. Interesting in 1999, 52% of patients stated they liked seeing the DTC advertisements, while in 2002 only 32% reported having positive views on seeing the advertisements.\textsuperscript{6} Some patients reported that the advertisements overstated drug efficacy and 60% reported both in 1999 and 2002 that advertisements did not have a balance between benefit and risk information.\textsuperscript{6} The majority of patients agreed DTC advertising made them aware of new prescription drugs. This also prompted patients to ask more questions to their healthcare providers.

A study by Murray et al, sought to determine the publics’ perceptions of the effect of DTC advertising on healthcare utilization, health behaviors, doctor-patient relationship, and the association with socioeconomic status.\textsuperscript{8} Overall, both positive and negative outcomes were found in the study. The greatest benefits were seen in patients with low socioeconomic status. A telephone interview taken from a nationally representative sample in 2000 was used to research the publics’ perceptions. 83% of all respondents admitted to having seen an advertisement within the past 12 months; 94% saw it on television, 62% read it in a newspaper or journal, and
22% heard it on the radio. In the previous 12 months, 20% of respondents admitted to viewing a drug advertisement relevant to their health and 10% discussed the information from the advertisement with their physician. Interestingly, 203 of the 3209 patients requested preventive care (screening or blood tests) after viewing an advertisement. This outcome was strongly correlated with socioeconomic status. Patients who had not completed high school, Hispanics, and chronic disease patients were more likely to seek preventive care. Many patients brought information about the advertisement to their physician after viewing the advertisement. The impact this had on the doctor-patient relationship was analyzed. Only 5% of patients reported a negative impact, while 13% perceived their doctor felt their authority had been challenged, and 21% reported dissatisfaction and sought a second opinion. Therefore, even though the advertisement prompted the patient to talk to the physician, the patient was often disappointed with the results of the interaction. The results of this study did show that patients of lower socioeconomic status are more likely to see their doctor after viewing an advertisement. Though, the tremendous amount of money spent on DTC advertising could have just as easily been spent on focusing on health interventions at a significantly lower cost.

The way physician’s view DTC advertising has also been studied. Many physicians have mixed views on advertising by pharmaceutical companies. Some physicians believe that DTC advertising is an effective means of providing medication information. Others believe the advertising is why patients are taking a more proactive approach to their own healthcare. They are making more doctor appointments, having more screening tests done to prevent health problems early on, taking their medications regularly, and becoming more involved in their treatment decisions. However, some physicians believe the advertisements are misleading in
promoting their products. The advertisements mention nothing about equally effective products that are less expensive.⁶

In the study, “Direct to consumer advertising: Physician’s views of its effects on quality of care in the doctor-patient relationship”, a national phone survey of physicians was completed similar to the study which looked at patient views on DTC advertising. The results showed that 83% of physicians questioned believed the advertising gave their patients confidence to talk to their doctor about their concerns.⁹ 81% of physicians thought DTC drives up the cost of prescription drugs while 59% believed it promotes unnecessary fears of side effects.⁹ As far as affecting patient care, 45% thought it promotes unneeded doctor visits, 39% believed it interfered with good doctor-patient relationships, and 53% said it caused patients to take up more of their time.⁹ Interestingly, 12% of physicians felt their authority being challenged by patients by the discussion of DTC advertising.⁹ Overall this study showed that DTC advertising has an impact on doctor-patient relationship and healthcare utilization. DTC advertising leads to patients making specific requests for medications seen in the advertisements. Physicians are left with facing three conflicting ethical obligations.⁹ First of all, physicians strive to “do no harm” to their patients. The primary goal for physicians is to do what is best for their patients and help them out to the best of their ability. Second, physicians seek to maintain a strong doctor-patient relationship to enhance a patient’s health outcomes. Also, patients ultimately decide on the satisfaction with their physician. If a patient is not satisfied with their physician, they will seek alternative care and find a new physician. Lastly, physicians have a duty to their patients to ensure equal allocation of healthcare resources and avoid wastefulness. In the end, physicians are attempting to deal with patient requests but this takes up more of their time and leads to an increase in healthcare costs.⁹
Some physicians believe by advertising prescription drugs it treats them like any other advertised product such as toys, cars, or food products. It leads patients to think that pills can solve all of their problems, never mentioning anything about lifestyle changes or other non-drug options. In 2002, the FDA questioned physicians on how DTC advertising influences their practices. This study showed that 85% of physicians said that their patients asked often or all the time about advertisements they had seen on prescription medications. Interestingly though, physicians stated that 62% of their patients asked about generic drugs. This may indicate that even though patients want the medications they saw advertised, they are still concerned about cost. Whether one is a proponent or opponent of DTC advertising, one can clearly see that it is leading to patients inquiring more about what they have seen or heard in the media.

Now that both the patient and physician views on DTC advertising have been analyzed, it is important to see what manufacturers think about the advertising they are doing. Pharmaceutical companies claim they are helping patients by promoting health awareness, new treatment options, and are compelling patients to stick to their drug therapy. According to the industry, the increase in prescription use and spending appears to be due to a few different factors, and not necessarily attributable to DTC advertising including: an increase in more prescriptions being written for the aging population to maintain health; a shift toward the use of newer higher priced medications; new standards of medical practice encouraging the use of more drugs; more treatment of untreated patients; and greater attention to prevent and manage diseases versus the cost of hospitalizing patients. Studies sponsored by industry and academic researches suggest that DTC advertising can lead to cost-effective treatments in some circumstances. The example given by experts is that “statin” drugs are cost-effective as secondary prevention in patients with existing heart disease, but they are much less cost-effective than primary prevention
such as weight control and exercise. This leads to a discrepancy of whether advertising by manufacturers is really cost effective or not.

Besides an increase in the amount of advertising by pharmaceutical companies, recently a surge of advertising by medical institutions has been occurring. Hospitals are competing for patients to come to their institution in times of need. Health systems are just like any business in that they need to make money in order to stay open. The way they make money is by treating patients when they are sick. The more patients a hospital attracts to their hospital the more money they make. A study by Larson et al, contacted 17 medical centers on *US News & World Report 2002* of “America’s Best Hospitals” for an interview regarding their institution’s advertising practices. The study also analyzed all non-research related printed advertisements placed in local newspapers. Advertising was used to attract patients in 16 of the 17 institutions, while only one institution used “word of mouth”. Also, 127 print advertisements appeared for the 17 institutions during 2002. The most commonly used marketing strategy was appealing to patient emotions, followed close behind with highlighting institution prestige. This means institutions are using patients’ emotions to attract them to their hospital.

Advertisements aired in the Detroit area seem to promote fast service and increased technology. For example, the Detroit Medical Center promotes the “29 minute ER guarantee”. Another health system, Beaumont, focuses its advertisements on having the newest technology and advancements along with the best patient care. These advertisements are promoting the fact that faster and better technology is always better. This may not always be the case. Consider the situation where a physician must hurry to see one of his or her patients in order to meet the standard set by the health system of seeing his or her patient in 29 minutes. While the physician is focusing on time, an important medical diagnosis could be missed in the process. As far as
technology, the best and newest technology might not be what the patient needs. Maybe the patient could have a much simpler test completed which would be less costly and less invasive. Newer technology may also promote an exaggerated sense of how good medical care is and ultimately provide false hopes and unrealistic expectations to the patient. In the end, hospital systems are taking advantage of patients when they are most vulnerable.

With this surge in advertising by health systems the question has arose when is it ethical to begin advertising for these services. In many incidences, hospitals are marketing for procedures which have not been fully validated in clinical trials. An example of this involves lung cancer screening with a spiral computed tomography (CT). In 2000, many hospitals were promoting using this screening tool because it is much faster than a standard CT. Even though at the time many insurance companies would not pay for the test, hospitals were advertising to their at risk patients to have the procedure done. Opponents argued that the trial which was used to support its use was not a randomized clinical trial. According to Dr. Peter Clark, a professor of ethics, he stated, “I don’t think it would pass the test of beneficence. With one clinical trial, I don’t think that’s enough. Therefore, unless we have enough data from long-term clinical trials on the accuracy and the false positives and false negatives, I don’t see how a hospital could advertise this in good conscience.” This ethical dilemma of whether to advertise to patients a service that has not been proven to be clinically significant is an interesting situation which has the potential to help or harm the patient. The benefit to the patient is to possibly detect lung cancer at an earlier time than with another device. The harm to the patient includes cost, false positives, and false negatives.

This paper has examined both advertising of prescription medications and by healthcare systems. The ethics involved has only been briefly touched on with the analyzing of healthcare
The ethical dilemma involved with advertising prescription medications is: is it ethical to advertise directly to consumers on prescription products? This paper has presented both reasons why it is helpful and harmful to advertise to the consumer. Both the facts and concepts have been clarified, but the ethical principles involved have not been discussed. The most important principles are autonomy and nonmaleficence. Drug manufacturers are using nonmaleficence in their advertisements. The advertisements simply present the facts, benefits, and risks of the advertised medication. Some would argue this is providing no harm to patients because the company is just relaying the facts to the patient. Opponents would argue that DTC advertising promotes more harm than benefit thereby violating the principle of nonmaleficence. For example, Frosch et al researched the content of television advertisements produced by pharmaceutical companies. The study found that 95% of the advertisements used emotional appeal to attract consumers. Advertisements portrayed to patients that they would regain control of lost functions or abilities by taking the medication. This is not true for all problems and all patients. Therefore, these advertisements are violating the principle of nonmaleficence. Autonomy is another principle which is violated by DTC advertising. Patients have the right to exercise their own decisions. By viewing DTC advertising this is persuading their decisions made about their own healthcare.

For the time being, since DTC advertising is legal in the United States, it is the pharmacist’s and physician’s duty to provide accurate information to patients. Patients have the right to know the truth. To accomplish this, patients need to be notified of all options to treat their condition including lifestyle modifications and other non-drug alternatives. It is important to inform patients that everything they see advertised in the media might not be their best option.
Healthcare providers can play a huge role in bridging the gap of information which is left out in the advertisements.

After finding various studies which looked at DTC advertising, I became curious to learn how people I know feel about advertising. In a very informal study, I asked participants three general questions. Responses to the questions were either “yes” or “no”. The first question was “do you think pharmaceutical companies should be able to advertise their drugs to patients?” The second question was “do you think hospitals should be able to advertise their services to patients?” The last question was “do you think the drug advertisements you have seen on television provide you with a good understanding of the drug advertised?” A total of twenty participants were questioned in the study. The study was designed in order to question patients that had not practiced or had any experience in the health care field.

The results of the study were quite interesting. All twenty participants said that they did not feel drug advertisements provide a good understanding of the drug advertised. A few participants stated that although they did not provide a good understanding, they at least made them aware of the drug. Eighteen of the twenty participants believed that pharmaceutical companies should be able to advertise their drugs to patients. One participant stated manufacturers have the right to free speech, but should not show misleading advertisements. In response to whether hospitals should be able to advertise their services, six of the twenty participants did not agree with hospitals advertising to patients. Overall, the majority of participants in this study agreed that DTC advertising should be allowed. Though, many participants felt the way advertising is currently being done is ineffective. One major limitation of the study was the wording of the questions and the requirement of giving a “yes” or “no”
response. Many participants stated that they may have answered differently if the questions were reworded or if they could respond with “maybe”.

With so much research being done on DTC advertising, what does the future entail? The Pharmaceutical Research and Manufacturers of America (PhRMA) has issued guiding principles for pharmaceutical companies to follow. Part of the guidelines state, “We know that DTC communications, particularly DTC television advertising, can be a powerful tool for reaching and educating millions of people, and we are committed to ensuring that our DTC communications provide accurate, accessible and useful health information to patients and consumers. DTC advertising of such important and powerful products as prescription drugs should be responsibly designed to achieve these goals and to encourage the appropriate use of these products.” One of the principles asks companies to properly educate health professionals on a new medication before commencing the first DTC campaign. Bristol-Myers Squibb has announced a voluntary moratorium on direct-to-consumer advertising for one year after a drug is FDA approved while Pfizer has agreed to a six month waiting period. A bill has been proposed in Congress and highly debated which would ban advertising of a drug for the first two years the drug is on the market. The theory on the ban is this would give time for post-marketing surveillance to be completed. Some opponents of the bill argue “banning advertising violates First Amendment protections of freedom of speech”. The issue of placing a two year ban on advertising is a current area of hot debate and will lay a framework for the future of DTC advertising.

In 2005, the FDA received 4,600 advertisements to analyze and had only four staff members to review them due to regulatory problems and staff shortages. This resulted in a decreased response time for staff members to review advertisements. Unfortunately in the mean
time, new drug advertisements were being aired for long periods of time before the FDA notified the manufacturer if there was a problem with the advertisements. Since this time a new law has been introduced to combat the problem. “On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 which includes the reauthorization and expansion of the Prescription Drug User Fee Act.” Part of this law includes resources for reviewing drug advertising including adding 27 staff members to the review team. This program gives companies the option to voluntarily submit their advertisements for FDA review before the public views them. The program requires manufacturers to pay a user fee for the FDA to review their material. This fee will be about $41,000 per advertisement if an estimated 150 advertisements are submitted by pharmaceutical companies. The FDA has set a performance goal of reviewing the advertisements within 45 days for 75 of the submissions. Although this law will increase the turn around time of reviewing advertisements, it is still a voluntary process for manufacturers.

In conclusion, DTC advertising has profound effects on the healthcare system. Patients are bombarded with information which they may or may not understand. It is estimated that Americans view 16 hours of prescription drug advertisements per year. This is a wealth of information which influences the decisions patients make about their healthcare. In my personal opinion from the information presented in this paper, I do not believe pharmaceutical companies should be allowed to advertise prescription medications to patients in the way it is currently being done. I also do not believe that health systems should be able to advertise their services to patients. Rhoda Weiss, a professional speaker on healthcare marketing and strategy, states “The best marketing is marketing that educates. Marketing can be great in terms of educating people and letting people know what’s out there. But it can also mislead people and take advantage of
people who are hypochondriacs or who are vulnerable because they’re ill.”

In my opinion, the marketing done by pharmaceutical companies and hospitals is done purely in order to sell more drugs and make more profit. In some rare cases, it is necessary to let patients know about new advances in medicine or new procedures done by hospitals which can be done to save lives. Though, this is the physician’s responsibility to stay informed on medical breakthroughs to help their patients. DTC advertising is threatening the physician-patient relationship. It has turned into the patient coming to the physician to request a medication from their physician.

Regardless if DTC should be legal or not, it is the role of the pharmacist to step in and help patients interpret the advertisements. It is important for pharmacists to inform their patients that the drug advertised or new technology offered in hospitals may not be the best option for them. The pharmacists should encourage patients to ask questions. Maybe the patient could try lifestyle modification first or there might be a generic option for them which is just as good as the advertised drug. Maybe instead of going to a hospital to have the newest, fastest diagnostic procedure, there is a less invasive test which is just as good. Pharmacists have the duty to their patients to encourage them to find the best treatment option. Hopefully by informing patients about DTC advertising, a decrease in unnecessary medications and the use of less expensive medications will lead to a decrease in overall healthcare costs.
References


