Direct to Consumer Advertising: Ethical Considerations

By

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A topic under constant criticism is advertising. Critics of advertising accuse it of increasing consumption of items for which we have no actual need, of making the public materialistic, of stereotyping, of brain washing children, of manipulating behavior, and even contributing to the downfall of our social system. It makes us feel like there is always something better to have and something else that we need. Advertising is also omnipresent. Ads are shown on commercials, newspapers, billboards, cars, buses, buildings, and even the back of our cereal boxes. It is nearly impossible for any American to go a day without seeing an advertisement of one type or another, and many of these advertisements will be for prescription medications. Recently, an area of particular concern in advertising is direct to consumer advertising, or DTC advertising, by pharmaceutical companies. DTC advertising has been defined as “any promotional effort by a pharmaceutical company to present prescription drug information to the general public through the lay media, i.e., newspapers, periodicals, television and radio” and is a controversial issue today, gaining much of its momentum and outrageous costs in the past decade. Today, these advertisements market prescription drugs directly to the public generally by portraying beautiful, happy people in euphoric situations, claiming to be taking a new expensive miracle medication that made their lives perfect, purposeful, or whole again. The criticisms and heated debates on DTC advertising will only continue to grow in the future, and therefore the topic encompasses many aspects worthy of evaluating, here most importantly its ethical implications on the medical professions, especially pharmacy.

Direct to consumer advertising of prescription drugs, as mentioned earlier, has only recently entered the spotlight of public and professional scrutiny. Major causes for this include lifted restrictions on pharmaceutical advertising, its massive amount of success, and its outstanding, far-reaching costs. In the 1980’s, marketing attention began to shift from health care professionals to the general public and in August 1997, the Food and Drug Administration announced a reinterpretation on its DTC advertising rules that allowed branded broadcast ads and increased the volume of DTC advertising several-fold. With this newfound interest and freedom, the pharmaceutical industry’s spending on direct to consumer advertising increased by a factor of more than seven by the year 2000, at a cost of more than $2.4 billion. Almost simultaneously, the traditional forms of promotion, particularly advertising in professional journals and hospital-based promotion, declined significantly. Consumers responded to advertisements by asking their physicians and pharmacists for drug information, requesting particular prescriptions by the brands they saw advertised on television, and inquiring about new medical conditions. This transition to a new form of advertising proved very beneficial to the pharmaceutical companies, as shown by the correlation in their top-selling drugs
being among those they most heavily marketed. Of those not as enthused with this new marketing tactic, are insurance companies. As much of the cost to the consumer is not direct, it has largely remained unnoticed by most of the general public. However, when insurance companies began paying for more medications that were newer and therefore more expensive in conjunction with more doctors’ visits to obtain the prescriptions, they soon took notice. In return, deductibles, co-pays, and premiums have increased to offset some of the cost bared by the insurance companies. When one evaluates all the hidden costs to society and postulates the magnitude of these costs, it is easy to see how DTC advertising achieved its position as a hot-button issue.

After reviewing the background of how DTC advertising came to be and how it grew into such a controversial issue, it is also important to point out that the pharmaceutical industry is protected in its advertising practices by the First Amendment and therefore through the right of free speech. The United States Constitution, through the First Amendment, places constraints on the government’s ability to repress free speech. Advertising is recognized as a form of “commercial speech” by the courts and has been defined as speech “which does no more than propose a commercial transaction.” Although it has not been recognized as being as valuable as other forms of speech by the courts, commercial speech is clearly protected by the First Amendment. Due to this protection, the government cannot regulate many criticisms aimed at DTC advertising. In Central Hudson Gas & Electric v. Public Service Commission, however, the Supreme Court declared that regulation of commercial speech can occur if, “it is misleading or concerns an illegal product,” and many critics argue that prescription medication commercials seemingly proposing a quick and easy fix to an illness via pill form with minimal side effects is, in fact, very misleading to the public. Studies report that in certain cases DTC advertising misled consumers by using claims that were unsupported about benefits from prescription medications. In one particular study published in the Lancet medical journal, Wade and colleagues asked pharmaceutical companies to substantiate marketing claims. Investigators concluded, “Standards of evidence used to justify advertising claims are inadequate.” Furthermore, data compiled in the United States and New Zealand, the only two countries to fully allow DTC advertising, has shown repeated misinformation of the public with DTC advertising of prescription medications. While it is easy to provide data in studies that has indicated how misleading drug commercials can be to the public, specific examples put the reality of the issue into a clearer perspective. A commercial for Lunesta®, a new prescription sleeping aid, depicts a peaceful setting with a green butterfly flying into an attractive younger woman’s bedroom. Soft music plays in the background and a woman begins to narrate the situation. She says that if you are having difficulty sleeping, it might be time to try a prescription sleep-aid that is non-habit forming, among other things. Meanwhile, the woman pleasantly sleeping in her bed has a small, peaceful-looking smile on her face. The commercial gives the impression that if you are not able to sleep, you can take Lunesta® and you will sleep wonderfully and peacefully without any major concerns of addiction. Finally, at the end of the commercial a brief summary of side effects is mentioned, but at this point the consumer is likely to have already made their mind up that Lunesta® looks like a great medication to take to help them sleep, and they are no longer listening to the narrator’s soothing voice when she
lists some possible side effects. As the Minnesota Medical Association’s Patricia Hanson, R.N. stated, DTC advertising has “increased prescribing of the advertised drugs, leading to unnecessary increases in drug expenditure.” It therefore appears, that while the pharmaceutical industry is protected under the First Amendment and has the right and liberty of free speech, the government may and should consider further limiting this right since it appears that drug companies are in violation of the rulings the Court has set forth and have mislead consumers all the way to the doctors office for their prescription.

So, with high costs and studies showing drug commercials are misleading, why do the work in the first place? The answer to this question is most likely found by looking at what the consumers and medical professionals think about these advertisements and their effect on their behaviors. First, the overall general consensus of the consumer is to be in favor of DTC advertising. The Journal of the American Board of Family Practice conducted a cross-sectional survey to determine public perceptions of the effect of direct-to-consumer advertising of prescription medications on health behaviors and health care utilization. The national, randomly conducted survey’s main outcome measures where: respondents who in the past 12 months, as a result of DTC advertising, requested preventative care or scheduled a physician visit; were diagnosed with a condition mentioned in advertisement; disclosed health concerns to a doctor; felt enhanced confidence or sense of control; or requested a medication change. The survey found that most respondents were fairly positive about the recent increase in drug advertisements and most thought it was a very good thing. This could be due to the fact that society has, over the past few decades, taken a more proactive approach to their personal healthcare and began to actively seek health-related information on diseases and conditions. Of 226 respondents to the study, 67 were given the medication mentioned in the drug advertisement and told by their doctors that it would improve their health and 168 of them said that they had felt more in control during the doctor visit as a result of the information in the DTC advertisement. Many also responded to the survey by saying they even felt more confident during the visit. It therefore appears that consumers hold very positive viewpoints toward DTC advertising due to the information and thus the confidence they gain from the ads. However, the confidence may be so much so that many sought a second opinion and some even changed their doctor or health care plan as a result of dissatisfaction in the discussion with their doctor about the drug in question. Additionally, doctors appear to be aware that some patients are willing to switch doctors until they find one that will prescribe them with the desired medication they saw on television. This seems to imply that the general public sees prescriptions drugs as nothing more than a consumer good, and will do what is necessary to obtain them. Dr. Berczeller, MD, retired professor of medicine at New York University commented on the issue:

When I was in practice, these ads weren’t really in vogue yet. But I was worried that they would remove the doctor as a filter, an essential provider of information. Prescribing drugs was intended to be a medical function, not a capitalistic stratagem. It’s wrong for us to be pressured to prescribe by a patient dazzled by a slick ad.
And pressured they are. With managed care and HMOs decreasing the amount prescribers are allowed to bill insurance companies per visit, many of them feel obligated to write prescriptions for medications their patients request, even if only to appease the patient and keep them as a customer of their practice. Besides the confidence that patients feel they gain from drug commercials, why are they suddenly so willing to go against the decisions of an experienced medical professional? Brian Kaatz, Pharm D, speculates what the patient may be thinking:

A patient may not be understanding if her physician tells her that he has no experience with a drug [and therefore will not prescribe it] when at the same time the patient has seen it advertised maybe 20 times in the last two weeks. [The patient wonders] “What is wrong with my doctor? Doesn’t he watch TV?”

If patients’ thought processes even somewhat resemble this, it is easy to see that combined with a convincing, confidence-boosting ad, they may have no problem switching physicians to obtain the medication they desire if they see the physician as uneducated about a drug they feel well educated on. In summary, we see that research has indicated the success of DTC advertising in raising consumers’ brand awareness, likelihood of making specific product requests, and prescribers’ propensity and reasons to comply with these requests.

Direct-to-consumer advertising of prescription drugs undeniably impacts patient attitudes, patient-provider communications, and ultimately medication use. While consumers and physicians may have differing viewpoints on DTC advertising, pharmacist’s behaviors and opinions are also impacted as a result of this phenomenon. When patients see drug commercials on television, in newspapers, or other forms of broadcast media, and are left with questions, many of them also decide to ask their pharmacist about the medication, even before heading to the physician. As the American Association of the Colleges of Pharmacy points out, nearly everyone is familiar with community pharmacists and the pharmacy in which they practice. Six out of every ten pharmacists provide care to patients in a community setting. Patients visit the community pharmacist more often than they do any other member of the health team. Pharmacists talk to people when they are healthy and when they are sick; when they are “just browsing” or when they are concerned with an emergency; when they have specific needs, and most importantly here, when they are seeking advice or information. According to one estimate on Purdue University’s School of Pharmacy and Pharmaceutical Sciences website, pharmacists receive more than two billion inquiries a year from their patients. Talking with the pharmacist has many benefits, as they are a reliable, easily accessible, unbiased, and a free source of information. While at first glance it may not appear that the pharmacist is involved in the implications of direct-to-consumer advertising, they are a valuable, informative resource to the public and therefore have a potential to be at the center of the issue as major players.
Next, we see that pharmacists’ viewpoints on direct-to-consumer advertising can be affected by many pros and cons of ethical issues. The largest ethical consideration of the pharmacist, according to research, deals mainly with the patient’s autonomy. Patient autonomy refers to the capability and right of patients to control the course of their own medical treatment and participate in the treatment decision-making process by being well informed. Drug commercials offer patients a large amount of information on disease states and medications used to treat them, while also explaining at least some of the more common side effects associated with their use. DTC advertising is meeting the increased demand for information from patients and is allowing them to make more informed decisions about their health care and therefore play a more active role in the decision-making process. Generally, a commercial for a prescription medication will start out by listing some of the symptoms of a given disease state or medical condition. The commercial then moves on to discussing how a medication now exists that are able to help manage this ailment. Many commercials offer visual depictions through animations of just how the medication works in the body against the disease and even describes the mechanism of action the drug has in layman’s terms. Patients receive a mini-educational lesson on how their body and the medication work. When the patient expresses to the physician that they feel they have the disease state they saw described on television and asks for a prescription for the medication they now feel knowledgeable about, the patient is more informed and involved with their healthcare and therefore is acting more autonomously. The respect of autonomy of the patient is a significant improvement in medicine. At one time, physicians operated on a paternalistic system in which they were considered the best decision-maker, since only they had the sufficient knowledge about a disease state, available alternatives, and the patient’s condition. Another benefit to patients playing a more active role in their health care management is that patients that feel they have helped decide on their health care choices, and have been prescribed the drug they requested, are much more likely to be compliant with their medication regimens. When the pharmacist first fills the prescription for the patient and is confronted with questions regarding it, the pharmacist is engaged with a more knowledgeable, empowered patient. When he discusses with the patient if the medication is right for them or not, the pharmacist can respect the patient’s autonomy by knowing that the patient has been informed about the medication at least partially already, and fill in any leftover gaps. Therefore, by the time the patient takes the prescription he receives three different sources of information: the informative drug commercial, the physician, and the pharmacist.

As we can see, direct-to-consumer advertising has the ability to have a positive impact on the patient’s autonomy by empowering the patient and forming a knowledge base on which other health care professionals can build on. However, one can also see a negative impact on the patient’s right of autonomy just as easy. For instance, much of the information given in commercials is displayed in such a way that the patient will almost always be left with a positive opinion of the medication even before the commercial hurriedly mentions some of the possible side effects. As patients have not had proper diagnostic education like physicians, they may diagnose themselves with the condition mentioned in the commercial falsely. When the patient presents to the physician requesting and sometimes demanding a prescription for the medication they
saw on television, and receives the prescription requested, the pharmacist is left with the ethical decision of whether or not to fill it when they may know the prescription to be unnecessary or suboptimal therapy for the patient. After all, the pharmaceutical industry does not spend billions of dollars a year advertising generic drugs that have a long history of efficacy and are more cost-effective for insurance companies and the patient. The pharmacist may be seen as negatively affecting the patient’s right of autonomy if they try to explain that lifestyle modifications or a cheaper drug may be a better option for a particular patient’s condition. Doing what is best for the patient at all costs, even if it appears to impinge on the patient’s right to autonomy, brings other ethical considerations to light. Beneficence and non-maleficence, as the American Society of Consultant Pharmacists points out, often need to be balanced against a patient’s autonomy. Beneficence is defined as a person’s moral obligation to help others, to contribute to the welfare of others, and to generally do good to the patient. For pharmacists, this means doing what is best for the patient at all times. If a pharmacist is to act on the principle of beneficence, then the pharmacist who has a patient present with a prescription for a new, expensive medication they feel the patient may not need, it may be the pharmacist’s duty to prevent the unnecessary cost of filling the prescription, and thus also save the patient from possible harmful side effects of the medication. For example, a middle aged, slightly overweight, male patient who is generally healthy sees a commercial on television about high cholesterol and how it can clog his arteries, eventually causing a heart attack and death. The patient becomes concerned about their cholesterol as they realize they have not had this checked before. Then, the commercial shows some physically fit happy men, explaining how they started taking a drug called Lipitor®, and the impression is left that the men no longer need to worry about their high cholesterol, because Lipitor® will certainly save them from heart attack and death. Next, the patient makes an appointment with their physician to have blood work done and finds their cholesterol to be 215. The patient requests Lipitor® to lower their cholesterol, since they know it to be effective and are familiar with it, and the doctor complies with the request to write the prescription. When the patient presents to the pharmacist, and the pharmacist in conversation finds that this is the first time the patient has had their cholesterol checked and that it was only 215, the pharmacist finds themselves in a moral dilemma. As pharmacists know, according to the Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), or ATP-III guidelines, cholesterol that is only moderately above 200 in a patient with no comorbidities presenting to the physician’s office for the first time with moderately elevated cholesterol, should first try diet and lifestyle modifications for 6 months before starting a cholesterol lowering medication. What is the pharmacist to do? On the one hand, the patient made the decision to obtain a prescription for a medication they are willing to take to do what they see as best for their condition of high cholesterol and the pharmacist should respect the patients decision and therefore their autonomy and fill the prescription for the Lipitor®. On the other hand, the pharmacist has more extensive knowledge then the patient on cholesterol lowering treatments via the ATP-III guidelines, and should tell the patient that diet and exercise has already been proven to be the best and safest treatment option for a patient of his type and in his particular situation. The pharmacist wants to do good for the patient, and also knows that diet and exercise have more far-
reaching, long term benefits than solely a cholesterol medication anyways. For example, if the patient thinks he is healthy by taking the cholesterol medication he is prescribed, he may not bother to address his weight issue and can eventually develop type II diabetes mellitus, leading to even more severe health outcomes, such as kidney failure. Society today may be headed towards a “pill for every ill” mentality, largely from seeing so many drug ads that convince them all their conditions are treatable and they are therefore invincible to disease. If the pharmacist fills the prescription, does he help to promote this mentality amongst his patients? After all, if the pharmacist unnecessarily fills his prescription for the expensive brand-name medication Lipitor®, he is causing the patient and the patient’s insurer to pay for it mainly for no good reason. Here, we see that pharmacists can face difficult ethical situations originally caused by DTC advertising that force them to balance the principles of autonomy and beneficence. Once again, a quote from Brian Kaatz, Pharm D, summarizes the difficult situation pharmacist face in maintaining the patient’s autonomy, and offers solution through his opinion on if pharmacists are even truly harming a patient’s autonomy that’s knowledge base is rooted in a DTC advertisement.

Patient autonomy has been argued elsewhere as being the preeminent ethics principle. There is a strong case for patients knowing as much as they can reasonably understand about disease processes and medication risks and advantages. There is also a strong case for patients being actively involved in their own therapeutic journeys and fully participating in these kinds of decisions. But can we relate direct-to-consumer advertising with true patient autonomy? Is advertising valuable in the effort to develop autonomous decision-making? There is a case for answering these questions in the [both the positive and] negative. It must be remembered that patient autonomy does not begin and end with the simple act of a patient making a decision. To the contrary, autonomous decision-making occurs only when there is a fully informed decision-maker. Autonomy is based upon that important element. Thus, one can readily see that a brief, colorful advertisement by itself offers little in the way of full disclosure and does not contain the complete tools necessary to make an autonomous decision.

Therefore it appears that at least in Dr. Kaatz opinion, a pharmacist may be justified in following his duty of beneficence without actually having to be too concerned about harming the patient’s autonomy, since the patient, via only a DTC advertisement, is not technically acting autonomously to begin with. This, however, does not solve the problem of another ethical issue that is brought into consideration in this situation: non-maleficence. Non-maleficence is defined as not doing evil, or doing no harm. This ethical principle has been apart of the medical community's code of ethics for quite some time as is evident in the Hippocratic Oath’s line: “First, do no harm.” Non-maleficence is brought into this scenario because the patient may experience one of the many side effects of the medication unnecessarily. While some side effects of the statin Lipitor®, are mild, they have been responsible for causing severe muscle breakdown known as rhabdomyolysis, liver disorder, kidney failure, and even death. What if the
pharmacist kills this patient by filling the prescription when the pharmacist was only trying to respect the patient’s autonomy? If the pharmacist is to do no harm, it may be argued once again that the prescription should not be filled for yet another ethical reason and that balance must be achieved between the two.

One of the pharmacist’s duties, which is paramount to the profession of pharmacy, is to uphold the covenantal relationship that exists between the pharmacist and the patient. The duty of the pharmacist to build and maintain the covenantal relationship is so important, that it is the first principle to be mentioned in the APhA Code of Ethics for Pharmacists. Without the covenantal relationship, it can be argued, pharmacy would no longer be considered a profession in health care. Direct-to-consumer advertising has both positive and negative effects on the pharmacist’s covenantal relationship, albeit indirectly. First, as mentioned earlier, consumers have an increased desire to gain knowledge and information about their disease states and medication options to treat them. When a 30 second commercial is over in the blink of an eye, the patient is left with questions that can easily be answered by their community pharmacist. This increased opportunity for open communication helps the pharmacist to strengthen the trust between himself and the patient by expressing to the patient that he is committed to their health care and their well being. The pharmacist shows he is there to be relied on should the patient need to obtain any medication or health related information. Also, the pharmacist serves as the patients advocate for unbiased, reliable information and therefore strengthens the covenantal relationship by building trust. On the other side, it can also be shown that DTC advertising has a negative effect on the covenantal relationship. As mentioned earlier, consumers are bombarded with advertisements daily that persuade them that they must have the product being advertised. When drugs are marketed to consumers just as clothes and groceries are, society begins to see prescription medication as just another consumer good which in turn is dispensed by just another “clerk.” The impression is given that pharmacy is a business and pharmacists exist to sell you their product via a prescription. This viewpoint negatively affects the pharmacist covenantal relationship with the patient since the patient loses trust in the pharmacist that they may feel is only there to get them to buy their products. Therefore, as is evident, DTC has indirect positive and negative effects on the covenantal relationship between the pharmacist and patient.

In conclusion, drug companies have been very successful in the past two decades with advertising their expensive, brand name drugs directly to consumers. There are many proponents and many critics on the issue. DTC advertising is a new form of selling that’s impact is not yet fully understood. However, one thing is apparent: given that these are advertisements that deal with a patient’s healthcare, there are many positive and negative ethical implications to consider for medical professionals, most importantly pharmacist since they must achieve a delicate balance between each ethical implication and maintain the covenantal relationship between themselves and the patient. John E. Schowalter, MD, states on his website that, “the topic of ethics is usually not thought about, but if one never thinks about ethical issues, one will never see them, until it is too late. Acknowledging and wrestling with ethical issues can lead to greater clinical wisdom.”
References


