Direct-to-consumer-advertising (DTCA) is an advertising effort targeted at patients by pharmaceutical companies to present prescription drug information through mass media\(^1\). DTCA has long been a subject of debate and discussion, with strong arguments both for and against its existence, and the varying degrees of regulation involved. By studying the foundational arguments from both sides, the ways that both patients and physicians react to DTCA, the implication of basic ethical principles, financial concerns and international stances on the debate, it becomes clear that DTCA is not only an unnecessary feature of the healthcare information system but also a harmful one.

The commercial promotion of medications has been in existence for many years, in many different forms. One common method of medication promotion is physician detailing where pharmaceutical representatives visit physicians directly to describe the benefits of their product, often leaving behind free samples or other gifts. Medications have also been advertised for years in professional and scientific journals, again targeting physicians and other healthcare providers who will be working with, prescribing or counselling patients about these medications. The most controversial form of prescription medication promotion is the marketing that directly targets patients instead of their healthcare professionals.

DTCA has been a presence in the healthcare field for quite some time, in many different forms. DTCA has received much attention and analysis this year because 2007 marked the ten-
year anniversary of changes made to the Food, Drug and Cosmetic Act (FDCA) created by the Food and Drug Administration (FDA) that allowed DTCA to be broadcast on television. The main changes made involved what information needed to be communicated to consumers. Prior to 1997, pharmaceutical companies were required to include all risk-related information in all promotional material, which proved to be cumbersome to creating concise advertisements directed at the general population as opposed to strictly healthcare professionals. The first change to the FDCA was the “adequate provision” requirement, which stated that instead of providing all of this information, it would be sufficient for a company to simply direct consumers to an alternate source of this information, such as a website, toll-free hotline or print ad. The other change to the FDCA enabling more widespread advertising was the “major statement” requirement, demanding that only the major risks and most common adverse events associated with using the advertised product be communicated in promotional material. Another important feature of DTCA regulations is the “fair balance” requirement, which ensures that both benefits and risks are presented to the patient.

There are several different forms of DTCA in existence. The first is the group of “reminder advertisements.” These advertisements exist only in the form of the brand and/or generic name of a medication being displayed, with no claims made regarding risks, benefits, or even what the medication is typically used for. Examples of reminder advertisements are pens or tote bags frequently acquired at healthcare conferences that have simply a drug name written on them. The other non-regulated form of DTCA is the group of “help-seeking advertisements,” which exist to promote general awareness about a disease state. There is no mention of any
specific medications. An example of a help-seeking advertisement would be a promotion encouraging patients to seek out preventative health screenings.

The form of DTCA under the most scrutiny is referred to as the “product-claim advertisements,” where a specific medication is promoted to have specific effects in a specific disease state. It is the product-claim advertisements that are subject to the major statement and fair balance requirements outlined above. The distribution and regulation of product-claim advertisements has important ethical implications because of its potential impact on patient and physician decisions, financial priorities of pharmaceutical companies, and the actual content of these advertisements.

Supporters of DTCA proclaim that advertising pharmaceuticals directly to patients enables patients to take a more active role in their healthcare because it creates a situation in which the physician is no longer the sole source of information. DTCA may help patients develop a two-way dialogue with their healthcare providers and, for better or worse, have a goal in mind in terms of what prescription will hopefully be written. Another popular argument made in favor of DTCA is its potential function as an educational tool. The idea behind this statement is that the advertisements for specific medications often include key symptoms of the disease state that the medication is intended to treat. People viewing the advertisements may recognize the described symptoms in themselves and seek medical attention more promptly then they may have otherwise².
Opponents of DTCA criticize the likely ability of the advertisements to undermine the professional authority and expertise of physicians because the information is being presented directly to patients who do not have the same level of training and thus ability to adequately interpret and evaluate the claims being made. Patients approaching their physicians demanding a certain medication they saw advertised may lead to an uncomfortable shift from the traditional model in which a physician decides independently which therapeutic choice is most appropriate for a given patient. There are also concerns that DTCA may contribute to over-consumption of medications. While the physician always gets the final say in whether a prescription is written, a dramatic increase in patients being exposed to DTCA and subsequently requesting those medications they see advertised is likely to eventually drive up medication use. Along the same lines of consumption arises another concern – the increasingly short time interval between FDA approval of a medication and the beginning of advertising campaigns for the newly approved drug. A recent study found that most new medication promotions began within one year of FDA approval. Heavy marketing shortly after approval may lead to greater than usual consumption of medication before sufficient post-marketing surveillance has been completed to identify rare but serious adverse effects. A key example of this is the Vioxx disaster. Vioxx was marketed very heavily very shortly after receiving its FDA approval. While the rare but serious cardiac effects would have been discovered eventually regardless of advertising, the strong promotion of Vioxx arguably led to a greater number of people being affected by this adverse effect than would have in a less aggressive marketing situation. This issue has led some consumer groups to call for a moratorium on advertising new medications for two to three years after approval. However, a problem exists here in the urgency for effective medications to be distributed in more dire situations, such as terminal cancer patients awaiting new treatments.
After considering the standing arguments, it may be helpful to review foundational ethical principles and how they can be applied to a discussion of the merits or shortcomings of DTCA. The important ethical principle of autonomy becomes an issue when considering direct-to-consumer advertising. Autonomy is the rule that “an individual’s thoughts, choices and actions are not to be interfered with.” Exposure to advertising, which by definition includes biased and influential materials, initially appears to be in direct violation of autonomy. However, the previously described argument for the ability of DTCA to play an educational role in healthcare must again be taken into consideration. Does contributing to knowledge not better enable a patient to shape informed thoughts, choices and actions? At this time the reader may take into account a different definition of autonomy, tailored to this subject: autonomy is “not the ability to choose a therapy, but the ability to actively participate in choices about healthcare.” It is a logical assumption that a patient choosing to research a medication by reading medical journals and textbooks would be better equipped to make healthcare decisions. When DTCA is considered to be another form of educational material, it can be argued that this form of advertising actually contributes to patient autonomy. However, this argument is accompanied by the crucial stipulation that the advertisements must provide a fair balance of risks and benefits. Even if this is achieved by the promotional material reaching patients, it is impossible for all background and contextual information be communicated in a short advertisement (although it could be argued that this is an impossible task for even the most detailed of textbooks or package inserts). While DTCA does provide a starting point in providing the information that contributes to a patient’s ability to actively participate in choices about his or her healthcare, the presence of bias, the absence of conclusive information and the ultimate goal of encouraging consumption
rather than promoting awareness discredits DTCA as a viable contributing factor to patient autonomy.

The ethical principle of paternalism factors into healthcare decisions, and more specifically into the reactions of patients and healthcare providers to DTCA. As acknowledged by McCarthy and Vivian⁶, paternalism can coexist with autonomy even though the two concepts appear to clearly contradict each other. It is the concept of weak paternalism, applied when a patient lacks the knowledge or ability to make an informed decision that is relevant in this situation. Healthcare providers should be responsible for helping patients better understand the information communicated in promotional materials, and more importantly supplementing this information with clinical data and judgement, contextual information and experience.

While there are sound arguments made on both sides of the DTCA debate and important ethical considerations, there is more value in research investigating how the public, both patients and physicians, are actually affected by DTCA. An Soontae tested patient response to DTCA as a function of how patients feel about the advertising technique in general, and as a function of the patients’ self-perceived knowledge of health and medicine⁸. Patient response to DTCA was measured in terms of how likely a patient would be to request a prescription for a medication he or she had learned about through DTCA. Survey respondents who considered themselves to have a strong understanding of health and medicine were most likely to inquire to their physician about a medication they had seen advertised. An increased likelihood of inquiring about advertised medications was also seen among those respondents who respond favorably to DTCA, that is, those who enjoy seeing this type of advertising. These results compliment each other
because they both show that there is a significant contribution of independent factors to a patient’s reaction to DTCA. This finding should be considered when deciding how DTCA affects patients’ autonomy. According to Soontae’s study, patient autonomy is maintained because it is the intrinsic values and perceptions that make the bigger impact on how one’s actions are influenced by DTCA. However, the results of this trial simultaneously negate a different argument made in favor of DTCA. As described earlier, proponents of DTCA maintain that the advertising method educates patients, thus enabling them to become active participants in their healthcare. Just as Soontae found that respondents who enjoyed DTCA and considered themselves to be knowledgeable about health and medicine were likely to pursue a conversation with their doctors, the study also proved that patients with low self-perceived knowledge and a poor impression of DTCA were much less likely to engage in these interactions. The study concluded that DTCA was an inadequate means of enabling patients in patient-physician encounters when patients did not already have independent qualities contributing to opening such dialogue.

Instead of studying patient response to DTCA, Mintzes et al. examined how DTCA impacts physicians. Using surveys following actual patient-physician encounters, researchers learned that doctors wrote a prescription for approximately 75% of the medications patients requested after having learned about them through DTCA^7. Another interesting finding was the measurement of physician confidence in the prescriptions written for requested medications. In the post-visit survey, physicians were asked whether they would have written the same prescription to a similar patient who did not make a request for an advertised medication. Of the options given, responses of “possibly” or “unlikely” were considered to indicate physician
ambivalence of the validity of the clinical decision made. Physicians expressed ambivalence about 50% of the prescriptions written for requested DTCA medications. Like Soontae’s study, this investigation counteracts a common argument defending DTCA – the notion that DTCA cannot cause patients harm because the physician always has the last say as to whether a prescription will be written. However, it is now seen that physicians can be swayed by patient requests and, most importantly, may make clinical decisions that they are not always completely confident in.

While societal trends are rarely indicative of what is ethically right, it is worth noting that America and New Zealand are the only countries in the world that permit DTCA. In recent years, debates similar to those going on in America have been taking place in New Zealand, with observers expecting a ban on DTCA in New Zealand. There have also been discussions in Europe after The European Commission made a public statement regretting its strong rejection of proposals to relax medication advertising regulations in 2005.

While parts of Canada, particularly those close to the American border, are exposed to American DTCA, Canadian law maintains that while help-seeking and reminder advertisements are acceptable, product-claim statements are not. Health Canada maintains its position on DTCA not as a means of limiting patient access to information, but as a means to provide only material that is unbiased and clinically sound. This does not mean that the debate is any less intense in Canada than it is in America. In late 2006, CanWest Global Communications, a prominent Canadian corporate communications corporation challenged the current laws, accusing them of suppressing freedom of expression. Also on the CanWest platform is the
unavoidable fact that so many Canadians are already being exposed to American DTCA. The challenge has brought forth a coalition of health and consumer groups lobbying to keep the laws the same and keep DTCA out of Canadian media. While much of the proceedings have called upon the main arguments for and against DTCA which have already been discussed, one of the simplest statements – that the current Canadian laws, and the restrictions that many American groups are hoping to impose upon DTCA, violate the basic right of free speech – makes for a complex debate.

Examining this rebuttal from the utilitarian perspective is a fairly simple task. If laws against DTCA indeed violate freedom of expression, it can be argued from the anti-DTCA standpoint that the ends justify the means. That is, the stifling of free speech, which on the surface appears to be a negative thing, is justified by the positive result of protecting patients from biased and potentially misleading information about a crucially important part of their lives.

Considering the debate over DTCA with respect to the right to free speech from the deontological perspective is different from each side of the debate. Those in favor of DTCA likely uphold freedom of expression as an absolute right, and would consider the suppression of this privilege to be an absolute wrong. Those opposed to DTCA would consider the advertising scheme an absolute wrong. In this case, it can be expected that suppression of DTCA is an absolute right. This is different from the utilitarian perspective because the focus is not justifying the typically negative process of violating freedom of expression, but only on whatever means are necessary to prevent DTCA from reaching patients.
Another source of concern about DTCA is the money being allocated toward advertising and particularly how spending on advertising will affect the costs of medications. The spending trends since DTCA regulations were loosened in 1997 are staggering. Total spending on all forms of prescription drug promotion (including DTCA, physician detailing, samples, reminder ads, etc.) increased from $11.4 billion in 1996 to $29.9 billion in 2005. In terms of money spent solely on DTCA, there was an increase from $791 million to $3.2 billion spent from 1996 and 2003. Physician detailing remained the primary spending area throughout the last ten years, though there was a greater increase in the proportion of spending directed to DTCA. Despite the increased funds being directed toward advertising, research shows that this is unlikely to impact costs to patients, as this is mainly based on product value. Of course, DTCA has been accused of increasing medication consumption, leading to a conclusion that advertising may indirectly increase prescription drug prices.

Given the controversy surrounding DTCA, it is surprising to learn that there are no rules in effect requiring pharmaceutical companies to have their advertisements pre-approved before being aired. Instead, pharmaceutical companies simply submit their promotional materials to the FDA at the same time they begin to be presented to the public. The FDA can only issue warning letters or order the removal of advertisements deemed to be noncompliant with guideline as stated in the FDCA.

While reminder and help-seeking advertisements are typically considered to be less stringently regulated forms of promotion, the FDA is still able to issue warnings when such
advertisements make claims that are not supposed to appear in such material. For example, a warning letter was issued in November 2007 to a company in regards to a mouse pad that was intended to serve as a reminder advertisement. While only the drug name was displayed, there was a picture of a man in a hospital drowning in water, alluding to the advertised drug’s use as a diuretic\textsuperscript{13}. Other letters published on the website of the FDA Center for Drug Evaluation and Research (CDER) cite companies for “overstating efficacy,” making “unsubstantiated superiority claims,” and “omitting material facts.” Letters are issued for both DTCA (print ad, reminder ads and other forms) as well as other forms of prescription drug promotion such as professional letters included in physician detailing. Letters can also be issued following site visits to pharmaceutical companies. Some examples of violations cited at site visits are non-compliance with current good manufacturing practice or with prior Institutional Review Board recommendations.

The warning letters being issued by the FDA are concise and effective, but an overriding flaw in the system is a significant lag time between the publication of inappropriate advertisements and warnings/reprimands from the FDA\textsuperscript{14}. In this time interval, inappropriate or misleading information can be distributed to and impact many people before action is taken to remove or edit the advertisements. A main reason for this problem is that there are too few staff members being assigned to regulate an exponentially growing responsibility. Perhaps even more serious of an issue than the time lapse between the airing of an advertisement and the issuance of regulatory warning letters is the concern that there may be noncompliant promotional material circulating without receiving any FDA notification at all. Based on the FDA CDER website, there were 165 warning letters issued in 1997 (the first year that widespread DTCA was
permitted) and only 34 letters in 2006\textsuperscript{13}. While there has been a significant decline in the number of letters issued, it appears that efforts have become more focused on the advertising reaching the consumer. Donohue et al. conducted a review of FDA regulatory letters and found that there is a significant increase in the percentage of letters being issued for DTCA-related offences as opposed to other promotional material such as reminder advertisements and physician detailing\textsuperscript{4}.

DTCA should be limited only to help-seeking advertisements, which raise patient awareness but do not promote a specific medication or make specific claims. The strongest arguments made in favor of DTCA reference its ability to educate patients. Without the underlying goal of endorsing a product, DTCA would take on the new shape of a public service announcement free of bias. Changing the role of DTCA to a strictly educational tool will protect and promote patient autonomy and remove concerns over a tendency toward paternalism, assuming that the information presented is accurate and applicable to the general public.

Another change that should be made to the current DTCA system is the regulatory review process. Advertisements should be reviewed prior to being aired. The current system is severely flawed in that messages that have not been approved are routinely reaching patients. Based on the FDA website’s plenitude of warning letters issued to pharmaceutical companies, it is clear that inappropriate advertisements are being aired on a regular basis. The fact that FDA resources become quickly saturated by the magnitude of DTCA should serve as an indication that something needs to change, either within the allocation of FDA staff or in the amount of DTCA that should be permitted to reach the public. The new policy should be adopted requiring all
advertisements to be reviewed by the FDA prior to being aired. Given the current system and its tendency to be overloaded, an obvious problem with this change would be a longer wait between a new medication being approved and its advertising campaign being launched. Considering that the currently short time interval between approval and advertising has been the focus of many criticisms in light of the Vioxx disaster, it should be expected that critics would respond favorably to this change. Finally, if the first proposed change were to be adopted, that is, allowing DTCA strictly in the form of help-seeking advertisements, there could possibly be a decline in the number of advertisements for the FDA to review. The regulation procedure for help-seeking advertisements would have some significant differences from the process of reviewing product-claim advertisements because instead of scrutinizing features such as efficacy statements, bias, and deletion of associated risks, reviewers could focus solely on the accuracy and relevance of information. This process would likely be less time consuming because producers of the help-seeking advertisements would no longer have an incentive to make selective over- and understatements.

DTCA has been in existence for years, in many different forms and regulated under many different standards. DTCA has been criticized for contributing to over-consumption of medications, undermining physician expertise and driving up drug costs. While DTCA has been credited as a means of patient education, help-seeking advertisements free of bias would more effectively meet this goal. Given the many viable alternatives for patients to receive important information through unbiased means, DTCA should be recognized for what it is -- purely advertising. Prescription drug promotion should be removed from its prominent place in patients’ lives and reverted back to the physician detailing model. Physician detailing comes
with another set of ethical issues, but it differs significantly from DTCA because the target audience is armed with the requisite knowledge and clinical experience to critically evaluate the information presented and make educated decisions.

Until the current practices of DTCA change, there is a professional responsibility for healthcare professionals to manage this environment where patients are getting information from many different sources, with varying degrees of bias and accuracy. While healthcare providers are often considered to contribute to the paternalism model, they can promote patient autonomy by providing patients with sound, unbiased information. Since DTCA is currently an important contributor to patient knowledge base, healthcare providers would be doing their patients a service to gain an understanding of what messages are being delivered. Having a common starting point in the form of DTCA will facilitate healthcare providers in counseling their patients, whose best interests must remain rooted in the minds of all participants in the DTCA debate.

Edited by Erica Scratch, 1/2008
Works Cited


