
by

Serena Tsai

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Approved by:

Content Reader: James Berlanti, MD

Second Reader: William Williamson, MPH
Abstract: Direct to consumer advertising (DTCA) is a polarized topic, with healthcare professionals (HCPs), patients and policy makers involved in the debate. Opponents of DTC marketing believe that this practice increases the use of more expensive drugs that may not show a benefit over older, less expensive drugs. They argue that this practice leads to an overall increase in drug costs for the United States, by both influencing patients to ask for the advertised product, as well as indirectly influencing physician to prescribe it. Opponents also feel that advertisements are skewed to inflate the benefits of the drugs, while mitigating the potential safety concerns of the products. Proponents of DTC marketing believe that mobilization of patients through increased disease awareness is a by-product of this practice, leading to better diagnosis and treatment of many patients. Surveys have shown that DTCA is believed to increase adherence to prescribed medications and plays a role in reducing the stigma associated with certain conditions. Interestingly, both patient and physician surveys addressing these issues have shown mixed results, leading to further debate about the impact of this practice. However, certain changes to the current way DTCA is being carried out could improve the perceived benefit that this and the pharmaceutical industry as a whole, affords the patients and HCPs of the United States.

Introduction:

The path to direct-to-consumer advertising (DTCA) has been a long and arduous one (Donohue, 2006; Wilkes, Bell, & Kravitz, 2000). Prior to 1938, lax drug approval standards meant that many drugs were available without a prescription and were marketed mainly to patients. This led to inherent concerns, as there were no regulations to control overstatements of efficacy and safety. In response to a catastrophe involving a
drug named elixir sulfanilamide, Congress stepped in and passed the 1938 Food, Drug, and Cosmetic Act (FDCA) which legally gave the Food and Drug Administration (FDA) the power to approve drugs based on their safety profiles. By the 1960s, largely due to this regulation, 90% of the pharmaceutical companies’ spending on marketing was geared towards physicians with the hope that their prescribing habits would favor the marketed drug; the rest of the efforts were directed towards other healthcare professionals (HCPs) such as nurses and pharmacists. Any marketing efforts were regulated through the Federal Trade Commission (FTC), not the FDA, limiting their ability to regulate claims being made by the pharmaceutical companies.

In the late 1950s to early 1960s, unethical pharmaceutical marketing practices were scrutinized, as companies over-marketed the benefits of products while minimizing associated risks. Congress responded in 1962 by passing legislation giving the FDA power to approve a product based on the products’ safety and efficacy profiles. This amendment, the Kefauver-Harris Amendments to the FDCA, also allowed the FDA jurisdiction over the advertising of prescription drugs, thereby taking this power from the FTC. By 1969, the FDA’s final advertising regulations stated that all advertisements must accurately present a true depiction of the actual safety, tolerability, and efficacy of the drug. This was termed “fair balance,” indicating that though a pharmaceutical company could talk about a drug’s demonstrated efficacy, it must do so in the context of the potential associated risks, thereby presenting a true risk benefit profile to the patient. These guidelines shaped future pharmaceutical marketing practices.

In the 1980s, DTCA started to become more popular again. Though there was negative feedback initially, especially from FDA Commissioner Arthur Hill Hayes, the
FDA sponsored a study assessing consumer perceptions of, and their behaviors related to, prescription drug advertising. This study found that consumers wanted more drug information. In 1985, the FDA put out regulations stating that advertisements to consumers must meet the same requirements as those geared towards physicians. However, due to the difficulties in presenting all the safety and efficacy information included in the drug analysis, most pharmaceutical companies avoided DTC marketing of prescription drugs.

As patients became more interested in learning about products and diseases, however, there was a shift towards an increased use of DTC marketing. In the 1990s, DTC marketing increased dramatically, and pharmaceutical companies found a new partner for their DTC initiatives with a newly conservative Congress. In 1997, the FDA released the Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements, which shortened the brief summary requirements for broadcast ads. (Food and Drug Administration [FDA], 1997). The final version was released in 1999. This led the way to a growth of DTC marketing that some believe was unforeseen by many FDA officials (Donohue, 2006).

Today, while much of the marketing is still aimed at HCPs, use of patient-oriented marketing has skyrocketed and now accounts for about 40% of pharmaceutical promotional spending. To demonstrate the growth curve, Intercontinental Marketing Services (IMS) records report that in 1993, $166 million was spent on DTCA; in 2005 that figure rose to $4.2 billion. For certain products, DTCA is now the leading expense in some pharmaceutical companies’ promotional spending budget. The average American television viewer sees as many as 16 hours of prescription drug advertisements
per year, far exceeding the average 15 minutes a patient will spend with his/her PCP (Frosch, Krueger, Hornik, Cronholm, & Barg, 2007; Brownfield, Bernhardt, Phan, Williams & Parker, 2004).

Throughout its history, DTC marketing has been a controversial topic. Multidisciplinary groups, including policy makers, HCPs, consumer groups, industry groups and others, have tried to shed light on whether DTC marketing is, in fact, beneficial or detrimental to the US public healthcare system (Donohue, 2006; Wilkes et al., 2000). This paper will report evidence for both the perceived positive and negative effects of DTC marketing and suggest guidance to better utilize DTC marketing to help achieve public health goals.

**Reviewing the Evidence: The Opposition to DTC Marketing.**

The reasoning behind opposition to DTCA is well known. There are dangers, critics maintain, to marketing a pharmaceutical product the same way one would market a bar of soap or another consumer product. Challengers to DTCA's benefit in public health and education state that this form of marketing encourages the use of expensive newer drugs that do not show any additional health benefits compared to the older drugs that may be generic and thus, cheaper (Avorn, 2003; Hollon, 2005; Hansen, Shaheen, & Schommer, 2005). In fact, some feel that the increase in usage of these expensive new products may be a major force in increasing the United States' pharmaceutical drug spending (Findlay, 2002; Bachlor & Laouri, 2003).

Opponents to DTC marketing maintain that it is skewed to show the benefits of products without providing a balanced presentation of potential risks, especially long-term ones, of products (Gahart, Duhamel, Dievler, & Price, 2003; Kaphingst & Delong,
Additionally, DTC marketing is believed to negatively influence HCP and patient dynamics, forcing physicians to spend more time with patients to correct inaccurate perceptions they may have due to the marketing efforts (Bellard, 2004; Robinson et al., 2004). A large majority of stakeholders, including physicians and patients, believe that the drug industry is too aggressive in promoting the unapproved uses of their products and present too little usable data about their products, presumably because they hear about these practices through the lay press (Price Waterhouse Coopers [PWC], 2007). A majority of surveyed participants believed that pharmaceutical companies manipulate data and present the best data to sell their drugs while minimizing the benefits of generic formulations. The upcoming section will review the evidence for these claims.

**Newer drugs, but no new benefit?**

One of the main reasons opponents of DTCA are so defiantly against this type of marketing is that many of the recently approved drugs are reproductions of older drugs with little advantage in safety or efficacy, but at a higher cost for patients and the healthcare system (Avorn, 2003; Hollon, 2005; Hansen et al., 2005). In fact, some high profile studies seem to support this opinion. Two such studies are described.

The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) compared the use of diuretics, an important, if older, class of antihypertensive drug, with some of the newer classes of antihypertensive medications, such as angiotensin converting enzyme inhibitors (ACE-Is) and calcium channel blockers (CCBs) (Davis et al., 2006; Ahmed, 2004; Siragy, 2003; ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group, [ALLHAT CRG] 2002).
In this study, patients receiving a diuretic, plus an optimal treatment regimen without ACE-I and CCBs, experienced fewer cardiovascular events than patients taking ACE-Is or CCBs plus an optimized regimen. Additionally, patients on diuretic regimen had a lower incidence of heart failure and strokes compared to those on an ACE-I regimen.

This 40,000 patient trial suggests that giving diuretics as the first line therapy instead of ACE-Is and CCBs, should be standard practice for indicated patients. Additional analysis assessing the differential costs of using the more expensive products also added to the debate (Anderson, 2003). According to some pharmacoeconomic analyses, diuretics cost between $0.06 and $0.10 a day, while an ACE-I could cost up to $1.46 a day. Switching from this newer class of drug to a diuretic could result in a savings of $250.00 to $650.00 per patient, per year (Hansson, 1997). A retrospective cost analysis of US data collected between 1985 and 1992 showed that the yearly cost of diuretics was about $133.00 compared to approximately $444.00 per year for ACE-Is. Though recently at least three ACE-Is have gone generic, studies such as the Heart Outcomes Prevention Evaluation (HOPE) trial that showed protective cardiovascular benefits for a specific, branded ACE-I, ramipril, continue to convince many physicians to use the more expensive branded ACE-Is instead of generic products (Hemiels et al., 2003).

However, when other healthcare costs, such as supplemental care, laboratory tests and hospital and clinic visits were accounted for, the actual difference between the treatments was slightly less, with the total cost with diuretics coming out to be about $1043.00 versus $1243.00 for the ACE-I treatment regimen (Hilleman et al., 2004). Also, there were some limitations of the trial design. Many suggest that this trial did not
incorporate optimal treatment of the patients, as, ideally, many patients would have
gotten a combination of diuretics and ACE-Is or CCBs to achieve better blood pressure
total monthly health costs up to 30% lower than those who took the more expensive
second generation products (Rosenheck et al., 2006). The NIMH concluded that the
older antipsychotics can still play a major role in treating schizophrenia.

As in the case of ALLHAT, there is compelling data to suggest that the older
products should be used more often. However, as in the case of ALLHAT, there were
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antipsychotics, termed extrapyramidal side effects or EPS, a collection of movement

The Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) trial was
carried out by the National Institute of Mental Health (NIMH). The trial was done to
compare the safety and efficacy between the different atypical antipsychotics, the newer
agents for treatment of schizophrenia, and between those agents and the typical
antipsychotics, or the older products (Nasrallah, 2007; Stroup et al., 2006; Envoy et al.,
2006; Lieberman et al., 2005). The newer antipsychotics are prescribed for a majority of
cases even though they are significantly more expensive than the typical antipsychotics
because there is a widespread perception of slight increase in efficacy and tolerability
over the older class of antipsychotics (De Oliveira & Juruena, 2006).

CATIE showed that there was no statistically significant difference in overall
effectiveness between the atypical antipsychotics and the first generation products.

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disorders, patients who were known to be susceptible to EPS were excluded from the arm of patients who were supposed to get the older drug, perphenazine. Still, people in the perphenazine group were more likely to suffer from EPS and drop out of the trial due to these symptoms (Glick, 2006; Casey, 2006). Therefore, the role of older generation drugs in schizophrenia is still under question.

These are just two studies suggesting that the usage of newer and more marketed brands may not necessarily provide great benefits to all patients. In these two cases, generic products provide at least comparable efficacy to the newer products used to treat the same disease. A large number of recently surveyed consumers seem to believe that pharmaceutical companies choose to develop “me too” and “lifestyle” drugs instead of drugs that fulfill an important role in disease treatment (PWC, 2007). Critics of DTC marketing argue that the higher profile of marketed products drives patients to ask for those specific products leading to more frequent, and sometimes inappropriate, prescribing of the more expensive drugs, resulting in immense increases in the nation’s pharmaceutical drug spending (Avorn, 2003; Batchlor & Laouri, 2003; Vogel, Ramachandran, & Zachry, 2003).

Is there a relationship between DTC marketing and pharmaceutical drug spending?

Costs for all aspects of healthcare in the United States have been rising and are expected to continue to do so (Cutler, Rosen, & Vijan, 2006; Borger et al., 2006; Smith, Cowan, Heffler, & Catlin, 2006). The question is, however, whether DTC marketing contributes to the rise in pharmaceutical drug spending. The Kaiser Foundation did some research to further elucidate this issue concluding, “on average, a 10% increase in DTC advertising of drugs within a therapeutic drug class resulted in a 1% increase in sales of
the drugs in that class”. Further analyses assessing the 25 drug classes with the highest retail sales in 2000 suggested that every dollar the pharmaceutical industry spent on DTCA yielded an additional $4.20 in drug sales, leading to a 12% increase in prescription drug sales or an additional $2.6 billion in 2000 (Henry J Kaiser Foundation [HJKF], 2003).

This is supported by the United States General Accounting Office’s Report to Congressional Requesters, released in October 2002. The report notes that “prescription drug spending increased at an annual rate of about 18 percent from 1997 through 2001 and is the fastest growing component of health care spending in the United States.” They note that those products directly promoted to patients tend to be the highest selling products, with the number of prescriptions for the most frequently advertised drugs rising up to 25% compared with 4% of drugs that were not heavily advertised (United States General Accounting Office [GAO], 2002).

Interestingly, the increase in drug spending had little to do with the rise of individual drug costs. From 1999 to 2000, the wholesale cost for highly marketed products only rose 6% compared with 9% for those that were not heavily marketed. Therefore, the GAO (2002) concluded that a major rise in prescription drug spending is actually due to the increasing number of patients being treated with a marketed prescription product. The question is whether the drugs are being prescribed for medically necessary conditions, or whether patients are simply getting medications just because they ask their physician for them.

Aiken, Swasy, and Braman (2004) tried to answer this question, noting that although 42% of patients expected a prescription at their most recent visit with their
doctor, most of them, 63%, expected this because they were asking for a refill of their current prescription; the commercials simply serve to remind them to ask their physician for a refill. Seventeen percent of patients believed that they truly had the disease and knew the drug would work for them, likely because they had previously suffered from the same condition in the past. Aiken and company showed that only 6% of patients said that they wanted a prescription due only to a television broadcast advertisement and 5% claimed that a print advertisement led them to expect the medication.

The healthcare professional-patient dynamic: a negative influence resulting in tension and unnecessary prescriptions?

The HCP is seen as the mediator between the pharmaceutical industry and the consumer, or patient (Donohue, 2006; Welch-Cline & Young, 2004). Therefore, opponents of DTCA claim that DTCA strategies are inevitably harming the relationship between HCPs and their patients (Robinson et al., 2004). Critics assert that patients asking for specific, advertised products make the physicians uncomfortable, bring tension into the relationship, and contribute to excess drug use simply because of the request (Allison-Ottey, Ruffin, & Allison, 2002). In addition, critics claim that physicians are already pressed for time with patients and that DTC marketing forces physicians to spend valuable time explaining and correcting misconceptions that are a result of DTCA, thereby reducing time efficiency (Robinson et al., 2004; Aiken, 2003; Murray, Lo, Pollack, Donelan, & Lee, 2003).

There seems to be evidence to support these statements. Wilkes, Bell and Kravitz (2000) show in their analysis of the trends of DTC marketing that even given the push from managed care to increase the use of generic drugs, many of the prescriptions being
written still tended to be for branded products. According to Allison-Ottey’s (2002) study, a survey of almost 900 general practitioners (GPs) and specialists, showed that of those physicians that were asked by their patient for a specific treatment, 38% of them felt additional pressure to justify which treatment they prescribe. Another study showed that 18% of the GPs surveyed felt that patients bringing up an advertisement led to problems, including time needed to correct misconceptions. More than 40% of patients in this study reported that they expected to get an advertised product with 69% reporting that they did indeed receive that product. Approximately half of the GPs surveyed did not feel any pressure to prescribe, and 50% felt some pressure; 7% of GPs reported feeling very pressured to prescribe a specific product. (Aiken 2003; Aiken, 2005)

Additionally, these studies showed that more than 60% of surveyed physicians felt increased tension because of DTCA, with about 80% attributing the tension to patients’ questioning and second guessing their diagnosis (Aiken 2003). Though the numbers were lower, Slaughter’s study for Prevention magazine (2003), supported this result by showing that 36% of physicians surveyed also believed that DTC marketing introduced tension into their relationships with patients, with 32% of them feeling that DTC made patients question their judgment and ability to treat them.

As a result of this increased tension, many physicians just prescribe the product that their patients ask for. In one study, 40% of the physicians surveyed prescribed the requested drug and but less than half of them were positive that it was the best drug for the patient. Almost 50% felt that other drugs would have been as effective but they wanted to accommodate the patients’ requests. Fortunately, very few physicians truly felt that another drug or treatment option would have been significantly better for their
patients, suggesting that physicians will not prescribe treatments if they feel their patients would be in danger (Weissman et al., 2004).

Other surveys showed that up to three quarters of surveyed GPs and specialists believed that DTC marketing pressured them into prescribing a drug that they would not have normally prescribed (Lipsky & Taylor, 1997; Aiken, 2003; Murray, et al., 2003). It is important to note that in many cases patients requested an additional test, change in medication, or specialist referral—the request was not specific to just wanting the medication shown in the DTC advertisement (Murray et al.).

Although all studies show that some physicians feel pressured to prescribe a specific product, some studies show that the actual effect is minimal. One study, for instance, showed that 89% of physicians said that their prescribing habits have not changed as a result of the ads, with 61% of physicians saying they don’t feel additional pressure to justify their choices (Allison-Otley et al., 2002). Additionally, there may be differences in perception of pressure depending on whether the physician is a general practitioner or a specialist, with specialists feeling less pressure to prescribe according to patients’ requests (Aiken 2003; Aiken, 2005; Petroshius, Titus, & Hatch, 1995). An Aiken (2003) study showed that over 90% of the surveyed physicians felt that the patient did not try to influence the course of treatment in a way that would have been harmful to him/her. Another multi-specialty physician survey showed that 36% of surveyed physicians were seriously concerned and 40% were moderately concerned about physicians being influenced by pharmaceutical companies to prescribe a certain product through direct contact with sales representatives, as well as DTCA; approximately the
same number of physicians was also worried about the potential habit of over-treating patients (Weber, 2005).

The Wilkes (2000) study demonstrated that many patients would be upset if their request for a specific product was not fulfilled. Half of the respondents felt that they would be disappointed if the physician turned down their request, 25% anticipated that they would try to change the doctor's mind, 24% thought they might attempt to obtain the prescription from a different doctor and 15% thought that they might switch to a new doctor.

The prescribing trends for one specific type of drug are often used to support the claim that physicians will prescribe other unnecessary products. As antibiotic-resistance continues to increase, the worry is that in the future, other strains of bacteria may become resistant to currently available antibiotics. In fact, according to the FDA, about 70% of bacteria that presently cause infections in hospitals are resistant to at least one of the drugs most commonly used to treat those infections. Goossens et al. (2005) conducted an analysis across Europe to assess resistance profiles, showing that those countries with the highest use of antibiotics tended to have the most resistant pathogens. Another study showed that of patients who had a diagnosis of common cold or upper respiratory tract infection, more than one third of patients received antibiotics even though the disease was viral, not bacterial (Gilberg, Laouri, Wade & Isonaka, 2003).

Is fair balance really being accurately presented?

Critics of DTC marketing claim that marketing pieces directed towards the consumer are biased to show the benefits of the drug, while minimizing any potential risks associated with taking the product. In order to better clarify whether this perception
is held by both patients and HCPs, many groups have conducted surveys to assess this phenomenon.

Multiple studies have shown that most physicians surveyed believe that patients confuse the relative risks and benefits of advertised products, with the majority of physicians also believing that their patients think that the drug is more effective than clinical evidence shows. Physicians in these studies also believe that, overall, DTCA does not provide information in a balanced manner and that DTCA encourages patients to seek a treatment that they may not need (Aiken 2003; Weissman et al., 2004; Slaughter, 2003).

Golodner's (2003) survey, another FDA-sponsored study from 2003, assessed patient opinions and showed that 60% of patients believe advertisements are mainly to help the pharmaceutical industry sell their drugs, with almost 50% of patients saying that these advertisements encourage patients to ask for drugs that they do not need or can not take. Since 2003, patient perception of the pharmaceutical industry has fallen even further, as results of the Price Waterhouse Cooper's (2007) patient surveyed showed a burgeoning distrust of the industry as a whole, with results showing that patients felt that profits are the most important goal for the pharmaceutical companies. The questionnaire provided a glimpse into why that has happened, with the majority of surveyed stakeholders believing that pharmaceutical companies often manipulate or suppress negative clinical trial results or prevent the sales of generic products in order to profit from their more expensive branded products.

There were additional investigations that assessed the ads themselves to determine the balance of benefits versus risks. Frosch et al.'s (2007) study showed that almost 95%
of product claim ads and 100% of the reminder ads they assessed used positive emotional appeals, often by depicting a happy character after taking the product. Sixty-nine percent of the ads used negative emotional appeals such as showing a character in a fearful state before using the product. Wilkes et al. (2000) assessed advertisements between 1989 and 1998 and showed that the most common appeals used were claims of effectiveness and symptom control. The advertisements also focus on the “innovativeness” of the product and try to sell the potential convenience associated with it.

Although the FDA is supposed to be watching out for these biased depictions, detractors maintain that the FDA does not have the manpower to adequately monitor the marketing tactics of the pharmaceutical industry and in many cases, penalizes companies long after consumers have been subjected to false claims. In addition, current regulations may handicap the FDA from sending out timely warnings to pharmaceutical companies (Donohue, 2006; Gahart et al., 2003). In late 2001, the United States Department of Health and Human Services required the FDA to wait for the approval of the Office of Chief Counsel before regulatory letters could be issued (GAO, 2002). Due to this additional step in the process, the length of time before a warning letter would be sent to the pharmaceutical company for a misleading advertisement increased significantly. These misleading advertisements may have completed their broadcast life cycle before the FDA issued the letters. Further evidence critics use to demonstrate the ineffectiveness of the FDA is the decrease in warning letters issued by the FDA. The number of warning letters issued by the agency for violations of federal advertising requirements has fallen by over 50%, from 1154 in 2000 to 535 in 2005, a 15 year low (GAO, 2002; Waxman, 2004).
Reviewing the Evidence: The Proponents of DTC Marketing.

With all this evidence against DTC marketing, what are proponents saying to support it? Supporters of DTC marketing believe that this type of marketing has raised awareness of many diseases that affect both morbidity and mortality. This increased awareness leads to improved health-seeking behavior by patients, empowers them, and allows for better and more productive dialogue between HCP and patient, which is believed to result in better diagnosis and treatment. In fact, DTC marketing advocates say it is an important approach to building better partnerships between HCPs and patients, by helping to educate patients so that they are more likely to have an educated and informed conversation with their HCP. Furthermore, DTC marketing is thought to de-stigmatize certain diseases, leading to more awareness and better treatment (Pharmaceutical Research and Manufacturers of America [PhRMA], 2005; National Medical Association [NMA], 2002; Calfee, 2005; Murray et al., 2004). This section will review the evidence for these claims, which, interestingly, come from the same studies and surveys that also report on the negative perceptions of DTC marketing.

Does DTC increase disease awareness, help seeking behavior, patient understanding of disease and patient empowerment?

According to December 2003 Federal Trade Commission comments to the FDA, “[DTCA] can empower consumers to manage their own health care by providing information that will help them, with the assistance of their doctors, to make better informed decisions about their treatment options…. Consumers receive these benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices” (Federal Trade Commission [FTC], 2003). This is important
considering that there is rampant under-diagnosis and under-treatment of many diseases, including asthma, cerebrovascular disease, congestive heart failure, diabetes, hip fracture, hyperlipidemia, and hypertension. (Shrank et al., 2006; “Landmark Study Finds American Adults Often Fail to Get Recommended Care, Posing ‘Serious Threats’ to Health,”, 2003; Bhatt et al., 2006).

Eighteen percent of patients surveyed in Aiken’s (2003) study claimed that an advertisement caused him/her to talk to his/her doctor about a medical condition or illness that they had never approached their doctor with before, with 87% of patients who requested a prescription actually having the disease. More than half of the surveyed patients agreed that these advertisements gave them enough information to decide whether they should discuss the drug with their physician and just less than half of the patients believed that the advertisements helped them have better discussions with their doctors. One third of patients believed that the advertisements helped them make better decisions about their health.

The surveyed physicians agreed; about 79% of physicians believed that DTC increased patient awareness of diseases earlier, 95% of physicians believed that patients are more aware of possible treatments, and 90% of physicians believe their patients are more involved in their healthcare. In fact, 78% of physicians stated that patients are more likely to seek treatment for potentially serious conditions, due to DTC marketing (Aiken, 2004). Results like these are seen in other studies as well (Slaughter, 2003; Lipsky & Taylor, 1997). Interestingly, after further analysis, Weissman et al. (2004) concluded that “approximately 41 percent of conditions initially discussed during the visit and 30% of new diagnoses were ‘high priority’ conditions according to the Agency of Healthcare
These conditions include four of the five most costly classes of conditions in 2002: heart conditions, cancer, mental disorders and pulmonary conditions (Olin & Rhoades, 2005).

In a specific study evaluating nicotine patches, results suggested that DTCA encouraged patients to seek treatment for smoking cessation; as 36% of patients first learned about the nicotine patch from the media, supporting the claim that DTCA influences patients to seek care (Lipsky & Taylor, 1997). Aiken et al. (2005) reported that almost 40% of respondents thought that DTC advertisements encourage patients to look for more information about potentially serious medical conditions.

Golodner (2006) reported that 31% of patients decided to talk to their doctor about a specific product, while 26% of patients sought more information. To obtain more information, 16% of patients talked to their pharmacist, 14% looked for information on the internet and 10% of patients talked to a nurse or called a toll-free information line set up by the pharmaceutical company. Twenty-one percent of patients said they felt more informed about the medicine advertised, 19% felt that it made them better able to address their health conditions and of those who actually did manage to speak to their doctors about the treatment, half reported that they wanted to find out if the medication was right for them while about 30% of patients said they wanted to find out the best way to treat their condition. Only 10% wanted or expected to get the drug that was advertised although 42% of them did a number consistent with what was shown in the Aiken studies (Aiken 2003; Aiken 2005).

Does that translate into better treatment?
Although most studies do show that 40% to 80% of patients will get the drug they speak to their HCP about, other treatment options are also discussed (Datti & Carter, 2006; Slaughter, 2003). Slaughter’s (2003) study also demonstrated that other physician actions included prescribing a different drug to almost 25% of patients, suggesting a lifestyle change in almost 40% of patients, and recommending an over the counter drug in more than 10% of patients. No action was taken in 18% of visits. Patients report that the most common reasons they did not receive the marketed product was because a different drug was believed to be more clinically appropriate, treatment was felt to be unnecessary or not indicated, or cost.

Allison-Ottoy’s (2003) study reported that 36% of physicians said that patients came in for a visit solely because of advertisements, with 90% stating that patients have asked for their opinion because of ads. Fifty-three percent of physicians said that the ads promote patient education regarding disease states. This is more or less supported by the patient arm of the study. Of the patients assessed, 23% reported that they had a question for the physicians as a result of the advertisement and this quest for knowledge prompted most of them to look for more information to help them discuss the issue with their physician. Forty-eight percent of patients felt that the ads helped them make better decisions or helped them become better informed of the disease and treatments available.

An interesting study showing better overall treatment of a population of patients was conducted. The purpose of the review was to examine whether the relative proportion of appropriate use and misuse of lipid lowering therapies, also known as statins, changed between 1997 and 1999. During this time, there was an increase in the use of DTC advertising in general and in particular, an increase in marketing this class of
drugs. Results show that statin use increased by 60% during this time period. Further analysis showed that almost 95% of patients on lipid lowering therapy had some documented objective level of cardiovascular risk, meaning either risk factors putting them at greater risk of a heart attack or stroke or a previous cardiovascular or cerebrovascular event. Therefore, the rising number of prescriptions came from appropriate prescribing of these products, suggesting an increased identification of patients needing this type of treatment (Dubois et al., 2002).

Another study, a quasi-experimental study examining the data from the MarketScan database for more than 30,000 patients between the years 1997 to 2000, suggests that DTCA had a beneficial effect on treatment of patients with depression. The investigators found that the number of patients diagnosed with depression and receiving appropriate treatment occurred in conjunction with an increase of DTC marketing of these products; in fact, patients had 32% higher relative odds of being put on therapy compared with times when DTC spending for marketing in the depression market was lowest. The investigators also assessed the effect of direct to physician marketing and found that marketing was not associated with either the initiation of treatment or with an appropriate duration of therapy with an antidepressant (Donohue, Berndt, Rosenthal, Epstein, & Frank, 2004).

*Does DTC enhance the healthcare professional to patient relationship?*

Although other studies have suggested an increased tension between doctor and patient due to reliance on DTC marketing, there has been some evidence supporting the beneficial effects of these conversations between HCP and patient. In fact, much of this evidence comes from the same studies reporting that some physicians feel increasing
tension from these marketing informed discussions. A survey by Murray et al. (2003) showed that 33% of physicians felt that discussion regarding DTC advertising improved the doctor-patient relationship; only 8% felt that it worsened it. Other studies showed that a large majority of patients reported that their doctor was very willing to talk to them about the advertised product and many felt that the interaction was positive (Slaughter, 2003; Aiken 2003; Aiken, 2005). In fact, in one study, forty-three percent of patients surveyed felt the ads help them have better discussions with their doctor. One third of patients felt the DTC advertisements helped them formulate questions they wanted to ask their physician. The corresponding physician survey showed that 89% of physicians also perceived that DTCA was beneficial to their discussions with patients; many physicians stated that their patients asked better questions about their disease and that DTCA promoted communication between physicians and patients (Aiken, 2003; Aiken, 2004). Similar results were seen in other studies (Golodner, 2003; Allison-Otteny et al., 2003).

When asked about compliance, 30% of patients believe that advertisements remind people to take their medicines or refill their prescriptions. In fact, the majority of patients surveyed wanted to be more educated about the products and diseases and felt that information they obtained as a result of DTCA helped them prepare for an informed conversation with their physician (Allison-Otteny et al., 2003).

This is very important as DTC marketing sets physicians up as mediators between the patient and the pharmaceutical products. Welch-Cline and Young (2004) analyzed multiple print advertisements and concluded that since almost all of the assessed advertisements read “ask your doctor about drug X,” this encourages the patient to initiate the interaction but established the physician as the general expert in this area,
putting the power and control directly on the HCP. This format was seen in approximately 75% of the advertisements. In only 15% of the analyzed advertisements are patients placed in control.

Does DTC reduce stigmatization of certain diseases?

There is evidence, or at least a perception, that DTC marketing can help to de-stigmatize certain diseases. Golodner (2003) reports that 42% of surveyed patients say that advertisements help de-stigmatize many conditions that may have gone untreated due to patient embarrassment and 46% say that advertisements help patients talk to their doctor about a condition that they believe they may have. Many patients are reluctant to talk to their physicians about potentially embarrassing diseases because they may feel that they are at fault for their disease state; in fact, medicalizing a condition and providing treatment for the disease may help patients overcome the embarrassment and seek treatment (Jones, 1998). Cutler and McClellan (2001) point out that “manufacturers of SSRIs encouraged doctors to watch for depression, and the reduced stigma afforded by the new medications induced patients to seek help. As a result, diagnosis and treatment for depression doubled over the 1990s.”. Incontinence is another disease that has become less stigmatized due to the marketing of certain drugs that treat it, such as Pfizer’s Detrol (Gulfo, 2002).

The stigmatization of diseases has been shown to lead to poorer quality of life for those suffering from them due to lack of interpersonal support as well as a reduction in health seeking behaviors, negatively affecting public health, especially for diseases that may lead to higher health expenditures for future emergency or chronic care of progressive disease with high morbidity. Additionally, this stigmatizing effect may lead
to reduced productivity of sufferers, which can have an economic effect due to lost wages and increased healthcare expenses for advanced disease treatment. Multiple groups have recommended broad methods to use to reduce stigmatization; these recommendations include public education and mass media campaigns using print, radio, and television, which are partly fulfilled by DTC marketing practices (Des Jarlais, Galea, Tracy, Tross & Vlahov, 2006; Klein, Karchner, & O’Donnell, 2002).

Harnessing the Power of DTC Marketing to Improve Public Health.

What has been obvious through this review of the evidence both for and against DTC marketing is that this is a controversial issue with no solid evidence definitively showing immense good or harm coming from this practice. In fact, in most of the studies presented in this paper, there was no general consensus about whether DTC marketing is inherently good or bad; most surveys showed that the participants acknowledged both beneficial and negative effects of DTC marketing as it is used today.

Interestingly, recent developments in the healthcare industry, such as worries about long term safety issues due to the COX-2 scandal, has changed the face of DTCA. Merck was believed to cover up potential evidence that showed that use of the non-steroidal anti-inflammatory drug Vioxx was related to an increased risk of cardiovascular events. Because of this, there has been a shift to more controlled marketing strategies by pharmaceutical companies, both at the behest of the FDA and on the part of the pharmaceutical companies themselves (Spence, Teleki, Cheetham, Schweitzer, & Millares, 2005; Young, 2005). The Pharmaceutical Research and Manufacturers of America (PhRMA) released a set of guidelines suggesting the advertisements be more focused on fair, balanced marketing that is meant to educate patients on a disease state
and any potential non pharmaceutical changes beyond pharmacological treatment. In addition, the advertisements should focus on fostering communication between HCPs and patients, with the pharmaceutical companies also spending more time educating the HCPs about questions the patients may have about their product prior to the release of DTC advertisements. The PhRMA guidelines also suggest that pharmaceutical companies submit any DTC television advertisements for FDA review before releasing the advertisements for broadcast (PhRMA, 2005).

Twenty seven pharmaceutical companies, such as Pfizer and Lilly, have adopted these guidelines ("Congress Likely To Debate Moratoriums On Direct-To-Consumer Prescription Drug Advertisement," 2007). Pfizer and Johnson & Johnson, for instance, have instituted a 6 month moratorium on DTC advertisements for new medications, agreeing not to market newly approved products to patients for a minimum of 6 months. They have also stated that they will improve the presentation of safety information for all their products ("Pfizer Announces It Will Limit DTC Ads To Medications That Have Been On Market For At Least Six Months," 2005; Freudenheim, 2007). Bristol-Myers Squibb has initiated a one year moratorium. Additionally, the companies have made a concerted effort to better target their audiences; for instance, Lilly is restricting the marketing efforts for a Cialis, a drug for treatment of erectile dysfunction, to those times when they believe that at least 80% of the audience attracted will be adults (HJKF, 2006). The FDA is looking to enact a regulation that will have the pharmaceutical companies pay a fee to increase and quicken review of all DTC television broadcast ads. These payments will go towards increasing manpower at the FDA ("FDA Proposes 29% Increase in User Fees Paid By Pharmaceutical Companies," 2007).
As the recent survey by Price Waterhouse Coopers (2007) shows, the public’s trust in the pharmaceutical industry has eroded significantly due, in large part, to misconceptions about the goals of the industry. Of course, this industry, like all industries, is interested in turning a profit. This profit, however, is crucial to the future of the healthcare system in the United States. Most of the innovative pharmaceutical treatments for the world are first available in the United States. However, for each treatment that is approved for use in patients, a multitude fails.

On average, economists estimate that it takes 10-15 years to develop a new drug. Additionally, they note that only about one out of five drugs that enter into human clinical trials is approved by the FDA. This does not include those that fail in preclinical studies and do not make it to clinical trials. Some economists estimate that only 20 in 5000 compounds make it into preclinical studies. This inevitably leads to very high drug development costs (Glover, 2002). Market dynamics then lead pharmaceutical companies to rely heavily on marketing practices, both to physicians and patients, with successful marketing allowing for additional investment in research and development (Calfee, 2000; Calfee, 2002). Increasing the pharmaceutical companies ability to continue to develop innovative new products to treat some of the world’s most challenging and pervasive chronic and acute diseases is crucial for the public’s health. Moreover, increased funding could allow pharmaceutical companies to also concentrate on diseases that may not be as widespread but cause significant morbidity or mortality to those affected.

Proponents note that the biggest benefit for DTC marketing is in its ability to promote disease awareness and, if the industry was more focused on unbranded disease
awareness marketing initiatives, DTC marketing would be looked upon more favorably by all stakeholders such as patients, federal officials, and HCPs (NMA, 2002; Welch-Cline & Young, 2004; Bodenheimer, 2003; PhRMA, 2005; Aiken, 2005). Therefore, partnerships between industry and the medical field to promote disease awareness through DTC of diseases that are not well understood, under-diagnosed, or stigmatized might be beneficial in promoting public health.

This is not to say that some movement towards increased disease awareness advertising has not occurred. Recent data examining awareness of DTC advertising from 1998 to 2005 showed that since 2001, awareness of disease awareness ads has increased 7%, suggesting a greater investment in that form of marketing could be beneficial if pharmaceutical companies focused more resources on that realm in order to increase overall disease awareness (Aiken, 2005).

Though DTC marketing of specific pharmaceutical products can not be completely eliminated, and arguably, should not be, the partnership of industry and the medical field could promote higher opinions of the field in general. Additionally, a closer relationship between medical associations and the FDA could potentially promote better presentation of medical data even in branded pieces--data that would be clinically and medically relevant to the patients in question and would contain less “spin” to confuse them about the potential benefits and risks of the products. More focus on non-pharmacological treatments, such as lifestyle changes, would also be an important component of these marketing initiatives.

Another important consideration for the future of DTCA is that diversity has not been well promoted in DTC marketing efforts. An analysis of different DTC print ads
showed predominately Caucasian models, with few African American (AA) or Hispanic models. In fact, those advertisements that used AA or Hispanic models were very specific to diseases like HIV. Therefore, the authors conclude that “beyond promoting social stereotypes lies the potential for [DTC’s] visual cues to reinforce already existing disparities in access to health information and, to the extent that ads promote visits to physicians, disparities in access to health care. To the extent that DTC has the educational potential that proponents have argued, DTC may widen the gap between the haves and have-nots” (Welch Cline & Young, 2004).

However, there is an opportunity for the pharmaceutical industry to better promote health for a multiracial population. Dr. Allison-Ottey, who was a leading figure for the National Medical Association (NMA), an organization for AA healthcare professionals, encourages the use of DTC marketing to increase disease awareness in the AA population, as long as the marketing is fair and provides an adequate fair balance assessment. (Allison-Ottey, 2002). Additionally, in the official position of the NMA to DTC marketing, the NMA (2002) suggests that they and the pharmaceutical industry partner so that the input of AA physicians and patients are included. The position statement concludes with the statement, “Physicians must be open to alternative methods of communicating health information such as DTC advertisements as long as the information is balanced and outlines the risks versus benefits of any products.”

The public health implications for effective DTCA are potentially great. Empowering patients by providing important information that could prepare them to ask the correct questions or feel more comfortable speaking with their physicians could increase health seeking behaviors and help them obtain treatment earlier and optimally
move them towards preventative practices to minimize their risk of future diseases. A more medically informed population of Americans could lead to a healthier population and reduce excess spending on emergency and chronic care. Proper health care and healthy behaviors could also reduce additional disease associated morbidities, that could have been avoided had patients been effectively managed from the beginning.

An example of this is Merck’s recent “Tell Someone” and “Make the Connection” campaigns supporting HPV disease education separately from promoting the vaccine. These multi-lingual disease awareness programs educate about the link between cervical cancer and HPV, encouraging regular screening and preventative care and providing support to national and local organizations to reach a broad, diverse target audience. The efficacy of this campaign is, in part, demonstrated by the media attention given to the importance of these vaccines and the political noise surrounding states that are debating making this vaccine mandatory for school aged girls (“Merck Launches National Advertising Campaign for GARDASIL®, Merck's New Cervical Cancer Vaccine,” 2006).

Conclusion:

A multitude of surveys and studies have shown that the role of pharmaceutical marketing, especially DTC marketing of specific products, plays in promotion of healthful practices is not well elucidated. Future studies should be done to continue to understand the impact of this marketing practice on furthering the public’s health. It is also important to be able to define what the effect of the demonstrated health seeking behavior has on public health outcomes, such as a reduction in overall costs to the
healthcare system, fewer emergency visits related to lack of optimal treatments, or reduction in morbidities associated with chronic or preventable diseases.

Current studies show that disease awareness campaigns, such as Merck’s “Tell Someone” is perceived as the best way to promote health benefits. Patient and physician associations seem to be especially likely to support these campaigns. Getting multiple stakeholders to support these marketing efforts by using more disease awareness campaigns could positively impact public health, but also, improve public perception of the pharmaceutical industry. Partnerships between stakeholders such as policy makers, public health associations, the medical field, and the pharmaceutical industry may be synergistic in benefiting the public’s health. At this point, our public health system needs as much help as it can get.
References:


