Direct-to-Consumer Drug Advertising

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It is hard to watch television or read a magazine today without seeing an ad for a prescription drug. Everywhere we turn, there is yet another fabulous drug being promoted to the public. The ads are all the same: happy people engaging in fun activities like running on the beach or playing with kids. Often times, the disease that the medication is for is not even revealed. We are supposed to ask our doctor if “drug x” is right for us having no clue what it is. Direct-to-consumer (DTC) drug advertising is a phenomenon that has grown immensely over the last few years and will continue to influence medication prescribing and ultimately health outcomes. As healthcare professionals we need to understand how DTC advertising affects prescribing so we know how to best educate our patients about these medications. In this paper, I will address many issues of DTC advertising. This includes its history and growth, impact on sales, effect on what patients request from their doctors, how physicians and patients feel about it, and current and future regulations. DTC advertising is a complex factor influencing healthcare decisions that exudes both positive and negative aspects. We as pharmacists need to better understand the role of DTC advertising in healthcare so we can use its advantages and disadvantages to better serve our patients.

The promoting of prescription drugs to the public is a relatively new concept. In fact, before the 1980s, the idea of promoting prescription drugs to the public was unheard of. This was due to the regulations set forth earlier in the century. The 1938 Food, Drug, and Cosmetic Act granted the FDA authority over pharmaceutical labeling and the Federal Trade Commission (FTC) had control over drug advertising. In 1962, the Kefauver-Harris amendment transferred the authority of prescription drug promotional material to the FDA. At that time, there were strict regulations regarding how prescription drugs could be advertised. Requirements included a summary of contraindications, adverse drug events, efficacy and a balanced coverage of risks and benefits. There were specific guidelines for the size of print and readability of the ads. However in 1981, the pharmaceutical industry shifted gears and proposed to the FDA the inclusion of consumers in its marketing strategies. The industry argued that the “educational” benefit of pharmaceutical advertising would provide the public with knowledge they would otherwise not have and that consumer protection should no longer be seen as simply providing the public with accurate claims. At that time, there was a shift towards allowing consumers to become more actively involved in their own medical decisions. The question was raised as to whether or not pharmaceutical companies could simultaneously incorporate the best public health needs for consumers with the demands of their shareholders. Ultimately, companies need to make their shareholders top priority. This leads to an inherent conflict of interest with what is best regarding consumers’ medication health and safety. A voluntary moratorium was requested by the FDA on September 2, 1983 so that it could adequately assess whether the regulations developed to target healthcare professionals were sufficient to protect consumers when applied to DTC promotion. The voluntary moratorium remained in effect until 1985 when the FDA published a notice in the federal register stating that current regulations
were sufficient to safeguard the consumer against false or misleading promotional material.\textsuperscript{6} Drug companies were allowed to advertise to the public but had to abide by existing standards. The FDA’s only request was that companies submit their ads for preliminary comments. Pharmaceutical manufacturers were not satisfied with these provisions. During a public hearing and debate in 1997, the FDA issued a draft proposal for new guidelines regarding DTC advertising. Broadcast drug advertisements were allowed to reveal both the name of the drug and conditions it treated without disclosing all of the drug’s risks. Only important risks needed to be addressed along with sources for additional information. For print advertisements, every risk addressed in the product’s approved labeling must be mentioned in the brief summary.\textsuperscript{8} The FDA wanted manufacturers to present drugs in a “fair balance” approach, meaning that claims of a drug’s benefits and efficacy be balanced with relevant disclosures of risks and limitations.

Promotion of prescription drugs encompasses three main components: detailing, sampling and DTC advertising. Detailing is the promotion of drugs directed towards physicians through drug representatives. It accounts for 29\% of all promotional drug spending. Sampling is the allotment of drug samples provided to physicians and accounts for 55\% of promotional drug spending. DTC advertising is the promotion of drugs targeted towards consumers through magazines, newspapers, television, and radio. It accounts for 14\% of promotional drug spending.\textsuperscript{4} Although the majority of spending is still directed toward physicians, there is a huge increase in the amount of money spent to target consumers, especially through television. Since the mid-1990s, pharmaceutical companies have more than quadrupled the amount of money they spend on advertising prescription drugs directly to consumers. In 1997, spending for DTC prescription drug advertising was just under 1 billion dollars in the U.S. In 2004, it surpassed 4 billion dollars (see graph below).\textsuperscript{1} GlaxoSmithKline spent 157 million dollars alone to promote its erectile dysfunction drug, Levitra® that year.\textsuperscript{1} It is not difficult to understand why corporations are investing so much in DTC ads. Drugs that are heavily advertised to consumers typically rank high in sales. Six of the top ten advertised drugs were in the top twenty drugs in dollar sales and number of prescriptions dispensed.\textsuperscript{4} A study done at the Harvard School of Public Health examined the changes in drug promotion and sales over a three year period for five classes of drugs: antidepressants, antihyperlipidemics, proton pump inhibitors, nasal sprays, and antihistamines. These five classes accounted for 30\% of all DTC advertising in 1999. The authors found that on average, a 10\% increase in DTC advertising of drugs within a particular class yielded a 1\% increase in sales of drugs within that class. Applying this to the 25 largest therapeutic drug classes, this means that the increase in DTC advertising from 1999-2000 accounted for 12\% of all drug sales during that period. They also found that although DTC advertising is not the primary driver of prescription drug spending, it does produce an additional $4.20 in sales for every dollar spent.\textsuperscript{4} Interestingly, DTC ads do not appear to affect the relative market share of individual drugs within their therapeutic class. A possible explanation for this is that DTC advertising encourages patients to talk to their physicians about untreated disorders, but that does not necessarily lead to a prescription for the particular drug that was advertised.
There are three specific types of DTC drug advertisements: health-seeking, reminders and product-specific. Health-seeking advertisements educate consumers about a disease or medical condition without revealing a specific drug name. Consumers are advised to see their doctor for possible treatment options. They do not need to include any kind of risk information. These ads are not regulated by the FDA; however the FDA strongly advocates their use. A recent example of this would be that cute ad about how there are two sources of cholesterol: food and family. There are two pictures displayed simultaneously, one of some type of high-cholesterol food and the other of a quirky family member. Although this is actually an ad sponsored by Merck in order to promote their new drug Vytorin®, the name of the drug is never mentioned in the ad. Reminder advertisements provide the name of the drug and may provide certain descriptive information like dosage forms or pricing information but do not discuss its use, effectiveness or safety. No brief summary is required for this type of ad. These ads can be confusing, frustrating and misleading to consumers as drug companies continue to test the limits of what might be considered a product claim. The FDA does not see a purpose for these ads and believes they have the potential to cause harm. Product-claim advertisements comprise the vast majority of prescription drug ads. They provide information about a drug’s therapeutic use, safety and efficacy. The “fair balance” regulations apply to these kinds of ads.

So what exactly is the content of a DTC drug advertisement? It is a mixture of messages all designed to create an image that taking the drug will enhance the quality of life for the consumer. There is no question that drug companies are trying to favorably
alter consumers’ perceptions of the drug. Take for example an ad in a magazine. The ad heavily focuses on the visual image, usually a person who looks very happy. It does not feel like drug ad, it feels more like a vacation photograph. The benefits of the drug are boldly stated on the picture while the risks require a magnifying glass to read. Ads on television are no different. They make emotional appeals to consumers using images we take pleasure in seeing like butterflies, puppies and kids. Headings and subheadings emphasize the drug’s benefits, while the side effects are buried in the narrative.\textsuperscript{6} Drug companies are trying to establish the existence of a need for the drug so that consumers will feel compelled to go to their doctors and ask for a prescription. The information about the drug itself is vague. There is not a lot about how the drug actually works and the advertisers make this important aspect seem insignificant. Instead, the advertisement persuades the consumer to believe that he or she has a certain medical condition and needs to seek out the specified drug based on a list of symptoms. The educational quality of DTC advertisements is highly variable. Valuable information about treatments is also lacking. One study found that supportive behaviors through lifestyle changes that could augment the treatment were only reported in 24\% of ads.\textsuperscript{6} Furthermore, a cause or risk factor was only present in 27\% of ads and only 9\% of ads gave an estimate of the drug’s success rate.\textsuperscript{6}

Despite the lack of quality in DTC prescription drug ads, there is a relationship between these ads and subsequent prescribing. A study was conducted in 2002 comparing the prescribing decisions in the U.S. (Sacramento, CA) where DTC advertising is legal and in Canada (Vancouver, BC) where DTC advertising is not legal but some cross-exposure occurs. The researchers determined the number of consumers that were exposed to some form of a DTC ad, the frequency of patients’ requests for the advertised drugs, and the frequency of prescriptions that were stimulated by the patients’ requests. Results showed that although exposure to a DTC ad was higher in Sacramento, 87.4\% of Vancouver patients had seen an ad for a prescription drug. Of the Sacramento patients, 7.7\% requested an advertised drug from their physician. This was statistically higher than the requests from Vancouver patients (3.3\%).\textsuperscript{7} Patients with more exposure to drug advertising requested more of those medications. Additionally, patients with conditions that were potentially treatable by advertised drugs and those with a greater reliance on advertising also requested more advertised drugs. Physicians fulfilled the requested drugs most of the time (78\% in Sacramento and 72\% in Vancouver).\textsuperscript{7} This difference was not significant but does illustrate how the presentation of a DTC ad eventually leads to the consumer taking the medication. Patients who requested DTC advertised drugs were much more likely to receive one or more new prescriptions (for requested drugs or therapeutic alternatives) compared with those who did not request DTC drugs. Interestingly, physicians judged 50\% of new prescriptions for requested DTC drugs to be “possible” or “unlikely” choices for other similar patients. These results suggest that DTC advertising leads to more requests for those drugs as well as more prescriptions. DTC advertising may stimulate more discussion between patients and their physicians. However, the end result is most likely to be a prescription for the advertised drug despite physician ambivalence about treatment choice.\textsuperscript{7}

The FDA conducted a much larger study in 2002 comparing the attitudes of both patients and physicians about DTC advertising to those in 1999. Nine hundred forty-three patients and 500 doctors participated in the 2002 study. All patients surveyed had
visited a healthcare provider in the past 3 months because these patients could provide insight on how DTC advertising influenced their relationship and interactions with healthcare professionals. The primary goal of the study was to document the impact DTC drug advertising had on physician-patient relationships.

The main objective of the patient survey was to assess the various ways DTC advertising could influence the subsequent interaction with their doctor. Both the 1999 and 2002 surveys inquired about patients’ awareness of DTC advertisements, the process used in seeking more information about the advertised drugs, behaviors in asking questions to healthcare professionals about these drugs, and their general opinions of DTC advertisements. The results found a nearly universal awareness of DTC advertising. Patients reporting exposure to any type of DTC advertisement increased from 72% in 1999 to 81% in 2002. Although television was the most common vehicle, print advertisements a close second and exposure to internet ads soared dramatically. Most patients were aware that these ads contained both benefits and risks, even if they did not completely understand its content. DTC ads motivated 43% of respondents to obtain more information about an advertised drug. This additional information was obtained primarily from physicians (89% in 2002). Other sources used by patients to get more information were pharmacists (51%), reference books (40%) and nurses (40%). The number of people using the Internet to look up information jumped from 18% in 1999 to 38% in 2002. The most commonly sought type of information was risks about the drug. Regarding all visits to a doctor, a drug ad only accounted for 4% of those visits. Most indicated that health-related problems were the reason for scheduling a doctor visit. DTC advertising did play a significant role in generating questions for physicians. The concern that DTC advertising generates expectations about receiving certain prescriptions was not strongly supported in this survey. Approximately 42% of patients expected to leave their doctor’s office with a prescription. Of these patients, 63% said they expected a prescription because it was a refill for a current one; only 6% said they expected a prescription because there was an ad for it. When patients asked their doctor if a medication would treat their condition, 39% asked about a specific brand of medication and these patients were more likely to receive a prescription for the requested drug compared to those who just asked whether any treatment was available.

The most interesting results of the survey were patient opinions about DTC advertising. Even though most agreed that DTC ads increased awareness of new drugs, the actual percentage of patients who felt this way decreased from 86% in 1999 to 77% in 2002. This is unusual given the big increase in the number of DTC ads presented between these years. In terms of the specific content of these ads, 60% felt that the ads do not provide enough information about the drug’s risks and 44% believed the ads lacked adequate benefit information. About 73% did not think the ads diminished the role of the physician in medication decisions. There was a decline from 1999 to 2002 in the number of patients who thought the ads enhanced the discussions with their doctor (62% vs. 43%). Furthermore, 10% (up from 7% in 1999) of patients were deterred from inquiring about an advertised drug due to the fear of creating a distrust of the doctor’s medical judgment. When asked about the accuracy of DTC advertisements, 58% of patients believed the ads overemphasize the benefits to make the drug seem better than it actually is. Forty-two percent of those surveyed thought the ads made the drug seem like it would work for everyone. Finally, patients were asked about how DTC advertisements
influence their own health. There was a decline from 47% in 1999 to 32% in 2002 in the belief that the ads help patients make better health decisions. Seventeen percent of those surveyed stated that DTC advertisements created an anxiety about their own health. On a positive note, 18% said that the ads reminded them to take their medications. The general outlook on DTC advertisements is becoming more negative. Only 32% indicated that they “liked seeing” a DTC ad; this is down from 52% in 1999.

Physicians who participated in the survey were divided into two categories, general practitioners (GPs) and specialists. The specialists included those from dermatology, allergy/pulmonology, endocrinology, and psychiatry. These specialties were based on the abundance of DTC advertising for drugs in these fields. In general, physicians reported an increase in the frequency of questions about healthcare topics in the last 5 years in all areas except over-the-counter drugs. The questions asked the most pertained to drug treatments. More GPs than specialists reported an increase in inquiries about prescription drugs. When physicians were asked about a specific encounter with a patient regarding a DTC advertised drug, 41% felt that this exposure led to benefits and 18% felt that it caused problems. The benefits included better patient-physician discussions and better awareness of treatments. Physicians also thought DTC advertising helped the patient become informed and educated about the drug being promoted. Problems physicians had with DTC advertising were an increased time in correcting misconceptions, requests for unnecessary drugs and requests for a specific drug when other treatments were just as effective. Overall, 73% of physicians thought the patient asked intelligent questions based on a DTC advertised drug. Forty-one percent of physicians, however, indicated that their patient was confused about the effectiveness of the drug being advertised.

There were differences in the prescribing requests for GPs versus specialists. The likelihood of granting a prescription for a requested drug was even between both groups, although GPs received more requests for prescription treatment in general (60% vs. 44%). But when requesting a specific brand name, GPs were not only more likely to receive requests (65% vs. 52%) but were also more likely to prescribe that drug (64% vs. 46%). There were also differences in reasons for denial of the requested medication. Reasons that GPs denied requests included the existence of a less expensive alternative, the patient did not need the drug, or the patient should engage in lifestyle modifications first. Specialists denied requests because a different drug was more appropriate, the drug was not right for the patient or drug had adverse effects unbeknownst to the patient. About half of the surveyed physicians felt a “pressure” to prescribe and this occurred more with GPs. Twenty-two percent of GPs felt “somewhat” or “very pressured” to prescribe a requested drug versus only 18% of specialists. In addition, more GPs than specialists thought that patients came to the visit expecting a prescription and this was more likely to influence their decision to prescribe.

Physicians seem to have differing perceptions of patients’ understanding about DTC drug advertisements. Approximately 92% believed that their patients knew these drugs were only available by prescription. Additionally, 78% of doctors thought that patients understood the benefits of these drugs. Their perceptions about patients’ comprehension of risks are quite different though. Only 40% thought patients understood the risks and possible negative effects of the drugs. Only 30% thought patients...
understood the limitations of a drug’s efficacy and 25% thought patients knew what types of persons should avoid the drug. Moreover, 65% of all physicians believed patients confuse the relative risks and benefits of DTC advertised drugs and 75% feel that this leads to overestimation of their efficacy.

By and large, both GPs and specialists thought that DTC drug advertising leads to both positive and negative consequences. General opinions of physicians about DTC advertising are divided with about one third believing they have a positive effect, one third believing they have a negative effect and one third believing they have no effect either way. GPs were more likely than specialists (38% vs. 27%) to rate the influence of DTC drug advertising as having an overall negative effect on their patients and practice.

Given the opinions of both patients and physicians about DTC advertising from the FDA survey, there are many benefits of DTC drug advertising. It provides patients with the opportunity to become educated about a particular illness and a specific treatment for that illness. It may enhance physician-patient relationships by stimulating discussion about disease states and treatment options. Some argue that the FDA’s current regulations for DTC advertising are sufficient enough to protect the patient and any further mandates would be unnecessary. The FDA survey showed that many physicians believe that DTC advertising increases not only awareness of possible treatments, but also facilitates earlier awareness of health conditions. It also enhances proper medication usage and may help patients to maintain their treatment over time. Patients may become aware of health issues overlooked by their doctor or may bring up a new treatment option not previously considered. This increase in patient inquiries may motivate practitioners to keep informed of new developments in drug therapy so they are better prepared for these types of questions.

Even though there are numerous benefits to DTC advertising, there is also a lot of potential harm that can result. It can lead to inappropriate demand for unnecessary medications when other treatment options are cheaper or better. If the physician decides not to prescribe the advertised drug, the patient may not understand why and feel shortchanged. Physicians in the FDA survey have indicated that DTC advertising has caused patients to question their diagnoses and has also created tension in the physician-patient relationship. Ultimately, trust could be lost and this could break the covenantal bond between the patient and the provider.

DTC drug advertising also poses a health risk. This is because drug companies promote newly approved drugs for which there has not been a lot of post marketing surveillance on. These drugs carry potential adverse effects not yet identified. Examples of this include Viagra® and Rezulin®. The erectile dysfunction drug Viagra® was marketed a great deal to consumers upon its arrival and to some degree, it still is. Its manufacturer Pfizer even recruited political celebrities to endorse the drug (remember Bob Dole?). Studies later linked the drug to coronary heart disease complications and sales have declined. Rezulin® (troglitazone) was introduced the U.S. in 1997 as a new oral medication for diabetes. It was widely promoted until it was found to be severely hepatotoxic. In 2000, Parke-Davis had to withdraw the drug from the market. The most prominent case occurred with the COX-2 inhibitor Vioxx®. It was the most heavily advertised drug to consumers in 2000. In fact, Merck’s advertising campaign for the anti-inflammatory drug financially surpassed campaigns for either Pepsi® or Budweiser® that
As a consequence, sales of the drug quadrupled. At a time when COX-2 inhibitors were dominating the market in arthritis treatments, many clinicians believed that NSAIDs (non-steroidal anti-inflammatory drugs) such as naproxen or ibuprofen would have worked just as well. Unfortunately Vioxx® was withdrawn from the market in 2004 due to as many as 140,000 serious cardiovascular events including heart attacks and stroke linked to it.\(^{11}\) It is hard to say how many of these tragic events could have been avoided had these drug manufacturers not marketed their drugs so aggressively. It is clear, however, that pharmaceutical companies are not excluding potentially dangerous drugs when choosing what to market to consumers.

Public misconception is another negative consequence of DTC advertising. It is already evident from the FDA survey that DTC advertisements blatantly overstate a drug’s benefits and minimize its risks. What's more is that many consumers are entirely misguided in their understanding of the regulation of DTC advertising. According to Dr. Sidney M. Wolfe of the Public Citizen Health Research Group in Washington D.C., a substantial portion of people believe that the FDA reviews all ads before they are released and that only the safest and most effective drugs are allowed to be promoted to the public.\(^{3}\) Another study conducted by Project HOPE in 2000, which surveyed health professionals as well as the general public, found that half of respondents believed DTC ads were submitted to the government for prior approval. Forty-three percent believed that only “completely safe” drugs could be advertised, 22% thought drugs with serious adverse effects were banned from DTC advertising and 21% thought only “extremely effective” drugs were allowed to be marketed.\(^{6}\) None of these statements are true. These misconceptions put a strain on healthcare professionals like doctors and pharmacists to correctly educate patients and convince them that what they see on TV is not necessarily what is in their best interest. Both health professionals and consumers need to be reminded that pharmaceutical manufacturers are corporations. This means that their number one obligation is to their shareholders, not to the health care of the general public. These corporations have vast amounts of money and power. They have lobbyists in all sects of government working to ensure that nothing interferes with their profit maximization. Doctors are also heavily seduced by drug companies with all types of incentives. This exacerbates many of the problems associated with advertised drugs because doctors feel compelled to promote these drugs and keep quiet about any clinical reservations they may have about them.

With all the harm that has resulted from DTC advertising, some members of congress and industries directly affected by healthcare costs have proposed changes to the regulation of DTC advertisements. In 2001, Representative Pete Stark (D-CA) introduced the Fair Balance Prescription Drug Advertisement Act. The bill would not allow any deductions for DTC advertisements that failed to release pertinent information or present the information in a balanced manner. It would also amend the Food, Drug and Cosmetic Act by requiring reports of such advertisements.\(^{16}\) Other government officials have become involved in tightening regulations.\(^{16}\) That same year, twelve state legislatures considered bills regarding DTC advertising. Some supported severe restrictions. Kentucky’s HCR 7, for example, would urge Congress, The Department of Health and Human Services and the FDA to limit, ban, or otherwise impose strict standards on DTC advertising.\(^{16}\) Others called for more accountability. More recently, Senators Charles Grassley (R-Iowa) and Christopher Dodd (D-Conn.) introduced a bill...
that would create a new FDA office that would have the responsibility of overseeing drug advertising. Senate Majority Leader Bill Frist (R-Tenn.) called for drug makers to wait two years before advertising new medications to consumers. Some manufacturers are acknowledging the benefit of this. Bristol-Myers Squibb announced that it would refrain from advertising drugs to consumers until they have been on the market for one year. In addition, the lobby group Pharmaceutical Research and Manufacturers of America (PhRMA) is drafting its own new guidelines encouraging ads to provide a better presentation of risks. These guidelines have come under criticism for being too lenient though. The FDA has also incurred criticism for its weak enforcement of DTC advertising. Its new commissioner, Lester Crawford, views DTC ads as valuable but sees the need for clearer guidelines. The FDA wants the focus of the ads to be more of a balance of risks and benefits. They held a public hearing on November 1st and 2nd of this year to thoroughly investigate the issues surrounding DTC advertisements. It provided the opportunity for all groups affected by DTC advertising to comment about the promotion of prescription drugs and other regulated medical products. Without a change by Congress however, the FDA is not likely to mandate any drastic changes in regulations.

Not only are government officials getting involved, corporations such as Ford Motor Company and Blue Cross Blue Shield are also advocating policy changes. The Ford Motor Company is pushing hard for generic drug use. It created a pilot program at a hospital, which provides financial incentives to physicians’ groups that prescribe an increased number of generic medications. General Motors launched a “Generics First” campaign which saved the company over $36 million by having its pharmacy benefits manager distribute free generic samples to doctors’ offices. Insurance companies are also encouraging the promotion of generics. Blue Cross Blue Shield is using its own DTC ad paradoxically to make statements like, “Chose the unadvertised brand.” The American Medical Association has its own reservations about DTC advertising. Although it does not advocate total prohibition, it is in favor of ads including phrases like, “Your physician may recommend other appropriate treatments.”

Direct-to-consumer drug advertising is only legal in the U.S. and New Zealand. New Zealand is currently considering a ban on DTC advertising, which would leave the U.S. alone in this arena. The U.S. will not consider banning these ads because it would violate the 1st amendment of the Constitution. Pharmacists are second only to physicians as a source that patients utilize to obtain medication information. Because DTC ads influence prescription decisions and create misconceptions, it is imperative for us as pharmacists to keep a very close watch on these ads. We need to monitor which drugs are advertised most and study the specific content of these ads. This will enable us to clarify any misunderstandings and properly educate patients about risks and benefits of these drugs based on their individual profiles and medical needs. We cannot rely on the FDA or anyone else to enforce stricter regulations. It is up to pharmacists and other healthcare providers to use the positive effects of these ads as a means to open up communication channels with patients so they can discuss all their health concerns with us.