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## **DIRECT-TO-CONSUMER (DTC) PHARMACEUTICAL MARKETING: IMPACTS AND POLICY IMPLICATIONS**

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*In 1997, the Food and Drug Administration (FDA) issued relaxed guidelines for direct-to-consumer (DTC) pharmaceutical marketing and in response, pharmaceutical industry spending on DTC promotion grew from \$791 million in 1999 to \$4.8 billion in 2006. For every \$1 spent on DTC pharmaceutical advertising, the pharmaceutical industry realizes \$4.20 in increased sales. Between 1998 and 1999, the top 25-marketed drugs were responsible for a \$7.2 billion increase in United States pharmaceutical spending. Healthcare costs rose 9.6% percent annually from 2000 to 2004, with the largest portion of the increase attributable to rising pharmaceutical costs. Patients look favorably upon DTC advertising of pharmaceuticals, while physicians largely do not. DTC pharmaceutical marketing influences physician-prescribing practices, and 60-65% of studied physicians want the practice to be scaled back or cease entirely. DTC pharmaceutical marketing seeks to maximize profits and some patients cannot afford advertised drugs. While the FDA does not recognize negative public health implications due to DTC pharmaceutical marketing, current regulations have failed to quell opposition to the practice. At a minimum, the FDA should not allow product claims advertisements, which persuade rather than inform patients.*

*Keywords: advertising, direct-to-consumer, expenditures, FDA, marketing, patients, pharmaceutical, physicians, policy, prescribing, prescription, product claims, regulation*

## **DIRECT-TO-CONSUMER (DTC) PHARMACEUTICAL MARKETING: IMPACTS AND POLICY IMPLICATIONS**

The Kefauver-Harris Drug Amendment of 1962 gave legislative authority to the Food and Drug Administration (FDA) to regulate prescription drug advertisements (Ta & Frosch, 2008). FDA policy required advertisements to include side effects, contraindications and effectiveness of the advertised prescription drug, and to present “fair and balanced” information (Hoek, 2008; Ta & Frosch, 2008). Although these lengthy requirements limited the types of media pharmaceutical companies were able to utilize, mass-media direct-to-consumer (DTC) advertising spending rose steadily (Lyles, 2002). In 1997, the FDA issued draft guidance (later finalized in 1999) titled *Guidance for Industry on Consumer-Directed Broadcast Advertisements*, which relaxed previous requirements and allowed pharmaceutical companies to make adequate provisions for consumers to obtain additional information on the drug through mechanisms such as a toll-free telephone number, print materials, a webpage, or healthcare providers (Hoek, 2008; Ta & Frosch, 2008). The pharmaceutical industry responded to this guidance by increasing DTC expenditures exponentially, particularly in television advertising (Ta & Frosch, 2008).

In the years following release of the new FDA guidelines, pharmaceutical industry spending on DTC grew from \$791 million in 1999 to \$4.5 billion in 2004 (Friedman & Gould, 2007) and \$4.8 billion in 2006 (Timko & Chowansky, 2008). With increased expenditures on advertising, sales increase. For every \$1 spent on DTC pharmaceutical advertising, pharmaceutical sales within the industry rise by roughly \$4.20 (Ta & Frosch, 2008; Timko & Chowansky, 2008). The

cholesterol-lowering statin medication, Lipitor, is an excellent example. With heavy marketing of statins, Lipitor passed \$1 billion in worldwide sales within the first year of its launch in the United States (Lorence & Churchill, 2007). Such rapid growth in spending, lucrative industry returns, and increased prevalence of pharmaceutical advertisements directed to consumers has led to scrutiny of the practice by various stakeholders, including physicians and policy-makers. Of particular interest is the impact the practice of DTC marketing of pharmaceuticals has on the doctor-patient relationship, overall cost and demand for prescription drugs, and more specifically, how such advertisements influence behaviors of the elderly, low income and other vulnerable populations.

This literature review examines multiple aspects of DTC marketing of pharmaceuticals, with an overview of the pros and cons of DTC marketing, costs and expenditures, beliefs and behaviors of physicians and patients (consumers), the impact on vulnerable populations, and policy implications of research findings. This in-depth analysis of existing research addresses the question: *What are the impacts of direct-to-consumer marketing of pharmaceuticals in the United States, and is policy revision necessary?*

## METHODS

Literature selected for this review was obtained through Grand Valley State University Library resources, and includes research conducted about or within the United States and written in the English language. Selected literature is published after the 1999 finalization of the FDA's *Guidance for Industry on Consumer-Directed Broadcast Advertisements*, as this guidance dramatically changed the pharmaceutical marketing environment in the United States. Literature included in this review provides both qualitative and quantitative data that attempts to validate whether or not DTC marketing of pharmaceuticals is effective in increasing consumer awareness and knowledge of conditions and treatment options, increases patient compliance with prescribed therapies, increases drug costs, leads to unsafe consumer practices, disproportionately impacts vulnerable populations, or detracts from the physician-patient relationship. This analysis examines these issues from the perspectives of both the healthcare industry and patients, and focuses on DTC pharmaceutical marketing's impact on healthcare costs, demand, physician and patient perceptions, policy implications of the findings, and provides a revised policy recommendation.

### *Perez v Wyeth Laboratories, Inc.*

One of the key protections pharmaceutical companies rely on, even when advertising pharmaceuticals directly to consumers, is that physicians are in the best position to discuss medication risk information with their patients. This is "a common-law doctrine called the learned intermediary rule (LIR)" (Mello, Rosenthal, and Neuman, 2003) existing since the late 1960s when pharmaceuticals were marketed to physicians, not directly to patients (Fushman, 2000). As long as pharmaceutical companies inform physicians of medication risks via FDA-required package inserts, the LIR "...allows pharmaceutical manufacturers to discharge their duty to warn patients of prescription drug dangers..." (Pateiro, 1999). In a landmark "...5-2 decision issued in August 1999..." (Gemperli, 2000), the New Jersey Supreme Court ruled that the LIR "...does not apply when [pharmaceutical] companies engage in direct-to-consumer (DTC) advertising" (Gemperli, 2000).

Beginning in 1995, five women individually sued Wyeth-Ayerst Laboratories (Wyeth) for failure to adequately warn of the potential side effects and surgical complications associated with Norplant, a contraceptive implant Wyeth mass marketed to consumers in the early 1990s (Gemperli, 2000; Pateiro, 1999). After consolidating twenty-six cases into one action, the five women in *Perez* became representatives of fifty Norplant users with similar claims (Fushman, 2000; Gemperli, 2000; Pateiro, 1999). The women complained of various personal injuries, but all alleged "...Wyeth failed to warn them of the pain and scarring that resulted from the removal of the Norplant capsules" (Fushman, 2000). Wyeth invoked LIR in its defense, providing evidence that their duty to warn patients was satisfied because they provided adequate risk information to physicians (Mello et al., 2003). The New Jersey Supreme Court evaluated the three most common LIR justifications, including: (1) manufacturers would unnecessarily intrude upon the patient-physician relationship if they were required to provide complete risk information directly to consumers, (2) physicians are better than manufacturers at conveying drug risks and benefits to their patients, and (3) drug manufacturers lack the means to effectively communicate directly with patients (Mello et al., 2000).

The court held that DTC marketing has altered physician prescribing practices due to pressure from patients, physicians lack sufficient time in the current managed care climate to adequately present comprehensive risks and benefits of medications to patients, and that the success of DTC marketing campaigns clearly shows that pharmaceutical manufactures *do* have effective means to communicate directly with patients (Mello et al., 2000). The court held that for companies that advertise pharmaceuticals directly to consumers, the LIR does not apply (Mello et al., 2000) and the case was remanded (Fushman, 2000). Although non-precedent setting outside of New Jersey, the *Perez* ruling may have larger implications for shared "failure to warn" liability between physicians, who traditionally hold all the risk, and pharmaceutical companies who market directly to consumers (Fushman, 2000). Although arguably too broad a rule, the *Perez* decision holds pharmaceutical companies accountable for advertising misinformation and does not allow them to escape liability behind the shield of the LIR (Fushman, 2000). Faced with the potential for new consumer lawsuits, pharmaceutical companies could face substantial costs. However, successful pharmaceutical marketing results in wide profit margins, suggesting that companies may absorb some of the cost or raise drug prices (Mello et al., 2000; Pateiro, 1999). "*Perez* has...been cited approvingly by the Connecticut Supreme Court as an example of how the law can adapt to changes in the health care marketplace" (Mello et al., 2000). Although the following literature review exposes inconsistencies in research findings and highlights the need for empirical studies, the FDA should also consider the implications of the *Perez* decision in future policy development and regulation of DTC pharmaceutical marketing.

## LITERATURE REVIEW

### *Origins*

As early as 1708, Americans have been exposed to medication advertisements, with patent medicine advertisements appearing in Boston newspapers (Friedman & Gould, 2006; Joseph et al., 2007). Modern regulation of such advertising did not begin until 1981 when at the request of the pharmaceutical industry; the FDA began working to clarify guidance on how DTC consumer advertising of pharmaceuticals could align with laws in existence at that time (Joseph et al., 2007). In 1983, the FDA began a voluntary moratorium on DTC pharmaceutical advertising until decision-makers determined in 1985 that existing regulations were sufficient to protect

consumers and published this notice in the Federal Register (Joseph et al., 2007). Until the late 1990s to early 2000s, however, television remained relatively unutilized as a DTC advertising medium (Joseph et al., 2007). In 1997, the FDA issued draft guidance (later finalized in 1999) titled *Guidance for Industry on Consumer-Directed Broadcast Advertisements*, which relaxed previous requirements and allowed pharmaceutical companies to make adequate provisions for consumers to obtain additional information on the drug through mechanisms such as a toll-free telephone number, print materials, a webpage, or healthcare providers (Hoek, 2008; Ta & Frosch, 2008). The pharmaceutical industry enthusiastically embraced these guidelines and DTC pharmaceutical advertising budgets were expanded, particularly for television advertisements (Cole, 2007; Friedman & Gould, 2006; Hoek, 2008; Joseph et al., 2005; Joseph et al., 2007; Joseph et al., 2008; Lyles, 2002; Ta & Frosch, 2008; Timko & Chowansky, 2008; Wakeam, 2009).

Viagra is an early example of how these relaxed regulations affected the pharmaceutical industry. Deregulation of the pharmaceutical industry and publication of the new FDA guidelines occurred just six months before Pfizer's release of Viagra. According to Cole (2007), "Second only to Prozac in the race to become America's first blockbuster drug (\$1 billion in annual sales), in 1998, Viagra news ranked just behind the coverage of the Clinton-Lewinsky scandal." Furthermore, in a previously unseen approach to DTC advertising, in 2002, Pfizer promoted Viagra by making it the official sponsor of Major League Baseball and securing former Texas Rangers first baseman, Rafael Palmeiro, as its spokesperson (Cole, 2007). Viagra sales reached \$1.74 billion in 2002 alone (Cole, 2007).

Similarly, Lipitor received market share increases because of a DTC marketing campaign (Lorence & Churchill, 2007). Although unintentional, Bristol-Myers Squibb facilitated some of this growth through extensive DTC marketing of Pravachol, their statin medication (Lorence & Churchill, 2007). As noted by Lorence and Churchill (2007), however, Bristol-Myers Squibb failed to extend this marketing to physicians, so when patients asked for cholesterol-lowering medications, doctors prescribed Lipitor. Lipitor sales worldwide exceeded \$1 billion in its first year of release, and at \$10.9 billion in 2004 sales, Lipitor was the largest selling drug in the world (Lorence & Churchill, 2007).

Anxious to explore new marketing avenues, Johnson & Johnson, Proctor & Gamble, and GlaxoSmithKline have secured the services of the Entertainment Resources and Marketing Association (ERMA) (Ta & Frosch, 2008). ERMA is "an association of entertainment marketing agencies, studio executives, and corporations who engage in the business of branded entertainment, product placement and integration," (Ta & Frosch, 2008). Additionally, Ta and Frosch (2008) report that Court TV had an information booth at the 2005 Pharmaceutical Marketing Congress. Reports of lucrative profits, non-traditional DTC marketing practices, and potential expansion into product placements have raised red flags for many stakeholders, and DTC pharmaceutical advertising practices have realized growing scrutiny.

In fact, the American Medical Association (AMA) and American College of Physicians (ACP) have both released opinions regarding DTC pharmaceutical marketing (Joseph et al., 2007). The ACP opposes DTC pharmaceutical marketing due to it undermining the patient-physician relationship and challenging physicians' medical judgment (Joseph et al., 2007). The AMA finds DTC pharmaceutical marketing an acceptable practice, provided it adheres to guidelines the AMA developed with the FDA (Joseph et al., 2007). In addition to professional organizations, the United States Congress has recognized the potential public policy implications of DTC marketing of pharmaceuticals. Although no legislation is enacted to date, in 2001, the

Senate Subcommittee on Consumer Affairs, Foreign Commerce and Tourism held a hearing on DTC pharmaceutical marketing, and in the 2004 Presidential race, candidate Howard Dean proposed eliminating the practice and reducing Medicare reimbursement for marketers of heavily advertised drugs (Friedman & Gould, 2006).

### *Oversight*

*Industry.* In response to the growing scrutiny, the Pharmaceutical Research and Manufacturers of America (PhRMA) developed a set of *Guiding Principles* in 2005 (Joseph et al., 2007) to promote higher standards in DTC promotions (Hoek, 2008). “Among other points, the 15 principles require advertisers to ensure their communications are not misleading, that they educate consumers and provide balanced information (including details of alternative treatments)” (Hoek, 2008), as well as a waiting period for newly approved drugs (Joseph et al., 2007). Additionally, the industry established the Office of Accountability, which receives comments and issues reports about compliance with the *Guiding Principles* (Hoek, 2008). This self-regulation is an attempt to quell growing concerns over DTC pharmaceutical marketing practices, particularly in the absence of adequate FDA oversight (Hoek, 2008).

*FDA.* The FDA has identified three categories of DTC pharmaceutical marketing: product-claims, help-seeking advertisements, and reminder advertisements (Lyles, 2002). Product claims “promote a specific product and must present a *brief summary* with a *fair balance* of benefits and of risks” (Lyles, 2002). Help seeking advertisements “provide information on diseases or conditions – they encourage consumers to consult their physicians regarding treatment options; specific prescription drugs or treatments cannot be mentioned, nor can the advertisement contain linkages to materials identified with a specific product” (Lyles, 2002). Reminder advertisements “...cannot contain or suggest the clinical role of the product” (Lyles, 2002).

Prior to airing, the FDA reviews some advertisements and monitors promotions throughout (Hoek, 2008). When appropriate, the FDA takes enforcement action (Hoek, 2008). Enforcement actions include untitled or warning letters; with untitled letters outlining the alleged violations of the Federal Food, Drug and Cosmetic Act, and warning letters carrying greater authority (Hoek, 2008). Untitled letters request a response from the responsible party and suggest corrective actions, whereas warning letters may request “corrective advertising to dispel incorrect beliefs” (Hoek, 2008). In a review of warning letters issued between 1997 and 2002, the most common violations were inadequate risk information and inaccuracy of efficacy information (Hoek, 2008). “This suggests advertisers are not consistently providing a ‘fair balance’ between risk and benefit information and raises questions about FDA oversight that the General Accounting Office has also noted” (Hoek, 2008). Short of a total ban on DTC marketing of pharmaceuticals, Wakeam (2009) calls for a specific government regulatory body to provide more control over accuracy of product promotions and notes that “governmental action might be able to provide a limit on pharmaceutical advertising as a consumer safeguard.”

In a recent example, in late 2008, Bayer HealthCare Pharmaceutical, Inc. (Bayer) President & Chief Executive Officer, Rienhard Franzen, received an official FDA Warning Letter from Thomas Abrams, Director of the FDA Division of Drug Marketing, Advertising, and Communications (DDMAC) for YAZ, an oral contraceptive that Bayer was marketing as also effective in reducing symptoms of premenstrual syndrome (PMS) and acne, despite YAZ being approved as an oral contraceptive effective in treating only premenstrual dysphoric disorder (PMDD) (Abrams, 2008). In the warning letter, the FDA asserts that “...two 60-second direct-to-consumer (DTC) broadcast television advertisements (TV Ads)...for YAZ®...are misleading

because they broaden the drug's indication, overstate the efficacy of YAZ, and minimize serious risks associated with the use of the drug...These violations are concerning from a public health perspective because they encourage use of YAZ in circumstances other than those in which the drug has been approved, over-promise the benefits and minimize the risks associated with YAZ" (Abrams, 2008). The warning letter further requests that Bayer immediately discontinue advertising YAZ without revising the promotional materials to reflect the FDA's suggested corrective language, and offers DDMAC assistance with developing new materials. Mr. Abrams (2008) closes with a warning that "Failure to correct the violations...may result in FDA regulatory action, including seizure or injunction, without further notice."

### *Implications*

*Pros and Cons.* Researchers agree on common pros of DTC pharmaceutical marketing. Advocates of DTC pharmaceutical marketing argue that it increases consumer awareness of common conditions and available treatment options; results in greater patient empowerment and assertiveness in health care; improves physician-patient communication; and enhances patient compliance with prescribed therapies (Hoek, 2008; Joseph, Spake & Finny, 2008; Joseph, Spake & Godwin, 2007; Joseph et al., 2005; Lyles, 2002; Ta & Frosch, 2008; Timko & Chowansky, 2008).

Opponents consistently assert that DTC advertising campaigns for pharmaceuticals lack information about alternate therapies, efficacy, and cost, and often provide inappropriate or misleading information for target audiences (Beltramini, 2006; Hoek, 2008; Joseph et al., 2007; Joseph et al., 2008; Lyles, 2002; Ta & Frosch, 2008; Timko & Chowansky, 2008). Additionally, opponents believe the physician-patient relationship is hindered, patients opt for advertised remedies as "quick-fix" options even when the therapy may not be appropriate and may be unsafe, and the costs of pharmaceuticals and medical care in general are increased due to DTC marketing of pharmaceuticals (Beltramini, 2006; Hoek, 2008; Joseph et al., 2007; Joseph et al., 2008; Lyles, 2002; Ta & Frosch, 2008; Timko & Chowansky, 2008). Many of the cons expressed in the research are consistent with the holdings of the New Jersey Supreme Court in *Perez v. Wyeth Laboratories, Inc.*

*Costs.* Researchers agree that subsequent to the relaxation of federal guidelines on DTC pharmaceutical advertising in 1997 (finalized in 1999), pharmaceutical industry spending on such advertising campaigns has grown exponentially (Cole, 2007; Friedman & Gould, 2006; Hoek, 2008; Joseph et al., 2005; Joseph et al., 2007; Joseph et al., 2008; Lyles, 2002; Ta & Frosch, 2008; Timko & Chowansky, 2008; Wakeam, 2009). Cole (2007) asserts that one year after the FDA loosened restrictions on DTC pharmaceutical advertising, pharmaceutical companies increased their advertising budgets by 400% and redirected marketing from physicians to their patients. Table 1 lists pharmaceutical industry spending on DTC advertising in various years ranging from 1991 to 2006 as reported in the literature, which captures the relaxation of federal regulations in 1997. In some instances, reported expenditures vary by researcher.

Researchers agree that for every \$1 spent on DTC advertising campaigns, sales within the pharmaceutical industry increase by \$4.20 (Ta & Frosch, 2008; Timko & Chowansky, 2008). From 1996 to 2000, pharmaceutical industry spending grew 216% in absolute dollars, with the majority of the increase concentrated in roughly 24 brands, representing a 34% increase in all prescription drug spending from 1998-1999 alone (Lyles, 2002). Between 1998 and 1999, the top 25-marketed drugs were responsible for an increase in United States pharmaceutical costs by

\$7.2 billion (Joseph et al., 2005). From 1999-2000, the costs of 50 of the most heavily advertised drugs rose 32%, compared to a 14% increase for all other drugs combined (Joseph et al., 2005). Joseph et al. (2007) report that healthcare costs rose in the United States 9.6% annually from 2000 to 2004, with the largest portion of the increase attributable to rising pharmaceutical costs.

Table 1. *Pharmaceutical Industry DTC Marketing Expenditures by Year*

Year	Expenditures	References
1991	\$55.3 million	Joseph et al., 2008
1995	\$340 million	Joseph et al., 2008
1996	\$791 million	Friedman & Gould, 2006
1997	\$220 million	Joseph et al., 2007
1998	\$1.2 billion	Joseph et al., 2005
1999	\$1.8 billion	Joseph et al., 2008
2000	\$2.5 billion	Joseph et al., 2005, Timko & Chowansky, 2008; Wakeam, 2009
2001	\$2.7 \$2.8 billion	Timko & Chowansky, 2008 Joseph et al., 2008
2002	\$2.2 billion (first 10 months)	Joseph et al., 2005
2003	\$3.2 billion	Friedman & Gould, 2006; Joseph et al., 2007; Timko & Chowansky, 2008
2004	\$4.5 billion	Friedman & Gould, 2006
2005	\$>4 billion \$8.4 billion	Hoek, 2008 Joseph et al., 2007
2006	\$4.8 billion	Timko & Chowansky, 2008

However, Ta and Frosch (2008) report that annual pharmaceutical industry promotional spending remains steady at about 14% of total spending. Pharmaceutical company advocates assert that cost increases are attributable to massive expenditures on research and development leading to high-demand drugs that replace traditional surgical procedures (Joseph et al., 2005). Friedman and Gould (2006) found that from discovery to launch of a new pharmaceutical, it takes approximately seven years and costs \$800 million.

Researchers agree that the pharmaceutical industry is a leader in advertising expenditures amongst spending categories. Some argue pharmaceutical advertising trails only the automotive industry and fast foods, while others argue pharmaceutical advertising ranks fifth (Joseph et al., 2007). In the first half of 2005, only the automotive industry exceeded the pharmaceutical industry in advertising expenditures (Ta & Frosch, 2008).

### *Key Stakeholders*

*Patients.* Lyles (2002) cautions that over 50% of respondents in a national poll believe their health plan is more worried about saving money than providing the best treatment, and 25% trust their physician less than in recent years. Beltramini (2006) reports that as a form of information about pharmaceuticals, advertising is trusted the least. Despite this skepticism, researchers agree that patients look favorably upon DTC advertising of pharmaceuticals, and

acknowledge that such advertising prompts patients to seek additional information on a condition or marketed drug (Beltramini, 2006; Hoek, 2008; Joseph et al., 2005; Joseph et al., 2007; Joseph et al., 2008; Lyles, 2002; Ta & Frosch, 2008; Timko & Chowansky, 2008). Joseph et al. (2008) surveyed customers at a grocery store pharmacy and found that 69% believe doctors prescribe the most effective medications, but 52% also believe incentives from the pharmaceutical industry play a role in prescribing behaviors. Lyles (2002) argues that DTC advertising “reflects the consumer’s growing role in prescription drug decisions in managed care, desire for information, and distrust in their providers.” Subsequently, many researchers have examined and documented actual patient behaviors after exposure to DTC pharmaceutical advertisements.

Existing research indicates that DTC pharmaceutical marketing leads to changes in patient behaviors (Joseph et al., 2008). Joseph et al. (2007) found that after viewing DTC pharmaceutical advertisements, some patients go to their doctor based on advertised symptoms to ask for a specific drug. If the physician does not prescribe the requested medication, some patients go to another doctor to obtain the desired medication (Joseph et al., 2008). In 2005, Joseph et al. found that 23-29% of patients who ask a doctor about a specific drug or condition for the first time are doing so because of exposure to DTC pharmaceutical advertisements, and 6-9% request a specific drug before any dialogue occurs. Additionally, Joseph et al. (2008) found that respondents are persuaded by DTC pharmaceutical advertisements to take action, with 41% asking a physician for a specific drug (51% of whom receive the requested drug), and 40% going to a doctor based on advertised symptoms. Interestingly, patients that ask physicians for medication are more likely to receive a prescription than those who do not ask (Beltramini, 2006; Hoek, 2008; Joseph et al., 2005; Joseph et al., 2007; Joseph et al., 2008; Lyles, 2002; Ta & Frosch, 2008; Timko & Chowansky, 2008; Wakeam, 2009), and 29% report favoring brand name to generic drugs (Joseph et al., 2008).

Beltramini (2006) compiled data from other existing patient-level surveys, including the 2001 Kaiser Family Foundation *Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising*, and 2002 Frank et al. study of “Trends in Direct-to-Consumer Advertising of Prescription Drugs.” Frank et al. found that 91% of respondents were aware of DTC pharmaceutical marketing, 30% talked to their doctor about an advertised medication, and 13% received their requested prescription (Beltramini, 2006). While the Kaiser Family Foundation found similar rates of respondents talking to their doctors about advertised medications (30%), 44% of respondents reported receiving the requested prescription as opposed to only 13% in the Frank et al. study (Beltramini, 2006). Regardless of the source of the findings, the results all support the notion that marketing pharmaceuticals directly to patients results in changes in patient behavior, and suggests patients are in favor of continued DTC pharmaceutical marketing.

*Vulnerable populations.* Much of the existing literature examines impact of DTC pharmaceutical marketing on patients in a broad sense. Not all patients, however, are affected in equal measure. Several factors, including an ever-diversifying, aging population; the implementation of Medicare Part D; and an ailing economy, have prompted researchers to focus greater attention on traditionally more vulnerable populations including minorities, women, senior citizens, and lower-income earners. Lyles (2002) reports variation in awareness of DTC pharmaceutical marketing amongst different races or ethnicities, socioeconomic status and gender; the lowest amongst minorities (particularly Hispanics) and those with annual household incomes less than \$25,000. Joseph et al. (2008) found income to be the only statistically significant factor in patient behavior. Income earners of \$80,000 or more approach their physicians about advertised drugs less than at other income levels, and those who earn \$20,000

or less report pharmaceutical advertisements persuade them to prefer brand name drugs and to consult a physician when they have symptoms mentioned in those advertisements (Joseph et al., 2008). Low-income individuals and senior citizens may be less accepting of generic medications, which is significant since costs of brand name pharmaceuticals are often much higher than equivalent generic medications (Joseph et al., 2008).

In addition to income level differences, senior citizens have been found to be more skeptical of DTC pharmaceutical advertisements and although most (77%) senior respondents in a 2007 study by Joseph et al. reportedly are aware of such advertising, less than half (43%) say they are motivated to see their doctor after exposure to such ads. Additionally, despite having the highest pharmaceutical consumption rates, senior citizens have the lowest comprehension and recall of DTC pharmaceutical advertisements (Joseph et al., 2007). This suggests that DTC pharmaceutical advertisements may be ineffective at reaching some target populations. Beltramini (2006) notes that seniors may be particularly vulnerable to DTC pharmaceutical marketing; however, because they are “consumers who *want* to believe these products will solve their problems.” In other words, many advertisements for pharmaceuticals do not influence senior citizens until a condition or medication “hits home,” at which time, older Americans may be disproportionately influenced to act.

Women are more likely than men to be aware of DTC marketing (Lyles, 2002, Joseph et al., 2005) and women are more likely to approach a doctor about advertised drugs (Joseph et al., 2007). The plaintiffs in *Perez v. Wyeth Laboratories, Inc.* alleged in their complaint that the massive Norplant advertising campaign directly targeted women, not physicians (Fushman, 2000). Joseph et al. found no differences between males and females, however (2008). Since data on gender differences are limited, future research in this area is needed, as available information suggests gender may impact awareness and behaviors subsequent to exposure to DTC pharmaceutical advertisements.

In addition to gender exploration, additional research into literacy levels is warranted, as Hoek (2008) suggests that early evidence shows patients with lower literacy levels have unbalanced comprehension and recall of DTC pharmaceutical advertisements. To understand fully the impacts of DTC pharmaceutical marketing on patients, greater focus should be placed on more defined patient populations to ensure disparate impacts are identified and understood, and appropriate safeguards can be put in place to protect the most vulnerable.

### *Physicians*

Pharmaceutical companies have long marketed directly to physicians, and Timko and Chowansky (2008) report that physicians tend to inappropriately prescribe medications if they rely only on information from pharmaceutical companies. Since the relaxation of FDA regulations in 1997, pharmaceutical industry promotion budgets have grown and shifted some of the emphasis from physician marketing to DTC marketing (Lyles, 2002), which encourages physicians to research medications beyond the information provided by pharmaceutical companies. While patients are generally in favor of DTC marketing of pharmaceuticals, the literature indicates the majority of physicians are less accepting (Friedman & Gould, 2006; Lyles, 2002; Joseph et al., 2008; Timko & Chowansky, 2008). Friedman and Gould (2006) found 53% of surveyed physicians feel that DTC marketing of pharmaceuticals leads to patients asking for and receiving unnecessary prescriptions, and 66% of surveyed physicians feel this includes an incorrect preference for brand name drugs when a generic is sufficient. Of

responding United States physicians, 60-65% want DTC marketing of prescription drugs to decrease or stop entirely (Joseph et al., 2008).

Despite this negative overall opinion of DTC pharmaceutical marketing, most physicians prescribe medications to patients who expect or ask for them, including prescriptions for specifically requested, advertised drugs, even if the physician feels it may not be the most effective therapy (Friedman & Gould, 2006; Lyles, 2002; Timko & Chowansky, 2008). Timko and Chowansky (2008) report that between 1994 and 2001, adolescents' physician visits in which psychotropic medications were prescribed rose by 250%, with the greatest increase after 1999, the first year DTC pharmaceutical advertising guidelines were relaxed. From 2000 to 2001, only 20.9% of adolescents who were prescribed psychotropic medications received an accompanying mental health diagnosis (Timko & Chowansky, 2008).

Wakeam (2009) opines that, when faced with a choice of two comparable medications, physicians will likely defer to patient preference, and in four out of five instances, patients are prescribed the drugs they ask for. Over 80% of polled physicians report receiving a direct, specific medication request, and 23.5% report altering prescribing methods because of such requests (Timko & Chowansky, 2008). Among those physicians, only half feel the prescribed medication was the best choice of treatment, and 5% prescribed the medicine simply to appease the patients (Timko & Chowansky, 2008). Non-drug therapies are discussed with 53% of patients who ask about an advertised drug, and this increases to 77% for diabetes, to 84% for overweight patients, and for hypercholesterolemia, to 92% (Lyles, 2002).

Physicians act as gatekeepers in the health of their patients, and patients cannot obtain prescription medications without approval of their physician. In the four quarters ending the first quarter of 2005, United States physicians wrote 3.5 billion prescriptions (Friedman and Gould, 2006). If physicians refuse to prescribe requested medications that are inappropriate or unnecessary, prescribe generic medications regardless of patient preference, and encourage lifestyle modification as opposed to prescription interventions, this change in prescribing behavior could have an impact on pharmaceutical company promotion methods. Current physician prescribing habits do not reflect the reported desires of 60-65% of United States physicians for DTC pharmaceutical marketing to be scaled back or eliminated entirely (Joseph et al., 2008).

## **POLICY DISCUSSION**

DTC marketing of pharmaceuticals is often used to promote new drugs, prior to loss of patent protection, in a way that maximizes profits (Hoek, 2008). When patents expire, companies often release new versions of the drug that offer improvements or differ in some other way (Hoek, 2008). While some drugs change substantially, others must rely more directly on marketing to generate sales, shifting demand from existing, to new and more expensive drugs (Hoek, 2008). Because many DTC promoted pharmaceuticals do not attract government subsidies, patients must pay for the drugs, and in some instances, they are unable to afford advertised medications (Hoek, 2008). Additionally, senior citizens and low-income individuals prefer brand name to generic drugs, which is significant because people over 65 years of age and those who qualify for state assistance are often on government healthcare programs, which could potentially increase government costs as a payer of healthcare services (Joseph et al., 2008).

It appears that DTC pharmaceutical promotions affect patients, but they are reluctant to admit it or are unaware of the influence on them (Joseph et al., 2008). In fact, DTC pharmaceutical

marketing may have led to social changes in which patients no longer use willpower to change their health status, but instead, rely on medical interventions (Hoek, 2008). Despite this, the FDA asserts that they are “unaware of any data supporting the assertion that the public health...is being harmed, or is likely to be harmed by the Agency’s actions in facilitating consumer-directed broadcast advertising” (Lyles, 2002). Current regulations, however, have failed to quell the strong, divergent stakeholder views regarding marketing pharmaceuticals directly to patients (Lyles, 2002).

In addition to altering patient behaviors, DTC advertising of pharmaceuticals may also alter current standards and perceptions of liability (Lyles, 2002). Legal precedent holds that “physicians are the ‘learned intermediary’ between pharmaceutical companies and patients, and that they are responsible for judging a prescription drug’s benefits and risks for their patients” (Lyles, 2002). As a result, pharmaceutical companies have been protected from having to warn patients directly (Lyles, 2002). As seen in *Perez v Wyeth Laboratories, Inc.*, there is growing concern over this protection from liability. When companies communicate directly with patients, manufacturer’s liability may increase, particularly if the FDA has issued corrective actions because of a DCT pharmaceutical advertising campaign (Lyles, 2002).

Without assurance that patients, payers, physicians, and pharmacists all agree that DTC marketing of pharmaceuticals benefits public health, it is unlikely the practice will continue in its current form (Friedman & Gould, 2006). While self-imposed industry guidelines are a first step, legislators are questioning the value of the practice, which ultimately may lead to significant changes to or cessation of DTC marketing of pharmaceuticals (Friedman & Gould, 2006). Wakeam (2009) proposes a government regulatory body to provide oversight and control of product portrayals in the absence of a total ban on DTC pharmaceutical advertising. Government action may be able to provide appropriate boundaries on pharmaceutical advertising as a safeguard for patients (Wakeam, 2009).

While not expressly focused on DTC pharmaceutical marketing, the Patient Protection and Affordable Care Act signed into law on March 23, 2010 has multiple measures that affect pharmaceutical manufacturers and is likely to influence future DTC pharmaceutical marketing strategies. Such provisions include elimination of the tax deduction for employers who receive Medicare Part D retiree drug subsidy payments in 2013; imposing billions of dollars in new annual fees on the pharmaceutical manufacturing sector on a graduated scale beginning in 2012; increasing the Medicaid drug rebate percentage for brand name drugs and non-innovator, multiple source drugs; authorizing the FDA to approve generic drugs and grant manufacturers twelve years of patent protection; providing incentives to Medicare and Medicaid beneficiaries to complete behavior modification programs; and requiring pharmaceutical manufacturers to provide a 50% discount on brand name drugs for prescriptions filled in the Medicare Part D coverage gap beginning in 2011 (Kaiser Family Foundation, 2010). While it is impossible to predict the effect on patient-centered pharmaceutical promotions at this point, it is fair to say that the future of DTC pharmaceutical marketing could look very different; however, changes in Congressional power resulting from the 2010 mid-term elections may result in changes to healthcare reform law. Future research is recommended as administrative rules are written and provisions are enacted. Regardless of the outcomes of healthcare reform, the FDA should act now to revise DTC pharmaceutical marketing policy.

### *Options and Outcomes*

In December 2001, the Council of the Royal Pharmaceutical Society of Great Britain stated the following position on DTC pharmaceutical marketing in that country:

The demand for information about prescribed medicines from patients and the public is likely to increase, but [direct-to-consumer advertising] DCTA is unlikely to be the best way of providing it because the aim of advertising is to persuade, not to give balanced information about benefits and risks. DCTA, moreover, carries a significant risk of exposing more patients to the adverse effects of new drugs. If DCTA is successful, it may well adversely affect doctor-patient relationships, distort public health priorities and disrupt the cost controls operated by the [National Health Service] NHS... (World Health Organization, 2002).

Countries around the world prohibit DTC pharmaceutical marketing for many of the same reasons. The United States and New Zealand are the only two countries that allow DTC marketing of pharmaceuticals, albeit both “by omission rather than design” (Hoek and Gendall, 2002). New Zealand successfully self-regulates DTC pharmaceutical marketing, largely because “...the knowledge that legislation would replace self-regulation if the latter proves ineffective provides a compelling incentive for the industry to maintain robust and transparent systems of accountability” (Hoek and Gendall, 2002).

As evidenced by situations such as *Perez v Wyeth Laboratories, Inc.* and the warning letter issued to Bayer HealthCare Pharmaceutical, Inc., the United States pharmaceutical manufacturing industry is unwilling or unable to regulate itself, as in New Zealand. The United States requires government regulation through the FDA to ensure patients receive fair and balanced information about prescription medications, including potential drug risks. Although opponents of DTC pharmaceutical marketing propose rescinding the practice altogether, it is highly unlikely that this will occur due to the vast resources and immense power and influence of pharmaceutical manufacturer lobbyists. Short of total reversal, however, the FDA should immediately revise its guidelines to eliminate the product claims advertisement category, which promote specific products, by name, for the treatment of specific conditions. Help-seeking and reminder advertisements should still be allowed, as they provide information on specific diseases, conditions, and even specific medications, without the negative consequences of persuading patients to seek brand name prescription medications for self-diagnosed conditions.

Both proponents and opponents of DTC pharmaceutical marketing would agree that patients would still be informed of conditions they may not know they have and would still be empowered to talk to their physicians, who have the knowledge of new, existing, and alternative therapies and can decide the most appropriate course of action with informed, not persuaded, patients. Pharmaceutical companies may see reduced profit margins if product claims advertising is not allowed, but as evidenced by *Perez v Wyeth Laboratories, Inc.*, they may also avoid putting people at risk of adverse effects and potentially large payouts in court settlements due to increased scrutiny of marketing practices and product liability. Table 2 summarizes the outcomes of three policy options for key stakeholders; (1) maintain the status quo, (2) totally ban DTC pharmaceutical marketing, and (3) ban DTC product claims advertisements.

## **CONCLUSION**

The top 25-marketed drugs accounted for \$7.2 billion in increased costs in pharmaceutical spending in the United States from 1998 to 1999, and healthcare costs increased annually by 9.6% between 2000 and 2004, largely due to increased pharmaceutical costs (Joseph et al., 2005;

Joseph et al., 2007). Pharmaceutical manufacturers enjoy staggering profits, often at the expense (and sometimes wellbeing) of the American public. Policy-makers question the appropriateness of continued widespread marketing of pharmaceuticals directly to patients, and courts have begun looking at who bears the liability of warning patients of the risks of advertised pharmaceuticals (*Perez v Wyeth Laboratories, Inc.*) (Lyles, 2002). However, despite growing costs, disapproval of physicians, and increased scrutiny, the FDA cannot directly link any negative impacts on public health due to allowing expanded DTC pharmaceutical advertising (Lyles, 2002). They have yet to uncover a “smoking gun.”

With the signing of the Patient Protection and Affordable Care Act into law on March 23, 2010, lawmakers may have drastically altered the future of DTC pharmaceutical marketing (Kaiser Family Foundation, 2010). However, changes in Congressional power resulting from the 2010 mid-term elections may result in changes to healthcare reform law. The United States should not wait on healthcare reform laws to influence DTC pharmaceutical marketing policies, as it is clear that without regulatory intervention, the industry will continue to flood the airwaves with product claims advertisements for the next “best” medications and bankroll huge profits, regardless of the risks or potential negative consequences for consumers. Instead of waiting to uncover the “smoking gun,” the FDA should proactively protect public health by revising DTC pharmaceutical marketing policy to eliminate product claims advertisements. Patients would still receive empowering information, and physicians would be in a better position to determine the most appropriate course of action, not simply the “as seen on TV” version.

**Table 2a. Summary of DTC pharmaceutical marketing policy options and outcomes in the United States.**

<b>Maintain the Status Quo (Do Nothing)</b>	
<b>Pharmaceutical Manufacturers/Industry</b>	<ul style="list-style-type: none"> <li>Pharmaceutical companies will continue to enjoy lucrative returns on advertising investments. Research shows that for every \$1 spent on DTC advertising, pharmaceutical industry sales increase by \$4.20.</li> <li>Pharmaceutical advertising will continue to be a leader among all advertising expenditure categories and pharmaceutical costs will continue to rise, contributing to increases in overall healthcare costs in the United States. Growing scrutiny by lawmakers and the FDA alike, along with court decisions such as <i>Perez v. Wyeth Laboratories, Inc.</i>, will increase the liability of pharmaceutical manufacturers who market directly to consumers, putting them at risk of potentially enormous legal fees and/or settlements.</li> </ul>
<b>Patients</b>	<ul style="list-style-type: none"> <li>Although research shows that as a form of information about pharmaceuticals, patients trust advertising the least; studies also show that patients look favorably on DTC pharmaceutical advertising as a way to learn about medical conditions and treatments, and are prompted to talk to their doctors.</li> <li>Patients will continue to diagnose themselves with conditions they see on television and will continue to request specific medications from their doctors – 40% do so now, and of that 40%, over half receive the requested medication.</li> <li>Patient prescription and healthcare expenses will continue to rise, particularly because roughly one-third of patients report they prefer brand name over generic medications.</li> </ul>
<b>Vulnerable Populations</b>	<ul style="list-style-type: none"> <li>Not all populations are equally impacted by DTC pharmaceutical marketing. Race or ethnicity, socioeconomic status, gender, and age are significant to the level of awareness of such marketing and subsequent actions. In general, minorities (particularly Hispanics) are less aware of DTC pharmaceutical advertisements. Women are more likely than men to be aware of pharmaceutical advertisements and subsequently see their doctors about advertised drugs. Low-income individuals (\$20,000 per year or less) are less aware of DTC pharmaceutical advertisements, but report being persuaded by such advertisements to prefer brand name drugs and to consult a physician when they have symptoms mentioned in advertisements.</li> <li>Patients with lower literacy levels have low, unbalanced comprehension and recall of DTC pharmaceutical advertisements.</li> <li>Senior citizens are more skeptical of DTC pharmaceutical advertising, but are the most vulnerable consumers. Senior citizens have the highest prescription usage rates, the lowest DTC pharmaceutical advertisement comprehension and recall rates of all age groups, yet, when an advertised medication “hits home” they are disproportionately influenced to act.</li> <li>DTC pharmaceutical advertisements will continue to miss some target audiences and disproportionately influence others. Low-income earners and senior citizens will continue to be persuaded to prefer brand name drugs, which is significant because the costs of brand name pharmaceuticals are often much higher than generic equivalents.</li> </ul>
<b>Physicians</b>	<ul style="list-style-type: none"> <li>Research shows that the majority of physicians feel that DTC pharmaceutical marketing leads to patients asking for and receiving unnecessary prescriptions, including a preference for brand name drugs where a generic is sufficient. Despite these findings, physicians continue to prescribe medication when they believe a patient is expecting it. When faced with a choice of two comparable medications, physicians will continue to defer to patient preference, even if it alters the physician’s prescribing methods or may not be the best choice of treatment. In roughly 5% of instances, doctors prescribe medications simply to appease patients.</li> <li>Physicians will continue to dislike DTC pharmaceutical marketing, but will also continue to alter prescribing practices based on patient pressure.</li> </ul>

**Table 2b. Summary of DTC pharmaceutical marketing policy options and outcomes in the United States.**

<b>Ban DTC Product Claims Advertisements</b>	
<b>Pharmaceutical Manufacturers/Industry</b>	<ul style="list-style-type: none"> <li>• Pharmaceutical companies will increase physician-directed marketing of specific drugs for specific conditions, and will simultaneously increase help-seeking and reminder advertisements directly to consumers.</li> <li>• Pharmaceutical manufacturers may increase costs of brand name prescription drugs in an effort to offset profit losses likely to result from discontinuing product claims advertisements.</li> <li>• R&amp;D may initially slow until pharmaceutical manufacturers realize actual financial impacts and make decisions based on new profit margins. By marketing drugs without claims of clinical role or effectiveness, fewer consumers may be impacted by negative consequences and manufacturer liability and associated costs would greatly diminish.</li> </ul>
<b>Patients</b>	<ul style="list-style-type: none"> <li>• Both proponents and opponents of DTC pharmaceutical marketing can agree that help-seeking advertisements will continue to inform patients of potentially serious medical conditions and symptoms, which will continue to prompt them to talk to their physicians.</li> <li>• Reminder advertisements may prompt patients to ask their doctors about specific medications, but they will put less pressure to prescribe that medication on their doctor if they have not previously convinced themselves that they have the medical condition that specific drug treats. Patients will be informed, not persuaded, and fewer will be impacted by potential negative effects from unnecessary or contraindicated “as seen on TV” pharmaceuticals.</li> </ul>
<b>Vulnerable Populations</b>	<ul style="list-style-type: none"> <li>• Information received through help-seeking advertisements will still empower vulnerable populations to talk to their doctors about signs and symptoms of medical conditions, without disproportionately persuading them to prefer specific, often expensive medications. Through increased patient-physician dialogue about various treatment options, acceptance of generic medications may increase and vulnerable populations may see the same positive health outcomes along with substantial monetary savings.</li> </ul>
<b>Physicians</b>	<ul style="list-style-type: none"> <li>• Physicians have the best knowledge of new, existing, and alternative therapies and can decide the best course of action when patients are informed, not persuaded, and prescribing decisions are put back in the hands of the experts.</li> <li>• Physicians would support scaling back patient-directed pharmaceutical marketing. Although physician-directed pharmaceutical marketing may increase, pressure from patients will decrease.</li> <li>• Physicians must continue to seek information from sources beyond just pharmaceutical representatives, however.</li> <li>• Physician-patient relationships and outcomes are likely to improve as physicians are able to spend more time talking to patients about options versus deflecting requests for advertised medications.</li> </ul>

**Table 2c. Summary of DTC pharmaceutical marketing policy options and outcomes in the United States.**

<b>Pharmaceutical Manufacturers/Industry</b>	<ul style="list-style-type: none"> <li>• Pharmaceutical manufacturers will raise drug prices in an effort to offset DTC marketing profit losses.</li> <li>• Physician-directed marketing will increase dramatically.</li> <li>• Research and development (R&amp;D) for new, innovative pharmaceuticals will be scaled back because the potential return on the substantial R&amp;D investment (of approximately seven years and \$800 million) is minimized.</li> <li>• Fewer consumers may be impacted by negative consequences and ultimately, pharmaceutical manufacturers would be less liable and would avoid litigation and legal fees.</li> <li>• The vast resources and strength of pharmaceutical industry lobbyists makes a total ban of DTC pharmaceutical marketing highly unlikely.</li> </ul>
<b>Patients</b>	<ul style="list-style-type: none"> <li>• Nearly two-thirds of patients report that they believe doctors prescribe the most effective medication, but nearly half also believe that incentives from the pharmaceutical industry play a role in prescribing patterns. Patients also report trusting their doctors less now than in the past and believe their health plans are more concerned with costs than their health.</li> <li>• Patient distrust is likely to rise and patients may be discouraged from talking to their doctors about potential medical conditions.</li> <li>• Some patients may not be aware that symptoms they are experiencing may be due to a serious medical condition and they could end up with worse, more expensive outcomes if they seek help later in the disease process.</li> </ul>
<b>Vulnerable Populations</b>	<ul style="list-style-type: none"> <li>• Preference for expensive, brand name medications over generic equivalents will decrease among senior citizens and low income earners.</li> <li>• Patient information and awareness will decrease. Physicians will be responsible for encouraging open dialogue with vulnerable patients to ensure all symptoms are openly discussed to avoid potential misdiagnoses or missed diagnoses.</li> <li>• Treatment options and expected outcomes must be easy to understand.</li> <li>• Vulnerable populations will be less influenced and persuaded by the outside environment when seeking medical care.</li> </ul>
<b>Physicians</b>	<ul style="list-style-type: none"> <li>• Nearly two-thirds of United States physicians report being in favor of a total ban on DTC marketing of pharmaceuticals, or at minimum, scaling back the practice.</li> <li>• Physicians would be relieved of some patient pressures, but would face increased pressure from the pharmaceutical industry.</li> <li>• Research shows that physicians who rely only on information from pharmaceutical manufacturers tend to prescribe inappropriately.</li> <li>• Physician-patient relationships may suffer if patients lack appropriate information and question the physician's motives – research shows that patients already assume prescribing practices are tied to incentives from pharmaceutical companies, which erodes trust.</li> <li>• Patients may not share as much information with physicians and early illness signs and symptoms may go unnoticed, resulting in worse outcomes.</li> </ul>

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