2018

Trends and Effects of Pharmaceutical DTCA

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Recommended Citation
Sathorn, P., Willis W., & Coustasse, A. (2018). Trends and effects of pharmaceutical DTCA. International Journal of Pharmaceutical and Healthcare Marketing, 12(1), 61-70.

TRENDS AND EFFECTS OF PHARMACEUTICAL DTCA

ABSTRACT

Purpose – The purpose of the review is to investigate the current trend of pharmaceutical Direct-to-Consumer Advertising (DTCA) in the US and its effect on patients, physicians, and drug utilization. DTCA by pharmaceutical firms may be defined as an attempt by pharmaceutical companies to advertise products directly to patients.
Design/methodology/approach – Methodology for this paper is a literature review approach.
Findings – Pharmaceutical DTCA demonstrated a reduction in total spending, while the online channel media experienced growth. DTCA has influenced the physician-patient relationship and patient satisfaction. Patients who received medication associated with DTCA showed higher satisfaction. DTCA of second-line drugs increased first-line drug utilization. Benefits of pharmaceutical DTCA include enhancing appropriate drug utilization and increasing awareness. DTCA might cause harm by interfering with physician decisions regarding drug choice.
Research limitations – Limitations include the availability of information on DTCA spending by pharmaceutical companies and the lack of quantitative data on the effect of pharmaceutical DTCA. Additionally, DTCA is sometimes affected by research bias.
Practical implication – Improvement in the physician-patient relationship and patient satisfaction, as well as improvement in the quality of care provided may be demonstrated.
Social implication – Pharmaceutical firms utilizing DTCA marketing advertisement methodologies can increase awareness of under-diagnosed conditions, affect medication costs, and the utilization of appropriate drug utilization.
Originality/Value – Literature review highlights current relationships between DTCA, patients, physicians, and drug utilization to explore the effects DTCA has on consumers.

Keywords – DTCA, Prescription drug coupons, physician/patient relationship, pharmaceutical advertising, medication utilization
Paper Type – Literature review

INTRODUCTION

Direct-to-Consumer Advertising (DTCA) of pharmaceutical firms may be defined as an attempt by the pharmaceutical companies to advertise or promote information regarding prescription drugs directly to patients. DTCA can be performed through a variety of advertising channels; for example, television broadcast, billboards, and consumer magazine (Abel et al., 2006).

There have been several types of DTCA, which have included: help-seeking ads, reminder ads, and product claim ads. (Ventola, 2011). The help-seeking ads variety has been categorized by the presence of information regarding a disease while omitting the drug information. The reminder ads provide limited information regarding prescription medications, such as the name of a drug, price, and strength. This variety of advertisement does not provide the indications or any claim on efficacy or any drug effects (Gellad & Lyles, 2007). The product claim ads variety is advertisement involving a more holistic provision of prescription drug information compared with the other types of advertisement. This kind of advertisement provides the indication, efficacy, and safety profile of the prescription drug (Connors, 2009). As some countries have allowed limited prescription drug advertisement, the U.S. and New Zealand have product claim ads allowing for drug advertisement on television and other broadcasting media (Abel et al., 2006; Vats, 2014).

The advertisement of prescription drugs via television broadcast has become more popular as less stringent Food and Drug Administration (FDA) regulations on DTCA began in 1997 (Morgan, 2007). The expenditure of DTCA was higher than $4 billion in 2004 and showed 23% growth when compared to the previous year (Gellad & Lyles, 2007). Even though the total spending of prescription drug promotion declined between 2006 and 2010, DTCA continually receives criticism due to the appropriateness and legal issues. For example, DTCA has been associated with “black box” warnings of prescription drugs that may cause serious side effects (Arnold & Oakley, 2013). The purpose of DTCA focuses mainly on the commercial aspects rather than aiming to educate patients.

DTCA has targeted a limited range of drugs. In 2000, 20 of the top products in the pharmaceutical industry accounted for 60% of total DTCA spending. Furthermore, the advertisement of a single medication, Vioxx was reported at $161 million in 2000, which surpassed many of the advertisement expenditures for consumer products such as Dell, Budweiser, Pepsi, and Nike (Rosenthal, Berndt, Donohue, Frank, & Epstein, 2002). In September 2004, after the discovery of severe side effects of Vioxx, (including stroke and myocardial infarction), the drug was withdrawn from the market (Schuchman, 2007).

Critics assert that DTCA is under-regulated and urge the need to strengthen regulations (Donahue, Cervasco, & Rosenthal, 2007). For example, the advertisement of prescription drugs requires no approval or any pre-clearance (pre-screening) before the time of broadcasting. In the event violation(s) of FDA regulations occur, the FDA could request revision of the advertisement; however, it would not change the fact that consumers have already been exposed to inappropriate advertising and possibly misled by the information provided (Shaw, 2008). Additionally, FDA regulatory guidance of DTCA by pharmaceutical firms is often perceived as unclear. For instance, the guidance only requires the pharmaceutical companies to include the most serious and the most common side effects of their products. Thus, allowing the pharmaceutical companies to decide which associated risks to disclose in their advertisement (Biegler & Vargas, 2013). Furthermore, critics point out the

establishment of DTCA guidance has been delayed for years. In 2004, a draft version for new guidance regarding risk communication was written, yet never received revision until 2015 (Christopher & Robertson, 2015).

DTCA impacts the public in both favorable and harmful ways (Almasi, Stafford, Kravitz, & Mansfield, 2006). The benefits of DTCA for the public have included; more empowered patients, enhancement in patient-physician relationship, and increased awareness to patients, especially for underdiagnosis of conditions (Delbaere & Smith, 2006). On the other hand, the opposing position claims DTCA leads to many drawbacks for the public; which include misled patients regarding drug information, interference with physician decisions in prescribing, and drug overutilization (Ventola, 2011).

According to the Centers for Medicare and Medicaid Service (CMS), prescription drug costs increased to $297.7 billion in 2014 with a 12.2% growth rate compared to 2013 (CMS, 2014). Rising healthcare expenditure is a problematic issue in the U.S. health care delivery system. The growing trend of DTCA could worsen the cost containment for prescription drug costs (Donahue et al., 2007).

The purpose of this research seeks to assess the current practice of DTCA in the U.S. health care system and help demonstrate the effect of DTCA on patients, physicians, and drug utilization.

METHODOLOGY

The methodology is a literature review, which followed a systematic review approach. The literature review consists of three distinct stages: (1) identifying relevant databases and keywords, (2) creating inclusion criteria, analyzing text for relevancy, and examining the literature data; and (3) classifying proper categories.

Step 1: Literature search and collection

The literature review search consisted of four databases, which included Marshall University EBSCOhost database, ScienceDirect, PubMed, and Google Scholar.
The keywords used in searching included: “direct-to-consumer advertising and expenditure or spending," “DTCA and expenditure or spending," “prescription drug advertising or DTCA and drug utilization," “DTCA and effect," and “prescription drug and spending."

Step 2: Literature analysis and inclusion criteria

Inclusion criteria for the literature or studies included: written in English, research studies explicitly conducted in the U.S. or New Zealand, and published year from 2000 to 2017. The literature published from 2006 or later was more favorable as it would provide a trend in DTCA promotion during the past 11 years. Eighty-seven articles met the inclusion criteria, with 42 of the articles selected for this review.

Step 3: Literature Categorization

The selected review articles or studies were categorized based on the conceptual framework and specific subheadings, which included *The Emerging of Online DTCA and Trend for Pharmaceutical Advertising; Prescription Drug Coupons, A New Form of DTCA;*

DTCA Effect Relationship Between Patient and Physician and Patient's Satisfaction; and The DTCA and Drug Utilization.

Conceptual Framework

The conceptual framework was adapted from Frosh, Grande, Tarn and Kravitz (2010) and constructs on the increasing protagonist of patients as consumers. Active participation of patients in clinical medical decision-making in the recent years is transforming patients from passive to active recipients of care. (Figure 1) DTCA by the pharmaceutical industry empowers consumers to enhance their involvement. Patients often request physicians to prescribe specific drugs because of DTCA marketing through high or low-quality information. Patient requests for particular drugs are driven by their past medical history, education, and advertisements the provide inaccurate and incomplete information or by sufficient and balanced information. These patient requests affect the physician-patient relationship because the physician may be unable to order the prescription requested by the patient. While DTCA enhances the patient's involvement, the extent of patient participation varies based on the quality of the information the patient accesses. Additionally, DTCA can result in decreasing the underprescribing of prescription medications as well as contribute to patient adherence to prescribed medications. DTCA benefits consumers by reminding them of their prescriptions, medical conditions and not leading to a specific prescription request (Figure 1).

FIGURE 1 ABOUT HERE

RESULTS

The Emerging of Online DTCA and Trend for Pharmaceutical Advertising

With the growth of Internet-based information, consumers began actively searching for information via online channels, including searches for medical information. Growth estimates projected a double-digit gain, between 2010 -2015, for expenditures of internet-based pharmaceutical advertising, or eDTCA, (Liang & Mackey, 2011). The advantage of eDTCA is the ability for pharmaceutical companies to spread advertisement globally via multiple channels such as websites, satellite TV, and social media (Mintzes, Morgan, & Wright, 2009).

Mackey, Cuomo, and Liang (2015) conducted research investigating the information regarding DTCA expenditures by pharmaceutical firms from 2005 to 2009. The data, collected from multiple marketing data firms such as IMS Health, Nielsen Co., Cegedim Strategic Data, and Kantar Media, allowed for analysis of total spending of DTCA and spending for each DTCA sub-category, which included television, print media, radio, outdoor ads, and internet (eDTCA).

The total spending of DTCA by pharmaceutical firms decreased from $4.8 billion in 2005 to $4.4 billion in 2009, equating to a 7.83% decline from 2005 to 2009. The most significant spending of DTCA sub-category during this period was television, with approximately $2.9 billion spent in 2009. However, this channel showed a decrease in expense by 13.20% from 2005 to 2009. Even though eDTCA sub-category accounted for a small amount of spending in total DTCA, it experienced a three-digit growth of 109 % in the same period. (Mackey et al., 2015). Additionally, the IMS Institute of Health Informatics estimated drug expenditure in the US of about $374 billion in 2014 and global spending on medications would reach $1.4 trillion by 2020 (IMS, 2014). According to Kantar Media, DTCA spending grew 4.6% from 2015 ($6.09 billion) to $6.38 billion in 2016. The television category demonstrated the growth of about 4%, while there was relatively no change in the internet category and the print media, radio, and outdoor group increased about 7 %. (Table 1)

Table1: DTCA expenditure in 2015 and 2016 ----

Kornfield et al. (2015) reported a significant decrease in household exposure to DTCA via television from 2007 to 2013. The average of televised DTCA household exposure was 195.3 times per month in 2007 compared to 111.1 times per month in 2011, which indicated a 43% reduction from 2007 to 2013. However, the household exposure of DTCA for depression medications increased 8.6 times per month in 2007 to 11.3 times per month in 2011 (Kornfield et al., 2015). The emergence of the online media advertisement contributes to a reduction in televised DTCA. (Liang & Mackey, 2011).

Prescription Drug Coupons, a new form of DTCA

The Prescription Drug Coupon (PDC) is an innovative form of pharmaceutical marketing offering exclusive discounts for branded drugs for patients having private insurance or patients paying out-of-pocket (Gagnon & Lexchin, 2008). The ideal goal of PDC is to alleviate the burden of cost related expenses of expensive branded drugs that might result in non-adherence and further complications. Access of the PDC is through a variety of media such as pamphlets in a physician office, websites, and eCoupons (Grande, 2012).

PDCs associate with the promotion of expensive branded drugs. According to Grande (2012) the result of an internet search, using keywords “prescription drug coupon” and the Google search engine, resulted in 9 products from top-10 selling drugs during November 2011 to November 2012. Six of the ten products had “black box” warnings relating to potentially serious complications. Furthermore, of concern became the question of whether PDC would indeed lead to lower prescription drug expenditures and/or appropriate use of medication (Gagnon & Lexchin, 2008). For example, Lipitor, a product engaged in PDC, offering a discount of $75 per month in 2014, resulted in an overall cost of $1,119.6 per year. However, Lipitor can be replaced with a generic product with an overall total expense of $192 per year in 2014, providing savings of $927.60 per year in 2014 (Mackey, Yagi, & Liang, 2014). Also, research indicates that patients exposed to PDC advertising are more likely to ask physicians for specific prescription drugs and have shown a more favorable attitude towards those products (Bhutada, Cook, and Perri, 2009).

DTCA Effect Relationship between Patient and Physician and Patient's Satisfaction

DTCA alters the way patients and physicians interact with each other in the U.S. health care system (Potter & McKinlay, 2005). DTCA exposure allows for increases in patient demand for specific prescription drugs by increasing the opportunity for a patient to ask a physician about those explicit drugs. Additionally, these authors showed that 43% of patients, who mentioned DTCA drugs during their last physician office visit, received the medication they requested (Weissman et al., 2004).

The effect of DTCA on patient satisfaction varies due to age and severity of conditions (Blose & Mack, 2009). A study conducted by using vignettes indicates that denial of a patient's request for a specific prescription affects patient satisfaction, trust, and commitment; however, the expectation of receiving the medication did not change those factors. (Shah, Bentley, & McCaffrey, 2006).

Lewin (2013) studied factors affecting patient satisfaction within patient groups who discussed information from DTCA with their physicians. The data, collected via random-digit telephone interview, provided results showing that receiving a diagnosis was not associated with increased patient satisfaction, yet receiving a prescription was associated with higher patient satisfaction. Furthermore, patients receiving a medication related to DTCA were more likely to report higher satisfaction by 42.2% compared with those receiving another prescription. Finally, patients not receiving a drug-related to DTCA were more likely to have higher satisfaction if they were explainedg the denial of the DTCA prescription (Lewin, 2013).

The DTCA and Drug Utilization

DTCA encourages patients to seek treatment with physicians, especially for under-diagnosed conditions and conditions associated with social stigmas, such as depression (Holmer, 2002). On the contrary, DTCA can lead to overdiagnosis and drug overutilization which might ultimately increase adverse drug reactions (Ross, & Kravitz, 2013). Currently, there has been no sufficient evidence identifying whether DTCA causes more harm than benefit or vice versa (Mintzes, 2012; Law, Majumdar, & Soumerai, 2008).

Irritable bowel syndrome (IBS) is a chronic condition affecting roughly 10% of the US population; however, only a small number of patients seek treatment due to low public awareness, social stigma, and absence of a practical solution (Cremonini & Talley, 2005). Tegaserod was an effective medication for irritable bowel syndrome. Tegaserod, heavily marketed between 2005 to 2007, was suspended from the market in March 2007 due to its significant risk of heart conditions (US FDA, 2008). DTCA of Tegaserod increased the public awareness of IBS, increased physician visits for this condition, and increased the number of scripts written for Tegaserod (Dorn, Farley, Hansen, Shah, & Sandler, 2009).

The effect of DTCA increasing the number of prescriptions can be appreciated in many drug classes, including statins, H2 receptor antagonists, and triptans. The beneficial outcome of DTCA on the increase in prescriptions has been ambiguous and may be difficult to evaluate. In other words, if the rise in prescriptions results from more awareness and usage of first-line medications, DTCA would be considered beneficial; conversely, it would be

detrimental if DTCA promoted the inappropriate use of second-line drugs (Skeldon, Kozhimannil, Majumdar, & Law, 2015).

Tamsulosin (Flomax) and Dutasteride (Adovart) were first lines and second line medications for benign prostatic hypertrophy respectively. Skeldon et al. (2015) examined the expenditure of DTCA, the web search interest, and drug utilization for both drugs from January 2003 to December 2007. DTCA spending for Tamsulosin was $139 million from 2003 to 2007 and was $231 million for Dutasteride, respectively. The effect of both campaigns was Tamsulosin, and Dutasteride resulted in an aggregate increase of both product awareness, which it was detected by web search interest, and drug utilization. For example, the DTCA of Dutasteride (second line medication) not only increased the utilization trend of Dutasteride but also increased the use of Tamsulosin (first line medication) nearly two times compared to Dutasteride. Thus, DTCA of competing products was likely to show beneficial outcomes of increased appropriate prescriptions by improving the awareness rather than the inappropriate use of a second line medication (Skeldon et al., 2015)

DISCUSSION

Those supporting and opposed to DTCA have criticized the practice of DTCA in the U.S. However, there is a minimal chance that DTCA would fade away in pharmaceutical advertising practices in the US. The results from Mackey et al. (2015) have shown a slight decrease in overall spending of DTCA by 7.83 % during 2005 to 2009, but the shifting from one type of DTCA to another less expensive form of DTCA is the possible causation of this decrease. According to the data presented by Kantar media, the television channel has served as the most important channel of DTCA as it consisted of approximately 65% of total spending with $ 4.1 billion in 2016. The television sub-category experienced an increase of 4% from 2015-2016, while the internet sub-category showed almost no change with a decrease of one million to $515 million in digital media according to this source. However, this amount does not consider the expenditure of websites, web videos, web audio, sponsored links, social media (which is in basically free), search engine marketing, mobile applications, and emails. A 2013 study reported that electronic internet promotion grew 109% between 2005 to 2009 to $117 million (Kornfield, Donohue, Berndt, & Alexander, 2013) and the findings of this study suggest that online DTCA has increased its spending at least 4.4 times from 2009 to 2016.

Liang and Mackey (2011) reported that the internet was the most popular source among consumers who searched for health-related information.

PDCs have been another trend that has emerged in DTCA in the U.S. that may have caused detrimental effects on patients since they are heavily involved with “black box” warnings for prescription drugs. Even though the pharmaceutical companies claim that PDCs intended to promote accessibility and adherence to medications, it was more likely for extending product life cycles, since most of the prescription drugs available with PDC are patent expired or close to the patent expiration date. If this trend of PDC continues to gain popularity, it might increase the cost of prescription drugs by promoting more expensive drugs, especially brand name drugs that could be substituted with lower expense generic drugs regardless of discount.

DTCA appeared to affect the way patients and physicians interact with each other. DTCA increased demand for specific drugs and patients have become engaged in mentioning particular medications to their physicians. Furthermore, those who received the medication showed greater satisfaction than other patients, who did not (Lewin, 2013; Weissman et al., 2004). This situation could put pressure on physicians desiring to satisfy their patient's requests, leading to inappropriate prescribing thereby, resulting in increased unsuitable drug utilization. The survey on physicians by Robinson et al. reported that DTCA has produced an increased inappropriate prescription volume and has affected prescribing patterns (Robinson et al., 2004).

DTCA can increase the drug utilization by raising the awareness of patients regarding a specific disease, especially conditions that are associated with social stigma. However, this increase of drug utilization has both beneficial and harmful consequences. Tegaserod prescriptions were increased by the effect of DTCA and were then withdrawn from the market in 2007 due to a significant risk of heart conditions. This similar issue was also found earlier with Vioxx in 2004. There were no strict regulations for DTCA on the new drugs, so full safety profiles need to be established (Liang & Mackey, 2011).

On the other hand, the benefits of DTCA has been realized in the case of Tamsulosin and Dutasteride. The promotion of Dutasteride, which was the second line therapy of benign prostatic hyperplasia, resulted in increased awareness of the condition and the increase in the prescription volume of Tamsulosin, which is the first line therapy. Thus, the promotion of Dutasteride through DTCA could be considered beneficial by increasing diagnosis and increasing appropriate drug utilization.

DTCA can have a significant impact on the healthcare system since it enhances awareness to the public of devices or therapies that are very expensive and may not be the standard of care for specific disease processes. Ball and Mackert (2013) reported that pharmaceutical advertisers use powerful tactics such emotional appeals as an opportunity to overcome distrust and to compete for patient's attention with other pharmaceutical ads. DTCA can cause potential harm; primarily by diminishing the time involved in the discussion of the DTCA information brought by the patient to the medical visit.

The trend of DTCA has been growing and has resulted in increased drug utilization through multiple mechanisms, which included increase demand of the patient for a specific drug, raise awareness regarding under-diagnosed condition, and promote dialogue between physician and patient. The content for each DTCA may result in different outcomes regarding the appropriateness of drug utilization.

The limitations of the study included: limited current information of DTCA spending from the pharmaceutical companies that were available to the public. There was a lack of the quantitative data on the effect of pharmaceutical DTCA. Thus it was difficult to evaluate the actual impact of DTCA on drug utilization. Additionally, DTCA has been a very subjective topic that is based on individual opinion so that it can be affected by researchers and publication bias. Future research should examine the association between DTCA spending and drug utilization. A systematic review and a meta-analysis should be performed to have a more precise measurement of the effects (i.e., expenditure, drug utilization, and cost) of DTCA in the US healthcare delivery system. Also, future research is needed in recognizing the five steps of patient's decision-making and if the effects of DTCA would be equivalent across the five steps (Mukherjee, Limbu and Wanasika 2013)

CONCLUSION

The online channel has been a critical advertising portal for DTCA by pharmaceutical firms. The DTCA of pharmaceutical companies has shown mixed results of potential benefits and harm.

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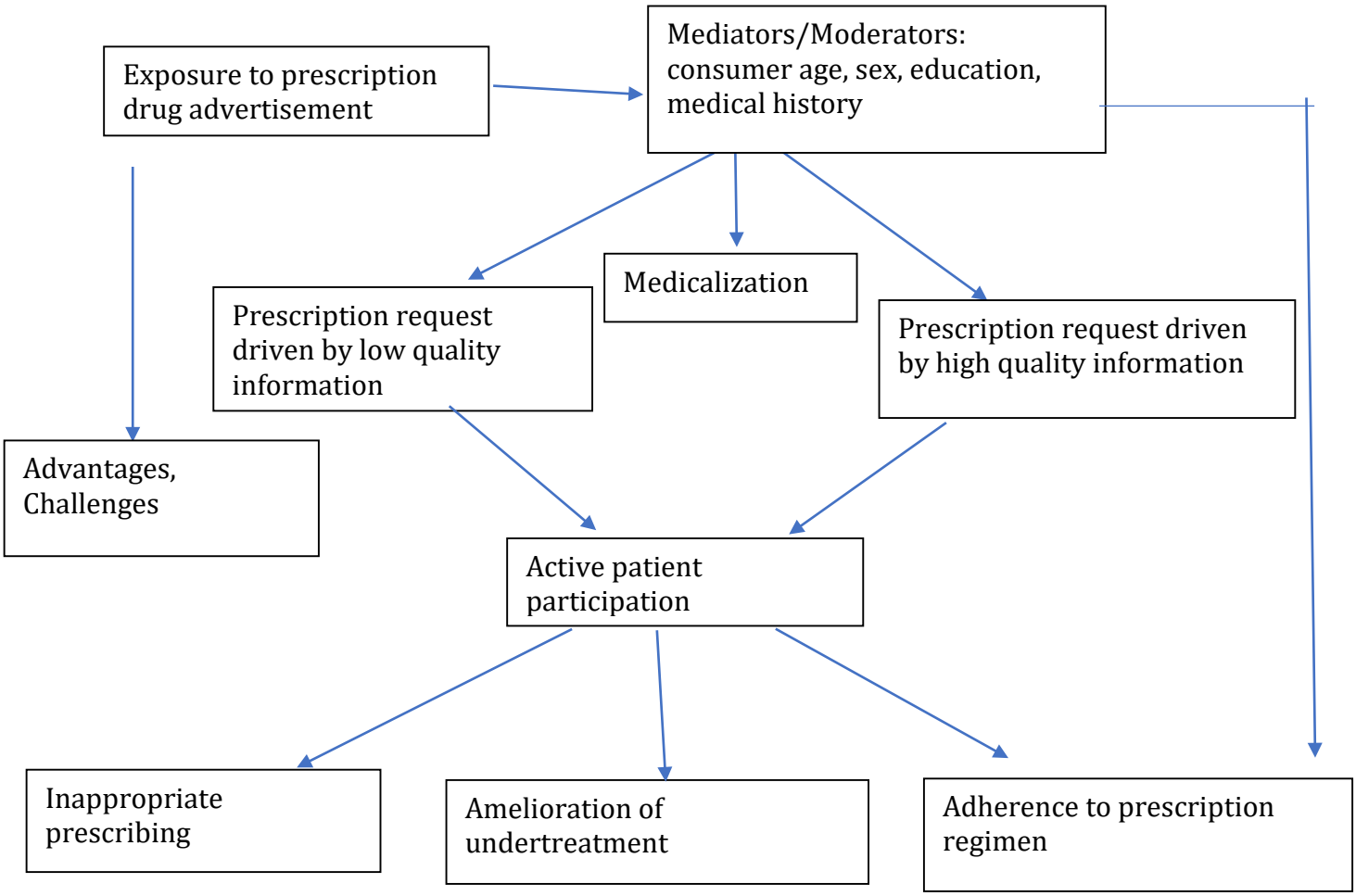

Source: Adapted from Frosch, Grande, Tarn, & Kravitz (2010

Figure 1: Conceptual Framework:

Table1: DTCA expenditure in 2015 and in 2016 (Kantar Media., 2016)

DTCA category	2015 US Media expenditure (millions)	2016 US Media expenditure (millions)	Change (%)
Television	$3,908	$4,064	4
Print media + radio + outdoor ads	$1669	$1795	7
Internet	$516	$515	-0.2
Total DTCA	$6,093	$6,375	4.6