Direct-to-consumer prescription drug advertising: concerns and evidence on consumers’ benefit

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Abstract
Purpose – The purpose of this study is to provide an overview of the economic and clinical impacts of direct-to-consumer (DTC) advertising on consumers and physicians.

Design/methodology/approach – Controversy around the benefits and concerns associated with DTC advertising are summarized. The sources are sorted based on their position toward DTC promotions: defending or opposing. Two recent works by Woloshin et al. and by Weissman et al. are discussed in depth to provide the empirical evidence for the impacts of DTC promotions.

Findings – Notwithstanding many concerns against DTC advertising, evidence-based papers report that both consumers and physicians are potentially benefited from it. Consumers rate the health-related information contained in DTC advertising as important. Physicians do not feel that they are pressured to prescribe inappropriate medications driven by DTC advertising. Physicians perceive improved communication and education among DTCA-influenced patients. However, consumers tend to overestimate drug effectiveness when the ads vaguely convey the benefit information and subsequently, seek unnecessary treatments. DTC advertising needs to be required to demonstrate the benefit information using actual data. This will help consumers avoid overuse of drugs.

Originality/value – This paper recognizes DTC advertising as a positive force for the public health and at the same time identifies its potential negative effects on the economic and clinical aspects of the health care markets. This can offer practical help policymakers develop the effective regulations on DTC advertisings to reinforce the beneficial outcome while attenuating the potential harms that might take place.

Keywords Medical prescriptions, Advertising, Drugs, Consumers

Paper type Literature review

An executive summary for managers and executive readers can be found at the end of this issue.

1. Introduction

As one of the fastest-growing components in the US health care market, prescription drugs command much attention. Spending on prescription drugs exceeded $150 billion in 2001, which is almost twice $79 billion spent in 1997 (National Institute for Health Care Management, 2002). In 2001, the industry spent more than $19.1 billion in promotional activities. The spending for direct-to-consumer (DTC) drug advertising increased from $1.1 billion in 1997 to about $2.7 billion in 2001, which is as dramatic as the increase in drug companies’ spending on research and development (R&D), from $19 billion to $30.3 billion (US General Accounting Office, 2002).

Following a public hearing and debate in 1997, the FDA issued a proposal for new guidelines on DTC advertising. This proposal was designed to entitle prescription drug manufacturers to give both the drug’s name and the condition without disclosing all of the product’s risks. The FDA guidelines clarified and relaxed the quantity of “balanced” information that was required in each broadcast advertisement. Yet, advertisers were required to mention important risks and to provide a statement explaining that additional information is available from other sources, such as toll-free telephone numbers and print advertising. The FDA thereby ensured that persons with varying levels of education and technological knowledge would have access to additional, detailed information.

DTC advertising is defined as “any promotional effort by a pharmaceutical company to present prescription drug information to the general public in the lay media”[1] (Conti et al., 1999). Among drug companies’ general promotions, direct-to-consumer advertising (DTCA) of prescription drugs is particularly interesting, because it affects patients, doctors, and health care organizations in profound but not always predictable ways. For example, Wilkes et al. (2000) report in a recent survey that more than one-third of respondents reported asking their doctors for information about a drug they had seen or heard advertised, and nearly one-quarter asked for the drug itself. Of these, three-quarters reported that their doctors provided the...
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requested prescription (American Pharmaceutical Association, 1997).

Since 1997 not only have the number of drugs advertised increased, but so have the drug companies’ advertising budgets directed at consumers. The advertisements have also become far more sophisticated. The consumer is no longer simply provided with information about a pharmaceutical product. Advertisers enlist well-known celebrities to endorse their products (T’Hoen, 1998; Wilkes et al., 2000).

Drug companies’ promotional spending leads to exposure, getting messages about prescription drugs to physicians and patients. Physician-oriented marketing consists of detailing (in-person visits by drug company representatives), advertising in journals, and continuing medical education events. Patient-oriented marketing has focused on advertising in various media, including print, broadcast, and online.

The position of pharmaceutical companies behind the rocketing increase in the DCTA spending is plain: “We believe that any health information for consumers is beneficial” (Kelly, 2004). However, there have been concerns that this belief can be true only when certain conditions are embedded: the information must be accurate and lead to more and better physician-patient encounters.

2. Concerns

Of concern is the question about whether the consumers’ exposure to the drug advertising fills a needed educational gap, or it merely promotes inappropriate and unnecessary use.

Pharmaceutical manufacturers and other proponents of DTC advertising claim that it is informative and educational: it teaches consumers and physicians about health conditions, new medicines and treatment options. It contributes to increased disease awareness, greater detection and patients’ compliance with medical care. Eventually, it improves the quality of overall public health (Rosenthal et al., 2002; Finter, 2002).

They argue that the FDA’s existing regulatory regime is sufficient to protect the public health and that the government should not mandate unnecessary restraints on commercial free speech. Indeed, there are studies to advocate drug promotion and advertising showing its usefulness as a means of educating the patient, its contributions to the doctor-patient relationship and the beneficial quality outcomes associated with new and, in some cases, high priority diagnosis (Jeffords, 2004).

Opponents of drug promotion are concerned about that information conveyed is inaccurate or unbalanced and promotes the inappropriate and unnecessary use of drugs. DTC advertisements may lead to inappropriate patient demands on providers and to overuse of prescription drugs against the doctors’ judgment. In some instances, it may encourage the use of more expensive brand-name medicines by consumers even with cheaper and equally effective alternatives available.

Payers are also concerned about the promotion of non-essential or lifestyle drugs, such as drugs to treat nail fungus and sexual dysfunction, which drive up their pharmaceutical spending without providing significant health benefits. According to World Health Organization, even among the drugs most heavily advertised directly to consumers, many are believed less effective than expected (Batchlor and Laouri, 2003).

Critics counter that promotion has fueled the rise in drug spending, chiefly in the form of inappropriate prescribing caused by ad-induced patient demand or incomplete information influencing physicians’ decisions, or both. As a recent medical journal stated, “The education of patients – or physicians – is too important to be left to the pharmaceutical industry” (Wolfe, 2002). Whether this is a valid conclusion or misguided assertion is one of the main questions around the controversy on DTC advertising. How policymakers should react to this controversy is another issue to be responded at once.

This paper provides an overview of recent evidence, both endorsing and defying, for the controversial issue. Using the recent literature to date, we review the economic and clinical impacts of DTC advertising on the consumer, the medical professionals, and the health care system. The leading concerns raised against DTC advertising are that it leads doctors to write unnecessary prescriptions under pressure from patients and that it increases the cost of prescription drugs. Because some critics believe that DTC advertising leads to overuse of costly drugs, it is not surprising that it has come under increasing scrutiny (Bonifazi, 2002; Weissman et al., 2004). Another concern is that if the information on drugs is inaccurate and misguided, the active involvement of patients in the medical decisions which is motivated by DCTAs is likely to end up with serious clinical mistreatment and eventually harm the quality of public health.

Recommended solutions to these problems reach from an outright ban on DTC advertising, to removing business tax deductions, and to strengthening the FDA’s oversight capacity (Jeffords, 2004). A critic on the role of FDA on regulating DTC advertising is that FDA enforcement against false and misleading advertisements have dropped sharply in recent years, raising concerns over consumer safety (Waxman, 2004).

2.1. Economic aspect: overuse of resources

Impact on consumers

From a public health point of view, the question we must address is whether it is the best way to spend nearly $3 billion on health communications to the American public. Avorn (2003) states this question in a practical context: even if more patients with high cholesterol or depression seek treatment because of DTCAs for Liptor or Proza, how many more could be treated if they were instead prescribed the equally effective generic drugs in the same classes, lovastatin or fluoxetine?

The publication of the Anti-hypertensive and Lip-lowering Treatment to Prevent Heart Attack Trial (ALLHAT) showed that the older thiazide drugs are both better and cheaper than many newer drugs in the management of hypertension. Then, it raises skepticism on the net public health benefit of costly advertisements and the promotion-driven use of these expensive products.

When there is no fervent promotions for generic drugs, DTC advertising for prescription drugs conveys the information that mislead viewers to lean more on the drugs whose prices embed the advertising costs even when they are aware of the availability of cheaper and equally-effective alternatives.
alternatives. Further, the frequent and repeated watching of DTCAs may enhance consumers’ dependency on drugs. Consumers are likely to demand specific drugs more than necessary and demand it immediately (Bell et al., 1999).

Of course, there is counter evidence by Dubois, Alexander, Wade, Mossos, Markson, Lu, Nagg and Berger (2002) that growth in a specific drug use, which corresponded to a time period of much pharmaceutical promotion, was associated not with inappropriate use or overuse, but rather with the identification of additional patients in need of that drug. This contends that promotion is not accompanied by excessive use.

**Impact on manufacturers**

Given the economic incentives, pharmaceutical companies may provide a more than optimal amount of advertising from a societal perspective (Carlton and Perloff, 2000; Dubois, 2003). Annual spending on DTC advertising rose gradually in the 1990s and then tripled between 1996 and 2000, when it reached $2.5 billion (Rosenthal et al., 2002). Although DTC spending had been increasing prior to 1997, the FDA guidelines issued in 1997 seem to correspond with the rapid increases in DTC spending that were observed thereafter.

In 2000, drug companies spend more than a billion dollars on marketing directly to consumers, up from $55 million in 1991 and represent five times larger amount compared to the spending in 1994 (Wilkes et al., 2000). The driving force for this rise has forced pharmaceutical manufacturers to stimulate consumer demand (Tully, 1993; Hollon, 1999).

**Impact on insurers**

People who benefit from the pharmaceuticals often do not pay for them directly. In recent years people with insurance have paid relatively little out of pocket for their medicines. A large proportion of the cost has been borne by their insurers and by purchasers (employers) in the form of insurance premiums. The fact that the consumers who view the advertising and are influenced to consume the drugs do not generally pay for them contributes to the controversy surrounding advertising prescription drugs to consumers.

According to the report by American Pharmaceutical Association, all of prescription filled in 1997, 79 percent are paid for at least in part by some type of private or public insurance. Even given the push from managed care and other payers to increase the use of generic drugs, most prescriptions written are still for brand-name medicines.

From the economic perspective, the impacts of DTCAs on consumers are threefold: first, the amount of DCT promotions may be socially excessive due to pharmaceutical manufacturers’ desire for high sale and large market share. High and rising spending for advertisements may result in high price of the prescription drugs (price effect). Second, the amount of consumption of prescription drugs may be far above necessary, which is advertising-induced (quantity effect). Lastly, as more drugs are prescribed, the insurance companies are doomed to increase the associated premiums charged on consumers (insurance effect).

### 2.2. Clinical aspect: inappropriate use of drugs

DTC advertising unfolds to consumers what kind of drugs is available in the market and what extent those drugs work. Typically, this sort of information has been monopolized by medical professionals and pharmacists. Continuous viewing of DTC advertising may interest consumers in their health conditions in a regular basis. The alert consumers can take actions to prevent or detect the outburst of a health problem in its early stage before it exacerbates. This entire conceptual and behavioral response of consumers to DTC advertisements can contribute to the improved quality of public health.

Well acknowledged of the medical information through DTC promotions, consumers begin to involve in the decisions on the medical treatment. By interacting with the physicians vigorously, the patients' compliance with physicians order is expected to be enhanced. Subsequently, health outcomes of any medical treatment on patients can be upgraded. However, as Wilkes et al. (2000) argued, there is evidence to suggest that clinical quality of care is harmed by DTC advertising.

**Impact on consumers**

From the DTC advertisement, patients and physicians receive the repeated and consistent education on a drug’s characteristics and its potential role. This is deemed to reduce the variation in therapy, that is, patients with a specific symptom are uniformly prescribed more expensive brand-name drugs they are exposed through the ads.

Although reduced variability of treatment is often translated to quality improvement, there are challenges that greater uniformity in use of medications may not necessarily appropriate (Dubois, Batchlor and Wade, 2002; Dubois, 2003). Even when we assume that the uniformity in practice render the improved quality of care, whether it is attributable at least in part to the educational role of drug promotion to physicians is neither proved nor refuted (Batchlor and Laouri, 2003).

In addition, receiving prescription drugs advertised in broadcast rather than possibly equally effective generic drugs may not be medically correct. Many new drugs are found to offer few advantages over pre-existent drugs. For worse, whose safety profiles are shown to be less well understood (Kessler and Pine, 1990). It is because DTC ads tend to emphasize the positive features of a drug and downplay the negative or unknown aspects. Side effects are typically discussed last or buried in the narrative. Only 35 percent of advertisements invited the viewer to learn more about the drug by obtaining information from the company (Wilkes et al., 2000).

Even when the information in DTC advertisements is balanced and accurate, it is still possible that consumers are confused and construct erroneous perceptions of a drug’s effectiveness and safety. Because most of consumers do not have the clinical and pharmacologic background to properly understand and evaluate DTC advertisements, the miscomprehension of drug advertisements is not a surprising phenomenon (Cohen, 1988; Morris et al., 1986). Ultimately, the argument that DTC promotions are educational for the public about medical conditions and their treatments hinges on the quality of drug information available to consumers through advertising.

**Impact on medical professionals**

With the explosion of DTC drug advertising, physicians begin to experience the change in their relationship with patients. The American College of Physicians feels that DTCA “is not a proper practice” and “undermines the patient-physician relationship” (American College of Physicians-American

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Society of Internal Medicine, 1998). However, Weissman’s et al. (2004) surveys of physicians show a mixed picture. Some physicians appreciate DTCA for increasing patients’ awareness, encouraging patients to seek medical advice for conditions that might otherwise go untreated, and improving doctor-patient communication (Allison-Ottey et al., 2002). Negative views are more frequently reported including concerns that when patients misperceive a drug’s effectiveness, physicians’ time is wasted in correcting the biased view on a drug’s pros and cons. DTCA advertisements may challenge physicians’ professional authority in the medical decision as the better-informed consumers intend to pressure their physicians to prescribe drugs either inappropriate in effectiveness or excessive in quantity and to order advertised drugs, perhaps against physicians judgment (Avorn et al., 1988; Petroshius et al., 1995; Lipsky and Taylor, 1997). This active patient involvement encouraged by DTCA promotions is a main reason for physicians’ reluctance to embrace the popular drug promotions.

3. Evidence

As the DTC advertising gets widespread and the associated spending proliferates, there is an enlightened discussion to know whether pharmaceutical promotion educates or misleads. The recent debate is focused on whether the potential benefit of educating physicians and consumers outweigh the potential clinic and economic harm of overuse (Kravitz, 2000). Although advocates of DTC advertising argued that there are no objective data showing that DTC advertising results in an inappropriate use of drugs (Ziegler et al., 1995), this argument was not particularly persuasive for opponents since there has been little reinforcing data for the positive impacts of DTCA advertisements.

Recently, a growing body of research shows that DTCA advertising is having some beneficial effect. Those studies claim that consumer-direct advertising raises awareness of diseases, treatment, and specific drugs – and that patients who are exposed to this information are more likely to request specific drugs. In particular, the papers by Weissman et al. (2004) and Woloshin et al. (2004) make indispensable contributions to understanding how DTC drug advertising is perceived by the two most important participants in this policy debate: the physicians and the patients.

3.1. Consumers’ perception of the DTC advertising effects

Woloshin et al. (2004) research question comes from recognizing that DTC advertising offers limited information on the efficacy of the drug. The US Food and Drug Administration (FDA) requires the advertisements to include information about potential harms. In contrast, information on drug benefit is not specifically regulated, and most advertisements assert that drugs do work using vague, qualitative terms rather than presenting actual data (Bell et al., 2000). Lacking from much of the debate surrounding DTCA was empirical evidence of its impact on patients’ health and health care.

Woloshin et al. (2004) describe consumers’ evaluation of a “prescription drug benefit box”. The benefit box is a table presenting the proportion of people experiencing various outcomes with and without the drug. In addition, one-word summary to describe the direction of effect was included in the benefit box. For each drug, the efficacy data came from the published article of the randomized trial cited in the FDA drug approval document, which matched the indication and outcome in the advertisement.

For this study a total of 203 in-person interviews were conducted with consumers selected from the greater Boston area. Experiments are performed in two ways. Before-after comparisons include the procedure that after people are trained to familiarize with the three elements of interest (the ad, the brief summary, and the drug benefit box), each participant is shown the standard version of the drug advertisements. They are then asked to indicate how they thought effective the drug was using a standardized five-point scale. Participants are then given the benefit box version of the ad and are again asked to rate the drug effectiveness.

In the randomized comparison, respondents are asked a few general questions about the benefit box itself such as whether they think the information is important, should be required, and is easy to understand to evaluate consumers’ perceptions on the benefit information. Then they are randomized into two groups. The intervention group is shown only the benefit box version of an ad. The control group sees only the standard version of the ad. Their findings are summarized as:

- Most participants in the experiment rate the health information provided by DTC advertising as “very important” or “important”.
- Almost all participants find the information in DTC promotions easy to understand.
- Most people can understand the data and are influenced by the drug advertising.
- Most people interviewed want benefit data in drug advertising.
- Perceptions of drug effectiveness drop after respondents saw the benefit box (in before-after compassion).
- Perceptions of drug effectiveness are much lower for drug advertising that incorporates the benefit box than for advertising that does not (in randomized comparison).

The main weakness is pointed out that the findings are based on an experiment over convenience samples. Nonetheless, the study has important qualitative message only extraordinarily powerful counter evidence could defeat. Consumers collect useful information on drugs from DTC advertisements. They have no particular difficulty in understanding the ads. Their perceptions and presumably consumption decisions on drugs are influenced by the ads. In general, the participants are very optimistic about the effectiveness of each drug with the standard form of drug advertising. However, the perceptions of effectiveness drop after seeing the benefit box of actual data. That illustrates the necessity of the drug benefit boxes on its ad to prevent possible illusion among viewers on how well and safely the drug works.

3.2. Physicians’ perception of the DTC advertising effects

Weissman et al. (2004) use a national survey of physicians who reported on recent patient visits during which they discussed advertised drugs. Their goal was to describe physicians’ perceptions of actual health care experiences and
their attitudes toward DTC advertising, and to predict the resulting outcomes as it affects medical practice.

The sample was randomly selected from a national list of physicians[2] provided by National Marketing Service. The questionnaire was designed to give physicians equal opportunities to express positive or negative views about DTC advertising. Physicians are asked to report their perception on whether the drug promotion might be beneficial, inconsequential, or harmful. The largest portion of the survey was designed to gather data on the health care events surrounding the most recent visits in which patients initiated discussions about prescription drugs they had seen advertised on any means of multimedia, so called “DTCA visits.” The findings are as follows:

• The majority of physicians could not feel that DTC advertising has pressured them to prescribe inappropriate medications.
• Patients reported that they benefited from their interactions with physicians related to DTCA, including diagnosis of new conditions and delivery of other health care services that are widely perceived as beneficial.
• DTCA discussions occurred in a small proportion of all physician visits (31 percent), but more than half of physicians that had participated in at least one DTCA visit in the past week.
• Physicians perceived improved communication and education but also thought that DTCA led patients seek unnecessary treatments.
• Physicians prescribed the advertised drugs in 39 percent of DTCA visits but also recommended lifestyle changes and suggested other treatments.
• Referring to visits when the DTCA drug was prescribed, 46 percent of physicians said that it was the most effective drug, and 48 percent said that others were equally effective.

The study confirms that consumers get educational benefit from the drug advertising. The information they gather from the ads enables them to have more productive encounters with physicians. Though DTC advertising induces unnecessary “DTCA visits” and pressures on physicians to prescribe the advertised drugs, these impacts are relatively mild. Physicians are likely to maintain their professional authority over patients in the decisions on the proper medical treatments and prescription of drugs.

4. Discussion and policy implications

DTC drug advertising has been controversial since its inception, with proponents and opponents debating the educational value of ads and their impact on the physician-patient relationship. For areas where it is known that a particular treatment option works well but it is underused, any means to educate and promote is probably beneficial. DTC advertising operates as a beneficial market-expanding mechanism, spreading awareness of newly drug therapies.

Perhaps the concern about promotion relates to utilization of prescription drugs in the absence of consensus or strong evidence for proper use. Most troubling is the potential for advertising to stimulate inappropriate demand for drugs. For instance, most would agree that Cox-2 inhibitors greatly help some patients with arthritis and pain. However, less costly alternatives are available for the broader population of people with these conditions and there is no consensus on its use. Promotion of Cox-2 inhibitors might provide patients with added clinical benefit, but perhaps at a higher cost.

Papers by Woloshin et al. (2004) and by Weissman et al. (2004) provide some validation for the views of both sides of the DTC advertising debate with more emphasis on the supporting evidence that DTC drug advertising appears to be a generally positive force for health. Yet, these studies are critiqued to be limited to draw definitive conclusions about key issues involving inappropriate use of expensive medications and their substitution for cheaper medications that are just as effective.

Avorn (2003) claims that the data presented in these two studies do not justify the conclusions that the effects of pharmaceutical promotion are beneficial. Further he argues that some of the data they present suggest a different conclusion. Since the factors initiating a visit to the doctor, the topics discussed between physicians and patients, and the subsequent events are all complex interactions so that it is not straightforward to interpret the results as supporting evidence for the consumers benefit from DTC advertising. Though it is appealing to think that DTCA may alert patients to diagnoses that have been undetected or under-treated by their physicians, it is criticized that among consumers of direct-to-consumer advertising, those heavily influenced by such DTC advertising were no more likely to have laboratory studies ordered or lifestyle changes recommended. Economic inefficiency of pharmaceutical promoting is severely criticized (Avorn, 2003).

Since the impact of promotion is neither uniformly efficient nor inefficient from a societal perspective, it would be hard to implement a rule that would selectively limit “relatively inefficient” promotional efforts. Proposals for stricter regulation may have to consider their potential impact on the desirable outcomes that accrue from pharmaceutical promotion.

Beyond the regulatory scope, the federal government, as a major purchaser of pharmaceuticals, may enforce drug makers to disclose information about safety and comparable effectiveness in their DTC advertising as part of any purchasing agreement (Jeffords, 2004).

From a market perspective, another approach is to regulate the content of DTC advertising to improve their educational content. The systematic provision of drug benefit data would educate consumers and promote informed decision making by providing easy access to scientific data on drug benefit whenever a drug advertisement appears.

5. Conclusion

We review the literature examining one of the most controversial issues in an ever more competitive health care market, the goods and bads of the DTC advertising. By and large, drug promotion is a mixed bag. In some cases it promotes educational benefit for consumers and appropriate use of drugs, but in others, it encourages inappropriate use. When drug promotion is aligned with evidence-based medicine, it may have a positive effect. Recently a growing body of research supports the view that the information presented in DTC advertising informs patients’ decision
making and leads to more productive physician/patient encounters by reducing the information gap between the two. Obviously, public debate should focus on making information about both the benefit and potential side effects clear and comprehensible so that consumers can get maximum value possible from DTC advertising.

Notes
1 Increasingly, the drug advertisements offer additional information to consumers through the internet. A total of 14 percent of advertisements provided a web site.
2 The list of physicians includes both American Medical Association (AMA) members and non-members and is updated in a weekly basis

References
American College of Physicians-American Society of Internal Medicine (1998), Direct-To-Consumer Advertising for Prescription Drugs, American College of Physicians-American Society of Internal Medicine, Philadelphia, PA.


**Further reading**

