Ethical and practical implications of pharmaceutical direct-to-consumer advertising

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Although only possible in two nations, New Zealand and the United States, direct-to-consumer advertising (DTC) of prescription medicine has generated international controversy. This paper examines how DTC emerged, compares the different regulatory structures used to govern it and analyses the debate over the ethics and effects of DTC. While the value of providing information to consumers is indisputable, serious questions remain over the quality of information provided via DTC, whether any benefits it might bring offset its wider social and economic costs, and how best to achieve a balance between commercial and public health objectives.

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Introduction

This paper examines healthcare marketing and discusses the evolution, ethics and effects of advertising that promotes prescription medicines directly to potential end-users. As a highly visible and controversial element of healthcare marketing, DTC merits special attention since its use is both restricted and under review, its regulation takes widely varying forms and its social and medical consequences have generated ongoing disputes.

Only New Zealand and the United States currently allow direct-to-consumer advertising (DTC) of prescription medicines, although permutations of DTC, such as disease-state-awareness advertising, have emerged in other nations (Lancet, 2002; Gardner et al., 2003). DTC has a ubiquitous media presence in both nations, and consumer awareness of promotions is very high (Alperstein and Peyrot, 1993; Hoek et al., 2004; Kaiser Family Foundation, 2005). Expenditure on DTC advertising of prescription medicines rose to over USD4 billion in 2005 (Government Accounting Office, 2006), while expenditure on prescription drugs accounted for over 10% of total US healthcare costs. Although New Zealand is a much smaller economy, DTC expenditure has also grown considerably and, in 2004, reached approximately $38 million and accounted for over a third of all ‘Analgesics, Remedies, Medicines’ advertising expenditure (Ministry of Health, 2006).

DTC’s emergence has generated considerable controversy in both countries as well as in nations considering whether to rescind bans on DTC (Meek, 2001; Miller and Waller, 2004;
Donohue, 2006). This paper examines how DTC evolved, the regulatory structures developed to manage its form and content, and its wider social and health effects.

**Emergence of DTC**

Neither American nor New Zealand regulators planned the introduction of DTC; instead, it became widespread by the late 1990s because it was not explicitly prohibited (Hoek and Gendall, 2002). The United States First Amendment affords protection to commercial speech and DTC proponents have claimed attempts to ban it would violate their right to communicate freely with potential end-users (Calfee, 2002). However, while the First Amendment enabled the development of DTC, its growth in broadcast media was inhibited by Food and Drug Administration regulations that required marketers to include detailed risk, contraindication and side effect information in advertisements. These regulations effectively limited DTC advertising to print media and its appearance in broadcast media occurred when the FDA issued revised broadcast guidelines in 1997. These provided for a ‘brief summary’ of key information that directed viewers to more informative sources and paved the way for integrated campaigns that appeared concurrently on television and in print media (Donohue, 2006).

In many respects, New Zealand has a similar legal framework to the United States. The NZ Bill of Rights Act 1990 (BoRA) also protects free speech, although it contains allows some freedoms to be circumscribed if these impinge on higher-level outcomes. Despite this caveat, advertisers and marketers have used the BoRA to support their claimed right to advertise prescription medicines; in addition, they have argued that health legislation, specifically the Medicines Act 1980 and the Medicines Regulations 1984, did not prohibit DTC.

Changes to the funding mechanisms applied to pharmaceutical expenditure may also have catalysed the emergence of DTC. The New Zealand Pharmaceutical Management Agency (PHARMAC) was established in the early 1990s and negotiates medicines supply. To obtain maximum returns from the funding available, PHARMAC operates tenders and does not subsidise all medicines indicated for specific conditions. Companies that do not obtain funding have generated demand by promoting their brands directly to potential end-users.

In summary, the changed pharmaceutical funding environment, the more liberal regulatory climate created by the BoRA, and international developments, particularly the FDA’s 1997 regulatory changes, stimulated the development of DTC in New Zealand.

Because neither country anticipated DTC, regulation developed in a re-active manner, although it has since evolved in response to ongoing concerns about DTC. The following section examines the regulation of DTC in both nations and explores the different regimes used.

**Regulation of DTC—United States**

Initially, regulation of medicines was split between the FDA, which had authority over drug labelling, and the Federal Trade Commission (FTC), which monitored advertising. However, the 1962 Kefauver-Harris amendment transferred advertising authority to the FDA, which required advertisers to include a summary of the drug’s contraindications, side effects and effectiveness in their materials, and made the ‘fair balance’ of risk and benefit information mandatory.

Initially, drug companies targeted health professionals; this simplified compliance as physicians could understand complex technical information, and use it to evaluate a drug’s suitability for their patients. However, environmental changes, such as increased costs of personal selling and growth in the number of ‘gatekeepers’ sales staff encountered, stimulated the development of promotions designed to reach potential end-users (Morris and Griffin, 1992).

By the early 1980s, drug companies were using press releases to communicate directly to consumers. However, a press release...
promoting Oraflex (an anti-arthritic drug) lacked sufficient cautions and led the FDA called for a voluntary moratorium on DTC (Basara, 1996). Regulators assessed whether existing policies provided adequate protection to lay consumers and examined DTC’s effects on potential end-users.

Research undertaken at this time found that consumers did not always understand the information provided in DTC and were more inclined to ascribe benefits than risks to the promoted drug (Morris et al., 1986). However, consumers generally supported access to DTC and, in 1985, the FDA confirmed the existing regulations.

By the 1990s, pharmaceutical manufacturers had complained that the FDA’s information requirements made it difficult for them to use broadcast media. The FDA subsequently agreed that advertisers could omit the ‘brief summary’ of product information taken from the drug labelling sheet but required them to submit broadcast advertisements for review. In 1997, the FDA issued draft DTC guidelines that stressed the need for ‘fair balance’ and required ‘adequate provision’ of information that was accessible to lay consumers. The FDA allowed advertisers to make ‘adequate provision’ by providing 0800 numbers, websites or brochures, or by referring consumers to print advertising, or to health professionals where additional information could be provided. However, broadcast advertisements still had to contain a ‘major statement’ outlining the drug’s main risks (Kopp and Bang, 2000).

Final guidelines on ‘adequate provision’ that confirmed major risk information could be provided through alternative sources were issued in 1999.

The FDA reviews some advertisements before these are aired and monitors promotions, taking enforcement action, such as writing untitled or warning letters, where deemed appropriate. Untitled letters note alleged violations of the Federal Food, Drug and Cosmetic Act, seek a response from the company responsible and suggest actions that might be taken to remedy the violation. Warning letters have greater authority and may request corrective advertising to dispel incorrect beliefs.

Sheehan (2003) reviewed warning letters issued between 1997 and 2002 and found the most common violations were inadequate risk information (nearly 38% of complaints) and inaccurate efficacy information (29% of complaints). 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 (GAO, 2006).

The FDA’s role is complemented by self-regulatory codes such as the Council of Better Business Bureaux Code of Advertising, which prohibits misleading or deceptive advertising. More recently, the Pharmaceutical Research and Manufacturers of America (PhRMA) developed Guiding Principles designed to promote higher standards in DTC promotions. 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). However, consumer advocates have criticised PhRMA’s actions, arguing that the Guiding Principles will see no material changes to DTC promotions (Ruskin, 2005).

PhRMA also established an Office of Accountability that receives comments about compliance with the Guiding Principles and issues reports outlining responses to these comments. The first report, issued in September 2006, noted receipt of 284 comments in the 6 months since the Guiding Principles came into effect. However, although the report documented the number of comments received in relation to each principle, it provided little information about the comments themselves.

It is too early to assess whether PhRMA’s Guiding Principles will improve the overall quality of DTC promotions; however, recent reviews note concern over DTC regulation. The US Government Accounting Office concluded that the FDA’s oversight of DTC requires improvement and called for the development and use of more formal review
criteria (GAO, 2006). The GAO noted the FDA did not review all materials submitted to it, thus warning letters may not represent all potential violations (GAO, 2006). Concern over the FDA’s capacity to review DTC materials in a timely manner has existed for nearly 2 decades (Morris and Griffin, 1992; Nixen, 2005), and is supported by consumer research (Huh et al., 2006).

In summary, FDA regulations govern US DTC promotions; these are supported by industry codes of practice. However, the rapid growth of DTC appears to have outstripped the FDA’s ability to oversee new promotions, and has arguably led to regulatory lacunae. Although New Zealand uses a self-regulatory framework, many of the criticisms levelled at FDA regulation have also been applied to its management of DTC.

DTC regulation—New Zealand

New Zealand regulators were also surprised by the first appearance of DTC, which they felt unable to prohibit retrospectively. Although DTC regulation could have been devolved to the Ministry of Health, New Zealand advertisers extended the self-regulatory model that was used to manage other types of advertising and assumed responsibility for DTC. The industry-funded Advertising Standards Authority (ASA) developed a Code for Therapeutic Advertising that it administers (see Hoek and Gendall, 2002, for a more detailed overview).

The ASA underpins New Zealand’s self-regulatory advertising framework and includes representatives from advertisers, advertising agencies and media groups. It aims to ensure that advertising is not misleading or deceptive, offers a system of voluntary self-regulation and provides an industry-funded Advertising Standards Complaints Board (ASCB) (Advertising Standards Authority, 2007). The ASA Codes undergo periodic review, although public health researchers have questioned whether these safeguard community concerns or promote industry objectives (Coney, 2002; Toop et al., 2003).

The ASA also manages the ASCB, which comprises lay and industry representatives. The Chair receives complaints and determines whether these are referred to the Board; of the 461 complaints received in 2005, 166 (or 36%) were ‘not accepted’ and thus not adjudicated by the Complaints Board. This statistic supports concerns over the ASCB’s recognition of social issues and community concerns (Coney, 2002). Health researchers have also questioned the process used to select ASCB members (Coney, 2002); research suggests that community members are often chosen from the ‘great and the good’, who may not represent broader community concerns (Harker, 2004).

Unlike the FDA, the ASA is self-monitoring, although advertising regulation periodically attracts government attention. Growing concerns among the public health and medical community and possible changes to the international regulatory climate recently prompted the New Zealand government to review DTC, although a final verdict on its future is still to be reached (Ministry of Health, 2006).

Regulation of DTC differs significantly and Table 1 summarises the two approaches employed by the United States and New Zealand.

Although the two systems differ, they have elicited a common reaction from public health researchers, who argue that neither system provides independent scientific and technical review of all advertisements, strict monitoring of promotions or meaningful penalties for non-compliance. The following section evaluates concerns over the ethics of DTC advertising.

Debate for and against DTC

DTC advertising may take three forms. Disease awareness advertisements do not name specific drugs and are used when only one drug is available to treat the disease outlined. Possible users are encouraged to consider whether they recognise symptoms described and, if so, to

1The New Zealand Code for Therapeutic Advertising was reviewed and revised in 1999 and 2005. It is now known as the Therapeutic Products Advertising Code.
contact their doctor. Brand awareness advertisements state the drug’s name, but do not outline the condition treated. This type of advertising avoids the need to provide the brief summary of indications, contraindications and side effects that the FDA requires of full brand advertising. Known as reminder advertising, these promotions may maintain the salience of a well-known brand and complement concurrent print campaigns.

The most common type of advertising is full brand advertising, which provides details of the drug’s name and the condition treated. These advertisements must satisfy the FDA’s ‘fair balance’ criterion or meet the New Zealand advertising code. Because these advertisements are more pervasive, they have attracted the most detailed scrutiny and this section examines arguments relating to this type of DTC.

Aside from arguing that DTC has a legal basis, proponents have claimed that it brings several benefits. They suggest it provides potential end-users with information they may not otherwise access, promotes more informed discussions with doctors and enables earlier diagnosis of conditions and improved treatment regimes (Donohue, 2006). These outcomes arguably reduce the need for subsequent interventions, thus representing potential healthcare savings (Bradford and Kleit, 2006). Public health researchers dispute these claims and note several negative outcomes that they have observed. They suggest DTC is confusing and unbalanced, that it leads patients to opt for ‘quick-fix’ solutions when these may not be appropriate and that it derogates the relationship doctors have with their patients (Hoffman and Wilkes, 1999; Lexchin, 1999; Mintzes et al., 2002).

**Patients: informed or confused**

The growth of DTC may reflect a changed model of healthcare. Whereas doctors once dispensed advice from a position of authority to patients who played a passive role in the discussion, healthcare today follows a partnership model where patients actively manage their health and the treatments that support their continued well-being (Deshpande et al., 2004; Donohue, 2006). Advocates of DTC argue that patients are entitled to receive information that may help them improve their health care and that doctors may not always provide this unprompted (Researched Medi-
According to this view, DTC prompts patients to request more information about their health status, and results in more co-operative and compliant patients (Researched Medicines Industry, 2000). Studies examining consumers’ perceptions of DTC reveal support for DTC (FDA, 1999, 2004; Hoek et al., 2004), particularly among those who have or who care for people with chronic conditions (Gönul et al., 2000). However, while consumers appreciate access to information, and are more likely to ask for specific medicines if they have a positive attitude to DTC, there is little evidence that DTC produces more knowledgeable patients (Herzenstein et al., 2005). Emerging evidence suggests potential end-users with lower literacy levels are less likely to recall risk information than benefit information, thus any knowledge that develops may be unbalanced (Kaphingist et al., 2005).

The pharmaceutical industry accepts that patients require guidance to interpret DTC and has relied on doctors to prescribe rationally and so minimise risks potential end-users may face from DTC. However, many doctors view the need to correct misapprehensions arising from DTC as an inappropriate use of their time and skills (Toop and Richards, 2004).

Advocates of DTC claim it may encourage individuals to seek advice that results in undiagnosed conditions being treated (Berndt, 2005; Burak and Damico, 1999). Since some diseases, such as diabetes and hypertension, are often not diagnosed at an early stage, this argument suggests DTC may foster earlier diagnoses, thus reducing the need for the more serious interventions required during the later stages of an illness. DTC’s mere presence is thus argued to increase the salience of health issues in general, assisting consumers to become more cognisant of their health status and more responsible for this. Researchers have also claimed DTC improves compliance and some have suggested it stimulates a ‘placebo effect’ that reduces the level of medical intervention required (Almasi et al., 2006).

Several doctors have disputed these claims, which they argue lack empirical support (ACP, 2005). They note the argument that DTC improves knowledge assumes it provides dispassionate information, a role they suggest is at odds with the commercial imperative that underpins marketing (Mansfield et al., 2005; NZMA, 2006). As a result, they claim that DTC is inevitably unbalanced, as marketers seek to promote the benefits of drugs, while minimising attributes that may make these appear less attractive (Toop et al., 2003).

Even where balanced information is provided, researchers have questioned whether consumers access and understand this; Day commented, ‘Risk information . . . is physically present, but functionally absent’ (cited in Young, 2005, p. 2582; see also Anthony et al., 2003). However, DTC advocates argue that a lack of specialised knowledge to assess unbalanced information is not problematic, since DTC only prompts requests for further information. This argument assumes doctors will advise patients about the suitability of medicines they have seen advertised or that they request. Many doctors resent the implication that they will assume this responsibility; recent research suggests pharmaceutical companies may no longer be able to rely on doctors to clarify confused or confusing information and may themselves be liable for the claims made in DTC (Cunningham and Iyer, 2005).

Providing information via other sources may not solve this problem as media offering detailed information, such as websites, are not necessarily trusted by consumers. Although content analyses of medicines websites suggest they are informative and balanced (Macias and Lewis, 2003), the material posted on Internet sites is not pre-vetted, resulting in highly variable standards. Studies examining consumers’ trust in Internet-based DTC communications have reported low levels of trust (Huh et al., 2005); this implies that regulators’ belief other sources will balance broadcast promotions may be overly optimistic.

Concerns that potential end-users may respond to benefit information and fail to appreciate the risks of advertised medicines have been well-documented. Morris et al. (1986, p. 630) noted, ‘. . . since advertising
represents such a highly promotional medium, patients could be persuaded about the benefits of a particular drug without a concomitant appreciation of the product’s risks. The risks that may result from poor information raise important questions about the standards of social responsibility DTC should attain.

**Social responsibility**

Both US and NZ regulators require advertisers to demonstrate ‘responsibility’. The New Zealand advertising code requires a ‘high standard of social responsibility’ and the PhRMA Guiding Principles note the need for ‘responsibility’, although neither provides specific criteria to judge whether this standard is reached. Despite the concerns expressed about DTC and its effects, there have been comparatively few complaints about DTC advertisements. Those who manage the self-regulatory process regard this as a sign of satisfaction with the regulatory regime; however, health researchers suggest it reflects their distrust of the complaints system.

In recent years, DTC promotions have used increasingly emotive themes (Wolfe, 2002). Though the use of emotion in advertising is not new, its application to products such as cancer drugs has prompted concerns that DTC may be reaching susceptible individuals in an inappropriate manner. The creative approaches used in DTC promotions have also attracted criticism. For example, the use of celebrities creates an emotional context that some believe is inappropriate (Wilkes et al., 2000). Potential end-users’ vulnerability may also make them more responsive to emotional claims and more likely to overestimate the efficacy of promoted medicines. Woloshin et al. (2004) reported that advertisements containing factual information about a drug’s benefits evoked lower efficacy ratings than when the drug was advertised using emotional appeals.

DTC has evolved into sales promotions and sponsorships and, in the view of critics, appears no different to fast-moving-consumer goods (Toop et al., 2003). Unlike advertising, sales promotions contain little information and instead focus on stimuli that prompt purchase. For example, free samples, obtainable from doctors, facilitate access to a drug and expedite diffusion and penetration of the medicine. Since the drugs promoted via samples (such as unfunded erectile dysfunction medicines) are typically expensive, sales promotions may reinforce the desirability of a drug without improving its affordability. Doctors have questioned the ethics of promoting treatments that not all individuals will be able to afford (Toop et al., 2003).

Sponsorship pairs brands with events and thus with values. For example, Propecia®, a hair loss remedy, has sponsored motor sport, which connotes speed, power and dominance. Sponsorship transfers these values via respondent conditioning (see Nord and Peter, 1980 for a more detailed explanation of this process), thus consumers purchase not merely a baldness medication, but the psyche associated with this.

While pairing develops personalities for many brands, its application to prescription medicines has led doctors to question whether the techniques applied to marketing of supermarket products can be properly used in the healthcare arena. This debate may see consultations as akin to checkout encounters, an analogy that has serious implications for the relationship patients have with their doctor.

**Doctor–patient relationships**

Wilkes et al. (2000) reported that lay consumers have limited knowledge of drugs and their effects. Medicines thus differ from other product categories, where consumers know and use a number of competing brands, and become knowledgeable about these (East, 2003). While consumers may understand the conditions for which the drug is indicated, they may know little about its side effects, its possible interaction with other medications or the risks it may pose.
Because of consumers’ limited knowledge, critics have claimed that benefit-oriented advertising leads to overestimation of efficacy and suitability, and prompts requests based on hope and emotion, neither of which provides a rational basis for prescribing (Roth, 1996; Pinto et al., 1998; Maguire, 1999; Mansfield, 1999; Mintzes et al., 2002). Even if DTCA promotions were fairly balanced, researchers have questioned whether consumers can relate the information provided to their own health conditions (Wilkes et al., 2000). If these arguments are correct, patients’ incomplete knowledge may create difficulties in their interactions with doctors.

The research evidence about the effect of DTC on doctor–patient relationships is mixed. Doctors generally agree that DTC provides information, and may appreciate their patients’ efforts to locate and use their own information sources. However, there is little evidence that DTC promotes more informed discussions, although it may prompt patients to raise issues with their doctor (Maubach and Hoek, 2005).

Recent studies suggest DTC has complicated consultations and increased the time pressure doctors are under (Weissman et al., 2004). Doctors report an increased need to correct mistaken beliefs about medicines and balance inadequately conveyed information, and suggest this restricts the time available to discuss more appropriate treatments (Hoffman and Wilkes, 1999; Murray et al., 2003; Toop and Mangin, 2006).

In addition, the number of patients requesting medications by name has risen since the introduction of DTC and some become dissatisfied if they do not receive the medicine they have sought (Hollon, 1999; Spurgeon, 1999; Toop et al., 2003). There is some evidence that patients insist on receiving a prescription for a particular drug, although there is less evidence of ‘doctor-shopping’, where patients search for a physician who will prescribe a drug (Mehta and Purvis, 2003). Although Holmer (1999, 2002) claimed DTC strengthened the relationship between doctors and their patients, his arguments have been disputed (Mansfield, 1999) and experimental studies suggest doctors who accede to patients’ requests may do so against their better judgement (Mintzes et al., 2003, although cf. Weissman et al., 2004).

Kravitz et al. (2005) questioned whether doctors act as gatekeepers; they found patients who made a general request for an anti-depressant were more likely to receive a prescription than those who made no request, while those who requested a specific drug were more likely again to receive a prescription for that brand. Although Kravitz et al. (2005, p. 2000) found patients making a request received better quality care than those who did not, they concluded that DTC was more likely to be beneficial if ‘the target condition is serious and the treatment is very safe effective and inexpensive’.

The debate over DTC has become re-framed as a debate over patient access to information and doctors’ willingness to share information. There is no evidence that doctors wish to restrict access to information that may support health management. However, many question DTC’s ability to provide information that is complete and balanced, and have noted a need for media literacy programmes (Bell et al., 1999) or factual information sources, such as websites run by government agencies (Toop et al., 2003). As the debate over DTC and its implications for health care marketing continues, researchers will need to evaluate how medical information should best be provided to a non-expert audience.

### Financial implications of DTC

Because DTC can accelerate the normal diffusion process, it is often used to promote new drugs so the returns pharmaceutical companies make prior to losing patent protection are maximised (Peyrot et al., 1998; Hollon, 1999). However, while some new drugs offer improvements over existing drugs, others differ less and are more reliant on marketing to create selling points (Toop et al., 2002; Donohue, 2006). Shifts in demand from existing to new and more expensive drugs
raise broader questions about the financial implications of DTC.

New Zealand evidence suggests DTC campaigns have prompted shifts in prescribing behaviour (see also Findlay, 2001; Mintzes, 2002; Rosenthal et al., 2003). Promotions for asthma medications stimulated demand for a new brand, even though several doctors argued that the new drug offered no improvement (NZ Medical Association, 2006). Doctors also reported that the campaign generated anxiety among asthma sufferers (some of whom were concerned that they had not received the 'best' drug) (Toop et al., 2003). The higher cost of prescribing the promoted drug led doctors to question the ethics of a campaign they believed misused health resources (Toop and Mangin, 2006).

However, pharmaceutical manufacturers note that campaigns for erectile dysfunction drugs have normalised a formerly taboo topic and prompted men to visit their doctor (Weissman et al., 2004). Since erectile dysfunction may indicate more serious health conditions, these visits enable preliminary tests to be undertaken and promote detection of these conditions before they develop into less easily treated forms. Pharmaceutical manufacturers claim that DTC may reduce health care costs by ensuring treatment begins at an earlier point than might otherwise have occurred (Everett, 1991; Levitt, 1995; Desselle and Aparasu, 2000). However, Mintzes (2006, p. 28) found no reliable evidence that DTC improved compliance, promoted earlier diagnosis of under-treated conditions or reduced the need for subsequent interventions.

Furthermore, while prescribing rates for hypertension or high cholesterol levels has increased, some researchers question whether these data indicate risk reduction among the wider population, or greater reliance on medicines where lifestyle changes may have been more suitable. Findlay (2001, p. 115) noted that epidemiological studies found those at marginal risk, and who could be treated via lifestyle changes, were receiving prescriptions while those at higher risk were not.

Health researchers note that heavily promoted medications are often expensive; if these drugs attract a subsidy, increased prescribing will increase expenditure and reduce funding available for other conditions (Wilkes et al., 2000; Findlay, 2001). These concerns are supported by a recent systematic analysis, which concluded: 'Direct to consumer advertising is associated with increased prescription of advertised products and there is substantial impact on patients' request for specific drugs and physicians' confidence in prescribing. No additional benefits in terms of health outcomes were demonstrated' (Gilbody et al., 2005, p. 246).

Gilbody et al. (2005) noted that since many advertised drugs treat non-life threatening conditions, increasing demand for medications to treat nail fungus or social anxiety disorder could divert funding from medicines that treat more serious health problems. In countries where private medical insurance is not widely held and government funded health care is limited, the need to trade-off the cost and accessibility of medicines against the conditions these treat has become increasingly important.

Assessing the cost-benefit implications of DTC is difficult, since the information that exists takes the form of case studies (such as asthma) or is anecdotal (such as claims of earlier diagnoses). However, Findlay (2001) examined this question and found that 'savings' produced by pharmaceutical interventions varied greatly by drug type and cost (see also Neumann et al., 2000). Although these findings help address an important unresolved issue, the question of whether increases in prescribing are appropriate is still unanswered and research estimating the financial consequences of DTC is required before its benefits can be assumed.

**Social implications of DTC**

The concerns discussed above highlight the growing reliance on drug-based interventions as an alternative to lifestyle changes. Wilkes
et al. (2002, p. 121) suggested: ‘DTC advertising may cultivate the belief . . . that there is a pill for every ill and contribute to medicalisation of trivial ailments, leading to an even more “overmedicated” society’. Woloshin et al. (2001) suggested common complaints (a runny nose) have been elevated to technical conditions (allergic rhinitis) that individuals believe require treatment (Norton, undated). DTC may thus have led to social changes, where individuals rely less on personal will-power to effect change and more on medical interventions (Sheffet and Kopp, 1990).

Proponents of DTC argue that progress involves labour-saving; thus the logic used to explain the popularity of fast food may also account for the popularity of pharmaceutical solutions to what are arguably lifestyle conditions (Moynihan et al., 2002). However, because many DTC promoted drugs do not attract subsidies, patients must pay for them. In some cases, patients have been unable to afford the advertised medicines they have requested, raising awkward questions about the equity of health care (Maubach and Hoek, 2005).

Evidence that consumers overestimate the safety of advertised medicines has also raised important questions, particularly since drugs have recently been withdrawn on safety grounds. The withdrawal of Vioxx®, one of the most heavily promoted drugs, raised questions about the safety of medicines and the point at which they are promoted to potential users. Mintzes (2006) noted that consumer spending on Vioxx® in 2000 exceeded expenditure on Pepsi Cola and suggested that the marketing of prescription medicines as though they were fast-moving consumer good status has had profound public health implications.

While patients who had been prescribed Vioxx® and their health professionals were addressing the implications of the Vioxx® withdrawal, in New Zealand, Celebrex®, a rival drug to Vioxx®, promoted itself as a safe alternative. A widely published newspaper advertisement sought to reassure Celebrex® users and stated that Celebrex® had ‘strong cardiovascular safety’. A complaint from medical researchers was upheld and New Zealand research linking Celebrex® to increased cardiovascular risk subsequently led to its withdrawal (ASCB, 2004; Medscape, 2005; see also Topol, 2004, for a more general discussion of Vioxx®). However, the use of comparative advertising to gain market advantage raises important questions about the extent to which DTC should parallel FMCG advertising.

**Future research**

Health care marketing raises important ethical and public policy issues that merit more detailed research attention. Knowledge of individuals’ understanding of DTC is still weak, and the relationship between exposure to DTC, knowledge acquisition and behaviour is still to be elucidated. Further research that examined recall of components of DTC promotions (benefits cf. risks) and the effect of alternative execution formats on recall and retention could help resolve long-standing concerns over the balance of information and whether and how this might be achieved. Comparison of alternative information sources, such as those proposed by Toop et al. (2003), and DTC would inform decisions about whether to replace DTC with government-managed information services.

As well as estimating the effects of DTC on consumers, researchers could also examine the societal implications of DTC, particularly its effect on prescribing and the implications for health funding decisions. Examination of long-run prescribing data would enable estimation of how DTC affects the portfolio of

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The advertisement contained, *inter alia*, the following statements: ‘Celebrex has been making people with pain and arthritis feel better for years. And now we want to ease your mind too. … You’ve probably heard that Vioxx®, a COX-2 drug for arthritis and pain, has been withdrawn from the market because it increased the risk of heart attacks and strokes. But, the information below should make you feel good about Celebrex®, which is also a COX-2 drug … Important patient studies with Celebrex show strong cardiovascular safety’ (ASCB, 04/396).
drugs doctors prescribe from and would provide insights into the potential costs of DTC. Establishment of a panel of doctors would also enable researchers to test claimed benefits of DTC, such as its potential to provide opportunities for screening, the proportion of individuals with underlying conditions diagnosed and the potential savings obtained through earlier diagnosis. Collection of these data would enable preliminary cost-benefit analyses to be undertaken and would support quantification of DTC’s benefits and costs.

Evaluation of regulatory processes, particularly consumers’ knowledge of these and their ability to access them, is also required to test the level of protection currently afforded and to address questions raised in recent regulatory reviews. Consumer surveys as well as more detailed analyses of complaints and the experience of complainants could inform decisions about the future of DTC and the effectiveness of existing regulatory regimes.

Because DTC remains such a contentious form of advertising, there is no shortage of research questions for those interested in assessing its social, economic or political effects. Providing an empirical basis for regulatory decisions will be increasingly important given the political prominence DTC has assumed.

**Conclusions**

Prescription medicine advertising epitomises issues affecting healthcare marketing in general. Few dispute the value of providing information to potential end-users; however, the format, content and style of DTC have led health professionals to see these promotions as unbalanced and potentially harmful. Marketers, however, consider DTC a democratic right and rely on doctors to ensure patients receive appropriate medications.

The costs of DTC have led regulators to review its economic and social effects and the United States and New Zealand are both currently reviewing DTC regulation. For health researchers, these reviews present an opportunity to reverse policies they argue have damaged public health; for marketers, the reviews have prompted a spirited defence of their rights and the systems used to manage DTC.

More generally, DTC raises questions about consumers’ knowledge of medicines and their access to these and the interaction between pharmaceutical and personal healthcare management, and about whether commercial and public health objectives can be balanced. The debate over DTC thus reflects more fundamental social and philosophical issues and the interchange between proponents and opponents seems unlikely to reach a consensus in the near future.

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