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ORIGINAL ARTICLE

Direct-to-consumer advertising under the radar: the need for realistic drugs policy in Australia

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Abstract

Direct-to-consumer advertising of prescription medicines (DTCA-PM) is currently banned in Australia. DTCA-PM is thought to increase health-care costs by increasing demand for drugs that are both expensive and potentially harmful. However, DTCA-PM is occurring in Australia despite the current prohibition. We argue that successful regulation of the practice has been undermined as a result of changes brought about by the ongoing communications revolution, the increasing centrality of patient choice in medical decision-making and the impossibility of drawing and maintaining a sharp distinction between information and advertising. The prohibition is further threatened by recent international trade agreements. These factors make DTCA-PM inevitable and legislative and professional bodies need to acknowledge this to create a more effective health-care policy.

Introduction

Increases in health-care spending in Australia are often linked to increased consumption of pharmaceuticals.[1] Australian legislators have sought to combat this problem by a combination of subsidy, control and prohibition: the cost of many drugs to consumers is subsidized through the Pharmaceutical Benefits Scheme (PBS);[2] access to drugs listed on the PBS is controlled by requiring consumers to obtain a written prescription from a registered medical practitioner; and under the *Therapeutic Goods Act* 1989 (Cth) it is illegal to publish or broadcast advertisements aimed at the general public that refer to prescription medicines. However, it is lawful to advertise such products directly to health professionals.

The prohibition of direct-to-consumer advertising of prescription medicines (DTCA-PM) is based on a simple logic. Advertising stimulates a perceived need for a drug.[3,4] This motivates patients to put pressure on their doctors to prescribe that drug.[5,6] Doctors tend to respond to this pressure by writing more prescriptions.[5,7] This increases expenditure on prescription pharmaceuticals and ultimately drives up the cost of health care to the community.[8] Banning DTCA-PM is primarily an attempt to disrupt this causal chain at its origin.

Although the PBS has been relatively effective in controlling health-care costs, we argue that the current legislative ban on DTCA-PM is naive in several respects.[2] There is also evidence that it is being sidestepped. We offer some explanations for why the prohibition of advertising is, on its own, an increasingly untenable and ineffective approach to deal with industry influence and suggest a range of supplementary strategies.

How Australia's ban on DTCA-PM is being sidestepped

There are at least three different ways in which DTCA-PM is currently occurring in Australia, despite the fact that it is legally prohibited:

1 *Internet advertising*: Drug company websites advertise prescription medicines, as do websites sponsored by drug

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companies. Drug companies also publicize the addresses of their own websites (URLs) in advertising campaigns that are conducted in other media. Given that access to the Internet is unrestricted in Australia, this constitutes a form of DTCA-PM.

2 *Email*: 'Spam' email campaigns remain common in Australia and they often promote prescription drugs.

3 *Infomercials*: Drug companies frequently sponsor 'disease awareness campaigns'.[9,10] In Australia, these include a new variety of late-night advertisement that typically combines an exhortation to the viewer to 'ask your doctor' about new treatments with one or more of the following features: a stylized representation of a health problem, the name or logo of a drug manufacturer and a telephone number or website. Although these 'infomercials' are virtually indistinguishable from other television advertisements, they evade the advertising ban by masquerading as community education and not mentioning the drug itself. Advertising campaigns targeting medical practitioners are often run concurrently to try to ensure that practitioners have a particular product in mind when patients (prompted by the latest disease awareness campaign) ask about new treatments.

Importantly, the ban on DTCA-PM also does not address a range of strategies of influencing consumers that are less 'direct,' but potentially as efficacious. These include 'placement' of stories about 'breakthrough' medical treatments on news and current affairs programmes, which are frequently planted in the press by drug companies; the journalists who present them may have even received consultation fees from the company that markets the featured product.[11] Pharmaceutical companies are also increasingly offering to support cash-strapped consumer groups by funding their activities or websites.[12] Although such support is often welcomed by the groups themselves, there is also evidence that sponsors exert commercial influence through the groups' newsletters and websites and that they spur the groups to lobby for the company's drugs to be included on lists of government-subsidized pharmaceuticals.[13,14]

Why DTCA-PM cannot be stopped

The information revolution and the rise of global markets

The Internet has changed the way that people become informed about health matters and gather information about their own health care.[15] Consumers are playing an increasingly active role in searching out information, thereby initiating interactions with drug companies as well as being the passive recipients of advertising. Furthermore, the global reach on the Internet means that it is difficult, if not impossible, to police the accuracy or intent of the available information, to control communication between consumers and drug companies or to frame or limit this communication according to national regulatory structures. It is no surprise, therefore, to find that Australian consumers have access to enormous amounts of 'information' about pharmaceutical products, much of which is produced or sponsored by the manufacturers of those products. For example, a Google search conducted in Australia on 21 March 2006 using the words 'depression' and 'medication' yielded over 25 million hits. Within the first 10 results was the homepage for Pfizer's Zoloft[16] and another website that displayed a prominent advertisement for one prescription medication and provided links to other 'sponsor' drug company websites.[17] When Australian health consumers use the Internet to search for information or advice, they are in effect plugging into a global pharmaceutical market, which is immune from national regulation.

Autonomy and rights in the 'information age'

During the late 20th century, health care in the developed world changed markedly as a result of broader shifts in social, political and economic relations. During the 1970s in particular, the dominance of medical expertise was challenged by the rise of new social movements and by bioethical critiques of medical practice. These challenges led to the current emphasis on the centrality of patient preferences, rights and autonomy in medical decision-making.[18] This important cultural shift has led to an unprecedented focus on the quantity and quality of the information that is provided to consumers,[19] and the manner in which it is communicated.

The principle of respect for autonomy demands that health-care workers should provide patients with access to accurate and relevant information to assist in decision-making. Patients and consumers may, however, seek information from other sources and that information may be inaccurate or biased. Even if it were possible to restrict their information-seeking efforts, it may be ethically problematic to do so, on the grounds that autonomy also entails a right to non-interference, an argument that has repeatedly been made with reference to DTCA-PM.

The second issue to consider is that medical experts are now only one group among many who produce health information. Other producers include the government,[20,21] disease awareness groups[22] and the pharmaceutical industry. Each may claim to be promoting patient autonomy by making information accessible,[23] but each also has a different agenda and vested interests in conveying certain messages. The quality of and the manner in which information is presented vary between stakeholders in accordance with their agendas and the resources they

have at their command. However, there are no simple evaluative principles to judge whether information meets a certain standard and no neutral benchmark by which to measure its quality, quantity and objectivity. This point is easily shown by considering the following excerpt from an information page for 'erectile dysfunction' (ED) on treatment options:

> These include the vacuum constriction device (VCD), oral medications, medication patches and gels, urethral and penile injection therapies and surgical therapies including penile prosthesis.... Currently, Sildenafil (Viagra) is the only FDA-approved oral medication for ED.... This is a very effective treatment for most men who have mild-to-moderate ED.... Consult your health care provider to see whether one of these treatments is right for you.[24]

Given that there is evidence that Sildenafil is effective in the treatment of ED,[25–29] there is nothing strictly false in this excerpt. But it is biased. It sets up a choice between one option that is singled out and evaluated as 'effective' and 'FDA-approved' and a set of other options that are referred to generically and which would strike many readers as invasive, sticky, painful or peculiar. Furthermore, those who use Viagra by implication do not have a *severe* problem getting an erection. The excerpt can be considered as information, but the way it frames consumer choice belies its persuasive intent. A government or consumer group announcement would be no less amenable to this kind of analysis. Texts are inevitably shaped by the purpose for which they were designed. Where this purpose includes influencing consumers, no guidelines for providing information will be able to obviate the potential for 'spin'.

The problem of differentiating types of human communication

To prohibit a certain practice, one must first be able to define it so that it can be clearly differentiated from other allowable practices. This apparently simple task creates particular problems for DTCA legislation because it is difficult to differentiate advertising from other forms of influence, such as health promotion or education.

Attempts have been made to address this difficulty within recent trade agreements between Australia and the only two countries where DTCA-PM is not banned – the USA and New Zealand (NZ). Negotiations over the Australia–US Free Trade Agreement (FTA) have resulted in a relaxation of the ban on Internet DTCA in Australia, while maintaining the prohibition on DTCA in other forms of media. The trans-Tasman agreement with NZ endeavours to draw dividing lines by distinguishing categories such as 'advertisement', 'disease awareness campaign' and 'unbranded advertisement'.

But new attempts to police distinctions between different types (or *genres*)[30] of communication (or police them in some media more than others) are no more likely to provide a basis for watertight legislation or regulation than current legislative distinctions based on whether something is directed towards the consumer. Is something an advertisement by virtue of the *intention* of its maker, by virtue of its objective properties as a text (its *form* and *content*) or by virtue of its *effect* on the reader? It would seem futile to distinguish between communicative genres purely on the basis of intention. Drug companies have an interest in creating a perceived need for their products and this will shape the meaning of all texts that they produce, irrespective of their stated intentions. Furthermore, we cannot assume that human intentions are singular, conscious or untainted by self-deception.[31] Differentiating advertising on the basis of content is similarly futile. Even if specific content is mandated, such as lists of side-effects, advertisers are masters of 'spin'.[10]

Finally, just because something has persuasive potential, its effect is another matter. If consumers read sponsored health information leaflets or 'infomercials' as advertisements, are they in fact advertisements and therefore in breach of the current legislation? It seems likely that different people interpret 'information' in different ways, so persuasive effect does not appear to be a promising way to police distinctions between one genre and another.

The challenge posed to national drugs policy by trade and regulatory agreements

Some of Australia's recent international trade agreements are likely to have a major influence on domestic drug policy. In particular, the relaxation of control over DTCA-PM on the Internet in the wake of the Australia–US FTA might provide pharmaceutical companies with a precedent to argue for the relaxation of the ban in other media. It is less clear what the effects of the trans-Tasman agreement will be. Just after the treaty was signed in December 2003, the NZ cabinet considered a submission from the NZ Minister of Health to ban DTCA and resolved to consider the 'harmonization' of drugs policy between Australia and NZ. Although the adoption of Australian standards could restrict DTCA in NZ (even if it were to permit some unbranded material promoting disease awareness), it is also possible that this 'harmonization' might go in the other direction, with Australia changing its laws so as to allow DTCA-PM, as does NZ.[32,33] Interestingly, despite claims to the contrary,[34] the agreement so far has retained more of the NZ system than the Australian one, most notably an emphasis on industry self-regulation – an approach that has been shown to be open to manipulation by pharmaceutical companies.[32]

Conclusion

Australia's current ban on DTCA-PM is ultimately a means of dealing with pharmaceutical company influence. Although comparisons with the USA and NZ would suggest that the legislative prohibition of DTCA-PM is effective, the fact that DTCA-PM is occurring in Australia in at least three different ways suggests that prohibition is, on its own, an inadequate policy response to DTCA-PM. We would argue that it is also a naive approach to the issue, first because the content of the Internet cannot be policed effectively by geographically defined legislatures and also because it is impossible to devise definitions or criteria that will consistently differentiate advertising from other forms of influence. Furthermore, even if prohibition were possible, it may be at least partially undesirable on the grounds that respect for autonomy should include the freedom to choose sources of information.

It is clearly time to rethink Australia's policy approach to drug advertising and Australia's recent trade agreements make this an especially timely exercise. We do not suggest unbridled DTCA-PM. Rather, we hope to stimulate thought and discussion about new strategies that would both foster respect for autonomy and account for the interest-laden nature of all information.

The causal chain of events outlined at the start of this article is a useful place to begin this process. It suggests that alternative strategies might target other points in the chain and form part of a broader approach that includes – but is not confined to – the limitation of advertising by legislative and other means. This is similar to the approach proposed by the Health Action International (HAI) Europe in 1998.[10] In addition to legislative prohibition of DTCA-PM, the HAI recommendations include (i) prohibitions based on categorizations of drug class, (ii) the involvement of consumers and doctors in setting and enforcing standards, (iii) more funding for independent information, (iv) a role for consumers and doctors in secondary school education to teach students how to be critical of drug information, (v) better monitoring of drug information and mechanisms for disseminating corrections to misinformation and (vi) and consumer groups to be more transparent about sources of funding or to use the so-called blind trusts (i.e. trusts designed to protect the independence of consumer groups by blinding them to the source of private contributions). Additional strategies for responding to DTCA-PM may include

- Increasing the transparency of government mechanisms for drug pricing and regulation[34]
- Public education campaigns to increase awareness of and scepticism towards commercial sources of influence
- Support for health programmes that encourage shared decision-making[35]
- Increased undergraduate and postgraduate education for health professionals about: (i) how the pharmaceutical industry participates in the generation and dissemination of evidence and 'creates' health needs, thereby contributing to the growing expenditure on prescription pharmaceuticals[3] and (ii) processes for establishing and maintaining standards for professional interactions with industry[36]

Given the marketing sophistication of the pharmaceutical industry, the intense competition between drug companies, the difficulty in establishing categorical boundaries that adequately capture the range of industry activities and the increasing attention on global trade agreements and on legislative harmonization across national borders, it seems clear that measures in addition to legislative prohibition will be required to respond to the challenges raised by drug company influence on consumers. But this requires that we first acknowledge that the current drug policy on DTCA-PM is being effectively sidestepped and also that it does not and cannot adequately address less 'direct' forms of influence.

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