

In conclusion, we should offer the same professional management and quality of care to the many patients with medically unexplained symptoms as we offer to patients with explicable symptoms. Today this is not the case, and we need to bring existing evidence into medical education and to renew our management of patients with medically unexplained symptoms in general practice. In this process we must also be ready to adjust paradigms about good communication based on new evidence. This process should be driven by comprehensive research into patients with medically unexplained symptoms and by health services research exploring the best possible implementation of appropriate management strategies.

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1 Burton C. Beyond somatisation: a review of the understanding and treatment of medically unexplained physical symptoms (MUPS). *Br J Gen Pract* 2003;53:231-41.

2 *ABC of psychological medicine*. London: BMJ Books, 2003.

3 Rosendal, M. General practitioners and somatising patients. Development and evaluation of a short-term training programme in assessment and treatment of functional disorders [PhD thesis]. Aarhus: Research Unit and Department of General Practice, Faculty of Health Sciences, University of Aarhus, 2003:1-238.

4 Fink P, Rosendal M, Toft T. Assessment and treatment of functional disorders in general practice: the extended reattribution and management model—an advanced educational program for nonpsychiatric doctors. *Psychosomatics* 2002;43:93-131.

5 Salmon P, Peters S, Stanley I. Patients' perceptions of medical explanations for somatisation disorders: qualitative analysis. *BMJ* 1999; 318:372-6.

6 Wileman L, May C, Chew-Graham CA. Medically unexplained symptoms and the problem of power in the primary care consultation: a qualitative study. *Fam Pract* 2002;19:178-82.

7 Reid S, Whooley D, Crayford T, Hotopf M. Medically unexplained symptoms—GPs' attitudes towards their cause and management. *Fam Pract* 2001;18:519-23.

8 Kroenke K, Swindle R. Cognitive-behavioral therapy for somatization and symptom syndromes: a critical review of controlled clinical trials. *Psychother Psychosom* 2000;69:205-15.

9 Blankenstein AH. Somatising patients in general practice. Reattribution, a promising approach [PhD thesis]. Amsterdam: Vrije Universiteit, 2001:1-129.

10 Morris R, Gask L, Ronalds C, Downes-Grainger E, Thompson H, Goldberg D. Clinical and patient satisfaction outcomes of a new treatment for somatized mental disorder taught to general practitioners. *Br J Gen Pract* 1999;49:263-7.

11 Salmon P, Dowrick CF, Ring A, Humphris GM. Voiced but unheard agendas: qualitative analysis of the psychosocial cues that patients with unexplained symptoms present to general practitioners. *Br J Gen Pract* 2004;54:171-6.

12 Dowrick CF, Ring A, Humphris GM, Salmon P. Normalisation of unexplained symptoms by general practitioners: a functional typology. *Br J Gen Pract* 2004;54:165-70.

Direct to consumer advertising

Is at the crossroads of competing pressures from industry and health needs

The challenge for governments evaluating direct advertising of prescription only drugs to the consumer is how to achieve maximum benefits for health and wealth while minimising harm. New Zealand's health minister, Annette King, has taken the advice of New Zealand's health professional and consumer groups and has decided that the potential benefits of "direct to consumer advertising" do not justify the harms and so plans to ban it from 2005.^{w1} That will leave the United States as the only industrialised country allowing full direct to consumer advertising of prescription medicines. An Australian review of drug legislation in 2001 concluded that prohibiting such advertising produces a net benefit for the community as a whole.¹ In 2002, the European Parliament rejected a proposal to allow advertising for drugs used to treat asthma, AIDS, and diabetes directly to the consumer. A 2004 Canadian parliamentary inquiry recommended against direct to consumer advertising because "Drug advertisements could endanger rather than empower consumers by minimizing risk information and exaggerating benefits" and "could contribute to increased or inappropriate drug consumption."²

Direct to consumer advertising increases the use of drugs and medical services and increases wealth for pharmaceutical, advertising, and media companies.³ It increases prescribers' workloads and increases expenditure by patients, taxpayers, insurers, and large

employers. For example, General Motors USA has identified direct to consumer advertising as a major cost driver increasing payments for health care for its workers and thus increasing the cost of building cars.^{w2} Such increased costs might be worth while if direct to consumer advertising delivered value for money by improving health.

Unfortunately, the situations where direct to consumer advertising could be most beneficial (by stimulating appropriate use of drugs for high priority health needs) do not often match the situations where it is most profitable. As one advertising industry executive explains: "Direct to consumer is suited for things where patients have a greater interest than doctors. Non-life threatening conditions, such as erectile dysfunction . . ."^{w3} Such promotion may be beneficial as well as harmful. For example, while the promotion of sildenafil and its competitors may motivate men, who might not do so otherwise, to see a general practitioner, and possibly address other health needs, it has been shown to increase distress if it raises expectations that are unfulfilled^{w4} and is a haphazard approach to health promotion for populations. Direct to consumer advertising is most profitable for expensive new drugs.⁴ Because the long term health effects of

new drugs are unknown it is often difficult to know whether the increased costs are justified. There are also opportunity costs when advertising stimulates rapid adoption of new drugs without established advantages over cheaper alternatives, especially in public health systems with finite resources.

Proponents of direct to consumer advertising claim it increases public knowledge. This might be so if it delivered reliable balanced information. Such advertising does increase awareness of drugs, but its purpose, as with all advertising, is to persuade rather than to inform. Direct to consumer advertising leaves many people with exaggerated perceptions of the benefits of drugs.⁵ Providing balanced information about harms, alternatives, and costs is likely to reduce efficacy and profitability of advertisement. Demand stimulated by such advertising creates dilemmas for doctors who aspire to be both patient centred and evidence based. For this reason, many health professionals and their representative organisations strongly oppose advertising directly to consumers.⁶

In countries where full direct to consumer advertising is illegal, drug companies are increasingly pushing the limits of regulatory systems, with disease oriented advertising, public relations campaigns, reminders, and unbranded direct to consumer advertising.³ Requirements to provide any balancing information do not exist because such advertising has arisen by default via regulatory loopholes. For example, in Canada a price advertising clause from 1978 has been used to allow reminder advertisements, including advertising in July 2004 for a contraceptive patch by name without warnings about adverse effects.⁷ Earlier this year Glaxo-SmithKline paid a celebrity, Impotence Australia, and a couple who had used vardenafil to promote the drug via the Australian news media.⁸ The brand name was mentioned without appropriate balancing information. In 2003 staff of the World Health Organization expressed concern that disease oriented advertisements in France that were funded by Pfizer, manufacturer of atorvastatin, "contained misleading statements and omissions likely to lead to unjustified medicine use."⁹ They recommended that governments "urgently increase vigilance with respect to drug promotion." Few if any governments seem to be heeding this advice. In 2004, Canada's health minister, Pierre Pettigrew, indicated that a nearly identical advertisement was not subject to regulation because it fell outside the legal definition of product specific advertising.¹⁰

Two studies of unbranded advertising directly to consumers have been published. Prescribing of sumatriptan was higher in cities in the United States that had been exposed to a campaign in 1993 recommending that people ask their doctor about a "surprisingly effective" new treatment for migraine.¹⁰ Novartis's unbranded television advertisements in the Netherlands increased consultations for onychomycosis and prescribing of terbinafine while decreasing use of its competitor.¹¹ The country's health inspectorate tried to stop this campaign, but a court allowed it because neither the product nor the company was named.

Governments are under pressure to create business friendly environments for politically powerful industries to invest.¹² At the same time they must manage

health services to give priority to health needs. Policy on direct to consumer advertising is at the crossroads of those competing pressures. In the face of unsuccessful attempts at legislative change to allow advertising directly to the consumer, lax enforcement of existing laws may ease pressure on governments from those politically powerful industries, but it is contrary to democratic principles and may harm both public health and national wealth.

The public is ill served when governments allow promotion of prescription drugs that stretches the limits of the law—and beyond. No country has been successful at regulating any type of direct to consumer advertising to ensure the public obtains reliable balanced information on drug benefits and risks.³ Repeated breaches by companies speak for themselves.³ The potential awareness raising benefits of direct to consumer advertising could be better targeted and sustained at lower cost with less harm through publicly funded and accountable drug information services and health campaigns.

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- Galbally R. *Review of drugs, poisons and controlled substances legislation (the Galbally review): final report*. Therapeutic Goods Administration (Australia), 16 October 2001. www.tga.health.gov.au/docs/html/rpdf.htm (accessed 11 Aug 2004).
- Brown B. Standing committee on health. *Opening the medicine cabinet: first report on health aspects of prescription drugs*. Ottawa, Ontario: House of Commons, 2004.
- United States General Accounting Office. *FDA oversight of direct-to-consumer advertising has limitations. Report to congressional requesters GAO-03-177*. October 2002. www.gao.gov/newitems/d03177.pdf (accessed 11 Aug 2004).
- National Institute for Health Care Management Research and Educational Foundation. *Prescription drugs and mass media advertising, 2000*. Washington, DC: NIHCM, 2001. www.nihcm.org/DTCbrief2001.pdf (accessed 14 Aug 2004).
- Woloshin S, Schwartz LM, Welch HG. The value of benefit data in direct-to-consumer drug ads. *Health Affairs* web exclusive 28 April 2004. <http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.234v1/DC1> (accessed 14 Aug 2004).
- Toop L, Richards D, Dowell T, Tilyard M, Fraser T, Arroll B. Direct to consumer advertising of prescription drugs in New Zealand: for health or for profit? Report to the Minister of Health supporting the case for a ban on direct to consumer advertising. New Zealand departments of general practice. Christchurch, Dunedin, Wellington and Auckland Schools of Medicine. February 2003. www.chmeds.ac.nz/report.pdf (accessed 11 Aug 2004).
- Gardner D, Mintzes B, Ostry A. Direct-to-consumer prescription drug advertising: permission by default? *CMAJ* 2003;169:425-7.
- Sweets' potent drug. *Media Watch ABC TV transcript*, 22 March 2004. www.abc.net.au/mediawatch/transcripts/s1071337.htm (accessed 11 Aug 2004).
- Quick JD, Hogerzheil HV, Rago L, Reggi V, de Joncheere K. Ensuring ethical drug promotion—whose responsibility? *Lancet* 2003;362:427.
- Basara LR. The impact of a direct-to-consumer prescription medication advertising campaign on new prescription volume. *Drug Inf J* 1996;30:715-29.
- 't Jong GW, Stricker BH, Sturkenboom MC. Marketing in the lay media and prescriptions of terbinafine in primary care: Dutch cohort study. *BMJ* 2004;328:931.
- Abraham J. The pharmaceutical industry as political player. *Lancet* 2002;360:1498-501.