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**An Assessment Of The Health System Impacts Of Direct-To-Consumer
Advertising Of Prescription Medicines (DTCA): Executive
Summary**

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An Assessment of the Health System Impacts of Direct-to-Consumer Advertising of Prescription Medicines (DTCA)

Executive Summary

The aim of this project was to identify and assess potential impacts of direct-to-consumer prescription drug advertising (DTCA) on health care delivery in Canada, estimate the costs of these impacts and consider potential risks and benefits, in terms of health consequences. This two-year project ran from September 1, 1999 – August 31, 2001. It was funded through Health Canada's Health Transition Fund.

The project has four main components:

- A literature review of empirical studies published between 1990 and 2000;
- A comparative patient/doctor survey in physicians' offices in Vancouver and Sacramento, assessing the impact of patient requests for medicines on prescribing;
- An opinion survey of drug policy experts in Canada, the US and New Zealand;
- An economic analysis of DTCA in terms of consumer welfare models for advertising.

A multidisciplinary expert advisory panel^a provided guidance on methodology, with particular attention to the design and conduct of the patient/doctor survey. The expert advisory panel met in December 1999.

Background – The policy environment

The United States and New Zealand are the only countries to allow direct-to-consumer advertising of prescription medicines (DTCA). Spending on DTCA in the US has grown rapidly, reaching US \$2.5 billion in 2000.¹ Since late 1997, when the US Food and Drug Administration (FDA) eased regulatory restrictions,² television advertising has grown dramatically. New Zealand's experience with DTCA is more recent than in the US.³

DTCA is not currently allowed under Canada's Food and Drug Act, except for advertising of 'name, price and quantity', a provision introduced in 1978 to allow comparative price advertising.⁴ However, the federal government is considering legislative change, and Canadians are increasingly exposed to cross-border US media-based drug ads, to web-based advertising, and to indirect advertising originating in Canada.⁵ Thus far no consensus has been reached, and some provincial governments have raised concerns that DTCA could exacerbate escalating drug costs.⁶

Canada is not alone in re-considering the regulation of DTCA. Australia carried out a legislative review in 2000, and recommended against introducing DTCA, with the exception of comparative price advertising.⁷ In July 2001 the European Commission (DG Enterprise) proposed legislative changes to allow public advertising of drugs for HIV/AIDS, diabetes and asthma.⁸ The European Parliament is expected to vote on this proposal in 2002.

DTCA is controversial, with many claims made about both beneficial and harmful effects. The latter concerns include stimulation of inappropriate and unnecessary prescription drug use, a negative effect on the doctor/patient relationship, and increased drug costs. Claimed benefits include education and empowerment for consumers, improved compliance, and earlier medicine use leading to better health and reduced hospitalization costs.

Known effects of DTCA on health and health care services

Surveys of random samples of the US public^{9 10 11 12 13} indicate that DTCA is having an effect on behaviours. Around one fourth of respondents spoke to their doctors about a drug or condition in response to advertising, 6-9% directly requested an advertised drug, and 80-84% of those who requested prescriptions received them. These surveys may be subject to bias as they rely on recall of events over long or undetermined time periods.

In one survey, one third of those taking advertised drugs, or 8% of the sample, reported being reminded by ads to take the drug or to refill prescriptions;⁹ in another survey, 28% said they would switch doctors to get a desired medicine.¹⁰ These findings suggest both positive and negative effects on compliance with doctors' instructions. However, actual behavioural changes and potential health consequences remain unexamined.

Misunderstanding of the regulatory context surrounding DTCA is common: in one survey 43% believed that only completely safe drugs were advertised to the public;¹⁴ in another 53% could not explain what prescription-only status means.¹³ The only published survey of physicians with adequate methodology¹⁵ found that 89% did not feel that DTCA enhances doctor/patient relationships and 71% thought physicians were pressured to prescribe drugs they would not normally use.

The regulatory experience in the US¹⁶ and New Zealand¹⁷ indicates that violations are common in environments where DTCA is permitted, mainly due to inadequate risk information and/or exaggeration of benefits. Analyses of print advertising content have found inaccuracies¹⁸ or inadequate risk information¹⁹ in about one-third of ads. In a New Zealand survey on a print ad later found to violate the Medicines Act because risk information was lacking, 45% of respondents thought the ad provided the information they needed for a treatment decision and 27% thought it clearly explained product risks.²⁰ A ten-year review of US ads in 18 major magazines found limited educational value: most omitted key information about a product and the condition it treats, such as the likelihood of treatment success or the existence of alternative treatments.²¹

DTCA spending in the U.S. is highly concentrated, with around 40% annually allocated to promotion of only 10 products.²² These are generally new, expensive drugs for chronic or intermittent long-term use by large target audiences -- a small subset of available medicines. The most heavily advertised drugs are strongly associated with increased US retail costs.^{23 24} The top 25 drugs by DTCA spending were responsible for 40.7% of the \$17.7 billion U.S. increase in 1999 retail drug costs relative to 1998. Doctors wrote 34% more prescriptions for these products in 1999 vs. 1998, as compared to 5% more prescriptions for all other drugs. These products were also heavily advertised to physicians, however.

In summary, there is evidence that DTCA affects consumer behaviours and prescribing, and evidence of an association between advertised products and increased costs. No research has been carried out to assess the effects of care-seeking behaviour or increased drug use attributable to DTCA on health, hospitalization rates, serious morbidity or mortality.

Comparative Patient/Doctor Survey in Vancouver and Sacramento

We carried out a comparative doctor/patient survey on direct-to-consumer advertising (DTCA) in 40 family physicians' offices in Vancouver, B.C. and 38 in Sacramento, California. The aim was to assess the frequency of patient requests for prescription drugs in primary care in US and Canadian urban environments. A total of 1431 patients participated (683 in Sacramento and 748 in Vancouver). These were 61% of patients consulting participating physicians on the days during which the survey was conducted.

Exposure to DTC ads was higher in Sacramento, but 90% of Vancouver patients reported having seen prescription drug ads. More Sacramento than Vancouver patients requested one or more medicines during observed consultations (15.8% vs. 9.0%, $p < .01$) and more than twice as many Sacramento patients requested advertised drugs (7.3% vs. 3.2%, $p < .01$).

Physicians in both settings responded by prescribing the requested drugs in a high proportion of cases (79.6% in Sacramento and 62.6% in Vancouver). We measured physicians' confidence in treatment choice by asking how likely they would be to prescribe the same drug to a similar patient with the same health condition. Physicians expressed some degree of ambivalence about 12.4% of new prescriptions not requested by patients. In contrast, they were ambivalent about the choice of treatment for 50% of DTC advertised drugs prescribed following a patient request ($p < .01$).

Patients who requested a medicine were nearly nine times as likely to receive a prescription as those who did not, after controlling for health, demographics, socio-economic status and drug payment.

In conclusion, we found that patient requests for medicines occurred commonly and were a major driver of prescribing decisions. There were significantly more requests in Sacramento than Vancouver, and this difference was largest for advertised drugs. However, Vancouver patients did request products that were being advertised in Canada during the study period, such as Zyban (bupropion) and Alesse (estradiol/levonorgestrel). The latter is not advertised in the US, and no US patients requested it. This suggests that current regulatory policies allowing some DTCA in Canada are affecting prescribing patterns. However, we found a larger increase in prescribing volume attributable to DTCA in a US environment with full DTCA. Of particular concern in both settings is the potential effect on prescribing appropriateness, given that physicians were highly likely to prescribe requested DTC advertised drugs, but they often expressed ambivalence about those treatment decisions.

Survey of Pharmaceutical Policy Experts

A faxed questionnaire was sent in February 2001 to 150 drug policy experts in sectors affected by DTCA in the US, New Zealand, and Canada, including health professional organizations, consumer and disease/patient groups, government agencies, private insurers, managed care, the pharmaceutical and advertising industry and media. They were identified through an Internet search for fugitive literature on DTCA, lists of participants in relevant advisory committees, and through government and industry contacts.

The response rate was 71% (106/150); 60 from Canada, 24 from the US and 22 from New Zealand. In the US, 79% of respondents had seen more than 10 brands advertised in the last year, as compared to 55% in New Zealand and 52% in Canada. Two thirds judged the

information on drug benefits and risks in DTCA to be poor or very poor, while 28%, mainly those from the drug and advertising industries, thought the information was good to excellent.

Most respondents judged the effects of DTCA on patient knowledge of drugs and diseases and on health care quality to be negative or at best neutral, with the exception of doctor/patient communication (41% positive, 38% negative). Respondents from all sectors believed that DTCA leads to increased drug costs and more doctor visits.

Over half of the respondents thought that a delay, ranging from six months to over 5 years, should be required between the product's market launch and initiation of DTCA campaigns, and 70% supported product-specific limits, mainly based on drug safety profile. Over 75% thought children should not be targeted and over 60% thought that adolescents, low income or disadvantaged groups, and the elderly should not be targeted. Most also thought that billboards (65%) and TV (59%) were inappropriate media. The Internet and magazines were judged more positively, with 49% and 51% respectively considering them to be appropriate.

We asked whether Canada should allow five types of prescription drug advertising aimed at the public. The greatest support was expressed for disease-oriented advertising, with 55% saying this should be allowed; 84% were opposed to full DTCA with promotional offers (56% were opposed to full DTCA without such offers); 62% were opposed to reminder advertising; and 55% opposed comparative price advertising (the latter is currently legal in Canada).

In summary, most of the surveyed policy experts from government, health professional and consumer/nonprofit groups and private payers believed that DTCA information quality is poor, that the effect on health care quality is negative, and that costs increase. Respondents from the advertising and pharmaceutical industry, and to a lesser extent patient groups, were much more positive, believing that DTCA has a positive effect and should be introduced.

Predicting the Welfare and Cost Consequences of DTC Advertising

Advertising tends to be viewed favourably in economic analyses when portrayed as a vehicle for disseminating information, rather than a vehicle for altering the preferences that consumers seek to satisfy. To endorse advertising *qua* information, one must assume that consumers are sufficiently well-informed to be able to evaluate the veracity of manufacturers' claims, thereby limiting the scope for misrepresentation and preference-based suasion. This would be true, for example, for advertisements about the taste or quality of a particular brand of coffee. In the pharmaceutical context, however, the very classification of a product as a "prescription-only" drug signals a legislative belief that an informed agent must stand between the patient and the interests of those promoting the treatment. Evidence concerning the content of advertising and marketing activities targeted at these medical agents, as well as those targeted at consumers, to the extent permitted, reveals the strong incentive for imbalance (e.g. of potential risk and benefit information), exaggeration and non-informative persuasion in promoting products ostensibly to be used (and promoted) on purely scientific grounds.

When placed in a historical context, calls for more lenient regulation of consumer-directed advertising appear not to be a response to consumers' demand for information, but rather as a response to the changing competitive environment for drug manufacturers. Specifically, recent increases in the level and sophistication of drug benefits management by third-party

payers have made consumer-directed advertising essential for many firms to achieve sales growth on new products that either do not fit with conventional notions of “medical necessity,” or are priced above therapeutic alternatives that would otherwise be judged more cost-effective by prescribers, benefits providers, or regulators. Since so-called “disease advertising”—advertising the availability of medical treatments without mentions of specific brands—has always been permitted in Canada, the ability to promote particular brands competing within therapeutic categories appears to be the primary motivation of firms. There is no convincing theory to predict that brand-specific advertising will lead to more competitive pricing, or health care savings, relative to currently-permitted disease advertising. If such advertising did make manufacturers more competitive, thus cutting into profit margins, they would not be the ones seeking the abolition of laws current prohibiting it.

Conclusions

Rapid increases in pharmaceutical industry spending on DTCA imply that this marketing strategy is having a positive effect on sales. Additionally, empirical studies suggest that DTCA affects patient behaviours, prescribing, and prescription drug costs.

The comparative study based in physicians’ offices in Vancouver and Sacramento is the first research to examine directly the effects of advertising on prescribing in primary care. Patient requests for advertised drugs occurred commonly, and physicians prescribed most requested drugs, often in spite of ambivalence about treatment choice. Our findings suggest a negative effect on treatment appropriateness. This is also the direction of effect predicted by policy experts in sectors representing providers and users of health care services. Industry experts were much more positive, but most respondents in all sectors believed costs would increase. Economic analyses of advertising, similarly, indicate a poor fit between the characteristics of prescription drug advertising and the assumptions underlying consumer welfare models of advertising.

We could find no evidence of improved drug utilization, improved doctor/patient relations, or reductions in hospitalization rates, serious morbidity or mortality attributable to DTCA.

The aim of the prohibition of prescription drug advertising in Canada is health protection. Any legislative change that would weaken the current restrictions on such advertising should be based on strong evidence that concerns about potential harm are unfounded, and – ideally – evidence of health benefits. On the contrary, we found a considerable body of evidence suggesting that such concerns are warranted, and no evidence that DTCA is likely to improve the health of Canadians.

^aMembers of the Expert Advisory Panel:

Wendy Armstrong, Consumers’ Association of Canada; Alan Cassels, Canada Drug Guide Project; Jean-Pierre Gregoire, University of Laval; Matthew Hollon, University of Washington; Patricia Kaufert, University of Manitoba; Joel Lexchin, University of Toronto; Bob Nakagawa, Simon Fraser Health Region, BC Ministry of Health; Nancy Ostrove, US Food and Drug Administration; Richard Pollay, University of British Columbia; and Ingrid Sketris, Dalhousie University.

References

- ¹ IMS Health. US Leading Products by DTC Spend. January 2000 – December 2000. IMS Health Incorporated; 2001. Available from: URL: [<http://www.imshealth.com/public/structure/discontent/1,2779,1203-1203-143221,00.html>].
- ² Department of Health and Human Services. Food and Drug Administration. Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements; August 12, 1997. Federal Register 62;155: 43171-43173.
- ³ New Zealand Ministry of Health. Direct-to-Consumer Advertising of Prescription Medicines. Wellington, October 2000; Discussion Document posted at: [www.moh.govt.nz/moh/nsf]
- ⁴ Therapeutic Products Programme. Direct-to-Consumer Advertising of Prescription Drugs. Discussion Document. Ottawa: Health Canada. April 6, 1999.
- ⁵ Silversides A. Direct-to-consumer prescription drug ads getting bolder. CMAJ 2001; 165(4):462
- ⁶ Dosanjh proposes two actions to protect medicare. News Release. Premier's Office. Government of British Columbia, May 24, 2000.
- ⁷ Galbally R. Review of Drugs, Poisons, and Controlled Substances Legislation. Draft Final Report. Therapeutic Goods Administration; Canberra, Australia, September 2000 [<http://www.health.gov.au/tga/docs/html/rdpdf.htm>]
- ⁸ EC Moves on direct-to-consumer advertising ban. Scrip 2433, April 30, 1999, p5
- ⁹ 1997 APhA/Prevention survey in: Hunt M. Direct-to-Consumer Advertising of Prescription Drugs. National Health Policy Forum, George Wash. Univ., April 1998; National Survey of Consumer Reactions to Direct-to-Consumer Advertising. Prevention, Rodale Press, 1998; Year two: A National Survey of consumer Reactions to Direct-to-Consumer Advertising. Prevention, 1999; Slaughter E. Schumacher M. Prevention's International Survey on Wellness and Consumer Reactions to DTC Advertising of Rx Drugs. Rodale Press. 2000/2001.
- ¹⁰ Consumer and Physician Attitudes Towards Direct-to-Consumer Advertising. Time Inc., August 1998; Levy S. DTC ads prompting patient discussions with health-care pros. Drug Top 1999;143(13):12.
- ¹¹ National Consumers League. Health Care Information and the Consumer. A Public Opinion Survey. Washington DC, 1998
- ¹² US FDA. Division of Drug Marketing, Advertising and Communication. Consumer Responses to Direct-to-Consumer Prescription Drug Advertising. [<http://www.fda.gov/cder/ddmac/RESEARCH.HTM>]
- ¹³ Foley L, Gross DJ. Are consumers well informed about prescription drugs? The Impact of Printed Direct-to-Consumer Advertising. AARP Public Policy Institute. Washington DC: 2000; [<http://research.aarp.org>]
- ¹⁴ Bell RA, Wilkes MS, Kravitz RL. Advertisement-Induced Prescription Drug Requests; Patients' Anticipated Reactions to a Physician Who Refuses. Journal of Family Practice 1999; 48 (6): 446-552.
- ¹⁵ Lipsky MS, Taylor CA. The opinions and experiences of family physicians regarding direct-to- consumer advertising . J Fam Pract 1997 45(6):495-9
- ¹⁶ Koerner C. US FDA. Division of Drug Marketing, Advertising and Communications. The Regulation of Direct-to-Consumer Promotion of Prescription Drugs. Presentation at Health Canada Multi-Stakeholders' Consultation on Direct-to-Consumer Advertising. Aylmer, Québec. April 14, 1999
- ¹⁷ Pratt P. Assessment of Regulatory Compliance for Medicines Advertised Direct to Consumer. Medsafe. New Zealand Ministry of Health. Wellington, 2000.
- ¹⁸ Drug advertising: Is this good medicine? Consumer Reports June 1996;62
- ¹⁹ Roth MS. Patterns in direct-to-consumer prescription drug print advertising and their public policy implications. J Pub Policy market 1996; 15:63-75
- ²⁰ PHARMAC. Pharmaceutical Management Agency Ltd. Submission for Ministry of Health Review of Direct to Consumer Advertising. Colmar Brunton Survey on Diane-35. Wellington, NZ, November 2000
- ²¹ Bell RA, Wilkes MS, Kravitz RL. The educational value of consumer-targeted prescription drug print advertising. Journal of Family Practice 2000; 49(12): 1092-1098

²² Media reports on annual spend in the US posted at: www.imshealth.com and www.scott-levin.com.

²³ Barents Group LLC. Factors affecting the growth of prescription drug expenditures. National Institute for Health Care Management Research and Educational Foundation, Washington D.C., July 9, 1999

²⁴ Findlay S. Prescription Drugs and Mass Media Marketing. National Institute of Health Care Management. Research Brief. September 2000. [www.nihcm.org]