

Direct-to-consumer prescription drug advertising in Canada: Permission by default?

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§ See related articles pages 405 and 421

The advertising of prescription drugs aimed directly at the public is prohibited in most countries, including Canada. However, a shift in interpretation of the policy governing this marketing strategy, known as direct-to-consumer advertising (DTCA), has occurred in Canada, resulting in its partial introduction without public and parliamentary debate.¹ Consultations on the potential introduction of DTCA have been held by Health Canada since 1996, but there has been little interest in allowing DTCA from health professional and consumer organizations or provincial governments.² Despite this, some forms of advertising of prescription drugs to consumers have become widespread. It is important for clinicians to be aware of how DTCA has developed in Canada, its current status and potential outcomes for health care.

There are 3 types of prescription drug advertisements aimed at the public: *product claim* advertisements, which include both the product name and specific therapeutic claims; *reminder* advertisements, which provide the name of a product without stating its use; and *help-seeking* advertisements, which inform consumers of new but unspecified treatment options for diseases or conditions. All 3 forms of advertising are permitted in the United States. In Canada, although all 3 forms appear to contravene the Food and Drugs Act, reminder advertisements and help-seeking advertisements are now everyday events in broadcast and print advertising, with little or no regulatory response.

Canada's Food and Drugs Act prohibits DTCA in 2 ways. First, it prohibits the advertising of any drug to the general public as a treatment, preventive or cure for serious diseases (Schedule A diseases). Second, it prohibits the advertising of prescription-only medicines (regardless of indication).^{2,3} The only relevant amendment to the Act occurred in 1978, in which a clause approving the advertising of drug prices was added. The amended section reads "Where a person advertises to the general public a Schedule F Drug [a prescription drug], the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug."³ This amendment, which was added to allow for competition between pharmacies, does not make allowances for the inclusion of additional information, such as text, sound or images. So, if the regulations have not changed to permit DTCA in Canada, what has? The answer appears to be found in policy statements published by

Health Canada that imply that the Act and its regulations have been reinterpreted.

In 1996, a policy statement that set out to define the boundary between information dissemination and advertising suggested that Health Canada was ready to relax its interpretation of the Act.⁴ It stated that Health Canada "recognizes the importance to the pharmaceutical industry and to the general public of being able to disseminate and access nonpromotional information regarding drugs for human use." The effect of this statement was tacit approval of help-seeking advertisements for serious diseases. A policy paper released in November 2000 suggested an even more liberalized reinterpretation of the Act.⁵ It explicitly stated that help-seeking and reminder advertisements, but not product claim advertisements, were legal.

The responsibility for interpreting and enforcing drug-advertising regulations lies with Health Canada. How this works in practice is complex and, because of resource limitations, involves other bodies with delegated mandates, including the Pharmaceutical Advertising Advisory Board (PAAB) and Advertising Standards Canada (ASC). PAAB regulates pharmaceutical advertising to health professionals and ASC has primarily focused on over-the-counter drug advertising targeted to consumers. Manufacturers submit advertisements to these bodies on a voluntary basis for pre-clearance. These bodies also handle complaints. There are important differences in the process for DTCA (Mr. Ray Chepesiuk, Commissioner, PAAB: personal communication, 2003). First, to comply with Health Canada's 1996 policy and the applicable laws the term advertisement cannot be used, because advertising prescription drugs to Canadians is illegal.⁴ Second, there is no option for pre-clearance. Instead, manufacturers can, on a voluntary basis, provide "nonpromotional information" submissions to PAAB or ASC requesting advice to determine whether or not they are in compliance with Health Canada guidelines.⁴ And, third, complaints are handled only by Health Canada.

The problems with this system are evident. Advertisements can be released to the general public without being reviewed by government regulators or their delegated bodies. Response to complaints tends to be slow, probably reflecting Health Canada's undercapacity to regulate DTCA, and, arguably, ineffectual.⁶ For example, a television advertisement for Zyban (bupropion) was allowed to run for months, although Health Canada judged it to contravene

the law.⁷ An added concern arises when Health Canada decisions on specific advertising campaigns appear to directly contravene the Food and Drugs Act. For example, reminder and help-seeking advertisements that appeared concurrently for Alesse (ethinyl estradiol and levonorgestrel) were each individually judged to be legal.⁸ In practice, this means that regulation of the accuracy of DTCA in Canada is haphazard.

The rationale for prohibiting the advertising of prescription drugs to consumers is public safety. Compared with over-the-counter drugs, prescription-only products are generally more toxic and are used to treat conditions that are not easily self-diagnosed and self-managed. Moreover, heavily advertised drugs tend to be newer and, thus, there is less information available regarding their relative benefits and risks. As a result, DTCA stimulates early uptake of these drugs in the marketplace⁹ and, in cases of unforeseen harms, magnifies the dangers of their use. Examples of drugs marketed to the public that were soon found to be harmful include benoxaprofen, cisapride, alosetron and troglitazone.¹⁰⁻¹³ The finding that 20% of new drugs eventually receive new black box warnings on the product monograph after marketing or are withdrawn from the market because of serious safety concerns supports the concern that DTCA may contribute to public harm.¹⁴

Supporters claim that DTCA responds to the consumer's right to information and need for information about prescription drugs and about health care choices.¹⁵⁻¹⁷ Whereas providing consumers with information about prescription drugs is a shared goal by those for and against DTCA, there is no evidence that DTCA adequately achieves this goal. In contrast, an evaluation of 320 magazine advertisements of 101 brand-name pharmaceuticals found that few advertisements reported illness-related precursors, illness prevalence or common misconceptions about the condition or its treatments, that alternative treatments were discussed in less than 30% of advertisements and that less than 10% of advertisements stated the treatment's success rate.¹⁸

Other stated benefits of DTCA include earlier diagnosis of serious conditions, better treatment adherence and improved health outcomes.¹⁵⁻¹⁷ However, evidence to support these claims is weak or absent.¹⁹ The only empirical study to test the effect of DTCA on disease diagnoses found that 11% of patients had new diagnoses of "high-priority" conditions as a result of consultations prompted at least in part by DTCA.²⁰ This study, however, failed to include a control group, making it impossible to estimate the effect of DTCA on the rate of new diagnoses.²¹ A final argument for DTCA is increased consumer awareness of new, improved drug therapies. There is ample evidence that DTCA has increased consumer awareness of advertised prescription products^{16,20,22,23} and that this has affected consumer behaviour and physician prescribing practices,²⁴ but very few new drugs have demonstrated advantages over standard therapies.^{25,26} Several evaluations of newly patented medications

have found that only a small proportion provide important therapeutic gains: 16% in the United States before 1992, 6% in Canada in 1996-2000 and 3.4% in France in 1981-2000.²⁷⁻³⁰ Moreover, new products can be inferior to comparable therapies, as was found with 2.6% of new approvals in France.³⁰ Another perspective is that DTCA helps consumers to become aware of consistently more expensive new treatment alternatives.^{9,19}

The costs associated with DTCA have generated significant concerns. In the United States, investment into DTCA grew from \$791 million in 1996 to \$2.5 billion in 2000, representing 32% of total spending on the promotion of prescription drugs (exclusive of product sample costs).⁹ This sharp increase in spending was a result of regulatory changes that facilitated radio and television advertising of prescription drugs.¹⁶ All expenses incurred by the pharmaceutical industry are incorporated into a drug's price and recovered through product sales. In other words, consumers pay for DTCA, either in the price of the prescription or through insurance premiums or through taxes. All those who pay insurance premiums or taxes feel the costs of DTCA, whether or not they take advertised medicines. Because of concerns that DTCA increases demand by consumers and drug expenditures for third-party payers, Canadian provinces have stated their preferences for a continued ban on DTCA in Canada.² Despite this, DTCA has moved forward in Canada.

In March 2002, federal Health Minister Anne McLellan questioned the value of DTCA based on the US experience: "The doctor tells them there is no increased or enhanced effectiveness by providing the drug advertised, but the patient is very persistent once they see the advertisement. One has to question whether you are getting better medical outcomes."³¹ Not addressed by this statement are the public health concerns and cost implications of Health Canada's recently relaxed policies regarding DTCA that allow for help-seeking and reminder advertisements. These policy changes are not in keeping with the spirit or the wording of the Act, its 1978 amendment or the view stated publicly by the health minister.

The aim of banning DTCA is not to limit consumer access to health information. On the contrary, the goal is to provide consumers with independently developed, balanced, comparative information on the full range of available medical treatments. The Canadian Medical Association, the Canadian Pharmacists Association and the Consumers' Association of Canada have all taken strong policy positions against the introduction of DTCA, calling instead for publicly financed alternatives.

The current state of DTCA in Canada, with regulatory creep occurring behind closed doors, is unacceptable. Legislation banning DTCA either needs to be reinforced or put to public and parliamentary debate. If loopholes exist in the Act, clarifying wording can be introduced along with regulations to further limit entry of US DTCA. The issues at stake — public health and the sustainability of health care services — are too important to be quietly set aside.

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